PHC-26-2014: Self management of health and disease: citizen engagement and mHealth

Grant agreement for: Research and Innovation action

Grant Agreement

Action acronym: iManageCancer

Action full title: "iManageCancer - Empowering patients and strengthening self-management in cancer diseases"

Grant agreement no: 643529

EUROPEAN COMMISSION

Directorate General for Communications Networks, Content and Technology

Sustainable and Secure Society

Health and Well-being

GRANT AGREEMENT

NUMBER — 643529 — iManageCancer

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

*the **European Union** ('the EU'), represented by the European Commission ('the Commission')*[1],

represented for the purposes of signature of this Agreement by Authorized Representative of the Director General, Miguel GONZALEZ-SANCHO,

and

on the other part,

1. 'the coordinator':

FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V (Fraunhofer) EV, VR4461, established in HANSASTRASSE 27C, MUNCHEN 80686, Germany, DE129515865, represented for the purposes of signing the Agreement by EU Projects Officer, Andrea ZEUMANN

and the following other beneficiaries, if they sign their 'Accession Form' (see Annex 3 and Article 56):

2. **FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS (FORTH)**, PD432/87, established in N PLASTIRA STR 100, HERAKLION 70013, Greece, EL090101655,

3. **UNIVERSITAET DES SAARLANDES (USAAR)**, established in CAMPUS, SAARBRUCKEN 66041, Germany, DE138117521,

4. **PHILIPS ELECTRONICS NEDERLAND B.V. (PHILIPS ELECTRONICS NEDERLAND B.V.)** BV, 17008551, established in Boschdijk 525, EINDHOVEN 5621JG, Netherlands, NL001902106B01,

5. **CANCER INTELLIGENCE LIMITED (Cancer Intelligence Ltd)** LTD, 04595666, established in Alma Vale Road 11, Bristol BS8 2HL, United Kingdom, GB811051486,

6. **UNIVERSITY OF BEDFORDSHIRE (BED)**, , established in PARK SQUARE, LUTON LU1 3JU, United Kingdom, GB600498850,

7. **ISTITUTO EUROPEO DI ONCOLOGIA SRL (ISTITUTO EUROPEO DI ONCOLOGIA SRL)** SRL, 1243795, established in Via Filodrammatici 10, MILANO 20121, Italy, IT08691440153,

8. **SERIOUS GAMES SOLUTIONS GMBH (SGS)** GMBH, HRB22627P, established in AUGUST BEBEL STRASSE 27, POTSDAM 14482, Germany, DE268028228,

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator.

The parties referred to above have agreed to enter into the Agreement under the terms and conditions below.

1 Text in *italics* shows the options of the Model Grant Agreement that are applicable to this Agreement.

By signing the Agreement or the Accession Form, the beneficiaries accept the grant and agree to implement it under their own responsibility and in accordance with the Agreement, with all the obligations and conditions it sets out.

The Agreement is composed of:

Terms and Conditions

Annex 1 Description of the action

Annex 2 Estimated budget for the action

Annex 3 Accession Form

Annex 4 Model for the financial statements

Annex 5 Model for the certificate on the financial statements

Annex 6 Model for the certificate on the methodology

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CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and the terms and conditions applicable to the grant awarded to the beneficiaries for implementing the action set out in Chapter 2.

CHAPTER 2 ACTION

ARTICLE 2 — ACTION TO BE IMPLEMENTED

The grant is awarded for the action entitled '***iManageCancer - Empowering patients and strengthening self-management in cancer diseases — iManageCancer***' **('action')**, as described in Annex 1.

ARTICLE 3 — DURATION AND STARTING DATE OF THE ACTION

The duration of the action will be ***42*** **months** as of *01/02/2015* ('**starting date of the action**').

ARTICLE 4 — ESTIMATED BUDGET AND BUDGET TRANSFERS

4.1 Estimated budget

The '**estimated budget**' for the action is set out in Annex 2.

It contains the estimated eligible costs and the forms of costs, broken down by beneficiary and budget category (see Articles 5, 6).

4.2 Budget transfers

The estimated budget breakdown indicated in Annex 2 may be adjusted by transfers of amounts between beneficiaries or between budget categories (or both). This does not require an amendment according to Article 55, if the action is implemented as described in Annex 1.

The beneficiaries may not however:

- add costs relating to subcontracts not provided for in Annex 1, unless such additional subcontracts are approved in accordance with Article 13.

CHAPTER 3 GRANT

ARTICLE 5 — GRANT AMOUNT, FORM OF GRANT, REIMBURSEMENT RATES AND FORMS OF COSTS

5.1 Maximum grant amount

The '**maximum grant amount**' is **EUR 4,856,174.00** (four million eight hundred and fifty six thousand one hundred and seventy four EURO).

5.2 Form of grant, reimbursement rates and forms of costs

The grant reimburses ***100% of the action's eligible costs*** (see Article 6) ('**reimbursement of eligible costs grant**') (see Annex 2).

The estimated eligible costs of the action are EUR **4,856,174.00** (four million eight hundred and fifty six thousand one hundred and seventy four EURO).

Eligible costs (see Article 6) must be declared under the following forms ('**forms of costs**'):

(a) for **direct personnel costs**:

- as actually incurred costs ('**actual costs**') or
- on the basis of an amount per unit calculated by the beneficiary in accordance with its usual cost accounting practices ('**unit costs**').

Personnel **costs for SME owners** or **beneficiaries that are natural persons** not receiving a salary (see Article 6.2, Points A.4 and A.5) must be declared on the basis of the amount per unit set out in Annex 2 (**unit costs**);

(b) for **direct costs for subcontracting**: as actually incurred costs (**actual costs**);

(c) *not applicable*

(d) for **other direct costs**: as actually incurred costs (**actual costs**);

(e) for **indirect costs**: on the basis of a flat-rate applied as set out in Article 6.2, Point E ('**flat-rate costs**');

5.3 Final grant amount — Calculation

The '**final grant amount**' depends on the actual extent to which the action is implemented in accordance with the Agreement's terms and conditions.

This amount is calculated by the *Commission* — when the payment of the balance is made (see Article 21.4) — in the following steps:

Step 1 – Application of the reimbursement rates to the eligible costs

Step 2 – Limit to the maximum grant amount

Step 3 – Reduction due to the no-profit rule

Step 4 – Reduction due to improper implementation or breach of other obligations

5.3.1 Step 1 — Application of the reimbursement rates to the eligible costs

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) declared by the beneficiaries (see Article 20) and approved by the *Commission* (see Article 21).

5.3.2 Step 2 — Limit to the maximum grant amount

If the amount obtained following Step 1 is higher than the maximum grant amount set out in Article 5.1, it will be limited to the latter.

5.3.3 Step 3 — Reduction due to the no-profit rule

The grant must not produce a profit.

'**Profit**' means the surplus of the amount obtained following Steps 1 and 2 plus the action's total receipts, over the action's total eligible costs.

The '**action's total eligible costs**' are the consolidated total eligible costs approved by the *Commission*.

The '**action's total receipts**' are the consolidated total receipts generated during its duration (see Article 3).

The following are considered **receipts**:

(a) income generated by the action; if the income is generated from selling equipment or other assets purchased under the Agreement, the receipt is up to the amount declared as eligible under the Agreement;

(b) financial contributions given by third parties to the beneficiary specifically to be used for the action, and

(c) in-kind contributions provided by third parties free of charge and specifically to be used for the action, if they have been declared as eligible costs.

The following are however not considered receipts:

(a) income generated by exploiting the action's results (see Article 28);

(b) financial contributions by third parties, if they may be used to cover costs other than the eligible costs (see Article 6);

(c) financial contributions by third parties with no obligation to repay any amount unused at the end of the period set out in Article 3.

If there is a profit, it will be deducted from the amount obtained following Steps 1 and 2.

5.3.4 Step 4 — Reduction due to improper implementation or breach of other obligations — Reduced grant amount — Calculation

If the grant is reduced (see Article 43), the *Commission* will calculate the reduced grant amount by deducting the amount of the reduction (calculated in proportion to the improper implementation of the action or to the seriousness of the breach of obligations in accordance with Article 43.2) from the maximum grant amount set out in Article 5.1.

The final grant amount will be the lower of the following two:

- the amount obtained following Steps 1 to 3 or

- the reduced grant amount following Step 4.

5.4 Revised final grant amount — Calculation

If — after the payment of the balance (in particular, after checks, reviews, audits or investigations; see Article 22) — the *Commission* rejects costs (see Article 42) or reduces the grant (see Article 43), it will calculate the '**revised final grant amount**' for the beneficiary concerned by the findings.

This amount is calculated by the *Commission* on the basis of the findings, as follows:

- in case of **rejection of costs**: by applying the reimbursement rate to the revised eligible costs approved by the *Commission* for the beneficiary concerned;

- in case of **reduction of the grant**: by calculating the concerned beneficiary's share in the grant amount reduced in proportion to its improper implementation of the action or to the seriousness of its breach of obligations (see Article 43.2).

In case of **rejection of costs and reduction of the grant**, the revised final grant amount for the beneficiary concerned will be the lower of the two amounts above.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS

6.1 General conditions for costs to be eligible

'**Eligible costs**' are costs that meet the following criteria:

(a) for **actual costs**:

(i) they must be actually incurred by the beneficiary;

(ii) they must be incurred in the period set out in Article 3, with the exception of costs relating to the submission of the periodic report for the last reporting period and the final report (see Article 20);

(iii) they must be indicated in the estimated budget set out in Annex 2;

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation;

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices;

(vi) they must comply with the applicable national law on taxes, labour and social security, and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency.

(b) for **unit costs**:

(i) they must be calculated as follows:

{amounts per unit set out in Annex 2 or calculated by the beneficiary in accordance with its usual cost accounting practices (see Article 6.2, PointA)}

multiplied by

{the number of actual units};

(ii) the number of actual units must comply with the following conditions:

- the units must be actually used or produced in the period set out in Article 3;
- the units must be necessary for implementing the action or produced by it, and
- the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 18).

(c) for **flat-rate costs**:

(i) they must be calculated by applying the flat-rate set out in Annex 2, and

(ii) the costs (actual costs or unit costs) to which the flat-rate is applied must comply with the conditions for eligibility set out in this Article.

6.2 Specific conditions for costs to be eligible

Costs are eligible if they comply with the general conditions (see above) and the specific conditions set out below for each of the following budget categories:

A. direct personnel costs;

B. direct costs of subcontracting;

C. *not applicable;*

D. other direct costs;

E. indirect costs;

'Direct costs' are costs that are directly linked to the action implementation and can therefore be attributed to it directly. They must not include any indirect costs (see Point E below).

'Indirect costs' are costs that are not directly linked to the action implementation and therefore cannot be attributed directly to it.

A. Direct personnel costs

<u>Types of eligible personnel costs</u>

A.1 **Personnel costs** are eligible if they are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action. They must be limited to salaries (including during parental leave), social security contributions, taxes and other

costs included in the remuneration, if they arise from national law or the employment contract (or equivalent appointing act).

Beneficiaries that are non-profit legal entities[2] may also declare as personnel costs **additional remuneration** for personnel assigned to the action (including payments on the basis of supplementary contracts regardless of their nature), if:

(a) it is part of the beneficiary's usual remuneration practices and is paid in a consistent manner whenever the same kind of work or expertise is required;

(b) the criteria used to calculate the supplementary payments are objective and generally applied by the beneficiary, regardless of the source of funding used.

Additional remuneration for personnel assigned to the action is eligible up to the following amount:

(a) if the person works full time and exclusively on the action during the full year: up to EUR 8 000;

(b) if the person works exclusively on the action but not full-time or not for the full year: up to the corresponding pro-rata amount of EUR 8 000, or

(c) if the person does not work exclusively on the action: up to a pro-rata amount calculated as follows:

{{EUR 8 000

divided by

the number of annual productive hours (see below)},

multiplied by

the number of hours that the person has worked on the action during the year}.

A.2 The **costs for natural persons working under a direct contract** with the beneficiary other than an employment contract are eligible personnel costs, if:

(a) the person works under the beneficiary's instructions and, unless otherwise agreed with the beneficiary, on the beneficiary's premises;

(b) the result of the work carried out belongs to the beneficiary, and

(c) the costs are not significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.3 The **costs of personnel seconded by a third party against payment** are eligible personnel costs, if the conditions in Article 11 are met.

[2] For the definition, see Article 2.1(14) of the Rules for Participation Regulation No 1290/2013: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

A.4 **Costs owners** of beneficiaries that are small and medium-sized enterprises ('**SME owners**') who are working on the action and who do not receive a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

A.5 **Costs of 'beneficiaries that are natural persons'** not receiving a salary are eligible personnel costs, if they correspond to the amount per unit set out in Annex 2 multiplied by the number of actual hours worked on the action.

Calculation

Personnel costs must be calculated by the beneficiaries as follows:

{{hourly rate

multiplied by

the number of actual hours worked on the action},

plus

for non-profit legal entities: additional remuneration to personnel assigned to the action under the conditions set out above (Point A.1)}.

The number of actual hours declared for a person must be identifiable and verifiable (see Article 18).

The total number of hours declared in *EU or Euratom* grants, for a person for a year, cannot be higher than the annual productive hours used for the calculations of the hourly rate:

{the number of annual productive hours for the year (see below)

minus

total number of hours declared by the beneficiary for that person in that year for other *EU or Euratom* grants}.

The '**hourly rate**' is one of the following:

(a) for personnel costs declared as **actual costs:** the hourly rate is the amount calculated as follows:

{actual annual personnel costs (excluding additional remuneration) for the person

divided by

number of annual productive hours}.

The beneficiaries must use the annual personnel costs and the number of annual productive hours for each financial year covered by the reporting period. If a financial year is not closed at the end of the reporting period, the beneficiaries must use the hourly rate of the last closed financial year available.

For the 'number of annual productive hours', the beneficiaries may choose one of the following:

(i) 1 720 hours for persons working full time (or corresponding pro-rata for persons not working full time);

(ii) the total number of hours worked by the person in the year for the beneficiary, calculated as follows:

{annual workable hours of the person (according to the employment contract, applicable labour agreement or national law)

plus

overtime worked

minus

absences (such as sick leave and special leave)}.

'Annual workable hours' means the period during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation.

If the contract (or applicable collective labour agreement or national working time legislation) does not allow to determine the annual workable hours, this option cannot be used;

(iii) the 'standard number of annual hours' generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the 'standard annual workable hours'.

If there is no applicable reference for the standard annual workable hours, this option cannot be used.

For all options, the actual time spent on **parental leave** by a person assigned to the action may be deducted from the number of annual productive hours;

(b) for personnel costs declared on the basis of **unit costs**: the hourly rate is one of the following:

(i) for SME owners or beneficiaries that are natural persons: the hourly rate set out in Annex 2 (see Points A.4 and A.5 above), or

(ii) for personnel costs declared on the basis of the beneficiary's usual cost accounting practices: the hourly rate calculated by the beneficiary in accordance with its usual cost accounting practices, if:

- the cost accounting practices used are applied in a consistent manner, based on objective criteria, regardless of the source of funding;

- the hourly rate is calculated using the actual personnel costs recorded in the beneficiary's accounts, excluding any ineligible cost or costs included in other budget categories.

The actual personnel costs may be adjusted by the beneficiary on the basis of budgeted or estimated elements. Those elements must be relevant for calculating

the personnel costs, reasonable and correspond to objective and verifiable information, and

- the hourly rate is calculated using the number of annual productive hours (see above).

B. Direct costs of subcontracting (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if the conditions in Article 13 are met.

C. Direct costs of providing financial support to third parties *not applicable.*

D. Other direct costs

D.1 **Travel costs and related subsistence allowances** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible if they are in line with the beneficiary's usual practices on travel.

D.2 *The **depreciation costs of equipment, infrastructure or other assets** (new or second-hand) as recorded in the beneficiary's accounts are eligible, if they were purchased in accordance with Article 10 and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.*

*The **costs of renting or leasing** equipment, infrastructure or other assets (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.*

*The costs of equipment, infrastructure or other assets **contributed in-kind against payment** are eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets, do not include any financing fees and if the conditions in Article 11 are met.*

The only portion of the costs that will be taken into account is that which corresponds to the duration of the action and rate of actual use for the purposes of the action.

D.3 **Costs of other goods and services** (including related duties, taxes and charges such as non-deductible value added tax (VAT) paid by the beneficiary) are eligible, if they are:

(a) purchased specifically for the action and in accordance with Article 10 or

(b) contributed in kind against payment and in accordance with Article 11.

Such goods and services include, for instance, consumables and supplies, dissemination (including open access), protection of results, certificates on the financial statements (if they are required by the Agreement), certificates on the methodology, translations and publications.

D.4 *The **capitalised and operating costs of 'large research infrastructure'** [3] directly used for the action are eligible, if:*

(a) the value of the large research infrastructure represents at least 75% of the total fixed assets (at historical value in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure [4]);

*(b) the beneficiary's methodology for declaring the costs for large research infrastructure has been positively assessed by the Commission ('**ex-ante assessment**');*

(c) the beneficiary declares as direct eligible costs only the portion which corresponds to the duration of the action and the rate of actual use for the purposes of the action, and

(d) they comply with the conditions as further detailed in the Horizon 2020 Grant Manual.

E. Indirect costs

Indirect costs are eligible if they are declared on the basis of the flat-rate of 25% of the eligible direct costs (see Article 5.2 and Points A to D above), from which are excluded:

(a) costs of subcontracting and

(b) costs of in-kind contributions provided by third parties which are not used on the beneficiary's premises.

(c) not applicable.

Beneficiaries receiving an operating grant[5] financed by the EU or Euratom budget cannot declare indirect costs for the period covered by the operating grant.

[3] '**Large research infrastructure**' means research infrastructure of a total value of at least EUR 20 million, for a beneficiary, calculated as the sum of historical asset values of each individual research infrastructure of that beneficiary, as they appear in its last closed balance sheet before the date of the signature of the Agreement or as determined on the basis of the rental and leasing costs of the research infrastructure.

[4] For the definition, see Article 2(6) of Regulation (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) (OJ L 347, 20.12.2013 p.104)-('**Horizon 2020 Framework Programme Regulation No 1291/2013**'): '**Research infrastructure**' are facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research, e.g. for education or public services. They include: major scientific equipment (or sets of instruments); knowledge-based resources such as collections, archives or scientific data; e-infrastructures such as data and computing systems and communication networks; and any other infrastructure of a unique nature essential to achieve excellence in research and innovation. Such infrastructures may be 'single-sited', 'virtual' or 'distributed'.

[5] For the definition, see Article 121(1)(b) of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 218, 26.10.2012, p.1) ('**Financial Regulation No 966/2012**'): '**operating grant**' means direct financial contribution, by way of donation, from the budget in order to finance the functioning of a body which pursues an aim of general EU interest or has an objective forming part of and supporting an EU policy.

6.3 Conditions for costs of linked third parties to be eligible

not applicable

6.4 Conditions for in-kind contributions provided by third parties free of charge to be eligible

In-kind contributions provided free of charge are eligible direct costs (for the beneficiary), if the costs incurred by the third party fulfil — *mutatis mutandis* — the general and specific conditions for eligibility set out in this Article (Article 6.1 and 6.2) and Article 12.

6.5 Ineligible costs

'**Ineligible costs**' are:

(a) costs that do not comply with the conditions set out above (Article 6.1 to 6.4), in particular:

(i) costs related to return on capital;

(ii) debt and debt service charges;

(iii) provisions for future losses or debts;

(iv) interest owed;

(v) doubtful debts;

(vi) currency exchange losses;

(vii) bank costs charged by the beneficiary's bank for transfers from the *Commission*;

(viii) excessive or reckless expenditure;

(ix) deductible VAT;

(x) costs incurred during suspension of the implementation of the action (see Article 49);

(b) costs declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU or Euratom budget and grants awarded by bodies other than the *Commission* for the purpose of implementing the EU or Euratom budget); in particular, indirect costs if the beneficiary is already receiving an operating grant financed by the EU or Euratom budget in the same period.

6.6 Consequences of declaration of ineligible costs

Declared costs that are ineligible will be rejected (see Article 42).

This may also lead to any of the other measures described in Chapter 6.

CHAPTER 4 RIGHTS AND OBLIGATIONS OF THE PARTIES

SECTION 1 RIGHTS AND OBLIGATIONS RELATED TO IMPLEMENTING THE ACTION

ARTICLE 7 — GENERAL OBLIGATION TO PROPERLY IMPLEMENT THE ACTION

7.1 General obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement and all legal obligations under applicable EU, international and national law.

7.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 8 — RESOURCES TO IMPLEMENT THE ACTION

The beneficiaries must have the appropriate resources to implement the action.

If it is necessary to implement the action, the beneficiaries may:

- purchase goods, works and services (see Article 10);
- use in-kind contributions provided by third parties against payment (see Article 11);
- use in-kind contributions provided by third parties free of charge (see Article 12);
- call upon subcontractors to implement action tasks described in Annex 1 (see Article 13);
- call upon linked third parties to implement action tasks described in Annex 1 (see Article 14).

In these cases, the beneficiaries retain sole responsibility towards the *Commission* and the other beneficiaries for implementing the action.

ARTICLE 9 — IMPLEMENTATION OF ACTION TASKS BY BENEFICIARIES NOT RECEIVING EU FUNDING

9.1 Rules for the implementation of action tasks by beneficiaries not receiving EU funding

not applicable

9.2 Consequences of non-compliance

not applicable

ARTICLE 10 — PURCHASE OF GOODS, WORKS OR SERVICES

10.1 Rules for purchasing goods, works or services

10.1.1 If necessary to implement the action, the beneficiaries may purchase goods, works or services.

The beneficiaries must make such purchases ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their contractors.

10.1.2 Beneficiaries that are 'contracting authorities' within the meaning of Directive 2004/18/EC[6] or 'contracting entities' within the meaning of Directive 2004/17/EC[7] must comply with the applicable national law on public procurement.

10.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 10.1.1, the costs related to the contract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 10.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 11 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES AGAINST PAYMENT

11.1 Rules for the use of in-kind contributions against payment

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties against payment.

The beneficiaries may declare costs related to the payment of in-kind contributions as eligible (see Article 6.1 and 6.2), up to the third parties' costs for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services.

The third parties and their contributions must be set out in Annex 1. The *Commission* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and
- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

[6] Directive 2004/18/EC of the European Parliament and of the Council of 31 March 2004 on the coordination of procedures for the award of public work contracts, public supply contracts and public service contracts (OJ L 134, 30.04.2004, p. 114).

[7] Directive 2004/17/EC of the European Parliament and of the Council of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors (OJ L 134, 30.04.2004, p. 1).

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs related to the payment of the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 12 — USE OF IN-KIND CONTRIBUTIONS PROVIDED BY THIRD PARTIES FREE OF CHARGE

12.1 Rules for the use of in-kind contributions free of charge

If necessary to implement the action, the beneficiaries may use in-kind contributions provided by third parties free of charge.

The beneficiaries may declare costs incurred by the third parties for the seconded persons, contributed equipment, infrastructure or other assets or other contributed goods and services as eligible in accordance with Article 6.4.

The third parties and their contributions must be set out in Annex 1. The *Commission* may however approve in-kind contributions not set out in Annex 1 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards the third parties.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the costs incurred by the third parties related to the in-kind contribution will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 13 — IMPLEMENTATION OF ACTION TASKS BY SUBCONTRACTORS

13.1 Rules for subcontracting action tasks

13.1.1 If necessary to implement the action, the beneficiaries may award subcontracts covering the implementation of certain action tasks described in Annex 1.

Subcontracting may cover only a limited part of the action.

The beneficiaries must award the subcontracts ensuring the best value for money or, if appropriate, the lowest price. In doing so, they must avoid any conflict of interests (see Article 35).

The tasks to be implemented and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2. The *Commission* may however approve subcontracts not set out in Annex 1 and 2 without amendment (see Article 55), if:

- they are specifically justified in the periodic technical report and

- they do not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiaries must ensure that the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) can exercise their rights under Articles 22 and 23 also towards their subcontractors.

13.1.2 The beneficiaries must ensure that their obligations under Articles 35, 36, 38 and 46 also apply to the subcontractors.

Beneficiaries that are ‘contracting authorities’ within the meaning of Directive 2004/18/EC or ‘contracting entities’ within the meaning of Directive 2004/17/EC must comply with the applicable national law on public procurement.

13.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 13.1.1, the costs related to the subcontract concerned will be ineligible (see Article 6) and will be rejected (see Article 42).

If a beneficiary breaches any of its obligations under Article 13.1.2, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 14 — IMPLEMENTATION OF ACTION TASKS BY LINKED THIRD PARTIES

14.1 Rules for calling upon linked third parties to implement part of the action

not applicable

14.2 Consequences of non-compliance

not applicable

ARTICLE 15 — FINANCIAL SUPPORT TO THIRD PARTIES

15.1 Rules for providing financial support to third parties

not applicable

15.2 Financial support in the form of prizes

not applicable

15.3 Consequences of non-compliance

not applicable

ARTICLE 16 — PROVISION OF TRANS-NATIONAL OR VIRTUAL ACCESS TO RESEARCH INFRASTRUCTURE

16.1 Rules for providing trans-national access to research infrastructure

not applicable

16.2 Rules for providing virtual access to research infrastructure

not applicable

16.3 Consequences of non-compliance

not applicable

SECTION 2 RIGHTS AND OBLIGATIONS RELATED TO THE GRANT ADMINISTRATION

ARTICLE 17 — GENERAL OBLIGATION TO INFORM

17.1 Obligation to provide information upon request

The beneficiaries must provide — during implementation of the action or afterwards — any information requested in order to verify proper implementation of the action and compliance with the obligations under the Agreement (see Article 41.2).

17.2 Obligation to keep information up to date and to inform about events and circumstances likely to affect the Agreement

Each beneficiary must keep information stored in the 'Beneficiary Register' (in the electronic exchange system; see Article 52) up to date, in particular, its name, address, legal representatives, legal form and organisation type.

Each beneficiary must immediately inform the coordinator — which must immediately inform the *Commission* and the other beneficiaries — of any of the following:

(a) **events** which are likely to affect significantly or delay the implementation of the action or the *EU*'s financial interests, in particular:

  (i) changes in its legal, financial, technical, organisational or ownership situation

(b) **circumstances** affecting:

  (i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

17.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 18 — KEEPING RECORDS — SUPPORTING DOCUMENTATION

18.1 Obligation to keep records and other supporting documentation

The beneficiaries must — for a period of *five* years after the payment of the balance — keep records and other supporting documentation in order to prove the proper implementation of the action and the costs they declare as eligible.

They must make them available upon request (see Article 17) or in the context of checks, reviews, audits or investigations (see Article 22).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Articles 22), the beneficiaries must keep the records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The *Commission* may accept non-original documents if it considers that they offer a comparable level of assurance.

18.1.1 Records and other supporting documentation on the scientific and technical implementation

The beneficiaries must keep records and other supporting documentation on scientific and technical implementation of the action in line with the accepted standards in the respective field.

18.1.2 Records and other documentation to support the costs declared

The beneficiaries must keep the records and documentation supporting the costs declared, in particular the following:

(a) for **actual costs**: adequate records and other supporting documentation to prove the costs declared, such as contracts, subcontracts, invoices and accounting records. In addition, the beneficiaries' usual cost accounting practices and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documentation;

(b) for **unit costs**: adequate records and other supporting documentation to prove the number of units declared. Beneficiaries do not need to identify the actual eligible costs covered or to keep or provide supporting documentation (such as accounting statements) to prove the amount per unit.

In addition, **for direct personnel costs declared as unit costs calculated in accordance with the beneficiary's usual cost accounting practices**, the beneficiaries must keep adequate records and documentation to prove that the cost accounting practices used comply with the conditions set out in Article 6.2, Point A.

The beneficiaries may submit to the *Commission*, for approval, a certificate (drawn up in accordance with Annex 6) stating that their usual cost accounting practices comply with these conditions ('**certificate on the methodology**'). If the certificate is approved, costs declared in line with this methodology will not be challenged subsequently, unless the beneficiaries have concealed information for the purpose of the approval.

(c) for **flat-rate costs**: adequate records and other supporting documentation to prove the eligibility of the costs to which the flat-rate is applied. The beneficiaries do not need to identify the costs covered or provide supporting documentation (such as accounting statements) to prove the amount declared at a flat-rate.

In addition, for **personnel costs** (declared as actual costs or on the basis of unit costs), the beneficiaries must keep **time records** for the number of hours declared. The time records must be in writing and approved by the persons working on the action and their supervisors, at least monthly. In the absence of reliable time records of the hours worked on the action, the *Commission* may accept alternative evidence supporting the number of hours declared, if it considers that it offers an adequate level of assurance.

As an exception, for **persons working exclusively on the action**, there is no need to keep time records, if the beneficiary signs a **declaration** confirming that the persons concerned have worked exclusively on the action.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 42), and the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 19 — SUBMISSION OF DELIVERABLES

19.1 Obligation to submit deliverables

The coordinator must submit the '**deliverables**' identified in Annex 1, in accordance with the timing and conditions set out in it.

19.2 Consequences of non-compliance

If the coordinator breaches any of its obligations under this Article, the *Commission* may apply any of the measures described in Chapter 6.

ARTICLE 20 — REPORTING — PAYMENT REQUESTS

20.1 General obligation to submit reports

The coordinator must submit to the *Commission* (see Article 52) technical and financial reports, including requests for payment.

The reports must be drawn up using the forms and templates provided by the *Commission* in the electronic exchange system (see Article 52).

20.2 Reporting periods

The action is divided into the following '**reporting periods**':

- RP1: from month 1 to month 12
- *RP2: from month 13 to month 30*
- *RP3: from month 31 to the last month of the project*

20.3 Periodic reports — Requests for interim payments

The coordinator must submit a periodic report within 60 days following the end of each reporting period.

The **periodic report** must include the following:

(a) a '**periodic technical report**' containing:

(i) an **explanation of the work carried out** by the beneficiaries;

(ii) an **overview of the progress** towards the objectives of the action, including milestones and deliverables identified in Annex 1.

This report must include explanations justifying the differences between work expected to be carried out in accordance with Annex 1 and that actually carried out.

The report must also detail the exploitation and dissemination of the results and — if required in Annex 1 — an updated '**plan for the exploitation and dissemination of the results**'*;*

(iii) a **summary** for publication by the *Commission*;

(iv) the answers to the '**questionnaire**', covering issues related to the action implementation and the economic and societal impact, notably in the context of the Horizon 2020 key performance indicators and the Horizon 2020 monitoring requirements;

(b) a '**periodic financial report**' containing:

(i) an '**individual financial statement**' (see Annex 4) from each beneficiary, for the reporting period concerned.

The individual financial statement must detail the eligible costs (actual costs, unit costs and flat-rate costs; see Article 6) for each budget category (see Annex 2).

The beneficiaries must declare all eligible costs, even if — for actual costs, unit costs and flat-rate costs — they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts which are not declared in the individual financial statement will not be taken into account by the *Commission*.

If an individual financial statement is not submitted for a reporting period, it may be included in the periodic financial report for the next reporting period.

The individual financial statements of the last reporting period must also detail the **receipts of the action** (see Article 5.3.3).

Each beneficiary must **certify** that:

- the information provided is full, reliable and true;
- the costs declared are eligible (see Article 6);
- the costs can be substantiated by adequate records and supporting documentation (see Article 18) that will be produced upon request (see Article 17) or in the context of checks, reviews, audits and investigations (see Article 22), and
- for the last reporting period: that all the receipts have been declared (see Article 5.3.3);

(ii) an **explanation of the use of resources** and the information on subcontracting (see Article 13) and in-kind contributions provided by third parties (see Articles 11 and 12) from each beneficiary, for the reporting period concerned;

(iii) not applicable;

(iv) a '**periodic summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for the reporting period concerned and including — except for the last reporting period — the **request for interim payment**.

20.4 Final report — Request for payment of the balance

In addition to the periodic report for the last reporting period, the coordinator must submit the final report within 60 days following the end of the last reporting period.

The **final report** must include the following:

(a) a '**final technical report**' with a **summary** for publication containing:

(i) an overview of the results and their exploitation and dissemination;

(ii) the conclusions on the action, and

(iii) the socio-economic impact of the action;

(b) a '**final financial report**' containing:

(i) a '**final summary financial statement**' (see Annex 4), created automatically by the electronic exchange system, consolidating the individual financial statements for all reporting periods and including the **request for payment of the balance** and

(ii) a '**certificate on the financial statements**' (drawn up in accordance with Annex 5) for each beneficiary , if it requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 5.2 and Article 6.2, Point A).

20.5 Information on cumulative expenditure incurred

not applicable

20.6 Currency for financial statements and conversion into euro

Financial statements must be drafted in euro.

Beneficiaries with accounting established in a currency other than the euro must convert costs incurred in another currency into euro at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union*, calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal of the European Union* for the currency in question, it must be converted at the average of the monthly accounting rates published on the Commission's website, calculated over the corresponding reporting period.

Beneficiaries with accounting established in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

20.7 Language of reports

All reports (technical and financial reports, including financial statements) must be submitted in the language of the Agreement.

20.8 Consequences of non-compliance — Suspension of the payment deadline — Termination

If the reports submitted do not comply with this Article, the *Commission* may suspend the payment deadline (see Article 47) and apply any of the other measures described in Chapter 6.

If the coordinator breaches its obligation to submit the reports and if it fails to comply with this obligation within 30 days following a written reminder sent by the *Commission*, the Agreement may be terminated (see Article 50).

ARTICLE 21 — PAYMENTS AND PAYMENT ARRANGEMENTS

21.1 Payments to be made

The following payments will be made to the coordinator:

- one **pre-financing payment**;

- one or more **interim payments**, on the basis of the request(s) for interim payment (see Article 20), and

- one **payment of the balance**, on the basis of the request for payment of the balance (see Article 20).

21.2 Pre-financing payment — Amount — Amount retained for the Guarantee Fund

The aim of the pre-financing is to provide the beneficiaries with a float.

It remains the property of the *EU* until the payment of the balance.

The amount of the pre-financing payment will be EUR **1,602,537.34** (one million six hundred and two thousand five hundred and thirty seven EURO and thirty four eurocents).

The *Commission* will — except if Article 48 applies — make the pre-financing payment to the coordinator within 30 days, either from the entry into force of the Agreement (see Article 58) or from 10 days before the starting date of the action (see Article 3), whichever is the latest.

An amount of EUR **242,808.70** (two hundred and forty two thousand eight hundred and eight EURO and seventy eurocents), corresponding to the 5% of the maximum grant amount (see Article 5.1), is retained by the *Commission* from the pre-financing payment and transferred into the '**Guarantee Fund**'.

21.3 Interim payments — Amount — Calculation

Interim payments reimburse the eligible costs incurred for the implementation of the action during the corresponding reporting periods.

The *Commission* will pay to the coordinator the amount due as interim payment within 90 days from receiving the periodic report (see Article 20.3), except if Articles 47 or 48 apply.

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as interim payment** is calculated by the *Commission* in the following steps:

Step 1 – Application of the reimbursement rates

Step 2 – Limit to 90% of the maximum grant amount

21.3.1 Step 1 — Application of the reimbursement rates

The reimbursement rate(s) (see Article 5.2) are applied to the eligible costs (actual costs, unit costs and flat-rate costs ; see Article 6) declared by the beneficiaries (see Article 20) and approved by the *Commission* (see above) for the concerned reporting period.

21.3.2 Step 2 — Limit to 90% of the maximum grant amount

The total amount of pre-financing and interim payments must not exceed 90% of the maximum grant amount set out in Article 5.1. The maximum amount for the interim payment will be calculated as follows:

{90% of the maximum grant amount (see Article 5.1)

minus

{pre-financing and previous interim payments}}.

21.4 Payment of the balance — Amount — Calculation — Release of the amount retained for the Guarantee Fund

The payment of the balance reimburses the remaining part of the eligible costs incurred by the beneficiaries for the implementation of the action.

If the total amount of earlier payments is greater than the final grant amount (see Article 5.3), the payment of the balance takes the form of a recovery (see Article 44).

If the total amount of earlier payments is lower than the final grant amount, the *Commission* will pay the balance within 90 days from receiving the final report (see Article 20.4), except if Articles 47 or 48 apply.

Payment is subject to the approval of the final report. Its approval does not imply recognition of the compliance, authenticity, completeness or correctness of its content.

The **amount due as the balance** is calculated by the *Commission* by deducting the total amount of pre-financing and interim payments (if any) already made, from the final grant amount determined in accordance with Article 5.3:

{final grant amount (see Article 5.3)

minus

{pre-financing and interim payments (if any) made}}.

At the payment of the balance, the amount retained for the Guarantee Fund (see above) will be released and:

- if the balance is positive: the amount released will be paid in full to the coordinator together with the amount due as the balance;

- if the balance is negative (payment of the balance taking the form of recovery): it will be deducted from the amount released (see Article 44.1.2). If the resulting amount:

    - is positive, it will be paid to the coordinator

    - is negative, it will be recovered.

The amount to be paid may however be offset — without the beneficiary's consent — against any other amount owed to a beneficiary by the *Commission* or an executive agency (from the EU or Euratom budget), up to the maximum EU contribution indicated, for that beneficiary, in the estimated budget (see Annex 2).

21.5 Notification of amounts due

When making payments, the *Commission* will formally notify to the coordinator the amount due, specifying whether it concerns an interim payment or the payment of the balance.

For the payment of the balance, the notification will also specify the final grant amount.

In the case of reduction of the grant or recovery of undue amounts, the notification will be preceded by the contradictory procedure set out in Articles 43 and 44.

21.6 Currency for payments

The *Commission* will make all payments in euro.

21.7 Payments to the coordinator — Distribution to the beneficiaries

Payments will be made to the coordinator.

Payments to the coordinator will discharge the *Commission* from its payment obligation.

The coordinator must distribute the payments between the beneficiaries without unjustified delay.

Pre-financing may however be distributed only:

(a) if the minimum number of beneficiaries set out in the call for proposals has acceded to the Agreement (see Article 56) and

(b) to beneficiaries that have acceded to the Agreement (see Article 56).

21.8 Bank account for payments

All payments will be made to the following bank account:

Name of bank: UNICREDIT BANK AG (HYPOVEREINSBANK)
Address of branch: 1, KARDINAL-FAULHABER-STRASSE MUENCHEN, Germany
Full name of the account holder: FRAUNHOFER GESELLSCHAFT ZUR FORDERUNG DER ANGEWANDTEN FORSCHUNG EV
Full account number (including bank codes):
IBAN code: DE40700202700036715570

21.9 Costs of payment transfers

The cost of the payment transfers is borne as follows:

- the *Commission* bears the cost of transfers charged by its bank;

- the beneficiary bears the cost of transfers charged by its bank;

- the party causing a repetition of a transfer bears all costs of the repeated transfer.

21.10 Date of payment

Payments by the *Commission* are considered to have been carried out on the date when they are debited to its account.

21.11 Consequences of non-compliance

21.11.1 If the *Commission* does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus three and a half points. The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only upon request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

Suspension of the payment deadline or payments (see Articles 47 and 48) will not be considered as late payment.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

21.11.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or the participation of the coordinator may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 22 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

22.1 Checks, reviews and audits by the Commission

22.1.1 Right to carry out checks

The Commission will — during the implementation of the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing deliverables and reports.

For this purpose the Commission may be assisted by external persons or bodies.

The Commission may also request additional information in accordance with Article 17. The Commission may request beneficiaries to provide such information to it directly.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

22.1.2 Right to carry out reviews

The Commission may — during the implementation of the action or afterwards — carry out reviews on the proper implementation of the action (including assessment of deliverables and reports), compliance with the obligations under the Agreement and continued scientific or technological relevance of the action.

Reviews may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the review is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission may carry out reviews directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The Commission may request beneficiaries to provide such information to it directly.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with external experts.

For **on-the-spot** reviews, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a '**review report**' will be drawn up.

The Commission will formally notify the review report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory review procedure**').

Reviews (including review reports) are in the language of the Agreement.

22.1.3 Right to carry out audits

The Commission may — during the implementation of the action or afterwards — carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Audits may be started **up to two years after the payment of the balance**. They will be formally notified to the coordinator or beneficiary concerned and will be considered to have started on the date of the formal notification.

If the audit is carried out on a third party (see Articles 10 to 16), the beneficiary concerned must inform the third party.

The Commission may carry out audits directly (using its own staff) or indirectly (using external persons or bodies appointed to do so). It will inform the coordinator or beneficiary concerned of the identity of the external persons or bodies. They have the right to object to the appointment on grounds of commercial confidentiality.

The coordinator or beneficiary concerned must provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. The Commission may request beneficiaries to provide such information to it directly.

For **on-the-spot** audits, the beneficiaries must allow access to their sites and premises, including to external persons or bodies, and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a '**draft audit report**' will be drawn up.

The Commission will formally notify the draft audit report to the coordinator or beneficiary concerned, which has 30 days to formally notify observations ('**contradictory audit procedure**'). This period may be extended by the Commission in justified cases.

The '**final audit report**' will take into account observations by the coordinator or beneficiary concerned. The report will be formally notified to it.

Audits (including audit reports) are in the language of the Agreement.

The Commission may also access the beneficiaries' statutory records for the periodical assessment of unit costs or flat-rate amounts.

22.2 Investigations by the European Anti-Fraud Office (OLAF)

Under Regulations No 883/2013[15] and No 2185/96[16] (and in accordance with their provisions and procedures), the European Anti-Fraud Office (OLAF) may — at any moment during implementation of the action or afterwards — carry out investigations, including on-the-spot checks and inspections, to establish whether, concerning the action funded under the Agreement, there has been fraud, corruption or any other illegal activity affecting the financial interests of the EU.

[15] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.09.2013, p. 1).

[16] Council Regulation (Euratom, EC) No 2185/1996 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

22.3 Checks and audits by the European Court of Auditors (ECA)

Under Article 287 of the Treaty on the Functioning of the European Union (TFEU) and *Article 161 of the Financial Regulation No 966/2012*[17], the European Court of Auditors (ECA) may — at any moment during implementation of the action or afterwards — carry out audits.

The ECA has the right of access for the purpose of checks and audits.

22.4 Checks, reviews, audits and investigations for international organisations

not applicable

22.5 Consequences of findings in checks, reviews, audits and investigations —Extension of findings

22.5.1 Findings in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to the rejection of ineligible costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44) or to any of the other measures described in Chapter 6.

Rejection of costs or reduction of the grant after the payment of the balance will lead to a revised final grant amount (see Article 5.4).

Findings in checks, reviews, audits or investigations may lead to a request for amendment for the modification of Annex 1 (see Article 55).

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations may also lead to consequences in other EU or Euratom grants awarded under similar conditions ('**extension of findings from this grant to other grants**').

Moreover, findings arising from an OLAF investigation may lead to criminal prosecution under national law.

22.5.2 Findings in other grants

The Commission may extend findings from other grants to this grant ('**extension of findings from other grants to this grant**'), if:

(a) the beneficiary concerned is found, in other EU or Euratom grants awarded under similar conditions, to have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — no later than two years after the payment of the balance of this grant.

[17] Regulation (EU, EURATOM) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, EURATOM)) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

The extension of findings may lead to the rejection of costs (see Article 42), reduction of the grant (see Article 43), recovery of undue amounts (see Article 44), suspension of payments (see Article 48), suspension of the action implementation (see Article 49) or termination (see Article 50).

22.5.3 Procedure

The Commission will formally notify the beneficiary concerned the systemic or recurrent errors, together with the list of grants affected by the findings.

22.5.3.1 If the findings concern **eligibility of costs**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings;

(b) the request to submit **revised financial statements** for all grants affected;

(c) the **correction rate for extrapolation** established by the Commission on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

The beneficiary concerned has 90 days from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method**. This period may be extended by the Commission in justified cases.

The Commission will determine the amounts to be rejected on the basis of the revised financial statements, subject to their approval.

If the Commission does not receive any observations or revised financial statements, does not accept the observations or the proposed alternative correction method or does not approve the revised financial statements, it will formally notify the beneficiary concerned the application of the initially notified correction rate for extrapolation.

If the Commission accepts the alternative correction method proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative correction method.

22.5.3.2 If the findings concern **improper implementation** or a **breach of another obligation**: the formal notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the flat-rate the Commission intends to apply according to the principle of proportionality.

The beneficiary concerned has 90 days from receiving notification to submit observations or to propose a duly substantiated alternative flat-rate.

If the Commission does not receive any observations or does not accept the observations or the proposed alternative flat-rate, it will formally notify the beneficiary concerned the application of the initially notified flat-rate.

If the Commission accepts the alternative flat-rate proposed by the beneficiary concerned, it will formally notify the application of the accepted alternative flat-rate.

22.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, any insufficiently substantiated costs will be ineligible (see Article 6) and will be rejected (see Article 42).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 23 — EVALUATION OF THE IMPACT OF THE ACTION

23.1 Right to evaluate the impact of the action

The Commission may carry out interim and final evaluations of the impact of the action measured against the objective of the *EU* programme.

Evaluations may be started during implementation of the action and up to *five* years after the payment of the balance. The evaluation is considered to start on the date of the formal notification to the coordinator or beneficiaries.

The Commission may make these evaluations directly (using its own staff) or indirectly (using external bodies or persons it has authorised to do so).

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

23.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the Commission may apply the measures described in Chapter 6.

SECTION 3 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND AND RESULTS

SUBSECTION 1 GENERAL

ARTICLE 23a — MANAGEMENT OF INTELLECTUAL PROPERTY

23a.1 Obligation to take measures to implement the Commission Recommendation on the management of intellectual property in knowledge transfer activities

Beneficiaries that are universities or other public research organisations must take measures to implement the principles set out in Points 1 and 2 of the Code of Practice annexed to the Commission Recommendation on the management of intellectual property in knowledge transfer activities[18].

This does not change the obligations set out in Subsections 2 and 3 of this Section.

[18] Commission Recommendation C (2008) 1329 of 10.4.2008 on the management of intellectual property in knowledge transfer activities and the Code of Practice for universities and other public research institutions attached to this recommendation.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

23a.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *Commission* may apply any of the measures described in Chapter 6.

SUBSECTION 2 RIGHTS AND OBLIGATIONS RELATED TO BACKGROUND

ARTICLE 24 — AGREEMENT ON BACKGROUND

The beneficiaries must identify and agree (in writing) on the background for the action ('**agreement on background**').

'**Background**' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that:

(a) is held by the beneficiaries before they acceded to the Agreement, and

(b) is needed to implement the action or exploit the results.

ARTICLE 25 — ACCESS RIGHTS TO BACKGROUND

25.1 Exercise of access rights — Waiving of access rights — No sub-licensing

To exercise access rights, this must first be requested in writing ('**request for access**').

'**Access rights**' means rights to use results or background under the terms and conditions laid down in this Agreement.

Waivers of access rights are not valid unless in writing.

Unless agreed otherwise, access rights do not include the right to sub-license.

25.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

(a) informed the other beneficiaries that access to its background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel), or

(b) agreed with the other beneficiaries that access would not be on a royalty-free basis.

25.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other access — under fair and reasonable conditions — to background needed for exploiting their own results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its

background is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel).

'**Fair and reasonable conditions**' means appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.4 Access rights for affiliated entities

Unless otherwise agreed in the consortium agreement, access to background must also be given — under fair and reasonable conditions (see above; Article 25.3) and unless it is subject to legal restrictions or limits, including those imposed by the rights of third parties (including personnel) — to affiliated entities[19] established in an EU Member State or '**associated country**' [20], if this is needed to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 25.1), the affiliated entity concerned must make the request directly to the beneficiary that holds the background.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

25.5 Access rights for third parties

not applicable

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

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[19] [19] For the definition, see Article 2.1(2) of the Rules for Participation Regulation No 1290/2013: '**affiliated entity**' means any legal entity that is under the direct or indirect control of a participant, or under the same direct or indirect control as the participant, or that is directly or indirectly controlling a participant.
'Control' may take any of the following forms:
(a) the direct or indirect holding of more than 50% of the nominal value of the issued share capital in the legal entity concerned, or of a majority of the voting rights of the shareholders or associates of that entity;
(b) the direct or indirect holding, in fact or in law, of decision-making powers in the legal entity concerned.
However the following relationships between legal entities shall not in themselves be deemed to constitute controlling relationships:
(a) the same public investment corporation, institutional investor or venture-capital company has a direct or indirect holding of more than 50% of the nominal value of the issued share capital or a majority of voting rights of the shareholders or associates;
(b) the legal entities concerned are owned or supervised by the same public body.

[20] For the definition, see Article 2.1(3) of the Rules for Participation Regulation No 1290/2013: '**associated country**' means a third country which is party to an international agreement with the Union, as identified in Article 7 of Horizon 2020 Framework Programme Regulation No 1291/2013. Article 7 sets out the conditions for association of non-EU countries to Horizon 2020.

SUBSECTION 3 RIGHTS AND OBLIGATIONS RELATED TO RESULTS

ARTICLE 26 — OWNERSHIP OF RESULTS

26.1 Ownership by the beneficiary that generates the results

Results are owned by the beneficiary that generates them.

'**Results**' means any (tangible or intangible) output of the action such as data, knowledge or information — whatever its form or nature, whether it can be protected or not — that is generated in the action, as well as any rights attached to it, including intellectual property rights.

26.2 Joint ownership by several beneficiaries

Two or more beneficiaries own results jointly if:

(a) they have jointly generated them and

(b) it is not possible to:

(i) establish the respective contribution of each beneficiary, or

(ii) separate them for the purpose of applying for, obtaining or maintaining their protection (see Article 27).

The joint owners must agree (in writing) on the allocation and terms of exercise of their joint ownership ('**joint ownership agreement**'), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement, each joint owner may grant non-exclusive licences to third parties to exploit jointly-owned results (without any right to sub-license), if the other joint owners are given:

(a) at least 45 days advance notice and

(b) fair and reasonable compensation.

Once the results have been generated, joint owners may agree (in writing) to apply another regime than joint ownership (such as, for instance, transfer to a single owner (see Article 30) with access rights for the others).

26.3 Rights of third parties (including personnel)

If third parties (including personnel) may claim rights to the results, the beneficiary concerned must ensure that it complies with its obligations under the Agreement.

If a third party generates results, the beneficiary concerned must obtain all necessary rights (transfer, licences or other) from the third party, in order to be able to respect its obligations as if those results were generated by the beneficiary itself.

If obtaining the rights is impossible, the beneficiary must refrain from using the third party to generate the results.

26.4 *EU* ownership, to protect results

26.4.1 *The EU* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to disseminate its results without protecting them, except in any of the following cases:

(a) the lack of protection is because protecting the results is not possible, reasonable or justified (given the circumstances);

(b) the lack of protection is because there is a lack of potential for commercial or industrial exploitation, or

(c) the beneficiary intends to transfer the results to another beneficiary or third party established in an EU Member State or associated country, which will protect them.

Before the results are disseminated and unless any of the cases above under Points (a), (b) or (c) applies, the beneficiary must formally notify the *Commission* and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *Commission* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

No dissemination relating to these results may before the end of this period or, if the *Commission* takes a positive decision, until it has taken the necessary steps to protect the results.

26.4.2 *The EU* may — with the consent of the beneficiary concerned — assume ownership of results to protect them, if a beneficiary intends — up to four years after the period set out in Article 3 — to stop protecting them or not to seek an extension of protection, except in any of the following cases:

(a) the protection is stopped because of a lack of potential for commercial or industrial exploitation;

(b) an extension would not be justified given the circumstances.

A beneficiary that intends to stop protecting results or not seek an extension must — unless any of the cases above under Points (a) or (b) applies — formally notify the *Commission* at least 60 days before the protection lapses or its extension is no longer possible and at the same time inform it of any reasons for refusing consent. The beneficiary may refuse consent only if it can show that its legitimate interests would suffer significant harm.

If the *Commission* decides to assume ownership, it will formally notify the beneficiary concerned within 45 days of receiving notification.

26.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to the any of the other measures described in Chapter 6.

ARTICLE 27 — PROTECTION OF RESULTS — VISIBILITY OF EU FUNDING

27.1 General obligation to protect the results

Each beneficiary must examine the possibility of protecting its results and must adequately protect them — for an appropriate period and with appropriate territorial coverage — if:

(a) the results can reasonably be expected to be commercially or industrially exploited and

(b) protecting them is possible, reasonable and justified (given the circumstances).

When deciding on protection, the beneficiary must consider its own legitimate interests and the legitimate interests (especially commercial) of the other beneficiaries.

27.2 *EU* ownership, to protect the results

If a beneficiary intends not to protect its results, to stop protecting them or not seek an extension of protection, *The EU* may — under certain conditions (see Article 26.4) — assume ownership to ensure their (continued) protection.

27.3 Information on EU funding

Applications for protection of results (including patent applications) filed by or on behalf of a beneficiary must — unless the *Commission* requests or agrees otherwise or unless it is impossible — include the following:

> "The project leading to this application has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 643529".

27.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 28 — EXPLOITATION OF RESULTS

28.1 General obligation to exploit the results

Each beneficiary must — up to four years after the period set out in Article 3 — take measures aiming to ensure '**exploitation**' of its results (either directly or indirectly, in particular through transfer or licensing; see Article 30) by:

(a) using them in further research activities (outside the action);

(b) developing, creating or marketing a product or process;

(c) creating and providing a service, or

(d) using them in standardisation activities.

This does not change the security obligations in Article 37, which still apply.

28.2 Results that could contribute to European or international standards — Information on EU funding

If results are incorporated in a standard, the beneficiary concerned must — unless the *Commission* requests or agrees otherwise or unless it is impossible — ask the standardisation body to include the following statement in (information related to) the standard:

> "Results incorporated in this standard received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 643529".

28.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced in accordance with Article 43.

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 29 — DISSEMINATION OF RESULTS — OPEN ACCESS — VISIBILITY OF EU FUNDING

29.1 General obligation to disseminate results

Unless it goes against their legitimate interests, each beneficiary must — as soon as possible — '**disseminate**' its results by disclosing them to the public by appropriate means (other than those resulting from protecting or exploiting the results), including in scientific publications (in any medium).

This does not change the obligation to protect results in Article 27, the confidentiality obligations in Article 36, the security obligations in Article 37 or the obligations to protect personal data in Article 39, all of which still apply.

A beneficiary that intends to disseminate its results must give advance notice to the other beneficiaries of — unless agreed otherwise — at least 45 days, together with sufficient information on the results it will disseminate.

Any other beneficiary may object within — unless agreed otherwise — 30 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the dissemination may not take place unless appropriate steps are taken to safeguard these legitimate interests.

If a beneficiary intends not to protect its results, it may — under certain conditions (see Article 26.4.1) — need to formally notify the *Commission* before dissemination takes place.

29.2 Open access to scientific publications

Each beneficiary must ensure open access (free of charge online access for any user) to all peer-reviewed scientific publications relating to its results.

In particular, it must:

(a) as soon as possible and at the latest on publication, deposit a machine-readable electronic copy of the published version or final peer-reviewed manuscript accepted for publication in a repository for scientific publications;

Moreover, the beneficiary must aim to deposit at the same time the research data needed to validate the results presented in the deposited scientific publications.

(b) ensure open access to the deposited publication — via the repository — at the latest:

(i) on publication, if an electronic version is available for free via the publisher, or

(ii) within six months of publication (twelve months for publications in the social sciences and humanities) in any other case.

(c) ensure open access — via the repository — to the bibliographic metadata that identify the deposited publication.

The bibliographic metadata must be in a standard format and must include all of the following:

- the terms *"European Union (EU)" and "Horizon 2020";*
- the name of the action, acronym and grant number;
- the publication date, and length of embargo period if applicable, and
- a persistent identifier.

29.3 Open access to research data

not applicable

29.4 Information on EU funding — Obligation and right to use the EU emblem

Unless the *Commission* requests or agrees otherwise or unless it is impossible, any dissemination of results (in any form, including electronic) must:

(a) display the EU emblem and

(b) include the following text:

"This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 643529".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *Commission*.

This does not however give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

29.5 Disclaimer excluding *Commission* responsibility

Any dissemination of results must indicate that it reflects only the author's view and that the *Commission* is not responsible for any use that may be made of the information it contains.

29.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 30 — TRANSFER AND LICENSING OF RESULTS

30.1 Transfer of ownership

Each beneficiary may transfer ownership of its results.

It must however ensure that its obligations under Articles 26.2, 26.4, 27, 28, 29, 30 and 31 also apply to the new owner and that this owner has the obligation to pass them on in any subsequent transfer.

This does not change the security obligations in Article 37, which still apply.

Unless agreed otherwise (in writing) for specifically-identified third parties or unless impossible under applicable EU and national laws on mergers and acquisitions, a beneficiary that intends to transfer ownership of results must give at least 45 days advance notice to the other beneficiaries that still have (or still may request) access rights to the results. This notification must include sufficient information on the new owner to enable any beneficiary concerned to assess the effects on its access rights.

Unless agreed otherwise (in writing), any other beneficiary may object within 30 days of receiving notification, if it can show that the transfer would adversely affect its access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

30.2 Granting licenses

Each beneficiary may grant licences to its results (or otherwise give the right to exploit them), if:

(a) this does not impede the rights under Article 31 and

(b) *not applicable.*

In addition to Points (a) and (b), exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights (see Article 31.1).

This does not change the dissemination obligations in Article 29 or security obligations in Article 37, which still apply.

30.3 *Commission* right to object to transfers or licensing

not applicable

30.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such a breach may also lead to any of the other measures described in Chapter 6.

ARTICLE 31 — ACCESS RIGHTS TO RESULTS

31.1 Exercise of access rights — Waiving of access rights — No sub-licensing

The conditions set out in Article 25.1 apply.

The obligations set out in this Article do not change the security obligations in Article 37, which still apply.

31.2 Access rights for other beneficiaries, for implementing their own tasks under the action

The beneficiaries must give each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

31.3 Access rights for other beneficiaries, for exploiting their own results

The beneficiaries must give each other — under fair and reasonable conditions (see Article 25.3) — access to results needed for exploiting their own results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.4 Access rights of affiliated entities

Unless agreed otherwise in the consortium agreement, access to results must also be given — under fair and reasonable conditions (Article 25.3) — to affiliated entities established in an EU Member State or associated country, if this is needed for those entities to exploit the results generated by the beneficiaries to which they are affiliated.

Unless agreed otherwise (see above; Article 31.1), the affiliated entity concerned must make any such request directly to the beneficiary that owns the results.

Requests for access may be made — unless agreed otherwise — up to one year after the period set out in Article 3.

31.5 Access rights for the EU institutions, bodies, offices or agencies and EU Member States

31.6 Access rights for third parties

not applicable

31.7 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

SECTION 4 OTHER RIGHTS AND OBLIGATIONS

ARTICLE 32 — RECRUITMENT AND WORKING CONDITIONS FOR RESEARCHERS

32.1 Obligation to take measures to implement the European Charter for Researchers and Code of Conduct for the Recruitment of Researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[22], in particular regarding:

- working conditions;
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and third parties involved in the action are aware of them.

32.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *Commission* may apply any of the measures described in Chapter 6.

ARTICLE 33 — GENDER EQUALITY

33.1 Obligation to aim for gender equality

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

33.2 Consequences of non-compliance

If a beneficiary breaches its obligations under this Article, the *Commission* may apply any of the measures described in Chapter 6.

ARTICLE 34 — ETHICS

34.1 General obligation to comply with ethical principles

The beneficiaries must carry out the action in compliance with:

[22] Commission recommendation (EC) No 251/2005 of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.03.2005, p. 67).

(a) ethical principles (including the highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity[23] — and including, in particular, avoiding fabrication, falsification, plagiarism or other research misconduct) and

(b) applicable international, EU and national law.

Funding will not be granted for activities carried out outside the EU if they are prohibited in all Member States.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

(a) aim at human cloning for reproductive purposes;

(b) intend to modify the genetic heritage of human beings which could make such changes heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed), or

(c) intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer.

34.2 Activities raising ethical issues

Activities raising ethical issues must comply with the '**ethics requirements**' set out in Annex 1.

Before the beginning of an activity raising an ethical issue, the coordinator must submit (see Article 52) to the *Commission* copy of:

(a) any ethics committee opinion required under national law and

(b) any notification or authorisation for activities raising ethical issues required under national law.

If these documents are not in English, the coordinator must also submit an English summary of the submitted opinions, notifications and authorisations (containing, if available, the conclusions of the committee or authority concerned).

If these documents are specifically requested for the action, the request must contain an explicit reference to the action title. The coordinator must submit a declaration by each beneficiary concerned that all the submitted documents cover the action tasks.

34.3 Activities involving human embryos or human embryonic stem cells

not applicable

[23] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.
http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

34.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 35 — CONFLICT OF INTERESTS

35.1 Obligation to avoid a conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the action is compromised for reasons involving economic interest, political or national affinity, family or emotional ties or any other shared interest ('**conflict of interests**').

They must formally notify to the *Commission* without delay any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The *Commission* may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

35.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43) and the Agreement or participation of the beneficiary may be terminated (see Article 50).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 36 — CONFIDENTIALITY

36.1 General obligation to maintain confidentiality

During implementation of the action and for four years after the period set out in Article 3, the parties must keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed ('**confidential information**').

If a beneficiary requests, the *Commission* may agree to keep such information confidential for an additional period beyond the initial four years.

If information has been identified as confidential only orally, it will be considered to be confidential only if this is confirmed in writing within 15 days of the oral disclosure.

Unless otherwise agreed between the parties, they may use confidential information only to implement the Agreement.

The beneficiaries may disclose confidential information to their personnel or third parties involved in the action only if they:

(a) need to know to implement the Agreement and

(b) are bound by an obligation of confidentiality.

This does not change the security obligations in Article 37, which still apply.

The *Commission* may disclose confidential information to its staff, other EU institutions and bodies or third parties, if:

(a) this is necessary to implement the Agreement or safeguard the *EU*'s financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

Under the conditions set out in Article 4 of the Rules for participation Regulation No 1290/2013[24], the Commission must moreover make available information on the results to other EU institutions, bodies, offices or agencies as well as Member States or associated countries.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was developed without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation, or

(e) the disclosure of the information is required by EU or national law.

36.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 37 — SECURITY-RELATED OBLIGATIONS

37.1 Activities raising security issues

not applicable

37.2 Classified deliverables

not applicable

37.3 Activities involving dual-use goods or dangerous materials and substances

not applicable

[24] Regulation (EU) No 1290/2013 of the European Parliament and of the Council of 11 December 2013 laying down the rules for participation and dissemination in "Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020)" (OJ L 347, 20.12.2013 p.81).

37.4 Consequences of non-compliance

not applicable

ARTICLE 38 — PROMOTING THE ACTION — VISIBILITY OF EU FUNDING

38.1 Communication activities by beneficiaries

38.1.1 General obligation to promote the action and its results

The beneficiaries must promote the action and its results, by providing targeted information to multiple audiences (including the media and the public) in a strategic and effective manner.

This does not change the dissemination obligations in Article 29, the confidentiality obligations in Article 36 or the security obligations in Article 37, all of which still apply.

Before engaging in a communication activity expected to have a major media impact, the beneficiaries must inform the *Commission* (see Article 52).

38.1.2 Information on EU funding — Obligation and right to use the EU emblem

Unless the *Commission* requests or agrees otherwise or unless it is impossible, any communication activity related to the action (including in electronic form, via social media, etc.) and any infrastructure funded by the grant must:

(a) display the EU emblem and

(b) include the following text:

> "This project has received funding from the *European Union's Horizon 2020 research and innovation programme* under grant agreement No 643529".

When displayed together with another logo, the EU emblem must have appropriate prominence.

For the purposes of their obligations under this Article, the beneficiaries may use the EU emblem without first obtaining approval from the *Commission*.

This does not, however, give them the right to exclusive use.

Moreover, they may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

38.1.3 Disclaimer excluding *Commission* responsibility

Any communication activity related to the action must indicate that it reflects only the author's view and that the *Commission* is not responsible for any use that may be made of the information it contains.

38.2 Communication activities by the *Commission*

38.2.1 Right to use beneficiaries' materials, documents or information

The *Commission* may use, for its communication and publicising activities, information relating to the action, documents notably summaries for publication and public deliverables as well as any other

material, such as pictures or audio-visual material that it receives from any beneficiary (including in electronic form).

This does not change the confidentiality obligations in Article 36 and the security obligations in Article 37, all of which still apply.

However, if the *Commission's* use of these materials, documents or information would risk compromising legitimate interests, the beneficiary concerned may request the *Commission* not to use it (see Article 52).

The right to use a beneficiary's materials, documents and information includes:

(a) **use for its own purposes** (in particular, making them available to persons working for the *Commission* or any other EU institution, body, office or agency or body or institutions in EU Member States; and copying or reproducing them in whole or in part, in unlimited numbers);

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes);

(c) **editing or redrafting** for communication and publicising activities (including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation);

(d) **translation**;

(e) giving **access in response to individual requests** under Regulation No 1049/2001[25], without the right to reproduce or exploit;

(f) **storage** in paper, electronic or other form;

(g) **archiving**, in line with applicable document-management rules, and

(h) the right to authorise **third parties** to act on its behalf or sub-license the modes of use set out in Points (b),(c),(d) and (f) to third parties if needed for the communication and publicising activities of the *Commission*.

If the right of use is subject to rights of a third party (including personnel of the beneficiary), the beneficiary must ensure that it complies with its obligations under this Agreement (in particular, by obtaining the necessary approval from the third parties concerned).

Where applicable (and if provided by the beneficiaries), the *Commission* will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the *European Union (EU)* under conditions."

[25] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

38.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 43).

Such breaches may also lead to any of the other measures described in Chapter 6.

ARTICLE 39 — PROCESSING OF PERSONAL DATA

39.1 Processing of personal data by the *Commission*

Any personal data under the Agreement will be processed by the *Commission* under Regulation No 45/2001[26] and according to the 'notifications of the processing operations' to the Data Protection Officer (DPO) of the *Commission* (publicly accessible in the DPO register).

Such data will be processed by the '**data controller**' of the *Commission* for the purposes of implementing, managing and monitoring the Agreement (including checks, reviews, audits and investigations; see Article 22).

The persons whose personal data are processed have the right to access and correct their own personal data. For this purpose, they must send any queries about the processing of their personal data to the data controller, via the contact point indicated in the 'service specific privacy statement (SSPS)' on the *Commission's* websites.

They also have the right to have recourse at any time to the European Data Protection Supervisor (EDPS).

39.2 Processing of personal data by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with applicable EU and national law on data protection (including authorisations or notification requirements).

The beneficiaries may grant their personnel access only to data that is strictly necessary for implementing, managing and monitoring the Agreement.

The beneficiaries must inform the personnel whose personal data are collected and processed by the *Commission*. For this purpose, they must provide them with the service specific privacy statement (SSPS) (see above), before transmitting their data to the *Commission*.

39.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under Article 39.2, the *Commission* may apply any of the measures described in Chapter 6.

[26] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.01.2001, p. 1).

ARTICLE 40 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE *COMMISSION*

The beneficiaries may not assign any of their claims for payment against the *Commission* to any third party, except if approved by the *Commission* on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the *Commission* has not accepted the assignment or the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the *Commission*.

CHAPTER 5 DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

ARTICLE 41 — DIVISION OF BENEFICIARIES' ROLES AND RESPONSIBILITIES

41.1 Roles and responsibilities towards the *Commission*

The beneficiaries have full responsibility for implementing the action and complying with the Agreement.

The beneficiaries are jointly and severally liable for the **technical implementation** of the action as described in Annex 1. If a beneficiary fails to implement its part of the action, the other beneficiaries become responsible for implementing this part (without being entitled to any additional EU funding for doing so), unless the *Commission* expressly relieves them of this obligation.

The **financial responsibility** of each beneficiary is governed by Articles 44, 45 and 46.

41.2 Internal division of roles and responsibilities

The internal roles and responsibilities of the beneficiaries are divided as follows:

(a) Each **beneficiary** must:

(i) keep information stored in the Beneficiary Register (in the electronic exchange system) up to date (see Article 17);

(ii) inform the coordinator immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 17);

(iii) submit to the coordinator in good time:

- individual financial statements for itself and, if required, certificates on the financial statements (see Article 20);

- the data needed to draw up the technical reports (see Article 20);

- ethics committee opinions and notifications or authorisations for activities raising ethical issues (see Article 34);

- any other documents or information required by the *Commission* under the Agreement, unless the Agreement requires the beneficiary to submit this information directly to the *Commission*.

(b) The **coordinator** must:

(i) monitor that the action is implemented properly (see Article 7);

(ii) act as the intermediary for all communications between the beneficiaries and the *Commission* (in particular, providing the *Commission* with the information described in Article 17), unless the Agreement specifies otherwise;

(iii) request and review any documents or information required by the *Commission* and verify their completeness and correctness before passing them on to the *Commission*;

(iv) submit the deliverables and reports to the *Commission* (see Articles 19 and 20);

(v) ensure that all payments are made to the other beneficiaries without unjustified delay (see Article 21);

(vi) inform the *Commission* of the amounts paid to each beneficiary, when required under the Agreement (see Articles 44 and 50) or requested by the *Commission*.

The coordinator may not delegate the above-mentioned tasks to any other beneficiary or subcontract them to any third party.

41.3 Internal arrangements between beneficiaries — Consortium agreement

*The beneficiaries must have internal arrangements regarding their operation and co-ordination to ensure that the action is implemented properly. These internal arrangements must be set out in a written '**consortium agreement**' between the beneficiaries, which may cover:*

- *internal organisation of the consortium;*
- *management of access to the electronic exchange system;*
- *distribution of EU funding;*
- *additional rules on rights and obligations related to background and results (including whether access rights remain or not, if a beneficiary is in breach of its obligations) (see Section 3);*
- *settlement of internal disputes;*
- *liability, indemnification and confidentiality arrangements between the beneficiaries.*

The consortium agreement must not contain any provision contrary to the Agreement.

41.4 Relationship with complementary beneficiaries — Collaboration agreement

not applicable

41.5 Relationship with partners of a joint action — Coordination agreement

not applicable

CHAPTER 6 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES — DAMAGES — SUSPENSION — TERMINATION — FORCE MAJEURE

SECTION 1 REJECTION OF COSTS — REDUCTION OF THE GRANT — RECOVERY — PENALTIES

ARTICLE 42 — REJECTION OF INELIGIBLE COSTS

42.1 Conditions

42.1.1 The *Commission* will — at the time of an **interim payment, at the payment of the balance** or **afterwards** — reject any costs which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 22).

42.1.2 The rejection may also be based on the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

42.2 Ineligible costs to be rejected — Calculation — Procedure

Ineligible costs will be rejected in full.

If the *Commission* rejects costs **without reduction of the grant** (see Article 43) or **recovery of undue amounts** (see Article 44), it will formally notify the coordinator or beneficiary concerned the rejection of costs, the amounts and the reasons why (if applicable, together with the notification of amounts due; see Article 21.5). The coordinator or beneficiary concerned may — within 30 days of receiving notification — formally notify the *Commission* of its disagreement and the reasons why.

If the *Commission* rejects costs **with reduction of the grant** or **recovery of undue amounts** , it will formally notify the rejection in the '**pre-information letter**' on reduction or recovery set out in Articles 43 and 44.

42.3 Effects

If the *Commission* rejects costs at the time of an **interim payment** or **the payment of the balance**, it will deduct them from the total eligible costs declared, for the action, in the periodic or final summary financial statement as set out in Articles 21.3 or 21.4 statement (see Articles 20.3 and 20.4). It will then calculate the interim payment or payment of the balance.

If the *Commission* — **after an interim payment but before the payment of the balance** — rejects costs declared in a periodic summary financial statement, it will deduct them from the total eligible costs declared, for the action, in the next periodic summary financial statement or in the final summary financial statement. It will then calculate the interim payment or payment of the balance as set out in Articles 21.3 or 21.4.

If the *Commission* rejects costs **after the payment of the balance**, it will deduct the amount rejected from the total eligible costs declared, by the beneficiary, in the final summary financial statement. It will then calculate the revised final grant amount as set out in Article 5.4.

ARTICLE 43 — REDUCTION OF THE GRANT

43.1 Conditions

43.1.1 The *Commission* may — **at the payment of the balance** or **afterwards** — reduce the maximum grant amount (see Article 5.1), if the action has not been implemented properly as described in Annex 1 or another obligation under the Agreement has been breached.

43.1.2 The *Commission* may also reduce the maximum grant amount on the basis of the **extension of findings from other grants to this grant**, under the conditions set out in Article 22.5.2.

43.2 Amount to be reduced — Calculation — Procedure

The amount of the reduction will be proportionate to the improper implementation of the action or to the seriousness of the breach.

Before reduction of the grant, the *Commission* will formally notify a '**pre-information letter**' to the coordinator or beneficiary concerned:

- informing it of its intention to reduce the grant, the amount it intends to reduce and the reasons why and

- inviting it to submit observations within 30 days of receiving notification

If the *Commission* does not receive any observations or decides to pursue reduction despite the observations it has received, it will formally notify **confirmation** of the reduction (if applicable, together with the notification of amounts due; see Article 21).

43.3 Effects

If the *Commission* reduces the grant at the time of **the payment of the balance**, it will calculate the reduced grant amount for the action and then determine the amount due as payment of the balance (see Articles 5.3.4 and 21.4).

If the *Commission* reduces the grant **after the payment of the balance**, it will calculate the revised final grant amount for the beneficiary concerned (see Article 5.4). If the revised final grant amount for the beneficiary concerned is lower than its share of the final grant amount, the *Commission* will recover the difference (see Article 44).

ARTICLE 44 — RECOVERY OF UNDUE AMOUNTS

44.1 Amount to be recovered — Calculation — Procedure

The *Commission* will — after **termination of the participation of a beneficiary, at the payment of the balance** or **afterwards** — recover any amount that was paid but is not due under the Agreement.

Each beneficiary's financial responsibility in case of recovery is limited to its own debt, except for the amount retained for the Guarantee Fund (see Article 21.4).

44.1.1 Recovery after termination of a beneficiary's participation

If recovery takes place after termination of a beneficiary's participation (including the coordinator), the *Commission* will recover the undue amount from the beneficiary concerned by formally notifying it a debit note (see Article 50.2 and 50.3). This note will specify the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *Commission* will **recover** the amount:

(a) by '**offsetting**' it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *Commission or an executive agency (from the EU or Euratom budget)*.
In exceptional circumstances, to safeguard the *EU's* financial interests, the *Commission* may offset before the payment date specified in the debit note;

(b) not applicable, and/or

(c) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date specified in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC[27] applies.

44.1.2 Recovery at payment of the balance

If the payment of the balance takes the form of a recovery (see Article 21.4), the *Commission* will formally notify a '**pre-information letter**' to the coordinator:

- informing it of its intention to recover, the amount due as the balance and the reasons why;

- specifying that it intends to deduct the amount to be recovered from the amount retained for the Guarantee Fund;

- requesting the coordinator to submit a report on the distribution of payments to the beneficiaries within 30 days of receiving notification, and

- inviting the coordinator to submit observations within 30 days of receiving notification.

[27] Directive 2007/64/EC of the European Parliament and of the Council of 13 November 2007 on payment services in the internal market amending Directives 97/7/EC, 2002/65/EC, 2005/60/EC and 2006/48/EC and repealing Directive 97/5/EC (OJ L 319, 05.12.2007, p. 1).

If no observations are submitted or the *Commission* decides to pursue recovery despite the observations it has received, it will **confirm recovery** (together with the notification of amounts due; see Article 21.5) and:

- pay the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is positive** or

- formally notify to the coordinator a **debit note** for the difference between the amount to be recovered and the amount retained for the Guarantee Fund, **if the difference is negative**. This note will also specify the terms and the date for payment.

If the coordinator does not repay the *Commission* by the date in the debit note and has not submitted the report on the distribution of payments: the *Commission* will **recover** the amount set out in the debit note from the coordinator (see below).

If the coordinator does not repay the *Commission* by the date in the debit note, but has submitted the report on the distribution of payments: the *Commission* will:

(a) identify the beneficiaries for which the amount calculated as follows is negative:

{{{{beneficiary's costs declared in the final summary financial statement and approved by the *Commission* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)},

minus

{pre-financing and interim payments received by the beneficiary}}.

(b) formally notify to each beneficiary identified according to point (a) a **debit note** specifying the terms and date for payment. The amount of the debit note is calculated as follows:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount set out in the debit note formally notified to the coordinator}.

If payment is not made by the date specified in the debit note, the *Commission* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *Commission or an executive agency (from the EU or Euratom budget)*.

In exceptional circumstances, to safeguard the the *EU's* financial interests, the *Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund**. The *Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) *not applicable,*

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

44.1.3 Recovery of amounts after payment of the balance

If, for a beneficiary, the revised final grant amount (see Article 5.4) is lower than its share of the final grant amount, it must repay the difference to the *Commission*.

The beneficiary's share of the final grant amount is calculated as follows:

{{{beneficiary's costs declared in the final summary financial statement and approved by the *Commission* multiplied by the reimbursement rate set out in Article 5.2 for the beneficiary concerned}

divided by

the EU contribution for the action calculated according to Article 5.3.1}

multiplied by

the final grant amount (see Article 5.3)}.

If the coordinator has not distributed amounts received (see Article 21.7), the Commission will also recover these amounts.

The *Commission* will formally notify a **pre-information letter** to the beneficiary concerned:

- informing it of its intention to recover, the due amount and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If no observations are submitted or the *Commission* decides to pursue recovery despite the observations it has received, it will **confirm** the amount to be recovered and formally notify to the beneficiary concerned a **debit note**. This note will also specify the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *Commission* will **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *Commission or an executive agency (from the EU or Euratom budget)*.

In exceptional circumstances, to safeguard the *EU's* financial interests, the *Commission* may offset before the payment date specified in the debit note;

(b) by **drawing on the Guarantee Fund**. The *Commission* will formally notify the beneficiary concerned the debit note on behalf of the Guarantee Fund and recover the amount:

(i) *not applicable*

(ii) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the date for payment in the debit note, up to and including the date the *Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

ARTICLE 45 — ADMINISTRATIVE AND FINANCIAL PENALTIES

45.1 Conditions

Under Articles 109 and 131(4) of the Financial Regulation No 966/2012, the *Commission* may impose **administrative** and **financial penalties** if a beneficiary:

(a) has committed substantial errors, irregularities or fraud or is in serious breach of its obligations under the Agreement or

(b) has made false declarations about information required under the Agreement or for the submission of the proposal (or has not supplied such information).

Each beneficiary is responsible for paying the financial penalties imposed on it.

Under Article 109(3) of the Financial Regulation No 966/2012, the *Commission* may — under certain conditions and limits — publish decisions imposing administrative or financial penalties.

45.2 Duration — Amount of penalty — Calculation

Administrative penalties exclude the beneficiary from all contracts and grants financed from the EU or Euratom budget for a maximum of five years from the date the infringement is established by the *Commission*.

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *Commission* may extend the exclusion period up to 10 years.

Financial penalties will be between 2% and 10% of the maximum EU contribution indicated, for the beneficiary concerned, in the estimated budget (see Annex 2).

If the beneficiary commits another infringement within five years of the date the first infringement is established, the *Commission* may increase the rate of financial penalties to between 4% and 20%.

45.3 Procedure

Before applying a penalty, the *Commission* will formally notify the beneficiary concerned:

- informing it of its intention to impose a penalty, its duration or amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *Commission* does not receive any observations or decides to impose the penalty despite of observations it has received, it will formally notify **confirmation** of the penalty to the beneficiary concerned and — in case of financial penalties — deduct the penalty from the payment of the balance or formally notify a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *Commission* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *Commission or an executive agency (from the EU or Euratom budget)*.

In exceptional circumstances, to safeguard the *EU's* financial interests, the *Commission* may offset before the payment date specified in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 2 LIABILITY FOR DAMAGES

ARTICLE 46 — LIABILITY FOR DAMAGES

46.1 Liability of the *Commission*

The *Commission* cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of implementing the Agreement, including for gross negligence.

The *Commission* cannot be held liable for any damage caused by any of the beneficiaries or third parties involved in the action, as a consequence on implementing the Agreement.

46.2 Liability of the beneficiaries

46.2.1 Conditions

Except in case of force majeure (see Article 51), the beneficiaries must compensate the *Commission* for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement.

Each beneficiary is responsible for paying the damages claimed from it.

46.2.2 Amount of damages - Calculation

The amount the *Commission* can claim from a beneficiary will correspond to the damage caused by that beneficiary.

46.2.3 Procedure

Before claiming damages, the *Commission* will formally notify the beneficiary concerned:

- informing it of its intention to claim damages, the amount and the reasons why and
- inviting it to submit observations within 30 days.

If the *Commission* does not receive any observations or decides to claim damages despite the observations it has received, it will formally notify **confirmation** of the claim for damages and a **debit note**, specifying the amount to be recovered, the terms and the date for payment.

If payment is not made by the date specified in the debit note, the *Commission* may **recover** the amount:

(a) by **offsetting** it — without the beneficiary's consent — against any amounts owed to the beneficiary concerned by the *Commission or an executive agency (from the EU or Euratom budget)*.

In exceptional circumstances, to safeguard the *EU's* financial interests, the *Commission* may offset before the payment date specified in the debit note;

(b) by **taking legal action** or by **adopting an enforceable decision** under Article 299 of the Treaty on the Functioning of the EU (TFEU) (see Article 57).

If payment is not made by the date in the debit note, the amount to be recovered (see above) will be increased by **late-payment interest** at the rate set out in Article 21.11, from the day following the payment date in the debit note, up to and including the date the *Commission* receives full payment of the amount.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2007/64/EC applies.

SECTION 3 SUSPENSION AND TERMINATION

ARTICLE 47 — SUSPENSION OF PAYMENT DEADLINE

47.1 Conditions

The *Commission* may — at any moment — suspend the payment deadline (see Article 21.2 to 21.4) if a request for payment (see Article 20) cannot be approved because:

(a) it does not comply with the provisions of the Agreement (see Article 20);

(b) the technical reports or financial reports have not been submitted or are not complete or additional information is needed, or

(c) there is doubt about the eligibility of the costs declared in the financial statements and additional checks, reviews, audits or investigations are necessary.

47.2 Procedure

The *Commission* will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day notification is sent by the *Commission* (see Article 52).

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining period will resume.

If the suspension exceeds two months, the coordinator may request the *Commission* if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the technical or financial reports (see Article 20) and the revised report or statement is not submitted or was submitted but is also rejected, the *Commission* may also terminate the Agreement or the participation of the beneficiary (see Article 50.3.1(l)).

ARTICLE 48 — SUSPENSION OF PAYMENTS

48.1 Conditions

The *Commission* may — at any moment — suspend, in whole or in part, the pre-financing payment and interim payments for one or more beneficiaries or the payment of the balance for all beneficiaries, if a beneficiary:

(a) has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement or

(b) has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2).

48.2 Procedure

Before suspending payments, the *Commission* will formally notify the coordinator:

- informing it of its intention to suspend payments and the reasons why and

- inviting it to submit observations within 30 days of receiving notification.

If the *Commission* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the suspension procedure is not continued.

The suspension will **take effect** the day the confirmation notification is sent by the *Commission*.

If the conditions for resuming payments are met, the suspension will be **lifted**. The Commission will formally notify the coordinator.

During the suspension, the periodic report(s) (see Article 20.3) must not contain any individual financial statements from the beneficiary concerned. When the *Commission* resumes payments, the coordinator may include them in the next periodic report.

The beneficiaries may suspend implementation of the action (see Article 49.1) or terminate the Agreement or the participation of the beneficiary concerned (see Article 50.1 and 50.2).

ARTICLE 49 — SUSPENSION OF THE ACTION IMPLEMENTATION

49.1 Suspension of the action implementation, by the beneficiaries

49.1.1 Conditions

The beneficiaries may suspend implementation of the action or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 51) — make implementation impossible or excessively difficult.

49.1.2 Procedure

The coordinator must immediately formally notify to the *Commission* the suspension (see Article 52), stating:

- the reasons why and
- the expected date of resumption.

The suspension will **take effect** the day this notification is received by the *Commission*.

Once circumstances allow for implementation to resume, the coordinator must immediately formally notify the *Commission* and request an **amendment** of the Agreement to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement or the participation of a beneficiary has been terminated (see Article 50).

The suspension will be **lifted** with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension of the action implementation are not eligible (see Article 6).

49.2 Suspension of the action implementation, by the *Commission*

49.2.1 Conditions

The *Commission* may suspend implementation of the action or any part of it:

(a) if a beneficiary has committed or is suspected of having committed substantial errors, irregularities, fraud or serious breach of obligations in the award procedure or under this Agreement;

(b) if a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (**extension of findings from other grants to this grant**; see Article 22.5.2), or

(c) if the action is suspected of having lost its scientific or technological relevance.

49.2.2 Procedure

Before suspending implementation of the action, the *Commission* will formally notify the coordinator:

- informing it of its intention to suspend the implementation and the reasons why and
- inviting it to submit observations within 30 days of receiving notification.

If the *Commission* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify **confirmation** of the suspension. Otherwise, it will formally notify that the procedure is not continued.

The suspension will **take effect** five days after confirmation notification is received by the coordinator (or on a later date specified in the notification).

It will be **lifted** if the conditions for resuming implementation of the action are met.

The coordinator will be formally notified of the lifting and the Agreement will be **amended** to set the date on which the action will be resumed, extend the duration of the action and make other changes necessary to adapt the action to the new situation (see Article 55) — unless the Agreement has already been terminated (see Article 50).

The suspension will be lifted with effect from the resumption date set out in the amendment. This date may be before the date on which the amendment enters into force.

Costs incurred during suspension are not eligible (see Article 6).

The beneficiaries may not claim damages due to suspension by the *Commission* (see Article 46).

Suspension of the action implementation does not affect the *Commission's* right to terminate the Agreement or participation of a beneficiary (see Article 50), reduce the grant or recover amounts unduly paid (see Articles 43 and 44).

ARTICLE 50 — TERMINATION OF THE AGREEMENT OR OF PARTICIPATION FOR ONE OR MORE BENEFICIARIES

50.1 Termination of the Agreement by the beneficiaries

50.1.1 Conditions and procedure

The beneficiaries may terminate the Agreement.

The coordinator must formally notify termination to the *Commission* (see Article 52), stating:

- the reasons why and
- the date the termination will take effect. This date must be after the notification.

If no reasons are given or if the *Commission* considers the reasons do not justify termination, the Agreement will be considered to have been '**terminated improperly**'.

The termination will **take effect** on the day specified in the notification.

50.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the open reporting period until termination; see Article 20.3) and

(ii) the final report (see Article 20.4).

If the *Commission* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *Commission* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

Improper termination may lead to a reduction of the grant (see Article 43).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.2 Termination of participation for one or more beneficiaries, by the beneficiaries

50.2.1 Conditions and procedure

The participation of one or more beneficiaries may be terminated by the coordinator, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must formally notify termination to the *Commission* (see Article 52) and inform the beneficiary concerned.

If the coordinator's participation is terminated without its agreement, the formal notification must be done by another beneficiary (acting on behalf of the other beneficiaries).

The notification must include:

- the reasons why;
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing);
- the date the termination takes effect. This date must be after the notification, and
- a request for amendment (see Article 55), with a proposal for reallocation of the tasks and the estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination takes effect after the period set out in Article 3, no request for amendment must be included unless the beneficiary concerned is the coordinator. In this case, the request for amendment must propose a new coordinator.

If this information is not given or if the *Commission* considers that the reasons do not justify termination, the participation will be considered to have been **terminated improperly**.

The termination will **take effect** on the day specified in the notification.

50.2.2 Effects

The coordinator must — within 30 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned and

(ii) if termination takes effect during the period set out in Article 3, a '**termination report**' from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20.3 and 20.4).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *Commission*, because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *Commission*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *Commission* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary and approved by the *Commission*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

    - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *Commission* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *Commission* will draw upon the Guarantee Fund to pay the coordinator and then notify a **debit note** on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

    - in all other cases (in particular if termination takes effect after the period set out in Article 3), the *Commission* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due and the *Commission* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

    - if the beneficiary concerned is the former coordinator, it must repay the new coordinator according to the procedure above, unless:

        - termination is after an interim payment and

        - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7).

      In this case, the *Commission* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due. The *Commission* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *Commission* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *Commission* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

Improper termination may lead to a reduction of the grant (see Article 43) or termination of the Agreement (see Article 50).

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

50.3 Termination of the Agreement or participation for one or more beneficiaries, by the *Commission*

50.3.1 Conditions

The *Commission* may terminate the Agreement or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 56);

(b) a change to their legal, financial, technical, organisational or ownership situation is likely to substantially affect or delay the implementation of the action or calls into question the decision to award the grant;

(c) following termination of participation for one or more beneficiaries (see above), the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants (see Article 55);

(d) implementation of the action is prevented by force majeure (see Article 51) or suspended by the coordinator (see Article 49.1) and either:

  (i) resumption is impossible, or

  (ii) the necessary changes to the Agreement would call into question the decision awarding the grant or breach the principle of equal treatment of applicants;

(e) a beneficiary is declared bankrupt, being wound up, having its affairs administered by the courts, has entered into an arrangement with creditors, has suspended business activities, or is subject to any other similar proceedings or procedures under national law;

(f) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has been found guilty of professional misconduct, proven by any means;

(g) a beneficiary does not comply with the applicable national law on taxes and social security;

(h) the action has lost scientific or technological relevance;

(i) *not applicable;*

(j) *not applicable;*

(k) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has committed fraud, corruption, or is involved in a criminal organisation, money laundering or any other illegal activity affecting the *EU*'s financial interests;

(l) a beneficiary (or a natural person who has the power to represent or take decisions on its behalf) has — in the award procedure or under the Agreement — committed:

(i) substantial errors, irregularities, fraud or

(ii) serious breach of obligations, including improper implementation of the action, submission of false information, failure to provide required information, breach of ethical principles;

(m) a beneficiary has committed — in other EU or Euratom grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant ('**extension of findings from other grants to this grant**').

50.3.2 Procedure

Before terminating the Agreement or participation of one or more beneficiaries, the *Commission* will formally notify the coordinator:

- informing it of its intention to terminate and the reasons why and

- inviting it, within 30 days of receiving notification, to submit observations and — in case of Point (l.ii) above — to inform the *Commission* of the measures to ensure compliance with the obligations under the Agreement.

If the *Commission* does not receive observations or decides to pursue the procedure despite the observations it has received, it will formally notify to the coordinator **confirmation** of the termination and the date it will take effect. Otherwise, it will formally notify that the procedure is not continued.

The termination will **take effect**:

- for terminations under Points (b), (c), (e), (g), (h), (j), and (l.ii) above: on the day specified in the notification (see above);

- for terminations under Points (a), (d), (f), (i), (k), (l.i) and (m) above: on the day after notification is received by the coordinator.

50.3.3 Effects

(a) for **termination of the Agreement**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a periodic report (for the last open reporting period until termination; see Article 20.3) and

(ii) a final report (see Article 20.4).

If the Agreement is terminated for breach of the obligation to submit the reports (see Articles 20.8 and 50.3.1(l)), the coordinator may not submit any reports after termination.

If the *Commission* does not receive the reports within the deadline (see above), only costs which are included in an approved periodic report will be taken into account.

The *Commission* will **calculate** the final grant amount (see Article 5.3) and the balance (see Article 21.4) on the basis of the reports submitted. Only costs incurred until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

This does not affect the *Commission's* right to reduce the grant (see Article 43) or to impose administrative and financial penalties (Article 45).

The beneficiaries may not claim damages due to termination by the *Commission* (see Article 46).

After termination, the beneficiaries' obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

(b) for **termination of the participation of one or more beneficiaries**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a report on the distribution of payments to the beneficiary concerned;

(ii) a request for amendment (see Article 55), with a proposal for reallocation of the tasks and estimated budget of the beneficiary concerned (see Annexes 1 and 2) and, if necessary, the addition of one or more new beneficiaries (see Article 56). If termination is notified after the period set out in Article 3, no request for amendment must be submitted unless the beneficiary concerned is the coordinator. In this case the request for amendment must propose a new coordinator, and

(iii) if termination takes effect during the period set out in Article 3, a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, an overview of the use of resources, the individual financial statement and, if applicable, the certificate on the financial statement (see Article 20).

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 20.3).

If the request for amendment is rejected by the *Commission* because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants, the Agreement may be terminated according to Article 50.3.1(c).

If the request for amendment is accepted by the *Commission*, the Agreement is **amended** to introduce the necessary changes (see Article 55).

The *Commission* will **calculate** — on the basis of the periodic reports, the termination report and the report on the distribution of payments — if the (pre-financing and interim) payments received by the beneficiary concerned exceed the beneficiary's EU contribution (calculated by applying the reimbursement rate(s) to the eligible costs declared by the beneficiary and approved by the *Commission*). Only costs incurred by the beneficiary concerned until termination takes effect are eligible (see Article 6). Costs relating to contracts due for execution only after termination are not eligible.

- If the payments received **exceed the amounts due**:

  - if termination takes effect during the period set out in Article 3 and the request for amendment is accepted, the beneficiary concerned must repay to the coordinator the amount unduly received. The *Commission* will formally notify the amount unduly received and request the beneficiary concerned to repay it to the coordinator within 30 days of receiving notification. If it does not repay the coordinator, the *Commission* will draw upon the Guarantee Fund to pay the coordinator and then notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - in all other cases, in particular if termination takes effect after the period set out in Article 3, the *Commission* will formally notify a **debit note** to the beneficiary concerned. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due and the *Commission* will notify a debit note on behalf of the Guarantee Fund to the beneficiary concerned (see Article 44);

  - if the beneficiary concerned is the former coordinator, it must repay the new coordinator the amount unduly received, unless:

    - termination takes effect after an interim payment and

    - the former coordinator has not distributed amounts received as pre-financing or interim payments (see Article 21.7)

    In this case, the *Commission* will formally notify a **debit note** to the former coordinator. If payment is not made by the date in the debit note, the Guarantee Fund will pay to the *Commission* the amount due. The *Commission* will then pay the new coordinator and notify a debit note on behalf of the Guarantee Fund to the former coordinator (see Article 44).

- If the payments received **do not exceed the amounts due**: amounts owed to the beneficiary concerned will be included in the next interim or final payment.

If the *Commission* does not receive the termination report within the deadline (see above), only costs included in an approved periodic report will be taken into account.

If the *Commission* does not receive the report on the distribution of payments within the deadline (see above), it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned, and that
- the beneficiary concerned must not repay any amount to the coordinator.

After termination, the concerned beneficiary's obligations (in particular Articles 20, 22, 23, Section 3 of Chapter 4, 36, 37, 38 and 40) continue to apply.

SECTION 4 FORCE MAJEURE

ARTICLE 51 — FORCE MAJEURE

51.1 Force majeure

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of third parties involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

The following cannot be invoked as force majeure:

- any default of a service, defect in equipment or material or delays in making them available, unless they stem directly from a relevant case of force majeure,
- labour disputes or strikes, or
- financial difficulties.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

The party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

CHAPTER 7 FINAL PROVISIONS

ARTICLE 52 — COMMUNICATION BETWEEN THE PARTIES

52.1 Form and means of communication

Communication under the Agreement (information, requests, submissions, 'formal notifications', etc.) must:

- be made in writing and
- bear the number of the Agreement.

Until the payment of the balance: all communication must be made through the electronic exchange system and using the forms and templates provided there.

After the payment of the balance: formal notifications must be made by registered post with proof of delivery ('formal notification on paper').

Communications in the electronic exchange system must be made by persons authorised according to the 'Terms and Conditions of Use of the electronic exchange system'. For naming the authorised persons, each beneficiary must have designated to the *Commission* — before the signature of this Agreement — a 'Legal Entity Appointed Representative (LEAR)'. The role and tasks of the LEAR are stipulated in his/her appointment letter (see Terms and Conditions of Use of the electronic exchange system).

If the electronic exchange system is temporarily unavailable, instructions will be given on the *Commission's* websites.

52.2 Date of communication

Communications are considered to have been made when they are sent by the sending party (i.e. on the date and time they are sent through the electronic exchange system).

Formal notifications through the **electronic** exchange system are considered to have been made when they are received by the receiving party (i.e. on the date and time of acceptance by the receiving party, as indicated by the time stamp). A formal notification that has not been accepted within 10 days after sending is considered to have been accepted.

Formal notifications **on paper** sent by**registered post** with proof of delivery (only after the payment of the balance) are considered to have been made on either:

- the delivery date registered by the postal service or
- the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

52.3 Addresses for communication

The **electronic** exchange system must be accessed via the following URL:

https://ec.europa.eu/research/participants/portal/desktop/en/projects/

The *Commission* will formally notify the coordinator and beneficiaries in advance any changes to this URL.

Formal notifications on paper (only after the payment of the balance) addressed **to the *Commission*** must be sent to the following address:

European Commission
Directorate General for Communications Networks, Content and Technology
Health and Well-being
BU31 01/36
B-1049 Brussels Belgium

Formal notifications on paper (only after the payment of the balance) addressed **to the beneficiaries** must be sent to their legal address as specified in the Beneficiary Register (in the electronic exchange system).

ARTICLE 53 — INTERPRETATION OF THE AGREEMENT

53.1 Precedence of the Terms and Conditions over the Annexes

The provisions in the Terms and Conditions of the Agreement take precedence over its Annexes.

The provisions in Annex 2 take precedence over Annex 1.

53.2 Privileges and immunities

not applicable

ARTICLE 54 — CALCULATION OF PERIODS, DATES AND DEADLINES

In accordance with Regulation No 1182/71[28], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

ARTICLE 55 — AMENDMENTS TO THE AGREEMENT

55.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

[28] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8.6.1971, p. 1).

55.2 Procedure

The party requesting an amendment must submit a request for amendment signed in the electronic exchange system (see Article 52).

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3).

If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why;
- the appropriate supporting documents;
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The *Commission* may request additional information.

If the party receiving the request agrees, it must sign the amendment in the electronic exchange system within 45 days of receiving notification (or any additional information the *Commission* has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date agreed by the parties or, in the absence of such an agreement, on the date on which the amendment enters into force.

ARTICLE 56 — ACCESSION TO THE AGREEMENT

56.1 Accession of the beneficiaries mentioned in the Preamble

The other beneficiaries must accede to the Agreement by signing the Accession Form (see Annex 3) in the electronic exchange system (see Article 52), within 30 days after its entry into force (see Article 58).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 58).

If a beneficiary does not accede to the Agreement within the above deadline, the coordinator must — within 30 days — request an amendment to make any changes necessary to ensure proper implementation of the action. This does not affect the *Commission's* right to terminate the Agreement (see Article 50).

56.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 55. It must include an Accession Form (see Annex 3) signed by the new beneficiary in the electronic exchange system (see Article 52).

New beneficiaries must assume the rights and obligations under the Agreement with effect from the date of their accession specified in the Accession Form (see Annex 3).

ARTICLE 57 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

57.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

57.2 Dispute settlement

If a dispute concerning the interpretation, application or validity of the Agreement cannot be settled amicably, the General Court — or, on appeal, the Court of Justice of the European Union — has sole jurisdiction. Such actions must be brought under Article 272 of the Treaty on the Functioning of the EU (TFEU).

If a dispute concerns offsetting or an enforceable decision under Article 299 TFEU (see Articles 44, 45 and 46), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice of the European Union — under Article 263 TFEU.

ARTICLE 58 — ENTRY INTO FORCE OF THE AGREEMENT

The Agreement will enter into force on the day of signature by the *Commission* or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

Andrea ZEUMANN with ECAS id nzeumaan signed in the Participant Portal on 26/11/2014 at 12:44:25 (transaction id SigId-7070-huLzrcldKHv54uHEJMujSVIq7iOF9EKxxztzYP2DKkRlEUKtptfiznSZ2aWAVtKyyMQ1FfXxztqwUUJbdhdLX2t-Jj71zxYb8yrGkT3b6dcQFG-ZPm0xRLap1g60zM02zhv5zO8Iqkolk0LezzUbXNPB7Ksm). Timestamp by third party at Wed Nov 26 12:44:30 CET 2014

For the *Commission*

Miguel GONZALEZ-SANCHO with ECAS id gonzamg signed in the Participant Portal on 08/12/2014 at 13:59:37 (transaction id SigId-8203-c8gXiSzp6AraBpv1azVycTuV9BMmFIrjhDmRvcmnsWXZiQCrlqzXMwsn5kUzfM2Ys2N6HYEi344quj0pEJuTRHK-PHslUMVSXYCxZAW3OHozsk-oE70rv3eyGhIPnYQMgxzoHozSgZ6NmHln2VFcAJbrXMG). Timestamp by third party at Mon Dec 08 13:59:40 CET 2014

European Commission

Directorate General for Communications Networks, Content and Technology

Health and Well-being

ANNEX 1 (part A)

Research and Innovation action

NUMBER — 643529 — iManageCancer

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1.1. The project summary

Project Number [1]	643529	Project Acronym [2]	iManageCancer

One form per project

General information	
Project title [3]	iManageCancer - Empowering patients and strengthening self-management in cancer diseases
Starting date [4]	01/02/2015
Duration in months [5]	42
Call (part) identifier [6]	H2020-PHC-2014-single-stage
Topic	PHC-26-2014 Self management of health and disease: citizen engagement and mHealth
Fixed EC Keywords	MEDICAL AND HEALTH SCIENCES
Free keywords	patient empowerment, mHealth, self management, personal health systems, serious games, decision support, disease management

Abstract [7]

Chronic cancer treatment places new demands on patients and families to manage their own care. The iManageCancer project will support this challenge and provide a cancer disease self-management platform designed according to the specific needs of patient groups and focusing on the wellbeing of the cancer patient with special emphasis on psycho-emotional evaluation and self-motivated goals. The platform will be centred in a Personal Health Record that will exploit recent advances on Health Avatars for the individual cancer patient surrounded by mHealth applications designed to encourage the patient, enhance clinician-patient communication, maximise compliance to therapy, inform about drug interactions, and contribute to the management of pain and other side-effects of cancer treatment. The Health Avatar PHR will regularly monitor the psycho-emotional status of the patient and will periodically record the everyday life experiences of the cancer patient with respect to the therapy side effects, while different groups of patients and their families will share information through diaries and clinicians are provided with clinical information. The PHR will help assess adherence to therapy, physiological and psychological status while the platform will recommend targeted informative applications and serious games according to the disease type and psycho-emotional status of the patients in order to promote a positive and healthier psycho-emotional state. The disease management platform will be further complemented by an integrated expert system with formal self-management models that will be oriented to decision support, the management of side-effects, adherence to therapy and guidance for patients including drug dose self-adjustments. The iManageCancer platform will be designed on clinical evidence and in close collaboration of clinical experts, IT specialists and patients and will be assessed in clinical pilots with adult and paediatric cancer patients.

1.2. List of Beneficiaries

Project Number [1]	643529	Project Acronym [2]	iManageCancer

List of Beneficiaries

No	Name	Short name	Country	Project entry month [8]	Project exit month
1	FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V	Fraunhofer	Germany	1	42
2	FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS	FORTH	Greece	1	42
3	UNIVERSITAET DES SAARLANDES	USAAR	Germany	1	42
4	PHILIPS ELECTRONICS NEDERLAND B.V.	PHILIPS ELECTRONICS NEDERLAND B.V.	Netherlands	1	42
5	CANCER INTELLIGENCE LIMITED	Cancer Intelligence Ltd	United Kingdom	1	42
6	UNIVERSITY OF BEDFORDSHIRE	BED	United Kingdom	1	42
7	ISTITUTO EUROPEO DI ONCOLOGIA SRL	ISTITUTO EUROPEO DI ONCOLOGIA SRL	Italy	1	42
8	SERIOUS GAMES SOLUTIONS GMBH	SGS	Germany	1	42

1.3. Workplan Tables - Detailed implementation

1.3.1. WT1 List of work packages

WP Number [9]	WP Title	Lead beneficiary [10]	Person-months [11]	Start month [12]	End month [13]
WP1	Management	1 - Fraunhofer	30.00	1	42
WP2	Concept definition and system requirements	3 - USAAR	45.00	1	7
WP3	System design and integration	1 - Fraunhofer	75.50	1	42
WP4	Health Avatar PHR	6 - BED	81.00	10	27
WP5	Central decision support and guidance system	4 - PHILIPS ELECTRONICS NEDERLAND B.V.	120.00	10	40
WP6	Psycho-emotional and health assessment tools	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	86.00	10	30
WP7	Serious games for self-management	8 - SGS	84.00	10	30
WP8	Smart analytical data services	2 - FORTH	41.00	18	30
WP9	Pilots	3 - USAAR	58.00	15	42
WP10	Dissemination, communication, exploitation	5 - Cancer Intelligence Ltd	52.00	1	42
		Total	672.50		

1.3.2. WT2 list of deliverables

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D1.1	Project Handbook	WP1	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D1.2	1st Periodic Management Report	WP1	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.3	2nd Periodic Management Report	WP1	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	30
D1.4	3rd Periodic Management Report	WP1	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	42
D1.5	Final Report	WP1	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	42
D2.1	Concept definition	WP2	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	Report	Public	4
D2.2	Scenarios and use cases	WP2	3 - USAAR	Report	Public	6
D2.3	Technical system requirements	WP2	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	7
D3.1	Initial iManageCancer architecture document	WP3	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the	9

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
					Commission Services)	
D3.2	Initial iManageCancer platform prototype	WP3	1 - Fraunhofer	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D3.3	Updated iManageCancer architecture	WP3	2 - FORTH	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D3.4	Extended integrated prototype of iManageCancer platform	WP3	2 - FORTH	Demonstrator	Public	30
D4.1	Patient-centric User Interface architectural design for an Avatar-based PHR for the cancer patient	WP4	6 - BED	Report	Confidential, only for members of the consortium (including the Commission Services)	15
D4.2	Health Avatar PHR services	WP4	6 - BED	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D4.3	Final version of Health Avatar PHR iManageCancer services	WP4	2 - FORTH	Demonstrator	Public	27
D5.1	Initial set of knowledge models for self-management	WP5	3 - USAAR	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D5.2	Initial decision support and patient guidance services integrated in iManageCancerPlatform	WP5	1 - Fraunhofer	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D5.3	Extended decision support and patient guidance services	WP5	4 - PHILIPS ELECTRONICS	Demonstrator	Public	30

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
			NEDERLAND B.V.			
D5.4	Updated decision support and patient guidance services and refined underlying models	WP5	4 - PHILIPS ELECTRONICS NEDERLAND B.V.	Demonstrator	Public	40
D6.1	Definition of psycho-emotional monitoring instrument and family evaluation tool	WP6	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D6.2	Generic health enquiry tool	WP6	1 - Fraunhofer	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	18
D6.3	Initial versions of psycho-emotional monitoring instrument, family evaluation tool and monitoring tool for life style and vital signs	WP6	2 - FORTH	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D6.4	Implemented application scenarios in iCancerPlatform using psycho-emotional and health assessment tools	WP6	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	Report	Public	30
D7.1	Prototypic serious game for paediatric cancer patients	WP7	8 - SGS	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D7.2	Integrated serious games for adults	WP7	6 - BED	Demonstrator	Public	27
D7.3	Serious game for paediatric cancer integrated in the iManageCancer platform	WP7	8 - SGS	Demonstrator	Public	30
D8.1	Implemented data analysis and data mining services	WP8	2 - FORTH	Demonstrator	Public	30

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D8.2	Implemented visualization techniques	WP8	6 - BED	Demonstrator	Public	30
D9.1	Documentation of preparation of the pilots as well as a report on initial tests of basic iManageCancer Platform	WP9	3 - USAAR	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D9.2	Pilot for children	WP9	3 - USAAR	Report	Public	34
D9.3	Pilot for adults	WP9	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	Report	Public	34
D9.4	Evaluation report of pilots	WP9	5 - Cancer Intelligence Ltd	Report	Public	42
D10.1	Elaborated plans on dissemination, communication and exploitation	WP10	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	5
D10.2	Report on the implemented External Advisory Panel	WP10	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D10.3	Report on dissemination, communication and exploitation activities and plans update	WP10	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	25
D10.4	Investigated service and business models; envisaged business model	WP10	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D10.5	Launch Event	WP10	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	42

Deliverable Number [14]	Deliverable Title	WP number [9]	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D10.6	Final report on dissemination, communication and exploitation activities and plans update	WP10	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	42

1.3.3. WT3 Work package descriptions

Work package number [9]	WP1	**Lead beneficiary** [10]	1 - Fraunhofer
Work package title	Management		
Start month	1	**End month**	42

Objectives

The objective of this WP is the overall management of the project, including: a) establishment of management committees and guidelines for their operation, b) establishment of technical and financial reporting guidelines, c) establishment of structures for execution of committee/co-ordination group tasks, d) provision of financial and technical monitoring and reporting, e) administration of Consortium Agreement and f) delivery of all necessary reports including periodic and final project reports. An internal project office will assist the coordinator in the technical and administrative management.

Description of work and role of partners

WP1 - Management [Months: 1-42]
Fraunhofer, FORTH, USAAR, PHILIPS ELECTRONICS NEDERLAND B.V., Cancer Intelligence Ltd, BED , ISTITUTO EUROPEO DI ONCOLOGIA SRL, SGS
T1.1 Project Coordination (FRAU, FORTH) (Month 1-42)
This task includes compilation of reports and other deliverables for submission to the European Commission, development of strategies and long-term project plans, chairing of the Steering Committee and follow-up of their decisions, transfer of documents and information connected with the project to and between the partners concerned, ensuring that an exploitation strategy is developed, approved and implemented, coordinating the entry and exit of partners from the consortium where necessary, and ensuring that work complies with national and EU Health and Safety regulations and Ethical Guidelines. The scientific coordination of the project will be carried out by FRAU in tandem with FORTH which will share the overall responsibility for the achievement of the project's objectives.

T1.2 Project Management (FRAU) (Month 1-42)
This management task includes reporting towards the Commission, monitoring of the project progress, risk assessment and the preparation of meetings. The coordinator in collaboration with his internal project office will compile quarterly progress reports and risk assessments, monitor progress against the plan, and implement corrective actions where necessary in collaboration with the Steering Committee. He will further prepare project meetings, in particular the General Assembly, the Technical Review and meetings of the Steering Committee. A web-based project tool will be created and maintained and it will be used for internal information exchange, partner coordination as well as for the monitoring of the works and assigned tasks.

T1.3 Financial and Administrative Management (FRAU) (Month 1-42)
This task covers the establishment of financial protocols and milestones for the consortium, financial monitoring and reporting to the Commission, the collection and delivery of cost statements and audit certificates to the Commission, and the distribution of the budget between partners. This task will also prepare, collect and maintain contractual documents and one of the first actions will comprise the preparation of the Consortium Agreement.

Participation per Partner

Partner number and short name	WP1 effort
1 - Fraunhofer	18.00
2 - FORTH	6.00
3 - USAAR	1.00
4 - PHILIPS ELECTRONICS NEDERLAND B.V.	1.00
5 - Cancer Intelligence Ltd	1.00

Partner number and short name	WP1 effort
6 - BED	1.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	1.00
8 - SGS	1.00
Total	30.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D1.1	Project Handbook	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	3
D1.2	1st Periodic Management Report	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D1.3	2nd Periodic Management Report	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	30
D1.4	3rd Periodic Management Report	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	42
D1.5	Final Report	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	42

Description of deliverables

D1.1 Project Handbook including risk assessment procedure (Lead: FRAU) (M3) D1.2 1st Periodic Management Report (Lead: FRAU) (M12) D1.3 2nd Periodic Management Report (Lead: FRAU) (M30) D1.4 4th Periodic Management Report (Lead: FRAU) (M42) D1.5 Final Report (Lead: FRAU) (M42)

D1.1 : Project Handbook [3]

The Project Handbook has two main functions. Firstly, it acts as a reference source for all Consortium members covering many of the day-to-day activities and providing links to further information where required. Secondly, it aims to standardise various elements of the project e.g. project reports, deliverables, file naming conventions etc. through the use of agreed procedures and templates where relevant.

D1.2 : 1st Periodic Management Report [12]
Periodic Management Report for first Reporting Period.
D1.3 : 2nd Periodic Management Report [30]
Periodic Management Report for second Reporting Period.
D1.4 : 3rd Periodic Management Report [42]
Periodic Management Report for 3rd Reporting Period
D1.5 : Final Report [42]
Mandatory final report of the Action

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

Work package number [9]	WP2	Lead beneficiary [10]	3 - USAAR
Work package title	Concept definition and system requirements		
Start month	1	End month	7

Objectives

This WP will elaborate on the concept definition and system requirements for the proposed technological and clinical research infrastructure to develop the iManageCancer platform. The specific objectives include:
1. Empowering of patients and their relatives to better manage the cancer disease in collaboration with their healthcare providers by: a) giving them access to internet based tools and services for knowledge discovery, early detection of health deteriorations, decision support and managing their treatment including prescriptions and medications, b) providing them personalized and context-sensitive information in layman's language, c) facilitating the usage of mobile devices to keep track of their health and disease status and to better communicate with their healthcare team, d) providing them serious games to manage the impact of the disease on their psychological status and to motivate them to participate in social life
2. Support citizens in following a healthy and active lifestyle by optional wearable sensors connected to the platform in combination with recommendations for health-conscious behaviour through the decision support system.
3. Development of the iManageCancer platform that a) provides an easy-to-use interactive cockpit on mobile platforms, b) includes a health avatar as the guide to the services of the platform and c) incorporates an instrument for data driven analysis in public health research.
As strong emphasis is put on the co-design principle for the system development feedback from patients, citizens and clinical care provider will be gathered through a questionnaire.

Description of work and role of partners

WP2 - Concept definition and system requirements [Months: 1-7]
USAAR, Fraunhofer, FORTH, PHILIPS ELECTRONICS NEDERLAND B.V., Cancer Intelligence Ltd, BED , ISTITUTO EUROPEO DI ONCOLOGIA SRL, SGS
T2.1 Concept definition (IEO, USAAR, CI-eCancer) (Month 1-4)
The task will start with a review of existing similar platforms, their interoperability and re-usage. It will provide the clinical perspective of the project as well as the perspective of patients. Especially the state of practice and usage in the healthcare domain of cancer will be elaborated. For that purpose a questionnaire will be developed that gives feedback from patients, citizens and clinical care providers. The concept will be developed according to the results of the review activities and the questionnaire. In addition, collaboration with other existing platforms like MyHealthAvatar will be discussed in detail to avoid overlapping activities. Interoperability issues with existing electronic health records (EHR), hospital information systems (HIS) and medical devices will be reviewed and established.

T2.2 Use case scenarios (USAAR, IEO, CI-eCancer) (Month 1-6)
This task will address the user needs and requirements for developing a seamless, secure and consistent integration of clinical care data provided by hospital information systems and clinical trials as well as clinical and basic research data. All these data will be linked to the iManageCancer platform. Use case scenarios will be developed in an iterative process between all stakeholders (patients, citizens, clinical care providers). Patient organizations will be contacted and a workshop will be held to finalize use cases. Key driver for use cases are patients, citizens and clinical care providers. All use case scenarios have to take into consideration that iManageCancer should provide clinicians, patients and relatives an interactive health assessment tool for the monitoring of the patient's current physiological and psychological health status, quality-of-life, and ability to perform activities of daily living. Developed tools will include standardized questionnaires and self-measurement devices linked to the platform. The use case scenarios will be developed and conducted in two pilots, one for adult cancer patients and one for children to evaluate the iManageCancer platform and its services in practice regarding the following criteria: acceptance, usability, performance, and outcome on quality of life of cancer patients, re-admission rates to hospitals and costs. The respective deliverable will be subject to regular updates if new scenarios need to be added or existing ones need to be revised.

T2.3 Ethical, legal and privacy constraints (CI-eCANCER, USAAR) (Month 2-6)
This task starts with a detailed analysis of the existing European and national rules concerning data security and privacy protection as far as they are relevant to iManageCancer. The outcome of this task will be a concrete description of the legal and ethical framework of the project. The framework will be compared with corresponding frameworks of other

European projects and adjusted accordingly. After 18 months of the project the framework needs to be adjusted to the finalized use case scenarios.

T2.4 Requirements elicitation (FRAU, FORTH, BED, SGS, PHILIPS) (Month 5-7)
The use case scenarios as developed in T2.2 will be broken down in technical use cases. The main system components will be identified and formal sequence diagrams will be drafted for each use case according to UML methodology. Technical requirements will be derived and listed. The legal requirements for each use case will be defined according to the developed ethical and legal framework in T2.3. The respective deliverable will be subject to regular updates if new scenarios need to be added or existing ones need to be revised.

Participation per Partner

Partner number and short name	WP2 effort
1 - Fraunhofer	4.00
2 - FORTH	2.00
3 - USAAR	12.00
4 - PHILIPS ELECTRONICS NEDERLAND B.V.	3.50
5 - Cancer Intelligence Ltd	5.00
6 - BED	1.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	16.00
8 - SGS	1.50
Total	45.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D2.1	Concept definition	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	Report	Public	4
D2.2	Scenarios and use cases	3 - USAAR	Report	Public	6
D2.3	Technical system requirements	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	7

Description of deliverables

D2.1 The patient's and clinical care perspective of the iManageCancer platform (Lead: IEO) (M4) D2.2 Scenarios and use cases including the ethical and legal aspects (Lead: USAAR) (M6) D2.3 Technical system requirement document (Lead: FRAU) (M7)

D2.1 : Concept definition [4]

The patient's and clinical care perspective of the iManageCancer platform. (Result of Task 2.1)

D2.2 : Scenarios and use cases [6]

Scenarios and use cases including the ethical and legal aspects as described in tasks T2.2 and T2.3 .

D2.3 : Technical system requirements [7]

Technical system requirement document as described in T2.4.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

Work package number [9]	WP3	Lead beneficiary [10]	1 - Fraunhofer
Work package title	System design and integration		
Start month	1	End month	42

Objectives

This work package drives the software development process of the iManageCancer platform. It has three major objectives:
1) Developing a robust, secure, scalable and modern system architecture taking into account privacy regulation and specifying interfaces and functionality of each component on the basis of the formal use cases and the technical requirements obtained from WP2. Security issues will be covered in the design. As a fundamental principle the patient is the owner of his data and controls access to them for others like his doctors.
2) Providing a semantic interoperability framework to integrate disparate heterogeneous data sources.
3) Integrating the different components, testing, documenting and releasing a basic and an advanced system prototype and providing a test bed for successive clinical validation.
An architecture based on loosely coupled RESTful services between the main components is envisaged with smartphones and tablets as the user interface devices for the patients, family members and doctors. A reference architecture for iManageCancer Apps will be proposed based on multi-channel app development frameworks such as PhoneGap and Gordova. This work package will implement the UML and SCRUM software development methodology that the project will follow.

Description of work and role of partners

WP3 - System design and integration [Months: 1-42]
Fraunhofer, FORTH, PHILIPS ELECTRONICS NEDERLAND B.V., BED , SGS
T3.1 SoA analysis of self-management tools and services, mHealth architectures, technologies, tools and standards (FORTH, FRAU, BED, PHILIPS, SGS) (Month 1-4)
The role of this task is to identify and evaluate mHealth for self-management standards, and ontologies/terminologies relevant for the iManageCancer environment. In this task, based on the user scenarios and requirements provided by WP1 and on the range of data available in our data sets, we will identify all standards to which iManageCancer should comply. As the mobile computing world advances dramatically this task also ensures that the developer team is aware of the latest trends, doesn't double existing tools and designs an advanced system that will not be surpassed by industrial progress during the lifetime of the project. It will be the responsibility of the partners in this task to continue to monitor technological trends after the official end of the task and to report them to the Steering Committee and the Exploitation Manager.
T3.2 System design (FRAU, FORTH, BED, PHILIPS, SGS) (Month 5-9)
The system architecture will be proposed from the results of the requirement engineering phase. Design alternatives will be identified. Pros and cons will be analysed as well as privacy and security aspects. A security framework for the chosen infrastructure will be derived. Communication interfaces between the main components will be specified as well as the functionality of each component. Mock-ups showing the main user interface functionality will be derived and agreed with the clinical partners. A vertical prototype will be proposed which is used to implement the main communication paths of the system architecture.

T3.3 Semantic Interoperability (FORTH, BED) (Month 10-24)
Besides system integration, semantic interoperability is a key issue in such a dynamic environment. This task will provide a unified view of the domain of interest by appealing to a common formal representation of domain knowledge. The main challenge that needs to be addressed in this task is the resolution of heterogeneities of different types (syntactic, lexical, and semantic) that arise when disparate data sources need to be integrated. This task will develop the knowledge infrastructure for modelling, storing and retrieving big, heterogeneous disparate data sources that we expect to change and evolve through time.

T3.4 System integration (FORTH, BED, FRAU, PHILIPS, SGS) (Month 18-42)
The different components will be integrated in the overall system platform. Integration tests and release tests will be planed and performed. Test beds will be provided for testing, demonstrating and for the pilots. Two versions of the iManageCancer Platform will be provided. A basic version that contains initial prototypic versions of the planned services and tools will be released in Month 21. The usability of this version will be internally assessed by the clinical

partners and in workshops with patient representatives. Results will be used to revise the iManageCancer Platform and to complement its components with further features. An advanced version will be released after testing in Month 30 for the pilots.

Participation per Partner

Partner number and short name	WP3 effort
1 - Fraunhofer	16.00
2 - FORTH	30.00
4 - PHILIPS ELECTRONICS NEDERLAND B.V.	9.50
6 - BED	14.00
8 - SGS	6.00
Total	75.50

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D3.1	Initial iManageCancer architecture document	1 - Fraunhofer	Report	Confidential, only for members of the consortium (including the Commission Services)	9
D3.2	Initial iManageCancer platform prototype	1 - Fraunhofer	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D3.3	Updated iManageCancer architecture	2 - FORTH	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D3.4	Extended integrated prototype of iManageCancer platform	2 - FORTH	Demonstrator	Public	30

Description of deliverables

D3.1 Initial iManageCancer architecture document including state of the art report (Lead: FRAU) (M9) D3.2 Initial iManageCancer platform prototype offering basic functionality (Lead: FRAU) (M21) D3.3 Updated iManageCancer architecture including semantic interoperability methodology (Lead: FORTH) (M24) D3.4 Extended integrated prototype of iManageCancer platform (Lead: FORTH) (M30)

D3.1 : Initial iManageCancer architecture document [9]

Initial iManageCancer architecture document including state of the art report as further described in tasks T3.1 and T3.2.

D3.2 : Initial iManageCancer platform prototype [21]

Initial iManageCancer platform prototype offering basic functionality as outlined in T3.4.

D3.3 : Updated iManageCancer architecture [24]

Updated iManageCancer architecture including semantic interoperability methodology as described in tasks T3.3 and T3.4

D3.4 : Extended integrated prototype of iManageCancer platform [30]

Extended integrated prototype of iManageCancer platform as indicated in T3.4.

Schedule of relevant Milestones

Milestone number [18]	**Milestone title**	**Lead beneficiary**	**Due Date (in months)**	**Means of verification**
MS1	Critical system design revision	2 - FORTH	9	D3.1 'Initial iManageCancer architecture document' available and accepted by Steering Committee
MS2	Initial iManageCancer platform prototype	1 - Fraunhofer	21	Initial iManageCancer platform prototype offering basic functionality. Software released for initial testing in workshops. Related deliverables submitted.
MS3	Extended integrated prototype of iManageCancer platform	1 - Fraunhofer	30	Extended integrated prototype of iManageCancer platform available. Software released for clinical validation. Related deliverables submitted.

Work package number [9]	WP4	Lead beneficiary [10]	6 - BED
Work package title	Health Avatar PHR		
Start month	10	End month	27

Objectives

Health Avatar PHR is the central access tool to iManageCancer services for clinicians, patients and relatives by using smart phones and tablets. PHR is the back end of the iManageCancer platform with a dedicated database able to support the needs of the iManageCancer services introduces by WP5, WP6, WP7 and WP8, while the health avatar is the front end supporting different views for the two user groups (clinicians, patients) and personalized interfaces based on user preferences for each user.
The objectives of this work package are: a) to define the patient-centric user interface architecture of the iManageCancer, b) to develop the central PHR of iManageCancer platform and assist cancer patients to manage their own disease, c) to create a digital avatar acting as a mediator between the end-users and the iManageCancer personal health record and d) to enable the 'clinical view' of the PHR and enhance clinician – patient communication.

Description of work and role of partners

WP4 - Health Avatar PHR [Months: 10-27]
BED , FORTH, USAAR, ISTITUTO EUROPEO DI ONCOLOGIA SRL
MyHealthAvatar is a research initiative through which the feasibility of an innovative representation of the health status of citizens for future healthcare is being developed (http://www.myhealthavatar.eu/). The goal is to create a digital avatar acting as a mediator between the end-users and health related data collections. It is envisaged as a personal container of heterogeneous sources of information (medical, environmental, lifestyle) all blended in a single framework, utilizing modern information and communication technologies, providing long-term and consistent health information along a person's a timeline. In this WP we focus on exploiting this Avatar architecture in the scope of serving as the central PHR of iManageCancer platform and assisting cancer patients to manage their own disease by using all the accompanied technologies.

T4.1 Patient-centric user interface design (BED, IEO, USAAR) (Month 10-27)
This task will follow a co-design methodology to design the interface of iManageCancer by extending and adapting the recent advancements in MyHealthAvatar project (http://www.myhealthavatar.eu/). We will heavily involve end-users in the system development process by asking the participants to participate in the key steps of the development. By doing so, we encourage the designer and the user to co-create the solutions, allowing for the final result to be more appropriate and acceptable to the end-users. To achieve this, the user requirements gathered in WP2 will play a key role in the user interface design. Special attention will be paid to the technology acceptability. It is worth mentioning that according to a recent survey the majority of people are interested in a personal 'Health Avatar' to have access to their health data and share information with their doctor, therefore the personal involvement of patient groups will guarantee that this positive view in this technology will be translated into a usable self-managing platform/UI for the cancer patient. Due to the variety of user profiles of the system, the patient user interface will stay as simple and intuitive as possible. For example, we will:
► endeavour to use conventional interaction elements;
► use large font, big buttons or extra colours to make clickable button obvious;
► try to make the contents simply structured by grouping similar topics together and fitting them within a single page without involving vertical and horizontal scroll;
► make sure there is a feedback on each action;
► offer additional feedback (such as voice) in addition to visual;
► support very simple page navigation;
► write the content in an end-user acceptable language without involving jargon technical terms.
The main feature of the patient user interface will be diary-based (described in T4.2). The dairy based patient health record will be coupled with scalable and temporal visualization techniques, allowing the users to fully interpret the large scale data with dynamically evolving natures. Also, the visualization can also be individually tailored – individual user profiles can be built according to their daily behaviours captured in the dairy and the visualization can highlight important information to each of the individual users.
The user interface will allow entering of user files, preference setting and privacy setting. The privacy setting defines the data sharing policy (i.e. which data is to be shared with whom at what degree, etc.). The users should also be able

to control the connection of their iManageCancer accounts with other external sources, such as sensors, social media and hospitals. We shall also design an assessment panel, through which the users can have access to a range of data analysis and other tools provided by the system, such as the emotion assessment tool, quality of life assessment tool, serious games, health chart (e.g. BMI chart). The web interface shall use a responsive design mode, which can be easily adapted by mobile devices such as mobile phones and tablets.

T4.2 Personal healthcare record & patient diary (FORTH, IEO, USAAR) (Month 10-27)
Central objective of the iManageCancer platform is to follow the patients during and after the end of the treatment, to monitor lifestyle, survival, recurrence, and serious side effects. This task will focus on the Personal healthcare record of iManageCancer which will provide solutions to gather, store and access the relevant information while adhering to all applicable privacy and security requirements. Uniform access to patient-generated data will add a new dimension of well-being and better support (more accurate) assessment of the risks and benefits of personal actions, at different time granularity (e.g. patient may describe side effects and symptoms when they happen), in a different context (patient at home) and on a great time span. Existing open source PHR solutions will be evaluated and used as the basis for the PHR of iManageCancer to ensure that this will be an 'open application' to all cancer patients. Mechanisms will be provided to the patients to share any type of data with another individual or class of individuals. Patients will be able to (a) give to a specified person time-limited read-only access or (b) give access to all members of a group (e.g., a primary care practice). In the context of iManageCancer, children with cancer play an important role. For that reason the platform will support delegation of credentials e.g. the parents of a child may be the primary decision makers, and may therefore be granted full privileges by that parent.
The patient diary will be primarily organised in a calendar mode. It will support day views, month views and year views and timeline views. The day view will visualise the user activities and behaviour within each day. The data type may include activity, location, food, sleep, mood, symptom, condition, treatment (medication), laboratory (blood pressure, glucose), alcohol, smoking – to name by a few. Data files (such as an image or a text file) will also be displayed in the diary. Each data item will be accompanied by icons that allow the user to access the data visualization tool as well as a series of operations such as data sharing, exporting and explanation, commenting, etc. In month and year views the users can see the highlights of their health-related events, which could be a hospital visit, heath examination, major improvement of health behaviour (e.g. compliance, hospital release). Filters will be used to select/hide different types of the data during visualization.
The timeline will be used as another display mode for the data. Within the timeline mode, all the data will be placed along a time axis to allow users to see the dynamic evolution of the data. Similarly, filtering will be allowed to select/hide the display of different data types.
Data from external sources will be also possible to import into the dairy. For example, by connecting the system to a hospital information system, the health record of the patient can be displayed and accessed in the diary. The diary will also allow activity planning and behaviour intervention. The doctors or patients themselves will be able to insert targets and their reminders in the diary – this could be, for example, a medicine needed at a specific time in the diary; a hospital visit scheduled on a specific day; or physical exercises recommendation.
In addition, summary pages will be made available to show the overall health profiles of each individual patient by using statistical analysis, for example, the level of compliance, the general quality of life, health indicators (e.g. weight, BMI, blood pressure). These will be presented as the latest health news of the patients to raise their self-awareness. We will also support health summary within a selected period of time. For example, users will be able to see their general health status in the last year.
A search bar will be made available to support data search. Users should be able to look for a specific data item according to the day, objects, and people. We will also include the functionality of linking the diary with external diary systems such as Google diary.

T4.3 Clinician - Patient interaction e-diary (FORTH, BED, IEO, USAAR) (Month 15-27)
This task will focus on developing the necessary technology components of the PHR system that will enable the 'clinical view' of the PHR and will enhance clinician – patient communication for optimising the self-management goals of the project. This task will first carefully review all the existing guidelines for physicians-patients efficient communication that will serve as a basis of a number of assisting technologies that will include an Assessment Module for allowing patients and their relatives to express/describe, record and interactively assess the burden of symptoms and all related problems through a dedicated e-diary. This module will allow the patient to record very specific information that will be shared with the clinician (unlike the diary in T4.2 that is a generic patient diary) in order to reduce symptom distress and non-necessary visits to the hospital and when necessary to allow prompt and opportune referral to the physician or other healthcare professionals in case of need by tearing down perceived barriers with clinicians. This specific information will include the level of anxiety and worrying as well as information that will lead to standardised scores of symptoms (such as the IPSS International prostate symptoms scores). To ensure efficient patient-clinician communication patients will be

invited to fill a weekly e-diary form describing the practical and psychological difficulties encountered in self-managing of symptoms or side-effects or treatment. This interaction will be enhanced by the psycho-emotional evaluation tools that will be developed in WP 6.
Additionally the clinician-patient e-diary will also enable patients to keep a holistic interactive animated record from their health history in an easy-to-use way with the possibility to integrate multi modal documents from the primary healthcare system (e.g. discharge letters, DICOM images, results of exams and lab analysis) that they wish to communicate with their physician. The advantage of e-diaries compared to paper and pen diaries, is that it reduces the bias produced by forward and back filling reporting symptoms, especially psychological and behavioural ones (Blondin et al., 2010, Piasecki et al., 2007, Gaertner et al., 2004). The iManageCancer eDiary for patient-clinician interaction has therefore the potential to effectively enhance self-management over time for cancer survivors.

Participation per Partner

Partner number and short name	WP4 effort
2 - FORTH	31.00
3 - USAAR	7.00
6 - BED	33.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	10.00
Total	81.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D4.1	Patient-centric User Interface architectural design for an Avatar-based PHR for the cancer patient	6 - BED	Report	Confidential, only for members of the consortium (including the Commission Services)	15
D4.2	Health Avatar PHR services	6 - BED	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D4.3	Final version of Health Avatar PHR iManageCancer services	2 - FORTH	Demonstrator	Public	27

Description of deliverables

D4.1 Patient-centric User Interface architectural design for an Avatar-based PHR for the cancer patient (Lead: BED) (M15) D4.2 Health Avatar PHR services (Personal health record, patient diary and e-diary for patient-clinician interaction) (Lead: BED) (M21) D4.3 Final (optimised) version of Health Avatar PHR iManageCancer services (Lead: FORTH) (M27)

D4.1 : Patient-centric User Interface architectural design for an Avatar-based PHR for the cancer patient [15]

Patient-centric User Interface architectural design for an Avatar-based PHR for the cancer patient as further specified in T4.1

D4.2 : Health Avatar PHR services [21]

Initial Health Avatar PHR services comprising personal health record, patient diary and e-diary for patient-clinician interaction.

D4.3 : Final version of Health Avatar PHR iManageCancer services [27]

Final (optimised) version of Health Avatar PHR iManageCancer services as described in tasks T4.1, T4.2 and T4.3.

Schedule of relevant Milestones

Milestone number [18]	**Milestone title**	**Lead beneficiary**	**Due Date (in months)**	**Means of verification**
MS2	Initial iManageCancer platform prototype	1 - Fraunhofer	21	Initial iManageCancer platform prototype offering basic functionality. Software released for initial testing in workshops. Related deliverables submitted.
MS3	Extended integrated prototype of iManageCancer platform	1 - Fraunhofer	30	Extended integrated prototype of iManageCancer platform available. Software released for clinical validation. Related deliverables submitted.

Work package number [9]	WP5	**Lead beneficiary** [10]	4 - PHILIPS ELECTRONICS NEDERLAND B.V.
Work package title	Central decision support and guidance system		
Start month	10	**End month**	40

Objectives

This work package will deliver the central knowledge based system for guidance and support of the decision making of the patient as well as a set of interrelated tools that focus on specific aspects of this decision process. The objectives are: a) to develop formal knowledge models for the management and self-management of side effects of cancer therapy, medication and long-term follow-up, b) to develop a predictive model on adverse events for chemotherapy monitoring, c) to execute these models in a Care Flow Engine and associated components of the iManageCancer Platform, d) to develop an advanced personalized drug self-management tool, e) to provide a Personal Medical Information Recommender as a decision aid to the patient, f) to develop an adverse events alerter based on the predictive model for chemotherapy monitoring, g) to develop a specific decision aid for the consultation process that support patients' participation in clinical decision making and h) to integrate these tools with the overall iManagerCancer Platform.

Description of work and role of partners

WP5 - Central decision support and guidance system [Months: 10-40]
PHILIPS ELECTRONICS NEDERLAND B.V., Fraunhofer, FORTH, USAAR, Cancer Intelligence Ltd, BED , ISTITUTO EUROPEO DI ONCOLOGIA SRL

T5.1 Knowledge Engineering – model development for self-management and therapy monitoring (PHILIPS, USAAR, IEO, FRAU,) (Month 7-40)

This task provides the self-management models of the knowledge base of the decision support system. This is a collaborative task between clinical partners and software partners based on available clinical data as well as expert knowhow on clinical guidelines and care pathways. Modelling comprises patient management and self-management related to long-term follow-up, long-term care and the detection, prediction and management of side effects of cancer therapy. The models will be converted to executable business process diagrams (BPMN 2.0) that are personalised and executed by the Care Flow Engine together with the user interface components of the iManageCancer Platform as presented in Task 5.2. The predictive models will be used in decision points of the process diagrams to decide about the next step in the management. While most of the models to be developed in this task rely on clinical guidelines and best practise in the management and self-management of specific aspects of the disease a predictive model for chemotherapy monitoring will be developed on retrospective data from cancer patients with the aim to early detect and prevent life-threatening adverse events.

T5.2 Decision Support Engine (FRAU, PHILIPS, FORTH, BED) (Month 10-40)

The models for cancer management will be further transformed to BPMN based models that can be executed by the Care Flow Engine. The Care Flow Engine is a based on a rule engine in combination with a task oriented business process engine that can execute BPMN 2.0 process plans. However, interfaces need to be developed to other components of the platform in order to process tasks for users with the help of these components. As a result the Care Flow Engine will seamlessly integrate with the PHR and patient's Health Avatar.

T5.3 Drugs self-management tool (FRAU, FORTH) (Month 10-30)

This task will provide two services.

a) Specific models will be developed for the Care Flow Engine for medication management and the adjustment of drug doses by the patient him- or herself depending on symptoms and results of health assessment tools. In addition, the models contain medication intake tasks that are interpreted as reminders by PHR Health Avatar to the patient to take his drug. Among others, developed and implemented models will comprise pain management.

b) A second service shall be developed to easily allow patients to check their prescribed drugs for drug-drug interactions and drug contraindications in relation to their disease and comorbidities. Available open repositories with drug information will be assessed and incorporated in this tool.

T5.4 Clinically-endorsed and managed patient self-care to improve safety manage treatment toxicities (PHILIPS, FRAU, BED) (Month 10-40)

This task will provide a software component for the oncologists and their patients to help them manage symptoms and adverse effects of treatments and warn them for the onset of adverse events related to chemotherapy. The component uses the corresponding models developed in T5.1 and ensures that the required clinical data from the patient is captured

and fed to the model to predict adverse events. The result is given to the doctor and the patient with recommendations on possible interventions while the patient will be monitored more closely. The component will be embedded in a wider process model of the Care Flow Engine for the management of the adverse event and integrated in the platform. The component will help (a) identify personalized risks, (b) detect onset of serious adverse events and (c) predict the neuropenic recovery after treatment cycles.
T5.5 Personal health information recommender (FORTH, CI-eCancer, IEO) (Month 10-30)
Smart access to cancer related content (for information and encouragement)
In clinical practice, clinicians have little time to spend with each patient and to give them all the relevant targeted information, and most of the times it is difficult for patients to identify information that is high quality, suited for their needs and focused on their disease.
The Personal health information recommender service will enable patients to find higher quality (rather than searching the Internet) and more relevant information and better discern between the different sources of knowledge with respect to quality and relevance. By providing high quality information targeted to their actual information goal we give the patients a better starting point to search for the information that they need. Well-informed patients will also be able to find better sources of information, understand better the content and decide what is relevant for them.
Moreover, intelligent alerts could help him/her and will provide the necessary semantic tools for gathering all relevant targeted information. Recommends specific informative applications, serious games and literature according to the disease type and psycho-emotional status (output of WP6 used) of the patients to promote encouragement, awareness and reduce anxiety and depression from patients.

T5.6 Decision aid to support patients' participation in consultations (IEO, FRAU, FORTH) (Month 10-30)
Patient's decision aids are tools that translate evidence into a patient-friendly form by providing, at a minimum, information on the options, benefits and risks, and implicit methods to clarify personal values. In addition, many decision aids also include information on the condition, probabilities of the outcomes of options (benefits/harms), exercises to help patients explicitly clarify their values, and guidance in the steps of decision making. A variety of decision aids have been developed and proved successful in increasing knowledge, enhance active involvement in decision making by patients, and decrease patients' decisional anxiety . These tools have the potential to facilitate patient empowerment in the decision-making process . However, there is the need to provide decision aids according the patient personal characteristics, such as the patient's thinking and decision styles.
iManageCancer will take these aspects into account to optimize patients behaviour in gathering the useful information and recognize that a decision needs to be made, understanding the current scientific evidence, clarifying their values associated with outcomes of options, and achieving a quality decision.
A consultation planning tool for patients will be provided in this task to increase their participation in the consultation process with their physicians and improve their satisfaction with the decision-making process. The tool prompts standardized sets of questions related to the patient's condition, treatment options and potential side effects, from which the patient can choose to create his own list of questions he wishes to discuss with his doctor. The list can be shared with the doctor in advance of the consultation.

Participation per Partner

Partner number and short name	WP5 effort
1 - Fraunhofer	40.00
2 - FORTH	13.00
3 - USAAR	2.00
4 - PHILIPS ELECTRONICS NEDERLAND B.V.	33.00
5 - Cancer Intelligence Ltd	2.00
6 - BED	2.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	28.00
Total	120.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D5.1	Initial set of knowledge models for self-management	3 - USAAR	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D5.2	Initial decision support and patient guidance services integrated in iManageCancerPlatform	1 - Fraunhofer	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D5.3	Extended decision support and patient guidance services	4 - PHILIPS ELECTRONICS NEDERLAND B.V.	Demonstrator	Public	30
D5.4	Updated decision support and patient guidance services and refined underlying models	4 - PHILIPS ELECTRONICS NEDERLAND B.V.	Demonstrator	Public	40

Description of deliverables

D5.1 Initial set of knowledge models for self-management (Lead: USAAR) (M12) D5.2 Initial decision support and patient guidance services integrated in iManageCancerPlatform: - Decision Support Engine supporting basic self-management models and integrated with Health Avatar PHR - Initial Personal Medical Information Recommender integrated in iManageCancer Platform - Initial version of the management and detection component enabling clinically-endorsed and managed patient self-care for selected adverse events (Lead: FRAU) (M21) D5.3 Extended decision support and patient guidance services integrated in iManageCancerPlatform: - Predictive knowledge models for therapy monitoring - Drugs self-management tool - Adverse event management and detection component for patients and clinicians - Decision aid for supporting patient participation in decision process integrated in iManageCancer Platform (Lead: PHILIPS) (M30) D5.4 Updated decision support and patient guidance services and refined underlying models based on the evaluation with clinicians and patients in clinical pilots (Lead: PHILIPS) (M40)

D5.1 : Initial set of knowledge models for self-management [12]

Initial set of knowledge models for self-management as described in T5.1.

D5.2 : Initial decision support and patient guidance services integrated in iManageCancerPlatform [21]

Initial decision support and patient guidance services integrated in iManageCancer Platform: - Decision Support Engine supporting basic self-management models and integrated with Health Avatar PHR - Initial Personal Medical Information Recommender integrated in iManageCancer Platform - Initial version of the management and detection component enabling clinically-endorsed and managed patient self-care for selected adverse events

D5.3 : Extended decision support and patient guidance services [30]

Extended decision support and patient guidance services integrated in iManageCancerPlatform: - Predictive knowledge models for therapy monitoring - Drugs self-management tool - Adverse event management and detection component for patients and clinicians - Decision aid for supporting patient participation in decision process integrated in iManageCancer Platform

D5.4 : Updated decision support and patient guidance services and refined underlying models [40]

Updated decision support and patient guidance services and refined underlying models based on the evaluation with clinicians and patients in clinical pilots.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS2	Initial iManageCancer platform prototype	1 - Fraunhofer	21	Initial iManageCancer platform prototype offering basic functionality. Software released for initial testing in workshops. Related deliverables submitted.
MS3	Extended integrated prototype of iManageCancer platform	1 - Fraunhofer	30	Extended integrated prototype of iManageCancer platform available. Software released for clinical validation. Related deliverables submitted.

Work package number [9]	WP6	**Lead beneficiary** [10]	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL
Work package title	Psycho-emotional and health assessment tools		
Start month	10	**End month**	30

Objectives

Techniques for smart recommendations will be based on the psycho-emotional status of the patient and family. These techniques will recommend to the patient educational resources related to their condition and they will assist them in depth for their health status or disease in order to make informed decisions regarding their healthcare. In order to integrate psychological and personal variables into multiscale data systems containing heterogeneous data from a patient, standardised questionnaires will be provided. This process will greatly improve the personalisation of decision support tools that will be delivered by the WP5 and will lead to better and more efficient decision support tools for physicians smart recommendations for the patients. In consequence, this work package will provide ICT based instruments to assess the psycho-emotional status of the patient and to evaluate the resilience in his family. A generic health enquiry tool will be developed that serves that purpose. In addition, support for the integration of off-the-shelve sensors and medical devices will be incorporated in the platform that allow to assess relevant vital signs and parameters related to lifestyle. Assessment services developed in this WP will especially be used in WP5 to further personalise decision support tools and to provide recommendations towards life style. Access to acquired sensor data is given to the patient through the user interface components developed by WP4 Health Avatar PHR.

Description of work and role of partners

WP6 - Psycho-emotional and health assessment tools [Months: 10-30]
ISTITUTO EUROPEO DI ONCOLOGIA SRL, Fraunhofer, FORTH, PHILIPS ELECTRONICS NEDERLAND B.V.

T6.1 Psycho-emotional status monitoring and management (IEO, FORTH, Philips) (Month 10-30)
iManageCancer uses standardized psycho-behavioural questionnaires to detect cognitive–psychological profile of users in order to allow a better fitting between the eHealth-Avatar and the patient. The Avatar could provide feedback and personalised information tailored on the predisposition of each individual patient. This will create the premises for the patient to a more constant monitoring of symptoms related to cancer.
Screening instruments to measure cognitive-psychological and self-management predisposition for cancer survivors include:
- Level of Patient activation: evaluating the States of change for levels of activation, starting to take a role, building knowledge and confidence, taking action, maintaining behaviours.
- Anxiety and depression: evaluating levels of anxiety and depression ranging from not clinical, to borderline to clinically relevant
- Distress and fatigue: Symptoms or clinical distress and fatigue related to the disease
- Locus of control: Health locus of control measures the extent to which patients perceive their health to be influenced by their own behaviour and choices (an 'internal' locus of control) versus by others, such as their healthcare providers (a 'powerful others' external locus of control), versus by chance or random events (a 'chance-external' locus of control).
- Patient's social needs like levels of isolation, social support and relationship difficulties
Psycho-emotional alerts on the electronic devices will remind the patient to periodically provide information on his psycho-emotional status.

T6.2 Family resilience evaluation tool (IEO, PHILIPS, FORTH) (Month 10-30)
An instrument to evaluate critical areas within the family will be created. The aim will be to evaluate and recognize the risk factors that will impede patient's empowerment and consequent health positive outcomes. While clinical factors are patient's intrinsic factors, psychological and emotional reactions to the disease will heavily affect also parents and siblings of the child with cancer, or the partner and children in the case of cancer in adults. While this influence is nowadays accepted, there isn't an efficient instrument to highlight this critical area, while diffuse are instruments to assess patient psycho-emotional status. In particular, the psychosocial dynamics among the family members and the overall family cohesion, communication, and coping styles will be investigated and analysed. Collecting these variables will allow the platform to foster the protective characteristics of the entire family. The outcome of such evaluation will provide information and recommendation to be integrated in iManageCancer platform.

T6.3 Health enquiry tool (FRAU, FORTH, PHILIPS) (Month 10-30)

A generic tool for clinical experts will be created in this task that allow them to dynamically create standardised questionnaires for the patients and their family members that are presented to them in pre-defined intervals and depending on pre-defined conditions through their Personal Health Avatar in combination with the Care Flow Engine. Answers are captured in a way that they can be further assessed by other components.

T6.4 Life style and vital sign monitoring (FRAU, FORTH, PHILIPS) (Month 10-30)
(Off-the-shelve) sensors will be integrated in this task that quantify information about lifestyle, in particular physical activity, stress and vital signs of relevance for self-management. The latter will include body weight, BMI and body temperature.
Furthermore, generic notification interfaces for mobile and wearable devices such as the android wear (http://www.android.com/wear/) will be explored and possibly used. The notification system will allow the iManageCancer platform to keep the patient informed about events, such as new messages or a calendar event and alerts important for the patient as they happen or a log that chronicles events while the patient is not paying attention. iManageCancer will be able to send data and actions, with data replication APIs and remote procedure calls (RPC), to any phone or wearable device which supports such technology, expanding the compatibility of the platform to a big ecosystem.

Participation per Partner

Partner number and short name	WP6 effort
1 - Fraunhofer	14.00
2 - FORTH	18.00
4 - PHILIPS ELECTRONICS NEDERLAND B.V.	10.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	44.00
Total	86.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D6.1	Definition of psycho-emotional monitoring instrument and family evaluation tool	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	Report	Confidential, only for members of the consortium (including the Commission Services)	18
D6.2	Generic health enquiry tool	1 - Fraunhofer	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	18
D6.3	Initial versions of psycho-emotional monitoring instrument, family evaluation tool and monitoring tool for life style and vital signs	2 - FORTH	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D6.4	Implemented application scenarios in iCancerPlatform using psycho-emotional and health assessment tools	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	Report	Public	30

Description of deliverables

D6.1 Definition of psycho-emotional monitoring instrument and family evaluation tool and their usage through other iManageCancer services and tools (Lead IEO) (M18) D6.2 Generic health enquiry tool (Lead: FRAU) (M18) D6.3 Initial versions of psycho-emotional monitoring instrument, family evaluation tool and monitoring tool for life style and vital signs integrated in iManageCancer Platform (Lead: FORTH) (M21) D6.4 Report on implemented application scenarios in iManageCancer Platform using psycho-emotional and health assessment tools (Lead: IEO) (M30)

D6.1 : Definition of psycho-emotional monitoring instrument and family evaluation tool [18]

Definition of psycho-emotional monitoring instrument and family evaluation tool and their usage through other iManageCancer services and tools as described in task T6.1 and T6.2.

D6.2 : Generic health enquiry tool [18]

Generic health enquiry tool as describer in T6.3

D6.3 : Initial versions of psycho-emotional monitoring instrument, family evaluation tool and monitoring tool for life style and vital signs [21]

Initial versions of psycho-emotional monitoring instrument, family evaluation tool and monitoring tool for life style and vital signs integrated in iCancerPlatform as described in tasks T6.1, T6.2 and T6.4.

D6.4 : Implemented application scenarios in iCancerPlatform using psycho-emotional and health assessment tools [30]

Report on implemented application scenarios in iCancerPlatform using psycho-emotional and health assessment tools in combination with other services of the platform.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS2	Initial iManageCancer platform prototype	1 - Fraunhofer	21	Initial iManageCancer platform prototype offering basic functionality. Software released for initial testing in workshops. Related deliverables submitted.
MS3	Extended integrated prototype of iManageCancer platform	1 - Fraunhofer	30	Extended integrated prototype of iManageCancer platform available. Software released for clinical

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
				validation. Related deliverables submitted.

Work package number [9]	WP7	Lead beneficiary [10]	8 - SGS
Work package title	Serious games for self-management		
Start month	10	End month	30

Objectives

This work packages aims at developing and integrating serious games for iManageCancer that help the patient and his/her relatives to deal with the psychological dimension of their disease. Serious games have been proposed as a strategy to encourage healthy habits, face disease fight in a different perspective, and promote disease management. They shall support the patient in reducing stress, anxiety and related negative impact of the disease on their lives and social relations, and thus contribute to keep a positive attitude towards the disease and life and actively fight the disease. Serious games can also enhance patient's knowledge through education, reduce feelings of uncertainty, and simultaneously increase confidence in decision making. In this perspective, serious games will provide also the opportunity to experience skills and coping strategies in facing cancer.
For children a novel adventure game will be created focussing on therapeutic interventions and socialization aspects and to fight cancer. For adult cancer patients a game will be developed to perform as a "virtual me" health and socialisation related missions in virtual scenarios of everyday life in order to keep positive and strengthen self-efficacy and adherence to therapy.

Description of work and role of partners

WP7 - Serious games for self-management [Months: 10-30]
SGS, USAAR, BED , ISTITUTO EUROPEO DI ONCOLOGIA SRL
T7.1 Serious games for self-management for adult cancer patients. (BED, IEO) (Month 10-27)
The aim of the serious game is to promote self-efficacy, i.e. the belief of the patients to be able to manage and to face their disease. The games will give them the opportunities to see through the virtual world how to make active decisions that could dramatically affect their quality of life under the constant pressure that they could, eventually, die. By working with the concept definition and system requirements, we will define a number of game scenarios to be fulfilled. The game should allow a user to create a "virtual me" with emotional, fitness and energy indicators in the scenario, giving the virtual character progressive aims and missions in different areas, such as maintain a balanced diet, adequate to the level of exercise, maintain his social life with his network of friends, short walks for shopping.
The game will also put the character in a critical situation for a strategy of solutions. Positive feedbacks will be received if the character takes the right strategy and hints will be given if the character needs help. With the increase of his confidence, the characters will be encouraged to take more physical exercises or make more social connections. The game will also give the character the opportunity to cope with side effects of treatment, such as fatigue and nausea from chemotherapy by eating a balanced diet which is rich in vitamins, and by doing exercises to manage urinary dysfunctions. The game will consist of short sessions with immediate feedback, use of only positive feedback during the game, use of hints and helps when the patient is having difficulties in the game. By doing so, the "virtual me" can behave as if in a living life environment, allowing the patients to reflect this into their real life.
Technically, the games will be developed with cross-platform game engines or by adapting existing open-source serious games. By carrying out user requirement analysis, a proper game Popular 2D and 3D game engines and platforms such as Cocos2d-x, Marmalade, PlayN, Corona, Unity3D, Unreal Engine 3 will be investigated in detail. Existing serious games for self-management will also be investigated on their usage for cancer patients. Games with a presumed benefit for cancer patients will be identified and linked to the iManageCancer Platform. Due to the portability and the increasing popularity of smart phones and tablets, the preferred game platforms or existing games should be able to run on major mobile platforms, especially Apple iOS and Google Android. Special concerns need to be taken into account in the process of integration. Considering the serious games are designed for aged people suffering from cancer. The games should use interfaces have to be considered carefully. We will look into guidelines for user interface design for older people. For example, the texts and icons in the game should be relatively larger and user-adjustable and the music should be gentle. The game session should be relatively shorter than normal games. 2D games maybe preferred over 3D games as their user interactions are less complex, especially for children and aged people.
The serious games will be developed in a cycle of design and design verification, prototype development and testing, patient trial, revision and release. The patient trial phase is critical for evaluation of the prototypes. Patients will use game prototypes in their real life and a detailed survey will be designed to evaluate the games in a quantitative way. There will be four major versions for every proposed serious game. While the first version is only an internal release for

design and function verification, the second version will be a formal prototype for patient trial. The third version will be an improved version based on survey responses from patients and doctors and the fourth version will be a formal release.

T7.2 Serious game development for children and adolescents (cancer adventure) (SGS, USAAR, IEO) (Month 10-30) An adventure game for children and adolescents but also their relatives will be developed for smartphones with the following approach. The gamers fight as virtual characters virtual cancer cells with different weapons that represent the therapeutic clinical tools against cancer. In this way the message is given that weapons exist and that they can combat cancer if properly applied. Socialisation aspects will be incorporated in the game to form team with co-players like parents, sisters and brothers, and friends but also other cancer patients via the iManageCancer platform. Means will be implemented in the game that support the assessment of its impact on the patients like playful answering of questions. Parameters on the usage of the game and the results of gaming will be stored in the patient's PHR. To achieve a maximum of accessibility, the plan is to realize the game on mobile hardware platforms. The cross-platform game engine Unity has been selected as the software development framework to rollout the game through a variety of operating system as iOS, Android or Windows. All platform versions of the game will be connected to the same web based system to make sure that all users can cooperate in the same user community. To achieve a maximum of acceptance, the game has to be highly attractive to the target audience. Defining attractiveness for a digital game includes multiple dimensions. Most important are an intuitive and easy-to-use user interface, an immersive game design and an easy to identify additional value for the user.

Participation per Partner

Partner number and short name	WP7 effort
3 - USAAR	2.00
6 - BED	15.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	20.00
8 - SGS	47.00
Total	84.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D7.1	Prototypic serious game for paediatric cancer patients	8 - SGS	Demonstrator	Confidential, only for members of the consortium (including the Commission Services)	21
D7.2	Integrated serious games for adults	6 - BED	Demonstrator	Public	27
D7.3	Serious game for paediatric cancer integrated in the iManageCancer platform	8 - SGS	Demonstrator	Public	30

Description of deliverables

D7.1: Prototypic serious game for paediatric cancer patients (Lead: SGS) (M21) D7.2: Report about integrated serious games for adults (Lead: BED) (M27) D7.3: Serious game for paediatric cancer integrated in the iManageCancer platform (Lead: SGS) (M30)

D7.1 : Prototypic serious game for paediatric cancer patients [21]

Prototypic serious game for paediatric cancer patients as outlined in T7.2

D7.2 : Integrated serious games for adults [27]

Integrated serious games for adults as further described in T7.1.

D7.3 : Serious game for paediatric cancer integrated in the iManageCancer platform [30]

Serious game for paediatric cancer integrated in the iManageCancer platform as decribed in T7.2.

Schedule of relevant Milestones

Milestone number [18]	**Milestone title**	**Lead beneficiary**	**Due Date (in months)**	**Means of verification**
MS2	Initial iManageCancer platform prototype	1 - Fraunhofer	21	Initial iManageCancer platform prototype offering basic functionality. Software released for initial testing in workshops. Related deliverables submitted.
MS3	Extended integrated prototype of iManageCancer platform	1 - Fraunhofer	30	Extended integrated prototype of iManageCancer platform available. Software released for clinical validation. Related deliverables submitted.

Work package number [9]	WP8	**Lead beneficiary** [10]	2 - FORTH
Work package title	Smart analytical data services		
Start month	18	**End month**	30

Objectives

The main objective of this work package is to build the data mining and knowledge discovery services to support the identified user scenarios with a data mining focus. These tools and services will be integrated into the iManageCancer platform and support the smart data analytics. The data driven tools to be implemented will analyse the information in the iManageCancer database and draw conclusions related to the usage of the self-management platform, reported adverse events and health issues, individual health status, quality-of-life, compliance, etc. This work package aims to: a) deliver a mechanism which will be able to identify patterns in the iManageCancer database and evolve while the end users feed the platform with data , b) reveal patterns or trends in data, c) screen for pre-frailty states, d) implement efficient and effective visualization based on specific patterns and e) develop a mechanism to export anonymized data for further analysis with external tools.

Description of work and role of partners

WP8 - Smart analytical data services [Months: 18-30]
FORTH, USAAR, Cancer Intelligence Ltd, BED , ISTITUTO EUROPEO DI ONCOLOGIA SRL
T8.1 Data analysis and data mining services (FORTH, USAAR, CI-eCancer, IEO), (Month 18-30)
This task aims to extract information from the diverse data of iManageCancer and transform it into an understandable structure for better knowledge and further use. The iManageCancer platform collects multidisciplinary data covering areas from the medical, the environmental and the lifestyle domains.
Data mining services of iManageCancer will try to go much further than traditional statistics and look at the raw data and then attempt to hypothesise relationships within the data. Such systems are able to produce quite complex characterisations of data relationships and attempt to discover humanly understandable concepts. The data mining services in iManageCancer focus on data discovery, identification and extraction of previously unknown interesting patterns and associations between available data and the patients in the iManageCancer platform. In order to advance data mining within the iManageCancer context, objectives and goals, special efforts will be forwarded in the utilization of main data mining standards (e.g. PMML - Predictive Model Markup Language) and open source environments and libraries like Weka and R-package.

T8.2 Visualisation (BED, USAAR, CI-eCancer) (Month 18-30)
Information of iManageCancer is characterized by its heterogeneity. Clinical, lifestyle, environmental data and personal preferences are stored and managed within the platform. Data of such a diverse information space is difficult to be delivered, especially to non IT users like the iManageCancer end users. The task will address the need for efficient visualization methods for data and for data analysis results. Data visualization methodologies for heterogeneous data sources will be implemented. State of the art visualization methodologies such as parallel coordinates, a common way of visualizing high-dimensional multivariate data able to transform high dimensions into easily seen 2D patterns, and chord diagrams (exploring relationships between groups of features) will be evaluated and possibly used. Furthermore the visualization techniques will empower clinicians to gather data blends from iManageCancer platform and stream them directly to the data mining services implemented in task 8.1. Visualizing data in a way that is appropriate for the user's needs is essential before a further more quantitative analysis take place. Furthermore the platform will support a mechanism to export anonymized data. Task 8.2 will also address the efficient and effective visualization of the data mining results delivered by task 8.1 to the end users. Special emphasis will be given to simple and easy interpretation of the knowledge, presenting results to the end users through well-chosen structures such as tables or graphs and taking into account of the cognitive skills of humans to show them extended information in a compact way.

Participation per Partner

Partner number and short name	WP8 effort
2 - FORTH	15.00
3 - USAAR	2.00

Partner number and short name	WP8 effort
5 - Cancer Intelligence Ltd	5.00
6 - BED	13.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	6.00
Total	41.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D8.1	Implemented data analysis and data mining services	2 - FORTH	Demonstrator	Public	30
D8.2	Implemented visualization techniques	6 - BED	Demonstrator	Public	30

Description of deliverables

D8.1 Report on implemented data analysis and data mining services (Lead: FORTH) (M30) D8.2 Report on implemented visualization techniques (Lead: BED) (M30)

D8.1 : Implemented data analysis and data mining services [30]

Implemented data analysis and data mining services as described in T8.1.

D8.2 : Implemented visualization techniques [30]

Implemented visualization techniques as described in Task 8.2.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS2	Initial iManageCancer platform prototype	1 - Fraunhofer	21	Initial iManageCancer platform prototype offering basic functionality. Software released for initial testing in workshops. Related deliverables submitted.
MS3	Extended integrated prototype of iManageCancer platform	1 - Fraunhofer	30	Extended integrated prototype of iManageCancer platform available. Software released for clinical validation. Related deliverables submitted.

Work package number [9]	WP9	Lead beneficiary [10]	3 - USAAR
Work package title	Pilots		
Start month	15	End month	42

Objectives

Evaluate the iManageCancer Platform in two steps for children and adults: 1) Test usability of the basic iManageCancer Platform available in Month 21 with representatives of the two patient groups in workshops and, 2) Prepare, conduct and evaluate sophisticated pilots for children and adolescents as well as fur adult cancer patients after extended iManageCancer Platform is released in Month 30.

Description of work and role of partners

WP9 - Pilots [Months: 15-42]
USAAR, Fraunhofer, FORTH, Cancer Intelligence Ltd, ISTITUTO EUROPEO DI ONCOLOGIA SRL
T9.1 Preparation and usability assessment of pilots (USAAR, IEO, CI-eCANCER, FRAU, FORTH) (Month 15-30)
This task deals with the preparation and usability assessment of the pilots that will evaluate the iManageCancer Platform. With this task the objectives, the trial outline definition, ethical, legal and regulatory issues are elaborated in an iterative process with all stakeholders of the project. This task deals with the preparation and usability assessment of the pilots that will evaluate the iManageCancer Platform. With this task the objectives, the trial outline definition, ethical, legal and regulatory issues are elaborated in an iterative process with all stakeholders of the project. This will include the procedures and criteria how patients are identified and recruited and how informed consent and assent will be ensured. It will also include measures how further enhancement of stigmatisation and vulnerability of the trial participants can be avoided if there is any risk. This will be laid down in D9.1 as well as in the protocols of the clinical pilots that will be submitted to the local ethical committees for approval together with the templates for informed consent including data protection issues. Preparation also includes the development of a data management plan for the clinical data collected in the pilots that details also how data protection is ensured. The data management plan will be subject to approval by the competent University Data Protection Officers.
During a workshop at month 24 together with patients, citizens and clinical care providers the pilots will be defined in detail including the conduction and evaluation of them. A strategy for the deployment of the iManageCancer platform for further usage in other pilots will be elaborated. This workshop also includes initial usability tests of the prototype platform of iManageCancer where a few patient representatives will try the system and give feedback in interviews and through questionnaires. The results will of this workshop will be used to further improve the system before running the pilots.

T9.2 Pilot for children (USAAR) (Month 18-40)
Primarily criteria need to be defined that allows judging if the pilots are of any help for the children. These criteria need to be asked by questionnaires during two phases. In the first phase without using tools and in the second phase with using the developed tools children and parents will be asked to fill in the questionnaire. This will allow us to analyse the impact of the tools on clinical care according to the preliminary defined criteria. After the definition of the pilot for children a protocol will be written starting after the first workshop done in T9.1 and ethical approval gained. Within the pilot protocol statistics are provided that allow comparing the two phases of the pilot. The initial first phase without using tools can already start as soon as the criteria and questionnaire are finalized. Together with parents groups and psychologists the second phase of the pilot for children will be conducted after informed consent given by the individual parents and children. Developed serious games will be part of the pilot. Common usability criteria, like satisfaction with the pilot, frequency of usage of the iManageCancer platform, will be defined and added to the questionnaire containing specific criteria for evaluation of the pilot. The second phase of the pilot will start at month 32. With the start of the first phase of the pilot data from the questionnaire will be collected and after one year first usability results will be presented. At the end of the project the pilot will be evaluated and a strategy described how to sustain the pilot and how new pilots can be developed and added to the platform.

T9.3 Pilot for adults (IEO, CI-eCANCER) (Month 22-40)
After the definition of the pilot for adults, based on the workshops conducted in T9.1, a protocol will be written and ethical approval gained. The pilot will be conducted after informed consent given by the patient. In a first pilot we will test the platform prototype, including serious games, starting from M22 and ending M28. Common usability criteria, like satisfaction, believes, acceptability, comfort and opinions on usability, frequency of usage of the iManageCancer

platform, will be defined. Focus groups may be conducted with a smaller number of pilot users to follow-up with qualitative analysis what will emerge through questionnaires. In addition specific psychological and biological criteria will be defined and data collected to evaluate not only the platform acceptability and usability, but also its efficacy on patient empowerment and stress management. M28-M30 will be used to analyse the data collected from the pilot and adjustments and improvements will be implemented in the platform advanced version. A pilot of the advance version of the platform, using the same methodology used in the pilot of the prototype will start at M32 and will end in M38. M39-40 will be used to analyse the collected data. The patients that will be enrolled in the two pilots will be 100 prostate cancer patients for each pilot. For each pilot the 100 patients will be randomly divided in two groups: group 1 that will used the platform and group 2 (control group) that will not use the platform, in order to have a clear and clean result on the platform effect.
Similarly, breast cancer and lung cancer patients will be enrolled for the evaluation of the clinically-endorsed and managed patient self-care component implementing the predictive models for severe adverse events. The pilot will aim to evaluate usability for both clinicians and patients, and the ability to predict the risk of a patient to develop a serious adverse event, the early detection of an event that has occurred reducing this way the suffering and the risk of further complications for the patient, and the prediction for neutropenic recovery for the patients after each treatment cycle to accurately predict when the patient is ready for the next treatment cycle.

T9.4 Evaluation of pilots (CI-eCANCER, IEO, USAAR) (Month 40-42)
During the development process of the pilots evaluation criteria will be defined (T9.3 and T9.4). The main drivers for these criteria are patients and parents. The workshop held in T9.1 will be used to interactively elaborate these criteria as one source. An evaluation workshop will be held one year after the start of the pilots to collect corresponding data. The evaluation will be used to refine the pilots. A summary of the evaluation process will be given in D9.4.

Participation per Partner

Partner number and short name	WP9 effort
1 - Fraunhofer	3.00
2 - FORTH	2.00
3 - USAAR	14.00
5 - Cancer Intelligence Ltd	11.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	28.00
Total	58.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D9.1	Documentation of preparation of the pilots as well as a report on initial tests of basic iManageCancer Platform	3 - USAAR	Report	Confidential, only for members of the consortium (including the Commission Services)	24
D9.2	Pilot for children	3 - USAAR	Report	Public	34
D9.3	Pilot for adults	7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	Report	Public	34

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D9.4	Evaluation report of pilots	5 - Cancer Intelligence Ltd	Report	Public	42

Description of deliverables

D9.1 Documentation of preparation of the pilots as well as a report on initial tests of basic iManageCancer Platform (Lead: USAAR) (M24). Documentation includes the protocols of the clinical pilots in English language, templates of the consent forms in English language, the data management plan and the details on patient recruitment, the consent/ assent procedure, measures to avoid stigmatisation as well as the approvals obtained from ethic committees and competent data protection officers. D9.2 Pilot for children including preparation and usability assessment (Lead: USAAR) (M34) D9.3 Pilot for adults including preparation and usability assessment (Lead: IEO) (M34) D9.4 Evaluation report of pilots (Lead: CI-eCANCER, M42)

D9.1 : Documentation of preparation of the pilots as well as a report on initial tests of basic iManageCancer Platform [24]

Documentation of preparation of the pilots as well as a report on initial tests of basic iManageCancer Platform. Documentation includes the protocols of the clinical pilots in English language, templates of the consent forms in English language, the data management plan and the details on patient recruitment, the consent/assent procedure, measures to avoid stigmatisation as well as the approvals obtained from ethic committees and competent data protection officers.

D9.2 : Pilot for children [34]

Pilot for children including preparation and usability assessment as described in Task 9.2

D9.3 : Pilot for adults [34]

Pilot for adults including preparation and usability assessment

D9.4 : Evaluation report of pilots [42]

Evaluation report of pilots as described in Task 9.4.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification
MS4	Evaluated pilots	5 - Cancer Intelligence Ltd	42	Evaluated pilots. Evaluation report of pilots available.

Work package number [9]	WP10	Lead beneficiary [10]	5 - Cancer Intelligence Ltd
Work package title	Dissemination, communication, exploitation		
Start month	1	End month	42

Objectives

The main objectives of this work package are to disseminate the findings of the project to all the key stakeholder groups and to ensure that the work of the project is sustainable with a robust exploitation and business strategy. In addition to providing publicity and disseminating project outcomes through a project website and across multiple online platforms and social media, this WP will identify and engage with key audience groups to help ensure adoption of the tools and services developed. The WP will also be responsible for ensuring the project partners have a clear strategy in place for long-term success of the tools and services including beyond the lifetime of the project.

Description of work and role of partners

WP10 - Dissemination, communication, exploitation [Months: 1-42]
Cancer Intelligence Ltd, Fraunhofer, FORTH, USAAR, PHILIPS ELECTRONICS NEDERLAND B.V., BED , ISTITUTO EUROPEO DI ONCOLOGIA SRL, SGS
T10.1 Dissemination plan and activities (CI-eCancer, all) (Month 1-42)
Successful dissemination involves the active buy in of all of the project partners; as such CI-ecancer will develop a dissemination plan in the first few months of the project alongside the rest of the consortium. The plan will include a project website, cross platform online and social media promotion, an e-newsletter and will also utilise CI-ecancer's website.

T10.2 Communication plan and activities (CI-eCancer, all) (Month 1-42)
In order to ensure the project is communicated effectively a communication plan will be developed which will also act as the brand guidelines of the project. This document will help to ensure the project has a consistent visual identity and will have a consistency of communication throughout the lifetime of the project to reinforce the project's brand. This task will also ensure the implementation of the communication activities as laid down in the plan and a regular update of the plan.

T10.3 Exploitation plan and activities (CI-eCancer, PHILIPS, SGS, all) (Month 1-42)
Integral with a business plan will be the exploitation plan which will ensure an effective strategy is in place for the long-term maintenance and availability of the iManageCancer platform.
T10.4 External Advisory Panel (CI-eCancer) (Month 1-42)
Key figures will be recruited for advice and guidance on the project and the environment development. The advisory board will represent different stakeholder groups and different nationalities. The Advisory Panel will attend the consortium meetings annually.
T10.5 Service and business models for sustainable self-management platform (PHILIPS, CI-eCancer, SGS) (Month 25-36)
To ensure the project is deemed a success, there must be a long-term plan for the technology to be sustained and utilised by the oncology community and patient groups. For this to happen a business model will be developed with the support of all of the project partners that creates a realistic and achievable plan. Potential public-private partnership models based on Hafen's concept of the Health Data Cooperative will be investigated, but also other models that can lead to a realistic business perspective on the long-term.
T10.6 Launch event (CI-eCancer, all) (Month 37-42)
A launch event will be run alongside a leading European conference to demonstrate the iManageCancer environment and tools to key figures in the world of oncology. Selected leading individuals and patient advocates will be invited to an educational event where key functionality and benefits will be demonstrated.

Participation per Partner

Partner number and short name	WP10 effort
1 - Fraunhofer	5.00

Partner number and short name	WP10 effort
2 - FORTH	3.00
3 - USAAR	2.00
4 - PHILIPS ELECTRONICS NEDERLAND B.V.	4.00
5 - Cancer Intelligence Ltd	29.00
6 - BED	3.00
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	2.00
8 - SGS	4.00
Total	52.00

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
D10.1	Elaborated plans on dissemination, communication and exploitation	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	5
D10.2	Report on the implemented External Advisory Panel	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	12
D10.3	Report on dissemination, communication and exploitation activities and plans update	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	25
D10.4	Investigated service and business models; envisaged business model	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	36
D10.5	Launch Event	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the Commission Services)	42
D10.6	Final report on dissemination, communication and exploitation	5 - Cancer Intelligence Ltd	Report	Confidential, only for members of the consortium (including the	42

List of deliverables

Deliverable Number [14]	Deliverable Title	Lead beneficiary	Type [15]	Dissemination level [16]	Due Date (in months) [17]
	activities and plans update			Commission Services)	

Description of deliverables

D10.1 Elaborated plans on dissemination, communication and exploitation (Lead: CI-eCANCER) (M5) D10.2 Report on the implemented External Advisory Panel (Lead: CI-eCancer M12) D10.3 Report on dissemination, communication and exploitation activities and plans update (Lead: CI-eCANCER) (M25) D10.4 Reported on investigated service and business models; envisaged business model (Lead: PHILIPS) (M36) D10.5 Report on the launch event (Lead: CI-eCancer) (M42) D10.6 Report on dissemination, communication and exploitation activities and plans update (Lead: CI-eCANCER) (M42)

D10.1 : Elaborated plans on dissemination, communication and exploitation [5]

Elaborated plans on dissemination, communication and exploitation as stated in tasks T10.1, T10.2 and T10,3.

D10.2 : Report on the implemented External Advisory Panel [12]

Report on the implemented External Advisory Panel as a result of T10.4.

D10.3 : Report on dissemination, communication and exploitation activities and plans update [25]

Report on dissemination, communication and exploitation activities and plans update according to tasks T10.1, T10.2 and T10.3.

D10.4 : Investigated service and business models; envisaged business model [36]

Reported on investigated service and business models; envisaged business model as described in T10.5.

D10.5 : Launch Event [42]

Report on the launch event as presented in Task 10.6.

D10.6 : Final report on dissemination, communication and exploitation activities and plans update [42]

Final report on conducted dissemination, communication and exploitation activities and plans update.

Schedule of relevant Milestones

Milestone number [18]	Milestone title	Lead beneficiary	Due Date (in months)	Means of verification

1.3.4. WT4 List of milestones

Milestone number [18]	Milestone title	WP number [9]	Lead beneficiary	Due Date (in months) [17]	Means of verification
MS1	Critical system design revision	WP3	2 - FORTH	9	D3.1 'Initial iManageCancer architecture document' available and accepted by Steering Committee
MS2	Initial iManageCancer platform prototype	WP3, WP4, WP5, WP6, WP7, WP8	1 - Fraunhofer	21	Initial iManageCancer platform prototype offering basic functionality. Software released for initial testing in workshops. Related deliverables submitted.
MS3	Extended integrated prototype of iManageCancer platform	WP3, WP4, WP5, WP6, WP7, WP8	1 - Fraunhofer	30	Extended integrated prototype of iManageCancer platform available. Software released for clinical validation. Related deliverables submitted.
MS4	Evaluated pilots	WP9	5 - Cancer Intelligence Ltd	42	Evaluated pilots. Evaluation report of pilots available.

1.3.5. WT5 Critical Implementation risks and mitigation actions

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
R1	One or more partners are not able or not willing to perform their duties at all, in part or in time. The quality of a result of a task is not sufficient. (Partner Problems / Expertise Risk)	WP1, WP10, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	First of all, this risk is limited as only well-known partners have been invited to join iManageCancer and they have experience in working together in other projects. Moreover, partners overlap in critical competences to reduce the impact in the unlikely event that problems arise with a partner. Expertise risk has been addressed by appointing a scientific manager, who has to observe expertise issues and react accordingly. However, in case of such problems the Coordinator specifies a clear and fair time limit for improvement after consulting the WP leaders. In case of failure the conflict resolution procedure will be applied all consequences as described in detail in the consortium agreement.
R2	One partner withdraws from the project. (Partner Problems / Expertise Risk)	WP1, WP10, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	Partners overlap in critical competences to reduce the impact in the unlikely event that problems arise with a partner. The partner will be replaced as soon as possible in accordance with the Commission. If the partner's responsibilities cannot be delegated to other partners in the consortium a new partner will be included in the consortium applying the respective procedure of the Commission.
R3	Over-spending or under-spending by a partner. (Project Execution Risk)	WP1, WP10, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	In both cases the coordination will ensure that the corresponding institutes give proper justification. Failure, for a given institution, to justify the over- or under-spending may results in a budget

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
			reallocation of it resources to other partner institutes in the project, in accordance with the general rules defined in the consortium Agreement.
R4	Consortium partners cannot agree because of different interests (Agreement Risk).	WP1, WP10, WP2, WP3, WP4, WP5, WP6, WP7, WP8, WP9	The implementation of various communication systems will meet this risk in order to generate a common understanding. In case there is a real conflict of interest, the provided conflict resolution process from the previous section will be used.
R5	HealthAvatar PHR is not available at the expected time and pilots cannot start. (Technological Risks)	WP4, WP9	This risk has been addressed by appointing a technical manager, whose task is to ensure a safe technology selection. Beside this defined process, all partners are well experienced and have a long history in the field. In case of different judgement of technology the conflict resolution process from the previous section will be used.
R6	Predictive models for chemotherapy monitoring can't be created due to insufficient data at the clinical sites. (Technological Risks)	WP5, WP9	Feasibility of such a model has been investigated in advance through previous research. The variables of such a model are subject to the research for model development. Toxicity data on chemotherapy treatment from 4200 patients is available at IEO. In case further data is needed the clinical site for the third pilot will be selected according the availability of such data.
R7	System integration and interoperability is too difficult/ complex to achieve. (Technological Risks)	WP3	The partners involved in WP3 are all well experienced and have a long history in the integration and interoperability from other projects.

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
R8	Delay of the evaluation results (Technological Risks)	WP9	All partners are quite experienced in the field to ensure no delay in the evaluation results. Also, evaluation activities will be implemented using a tight co-operation with the support of development teams. Finally whenever possible preliminary prototypes will be planned to avoid this delay.
R9	No major customers for using the results are found (Dissemination / Exploitation Risks, Market and User related Risks)	WP10	This risk has been addressed by appointing a quality manager. It's his responsibility to identify this risk in an early stage and suggest reasonable actions. In terms of conflicting interests the conflict resolution process from the previous section will be used.
R10	Not all participating users accept to use our solution. (Dissemination/ Exploitation Risks, Market and User related Risks)	WP9	Early involvement of the end-users, intensive cooperation during the design phase and the explanations of the reasons behind the installation of such a system will be performed by the use case partners.
R11	The outcome platform is not compliant with European regulations or the pilots are not authorized by the ethical committees of the institutes of the medical partners.	WP3, WP4, WP5, WP6, WP7, WP8, WP9	Due to their nature and the safety risks some of the tools may be considered as medical devices according to European regulations. Compliance need to be ensured and risk management will be implemented in the software development process according to ISO 14971 as the basis for compliance with regulations. Clinical pilots will be designed in a way that risks to patients are excluded as far as possible. A contingency budget is reserved for eventually required services

Risk number	Description of risk	WP Number	Proposed risk-mitigation measures
			of Notified Bodies or other authorities.
R12	A competing solution comes up and makes the results less valuable (Competition Risks)	WP10	All project partners are well situated within their respective research community and therefore have a detailed knowledge on current streams/trends in research. The scientific manager will coordinate partners in keeping current with similar approaches and potential competition.

1.3.6. WT6 Summary of project effort in person-months

	WP1	WP2	WP3	WP4	WP5	WP6	WP7	WP8	WP9	WP10	Total Person/Months per Participant
1 - Fraunhofer	18	4	16	0	40	14	0	0	3	5	100
2 - FORTH	6	2	30	31	13	18	0	15	2	3	120
3 - USAAR	1	12	0	7	2	0	2	2	14	2	42
4 - PHILIPS ELECTRONICS NEDERLAND B.V.	1	3.50	9.50	0	33	10	0	0	0	4	61
5 - Cancer Intelligence Ltd	1	5	0	0	2	0	0	5	11	29	53
6 - BED	1	1	14	33	2	0	15	13	0	3	82
7 - ISTITUTO EUROPEO DI ONCOLOGIA SRL	1	16	0	10	28	44	20	6	28	2	155
8 - SGS	1	1.50	6	0	0	0	47	0	0	4	59.50
Total Person/Months	30	45	75.50	81	120	86	84	41	58	52	672.50

1.3.7. WT7 Tentative schedule of project reviews

Review number [19]	Tentative timing	Planned venue of review	Comments, if any
RV1	12	TBD	
RV2	30	TBD	
RV3	42	TBD	

1.4. Ethics Requirements

No ethics requirements indicated

1. Project number

The project number has been assigned by the Commission as the unique identifier for your project. It cannot be changed. The project number **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

2. Project acronym

Use the project acronym as given in the submitted proposal. It can generally not be changed. The same acronym **should appear on each page of the grant agreement preparation documents (part A and part B)** to prevent errors during its handling.

3. Project title

Use the title (preferably no longer than 200 characters) as indicated in the submitted proposal. Minor corrections are possible if agreed during the preparation of the grant agreement.

4. Starting date

Unless a specific (fixed) starting date is duly justified and agreed upon during the preparation of the Grant Agreement, the project will start on the first day of the month following the entry into force of the Grant Agreement (NB : entry into force = signature by the Commission). Please note that if a fixed starting date is used, you will be required to provide a written justification.

5. Duration

Insert the duration of the project in full months.

6. Call (part) identifier

The Call (part) identifier is the reference number given in the call or part of the call you were addressing, as indicated in the publication of the call in the Official Journal of the European Union. You have to use the identifier given by the Commission in the letter inviting to prepare the grant agreement.

7. Abstract

8. Project Entry Month

The month at which the participant joined the consortium, month 1 marking the start date of the project, and all other start dates being relative to this start date.

9. Work Package number

Work package number: WP1, WP2, WP3, ..., WPn

10. Lead beneficiary

This must be one of the beneficiaries in the grant (not a third party) - Number of the beneficiary leading the work in this work package

11. Person-months per work package

The total number of person-months allocated to each work package.

12. Start month

Relative start date for the work in the specific work packages, month 1 marking the start date of the project, and all other start dates being relative to this start date.

13. End month

Relative end date, month 1 marking the start date of the project, and all end dates being relative to this start date.

14. Deliverable number

Deliverable numbers: D1 - Dn

15. Type

Please indicate the type of the deliverable using one of the following codes:

R	Document, report
DEM	Demonstrator, pilot, prototype
DEC	Websites, patent fillings, videos, etc.
OTHER	

16. Dissemination level

Please indicate the dissemination level using one of the following codes:

PU	Public

CO Confidential, only for members of the consortium (including the Commission Services)
CI Classified, as referred to in Commission Decision 2001/844/EC

17. Delivery date for Deliverable

Month in which the deliverables will be available, month 1 marking the start date of the project, and all delivery dates being relative to this start date.

18. Milestone number

Milestone number:MS1, MS2, ..., MSn

19. Review number

Review number: RV1, RV2, ..., RVn

20. Installation Number

Number progressively the installations of a same infrastructure. An installation is a part of an infrastructure that could be used independently from the rest.

21. Installation country

Code of the country where the installation is located or IO if the access provider (the beneficiary or linked third party) is an international organization, an ERIC or a similar legal entity.

22. Type of access

VA if virtual access,
TA-uc if trans-national access with access costs declared on the basis of unit cost,
TA-ac if trans-national access with access costs declared as actual costs, and
TA-cb if trans-national access with access costs declared as a combination of actual costs and costs on the basis of unit cost.

23. Access costs

Cost of the access provided under the project. For virtual access fill only the second column. For trans-national access fill one of the two columns or both according to the way access costs are declared. Trans-national access costs on the basis of unit cost will result from the unit cost by the quantity of access to be provided.

PART B

iManageCancer

Empowering patients and strengthening self-management in cancer diseases

History of changes

Issue Date	Version	Changes Made / Reason for this Issue
20/10/14	V1.01	Second version of the DoA produced on request of the Commission incorporating the following changes: - In the budget table of IEO an explanation for audit costs in the amount of € 4.000 under "Other goods and services" has been given. - Update of Philip's profile: The department 'Precision and Decentralized Diagnostics' was added as a second department that will be involved in the tasks of Philips.
28/09/14	V1.0	First version of the DoA produced incorporating the following changes: - Measures and information included in DoA to meet the requirements of the Screening-Ethics Consensus Report: o Several paragraphs in section 2.3.6.1 added with information about planned patient recruitment and consent/assent procedure, in particular with respect to the participation of children in the pilots. o Task 9.1 and D9.1 "Preparation and usability assessment of pilots" further detailed to respect requirements of the outcome of the Ethics Review. o Composition of External Advisory Panel: An independent Ethics Advisor will complement this panel as requested by Screening-Ethics

		Consensus Report o Clarification that blood samples are collected in the pilot trials for adult cancer patients - Key person added for SGS (Stefan Hoffmann) - CV of Lefteris Koumakis updated

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2.1. Excellence

2.1.1 Objectives

Significant improvements due to cancer research have led to more cancer patients being cured, and very many more enabled to live with their cancer. The disease is now frequently managed as a chronic illness requiring long-term surveillance and, in some cases, maintenance treatment. Cancer care occurs on a continuum that stretches from prevention to the end of life, with early detection, diagnosis, treatment, and survivorship in between. This implies a transformation in the nature of healthcare from reactive to preventive, and to personalised medicine. As a chronic illness, however, there is an urgent economic and pragmatic need for patients and families to manage their own care, and for the healthcare system to develop efficient strategies in supporting the achievement of this objective. Self-management support is defined as "what health services do in order to aid and encourage people living with a long term condition to make daily decisions that improve health related behaviours and clinical and other outcomes"[1]. Educating patients to self-management of disease strengthens health behaviours by promoting health literacy and collaborative decision-making skills, problem solving and action planning related to their condition. Such an approach is being embraced by government policies[2] and in clinical practice, as demonstrated by the increasing number of initiatives and trials for patients' self-management[3]. Advances in information and communication technology (ICT), together with the recent spread of portable devices such as smartphones and tablets, offer the opportunity to re-design self-management. In this project, ICT will provide the means to transform the role of the patient from a passive recipient of health care services to an active, informed participant of medical decision making processes in charge of his own well-being.

Each patient young or old undergoes different treatments with varying clinical and psychological symptoms and side-effects that may result in different needs for support. More specifically, failure to account for several psychosocial variables, such as negative perceptions, degree of social support, levels of symptom distress and depression seems to be associated with poor uptake of existing eHealth applications[4]. Children with cancer have special issues, as do their parents. While outcomes of care for children are very good, the journey is long, convoluted and complicated with numerous physical side effects and psychological reactions. Much more than with adults, in order to empower children with cancer it is necessary to start from the whole family. How a family responds to adversity influences the child's responses and functioning, in a circular sequence of effects[5]. A bidirectional effect can be found between parental difficulties and low empowerment in children with cancer. Parental distress has been found to be positively related to distress in children. For example, children of depressed mothers display a variety of internalizing and externalizing symptoms, above and beyond those displayed by children of non-depressed mothers[6]. Similarly, anxiety in parents has been linked to anxiety in children. Parents of children with cancer may display more internalizing difficulties than parents of healthy children[7], which in turn may leave children with cancer more vulnerable to internalizing difficulties. In this perspective, it is crucial to enhance empowerment and resilience of the child with cancer also through an empowerment of all family members.

In the case of adults a good model which this project will highlight is cancer of the prostate. Prostate cancer induces negative emotional and psychological reactions at different stages of the disease, from

[1] Adapted by the British National Cancer Survivorship Initiative from The Health Foundation, Co-creating Health Programme 2008.

[2] UK Department of Health, Supporting People with Long Term Conditions to Self Care, 2006.

[3] McCorkle, R., Ercolano, E., Lazenby, M., Schulman-Green, D., Schilling, L. S., Lorig, K., & Wagner, E. H. Self-management: Enabling and empowering patients living with cancer as a chronic illness. CA: a cancer journal for clinicians 2011, 61(1), 50-62.

[4] Børøsund, E., Cvancarova, M., Ekstedt, M., Moore, S.M., Ruland, C.M. How user characteristics affect use patterns in web-based illness management support for patients with breast and prostate cancer. J Med Internet Res. 2013, 15(3), 34.

[5] Patterson, J.M., Garwick, A.W. The impact of chronic illness on families: A family systems perspective. Ann Behav Med, 1994, 16, 131–142.

[6] Brennan, P.A., Hammen, C., Katz, A. R., & LeBrocque, R. M. Maternal depression, paternal psychopathology, and adolescent diagnostic outcomes. Journal of Consulting and Clinical Psychology, 2002, 70, 1075–1085.

[7]Robinson KE, Gerhardt CA, Vannatta K, and Noll RB. Parent and Family Factors Associated with Child Adjustment to Pediatric Cancer. Journal of Pediatric Psychology, 2007, 32(4), 400–410.

diagnosis, to treatment, until the chronic phase. Anxiety is the most reported symptom, together with irritability or depression and fear of side effects, coupled with denial. Men are not attuned to the healthcare system, as there are no screening tests which bring them in contact with doctors. In addition, men have a silent conviction of their "immortality" so when confronted with potential lethal illness, react adversely. Prostate cancer has a considerable impact relative to physical symptoms, such as faecal and urinary incontinence, impotence and infertility, which negatively influence personal identity, relationships and intimacy.

Men with prostate cancer have reported that they feel a lack of support for what concerns psychological distress, emotions and coping[8], sexuality related issues, and the management of enduring lower tract urinary symptoms and other side effects of the disease or associated treatments, not to mention fear of recurrence[9]. Even though prostate cancer survivors are often assertive in self-managing their condition, they feel inadequately supported in the effort to cope with the physical and psychological consequences of their disease or their treatment[10]. For this reason we need to consider the specific profile of these patients - eHealth users, for a better understanding of patients' varying need of support.

In consequence, the project sets the following clinical, technological and exploitation related objectives. Each of them is associated with a concrete and measurable target in the work plan (in brackets) that will be monitored during the project.

1. **Empower patients and their relatives through an ICT based self-management service platform** for mobile devices to better manage the cancer disease in all phases of the care continuum in collaboration with their healthcare providers (WP3 Del.3.4).
2. Allow patients through an easy-to-use interface for mobile devices **to keep track of their health and disease status**, of therapies and results of clinical interventions or tests, and to keep a health diary on personal clinical observations such as side effects of therapies which the patient can share with his healthcare providers (WP4, Del.4.2-4.3).
3. Provide the patients with **personalized, context-sensitive, data driven information services** in a language they understand and help them to make informed choices on treatment options in collaboration with their health carers (WP5, Del.5.2-5.3).
4. Help adult and young cancer patients through **serious games** to manage the impact of the disease on their psychological status, such as negative emotions, anxiety, or depression and motivate them to stay positive and to participate in social life (WP7, Del.7.1-7.3).
5. Provide patients with **decision support and guidance through a knowledge base of formal care flow plans** which represent best practice expert models for the management of cancer care for managing side effects such as pain and nausea, managing drug intakes and drug doses and follow-up (WP5, Del.5.1-5.3).
6. Support patients and their doctors in **managing medications**. Cancer patients often receive a variety of drugs prescribed by different doctors for different clinical conditions and comorbidities. An easy-to-use tool for mobile devices will be provided which helps them to check for potential drug-drug interactions and predictable side effects due to their clinical condition (WP5, Del. 5.3).

[8]Sanda, M.G., Dunn, R.L., Michalski, J., Sandler, H.M., Northouse, L., Hembroff, L., et al. Quality of life and satisfaction with outcome among prostate-cancer survivors. N Engl J Med. 2008, 358(12), 1250-61.

[9]Carter, N., Bryant-Lukosius, D., DiCenso, A., Blythe, J., Neville, AJ. The supportive care needs of men with advanced prostate cancer. Oncol Nurs Forum. 2011, 38(2), 189-98.

Ream E, Quennell A, Fincham L, Faithfull S, Khoo V, Wilson-Barnett J, Richardson A. Supportive care needs of men living with prostate cancer in England: a survey. Br J Cancer. 2008, 98(12), 1903-9. doi: 10.1038/sj.bjc.6604406.

Boberg, E.W., Gustafson, D.H., Hawkins, R.P., Offord, K.P., Koch, C., Wen, K.Y., Kreutz, K., Salner, A. Assessing the unmet information, support and care delivery needs of men with prostate cancer. Patient Educ Couns. 2003, 49(3), 233-42.

[10] Department of Health Macmillan Cancer Support & NHS Improvement, 2010.

Lintz, K., Moynihan, C., Steginga, S., Norman, A., Eeles, R., Huddart, R., et al. Prostate cancer patients' support and psychological care needs: Survey from a non-surgical oncology clinic. Psychooncology. 2003, 12(8), 769-83.

7. Provide clinicians and patients an **interactive psycho-emotional health assessment instrument** for the monitoring of a patient's current psychological and physiological health status in order to assess mental but also physical health deteriorations and social withdrawal and to provide personalised information for coping strategies (WP6, Del. 6.1-6.4).
8. Increase patients' safety by developing and incorporating **predictive models in the system for the early detection of severe adverse events during chemotherapy** (WP5, Del. 5.1, 5.3).
9. **Support patients in following a healthy and active lifestyle** by optional wearable sensors connected to the platform in combination with recommendations for health-conscious behaviour through the decision support system (WP6, Del. 6.3).
10. Follow the design-for-all principle in the development of the iManageCancer platform and provide the patient with an easy-to-use **interactive cockpit for disease self-management** on mobile platforms empowered by a health avatar as the guide to the services of the platform (WP4, Del.4.1).
11. Incorporate an instrument in the platform for **data driven analysis services** on anonymised clinical information to be used for public health research (WP8, Del.8.1-8.2).
12. Conduct and assess **three pilots**, two for adult cancer patients and one for children to evaluate the iManageCancer platform and its services in practice regarding feasibility, acceptance, usability, performance, costs, and outcome on quality of life of cancer patients (WP9, Del.9.2-9.4).
13. Design an innovative **ecosystem for the empowerment of cancer patients** based on the self-management principle through the involvement of the main stakeholders and with the patient in the driver seat. Develop and assess public-private-partnership based service- and business models around such an ecosystem oriented to a **Health Data Cooperative** to make sustainable iManageCancer services available on the internet (WP10, Del. 10.1-10.6).

2.1.2 Concept and approach

2.1.2.1 iManageCancer – Idea

Cancer as a chronic illness is among the most prevalent and costly of all global health problems[11]. Surviving and living with or beyond cancer is rising at an estimated 3.2% per year in the United Kingdom[12]. All these changes are leading to an increasing need for cancer patients to be supported to take an active and leading role in their rehabilitation, ongoing care and improved quality of life. This shift from acute to chronic care brings emphasis to self-management of cancer, where patients need to have an active and informed role in managing physical, psychological, and social aspects of health. As chronic illness management will continue to be an important component of health care, identification of self-management processes for cancer can help to guide future research and clinical practice that support self-management efforts. The project's concept is based on the *patient empowerment concept* and the mission of the project is to motivate the cancer patient to take a more active role in the management of his/her disease through a dedicated ICT platform offering a range of mHealth services aiming to assess and improve his/her psycho-emotional status, improve his/her understanding of the disease and involve more efficiently his/her family and treating physician in the therapy process.

Anna is 12 years old and has leukaemia. Since she began chemotherapy she had been feeling sad and often doubting she can really cope with all the stress, stand all the clinical procedures she needs to go through and defeat her cancer. Recently her doctor recommended her to try the iManageCancer App. She loves playing the Cancer Fighter game as it gives her the feeling that she can kill the cancer cells with the weapons she receives as her therapy. She started to understand how these clinical tools can help her to combat the disease and now seems to be more willing to accept the painful treatment. Her best friend also started playing Cancer Fighter with her giving her the feeling that she is not alone in her fight against the disease. Anna also started using the e-diary and finds every

[11] World Health Organization, Scaling up action against noncommunicable diseases: How much will it cost?, 2011.
[12] Maddams, J., Brewster, D., Gavin, A., Steward, J., Elliott, J., Utley, M., & Møller, H. Cancer prevalence in the United Kingdom: estimates for 2008. British Journal of Cancer, 2009, 101(3), 541-547.

day useful individualised advices to help her understand what's she's going through. Anna's parents do use iManageCancer as well learning more on how they can assist and support their child in her fight against cancer and help her to manage side effects of her therapy. Thanks to an alarm system within iManageCancer, they spotted an unusual rash which turned out to be an unusual infection. This was quickly eradicated by immediate referral and treatment by the local doctor. Anna regularly completes questionnaires that will allow her doctor to better understand her psycho-emotional status and act accordingly. Anna, her parents and friends as well as her doctor appreciate the iManageCancer platform as it optimised her care and Anna learned to actively fight against her cancer together with her family and friends.

2.1.2.2 iManageCancer – Approach

The iManageCancer project will provide a cancer disease self-management platform designed accordingly to the specific needs of patient groups and focusing on the wellbeing of the cancer patient with special emphasis on psycho-emotional evaluation and encouragement. The platform will be centred in a Personal Health Record that will exploit recent advances on Health Avatars for the individual cancer patient surrounded by m-health applications designed to encourage the patient to become more involved in their treatment management, enhance clinician-patient communication, maximise compliance to therapy, predict, detect and manage side effects, inform about drug interactions and contribute to pain management through minimisation of patient's anxiety. The Health Avatar PHR will regularly monitor the psycho-emotional status of the patient and will record in a timeline fashion everyday life experiences of the cancer patient regarding pain status and drug side effects while different groups of patients and their families will share information through diaries. The clinical view of the PHR will be used to provide valuable information about his/her patients to the clinician, to assess the adherence of patients to therapy and their psychological status while the platform will recommend specific informative applications and serious games according to the disease type and psycho-emotional status of the patients. This will promote encouragement, awareness and reduce anxiety and depression from them. The disease management platform will be further complemented by an integrated expert system with formal self-management models executed by a Care Flow Engine and oriented to decision support, adherence to therapy and guidance for patients including drug doses self-adjustments. The Care Flow Engine will seamlessly integrate with the Health Avatar PHR. It will allow experts to model management plans that are personalised in cooperation with the patient.

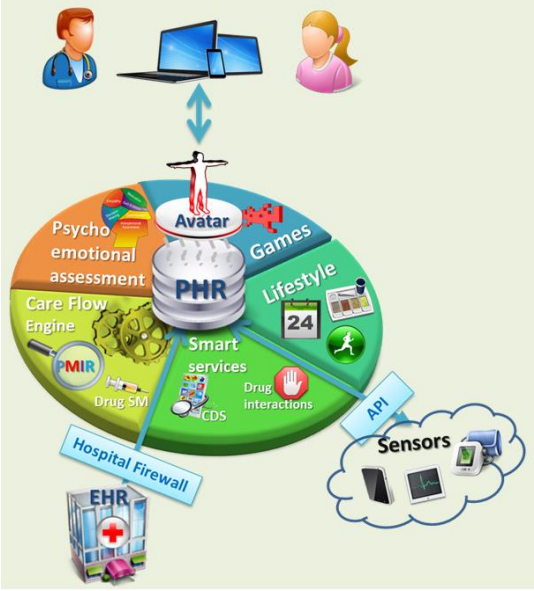

Figure 1. iManageCancer approach.

Figure 1 gives an overview of the iManageCancer development approach. The approach to implement iManageCancer will involve ten work packages centred around an Avatar-based Personal Health Record (WP3) which will offer the patient diary (e.g. for recording pain and side effect status) as well as the services for the patient-clinician communication. Figure 5 illustrates the proposed WP structure of iManageCancer with the main interaction of its components and the integration strategy which will involve the interaction of the smart and analytical services (WP8), the psycho-emotional and health assessment tools (WP6), Central Decision Support & Guidance (WP5) and Serious Games for Self-Management (WP7) through the main Health Avatar PHR platform (WP4).

2.1.2.3 The iManageCancer High Level Architecture

The architecture of the iManageCancer, here provided as a high-level description, will be based on scrum -an agile methodology- focusing on iterative incremental processes for software development. Short iterations will help to keep quality under control by driving to a releasable state frequently, which will prevent iManageCancer from collecting a large backlog of defect correction work. Key driver for defining

the architecture of iManageCancer are patients, citizens and clinical care providers. For that purpose questionnaire focusing on state of practice and usage in the healthcare domain of cancer will be developed and the feedback will be used as the starting point for the definition of the architecture. Use case scenarios will be developed in an iterative process between all stakeholders (patients, citizens, clinical care providers). Patient organizations will be contacted and a workshop will be held to finalize the use cases. The main system components/requirements will be identified and formal sequence diagrams will be drafted for each use case. Communication interfaces between the main components will be specified as well as the functionality of each component. Mock-ups showing the main user interface functionality will be derived and agreed with the clinical partners.

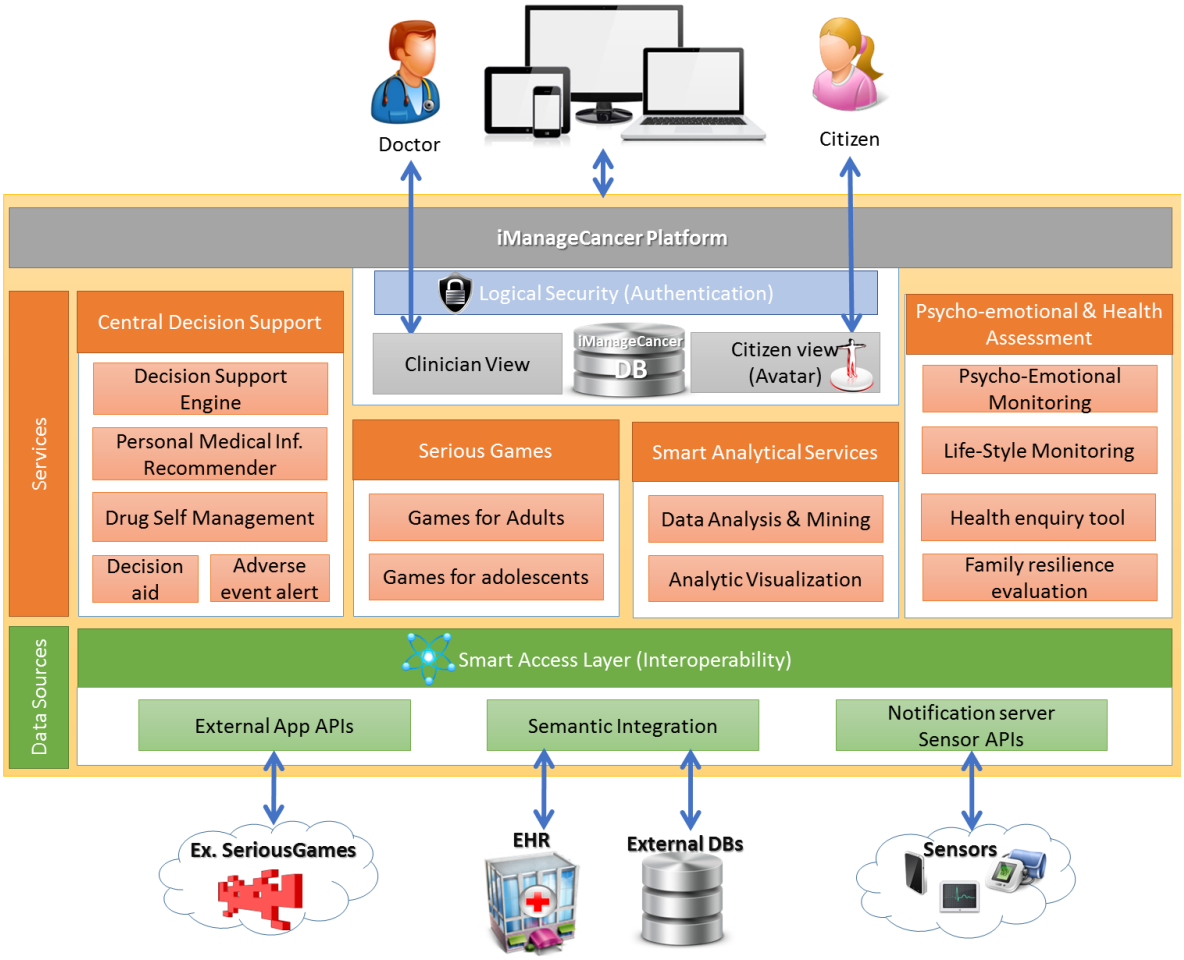

Figure 2. High-level architecture of iManageCancer Platform.

A vertical prototype will be proposed which is used to implement the main communication paths of the system architecture. Central to the iManageCancer platform is the personal health record database which will provide solutions to gather, store and access the relevant information in a unified way. User interfaces will differ according to user groups. The patient-centric user interface (Avatar) will be diary-based, allowing the patients to enter and to view their activities and behaviours across different period of time. The clinical view will be used to provide valuable information about patients to the clinician.

Apart from the PHR and the Health Avatar, which are the backbones of the architecture, a list of tools and services will complement the iManageCancer platform. Decision support systems and self-management models related to long-term follow-up, long-term care and the detection, prediction and management of side effects of cancer therapy will be developed and integrated. A consultation planning tool for patients will be provided to increase their participation in the consultation process with their physicians and improve their satisfaction with the decision-making process. Smart recommendation service based on the psycho-emotional status of the patient and family will assist patients in depth for their health status or disease in order to make informed decisions and will greatly improve the personalisation of decision support tools. Serious games will encourage healthy habits, face disease fight in a different perspective,

and promote disease management. Smart data analytics will provide mechanisms able to identify patterns or trends in data, screen pre-frailty states and provide different views of data for new management plans.

2.1.2.4 iManageCancer – Method

Figure 3 illustrates the research and development methodology of iManageCancer project proposal focusing on the three main phases of the project:

Design phase: The design methodology will involve an intense interaction between cancer patients (specialised workshops will be organised to this respect), clinicians and IT specialists coordinated by CI-eCANCER, online through ecancer.org and ecancerpatient.org (which enjoy over half a million unique visitors per year), and face to face workshops. The main goal of this interaction will be to ensure that the basic principles/functionalities of the design phase will reflect the patient needs (user-driven design) and patients are well included in the process. To this end the Design for All[13] principles will be applied.

Development Process: The development methodology will be largely influences from the Scrum software development framework[14] in order to ensure frequent communication between all stakeholders in the development phase and provide the necessary implementation flexibility for the patients to re-iterate and adjust their demands during the technological implementation stages. To realise this, the Clinicians, IT developers and representatives from the participating pilots (paediatric and adult cancer patients) will be constantly interacting until the prototype reaches its initial form (Milestone 2: Initial iManageCancer platform prototype offering basic functionality in Month 21). Risk management will be implemented in the software development process according to ISO 14971 as the basis for compliance with European medical device regulations which may apply to some of the tools of the platform. Software development will follow the SCRUM methodology.

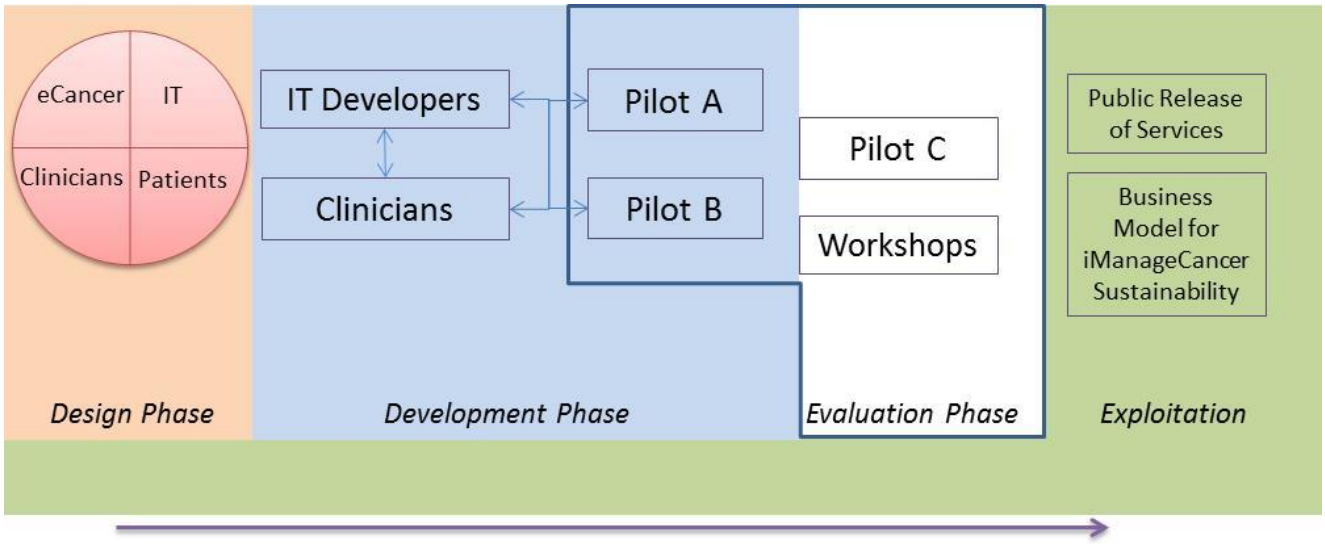

Figure 3. Methodology of iManageCancer Platform proposed R&D.

Evaluation Phase: During this phase the software released will initially be tested in workshops but more importantly, a third pilot will be introduced to the project to ensure that the evaluation will include at least one pilot that didn't participate in the design and development phase. This is expected to provide significant evidence concerning the added value of this continuum care model for the cancer patient with respect to the quality of life and rationalisation of hospital visits and more importantly the alert/prediction concerning side effects. The pilot evaluation will be conducted online and face to face under the appropriate ethical and legal framework ensuring also data protection and privacy. The outcome result will also influence the business/exploitation plan especially shedding light in the added value of including the patient as a co-producer of his health management from the design to the implementation phase including all methodological and technological aspects.

[13] http://designforall.org/

[14] https://www.scrum.org/

Exploitation Phase: This phase spans throughout the project and after completion continues via the sustainability plan and release of services that is planned to take place through the eCancer platform.

2.1.2.5 Linked related projects and positioning of iManageCancer

The partners of iManageCancer contribute or lead various international research and development activities in the domain of cancer research, ICT infrastructures and tools for cancer research, personal health systems and novel health information systems. In the following we list projects whose results will be exploited in the context of this research and innovation activity. The corresponding ICT technologies will provide a solid foundation to achieve the ambitious technological goals in time and on a technology readiness level TRL 6 to TRL 7 (depending on the component) that will allow us to evaluate the platform as a whole in real clinical settings.

MyHealhAvatar - *A Demonstration of 4D Digital Avatar Infrastructure for Access of Complete Patient Information (FP7-ICT-2011-9):* MyHealthAvatar is an attempt at a proof of concept for the digital representation of patient health status. It is designed as a lifetime companion for individual citizens that will facilitate the collection of, and access to, long-term health-status information. It will contribute to individualized disease management, prevention and support healthy lifestyles and independent living. This will be extremely valuable for clinical decisions and offer a promising approach to acquire population data to support clinical research, leading to strengthened multidisciplinary research excellence in supporting innovative medical care. It is expected to exert a major influence on the reshaping of future healthcare in the handling of increased life expectancy and the ageing population in Europe. This complies with the priority and strategy of EC ICT for healthcare. Since key partners in this project are USAAR, FORTH and BED all project results can be directly transferred to iManageCancer.

EURECA - *Enabling information re-Use by linking clinical REsearch and CAre (FP7-ICT-2011-7):* EURECA aims to build an advances, standards-based and scalable semantic integration environment enabling seamless, secure and consistent bi-directional linking of clinical research and clinical care. It is an ongoing project, coordinated by PHILIPS and USAAR, FRAU and FORTH are also involved as partner. More specifically, FORTH is building intelligent reasoning mechanisms for patients within a custom-tailored PHR system. Those mechanisms include smart patient recommendations, information delivery optimization, semantic linking of eHealth infrastructures, safety services for patients etc. Semantic integration approach and the approach on ethics and security can be reused in the context of iManageCancer.

p-MEDICINE - *From data sharing and integration via VPH models to personalized medicine (FP7-ICT-2009.5.3)*: p-Medicine tries to formulate an open, modular framework of tool and services for efficient, secure sharing and handling of large personalized data sets. This ongoing project is coordinated by USAAR with FORTH, PHILIPS, FRAU and IEO as partners. FORTH builds a collaborative environment for patient empowerment. The entry point for the patients is a custom-tailored PHR system, where a patient profile is constructed and then exploited to optimize information delivery to patients and to increase patient level of awareness and understanding. PHILIPS develops a decision support system for adverse event detection in clinical trials. IEO created and validated a cancer patient profiling tool to improve physician-patient communication. Results will be available for adoption and adaptation in iManageCancer.

eHealthMonitor - *Intelligent Knowledge Platform for Personal Health Monitoring Services (FP7-ICT-2011-7)*: The eHealthMonitor project provides a platform that generates a Personal eHealth Knowledge Space (PeKS) as an aggregation of all knowledge sources (e.g., EHR and PHR) relevant for the provision of individualized personal eHealth services. More specifically, FORTH is providing the semantic backbone to a PHR-like platform, allowing the integration of heterogeneous, disparate data sources. Reasoning mechanisms provide useful medical recommendations to patient. iManageCancer will capitalize semantic infrastructure developed in eHealthMonitor and will explore the reuse of the components developed there for monitoring patients.

INTEGRATE - *Driving Excellence in Integrative Cancer Research through Innovative Biomedical Infrastructures (FP7-ICT-2009.5.3):* INTEGRATE is an ongoing project coordinated by PHILIPS. The project aims to build solutions that support a large and multidisciplinary biomedical community ranging

from basic, translational and clinical researchers to the pharmaceutical industry to collaborate, share data and knowledge, and build and share predictive models for response to therapies, with the end goal of improving patient outcome. In this project FORTH is building a collaboration environment allowing health professionals to remotely offer/receive consultation. Experience in legal, ethical, semantic integration and collaborative environments can be exploited in the context of iManageCancer.

d-LIVER - *ICT-enabled, cellular artificial liver system incorporating personalized patient management and support (FP7-ICT-2010.5.1).* Among others, this project provides under the leadership of FRAU a disease management platform for patients with chronic liver diseases with an integrated decision support and guidance system for patients and doctors. This decision support system and an app for patients named Personal Health Manager will be exploited in this project.

CHRONIOUS - *An Open, Ubiquitous and Adaptive Chronic Disease Management Platform for COPD and Renal Insufficiency (FP7-ICT-2007.5.1).* This successfully completed project developed and tested wearable personal health technologies in combination with an expert system for life style optimisation and a semantic search system for clinical guidelines. The latter one provides NLP technologies to iManageCancer to process unstructured clinical information.

2.1.2.6 iManageCancer Maturity and Technology Readiness Level

We have adopted the Technology Readiness Level (TRL) model (as appears in general annex G of Horizon 2020 work-programme), to assess the maturity of evolving technologies either as individual services or as part of the iManageCancer platform. In Table 2.1.2.6a, we list the expected outcome of the project in terms of outcome technologies and discuss their initial end final (at the end of the project) maturity/TRL. Since the project will deploy and evaluate the technological components in two dedicated pilots enrolling cancer patients, in most cases the technologies will achieve a TRL7 and be used in the planned operational environment (clinical pilots for cancer patient self-management). This will also have a direct impact in the evaluation-feedback process regarding the results from testing a prototype system in an operational environment. Who performed the evaluation test? How did the test compare with expectations? What problems, if any, were encountered? What are/were the plans, options, or actions to resolve problems before moving to the next level?

Table 2.1.2.6a: iManageCancer results and their maturity level at the start and end of the project

iManageCancer technologies	Initial TRL	Target TRL	Comments
HEALTH AVATAR PHR	4	7	The project will utilize the technology developed in MyHealthAvatar project (http://www.myhealthavatar.eu/) and expand it to a fully-fledged PHR solution based on health avatar concept used by cancer patients throughout their therapy process.
PSYCHO-EMOTIONAL AND HEALTH ASSESSMENT TOOLS	4	7	Initial work has been made in the p-Medicine project (lead by USAAR also partner of iMangeCancer) and it is expected to drive them to the actual operational environment in the context of real clinical pilots involving cancer patients.
SERIOUS GAMES FOR SELF-MANAGEMENT	4	7	Serious games for the benefit of cancer self-management is understudied (to date there is only one small study concerning Serious Games in Adult prostate cancer patients)[15] therefore we expect to provide a significant validation milestone after the completion of the two dedicated pilots (paediatric and prostate cancer).
SMART ANALYTICAL DATA SERVICES	2	6	These tools will analyse the information in the PHRs and draw conclusions related to the usage of the self-management platform, the user profiles, reported adverse events and health issues, individual health status, quality-of-life, compliance with the goal to identify

[15] Reichlin, L., Mani, N., McArthur, K., Harris, A.M., Rajan, N., Dacso, C.C. Assessing the acceptability and usability of an interactive serious game in aiding treatment decisions for patients with localized prostate cancer, J Med Internet Res. 2011 12, 13(1).

			patients that require medical attention and screen for pre-frailty states. While they will be used in the pilots they will play a supportive role for initial assessment and reach TRL6.
iMANAGECANCER CENTRAL DECISION SUPPORT AND GUIDANCE SYSTEM	3	6	The underlying goal of the project is to transform the cancer care continuum concept from a useful paradigm[16] to a valuable practice for helping cancer patients. The integrated central decision and guidance system used in the pilots will lead to initial deployment experience (TRL6) which will set the basis for scaling up to the desired configuration for full deployment as a mHealth process.

2.1.3 Ambition

For the first time in the world an innovative set of integrated mobile personalised services specially designed for the empowerment and self-management of patients with cancer diseases will be developed and validated in this project. As a result, the following advances and innovations are expected.

Clinical advances:

- **Novel approach for the collaborative management of cancer diseases with the informed and encouraged patient in a central role in the decision making process:**

iManageCancer aims to arrange planned e-health decision making aids in cancer, promoting a self-aware and informed decision making approach, compensating difficulties in shared decision making approach with clinicians. In clinical practice, barriers to using shared decision making are multiple. The most common barriers are health care professionals' concerns about not having enough time, perception that patient characteristics or clinical situations were not conducive to shared decision making, the belief that some patients prefer a paternalistic approach without asking patients about their preferred role in decision making, and limited familiarity with shared decision making[17]. On the other side, patients with cancer are faced with an over-complex range of choice in cancer screening, detection tests and/or treatment modalities which neglect important issues such as outcomes, side effects and psycho-social complications. They often experience decisional conflict, anxiety, worrying and frustration. Decisional conflict occurs when individuals experience "uncertainty about which course of action to take when choice among competing options involves risk, loss, regret, or challenge to personal life values."[18] Distress or tension are the first obstacles to informed and responsible decisions, and are often due to lack of knowledge. Patient decision aids were found to consistently improve knowledge, reduce decisional conflict, and result in choices that were congruent with patients' values that is eventually translated in patient empowerment. However, according to the family systems theory[19] individuals cannot be understood in isolation from one another, but rather as a part of their family, as the family is an emotional unit[20]. Therefore a family empowerment, especially for childhood cancer, is desirable.

- **Enhanced patient empowerment through a novel disease self-management platform for cancer**:

The iManageCancer integrated mobile services platform represents the entry point for interactive disease self-management in close collaboration with the healthcare team. iManageCancer advances disease management through reinforcement of the role of the patient in the management process, better collaboration and interaction of informed patients with doctors, better planning of management processes and better compliance of patients to therapy through the mobile services of the platform. Available ICT enabled services dedicated to cancer patients mainly represent non-personalised information places which may improve health literacy of cancer patients. PHR related services allow keeping a health record (i.e.

[16] McCorkle, R, Ercolano, E., Lazenby, M., Schulman-Green, D., Schilling, L.S., Lorig, K., Wagner, E.H., Self-management: Enabling and empowering patients living with cancer as a chronic illness, CA Cancer J Clin., 2011, 61(1), 50-62.

[17] Gravel, K., Légaré, F., Graham, I.D.. Barriers and facilitators to implementing shared decision-making in clinical practice: a systematic review of health professionals' perceptions. Implement Sci, 2006, 1-16.

[18] O'Connor, A.M., Validation of a decisional conflict scale. Med Decis Making, 1995, 15, 25–30.

[19] Bateson, G., A Systems Approach. International Journal of Psychiatry, 1971, 9, 242 – 244.

[20] Kerr, M.E., Bowen, M.. Family Evaluation: An Approach Based on Bowen Theory. New York: Norton & Co., 1988.

MS HealthVault[21]) and exchanging experience with other patients (i.e. PatientsLikeMe[22]) on any disease. Various Apps for self-management are available with a focus on a particular aspect of the management process like medication management, drug-drug interaction, serious games for anxiety therapy or cancer shooter games. However, they exist only as isolated solutions and not within cancer related portal as central access point to personalised services and Apps for cancer management and further data driven tools. This approach results in:

1. Promoting patients' literacy and knowledge about their disease. Access to up-to-date information about the specific cancer disease, treatment options and advances in therapies, adverse effects and their management strategies, all delivered in a language that is accessible to patients.
2. Increased participation of the patient in decision making processes with his/her physicians.
3. Psychological and emotional assessment and encouragement tools that will be used by patients and their relatives in collaboration with healthcare professionals in order to organize proper interventions when needed.
4. Promoting health-related behaviours. Provide recommendations for healthy behaviours (such as smoking cessation and adequate physical activity load), support patients in following a healthy and active lifestyle, keep track of their progresses and enhance self-efficacy.
5. Involving family members and carers in empowering the patient. Through the platform, family members, close friends and relatives have a channel to obtain information about the disease and suggestions on patient's care, thus sharing experience, feeling in touch and part of a unique network supporting the patient.

Technical advances/ innovation:

- **Decision support for patients and disease (self-) management - new methodology to collaboratively manage cancer diseases:**

A novel approach to integrated decision support and guidance for patients will be implemented in iManageCancer. A design tool for clinical experts from multiple disciplines will be provided to draft formal process plans for disease management that form the knowledge base and that interact with the patient and guide him through different aspects of the management of his/her disease such as drug doses self-management depending on symptoms and clinical parameters, management of side effects, complications, comorbidities and follow-up by the patients themselves or in close collaboration with their healthcare team. Personalised instances of the process plans are executed by a Care Flow Engine that interacts with the patient's e-diary and his main user interface to guide him through the management. It is expected that this approach will contribute to

- better management of side effects of cancer therapies such as oral mucositis, nausea and vomiting, fatigue, infection, pain, anxiety, depression and psychological distress through personalised access for the patient to context based health information and guidance through formal plans for the self-management of these side effects;
- less complications and readmissions due to regular assessments of health conditions and earlier detection of side effects;
- improved follow-up management due to corresponding care flow plans implemented in an integrated decision support engine oriented to care pathway planning and patient guidance also coherently with patient's decision style.

The main idea behind this is that formal Disease Management Programs (DMP) are designed with an design tool by domain experts on the basis of clinical guidelines, knowledge on care pathways and an organisational model for integrated care with the patient as the co-manager of his health in the centre of it. Such a Disease Management Program is represented as a complex formal process diagram of the care

[21] https://www.healthvault.com/

[22] http://www.patientslikeme.com/

flow with different branches for co-morbidity management in combination with the treatment of the main disease. These formal Disease Management Programs are personalised for a specific patient in Individual Care Flow Plans and executed by the Central Decision Support Unit of the iManageCancer Platform in the so-called Care Flow Engine. The Care Flow Engine will now guide the patient but optionally also the healthcare team through the management of his disease and related co-morbidities by issuing tasks and recommendations to the patient, the family and to the different members of the care team and by controlling the execution of the Care Flow Plan based on the results of tasks and monitored health status of the patient. In the design phase of the Care Flow Plan, further knowledge is modelled as a set of clinical rules that control execution of the plan.

The iManageCancer Health Avatar will download and process tasks for the patient issued by the Care Flow Engine (for example, tasks for patient are typically medication intake, health assessment, psycho-emotional and cognitive tests, etc.). Results are sent back to the Care Flow Engine for further assessment and control. In that way a flexible management of aspects of the patient's disease during his/her day life adapted to his actual conditions and clinical symptoms is achieved together with a strict and clear integration among specialists, therapists and care-givers according to a formal plan of the care process.

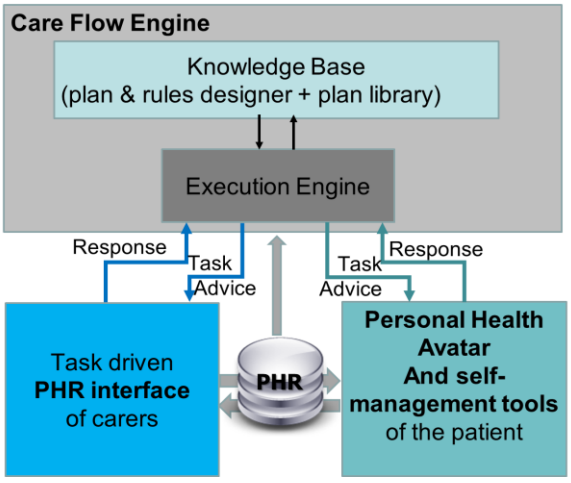

Figure 4. Care flow driven central decision support unit of iManageCancer as the control instance of the applications of the users.

Currently, clinical decision support systems address the clinical users and not the patient. Only a few clinical decision support systems benefit time efficiency, it is common that computer-generated decision-support advices are ignored and many systems are abandoned altogether. In order to overcome these issues, it is of utmost importance that user scenarios and care pathways have to drive the technology development and not vice versa. In addition, the up-to-date medical knowledge implemented in clinical decision support systems is primarily derived from evidence-based clinical guidelines. However, these clinical guidelines usually represent unstructured, narrative documents that neither contain sufficient detail for computing nor do they adequately address patient self-management in outpatient settings. Another problem that is often faced by clinical decision support systems is the system interoperability issue. iManageCancer will follow a novel approach of decision support for chronic disease management which has already been investigated and prototypically implemented in the FP7 Integrated Project d-LIVER for the management of chronic liver diseases[23]. As described before, this decision support approach is based on a formal process model of the care pathways for patient management with this disease following Business Process Model Notation standard 2.0. As a result the care flow including the monitoring of the patient through questionnaires and devices can be exactly modelled by clinical experts as formal process diagram that can be executed by a process engine.

A set of care flow diagrams will be modelled in iManageCancer by oncologists for different aspects of the management of cancer with a focus on those aspects of the disease that can be managed by the patient him/herself. In this way passive and active decision support, reminders, questionnaires and guidance is all incorporated in the process diagram. Proper integration with the e-diary of patients is achieved by implementing client functionality in these systems in order to download tasks, to process them and to send results of their execution back. As the next steps in the evolution of such a decision support solution it will be adapted to the needs of outpatient management and self-management of cancer and its complications. Design tools for care flow process diagrams will be further customized to be used by clinical experts.

[23] Kiefer, S., et al. A novel approach to integrated decision support and guidance in personal health systems for disease management, MIE, 2014, (accepted paper).

► **Predictive models for advanced chemotherapy monitoring:**

Chemotherapy monitoring is becoming a vital aspect for a patient's quality of life management and fate determination[24]. The majority of the patients undergoing chemotherapy experience side effects such as diarrhoea, constipation, fatigue, and drowsiness[25],[26] which affect their quality of life. Notably, the most serious adverse events are related to treatment-induced immunosuppression[27]. Neutropenia (low neutrophil count) can occur as a result of cancer itself or due to the myelosuppressive nature of many cytotoxic chemotherapeutic agents and radiotherapy[26],[28],[29],[30]. Generally, therapeutic regimens, specifically cytotoxic drugs and radiotherapy, have toxic effects on healthy tissue such as on the intestine and bone marrow: A group of therapeutic agents have been demonstrated to have a higher probability to cause or be the source of acquiring infections such as with the interruption of the protective barriers (some are listed in Table A). In relation to this, regimen-induced bone marrow toxicity results in anaemia and leukodepletion which may result in fatigue, decreased energy and shortness of breath[25], and it compromises the immune system's ability to fight infections, respectively[31]; Adjustments in therapeutic dose have been investigated with respect to both the intensity of the treatment and the scheduling of the delivery, in order to assess a biologically significant dose with minimal side effects[32]. It has been recently documented that increasing drug dose relates to increasing hematologic and non-hematologic toxicities which are thereafter related to higher frequency of neutropenic complications (especially grade 3 and 4 neutropenia)[33]. Severe neutropenic episodes (grade 4) are a major contributing factor in worsening the patient's quality of life but also in increasing mortality rates[34].

Several studies have reported an incidence in 51% of patients treated for lymphoma and solid tumours[35] and was reported to cause death in 4-21% of patients[34], where solid tumours had significantly lower mortality rate when compared to lymphoma[35]. Clinical conditions such as febrile neutropenia (infections in neutropenic patients with pyrexia) are likely to manifest and without prompt clinical intervention they may ultimately lead to death[36]. Notably, approximately up to 25% of the patients undergoing chemotherapy are expected to develop a febrile neutropenic episode[37] while an increase up to 96% could occur with respect to tumour type. Intervention with prompt administration of antibiotics, normally within an hour of triage, is crucial in neutropenic patients with pyrexia[38], while follow-up will determine whether they are eligible for outpatient management or hospital administration[39]. It is apparent that a patient's visit and length of stay to the hospital increases the probability of infections and mortality, and thus close

[24] Nimako, K., et al., A pilot study of a novel home tele-monitoring system for oncology patients receiving chemotherapy. Journal of Telemedicine and Telecare, 2013, 19(3), 148-152.

[25] Nicole, M.R., Marcovic, S.N., Porrata, L., The Role of Complete Blood Cell Count in Prognosis—Watch this Space! Oncology and Hematology Review, 2012. 8(1).

[26] Lyman, G.H., et al. Predicting individual risk of neutropenic complications in patients receiving cancer chemotherapy. Cancer, 2011, 117(9), 1917-1927.

[27] Zitvogel, L., et al. Immunological aspects of cancer chemotherapy. Nat Rev Immunol, 2008. 8(1), 59-73.

[28] Barrett, J., Le Blanc, K. Cancer Chemotherapy and Immune Regulation. American J. of Immunology, 2009, 5(1), 8-16.

[29] Crivori, P., et al. Predicting Myelosuppression of Drugs from in Silico Models. Journal of Chemical Information and Modeling, 2011, 51(2), 434-445.

[30] ASCO, Guideline on Fever and Neutropenia Management for Adult Patients with Cancer; Endorses International Pediatric Neutropenia Guideline, 2013, American Society of Clinical Oncology.

[31] Rapoport, B.L., Management of the Cancer Patient with Infection and Neutropenia. Seminars in Onc., 2011. 38(3), 424-430.

[32] Landreneau, J., et al. Immunological Mechanisms of Low and Ultra-Low Dose Cancer Chemotherapy. Cancer Microenvironment, 2013, 1-8.

[33] Colozza, M., et al., Achievements in Systemic Therapies in the Pregenomic Era in Metastatic Breast Cancer. The Oncologist, 2007, 12(3).

[34] Janssen-Heijnen, M.L.G., Extermann, M., Boler, I.E. Can first cycle CBCs predict older patients at very low risk of neutropenia during further chemotherapy? Critical reviews in oncology/hematology, 2011. 79(1), 43-50.

[35] Lalami, Y., et al., Can we predict the duration of chemotherapy-induced neutropenia in febrile neutropenic patients, focusing on regimen-specific risk factors? A retrospective analysis. Annals of Oncology, 2006. 17(3), 507-514.

[36] Shayne, M., et al., ASCO, Guideline on Fever and Neutropenia Management for Adult Patients with Cancer; Endorses International Pediatric Neutropenia Guideline, 2013, American Society of Clinical Oncology.Risk factors for in-hospital mortality and prolonged length of stay in older patients with solid tumor malignancies. Journal of Geriatric Oncology, 2013. 4(4), 310-318.

[37] San Matías, S., et al., Predicting the duration of chemotherapy-induced neutropenia: new scores and validation. Annals of Oncology, 2011. 22(1), 181-187.

[38] Crawford, J., D.C. Dale, and G.H. Lyman, Chemotherapy-induced neutropenia. Cancer, 2004. 100(2), 228-237.

[39] Lyman, G.H., Crawford, J., Dale, D.C., Chen, H., Agboola, O., Lininger, L. Clinical prediction models for febrile neutropenia (FN) and relative dose intensity (RDI) in patients receiving adjuvant breast cancer chemotherapy. Proc Am Soc Clin Oncol, 2001.

management of neutropenia has attracted the attention of health specialists[24],[27],[30]. Severe health conditions could be tackled through intensive monitoring of the patient's physiological parameters such as body temperature[24],[40],[41], and combined with additional feedback from patient-reported outcomes (health assessment questionnaires): The objective is to receive an alert, enabling the clinician to decide on an early intervention, and to intervene before a serious event occurs.

iManageCancer will develop predictive models which will provide information to the physician to intervene before life-threatening adverse events occur, but also to increase patient awareness with respect to disease state and associated health complications, and thus the analysis will primarily focus on creating an informative association between the patient's health status and the clinician's decision. Initially, the models will focus on understanding the relationship between the current therapeutic interventions for different tumours with respect to chemotherapy-induced leukopenia, and specifically neutropenia: The pharmacodynamics and pharmacokinetics of the drugs will be thoroughly examined. In parallel, the time-related recovery from neutropenia (duration and intensity) will be monitored. The aim is to identify the optimal chemotherapeutic schedule for cancer patients, and to build the foundation for future studies that will determine the essential interventions required for the best therapeutic outcome and quality of life. A key aspect of a successful model is based on indexing the therapeutic (i.e. drug) mode of action and toxicity with respect to immunosuppression and mortality. Information such as the pathophysiology of the cancer and the response of the administered drug(s) (including the severity, incidence and duration of adverse events, neutropenic incidence in individual chemotherapy cycles), the standard blood test analysis for cancer patients, vital signs but also other essential parameters on the physiological and psychological state of the patients, for example the body mass index [27], [42], [43] could be incorporated in the prognostic modelling which will eventually provide insights for planning a personalised cancer therapy.

In detail, tumour type and malignancy such as primary, metastatic, and the likelihood of relapse but also the pathophysiology and the type of tumour i.e. solid or hematologic[37],[38] have been investigated in clinical trials and will be assessed in the models. As it concerns the therapeutic category, the drug mode of action and sensitivity and specificity, drug half-life/body clearance will be investigated, as well as radiation therapy. As research in the area of tumorigenesis and tumour elimination has advanced throughout the years, the selection of the parameters will be thoroughly investigated in order to comply with current and prospective clinical research and practice.

In conjunction, tumour biomarkers that are currently generally available and routinely analysed for diagnosis, screening, staging, prognosis, detecting recurrence and monitoring therapy of different tumour types have been identified could potentially be deployed in models, where necessary. Predictive models require broad data sets and multi-disciplinary expertise; hence, it is important to work closely with oncology specialists. Retrospective datasets from studies performed in the past and from clinical care and prospective biomarker analysis (predictive and prognostic markers and their association with overall survival and recurrence-free survival that are dependent or independent to the therapeutic administration) from current and future clinical trials need to be combined in order to generate a robust schematic representation of the chemotherapy response.

The aim will be to apply a practical approach to problems currently faced in oncology and most importantly to target the early detection and ultimately the prevention of adverse events. Lifestyle patterns from control studies in healthy individuals could be implemented as necessary for predictive comparisons i.e. normal full blood cell count.

[40] ASCO, Early recognition and treatment of febrile neutropenia in community hospital. 2012 ASCO's Quality Care Symposium.

[41] Aapro, M.S., et al., Update of EORTC guidelines for the use of granulocyte-colony stimulating factor to reduce the incidence of chemotherapy-induced febrile neutropenia in adult patients with lymphoproliferative disorders and solid tumours. European journal of cancer , 2011. 47(1), 8-32.

[42] Donskov, F., Immunomonitoring and prognostic relevance of neutrophils in clinical trials. Seminars in Cancer Biology, 2013. 23(3): p. 200-207.

[43] harma, S., Tumor markers in clinical practice: General principles and guidelines. Indian Journal of Clinical Biochemistry, 2009. 30(1): p. 1-8.

Table A. Agents prone to cause or be the source of increasing the probability of infections[44]
Docorubicin, Daunorubicin, Ifarubicin, Mitotraxone
Epirubicin, Actinomycin D, Belomycin, Mitomycin
Melphalan, Streptozocin, Nitrogen mustard, BCNU
Vinblastin, Vincristine, Oxaliplatin, Vinorelbine
Etoposide (VP-16), Cisplatin, Paclitaxel, Docetaxel

Table B. Combinations of cytotoxic agents with respect to neutropenia and the level of complication[33]
Paclitaxel with doxorubicin results in higher incidence of neutropenia (Grade 3 or Grade 4)
Doxorubicin and cyclophosphamide (TAC) have higher incidence of neutropenia than docetaxel and doxorubicin (AD) (Grade 3 and grade 4 hematological toxicities)
Taxane-based combinations without antracyclines, i.e. docetaxel plus capecitabine neutropenic complications
Vinorelbine with 5-fuorouracil has higher incidence of neutropenia when compared with standard paclitaxel
Amrubicin with cisplatin (AP) [53]

Table C. Chemotherapy regimens correlated febrile neutropenia [45]
[1] Chemotherapy regimens that have been correlated with a high risk of febrile neutropenia
MVAC (Bladder cancer), Dose Dense AC-T, AT and TAC (breast cancer), TC (cervix cancer), DCF (Gastric/head and neck), DP (non-small cell lung cancer), BEACOPP (Hodgkin lymphoma) CFAR, ICE, RICE, CHOP-14, MINE, ESHAP, HyperCVAD with Rituximab, DHAP and ESHAP (non-Hodgkin's lymphoma), Topotecan, Paclitaxel and Docetaxel (ovarian cancer), all induction regimens for acute lymphoblastic leukaemia, Doxorubicin with Gemcitabine (kidney cancer) and VIP, VeIP, BEP, TIP (testicular cancer).
[2] Chemotherapy regimens that have been correlated with an intermediate risk of febrile neutropenia
FEC-D, FEC 100, Docetacel, AAC, Gemcitabine and Carboplatin (breast cancer), FOLFOX (colon cancer), CHOP-R (non-Hodgkin's lymphoma), Cisplatin with Paclitaxel, Cisplatin with Docetaxel, Docetaxel with Gemcitabine, Vinorelbine with Cisplatin (non-small cell lung cancer), Cisplatin with Topotecan and Etoposide with carboplatin (small cell lung cancer)[54]. Normally, patients in the high risk group are required to undergo treatment with G-CSF (cytokine influencing apoptosis and differentiation of neutrophils) and possible prophylactic use of antibiotics

Table D. Effect of consistent drug type of administration related febrile neutropenia risk with respect to tumour type[46]	
Paclitaxel/carboplatin	
Non-small cell lung cancer *[1]	0-9%
Ovarian cancer	3-8%
Urothelial cancer	25%
*[1] Drug response varied with different combinations with other regimens, when tested on the same tumour, i.e. in NSCL cancer, Docetaxel/carboplatin resulted to 26%.	

Models developed according to literature and previous clinical trials are to be investigated and potentially validated in a separate patient study population, and modified accordingly. The outcome will act as a guide and starting point for the development of new robust sophisticated predictive risk models that will be up-to-date with current clinical practice. There are many examples of risk models for predicting clinical outcome in several cancers that could be considered. Previous research[47] developed risk models

[44] Perry, M.C., Perry's The Chemotherapy Source Book. Vol. 5th 2012.
[45] L. Sax, K.L., A. Granic & M. Abdallah, T. McFarlane. Algorithm for White Cell Growth Factor (G-CSF) Support. 2008.
[46] Aapro, M.S., et al., Update of EORTC guidelines for the use of granulocyte-colony stimulating factor to reduce the incidence of chemotherapy-induced febrile neutropenia in adult patients with lymphoproliferative disorders and solid tumours. European journal of cancer, 2011. 47(1), 8-32.
[47] Klastersky, J., et al. The Multinational Association for Supportive Care in Cancer Risk Index: A Multinational Scoring System for Identifying Low-Risk Febrile Neutropenic Cancer Patients. Journal of Clinical Oncology, 2000.

for prognosis of febrile neutropenic episodes. However, the models had some limitations: Despite the reliable prediction of the febrile neutropenic patients at low risk of complications, its validation with a patient population was proven not to be efficient in identifying the individuals that would safely benefit from home-therapy (~30% of the patients required readmission). Thereafter, risk-stratification models identified a subset of cancer patient population with a higher risk in developing neutropenia; however, the models lacked in monitoring and determining the relation with the duration or severity of chemotherapy-induced neutropenia[35]. A study indicates that an increased duration of neutropenia results in increasing infection risk[37]. In accordance to this, another study demonstrated certain characteristics that were identifiable at the onset of febrile neutropenia that succeeded in safely predicting a patient population at low risk of serious medical complications and poor disease outcome (the study externally validated the Multinational association for supportive care in cancer score)[47]. The time-related recovery from neutropenia in relation to drug toxicity on solid tumours was considered in new improved models and the study identified two groups where the one of the two required 2x recovery time[37], stressing the importance of evaluating this parameter. Additionally, validation studies of risk prediction models for severe sepsis in children and high-risk febrile neutropenia highlighted the importance of early identification with the aim of improving prognosis, and aligning immediate aggressive management approaches[48]: Although the model (based on the analysis of relatively simple parameters) is pending for local evaluation, it provided an initial significant relative risk which can lead to reproducing the results in diverse populations. Improvement areas included a limited statistical power for comparing a group of variables[48]. Other more sophisticated risk models designed in assessing and predicting febrile neutropenia in any cycle of chemotherapy in breast cancer patients have identified a set of risk factors that include chemotherapy, patient and genetic categories, and have demonstrated that the implementation of genetic factors can improve the predictive ability of the models. However, despite these improvements, the overall predictive ability of the models remained low[49].

- **Clinically-endorsed and managed patient self-care**

The predictive models developed in the project can provide support to both the patient and the care giver in several ways:

- Predict the risk of an individual patient to develop a serious adverse event to the treatment. Based on this risk assessment the clinicians could for instance identify the patients that need close monitoring during treatment.
- By monitoring the patient at home early identify the onset of a serious adverse event that needs the intervention of the health provider. An alert can be generated through the iManageCancer platform to notify the treating physician.
- Predict the neutropenic recovery of an individual patient to aid in the elaboration of a personalized treatment schedule and avoid unnecessary visits of the patient to the hospital.

Assisting a physician's decision could be beneficial for decreasing the associated health complications[24, 50]. We propose to encapsulate the derived predictive models in a software component integrated in the iManageCancer platform that will create a direct line of communication between the patient and the doctor. The ultimate aim is to decrease the incidence and duration of adverse events with respect to a personalised approach and create an alert should an adverse event occurs that will feedback to the clinician to alleviate symptoms. Also, reporting physiological parameters and communicating with the clinician remotely increases the psychological comfort of "feeling secure at home"[24] and allows the patient to feel control over their disease in the environment/site they choose (with respect to the severity of the condition[30]), either at home or hospital. Moreover, assessing the timing and the eligibility in scheduling the next therapeutic intervention based on vital signal detection and adverse event reporting, both to patient and clinician, would help the patient understand the better underlying disease and assist the clinician in scheduling a personalised therapy at the required time-frame: This will also help cancer

[48] Santolaya, M.E., et al., Prospective Validation of a Risk Prediction Model for Severe Sepsis in Children with Cancer and High Risk Fever and Neutropenia. The Pediatric Infectious Disease Journal, 9000. DOI: 10.1097/INF.0000000000000015.

[49] Pfeil, A.M. et al. Multivariable regression analysis of febrile neutropenia occurrence in early breast cancer patients receiving chemotherapy assessing patient-related, chemotherapy-related and genetic risk factors. BMC Cancer, 2014.

[50] ASCO, Factors influencing patient preferences for outpatient treatment of febrile neutropenia. ASCO Annual Meeting, 2011.

patients to manage their personal time, if in out-patient care. Personalized indication of neutropenic recovery after each treatment cycle can result in a reduction in the unnecessary visits to the hospitals and a reduction in the economic impact caused by missed and scheduled appointments (in the course of arranging the next chemotherapy cycle)[50],[51].

- **Decision aid for improved consultation process:**

Patient's decision aids are tools that translate evidence into a patient-friendly form by providing, at a minimum, information on the options, benefits and risks, and implicit methods to clarify personal values. In addition, many decision aids also include information on the condition, probabilities of the outcomes of options (benefits/harms), exercises to help patients explicitly clarify their values, and guidance in the steps of decision making. A variety of decision aids have been developed and proved successful in increasing knowledge, enhance active involvement in decision making by patients, and decrease patients' decisional anxiety[52]. These tools have the potential to facilitate patient empowerment in the decision-making process[53]. However, there is the need to provide decision aids according to the patient's personal characteristics, such as the patient's thinking and decision styles. iManageCancer will take these aspects into account to optimize patients behaviour in gathering the useful information and recognize that a decision needs to be made, understanding the current scientific evidence, clarifying their values associated with outcomes of options, and achieving a quality decision.

A consultation planning tool for patients will be provided to increase their participation in the consultation process with their physicians and improve their satisfaction with the decision-making process. The tool prompts standardized sets of questions related to the patient's condition, treatment options and potential side effects, from which the patient can choose to create his own list of questions he wishes to ask his doctor. The list can be shared with the doctor in advance of the consultation.

- **Advanced medication management for patient safety and increased compliance to medication:**

A tool will be provided as an App to easily compile a medication plan by the patient him-/herself. The App will allow patients to insert their drugs and the daily schema for their intake in the plan for sending reminders while a backend service of the system checks for drug-drug interactions with the help of open external registries like Rote Liste[54] and warns the patient appropriately. Similar apps exist already on the market (i.e. Drugs.com, Micromedix), however, access to PHR data will allow to further personalise such services through a comparison of experienced and reported side effects with listed side effects and interactions of the patient's drug. In addition, the system will facilitate entering medications by taking and analysing pictures of drug packages as an alternative input mode. Finally the medication plan will be linked with the decision support system and its models to propose drug doses adaptations in relation to symptoms for situations where self-management of the dose of a drug is therapeutic option (i.e. pain management).

- **Interactive animated personal health record:**

The personal health record will be mainly portrayed through a diary, allowing the patients to enter and to view their activities and behaviours across time. The dairy based patient health record will be coupled with scalable and temporal visualization techniques, allowing the users to fully interpret the large scale data with dynamically evolving natures. Also, the visualization can also be individually tailored – individual user profiles can be built according to their daily behaviours captured in the dairy and the visualization can highlight important information to each of the individual users. Also, a 3D virtual

[51] ASCO, Treatment strategies for low-risk febrile neutropenia in adult cancer patients: A cost-utility analysis. ASCO Annual Meeting, 2010.

[52] Isebaert, S., Van Audenhove, C., Haustermans, K., Junius, S., Joniau, S., De Ridder, K., Van Poppel, H. Evaluating a decision aid for patients with localized prostate cancer in clinical practice. Urol Int., 2008, 81(4), 383–8.
Reichlin, L., Mani, N., McArthur, K., Harris, AM, Rajan N, Dacso CC. Assessing the Acceptability and Usability of an Interactive Serious Game in Aiding Treatment Decisions for Patients with Localized Prostate Cancer. J Med Internet Res. 2011 Jan-Mar, 13(1).

[53] Lin, G.A., Aaronson, D.S., Knight, S.J., Carroll, P.R., Dudley, R.A. Patient decision aids for prostate cancer treatment: a systematic review of the literature. CA Cancer J Clin. 2009, 59(6), 379-90.

[54] http://www.rote-liste.de

human model will be made available which offers an intuitive means to visualize the personal health record in addition to the diary – users will be able to click on an organ to display relevant health records.

The guiding principle behind the PHR is that the patient as the owner of his health data decides with whom he wants to share the data for healthcare provision and who will be allowed to use his anonymized data for research including the kind of research. The technical challenges of the work includes:

- Scalability: While significant progresses has been made in visual representation and exportation of large datasets, scalability still remains as a challenging issue. Large scale data can lead to overplotting, which significantly hampers the capability of human vision in identifying data patterns and hence reduces the effectiveness of visualization.
- Temporal information: The diary contains significant information in the temporal domain. To explore the patterns that exist within patients, often multiple records are placed together in parallel. One of the most well-known methods is the Lifeline. Currently, most of the existing techniques do not aggregate information therefore face problems in scalability. Some recent works have introduced aggregation approaches by using Lifeflow or Outflow.

- **Advanced assessments of psycho-emotional status and health condition of cancer patients for personalised service provision:**

In order to provide personalised services to cancer patients it is essential to be able to assess their health conditions, physical activities and vital signs. However, a human being cannot be considered as unique by only referring to him/her as a biological and genetic entity. Instead, what makes a human being unique is also his/her specific needs and value, habits and behaviours, hopes and fears, beliefs and cognitive dispositions[55]. In order to achieve personalised service provision the information that should be exploited includes both factual data and patients' considerations. While the former is derived from clinical tools providing information about patient health information and supposed treatments, the latter is provided by patient profiling techniques providing health related quality of life information (HRQL). Barnato et al.[56] noted that "in an ideal world […] patients would come to a cancer consultation armed with sufficient knowledge, clarity about their personal value, and the ability to engage in a thoughtful discussion about the pros and cons of treatment options. Providers, in turn, would be prepared to support their patients, armed with an understanding of the patient's knowledge gaps, personal values about possible outcomes and treatment preferences." (p.627). Moreover, governmental and professional organizations have advised routine screening for the presence of heightened psychological distress in cancer patients (NICE, Rebalance Action Focus Group).

This gap between an optimal and many actual encounters (virtual or real) could be reduced by implementing smart patient profiling techniques that raise awareness of patient considerations, facilitate the discussion of these aspects and thereby actively involve the patient in the medical decision process. In iManageCancer we intend to address these challenges by merging the two aspects of personalised medicine (clinical and psychological dimensions) by developing a novel patient profiling environment, i.e. the Health Avatar PHR. This environment will collect all clinical information of patients, will be able to communicate with medical devices and sensors, to monitor the psycho-cognitive status and ultimately to exploit this information for providing him/her with the chance of making his/her own, well-discussed and well-informed, choice concerning the treatment.

Patients and family will be periodically assessed to moderate iManageCancer intervention. The assessment will be performed using ALGA questionnaire, enquiry component, distress and coping assessments, physical activity monitoring and vital sign monitoring. In particular, patients have the possibility to receive alerts on their electronic device that remind them to access the assessment tools.

- **Advanced health information management - Access to high quality cancer information suitable for patients for decision making:**

[55] Gorini, A., Pravettoni, G. P5-medicine: a plus for a personalized approach to oncology. Nat Rev Clin Oncol, 2011, 8, 444.

[56] Barnato, A.E., Llewellyn-Thomas, H.A., Peters, E.M., Siminoff, L., Collins, E.D., Barry, M.J. Communication and Decision Making in Cancer Care: Setting Research Priorities for Decision Support/Patients' Decision Aids. Med Decis Making, 2007, 27, 626-634.

One of the key features of iManageCancer is patient empowerment through interactivity. Patient empowerment refers to the possibility of a patient to view data organized according to his/her perception of a domain, to retrieve patient-understandable information and, finally to state a preferred decision. According to the US National Research Council[57] health literacy involves the "degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions".

Currently patients are using search engines like Google and Bing to find health related information[58,59]. For example, in Google, five percent of all searches are related to health. While patients drown in information found in the Internet, they still have to personalize the information, i.e. translate generic recommendations and rules into ones that fit their own context. This requires not only context-sensitive selection and presentation, but also adaptation to the patient's literacy level that might depend on education, age or even ethnic background.

On the other hand, Personal Health Records represent an important and increasingly accepted health information technology necessary to support patient-centred care, self-management and effective use of health care resources[60]. However, although numerous such approaches exist already, such as WebMD[61], MayoClinic Patient Care and Health Info[62] etc., they are not dynamically adapted according to patient's preferences of medical history[63,64] and lack the incorporation of intelligent factors such as intelligent alerts, recommendations etc. The iManageCancer platform targets at improving the opportunities that patients have to inform themselves on the internet about their disease and possible treatments, and providing them with personalized information and recommendations in a language respecting their emotional and psychological condition. The goal here is threefold (1) to deliver relevant information to patients, based on their current situation as represented in their personal healthcare record data which includes also psychological information, (2) to ensure the quality of the presented information by giving doctors the chance to control the information that is given, and (3) to facilitate an easy uptake of the new system by minimizing the necessary manual effort.

► **Serious gaming to fight psychological dimension of the disease:**

Scientific research shows that specially designed games can improve cancer treatment adherence and boost self-efficacy. Study results of a randomised trial with the game Re-Mission indicated that playing led to more consistent treatment adherence, faster rate of increase in cancer knowledge, and faster rate of increase in self-efficacy in young cancer patients[65]. The Re-Mission games[66] of the non-profit US organisation HopeLab puts players inside the human body to fight cancer with weapons and super-powers, like chemotherapy, antibiotics and the body's natural defences. iManageCancer will go a step further and implement methods in a new adventure game for children and adolescence for enhancing self-efficacy including:

- Mastery: success with cancer fight skills raises perceived self-efficacy in fighting the disease in real life

[57] National Research Council, Health Literacy: A Prescription to End Confusion. Washington DC: The National Academies Press, 2004.

[58] Eysenbach, G., Köhler, C. Health-related searches on the Internet. JAMA, 2004, 291(24), 2946.

[59] Van De Belt, T. Definition of Health 2.0 and Medicine 2.0: A Systematic Review. J Med Internet Res, 2010.

[60] Brennan, P. F., Downs, S., Casper, G. Project HealthDesign: rethinking the power and potential of personal health records. J Biomed Inform, 2010, 43(5 Suppl), S3-5.

[61] http://www.webmd.com/

[62] http://www.mayoclinic.org/patient-care-and-health-information

[63] Genitsaridi, I., Kondylakis H., Koumakis L., Marias K. and Tsiknakis M. Towards Intelligent Personal Health Record Systems: Review, Criteria and Extensions , ICTH, 2013, 327-334.

[64] Genitsaridi, I., Kondylakis, H., Koumakis, L., Marias, K., Tsiknakis, M. Evaluation of Personal Health Record Systems through the Lenses of EC Research Projects, Computers in Biology and Medicine, 2014.

[65] Kato, P., Cole, S., Bradlyn, A., Pollock, B. A Video Game Improves Behavioral Outcomes in Adolescents and Young Adults With Cancer: A Randomized Trial. In Pediatrics Vol. 122 No. 2 August 1, 2008, 305 - 317.

[66] http://www.re-mission2.org

- Vicarious experience: seeing others (family members, friends or other patients) succeeding in cancer fight
- Verbal persuasion: positive feedback on success during the game concerning a cancer fight

An adventure game for children and adolescents but also their relatives will be developed for mobile platforms with the following approach. As in Re-Mission the gamers fight as virtual characters virtual against cancer cells with different weapons that represent the therapeutic clinical tools against cancer. In this way the message is given that weapons exist and that they can combat cancer if properly applied. In addition, socialisation aspects will be incorporated in the game to form team with co-players like parents, sisters and brothers, and friends but also other cancer patients via the iManageCancer platform. Means will be implemented in the game which supports the assessment of its impact on the patients like playful answering of questions. Parameters on the usage of the game and the results of gaming will be stored in the patient's PHR. In particular, physiological feedback will be obtained by monitoring physiological responses during and after the game (signal emotional discharge or relaxation). The game leverages also the information available in the patient's PHR like is current psycho-emotional status in order to change the game experience for the player dynamically to provide a maximum of supporting impact to the player. The game itself will attract both male and female patients, it will cover all educational and social backgrounds by choosing basic game mechanisms that will work independently from language or cognition related skills.

Another game will be created for patients with prostate cancers. The game will allow a user to create a "virtual me" with emotional, fitness and energy indicators in the scenario, giving the virtual character progressive aims and missions in different areas, such as maintain a balanced diet, adequate to the level of exercise, maintain his social life with his network of friends, walks and shopping. The game will also put the character in a critical situation for a strategy of solutions and will also give the character the opportunity to cope with side effects of treatment, such as fatigue and nausea from chemotherapy by eating a balanced diet, rich in vitamins, and by doing specific exercises to manage urinary dysfunctions. The games will consist of short sessions with immediate feedback, use of only positive feedback during the game, use of hints and helps when the patient is having difficulties in the game. By doing so, the "virtual me" can behave as if in a living life environment, allowing the patients to reflect this into their real life and promote their self-efficacy in fighting with the cancer.

► **Novel analysis tools for public health research on cancer**:

Surviving and living with or beyond cancer is rising at an estimated up to 3.2% per year for specific types of cancer survivors[67]. Cancer as a chronic illness places new demands on patients and families to manage their own care. Current trends in cancer self-management are limited to care programs as in-hospital activities or workshops where small groups are led by trained peer leaders who have had a cancer experience. iManageCancer platform aims to provide a system focused around the needs of the patient with collection of data that can be analysed over a long period of time and used to empower the patient.

Innovative analysis tools will be implemented for new knowledge discovery, by the effective integration of intelligent data analysis with expert knowledge. Visual analytics will makes use of information from iManageCancer data sources, and bring together valuable information in visual form to support exploration. Such a system successfully overcomes the limitation of traditional intelligent data analysis that works only with a small number of well-defined and well trained cases. It will be supported by the reasoning tools offered by ontology and linked data.

An important ideal of public health is to better enable individuals themselves to be participants and guides in their own health management. Lifestyle, clinical and vital signs will be continuously evaluated against the personal health record and history, and feedbacks towards individuals will be automatically generated at the point of need. The heterogeneity and scale of clinical, environmental and lifestyle data raises the demand for seamless data access along with the availability of powerful and reliable data analysis operations, tools and services. iManageCancer platform will provide self-management services designed

[67] Maddams, J., Brewster, D., Gavin, A., Steward, J., Elliott, J., Utley, M., & Møller, H. Cancer prevalence in the United Kingdom: estimates for 2008. British Journal of Cancer, 2009, 101(3), 541-547.

according to the specific needs of individual groups and focusing on the wellbeing of the individual with special emphasis on clinical and lifestyle data. The advanced data analysis services of iManageCancer, fed by retrospective and prospective data, have a central role in the iManageCancer platform. Pilots will assess the added value on health and quality of life of the decision support and analysis tools and the platform as a whole.

- **Advances in semantic integration of heterogeneous eHealth data:**

Semantic Integration is the problem of providing unified and transparent access to a collection of data stored in multiple, autonomous and heterogeneous data sources using semantic models. During the last years, ontologies have been used in order to integrate structured and semi-structured data[68]. However, there is not a single correct way to model a domain and several ontologies exist. Example such ontologies include Symptom Ontology[69], was designed around the guiding concept of a symptom, the Disease Ontology[70] (DO) is trying to link disparate datasets through disease concepts, the Foundational Model of Anatomy[71] has to do with the phenotypic structure of the human body, whereas Adverse Event Ontology[72] tries to model adverse events. The Experimental Factor Ontology focuses on experimental variables in Gene Expression Atlas[73], the Clinical Care Classification System [74]tries to code health care settings and the Current Procedural Terminology (CPT)[75] is a medical nomenclature used to report medical procedures and services under public and private health insurance programs. UMLS[76], the Unified Medical Language System, is a unifying framework which integrates different terminologies which are relevant to medicine and biomedical information technologies. The Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) is a clinical terminology, which has been promoted as a reference terminology for electronic health record (EHR) systems. SNOMED CT is used by the College of American Pathologists[77,] the UMLS Metathesaurus[78], the European project epSOS[79] and the European project SemanticHealthNet[80]. The Medical Subject Headings (MeSH)[81] are a medical thesaurus published and annually updated by the US National Library of Medicine (NLM). It is used for cataloguing of the library holdings and for indexing of the databases that are produced by the NLM (e.g. MEDLINE). ACGT MO[82] tires to model medical knowledge in the Cancer domain. The International Classification of Diseases[83] is the world's standard tool to capture mortality and morbidity data. LOINC[84] is a database and a universal standard for identifying medical laboratory and clinical observations and Medical Dictionary for Regulatory Activities[85] (MEDRA) is a clinically validated international medical terminology for diagnoses, symptoms, surgeries and other medical procedures. The Thesaurus of the National Cancer Institute (NCI)[86] covers vocabulary for clinical care, translational and basic research and public information and administrative activities. Moreover other ontologies try to model multiscale data

[68] Calvanese, D., De Giacomo, G., Lembo, D., Lenzerini, M., Poggi, A., Rodriguez-Muro, M., Rosati, R. Ontologies and Databases: The DL-Lite Approach, Reasoning Web, 2009, 255-356.
[69] http://symptomontologywiki.igs.umaryland.edu/wiki/index.php/Main_Page
[70] http://www.obofoundry.org/cgi-bin/detail.cgi?id=disease_ontology
[71] http://sig.biostr.washington.edu/projects/fm/AboutFM.html
[72] He, Y., Xiang, Z., Sarntivijai, S., Toldo, L., Ceusters W. AEO: A Realism-Based Biomedical Ontology for the Representation of Adverse Events, Int. Conf. on Biomedical Ontology, Representing Adverse Events Workshop, July 26, 2011
[73] http://www.ebi.ac.uk/gxa/
[74] http://en.wikipedia.org/wiki/Clinical_Care_Classification_System
[75]http://www.ama-assn.org/ama/pub/physician-resources/solutions-managing-your-practice/coding-billing-insurance/cpt.page
[76] http://www.nlm.nih.gov/research/umls/
[77] http://www.cap.org/apps/cap.portal
[78] http://www.nlm.nih.gov/pubs/factsheets/umlsmeta.html
[79] http://www.epsos.eu/
[80] http://www.semantichealthnet.eu/
[81] http://www.ncbi.nlm.nih.gov/mesh
[82] http://bioportal.bioontology.org/ontologies/1126
[83] http://www.who.int/classifications/icd/en/
[84] http://en.wikipedia.org/wiki/LOINC
[85] http://www.meddra.org/
[86] http://ncit.nci.nih.gov/

such as the Systems Biology Ontology[87] and Gene Ontology (GO)[88] which supports biologically meaningful annotation of genes and their products in different databases.

Besides these ontologies that refer to core medical knowledge mostly other ontologies try to cover the domain of social entities that are related to health care such as Ontology of Medically Related Social Entities[89] and the BioCaster Ontology[90] (BCO) which tries to describe the terms and relations necessary to detect and risk assess public health events. The FHHO[91] (Peace & Brennan, 2007) is representing the family health histories of persons related by biological and/or social family relationships (e.g. step, adoptive) who share genetic, behavioural, and/or environmental risk factors for disease. Obviously the amount of information available, the heterogeneity of the information and the wide range of proposed ontologies dictate the identification of a solution being able to handle all this information available. In iManageCancer, we intend to explore interlinking several ontologies as global schema to integrate all internal and external data. Personal health information will be stored in a central repository which will then be combined with a semantic integration solution on top to integrate both internal and external data. Moreover, when having heterogeneous eHealth streams of data available, performance and scalability issues arise that dictate the use of novel solutions. We intent to go beyond the state of the art by exploring the ontology-based data integration of new storage approaches (such as NoSQL databases) and trying to resolve the challenges occurring in such a setting.

Exploitation advances:

- **Novel service and business model for the iManageCancer ecosystem oriented to the Health Data Cooperative with the participation of the patient:**

Aggregated personal data has become a new asset class and many commercial entities are competing for this new asset (i.e. Google, Facebook)[92]. The Boston Consulting Group estimates that the market value of personal data for targeted marketing and loyalty programs from Europeans alone will increase from €350 billion in 2011 to € 1 trillion in 2020[93]. In the realm of health data the interest from pharmaceutical companies, research organizations and insurance companies is increasing. Currently, access to such data is restricted by the decentralized storage of these data and by privacy legislation that protect the individual donor of the data. The relative success of health data repositories such as 23andme and PatientsLikeMe indicates that citizens are willing to participate in research even if the commercial value of these data does not go back to the collective of users. The value of personal health, however, can best be fully valued to the benefit of the citizen as the source of the data and society at large when the data are controlled by the citizens themselves. In consequence, Hafen proposed in 2014 the Health Data Cooperative business model[94] (HDC) for health data platforms in which patients are members that own and control the cooperative. Patients as members determine which data they want to share with doctors and they want to contribute to research for their benefit and the benefit of the society and how revenues generated with the sharing of data for research are re-invested in the coorperative. Putting the decision who can access the personal health data in the hand of the patient in an empowerment but also a burden. Based on the model of Hafen the iManageCancer consortium will pursue and develop a public-private-partnership model in its exploitation strategy of the project which will involve and be run in a cooperative fashion by patients and professionals together. This model will be respected in the design of the platform by giving the patient the control over access to his data not only for healthcare provision but also for research on his anonymized data. The industry partners in iManageCancer will be responsible for finding private investment, and the patient cooperative will seek charitable support based on the agreed business

[87] http://www.ebi.ac.uk/sbo/main/
[88] http://www.geneontology.org/GO.consortiumlist.shtml
[89] http://omrse.googlecode.com/svn/trunk/omrse/omrse.owl
[90] Collier, N., et al. An ontology-driven system for detecting global health events, Int. Conf. on Computational Linguistics (COLING), 2010, 215-222.
[91] Peace, J, Brennan, P.F. Ontological representation of family and family history, at AMIA Annu Symp Proc. 2007.
[92] Forum, W.E. Personal Data: The Emergence of a New Asset Class: World Economic Forum 2011.
[93] Rose, J., Rehse, O., Röber, B. The Value of our Digital Identity. Boston Consulting Group 2012.
[94] Hafen, E., Kossmann, D., Brand, A. Health data cooperatives - citizen empowerment. Methods Inf Med. 2014, 21,53(2),82-6

plan. The model public private partnership would expect to break even within two years after the end of the iManageCancer project, and generate profit thereafter.

2.2 Impact

2.2.1 Expected impacts

2.2.1.1 Expected impact with respect to the work programme

The following table presents a list of the expected impacts of the PHC-26-2014 (ii) mHealth applications for disease management call and the iManageCancer expected impact with targets/indicators:

Table 2.2.1a Expected Impact of iManageCancer with respect to the work programme PHC 26 – 2014

Expected Impact of iManageCancer with respect to the work programme PHC 26 – 2014		Quantified indicators and targets
PHC26 expected impact	Improved self-management of health, disease prevention, management of diseases and/or expenditure.	***iManageCancer quantified indicators and targets***
iManageCancer impact	The project will empower cancer patients and their relatives to better manage the cancer disease in all phases of the cancer care continuum in collaboration with their healthcare providers. The envisioned ICT service platform for self-management will inform the patients about their condition through personalised data driven information services and help them participate in the care process by sharing pain and side effect information with their doctor and keeping track and managing their therapy and health status. It will also alleviate the psychological burden by dedicated serious games for adult and young patients while the dedicated drug-drug interaction, psycho-emotional evaluation and clinician-patient communication services will reduce unnecessary visits to the hospital while ensuring that serious deterioration of the disease will be assessed earlier detected or even prevented.	The main target towards this impact is the implementation of three clinical pilots and the pertinent evaluation that will take place in the last 12 months of the project. Quantified indicators include the timely delivery of D4.3 regarding the final version of Health Avatar PHR (M27) and D5.3 for the extended decision support and patient guidance services integrated in iManageCancer Platform in (M30). *The degree of patient involvement in the design and implementation phase will also be used as an indicator for impact realisation (D2.1, D2.3)*
PHC26 expected impact	Strengthened evidence base on health outcomes, quality of life, care efficiency gains and economic benefits from the use of ICT in new care models, in compliance with data protection requirements.	***iManageCancer quantified indicators and targets***
iManageCancer impact	The project will conduct and assess two pilots, one for adult cancer patients and one for children to assess the value of the iManageCancer platform and its services regarding feasibility, patient acceptance, usability, performance in terms of service delivery, reduce costs due to optimised patient-doctor communication, and effect on quality of life of cancer patients. These pilots in two diverse age groups of cancer patients will give critical evidence that is expected to pave the way for wider use and faster adoption of this technology in Europe.	The main target in this direction will be the involvement of the clinical organisation pilots to the evaluation process and the assessments of the results by eCancer an organisation with vast experience on assessing impact of technologies in care efficiency and patient quality of life (QoL). Such indicators (QoL, rationalisation of care

		and benefits estimators) will be reported in D9.4 as an evaluation result of the pilots.
PHC26 expected impact	Increased confidence in decision support systems for wellbeing and disease / patient management.	***iManageCancer quantified indicators and targets***
iManageCancer impact	The project will provide patients with decision support and guidance through a knowledge base of formal care flow plans that represent best practise expert models for the management of cancer care with close participation of the patients for supporting them during therapy, managing side effects such as pain and nausea, managing drug intakes and drug doses and follow-up. Care flow plans, including an advanced drug self-management tool, *will be personalised in close collaboration between the doctor and the patient* in order to maximise confidence in the platform and increase the performance of the proposed CDS tool on adverse events prediction for optimising chemotherapy monitoring and disease management.	Decision support is a central direction of the project with the target to demonstrate that the mHealth technologies will promote decision support for encouraging wellbeing and cancer self-management. WP5 will deliver the central knowledge based system for guidance and support of the decision making involving the patient in the whole process. Indicators include the timely delivery of D5.3 offering tools for therapy monitoring, drugs self-management, adverse event alerter and decision aid for patient participation
PHC26 expected impact	Strengthened evidence and improved knowledge about individuals' behaviour related to wellbeing, disease prevention or management facilitating the creation of new personalised behavioural health interventions.	***iManageCancer quantified indicators and targets***
iManageCancer impact	The project will provide valuable evidence related to the effect of individual's behaviour with respect to the cancer management technologies offered and the way the personalised ICT and m-health services may have a positive effect in improving disease management and wellbeing of the cancer patient. Special focus will be given in developing novel tools for smart recommendations based on the *psycho-emotional status of the patient and family*. These tools will recommend to the patient specialised content related to their condition and assist them to make informed decisions regarding their health management. This process will greatly improve the personalisation of decision support tools lead to better and more efficient decision support tools for physicians' smart recommendations for the patients.	WP6 on Psycho-emotional and health assessment tools will target on tailoring smart recommendation and em-powerment/ self-management services to the individual needs of each patients. D6.4 (Report on implemented application iCancerPlatform scenarios using psycho-emotional and health assessment tools) on M30 will be a critical indicator assessing the successful implementation of such services with respect to personalised behavioural health interventions for the cancer patient.
PHC26 expected impact	Improved service offering and business concepts and models	***iManageCancer quantified indicators and targets***
iManageCancer impact	iManageCancer will design an innovative ecosystem for the empowerment of cancer patients based on the self-management principle through the involvement	The project will not only target on deploying and evaluating three pilots on cancer self-

	of all stakeholders involved in the therapeutic process. The project will contribute to novel business concepts and a model for health promotion in cancer patients that is centred on individualised service provision based on psycho-emotional assessment and patient's participation in customising the ICT environment and personal health record which will be a novel service provision for more efficient disease self-management and service efficiency.	management but will also design and evaluate the whole process from the business/service standpoint and to this respect the Task 10.5 "Service and business models for sustainable self-management platform" led by Philips will shed light on improved business concepts for participatory health management of cancer patients.
PHC26 expected impact	Impact in several of the following facets of mHealth e.g., patient safety, contribution to or revision of (guidelines of) relevant legal frameworks, medical guidelines, harmonisation (across borders), standards, co-ordination of therapies, recognition of mHealth as a reimbursable cost, improved accessibility, liability, inter-operability, more reliable connectivity, patient empowerment, improved patient-health professional interaction, maturing personalised health systems, sustainability, usability and user-acceptance.	***iManageCancer quantified indicators and targets***
iManageCancer impact	The inclusion of cancer patients for assessing self-management mHealth technologies is very difficult due to the legal and ethical implications as well as the psycho-emotional burden of the patients. In order to bring real impact iManageCancer will deploy two important pilots one in paediatric oncology patients and one in prostate cancer. This is expected to introduce new paradigms in the design of health programmes for promoting health and quality of life in cancer patients at all times, in all places and under all circumstances via the dedicated Avatar –enhanced personal health record, m-health technologies, the specialised serious games and psycho-emotional assessment tools. The side effect assessment and clinical decision support tools will also add safety to the therapeutic process and improve therapy coordination and optimisation. Central to all the above is the patient-doctor co-design in the customisation of these services for increasing adoption and efficiency. The outcome of these important pilots is expected to lead to an increased confidence in mHealth patient empowerment and therapy assistant applications for the cancer patient and contribute to the recognition of mHealth as a reimbursable cost. Concerning sustainability, the tools and services developed in the project will be made available through the ecancer's web platforms to be accessed by patients and healthcare professionals and any revenue that can be gained through advertisement or other sources will then be re-invested into the maintenance and further development of the software. To achieve this, iManageCancer tools will conform to the European Medical Device Regulation regarding product liability and interaction with competent authorities and Notified Bodies, before they can be	iManageCancer will include an impact conclusion report (part of D9.4) that will include the following six indicators derived from the three clinical pilots of the project: I1: Indicator concerning patient involvement in the design phase. I2: Assessment result concerning the reduction of unnecessary visits to the hospital during project's pilots. I3: Mutual assessment of patient-clinician regarding improved communication in a continuous fashion. I4: Clinical score of reliability of side effect alerts and prediction components I5: Cost Benefit indicator for the three clinical organisations involved I6: Patient/user indication (based on feedback) for system satisfaction and acceptance of mHealth services as part of the therapeutical eco-system. Based on these indicators the next target will be to ensure conformance with Medical Device Regulation clinical

	made available to the public. Usability and user-acceptance will be maximal due to the customisation functionality that will allow the users to participate in the service design and communication process.	guidelines and then release the services to the public via eCancer.
PHC26 expected impact	Improved interaction between patients, their relatives and care givers, facilitating more active participation of patients and relatives in care processes	***iManageCancer quantified indicators and targets***
iManageCancer impact	The main expected impact of the proposed platform is improved and more effective interaction between the patient, his/her family and the clinician, caregiver. The 'clinical view' of the PHR in combination with the e-diary timeline annotations of the patient, as well as the patient's own notes on pain/ side effects will optimise these interactions while offering to the patients specific decision aids for the consultation process that will support them to participate more actively in clinical care process. To ensure that this will really work out for the individual patient, iManageCancer will provide ICT based instruments to assess the psycho-emotional status of the patient and to evaluate the resilience in his family and support the integration of off-the-shelve sensors and medical devices that will allow assessing relevant vital signs and parameters related to lifestyle for further enhancing patient involvement and active participation in the therapy care process.	The main indicators for this impact in the project will be through the successful implementation/delivery of: a) D4.1 regarding the patient-centric User Interface design for an Avatar-based PHR for cancer patients, b) D6.3 regarding the psycho-emotional monitoring instrument, family evaluation tool and monitoring tool for life style and vital signs, and c) D5.3 that will provide the extended functionality for supporting patient participation in the decision process.
PHC26 expected impact	Improving the management of disease by reducing the number of severe episodes and complications.	***iManageCancer quantified indicators and targets***
iManageCancer impact	The project will develop formal knowledge models for the management and self-management of side effects of cancer therapy, medication and long-term follow-up as well as a predictive model on adverse events for chemotherapy monitoring both of which are expected to improve the management of cancer and reduce as much as possible the severe episodes and complications since the clinician and the patient will share such information continuously via the Care Flow Engine and associated components of the iManageCancer Platform while an adverse events alerter based on the predictive model for chemotherapy monitoring will ensure that the clinician acts fast when things go wrong. To realise this impact the project will also develop an advanced personalized drug self-management tool and provide to the patient a Personal Medical Information Recommender as a decision aid further empowering the patient.	The target in this direction is to include in the pilots the Adverse event alerter (T5.4), the drug self-management tool (T5.3) and Phsyco-emotional statue monitoring and management (T6.1). This triplet of technologies will report on 9.4 specific quantitative statistics regarding the added value of the participants in the three pilots with respect to a) reducing unnecessary hospital visits, b) encouraging patients to fight disease, c) reducing complications due to empowering information and drug management tools.
PHC26 expected impact	Increased level of education and acceptance by patients and care givers of ICT solutions for personalised care.	***iManageCancer quantified indicators and targets***
iManageCancer impact	iManageCancer will give special focus in the educational and acceptance based on tools for smart recommendations which will be based on the psycho-	To achieve this impact iManageCancer will target to bring together patietns, family,

	emotional status of the cancer patient and family. These techniques will recommend to the patient educational resources related to their condition and they will assist them in depth for their health status or disease in order to make informed decisions regarding their healthcare. Patients and family, caregivers will all be central to the user interface architecture of the iManageCancer while the digital avatar acting as a mediator between the end-users and the iManageCancer personal health record will facilitate information sharing, enhance education and accelerate acceptance of the proposed technology.	clinicians and IT specialists by organising two workshops (T9.1, indicator D9.1). These will be conducted by the clinical partners during the pilot phase in order patients and family, increase acceptance of the proposed technology and collect feedback for further improvements (e.g. added features) with a focus on usability aspects for ICT driven personalised care.

2.2.1.2 Improving innovation capacity and the integration of new knowledge

Despite significant support in the society for patient empowerment, the involvement of cancer patients in the management of their care is still limited. The ICT platform of iManageCancer and the realistic pilots including care givers and patients have the potential to convince the cancer community of the validity of our approach, and of the urgency and the benefits of including cancer patients in the decision process and in taking a holistic and personalized approach to their care. Proper management of cancer patients must include the evaluation of the psycho-social aspects and provide sufficient emotional support. Providing tools for clinician-supervised self-care and enabling close monitoring of symptoms including those induced by the cancer treatments have the role to improve safety and quality of life of cancer patients and to give them back their confidence and the feeling of control. The success of the iManageCancer pilots can facilitate a culture-change and clear the way for increased innovation in this area.

Knowledge and information access and maintenance are key for the effectiveness and success of CDS: Medical knowledge, especially in a complex genetic disease such as oncology, is changing and growing at an unprecedented rate. New evidence is found and gradually brought into clinical care, new medication and treatments are introduced, the evidence-based guidelines are evolving and expanding. The flexible architecture of the iManageCancer platform will enable the integration of new knowledge when this becomes available. Our approach to predictive modelling and data mining will leverage the available community knowledge. We evaluate and extend existing models making use of the large retrospective datasets available in the iManageCancer project. These updated models together with the new models that we develop will be integrated in the iManageCancer platform and used to provide support to clinicians and patients. The environment enables the continuous evaluation of the prediction and decision models implemented as new knowledge and data becomes available in the platform. The integration of several open source systems in the platform has the potential to encourage researchers outside the iManageCancer consortium to join and contribute tools and models to the platform.

2.2.1.3 Barriers to innovation

There most significant barrier that iManageCancer will have to overcome in order to realise its goals and lead to real impact in cancer management is the clinical acceptability of this new technology within the cancer community. While for several of the technological components there is already evidence that they can work in the benefit of the patient (e.g. serious games, psycho-emotional evaluation for improving therapy services etc.) the clinical pilots that will be deployed in this project will have to eventually face and overcome any scepticism regarding the acceptance of such mHealth empowering technologies designed for the cancer patient. iManageCancer will overcome this obstacle by its serious commitment in the clinical pilots (paediatric oncology and adult oncology (prostate, breast and lung cancer)) as well as the continuous focus on the cancer patient, offering technology for the best possible care targeting on making cancer therapy a more personalised continuous, and participatory experience. Another barrier to innovation relates to the unavailability of clinical data. There are usually also significant complexities with respect to involving both clinicians and patients in real-life pilots. The large datasets available in the

iManageCancer project and the real-life evaluations with patients and clinicians will speedup innovation in areas such as data mining and clinical decision support.

2.2.2 Measures to maximise impact

2.2.2.1 Dissemination, communication and exploitation of results

The work of the project will be disseminated through all available communication channels with the main focus being directed through ecancer. The main platform for this is ecancer.org the open access website that publishes education and information to the oncology community with the goal of optimising patient care and outcomes (ecancer.org has 40,000 visitors a month from across the global oncology community). By utilising ecancer's additional online and social media presence the project's work will also be distributed on twitter, Facebook, LinkedIn and ITunes University to a network of over 15,000 existing contacts in the oncology community. ecancer also publishes a patient focused website (www.ecancerpatient.org) which will be used to engage with patients as well as share key project information and developments. ecancer will also distribute project information through its existing partnerships with organisations such as the European Cancer Organisation (ECCO), the Organisation of European Cancer Institutes (OECI) and the European Cancer Patient Coalition (ECPC).

The focus of the dissemination will be on the benefits to healthcare professionals and patients of using the tools and services developed by the project. By focusing on the benefits and ensuring that these are communicated effectively, we will aim to create a network of project ambassadors including key patient advocates who will recommend the tools to each other and create a buzz across all the key audience groups. iManageCancer will have a full presence within the ecancer.org to ensure maximum exposure, dissemination activities will include:

- Project website where content will be collated by different stakeholder group so the information they require is as easy as possible to access.
- A project microsite within the ecancer.org platform where the project environment will be accessed – this area will then be hosted and maintained after the lifetime of the project to ensure the project has a continued promotional presence.
- Publish a 'special issue' which will showcase the work of the project in our gold open access peer-reviewed scientific journal which is indexed in pubmed as well as other leading journal depositories (an example of a project special issue can be found at http://ecancer.org/special-issues/3-the-personalised-medicine-project.php).
- Publication of all project news and updates with dissemination across all the key social media platforms.
- Video interviews with work package leaders to fully explain the objectives and progress of the project as a whole and each of the different elements. These will be produced annually and be distributed through ecancer.org as well as other leading video platforms such as YouTube and iTunes University as well as through ecancer's iPhone, iPad and Android apps.
- ecancer along with the other project partners will distribute information and promote iManageCancer as they attend cancer conferences and other relevant events across Europe and beyond.
- Publish content and updates on the ecancerpatient website to encourage engagement with key patient advocates and advocate groups alongside the European Cancer Patient Coalition.
- A launch event will be held alongside a leading European conference to demonstrate the iManageCancer environment focusing on the benefits delivered to patients and healthcare professionals.
- Two workshops with stakeholders and patient representatives will be conducted by the clinical partners during the pilot phase to demonstrate the basic prototype of the iManageCancer platform and collect feedback for further improvements with a focus on usability aspects.
- Press releases are planned when the project will be kicked-off and when important milestones and results are achieved.

- Further to this, scientific papers about clinical results and ICT innovations will be prepared and submitted to international conferences. Main events that the project will address are pHEALTH, and the European Medical Informatics Conference.

For the purpose of publications beyond the open access journal ecancer a process will be implemented in the project that ensures that papers are only submitted to conferences and journals where open access to the publications is guaranteed. However, iManageCancer will not participate in the open access to research data pilot of article 29.3 of the model grant agreement. The exploitation of the project will be led by ecancer and will include ongoing consultation with all the internal and external stakeholders to ensure the tools and services are adopted by the oncology community with maximum gain to both the project partners and the wider healthcare community including patients. The initial exploitation plan envisages the following exploitation routes:

- The tools and services developed in the project will be made available through the ecancer's web platforms to be accessed by patients and healthcare professionals if they show proof of a sufficient technological readiness level during the pilots. Any revenue that can be gained through our analytical data services, through advertisement or other sources will then be re-invested into the maintenance and further development of the software. This exploitation route is oriented to the model of the Health Data Cooperative and aims at a partnership between patients, service providers and technology partners. It will be further investigated in comparison to other potential models in the context of WP10.
- Other interested stakeholder groups will be offered licensing of the project technology especially focusing on taking expanding the tools and services to cover other disease groups.
- Individual exploitation plans will be developed in partnership with each project partner to ensure their specific needs are met.

An important activity in the dissemination and exploitation plans represents the inclusion of another pilot site in another European country in the course of the project. The pilot site will be selected based on the clinical cancer expertise, access to cancer patients and research data, prevailing needs of the project and the achievable benefit for its dissemination and exploitation. Some of the proposed tools need to conform to the European Medical Device Regulation which requires further investments and organisational efforts regarding product liability and interaction with competent authorities and Notified Bodies, before they can be made available to the public. The consortium will address these issues in WP10 and WP9.

2.2.2.2 Knowledge management and IPR protection

The Consortium is convinced of the innovation potential of the expected results and will invest in their development and subsequent exploitation by taking the appropriate steps in the course of the project.

Knowledge Management activities in the first months of the project are triggered by the Coordinator and will address the detailed description of the background the partners bring into the project and a common agreement on the methodologies to be applied in the R&D work in form of a Consortium Agreement. These activities are covered by WP1 task 1.3.

During the implementation of the project, knowledge and results generated with high innovation potential will be identified and documented. This process will mainly be driven by the Exploitation Manager, but can also be initiated bottom-up by the partner who owns the knowledge. Firstly, the knowledge will be examined to determine if it describes a novel concept, technique, process when compared to the background technology in that particular field. Secondly, the knowledge will be appraised with respect to its patentability. Not only will the intellectual parameters of patentability be determined in each case, but more importantly, an assessment will be made of the likely patent position which can be created, supported and sustained with a view to building a commercial proposition.

It will be important to understand how a potential new product derived from that knowledge will fit within a market, how it relates, complements or competes with products already in that market, and what strategies might need to be implemented to enter and compete in that market. Based on this, potential ways of exploitation of project results in various industrial applications will be identified as well as the need for further exploitation activities. Protection of innovative results will be a priority. The Exploitation

Manager together with the Coordinator will monitor this aspect closely and will initiate suitable actions in cooperation with the individual partners as well as the lawyers and technology transfer offices of the partner institutions. All this will be done jointly by all partners, under coordination of the Coordinator and the Steering Committee.

Apart from the EC Grant Agreement, the Consortium Agreement will be the main legal basis for dealing with intellectual property rights and exploitation issues within and beyond the project implementation period. The latter in particular offers the possibility of agreement on project-specific, individual rules for the dissemination and exploitation of project results. As a general rule, foreground generated will become intellectual property of the partner(s) who generated it. All project partners will grant each other free access rights in order to carry out the project, the conditions for access to results necessary for the exploitation of own results (beyond the project) will be determined in the Consortium agreement and separate agreements as appropriate. As a general principle, the partners will strive to protect and exploit the foreground they develop Consequently, the beneficiaries will establish a regulatory framework, which guarantees that the publication of project results will in no way negatively affect those results' protection.

Apart from the general legal conditions, proper management structures and decision-making processes will be designed as described in Section 2.3.2, in order to avoid problems with intellectual property protection when it comes to exploitation. This is the main reason why the project coordination and management will give special attention to the management of intellectual property and will constantly be supported by WP 10 in this area.

2.2.2.3 Research data management

For each of the pilots trial, protocols will be developed during the project. They will get approval by ethical committee of the principal investigator (PI). The protocol will include a complete description of the data used within the pilot. The corresponding database will contain for each participant personal data (e.g: age, gender), clinical data (e.g.: diagnosis, treatment) and collected data from the project (e.g. from medical devices, from interacting with serious games and other tools used in the pilot).

The data will be specified within the pilot trial protocol and corresponding CRFs will be developed. From a technical perspective these data will be collected using ObTiMA as a GCP compliant data management system that is developed within several projects funded by the EU (ACGT, p-medicine, EURECA, CHIC). As ObTiMA is able to link data to Ontologies sematic interoperability is achieved by this data management system. Within ObTiMA all personalized data are pseudonymised and stored in an encrypted way. Access to the data of the pilot within ObTiMA is regulated via a rights and roles management system guaranteeing data security. All these data are under the responsibility of the PI of the pilot. He also is in duty to curate the data. ObTiMA supports standardized import (and export of trials data) (CDISC-ODM or CSV) for PIs, while iManageCancer will also support exporting de-personalised export of data acquired with this system during the pilots. This will allow the PI to merge these data with the trial data and to curate them.

Data collected during the pilots will be pseudomised, analysed and preserved in compliance with the national laws. Privacy will also be protected when results or data are presented. The general rule will be to restrict all presentation of data to aggregations, or to line listings deprived of personal identifiers so that the identity of the study subject cannot be deduced (no backward identification). After completion of the project, all assembled datasets will be destroyed if the individual patient will not give an informed consent to maintain the data for further analyses in a succeeding project. This informed consent needs to provide all information about the further usage of the data. This procedure has to comply with each partner's national legal and ethical guidelines for preserving raw data and guidelines for post-analysis (irreversible) data destruction.

The production system of the iManageCancer Platform as well as the trial management system ObTiMA used in the pilots will be operated in compliance with good clinical practice in clinical trials. Organisational procedures will be put in place to protect the data for unauthorized access and for loss and damage in accordance with national laws. The system will allow the PIs of the pilots to export the de-personalised pilot data for further analysis and for keeping a record of the pilot in compliance with national laws.

2.3. Implementation

2.3.1 Work Plan

The project's concept is based on the *patient empowerment concept* and the mission of the project is to motivate the cancer patient to take a more active role in the management of his/her disease through a dedicated ICT platform offering a range of mHealth services aiming to assess and improve her psycho-emotional status, improve her understanding of the disease, assist in the management of certain aspects of the disease and involve more efficiently her family and treating physician in the therapy process.

Figure 5. The proposed WP structure of iManageCancer with the main interaction of its components.

The **iManageCancer** consortium will implement the project within **42 months** aiming to dedicate the last 12 months for assessing the platform through its pilots. The work in the project plan has been divided into 10 Work Packages. This breaking down enables us to explain the envisaged strategy for realising the goals of the project. Although each WP has a degree of autonomy, there is also a high degree of interconnections that are designed to enhance the necessary partner interactions between the IT and clinical partners. The WP division has been made under two important strategic decisions: a) to create a technical platform/environment designed to encourage, help and empower cancer patients to fight their

disease and, b) to run two clinical evaluation scenario on cancer patients (WP9 Pilots), providing a significant baseline for the subsequent, wider use of this system after the end of the project. The approach to implement iManageCancer will involve ten work packages centred around an Avatar-based Personal Health Record (WP3) which will offer the patient diary (e.g. for recoding pain and side effect status) as well as the services for the patient-clinician communication. Figure 5 illustrates the proposed WP structure of iManageCancer with the main interaction of its components and the integration strategy which will involve the interaction of the smart and analytical services (WP8), the psycho-emotional and health assessment tools (WP6), Central Decision Support & Guidance (WP5) and Serious Games for Self-Management (WP7) through the main Health Avatar PHR platform (WP4).

The timing of the implementation of the project is illustrated in the Gannt chart in Figure 6. The project will involve three implementation phases: Phase I will complete the user requirements (PM1-6) while Phase II will involve the main technical work and integration of components (PM6-30). Phase III of the project (PM21-42) will involve usability tests with subsequent optimisation of the integrated platform as well as the deployment and evaluation of the project's pilots and the definition and initial implementation of the exploitation plan.

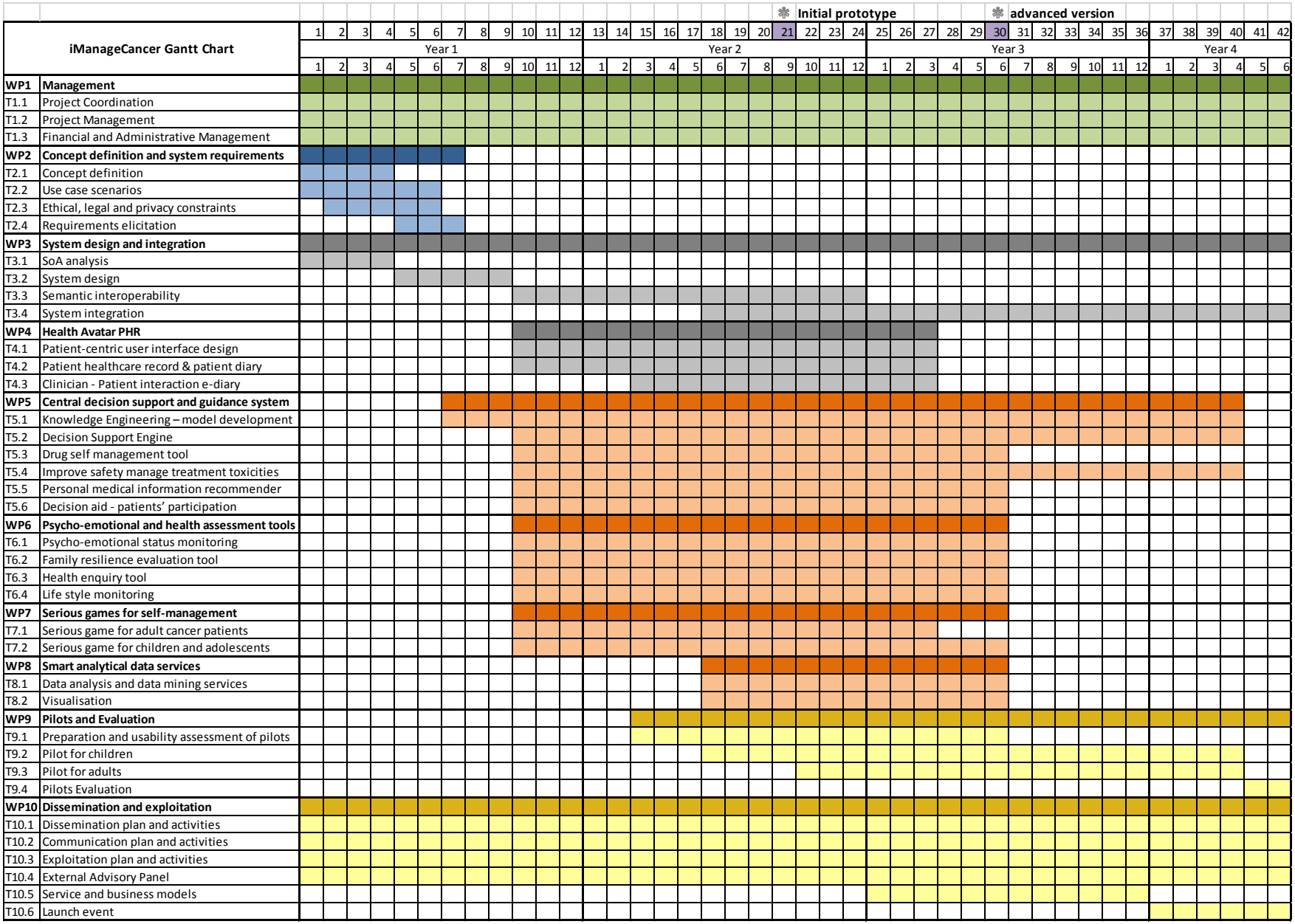

Figure 6. Gantt chart of the iManageCancer Project.

2.3.2 Management structure and procedures

iManageCancer is an ambitious project comprising various types of interrelated activities. Thus, it requires an efficient management structure which can handle the project complexity and assure a smooth implementation and achievement of the project's challenging goals. The aim of the described project management structure and procedures is to organise and manage the foreseen resources in such a way that the iManageCancer project is completed within defined scope, quality, time and cost constraints. Project management activities will cover legal, financial, administrative, scientific and knowledge and innovation aspects, i.e. coordination of activities, planning the work according to the objectives, risk management, allocation and controlling of resources, assigning tasks, controlling project execution, tracking and reporting progress, analysing the results based on the facts achieved, forecasting future trends in the project, quality management, conflict resolution, coordination of dissemination activities and management of intellectual property and innovations. Among others, processes that maximise the dissemination and exploitation of the extensive knowledge developed through the scientific and technical progress and the product innovation cycles will be put in place through the project management.

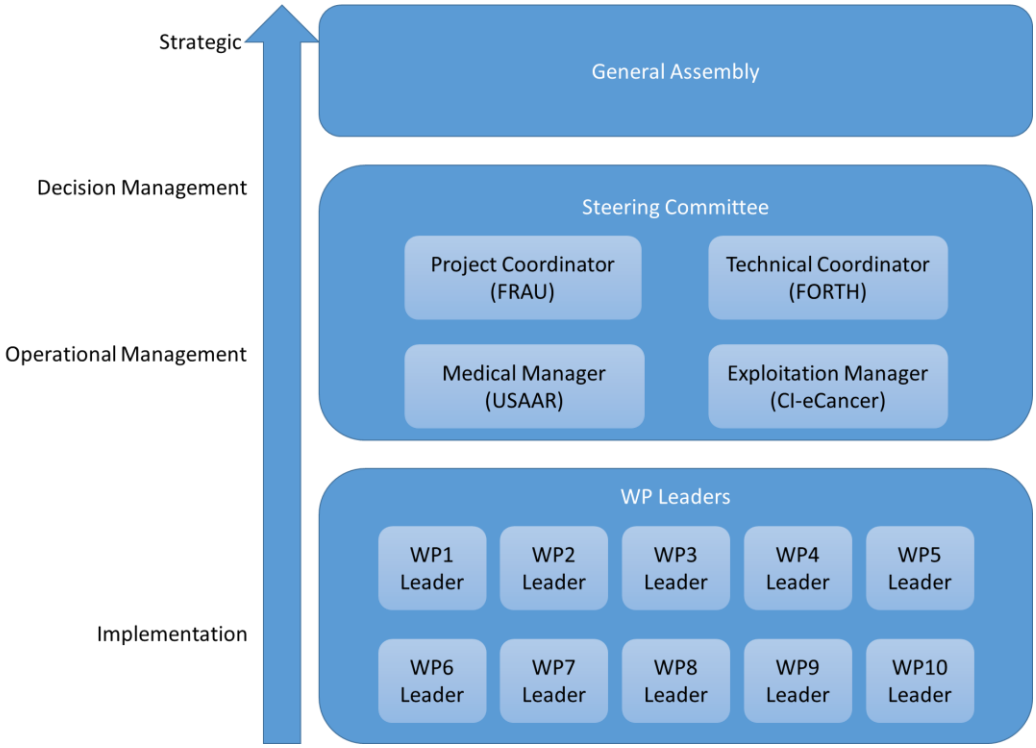

Figure 7. Project Management Structure

2.3.2.1 Project Management Organization

iManageCancer has been structured in the form of several work packages. WP2 to WP8 are technical work packages, one work package addresses pilots and evaluation (WP9) and one work package addresses dissemination, cooperation and standardization (WP10). WP1 is dedicated to project management and will assure the deployment of best practices in project management and coordination. Each technical work package is led by an expert nominated by the responsible partner who is supported by task-leaders as appropriate. Management within each work package is performed by the participating partners, whereas inter-work package management is established via the General Assembly. In order to ensure that inter-task communication is efficiently performed, technical progress is achieved with the requested degree of excellence, and generated know-how is properly disseminated, the management of the project will be carried out according to the principles of the ISO 10006 European Standard in project management. The coordinator will set up and implement the management in order to ensure a high quality management. Coordination will follow the Total Quality Management (TQM) recommendations, applying the principle of continuous process improvement (PDCA: Plan, Do, Check, Act). The Project

Management Organisation is depicted in Figure 7 and each of the roles is described in the following sections.

2.3.2.2 Project Management Organization Roles

The General Assembly is the ultimate decision-making board of the Consortium; it is in charge of setting policy and strategic decision making and will normally meet ***once per year***. The GA will be chaired by the PC or a senior executive appointed by the PC and all partners shall be entitled to nominate one voting representative. The GA will be the main legislative body of the project, and its decisions will be binding on all partners. It shall have decision-making powers in all fundamental questions of project execution, such as:

- Approval and review of the project's progress
- The main strategy of the consortium to achieve the project's objectives
- Modifications and adaptations of the work plan and decisions affecting the Consortium Agreement
- All budget-related matters and major exploitation issues
- Conflicts that cannot be resolved in the SC and actions with regard to a defaulting party
- Nomination of the specialist Advisory Panel members and replacements for members of the Steering Committee if required
- Proposals for the review and/or amendment of the terms of the EC contract.

Within the General Assembly, conflict resolution will be handled and solved by consensus. Should a consensus among all partners not be achievable, a majority vote of two-thirds will be used. However, the General Assembly shall not take any decision unless a quorum of 2/3 of its members is present or represented.

The Project Coordinator will be Dipl.-Inform. Stephan Kiefer of Fraunhofer Institute for Biomedical Engineering (FRAU). Stephan Kiefer has extensive experience over many years in coordinating and contributing to international and national research and innovation activities in the area of eHealth and biomedical informatics and will be the project interface to the EC. He will be supported by the Technical Coordinator and a project office within his organisation. Additional support by project management bodies will also be provided. He will be in charge of the scientific management of the project. His task is to ensure a high quality of research work according to the research objectives, co-ordinate scientific actions, synchronize and integrate scientific results, monitor the scientific achievements and represent the project in the communication with the European Commission. The scientific manager leads WP1 dedicated to project management, establishes an inter-work package communication and chairs the General Assembly and the Steering Committee and acts upon their decisions. He monitors risks and checks that progress, deliverables and reports are produced according to the plan and with high quality. For this purpose he introduces a quality management system mainly concerned with the set-up of internal review processes for deliverables. In addition, the Project Coordinator will issue a project handbook that describes the main procedures implemented in the project and contains the templates required for deliverables and reports.

The Technical Coordinator will be Dr. Kostas Marias Research Director at FORTH whose task will be to ensure an efficient software development process. The technical manager is an experienced senior software developer who manages the implementation cycles as a core partner, monitors the specification, implementation, testing and documentation cycles, takes care of critical architectural issues, and analyses main risks in terms of used development and deployment infrastructure. Through the involvement in the Steering Committee, a tight communication is guaranteed to setup and fulfil state of the art software development.

The Medical Coordinator will be Prof. Norbert Graf from USAAR will take the lead to bridge the technical and medical community as well ensure the coherence of each study so that a holistic evaluation of the system under development can be made. This includes the management of dependencies between

various tasks, coordination of medical-related work, review and approval of medical-related reports and deliverables, and resolution of problems of a medical related nature. The medical coordination is not considered as management effort within iManageCancer, but RTD. The iManageCancer project involves medical professionals from the three clinical partners USAAR, CI-eCancer and IEO. The Medical Coordinator has also the task to review the research protocols of the clinical partners on compliance to European regulations and national laws and how ethical aspects are addressed. He will report any issue that he will discover to the Steering Committee and proposes corrective actions.

The Exploitation Manager will be Prof. Gordon Mcvie from CI-eCANCER whose task is to review both the technology within the consortium and the market drivers affecting its exploitation. He will identify potential areas of exploitation over and above those already identified and provide market guidance to the Steering Committee to steer the direction of work and decide upon new exploitation activities. He will also initiate discussions between partners and the Steering Committee on the protection of Intellectual Property.

The Work Package Leader (WPL) is nominated by the leading partner and is responsible for the technical coordination, planning, monitoring and reporting of the WP and for the inter-WP communication. WPLs will organise the necessary technical coordination meetings – mainly by participating other WPs events as implemented in the resources allocation - to guarantee a consistent progress with regard to the overall project objectives. The WPLs represent the project coordinator at WP level, and are clearly committed to: (a) coordinating and continuously monitoring all the WP tasks and progress, (b) reporting to the project coordinator and to the partners on a quarterly basis as well as (c) ensuring that WP milestones and deliverables are timely completed, and complies with required quality standards set by quality management. Each WPL is supported by task leader who is responsible for the achievements within the tasks. Each WPL specifies a work package plan with reporting mechanisms that are appropriate for the work package.

The Steering Committee (ST) will comprise of the Project Coordinator, the Medical Coordinator, the Technical Coordinator and the Exploitation Manager. The Steering Committee will be responsible for the overall execution of the project, making executive decisions on key issues and will be a strongly influential body, having a major impact on the overall outcomes and success of the partnership, as decisions concerning the best technological developments to pursue will be taken here. Major decisions concerning the composition and structure of the consortium will also be taken here, affecting the probability of a successful and durable partnership beyond the life of this project.

Policies such as positive action of gender equality, ethical standards, quality management, and knowledge management will be approved by the SC. Approval of plans for future new partners, technologies or products will also require SC approval. The SC is, however, subject to the decisions made by the General Assembly. Quarterly meetings mainly via Internet will be held to review project progress. They will also meet, either personally or by teleconference, in instances where this will be desirable, according to the opinion of the co-ordinator or upon request of at least two members. In the event of disputes, every effort will be made to resolve them by consensus and for a motion to be carried.

An **External Advisory Panel** (EAP) will be installed during the first 6 months of the project. The EAP will be composed of at least 3 stakeholders in the domain of the project who advise the consortium on all aspects of the works but in particular on exploitation. The EAP shall be composed of representatives of patient organisations or cancer charities, health insurances, health authorities, care organisations or industrial stakeholders. In addition, the EAP will include an independent ethical advisor who shall monitor that ethical issues are adequately addressed by the consortium and who will provide a regular report on this that is made available to the Commission. EAP members will meet annually with the Steering Committee of the consortium. The EAP serves also a strategic instrument to develop an ecosystem of stakeholders around the iManageCancer platform. Requested EAP nominates are Dr. Renate Heymanns from Deutsche Kinderkrebsstiftung (cancer charite), Dr. Dimitrios Papapaulou from HealthWatch Assistance (health insurance), Prof. Dr Stefaan Van Gool, oncologist from University Hospital Leuven and Prof. Marco Foiani, scientific director of the FIRC Institute of Molecular Oncology Foundation (IFOM).

2.3.2.3 Project Management Processes

The partners of the iManageCancer consortium will cooperate in order to achieve the common project goal. Each partner will do research and develop pieces of technology that will be beneficial to their organisation; however, the consortium is aware that the synergy developed within the consortium will provide an outcome of a greater value than the addition of each individual result.

Meeting Processes: The project will start with a Kick-Off Meeting. Then, plenary meetings will be organised to evaluate the overall progress and enable working meeting between partners. A two-day meeting will take place every 6 months with meeting's location rotation through partners' sites. The project manager will produce and send appropriate notes on main decisions to the partners within one week after the meeting. In addition, regular virtual plenary meetings will take place once a month to closely monitor the progress, identify and react on risks and coordinate the upcoming works. Work package or technical meetings will also be established when the need arises, organised by the respective WPL notifying the project manager. Review meetings will organised additional to deliverables and reports prepared as a validation and checking mean for the EC on the project's progress. Review meetings with the EC will be defined by PO. It is also foreseen that additional meetings could be organized through internet conference facilities. As the Scrum methodology for software development will be applied regular virtual Sprint planning meetings will be hold during the software development phase in addition to the virtual monthly plenary meetings.

Quality Control and Assurance Processes: The quality manager will establish appropriate quality control and assurance mechanisms and procedures, which allow maximum flexibility while maintaining a clear distinction of roles and responsibilities between partners. The procedures will be clearly specified and described at the beginning of the project in a project handbook and address the whole range of administrative, financial and technical issues, defining internal reviews for all project deliverables. Systematic review of these mechanisms by the quality manager will ensure the smallest possible bureaucratic overhead and necessary adaptations will guarantee appropriate flexibility.

Innovation Management and Intellectual Property Provisions: In order to ensure that knowledge developed within the programme is used to its greatest advantage, the exploitation manager will regularly review the project outputs and the market drivers affecting their exploitation. He will identify potential areas of exploitation over and above those already identified and provide market guidance to steer the direction of work. It is envisaged that the exploitation manager will be in constant review of the project outputs, being supplied with data from the project coordinator and knowledge of the market, providing to the Steering Committee quarterly reports of potential areas of exploitation and exploitation opportunities for technological results and clinical knowledge generated in the project. The Steering Committee will then decide on additional exploitation activities in its regular meetings.

The Exploitation Manager will coordinate discussions between partners and the Steering Committee on the protection of Intellectual Property. This is to ensure that appropriate protection is obtained prior to publication and that knowledge rights are assigned appropriately to partners. IPR protection within the consortium is covered in the Grant Agreement and Consortium Agreement. In order to make full use of the project's IPR potential, an IPR Directory will be maintained by the Exploitation Manager. It will list all relevant items of knowledge relating to the project and make clear for each item including a) the owner, b) the nature of the knowledge and its expected exploitation potential, c) the current status of the knowledge e.g. patent applications, access rights, use plans, dissemination plans, and d) actions required for the item.

Consortium Agreement: Before the project starts, the consortium members will sign a formal Consortium Agreement (CA) in which roles, responsibilities and mutual obligations will be defined. Major issues are the definition of the General Assembly (such as representation, delegation, and quorum), IPR regulations (pre-existing knowledge), financial payment mechanisms (result depending payment release) as well as escalation strategies. All partners will sign it before project start and the EC contract is signed. The CA will follow the DESCA Horizon 2020 Model Consortium Agreement.

Conflict Resolution Processes: Special focus will be kept on areas that most likely might lead to conflicting situations. Decision-making processes within the consortium will aim to build consensus and

avoid situations whereby the activities of one partner have adverse effects on the activities of another. In the event that disputes or differences arise that cannot be resolved, the following process will be followed. Diverging views on project roll-out strategies, encompassing medium-term objectives and longer term exploitation policies. Such situation will be first aimed to be solved via SC mediation; if no satisfactory solution can be achieved it will be passed to the GA. If no consensus might be achieved, the voting mechanisms specified in the consortium Agreement will lead to a decision. Diverging views on technical assessments, choices and implementation routines, development procedures or similar problems will mainly fall in the competence of the work package leader. The SC will support to find a consensus by a thorough technical evaluation and provide a recommendation. Is still no agreement possible, the project manager will take the responsibility to get an external and independent expert as a referee whose judgement will be presented to GA.

Planning and Reporting: All formal meetings will be announced at least two weeks in advance. Agenda, proposed resolutions, decisions and supporting documents will be provided at least one week before the meeting. Issuing all documents will be the responsibility of the project manager. All meetings will be formally documented and minutes will be provided within one week after the completion of the meeting. The project coordinator will collect internal reports, working papers, deliverables and cost statements. Technical reporting will be collected from the work package leader on a three-monthly basis including progress status, resources spend, estimation about time and person month needed to complete work, report on the compliance with the work plan, pointing out any deviations. Administrative information will be collected by all partners on a three-monthly basis involving spent resources on task level. Financial information will be collected at the end of each reporting period by the coordinating partner. All reported figures and results will be evaluated through comparison to the initial plan.

Communication: Templates and a collaborative infrastructure will be provided by the project coordinator, this will include conferencing tools, file-sharing systems, email-groups, reporting templates and a project monitoring cockpit that shows the project status to all project members. A secure document server will be set up to serve as an information resource for contractual and financial information, minutes of meetings, progress reports, etc. and correspondence between the Coordinator and the Commission and Reviewers. Further to this, specific tools for collaborative software development will be introduced such as an issue tracker and a versioning system for source codes.

2.3.2.4 Project Management Contact Persons

The following list indicates the responsible contact persons for setting up project management: FRAU: Stephan Kiefer, FORTH: Dr. Kostas Marias, USAAR: Prof. Norbert Graf, PHILIPS: Dr. Anca Bucur, CI-eCANCER: Prof. Dr. Gordon McVie, BED: Prof. Dr. Feng Dong, IEO: Prof. Gabriella Pravettoni, SGS: Mr Ralph Stock.

2.3.2.5 Milestones and Project Risks Management

The critical path of the project is indicated in Table 2.3.2 a: List of milestones in a form of milestones list. The iManageCancer project presents a certain number of risks that are inherent to the nature of an international collaborative project and to our ambitious objectives and the work planned by the partners. It is of high importance that those risks are clearly identified, assessed, and suitable counter measures are in place. Potential risks can be classified into:

- Partner problems (e.g. a partner is underperforming or a key partner is leaving the project)
- Expertise risk (e.g. a key person with a specific expertise is leaving the project)
- Project execution risk (e.g. key milestones or critical deliverables are delayed)
- Agreement risk (e.g. consortium partners cannot agree because of different interests)
- Technological and data risks (e.g. key technologies or data are not available at the expected time)
- Dissemination/exploitation risks (e.g. no major customers for using the results are found)
- Market and user related risks (e.g. the market environment changes and makes the results obsolete)
- Competition risks (e.g. a competing solution comes up and makes the results less valuable).

Several of these potential risks can be assessed concerning their probability and level of impact. Risks with a high probability and a severe impact are handled with particular caution during the project. Distinct measures are foreseen to meet these risks accordingly. Details can be found in Table 2.3.2 b: Critical risks for implementation. A risk assessment procedure will be implemented whereby further risks will be identified and categorised. A special on-going review of the most critical risks will be undertaken in the internal reporting structure of the project together with contingency planning. A separate section of the quarterly report will be constructed for this purpose.

Table 2.3.2 a: List of milestones

Milestone number	Milestone name	Related work package(s)	Estimated date	Means of verification
1	Critical system design revision	WP3	Month 9	D3.1 'Initial iManageCancer architecture document' available and accepted by Steering Committee
2	Initial iManageCancer platform prototype offering basic functionality	WP3, WP4-WP8	Month 21	Software released for initial testing in workshops. Related deliverables submitted.
3	Extended integrated prototype of iManageCancer platform	WP3, WP4-WP8	Month 30	Software released for clinical validation. Related deliverables submitted.
4	Evaluated pilots	WP9	Month 42	Evaluation report of pilots available (D9.4)

Table 2.3.2 b: Critical risks for implementation

	Description of risk	Nature[95]	Proposed risk-mitigation measures
1	One or more partners are not able or not willing to perform their duties at all, in part or in time. The quality of a result of a task is not sufficient. *(Partner Problems / Expertise Risk)* **Probability**: Low **Impact**: Severe **Involved WPs**: All	CR	First of all, this risk is limited as only well-known partners have been invited to join iManageCancer and they have experience in working together in other projects. Moreover, partners overlap in critical competences to reduce the impact in the unlikely event that problems arise with a partner. Expertise risk has been addressed by appointing a scientific manager, who has to observe expertise issues and react accordingly. However, in case of such problems the Coordinator specifies a clear and fair time limit for improvement after consulting the WP leaders. In case of failure the conflict resolution procedure will be applied all consequences as described in detail in the consortium agreement.
2	One partner withdraws from the project *(Partner Problems / Expertise Risk)* **Probability**: Low **Impact**: Medium **Involved WPs**: All	CR	Partners overlap in critical competences to reduce the impact in the unlikely event that problems arise with a partner. The partner will be replaced as soon as possible in accordance with the Commission. If the partner's responsibilities cannot be delegated to other partners in the consortium a new partner will be included in the consortium applying the respective procedure of the Commission.

[95] **CR**: Consortium related Risk, **STR**: Scientific and Technological Risk, **RFR**: Resources and Financial Risk

3	Over-spending or under-spending by a partner *(Project Execution Risk)* **Probability**: High **Impact**: Low **Involved WPs**: All	RFR	In both cases the coordination will ensure that the corresponding institutes give proper justification. Failure, for a given institution, to justify the over- or under-spending may results in a budget reallocation of it resources to other partner institutes in the project, in accordance with the general rules defined in the consortium Agreement.
4	Consortium partners cannot agree because of different interests *(Agreement Risk)* **Probability**: High **Impact**: Medium **Involved WPs:** All	CR	The implementation of various communication systems will meet this risk in order to generate a common understanding. In case there is a real conflict of interest, the provided conflict resolution process from the previous section will be used.
5	HealthAvatar PHR is not available at the expected time and pilots cannot start. *(Technological Risks)* **Probability**: Low **Impact**: Medium Involved WPs: **WP4, WP9**	STR	This risk has been addressed by appointing a technical manager, whose task is to ensure a safe technology selection. Beside this defined process, all partners are well experienced and have a long history in the field. In case of different judgement of technology the conflict resolution process from the previous section will be used.
6	Predictive models for chemotherapy monitoring can't be created due to insufficient data at the clinical sites. *(Technological Risks)* **Probability**: Medium **Impact**: Low **Involved WPs:** WP5, WP9	STR	Feasibility of such a model has been investigated in advance through previous research. The variables of such a model are subject to the research for model development. Toxicity data on chemotherapy treatment from 4200 patients is available at IEO. In case further data is needed the clinical site for the third pilot will be selected according the availability of such data.
7	System integration and interoperability is too difficult/ complex to achieve. *(Technological Risks)* **Probability**: Low **Impact**: High **Involved WPs:** WP3	STR	The partners involved in WP3 are all well experienced and have a long history in the integration and interoperability from other projects.
8	Delay of the evaluation results *(Technological Risks)* **Probability**: Low **Impact**: High **Involved WPs:** WP9	STR	All partners are quite experienced in the field to ensure no delay in the evaluation results. Also, evaluation activities will be implemented using a tight co-operation with the support of development teams. Finally whenever possible preliminary prototypes will be planned to avoid this delay.
9	No major customers for using the results are found *(Dissemination / Exploitation Risks, Market and User related Risks)* **Probability**: Medium **Impact**: Medium **Involved WPs:** WP10	STR	This risk has been addressed by appointing a quality manager. It's his responsibility to identify this risk in an early stage and suggest reasonable actions. In terms of conflicting interests the conflict resolution process from the previous section will be used.
10	Not all participating users accept to use our solution. *(Dissemination/ Exploitation Risks, Market and User related Risks)* **Probability**: Low **Impact**: Medium **Involved WPs:** WP9	STR	Early involvement of the end-users, intensive cooperation during the design phase and the explanations of the reasons behind the installation of such a system will be performed by the use case partners.

11	The outcome platform is not compliant with European regulations or the pilots are not authorized by the ethical committees of the institutes of the medical partners. **Probability**: Low **Impact**: High **Involved WPs:** All WPs related to software development (WP3 to WP8) and WP9 (Pilots)	STR	Due to their nature and the safety risks some of the tools may be considered as medical devices according to European regulations. Compliance need to be ensured and risk management will be implemented in the software development process according to ISO 14971 as the basis for compliance with regulations. Clinical pilots will be designed in a way that risks to patients are excluded as far as possible. A contingency budget is reserved for eventually required services of Notified Bodies or other authorities.
12	A competing solution comes up and makes the results less valuable *(Competition Risks)* **Probability**: Low **Impact**: Medium **Involved WPs:** WP10	STR	All project partners are well situated within their respective research community and therefore have a detailed knowledge on current streams/trends in research. The scientific manager will coordinate partners in keeping current with similar approaches and potential competition.

2.3.3 Consortium as a whole

iManageCancer targets a specific research goal in a sharply focused approach while at the same time it includes a coherent set of activities dealing with multiple issues related and providing state-of-the-art responses to the main challenge identified in the call, i.e. the personalisation of care for the cancer patient, self-management of certain aspects of the disease and the empowerment through ICT technologies. Special emphasis is given in making sure that the supporting technological infrastructure offering tools, services and applications to be developed in iManageCancer, will also be evaluated on their effectiveness and their ability to interface with existing clinical practices and provide added value within the context of the project's pilots. *In order to build, verify and demonstrate the proposed solutions, iManageCancer has brought together 8 leading organisations from 5 European countries*. The collective expertise, commitment and prior research track record of these organisations, which were specifically selected for their diverse experience and essential competencies as well as for their complementarity, guarantee the successful outcome of the proposed project. The ICT partners have already demonstrated excellence by either coordinating or participating in most of the recent cancer related FP7 projects. This has been an important criterion in defining the iManageCancer team, since proven experience is compulsory in order to be able to drive ICT technologies towards the actual empowerment of the patient in self-managing his/her disease, as is required in the call.

The clinical partners USAAR and IEO have been selected for evaluating the platform by engaging cancer patients, and for paving the way to the wider adoption in Europe for the benefit of the patient. As advocates of the patients for their closer participation in decision making in the healthcare process and for their empowerment USAAR and IEO have contributed the main ideas for the iManageCancer project. They have evolved "bottom-up" over a significant period of time, as a result of experiences and R&D results from previous national and EU projects.

The consortium comprises relevant partners and stakeholders from ICT organizations, clinical organisations, academic and research institutions, as well as big industry (PHILIPS) and specialised SMEs (CI-eCANCER, SGS). All these diverse organisations are needed in order to build and verify the envisaged computational and service delivering environment of the iManageCancer project. A key role for the exploitation of the platform and the development of a surrounding ecosystem of stakeholders is given to CI-eCANCER which offers with its internet services ecancer.org and ecancerpatient.org excellent communication and dissemination channels to the project.

Successful completion of the iManageCancer work plan and realization of its objectives requires the concurrent presence (and obviously successful collaborative, interdisciplinary work) of a diverse set of expertise. Specifically:

1. *CLINICAL RESEARCH*: The development and implementation of useful mHealth tools for the empowerment and engagement of cancer patients in the management of their disease requires the strong

participation and guidance of clinical experts to ensure that tools are built on evidence base and to assess their acceptance and efficacy in clinical pilots. USAAR and IEO provide that deep clinical knowledge on cancer management to carry out the required clinical research and guarantee patient participation in the design and evaluation of the iManageCancer Platform.

2. *COGNITIVE SCIENCES*: Research in the cognitive and psychological dimensions involved in medical decision making processes is required to develop effective ICT based decision aids for patients and psycho-emotional assessment tools. IEO represented by a respective research unit on cognitive sciences together with FORTH have already demonstrated in previous collaborative research the successful development of ICT based instruments for the monitoring of the psychological dimension of the disease and for patient empowerment.

3. *HEALTHCARE ICT*: In the Healthcare ICT section, the project requires knowledge and expertise in healthcare information technology, healthcare related standards, and methodological approaches to semantic interoperability. A number of such organisations have been selected with a proven track record of involvement in such R&D activities. Philips, FRAU FORTH, and BED have a proven record of healthcare ICT development. They are also strongly linked and contributors to key standardisation activities, such as CEN, HL7, IHE. Also, significant expertise on Semantic Web Technologies, CEN 13606 and HL7 standards, and Semantic Interoperability in e-Health is available.

4. *SERVICE ORIENTED R&D*: Taking into consideration that our ambition is to deliver a functional platform for cancer self-management and empowerment of cancer patients, the obvious architectural choice is a "service oriented approach". A number of iManageCancer partners have demonstrable experience in developing state-of-the art SOA compliant solutions in healthcare. Philips, FORTH, and FRAU are such partners.

5. *PATIENT EMPOWERMENT AND CLINICAL DECISION SUPPORT TECHNOLOGIES:* PHILIPS, FRAU and FORTH have extensively worked in related EC projects (including ACGT, INTEGRATE, smartHEALTH, d-LIVER and p-medicine) where they have collected significant expertise for the development for predictive models and decision support tools in oncology, but more importantly for their clinical use and eventual translation within the wider VPH European efforts. In this sense, the consortium as a whole, has the expertise needed to tackle all the ICT issues including data integration/sharing, security and tools/services that surround the development of predictive models, decision aids and improved therapy of cancer within an iManageCancer ICT environment.

6. *mHEALTH TECHNOLOGIES:* Significant experience is required in the domain of mobile health for this project in order to ensure that self-management tools and services of iManageCancer are available for smartphones and tablets of patients and can leverage the advantages of these platforms to access Internet anywhere at any time and to easily integrate with external sensors ad devices. FRAU has a track record in developing mobile disease management solutions and personal health systems incorporating decision support and guidance for patients and doctors.

7. *SERIOUS GAMES DEVELOPMENT:* Serious games represent an important instrument to strengthen self-efficacy of patients in their fight against cancer and their knowledge in clinical interventions and the management of side effects of the therapy. Experiences in the design and implementation of games related to health is required to ensure an attractive immersive gaming experience by the user. With SGS the consortium has identified a SME with successful health related games solutions on the market. This expertise is complemented by academic experiences of BED on visual analytics technologies.

8. *EXPLOITATION:* Realizing the huge exploitation potential that lies behind the iManageCancer scientific and technological objectives has also been at the centre of our strategic planning for the consortium. In maximizing this potential we have selected, PHILIPS and CI-eCANCER to undertake this important task. PHILIPS considers iManageCancer project as a strategic initiative and opportunity to take Clinical Decision Support Systems from research to care and is interested in exploitation of results. CI-eCANCER provides with its ecancer information services a unique communication and dissemination channel to the project to develop an ecosystem of stakeholders around the platform for the exploitation of its results. CI-eCANCER represents with its internet service ecancerpatient.org **task is the resolution of heterogeneities** also an important stakeholder for the exploitation of iManageCancer platform as part of its on-line services for cancer patients. In addition, the consortium has already led the basis for cooperation with relevant EU and international projects and initiatives. To this end we have setup an External

Advisory Panel, which will include stakeholders to assist in building an ecosystem and transferring our results to the clinic and to the market.

Expertises and roles of the participants

The participants, as well as their role, skills and experience are described in detail in Table 2.3.3.a, which follows below.

Table 2.3.3.a: Consortium Overview

Partici-pant	Type	Country	Expertise	Role in the project
FRAU	RES	D	Personal health systems and technologies, disease management platforms, integrated decision support solutions. Service oriented architectures and semantic biomedical data integration, service oriented architectures,	FRAU will be the official coordinator and manager of the project towards the EC. FRAU and FORTH will jointly coordinate the research activities of iManageCancer and will lead in particular the system development. In consequence, FRAU leads WP2 on system design and integration. FRAU will also lead the activities in WP5, where FRAU contributes the decision support engine, develops the knowledge base in collaboration with clinical experts and implements associated mobile tools for medication management, patient enquiry and decision aids for consultation. In addition, FRAU integrates off-the-shelf devices for the monitoring of life style and health related parameters in the iManageCancer Platform.
FORTH	RES	GR	Innovative computer methods and tools in medical informatics and computational oncology. Service oriented architectures, standards and component based SW integration, Bioinformatics, Social and semantic web technologies. Medical imaging and bioinformatics.	FORTH assists FRAU in coordinating the research activities of iManageCancer and will guide in particular the system development with Dr. Kostas Marias as the Technical Coordinator. FORTH will lead WP8 on smart analytical data services based on the experience from a number of EC project including p-Medicine and TUMOR. Furthermore, FORTH, working on Personal Health Record systems in several projects such as p-Medicine, eHealthMonitor and EURECA will rapidly respond to the occurring needs for diary-like representation of information and providing relevant, personalized information to patients. FORTH will also work on a number of tools related to the assessment of the psycho-emotional status of the patient and his health and lifestyle (WP6) Finally, FORTH will also be involved in system integration and semantic interoperability based on the experience of a number of EC projects including ACGT, p-Medicine, EURECA and eHealthMonitor
USAAR	RES	D	Paediatric oncology, clinical cancer research and care, clinical trial management, patient empowerment, ICT tools for cancer research, decision support and patient empowerment.	USAAR is leading WP2 (User Requirements) and is enrolled in WP5 (Central decision support and guidance system) leading the task for knowledge engineering, WP7 (Serious games for self-management) leading the task for analysis of existing serious games for cancer patients and the theoretical background, WP8 (Smart analytical data services), WP9 (Pilots and their evaluation) leading the task for pilots for children.

Partici-pant	Type	Country	Expertise	Role in the project
PHILIPS	IND	NL	Clinical technology, clinical information systems, bioinformatics, information integration, domain modelling, medical imaging, standardization and interoperability, semantic web.	Philips will develop models and a corresponding software component for the prediction of adverse events during chemotherapy in the context of WP5. It will also contribute to the development of health assessment tools related to chemotherapy monitoring. Philips will also contribute to the elaboration of sustainability and exploitation strategies for wider adoption of CDS technologies.
CI-eCANCER	IND	UK	Cancer research, community websites, dissemination and exploitation activities	As the publisher of ecancer and eCancerpatient CI-eCANCER place a central role in the strategies and activities for dissemination, communication and exploitation of the project's results and leads the corresponding work package (WP10). Due to its background in cancer research and patient empowerment CI-eCANCER will also support the preparation und conduction of the pilots on adult cancer patients.
BED	RES	UK	computer graphics, computer animation and visualisation, personal health records, user interface design, eHealth	BED will contribute visual analytics techniques to the project (WP4, WP5, WP8) and will lead WP4 for the provision of the interactive PHR health avatar. It will further support the development and integration of serious games.
IEO	RES	IT	Cognitive sciences, cancer patient empowerment and personalised medicine, psychological components related to use of ICT for cancer patient self-management, strategies to support patients in adopting healthy life-styles	IEO has extensive expertise in the study of psychological aspects related to cancer screening and prevention, and to health-related behaviours. IEO's role will be design and help create tools for patient empowerment. The competences on the cognitive processes of decision-making allows interfacing with more technical partners in order to develop decision aids taking into account not only normative decision rules, but personal values as well. Also, IEO's documented experience with ICT for cancer disease management will bevery important for assessing the impact of iManageCancer on patients' and family w.r.t. well-being and quality of life in the clinical pilots. IEO will conduct small-scale pilots with patients with prostate cancer, lung and breast cancer.
SGS	IND	D	game based learning solutions and serious games for different sector including health, game concept design, 3D/2D graphics design, animation design	Due to the business focus of the company SGS leads the gamification aspects of the project (WP7) where it contributes an adventure game for children to actively fight their cancer. As an SME partner SGS is also involved in the exploitation activities of the project.

Complementarity between participants

Each of the partners of the project has been selected in a way that ensures that the full spectrum of skills and expertise required for carrying out the proposed project are present in the iManageCancer consortium. It must be emphasised once again that the partners were selected to be complementary in terms of their skills and knowledge, as well as for the role they will play within iManageCancer. Each partner has an impressive track record in knowledge creation and innovation in their respective domains of expertise. As a result, the partners that have been included in the consortium were selected, based on their ability to add value to the project, through their commitment to joint innovation at a Pan-European level, their specific knowledge, and their capacity for bringing ICT technology to validation and adoption. This plan also incorporates the extensive experience and knowledge of the other members of the consortium in participating in previous EU framework programmes.

These points become more evident from the short description of roles, expertise and experience which are presented in Table 2.3.3.a. Moreover, Table 2.3.3.a clearly highlights the roles and the functions (responsibilities and involvement) of each participant in the iManageCancer activity. The more extensive profiles of the partners of the iManageCancer project, as well as the short CVs of key personnel from all project participants are presented in Section 2.3.4.1. Figure 8 graphically depicts the areas of expertise that are needed to materialise the goals of the iManageCancer workplan and highlights the partners who have proven expertise in these domains.

As previously mentioned, we have taken special care in selecting our clinical partners. The most important criteria for their selection were: (a) clinical involvement with cancer patients, (b) willingness to enrol patients in the project and participate in the evaluation of the platform, (c) innovation in research methodologies and methods for personalised medicine and patient empowerment (d) adherence to and compliance with legal and ethical issues. Finally, it is our experience that an additional attribute that in many cases influences the success of a project is the ability of the various partners to function together as a coordinated and coherent group and perform high-level collaborative research.

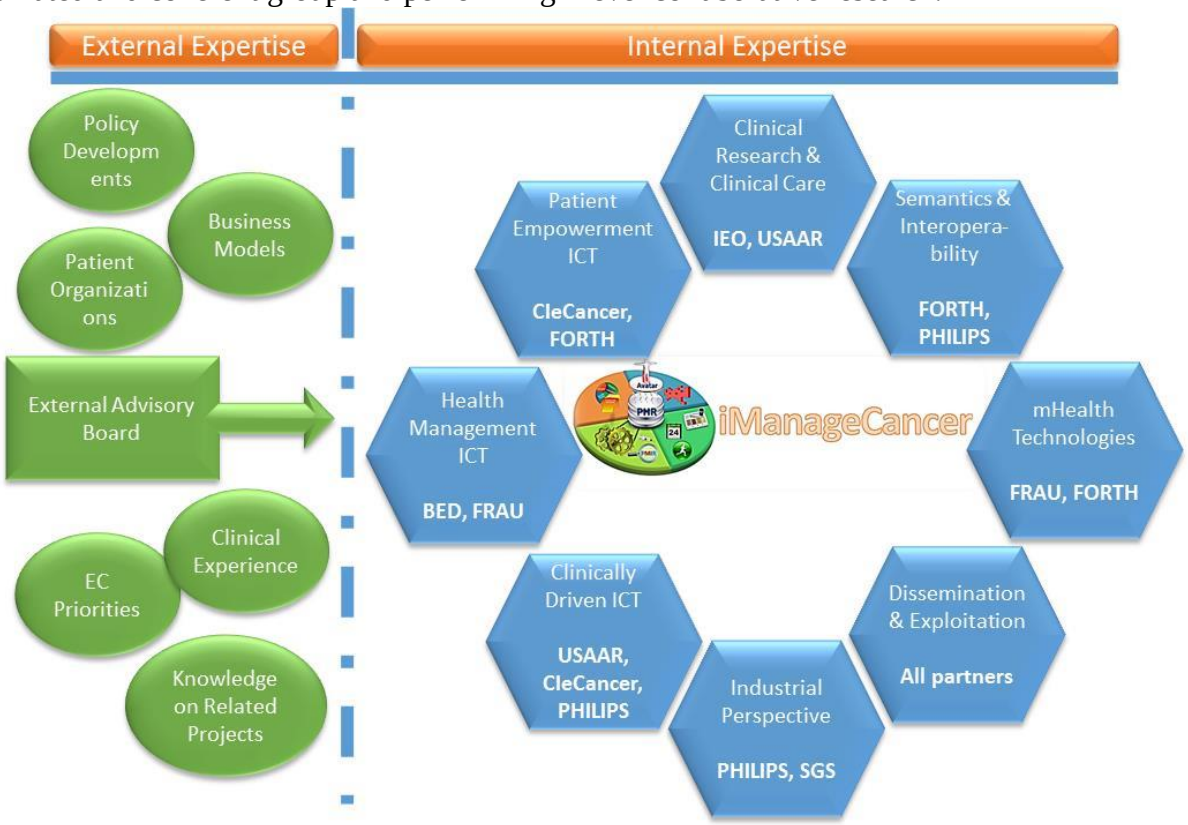

Figure 8. iManageCancer Consortium Expertise Overview

To this end, the partners in the iManageCancer Consortium have a proven ability to working together having successfully collaborated in a number of related flag-ship FP7 projects on cancer. The strong leadership of the project will also assist in further developing the "collaborative innovation culture" of the consortium. The project coordinator, with the support of the very experienced partners (such as FORTH, USAAR and CI-eCANCER), will focus on efficient, effective accomplishment of planned tasks, including proper handling of the consortium agreement, intellectual property rights, etc. Last, it is important to mention that members of the iManageCancer consortium are/were also key participants/co-ordinators in the following ICT cancer related projects funded by the European Commission: p-medicine, ACGT, ContraCancrum, TUMOR, EURECA, smartHEALTH, INTEGRATE and CHIC. These projects address the cancer domain in particular.

Industrial participation and involvement of SMEs

Industrial involvement in this activity will drive exploitation of the results of iManageCancer. Three of eight partners come from the industry, two of them represent SMEs.

CI-eCANCER has been selected as the strategic partner for dissemination, communication and exploitation of the project's results due to its leading position in Europe in the electronic information market for the academic cancer community and for patients which is clearly reflected in the project's dissemination and exploitation activities. Together with PHILIPS they form a tandem to identify and assess exploitation routes, market opportunities and potential service and business models.

The participation of PHILIPS as the industrial partner for the development of the iManageCancer Platform ensures that the focus is placed on creating innovations with relevance for the market and with industrial quality. **With Serious Games Solutions GmbH** also a specialist SME is involved taking the lead in gamification aspects of the platform and providing an exploitation routes for the games developed in the project that will strengthen its position on the market.

Third party support and subcontracting

No third party support is planned. However, a contingency budget is reserved under the budget of the Coordinator to serve the exploitation and dissemination strategy of the project by extending the pilots to another site. We will initiate another clinical pilot after the initial platform prototype has successfully passed the first assessments in the Italian and German pilot site. The new pilot site will be selected depending on the needs of the projects regarding validation and dissemination of the technology. It is envisaged to involve the clinical site as full partner to the maximum benefit of the project.

Other Countries

No Other Countries will be involved as beneficiaries.

2.3.4 Capacity of participants and links to third parties

2.3.4.1. Participants (applicants)

Name	**1) Fraunhofer Gesellschaft für Angewandte Forschung e.V. (FRAU)** Fraunhofer Institute for Biomedical Engineering		
Country	Germany	**Type**	Research Organization
Organization Description	Fraunhofer-Gesellschaft (FRAU) undertakes applied research to drive economic development and serves to wider benefit of society, and also maintains more than 80 research units in Germany, including 60 Fraunhofer Institutes with over 20,000 qualified scientists and engineers and the annual research budget of €1.8 billion. The Fraunhofer Institute for Biomedical Engineering (IBMT) is one of the six institutes of the Alliance Life Sciences of the Fraunhofer-Gesellschaft. The institute conducts r+d activities in the areas of biomedical and medical engineering, molecular and cellular biotechnology and biohybrid technology, cryobiotechnology and nanobiotechnology, ultrasound technologies, as well as medical sensor technology, biomedical informatics and e-health. IBMT provides and maintains IT-infrastructures for e-health, telemedicine, biobanking and clinical cancer research. IBMT develops advanced IT-platforms for mobile & home based disease management with integrated decision support and personal electronic health record linked to e-health infrastructures. Among others, IBMT developed in collaborative European research the d-LIVER disease management platform LPMS with integrated decision support and guidance for patients and doctor to support the management of chronic liver diseases at home, but also SmartHEALTH, an intelligent biodiagnostic POCT platform for cancer markers. IBMT's Department Laboratory and Information Technologies will contribute in particular its expertise on smart personal health systems with integrated decision support to the project, to provide the Care Flow Engine with its knowledge base for the self-management and cooperative		

	management of cancer diseases. **Roles and main tasks in the project:** FRAU will be the official coordinator and manager of the project towards the EC. FRAU and FORTH will jointly coordinate the research activities of iManageCancer and will lead in particular the system development. In consequence, FRAU leads WP2 on system design and integration. FRAU will also lead the activities in WP5, where FRAU contributes the decision support engine, develops the knowledge base in collaboration with clinical experts and implements associated mobile tools for medication management, patient enquiry and decision aids for consultation. In addition, FRAU integrates off-the-shelf devices for the monitoring of life style and health related parameters in the iManageCancer Platform.
Relevant skills, experiences, technologies and previous projects	**Relevant Publications** • Kiefer S., et al.: "A novel approach to integrated decision support and guidance in personal health systems for disease management"; MIE2014 conference proceedings (submitted) (2014) • Ali S., Kiefer S.: "µOR – A Micro OWL DL Reasoner for Ambient Intelligent Devices", In Proc. of 4th International IEEE Conference on Grid and Pervasive Computing, Geneva, Switzerland, Lecture Notes in Computer Science 5529, 305-316 (2009) • Ali S., Kiefer S.: "Semantic Coordination of Ambient Intelligent Medical Devices – A Case Study", In Proc. of ACM SIGCHI, IEEE, EMB International Conference on Pervasive Computing Technologies for Healthcare, London , UK (2009) • Kiefer S., Schäfer M., Ali S., Ruff R., Hoffmann K.-P.: „Personal Healthcare Systems for Stroke Rehabilitation – Experiences from Pilot Projects". In Proc. of Ambient Assisted Living, 1st German AAL Congress 2008, Berlin, Germany 357–361 (2008) • Schera F., Weiler G., Neri E., Kiefer S., Graf F.: "The p-medicine portal – A collaboration platform for research in personalized medicine". ecancer Medical Science Journal 8 398 (2014) **Relevant projects/activities** • FP7-ICT-2010.5.1–270089 d-LIVER - ICT-enabled, cellular artificial liver system incorporating personalized patient management and support; 10/2011 – 9/2015; http://www.d-liver.eu/ Technology to be exploited in iManageCancer: Integrated clinical decision support system and personal health manager app; • FP6-ICT-NMP–2-016817 smartHEALTH – Smart biodiagnostic devices for cancer marker analysis; 2/2005 – 5/2010; http://www.smarthealthip.com/ • FP7-ICT-2007–1–216461 CHRONIOUS - An Open, Ubiquitous and Adaptive Chronic Disease Management Platform for COPD and Renal Insufficiency; 2/2008 – 5/2012; http://www.chronious.eu/ Technology to be exploited in iManageCancer: Semantic clinical literature search engine
Key Personnel	**Stephan Kiefer**, male, has received his diploma degree in informatics from the University of Saarland, Germany in 1991. He joint Fraunhofer already as a student and works as a scientist in the Institute for Biomedical Engineering (IBMT) since 1991. In his early years at Fraunhofer he developed embedded medical devices and

	industrial sensory systems. Among others, he became an expert in advanced signal processing methods with a focus on neural networks and fuzzy logic. In 1998 he became responsible for a working group in telemedicine and home monitoring solutions. In this position he leaded pioneering national innovation and pilot projects for the rehabilitation of stroke patients at home. He was the architect of various personal health systems for disease management developed by IBMT in the context of European ICT research. His expertise includes among others data fusion and analysis, innovative information technologies for home-, mobile- and telemedicine applications, clinical decision support, semantic biomedical data integration, e-infrastructures for biomedical research and integrated biobanking solutions. Stephan Kiefer has now more than 18 years of experience in coordinating and contributing to national and international r+d projects and pilot trials in the area of e-health and biomedical informatics. Among others, he coordinated the FP5 ICT project TOPCARE and the European Latin-American telemedicine pilot project T@lemed. He further leaded the ICT development in several integrated FP6 and FP7 projects like SmartHEALTH and d-LIVER and contributed as an expert to FP7 road mapping activities for innovative personal health systems (PHS2020). In his current position as group manager for Smart Health Information Systems he is responsible for ICT driven innovations in e-health and e-infrastructures for biomedical research. **Dr. Gabriele Weiler** holds a PhD in computer science from the University of Kaiserslautern and a diploma degree in medical informatics from the University of Heidelberg. She joined IBMT at 2005 and works there as a postdoctoral researcher at the health information systems group. She has worked in several European research projects in the biomedial domain including p-Medicine, EURECA, Chronious and ACGT. Her research interests focus on applications of semantic technologies in healthcare, data consistency checking, semantic integration, decision support and design and development of health information systems. **Michael Schäfer** studied applied informatics at the Hochschule für Technik und Wirtschaft des Saarlandes where he received his diploma in 2000. He joined IBMT already during his studies and works there as a senior software engineer in the department Laboratory and Information Technologies. He develops software applications for embedded and wearable personal health systems as well as for telemedicine platforms on various operating systems in international and national r+d projects.

Name	**2) Foundation for Research and Technology Hellas FORTH** Institute of Computer Science		
Country	Greece	**Type**	Research Organization
Organization Description	The Institute of Computer Science has a recognized tradition in conducting basic and applied research, developing applications and products, providing consulting services, and playing a leading role in ICT in Greece and internationally. The mission of the Computational Medicine Laboratory (CML) is to develop novel ICT technologies in the wider context of predictive, individualized, preventive and participatory (the P4) medicine aiming at a)the semantic interoperability of biomedical data tools and models for enhancing biomedical knowledge discovery b) the optimal management of chronic diseases (such as diabetes, cardiovascular disease) c) the optimization of diagnosis and treatment through the development of novel predictive models, medical imaging analysis and clinical decision support tools and d) the implementation of well-established in silico methods and tools towards		

	novel approaches that could be incorporated in the medical clinical research. The CML laboratory is coupled with the Center for eHealth and Applications and Services for evolving R&D results into commercial products focused on Integrated Care Solutions. In the last 7 years, CML has received research funding exceeding 4 M€ and participated in more than 40 European and National research projects. **Roles and main tasks in the project:** FORTH assists FRAU in coordinating the research activities of iManageCancer and will guide in particular the system development with Dr. Kostas Marias as the Technical Coordinator. FORTH leads WP8 on smart analytical data services and contributes tools to the platform like the Personal Medical Information Recommender, the eDiary and the psycho-emotional assessment tool.
Relevant skills, experiences, technologies and previous projects	**Relevant Publications** • Kondylakis, H., Kazantzaki, E., Koumakis, L., Genitsaridi, I., Marias, K., Gorini, A., Mazzocco, K., Pravettoni, G., Burke, D., McVie, G., Tsiknakis, M., Development of Interactive Empowerment services in support of personalized medicine, *eCancer Medical Science Journal*, 8, 400, 2014. • Kondylakis, H., Koumakis, L., Tsiknakis, M., Marias, K., Genitsaridi, I., Pravettoni, G., Gorini, A., Mazzocco, K., Smart recommendation services in support of patient empowerment and personalized medicine., *Multimedia Services in Intelligent Environments – Recommendation Services* , 2013 • Genitsaridi, I., Kondylakis, H., Koumakis, L., Marias, K., Tsiknakis, M., Evaluation of Personal Health Record Systems through the Lenses of EC Research Projects, *Computers in Biology and Medicine Journal*, 2013. • Maniadi, E., Kondylakis, H., Spanakis, E.G., Spanakis, M., Tsiknakis, M.N., Marias, K., & Dong, F. (2013). Designing a digital patient avatar in the context of the MyHealthAvatar project initiative. *13th IEEE International Conference on BioInformatics and BioEngineering (BIBE) 2013*. • Kondylakis, H., Koumakis, L., Genitsaridi , E., Tsiknakis, M.N., Marias, K., Pravettoni, G, Gorini, A., & Mazzocco, M. (2012). IEmS: A collaborative Environment for Patient Empowerment. *IEEE International Conference on BioInformatics and BioEngineering (BIBE), 2012*. • Kondylakis, H., Plexousakis, D., Exelixis: Evolving Ontology-Based Data Integration System, *SIGMOD Conference*, 2011. **Relevant projects/activities** • MyHealhAvatar - A Demonstration of 4D Digital Avatar Infrastructure for Access of Complete Patient Information (FP7-ICT-2011-9) • EURECA - Enabling information re-Use by linking clinical REsearch and CAre (FP7-ICT-2011-7) • p-MEDICINE - From data sharing and integration via VPH models to personalized medicine (FP7-ICT-2009.5.3) • eHealthMonitor - Intelligent Knowledge Platform for Personal Health Monitoring Services (FP7-ICT-2011-7) • Integrate - Driving Excellence in Integrative Cancer Research through Innovative Biomedical Infrastructures (FP7-ICT-2009.5.3)

Key Personnel	**Dr Kostas Marias** is a Principal Researcher in ICS-FORTH and was previously a Researcher at the University of Oxford, where he completed his PhD in Medical Image Analysis/ Medical Physics. He was also a senior consulting scientist with the diagnostic software company Mirada Solutions Ltd. (UK), a spin-off from the University of Oxford. He has an MSc in Physical Science and Engineering in Medicine from Imperial College, UK and an Electrical Engineering Diploma from the National Technical University of Athens (NTUA). Currently he is the coordinator of 2 EC projects on cancer modelling (ContraCancrum and Tumor) and is actively involved in providing open access image analysis/modelling tools in the clinical setting for the promotion of predictive oncology. He has published more than 80 papers in international journals and conference proceedings in the above fields. **Dr. Haridimos Kondylakis** is a postdoctoral researcher with the CML. He received his PhD degree in Computer Science from the Univ. of Crete. His research interests span the following areas: Semantic Integration; Knowledge Evolution; Applications of Semantic Technologies to eHealth Systems; Personal Health Systems. He has extensive experience in participating in European Projects and he has more than 35 publications in international conferences, books and journals. **Dr. Lefteris Koumakis** received the B.Sc. degree in Computer Science, in 2001, from the University Of Crete, the M.Sc. degree in Computer Science, in 2004, and the PhD degree from the Production Engineering and Management School of Technical University of Crete, in 2014. Since 2005 is collaborating with the CML of FORTH-ICS. His research interests focus on intelligent data-analysis and mining of clinical and genomics data, clinical decision support, personal health systems and cognitive linguistics. He has participated in various international and national R&D projects including InfoBioMed, ACGT, GEN2PHEN, P-Medicine, Eureca and ENCCA.

Name	**3) Saarland University (USAAR)**		
Country	Germany	**Type**	Research Organization (University)
Organization Description	The Saarland University was founded in 1948 in co-operation with France. Today the University counts 15.500 students of whom 7 percent are foreign students. The Saarland University has 8 faculties and provides the broad spectrum of disciplines typical of a classical universitas litterarum. At the Faculty of Medicine (University Hospital), located in Homburg / Saarland more than 1800 people are studying medicine. There are 36 hospitals or institutions treating more than 54.000 inpatients and nearly 190.000 outpatients each year. Participant from the Saarland University is the department of Paediatric Oncology and Haematology responsible for the care of children and teenagers with cancer in the Saarland and the surrounding area. The focus in research of the Department of Paediatric Oncology and Haematology is nephroblastoma (clinical study and trial and basic research in cooperation with different institutes) and brain tumour. **Roles and main tasks in the project:** USAAR is leading WP2 (User Requirements) and is enrolled in WP5 (Central decision support and guidance system) leading the task for knowledge engineering, WP7 (Serious games for self-management) leading the task for analysis of existing serious games for cancer patients and the theoretical background, WP8 (Smart		

	analytical data services), WP9 (Pilots and their evaluation) leading the task for pilots for children.
Relevant skills, experiences, technologies and previous projects	**Relevant Publications** • Bucur Anca, van Leeuwen Jasper, Cirstea Traian Cristian, Graf N: Clinical decision support framework for validation of multiscale models and personalization of treatment in oncology. IEEE 13th International Conference on Bioinformatics and Bioengineering (BIBE), Chania, Greece, Date of Conference: 10-13 Nov. 2013, http://dx.doi.org/10.1109/BIBE.2013.6701695 • Stamatakos GS, Kolokotroni E, Dionysiou D, Veith C, Kim YJ, Franz A, Marias K, Sabczynski J, Bohle R, Graf N: *In silico oncology: Exploiting clinical studies to clinically adapt and validate multiscale oncosimulators.* Conf Proc IEEE Eng Med Biol Soc. 2013;2013:5545-9. doi: 10.1109/EMBC.2013.6610806 • Montserrat Cases, Laura I. Furlong, Joan Albanell, Russ B. Altman, Riccardo Bellazzi, Scott Boyer, Angela Brand, Anthony J. Brookes, Søren Brunak, Timothy W. Clark, Joaquim Gea, Peter Ghazal, Graf, N, Roderic Guigó, Teri E. Klein, Núria López-Bigas, Víctor Maojo, Barend Mons, Mark Musen, José L. Oliveira, Anthony Rowe, Patrick Ruch, Amnon Shabo, Edward H. Shortliffe, Alfonso Valencia, Johan van der Lei, Miquel A. Mayer, Ferran Sanz. Improving data and knowledge management to better integrate healthcare and research. *J Int Med* 274:321-328, 2013 • David Johnson, Steve McKeever, Georgios Stamatakos, Dimitra Dionysiou, Graf N, Vangelis Sakkalis, Konstantinos Marias, Zhihui Wang, Thomas S. Deisboeck: Dealing with Diversity in Computational Cancer Modelling. Cancer Informatics 12:115-124, 2013 • Peter V. Coveney, Vanessa Diaz-Zuccarini, Graf N, Peter Hunter, Peter Kohl, Jesper Tegner, Marco Viceconti: Integrative approaches to computational biomedicine. Interface Focus 3:20130003, 2013; http://dx.doi.org/10.1098/rsfs.2013.0003 **Relevant projects/activities** USAAR is participating in several EU funded projects. (Coordination of p-medicine and partner in EURECA, CHIC and MyHealthAvatar). USAAR was partner in different EU funded projects (ACGT, ContraCancrum, Contract and TUMOR). USAAR is chairing the SIOP-RTSG (Renal Tumor Study Group of the International Society of Paediatric Oncology) that is running different clinical trials.
Key Personnel	**Prof. Dr. Norbert Graf** is Professor of Paediatrics and Director of the Clinic for Paediatric Oncology and Haematology and a member of the Faculty of Medicine of the Saarland University, being currently the dean for study affairs. He is the chairman of the Renal Tumour Study Group of the International Society of Paediatric Oncology (SIOP-RTSG) and the Principal Investigator of the current Trial for Childhood Renal Tumours within SIOP. He is an Associate Member of COG (Children's Oncology Group, North America) and closely cooperating with the COG Renal Tumor Study Group. Prof. Graf has more than 25 years of experience in running clinical trials. He is a member in many national and international scientific societies. As the coordinator of p-medicine, an EU funded large integrated project, he tries to pave the way to personalized medicine. He is also a member of the board of the VPH-Institute. **Holger Stenzhorn** studied computational linguistics at the Saarland University in Saarbrücken, Germany and currently works as research associate at the Department of Paediatric Oncology and Haematology of the Saarland University Hospital in

	Homburg, Germany where he collaborates in the FP7-projects p-medicine and EURECA. Before, he had research positions at the Institute for Medical Biometry and Medical Informatics of the Freiburg University Medical Center, Germany and the Institute of Formal Ontology and Medical Information Science in Saarbrücken, Germany, and was visiting the Digital Enterprise Research Institute in Galway, Ireland. He also has industrial experience form working as software engineer at XtraMind Technologies in Saarbrücken, Germany. His work interest in biomedical informatics focuses on representing and managing information and data through ontologies/terminologies and Semantic Web technologies, natural language processing, user interfaces as well as software design and development. In the past he participated in the development of systems for multilingual document retrieval, information extraction and natural language generation (both in industry and academia). He has been involved in several ontology engineering and application tasks, like an ontology for clinical trials on nephroblastoma and breast cancer (FP6-project ACGT), an ontology for the research on cerebral aneurysms (FP6-project @neurIST) as well as the BioTop top-domain ontology. His current work centers on developing a software system (ObTiMA) for improved management of clinical trials that integrates novel technologies based on his research interests. Further, he participates in the Healthcare and Life Sciences Interest Group of the World Wide Web Consortium.

Name	**4) Philips (PHILIPS)**		
Country	Netherlands	**Type**	Industry
Organization Description	Royal Philips is a diversified health and well-being company, focused on improving people's lives through meaningful innovation in the areas of Healthcare, Consumer Lifestyle and Lighting. Headquartered in the Netherlands, Philips posted 2013 sales of EUR 23.3 billion and employs approximately 115,000 employees with sales and services in more than 100 countries. We focus on delivering the most technologically advanced products and solutions, as we help clinicians diagnose, treat and manage many of today's most prevalent diseases. We expand access to care by promoting the adoption of new mobile and remote technologies and developing new protocols that can lead to more efficient and productive health care systems. The **'Precision and Decentralized Diagnostics'** department focuses on two areas of research: Oncology precision diagnostics and Decentralized diagnostics. Decentralized diagnostics (DDx) follows a macro trend towards greater decentralization, driven by the need for greater access and improved workflow leading to lower cost of care. DDx finds entry points in the hospital at the point of need, e.g., in the emergency room or in other setting where acute situations arise and where pertinent diagnostic information can be used for rapid and appropriate response. In addition to hospital-based diagnostics, increasingly diagnostic tests find an entry in decentralized locations, e.g., in out-patient settings and the physician's office, in community care facilities and, increasingly, in the home. Oncology precisions diagnostics: An increasing number of patients in the world are suffering from cancer, which by now is the #1 cause of death in the Western world. The largest rise in incidence of cancer, however, is occurring in the growth economies. Cancer care is becoming more and more complex as new treatment approaches are reaching the market, as yet in a significant number of cases it is impossible to predict which patient will respond to which treatment. Scientific and technical breakthroughs in understanding the origin and causative pathways for tumor		

	growth and risk of metastasis are leading to personalized treatment and management of cancer patients, with first signs of improved outcomes. The complexity of treatment options and diagnostic information leads to a need to aggregate, analyze, interpret and disseminate information. The mission of the **'Chronic Disease Management'** department is to "make home a better place for clinical care". The department is focusing on the exploration and development of propositions for the (self) management of patients with one or more chronic conditions. The department focuses on: - Creating new innovative propositions combining clinical knowledge about chronic conditions as COPD, Cancer, Heart Failure etc. as well as comorbidities with market- and healthcare organizational knowledge. - Combining care planning and care management practices with innovative solutions on motivation and behavioural change to support healthcare organisations as well as patients and their social ecosystems in the (self) management of chronic diseases. - Exploring new treatment-, care management- and behavioural change propositions based on deep clinical insights in the analysis of disease and care management-specific data collected throughout the patient journey and the care cycles. **Roles and main tasks in the project:** Philips will develop models and a corresponding tool for the prediction of adverse events during chemotherapy in the context of WP5. Philips will further play a central role in the exploitation of the iManageCancer platform.
Relevant skills, experiences, technologies and previous projects	**Relevant Publications** • Bucur, J. van Leeuwen, T.C. Cirstea, N. Graf: Clinical decision support framework for validation of multiscale models and personalization of treatment in oncology. BIBE 2013. • S. Rüping, A. Anguita, A. Bucur, T.C. Cirstea, B. Jacobs, A, Torge, "Improving the Implementation of Clinical Decision Support Systems", EMBC 2013. • J. van Leeuwen, A. Bucur, B. Claerhout, K. De Schepper, D. Perez-Rey and R. Alonso-Calvo, "BRIDG-based Trial Metadata Repository: Need for standardized machine interpretable trial descriptions", HEALTHINF 2014. **Relevant projects/activities** The FP7 EURECA project focuses on identification, prediction, detection and management of serious adverse events of cancer treatments. The project also addresses the contextualization of information and knowledge to support the information goals of both patients and clinicians.

Key Personnel	**Anca Bucur, Ms.** holds a PhD in Computer Science from Delft University of Technology and a master degree from the Technical University of Bucharest. She a senior scientist with Philips Research Europe. In Philips, she has contributed to and coordinated several industrial research projects in the healthcare domain related to Clinical Information Systems, healthcare information management, clinical decision support, high performance computing, and computational genomics. She is the coordinator of the EU-funded FP7 projects INTEGRATE (Driving Excellence in Integrative Cancer Research through Innovative Biomedical Infrastructures) and EURECA (Enabling information re-Use by linking clinical REsearch and Care) and leads Philips' contribution to several other FP7 projects. Her research interests and expertise include clinical information systems, healthcare information management, clinical decision support, and tools to streamline clinical research and to support the execution of clinical trials. She has published many research papers in the above areas. **Evangelia Vezouviou** holds a BSc in Molecular Medicine from the University of Sussex, UK, and a PhD in Biotechnology from University of Cambridge, UK, which was co-funded by EPSRC and Philips Research UK. Research area of specialization during her undergraduate degree, at the Genome and Stability Center) included interactions between ionizing radiation and Temozolomide for the treatment of multiple human malignant glioma cell lines. Clonogenic survival assays and immunofluorescence staining experiments were performed with the scope of determining the effectiveness of ionizing radiation alone or in combination with Temozolomide, at various radiation intensities and drug concentrations when applied to gliomas cell lines with varied genetic mutations and malignancies. During her PhD, at the department of Chemical Engineering and Biotechnology Evangelia has developed a novel potentially implantable optical biosensor for diabetes management, which is currently under investigation for patent registration. She is currently a scientist with Philips Research.

Name	**5) Cancer Intelligence ecancer (CI-eCANCER)**		
Country	UnitedKingdom	**Type**	SME
Organization Description	Cancer Intelligence is an academic publisher which publishes ecancer (or ecancermedicalscience). This is a free, online open-access cancer journal, publishing science articles, events and conferences, reporting on cancer news, and providing an online community for those involved in all fields of cancer research and treatment. ecancer actively encourages the communities of sub-specialized scientists and cancer carers to exchange ideas and research, speeding up the time it takes from discovery to patient benefit, and has recently won the Best online educational tool for healthcare professionals category at the PM Digital Media Awards CI-eCANCER will act as the web address and reservoir for all papers, reports and publications. Currently ecancer is visited by 500,000 scientists and oncologists each year from 191 countries. There are more than 2000 videos on the site that have been watched over 2.7 million times. ecancerpatient is the patient focused area of eCancer containing relevant patient content. ecancerpatient disseminates relevant video, news items and hosts patient forums. The site is being developed with input from cancer patients and support groups. ecancerLatinoAmerica is the Spanish and Portuguese version of ecancer. **Roles and main tasks in the project:** As the publisher of ecancer and ecancerpatient Cancer Intelligence place a central		

	role in the strategies for dissemination, communication and exploitation of the project and leads the corresponding work package (WP10).
Relevant skills, experiences, technologies and previous projects	**Relevant Publications** • Sullivan R, Peppercorn J, Sikora K, Zalcberg J, Meropol NJ, Amir E, Khayat D, Boyle P, Autier P, Tannock IF, Fojo T, Siderov J, Williamson S, Camporesi S, McVie JG, Purushotham AD, Naredi P, Eggermont A, Brennan MF, Steinberg ML, De Ridder M, McCloskey SA, Verellen D, Roberts T, Storme G, Hicks RJ, Ell PJ, Hirsch BR, Carbone DP, Schulman KA, Catchpole P, Taylor D, Geissler J, Brinker NG, Meltzer D, Kerr D, Aapro M.: Delivering affordable cancer care in high-income countries. *Lancet Oncol. 2*011 Sep;12(10):933-80. doi:10.1016/S1470-2045(11)70141-3. • Payne S, Burke D, Mansi J, Jones A, Norton A, Joffe J, Cunningham D, McVie G, Agarwal R.: Discordance between cancer prevalence and training: a need for an increase in oncology education. *Clin Med.* 2013 Feb;13(1):50-6. • Kondylakis, H., Kazantzaki, E., Koumakis, L., Genitsaridi, I., Marias, K., Gorini, A., Mazzocco, K., Pravettoni, G., Burke, D., McVie, G., Tsiknakis, M., Development of Interactive Empowerment services in support of personalized medicine, *eCancer Medical Science*, 8, 400, 2014. • Kondylakis, H., Koumakis, L., Tsiknakis, M., Marias, K., Genitsaridi, I., Pravettoni, G., Gorini, A., Mazzocco, K., Smart recommendation services in support of patient empowerment and personalized medicine., *Multimedia Services in Intelligent Environments – Recommendation Services* , 2013 • Kondylakis, H., Koumakis, L., Genitsaridi , E., Tsiknakis, M.N., Marias, K., Pravettoni, G, Gorini, A., & Mazzocco, M. (2012). IEmS: A collaborative Environment for Patient Empowerment. *IEEE International Conference on BioInformatics and BioEngineering (BIBE), 2012*. **Relevant projects/activities** • Eurocanplatform- ecancer is the communication and dissemination workpackage leader • EURECA - Enabling information re-Use by linking clinical REsearch and CAre (FP7-ICT-2011-7) • p-MEDICINE - From data sharing and integration via VPH models to personalized medicine (FP7-ICT-2009.5.3)
Key Personnel	**Prof. Gordon McVie** is currently responsible for Clinical Research Coordination, Strategy and International Affairs at the IEO. Previously, Prof. McVie was Joint Director General of Cancer Research UK, the largest grant giving charity in the UK, as well as Clinical Research Director at the National Cancer Institute of the Netherlands and Consultant in Oncology at the Antoni van Leewenhoek Hospital, Amsterdam. He set up the Drug Development Group in Brussels (as President of EORTC), the European New Drug Development Network (with NCI support) and the Cancer Trials Networks in Scotland, Wales, and England, as well as the National Cancer Research Institute.

Name	**6) University of Bedfordshire (BED)**

Country	United Kingdom	**Type**	University Research Centre
Organization Description	The University of Bedfordshire, formed in August 2006 from an amalgamation of the University of Luton and the Bedford campus of De Montfort University, now has 25,000 students. The Department of Computer Science & Technology comprises 40 academic staff and is responsible for the delivery of 20 awards. The Department regularly enrols over 500 postgraduate students on its taught Masters degrees and it has more than 50 PhD students. The Department has a strong record of international collaboration, in both research and in teaching, where it has collaborative agreements with universities in many countries. The research lab currently contains researchers of 13 different nationalities. **Roles and main tasks in the project:** BED will contribute visual analytics techniques to the project and will lead WP4.		
Relevant skills, experiences, technologies and previous projects	**Relevant Publications** • C. Wang, Y. Yue, F. Dong, Y. Tao, X. Ma, G. Clapworthy, X. Ye, Enhancing Bayesian estimator for removing camera shake, Computer Graphics Forum 32(5) (2013) • Xiangrong Zhang, Yang Yang, L. C. Jiao, Feng Dong: Manifold-constrained coding and sparse representation for human action recognition. Pattern Recognition 46(7): 1819-1831 (2013) • Chao Wang, Yong Yue, Feng Dong, Yubo Tao, Xiangyin Ma, Gordon Clapworthy, Hai Lin, Xujiong Ye: Nonedge-Specific Adaptive Scheme for Highly Robust Blind Motion Deblurring of Natural Imagess. IEEE Transactions on Image Processing 22(3): 884-897 (2013) • Baoquan Liu, Gordon Clapworthy, Feng Dong, Edmond C. Prakash: Octree Rasterization: Accelerating High-Quality Out-of-Core GPU Volume Rendering. IEEE Trans. Vis. Comput. Graph. 19(10): 1732-1745 (2013) • Yubo Tao, Hai Lin, Feng Dong, Chao Wang, Gordon Clapworthy, Hujun Bao: Structure-Aware Lighting Design for Volume Visualization. IEEE Trans. Vis. Comput. Graph. 18(12): 2372-2381 (2012) **Relevant projects/activities** The Centre for Computer Graphics and Visualisation (CCGV) has undertaken research in computer graphics, computer animation and visualisation for over 20 years. It specialises in developing visualisation solutions to real-world problems and has been particularly active in the area of medical applications. It has extensive knowledge and experience of GPU algorithms through research. It has been involved in 25 internationally funded projects (including projects in FPs 4,5,6,7) over the last 14 years, 8 of these as Project Coordinator. CCGV is housed in a new, purpose-built lab which opened in April 2009.		

Key Personnel	**Feng Dong** is Professor of Visual Computing. He joined CCGV in September 2007 from Brunel University. Prof Dong was awarded a BSc, MSc and PhD from Zhejiang University, where he became a member of academic staff at the State Key Lab of CAD and Computer Graphics, the leading computer graphics lab in China. He has many interests within computer graphics, including medical visualisation, and image processing; his recent work has also developed new areas in texture synthesis, image-based rendering and figure animation. He is currently coordinating two EC projects with a very good experience in project coordination. **Gordon Clapworthy** is Professor of Computer Graphics and Head of CCGV. He has a BSc (Hons, Class 1) in Mathematics and a PhD in Aeronautical Engineering from the University of London and an MSc (distinction) in Computer Science from City University. He spent a sabbatical year developing computer animation applications with Electronic Arts. He has produced 200 refereed publications. Recently, his main activity has been the development of novel visualisation algorithms for biomedical data. **Enjie Liu** is a Reader and member of CCGV. She joined University of Bedfordshire in 2003, and before that she worked as Research Fellow at University of Surrey. She received a PhD in Communication Networks from Queen Mary University of London, and a BSc in Computer Science in China. She has previously worked on several European projects both at BED and at her previous universities. One of her main research interests is the deployment and security of web services; she will be responsible for the development of the Web Services framework. **Youbin Zhao** is a Research Fellow in CCGV. He received his PhD from the State Key Lab of CAD and Computer Graphics, the leading computer graphics lab in China. He joined CCGV in 2008. His main research interest is 3D computer graphics and game development.

Name	**7 European Institute of Oncology (IEO)**		
Country	Italy	**Type**	Research and Care Institution
Organization Description	The European Institute of Oncology, IEO, is a comprehensive cancer centre located in Milan, Italy. The institute strives for excellence in the prevention, diagnosis and treatment of cancer by developing clinical and scientific research coupled with innovative model for health and advanced research in the international oncology field. Its Division and Unit Directors come from eight European countries. The Applied Research Unit for Cognitive Science focused mainly on the cognitive and psychological dimensions involved in medical decision making processes. The Unit has conducted a number of research projects on cancer patient empowerment and personalised medicine, as well as on the psychological components related to use of ICT for cancer patient self-management. Psychologists and researchers affiliated also to the University of Milan, also participate in activities for prevention and for the development of new strategies to support patients in adopting healthy life-styles (e.g., the IEO antismoking service). **Roles and main tasks in the project:** This solid expertise makes IEO an optimal managing partner for the study of psychological aspects related to cancer screening and prevention, and to health-related behaviours. The daily experience with patients' psycho-oncological support makes this Unit an optimal resource to understand patient and family needs in self-		

	management in cancer disease and thus to help creating tools for patient empowerment. The competences on the cognitive processes of decision-making allows interfacing with more technical partners in order to develop decision aids taking into account not only normative decision rules, but personal values as well. Furthermore, IEO documented experience with ICT for cancer disease management makes this centre a valuable member of the project in investigating the impact of iManageCancer on patients' and family psychological well-being and quality of life. In particular, IEO will conduct small-scale pilots with patients with lung, breast and prostate cancer.
Relevant skills, experiences, technologies and previous projects	**Relevant Publications** • Kondylakis H, Kazantzaki E, Koumakis L, Genitsaridi I, Marias K, Gorini A, Mazzocco K, Pravettoni G, Burke D, McVie G, Tsiknakis M. Development of interactive empowerment services in support of personalised medicine. Ecancermedicalscience. 2014;8:400. eCollection 2014. • Lucchiari C, Pravettoni G. The role of patient involvement in the diagnostic process in internal medicine: a cognitive approach. Eur J Intern Med. 2013;24(5):411-5. doi: 10.1016/j.ejim.2013.01.022. • Lucchiari C, Pravettoni G. Cognitive balanced model: a conceptual scheme of diagnostic decision making. J Eval Clin Pract. 2012;18(1):82-8. doi: 10.1111/j.1365-2753.2011.01771.x. • Gorini A, Pravettoni G. P5 medicine: a plus for a personalized approach to oncology. Nat Rev Clin Oncol. 2011;8(7):444. doi: 10.1038/nrclinonc.2010.227-c1. • Pravettoni G, Gorini A. A P5 cancer medicine approach: why personalized medicine cannot ignore psychology. J Eval Clin Pract. 2011;17(4):594-6. doi: 10.1111/j.1365-2753.2011.01709.x. **Relevant projects/activities** 2014: B-Thalassemia patients profile in treatment management. First step funded by Novartis Farma S.p.A. 2014: Mind the risk - Ethical, psychological and social implications of provision of risk information from genetic and related technologies. A joint European research program", funded by Riksbankens Jubileumsfond (RJ) – The Swedish Foundation for Humanities and Social Sciences. 2014: Benefits of Tobacco Free Cigarette among heavy smokers undergoing a lung cancer screening program: a Randomized Control Study (Funding: Umberto Veronesi Foundation) 2011: P-MEDICINE From data sharing and integration via VPH models to personalized medicine (Funding European Commission-FP7) **Infrastructure** IEO will provide its expertise in collaboration with the University of Milan supported by the following infrastructures: - Psycho-oncological evaluation clinic: patients referring to EIO have access to this service for psycho-oncological support and consultation - Applied Research Unit for Cognitive and Psychological Science: for data collection, analysis and interpretation

	- Administrative and grants office: for research management procedures - Epidemiology and Health Statistics Unit: for data analysis
Key Personnel	**Prof. Gabriella Pravettoni** has an MS in Experimental Psychology, a Degree in clinical psychology and a PhD in Cognitive Science. She is Full Professor of Cognitive Psychology at the Department of Health Sciences, and member of the Interdisciplinary Research Center on Decision Making Processes (IRIDe) at University of Milan. She is Director of the Applied Research Unit for Cognitive and Psychological Science and Director of Anti-Smoking Centre, at the European Institute of Oncology (IEO) in Milan. Gabriella Pravettoni is also Professor of Psychology of Decision Making at European School of Molecular Medicine (SEMM) in Milan, and Visiting Professor at Guy's Hospital, King's College of London. She has a position as Researcher at the Institute of Cognitive Sciences and Technologies – National Research Council. Prof. Pravettoni trains Italian physicians and health insurance brokers in decision making and understanding of errors, risks and uncertainties. Her research interests focus principally on health psychology, personalized medicine, cognitive processes, shared decision making and patient empowerment. **Dr. Ketti Mazzocco** has an MS in Experimental Psychology, a Degree in clinical psychology and a PhD in Cognitive Science. She has a position as researcher at the Department of Health Science, University of Milan, Italy, where she teaches medical decision making and communication skills. She is member of the Applied Research Unit for Cognitive and Psychological Science at the European Institute of Oncology, where she performs research and clinical activity in psycho-oncology. Her research interests focus primarily on medical decision making, information processing, and patient empowerment. **Barbara Alicja Jereczek-Fossa M.D., Ph.D.** is a Senior Deputy Director of the Division of Radiotherapy&Advanced Radiotherapy Center at the European Institute of Oncology in Milan and Assistant Professor of Radiation Oncology at the University of Milan, Italy. She gained her first medical degree M.D. from the University of Gdansk in 1992 and then in 1997 from the University of Milan. In 1996 she gained a Ph.D. She is a specialist in radiation oncology (Cancer Institute of Warsaw, Poland and University of Milan, Italy). She is actively involved in clinical, educational and research activities. Her main clinical and research interests have focused on urological malignancies, combined modality approach, high precision radiotherapy, oligometastatic cancer, and new prognostic and predictive factors. She serves as a teacher at the ESTRO course on the Evidence Based Radiation Oncology and is the ESTRO course director for the Combined Drug Radiation Treatment. She is the recipient of numerous awards and an active member of many national and international societies (including European Society for Therapeutic Radiology and Oncology ESTRO, Italian Society of Radiation Oncology AIRO, She served as a member of the ESTRO Clinical Radiotherapy Committee (2007-2012) and the ESTRO Education and Training Committee (2009-ongoing). Between 2010 and 2012 she was a coordinator of the National Prostate Research Working Group of the Italian Society of Radiation Oncology. She is a member of editorial boards and committees of Reports of Practical Oncology and Radiotherapy, Oncologia Europea and ecancermedicalscience. She is the author of over 100 peer-reviewed scientific papers and 4 book chapters. Recent scientific commitments include research projects like ALLEGRO project of European Atomic Energy Community's Seventh Framework Programme [FP7/2007-2013] and projects of the Italian Ministry of Health, University of Milan, and Italian Association of Cancer Research (AIRC).

Name	8 Serious Games Solutions GmbH (SGS)		
Country	Germany	**Type**	SME
Organization Description	Serious Games Solutions GmbH is a developer of game based learning solutions and serious games for customers from different sectors including health. Its expertise covers game design skills like game concept design, 3D graphics design, 2D graphics design, animation design, as well as skills like producing and project management. Serious Games Solutions GmbH has a complete infrastructure to design and develop computer games. Serious Games Solutions GmbH works in close cooperation with Promotion Software GmbH which keeps offices in Tübingen and Potsdam. Both companies live a close cooperation model and are able to handle even larger development projects. **Roles and main tasks in the project:** Due to the business focus of the company SGS leads the gamification aspects of the project (WP7) where it contributes an adventure game for children to actively fight their cancer. As an SME partner SGS is also involved in the exploitation activities of the project.		
Relevant skills, experiences, technologies and previous projects	**Relevant projects/activities** - EMERGENCY (Apple AppStore for iPad and iPhone, Google Store) Serious Strategy Game with Serious Game components, the Game is tremendously successful in the electronic Stores. - Menschen auf der Flucht ("Refugees") (interactive mobile Expo) Mobile Serious Game for students presented in a large truck. The game was awarded with "Deutscher Computerspielpreis" in 2013, the most important award for Serious Games in Europe - VoTeKK (Game based learning system for doctors and paramedics): VoTeKK was developed in cooperation with Universität Bonn and others in a national call of BMBF. Medical professionals train to cope emergency situations aside the daily routine. - Siemens PowerMatrix Game The Game Based Learning System educates students regarding the problems of a sustainable public energy grid.		
Key Personnel	**Ralph Stock**, Managing Director and Game Designer He is Game Designer with his first game publication in 1984 and influenced the Digital Game Design sector with titles like Mad TV. He designed more than 200 games and works today with a team of 30 game specialists in Studios located in Tübingen and Potsdam Babelsberg. Ralph Stock is not only interested in designing successful consumer games for the mass market, his special focus is the development of innovative Serious Games and Game Based Learning Systems. Being recognized as one of the pioneers of Game Development in Europe he tries to support all ambitions to strengthen the education infrastructure for computer games sciences in Germany and Europe. **Apostolos Benisis**, Head of Software Design He is received a M.Sc. for Artificial Intelligence from the University in Thessaloniki and holds a M.Sc. in Business Administration and Engineering. His main focus is analysis and design of the development processing. He is responsible for the process of Software Design at Serious Games Solutions GmbH.		

	Andreas Epple, Head of Development After studying mathematics at the University of Tübingen he focused on the development of computer games. He is responsible for the technical development process of both, consumer and serious games and has more than 20 years of experience in the games industry. The integration of all relevant development aspects at Serious Games Solutions is a very important part of his work as well as the identification and utilization of the latest results of research in digital game and software science. **Florian Wendel**, Head of Game Design Florian Wendel holds a diploma in informatics from the TU Munich. He was involved in the design of many of the most successful and awarded projects realized by Serious Games Solutions GmbH. **Stefan Hoffmann**, Head of eHealth and mHealth Development Stefan Hoffmann is Serious Game Development expert with a focus on Serious Games for Health, especially in mobile health games. He is engaged in projects for major pharmaceutical companies and is specialist for Life Style Intervention and Self Management Games for patients. His development approach is being focused on the edge between scientific and functional determination and motivational needs.

2.3.4.2 Third parties involved in the project (including use of third party resources)

Does the participant plan to subcontract certain tasks (please note that core tasks of the project should not be sub-contracted)	Y
A contingency budget is reserved under the budget of the Coordinator to serve the exploitation and dissemination strategy of the project by extending the pilots to another side and to cover unexpected expenses for external services required for regulatory affairs around the iManageCancer platform. - We will initiate another clinical pilot after the initial platform prototype has successfully passed the first assessments in the Italian and German pilot site. The pilot site will be selected depending on the needs of the projects regarding validation and dissemination of the technology. - External services may need to be contracted in the context of regulatory affairs such as the involvement of a Notified Body to certify compliance of tools or platform as a whole with European Medical Device Regulations if required for the pilots. This depends from the design of the pilots but also from requirements of national ethics committees. - Travel support will be given to the members of the External Advisory Panel for meetings with the consortium. 3 EAP meetings are planned in the project. Furthermore, external financial services will be needed by most of the partners to obtain audit certificates for Financial Statements.	
Does the participant envisage that part of its work is performed by linked third parties[96]	N
If yes, please describe the third party, the link of the participant to the third party, and describe and justify the foreseen tasks to be performed by the third party	

[96] A third party that is an affiliated entity or has a legal link to a participant implying a collaboration not limited to the action. (Article 14 of the Model Grant Agreement).

Does the participant envisage the use of contributions in kind provided by third parties (Articles 11 and 12 of the General Model Grant Agreement)	N
If yes, please describe the third party and their contributions	

2.3.5 Planned use of resource

iManageCancer is an ambitious research and innovation project with a comprehensive workplan aiming to develop and validate an advanced IT platform for empowering patients in cancer diseases. However, many of the project partners have previously worked successfully together in European projects focusing on developing large scale IT platforms for healthcare (e.g. in several IPs under FP7 like p-medicine, EURECA, MyHealthAvatar). The consortium envisages the implementation of the iManageCancer philosophy and development based on fair and adequate resources, where the experience and results gained in former projects clearly helps to achieve this aim. An overview of the person-months requested to complete the different activities within iManageCancer is given in Table 2.3.5c. The consortium includes technical groups (FRAU, FORTH, BED; Philips; SGS) who are world-leading experts in their respective fields, thus ensuring that the design and development of the iManageCancer platform, while challenging, are clearly achievable within the planned budget and timeframe. The inclusion of clinical end users caring for patients (USAAR, IEO) and an SME for exploitation (CI-eCANCER), running a leading information platform for cancer patients, will ensure that the iManageCancer platform development will be driven by the application demands and thus will be suitable for use by the end users and for rapid adoption by the users. This goal is clearly reflected in the balance of resources requested by the partners as will be described below. Successful project implementation and exploitation is further assured by the inclusion of a dedicated Project Coordinator (FRAU) in close collaboration with a Technical Coordinator (FORTH) and an Exploitation Manager (CI-eCANCER) with the requisite skills and experience in performing, managing and commercialising research and development.The total budget for iManageCancer is € 4.856.174 with a requested EC contribution of € 4.856.174. The total project effort is 672,5 person months, thus representing an average cost of around € 4.971 per person month. A further break-down of the costs and work in different categories is presented in the tables below.

Table 2.3.5 c: Work allocation per Work Package

Work Package	Number of PMs	Percentage of total PMs
1. Management	30	4,46%
2. Concept definition and system requirements	45	6,69%
3. System design and integration	75,5	11,23%
4. Health Avatar PHR	81	12,04%
5. Central decision support and guidance system	120	17,84%
6. Psycho-emotional and health assessment tools	86	12,79%
7. Serious games for self-management	84	12,49%
8. Smart analytical data services	41	6,10%
9. Pilots	58	8,62%
10. Dissemination, communication, exploitation	52	7,73%
Total	**672,5**	100%

Work allocation per work package is shown in Table 2.3.5c. The technological advances necessary for the development of decision support services and the related tools required justifies the higher level of effort dedicated to these activities. The next largest activities cover the Health Avatar PHR and serious games

for self-management, which are innovative and research intensive developments crucial for the successful self-management of the patients. Beside the technical work packages considerable effort has been allocated to pilots and dissemination, communication and exploitation to guarantee suitability for the end users and adoption by the market. The effort allocated to each work package is consistent with the available budget. The corresponding costs are further detailed in Table 2.3.5d.

Table 2.3.5d: Budget Distribution by partner and cost category

Partner short name	Personnel	Travel	Equipment	Other direct costs	Sub-contracting	Indirect Costs	Total costs	PMs
FRAU	670.000	33.600	15.000	46.000	100.000	191.150	1.055.750	100,0
FORTH	540.000	35.000	20.000	3.000	0	149.500	747.500	120,0
USAAR	264.600	25.000	10.000	0	0	74.900	374.500	42,0
PHILIPS	534.419	25.000	0	0	0	139.855	699.274	61,0
CI-eCANCER	265.000	20.000	0	71.000	0	89.000	445.000	53,0
BED	451.000	20.000	4.000	8.000	0	120.750	603.750	82,0
IEO	261.250	25.000	11.900	73.170	0	92.830	464.150	155,0
SGS	357.000	6.000	6.000	4.000	0	93.250	466.250	59,5
Total	3.343.269	189.600	66.900	205.170	100.000	951.235	4.856.174	672,5
% of total	68,85%	3,90%	1,38%	4,22%	2,06%	19,59%	100,00%	

Personnel costs: As shown in Table 2.3.5d, the main part of the costs will be personnel costs used to finance 672,5 person months. The distribution of person month to the major activities of the project is shown in Table 2.3.5c. **Travel:** Travel costs will be used to finance travels to 7 plenary meetings, 4 review meetings, workshops, EAP meetings, additional technical meetings as required as well as the participation of partners in selected and highly relevant conferences to present the project and its results. Meeting and conference participation will be carefully planned. Wherever possible, the partners will strive to make use of tele- or videoconferences and try to combine conference participations and meetings. **Equipment:** Several partners need to purchase mobile devices, tablets, servers as well as infrastructure-related hardware. **Other direct costs**: A *contingency budget* in the amount of € 42.000 is reserved under this budget category in the budget of the Coordinator to cover travel cost of the External Advisory Panel (€ 12.000) and to cover expenses for external services eventually required for compliance declaration with the European Medical Device Regulations (€ 30.000). Furthermore, CI-eCancer will spent € 30.000 on the development and management of the project website and environment hosting, € 16.000 on publication costs for articles, news and video production and € 20.000 for launching events, workshops and focus group costs. IEO will spent € 73.170 on consumables, lab materials and kits relevant for running Physiological Lab Test on 200 patients. **Subcontracting**: A budget of € 100.000 is reserved under the budget of the Coordinator to initiate an additional clinical pilot after the initial platform prototype has successfully passed the first assessments in the Italian and German pilot site. The pilot site will be selected depending on the needs of the projects regarding validation and dissemination of the technology. The clinical site shall become a full partner of the consortium.

Table 2.3.5e: Budget Distribution by type of partners

Type of Partner	Percentage of Total Budget
ICT Research (FRAU, FORTH, BED)	49,57%
Clinical Research (USAAR, IEO)	17,27%
Industry (PHILIPS)	14,40%
SME (CI-eCancer, SGS)	18,76%

In Table 2.3.5e it can be seen that the consortium has achieved a major success in involving SMEs in the project (with collectively 18,76% of the budget). The strong, proactive management giving support for all their activities will assist their ability to operate in an integrated environment. SMEs are involved in both

the technology development and the exploitation. The largest amount of the budget is allocated to ICT research organizations to ensure that the iManageCancer platform comprises the latest innovations in ICT development. Furthermore, a considerable amount of the resources is allocated to clinical research organizations to guarantee suitability of the platform for end users.

Table 2.3.5b: 'Other direct cost' items (travel, equipment, other goods and services, large research infrastructure)

1 / Frau	Cost	Justification
Travel	€ 33.600	7 regular project meetings, 4 Technical Review meetings; each with two persons of FRAU; 4 technical meetings: 800 € per trip; total: € 24.000€ 1 pilot launch event, 2 workshops, 6 dissemination events, 3 EAP meetings; 1 person; 800 € per trip; total: € 9.600
Equipment	€ 15.000	1 server for iManageCancer test and pilot bed; mobile devices
Other goods and services	€ 46.000	A contingency budget in the amount of € 46.000 is reserved under the budget of the Coordinator to serve the exploitation and dissemination strategy of the project and to cover unexpected expenses for external services required for regulatory affairs around the iManageCancer platform: - € 30.000 have been reserved for external services in the context of regulatory affairs such as the involvement of a Notified Body to certify compliance of tools or the platform as a whole with European Medical Device Regulations if required for the pilots. - € 12.000 have been reserved for travel costs of the members of the External Advisory Panel (4 advisors, 3 meetings during the project, € 1.000 per trip) For an audit certificate we reserve a budget of € 4.000
Total	€ 94.600	

5 / CI-eCANCER	Cost	Justification
Travel	€ 20.000	Attendance at consortium meetings as well as workshops and launch event
Equipment	0	
Other goods and services	€ 71.000	15,000 - project website development and management, 15,000 - environment hosting/web development, 6,000 publication costs for articles, news, 10,000 video production, 10,000 launch event, 10,000 workshop and focus group costs, 5,000 - audit costs
Total	€ 91.000	

7 / IEO	Cost	Justification
Travel	€ 25.000	Participation to project meetings and national and international conferences to disseminate project results.
Equipment	€ 11.900	Depreciation charge for the purchase of 3 PC and 20 tablet
Consumables and lab materials	€ 69.170	Purchase of consumables, lab materials, kits relevant for running Physiological Lab Test on 200 patients
Other goods and services	€ 4.000	Audit costs are calculated with € 4.000
Total	€ 110.070	

2.3.6 Ethics and Security

2.3.6.1 Ethics

iManageCancer will involve research on cancer patients of several age groups including children and adolescents. It is the aim of **iManageCancer** to collect, join, share and analyse heterogeneous data of patients under European legal and ethical regulations. The use of clinical and research data entails several legal and ethical implications.

The core idea of **iManageCancer** is the development of a cancer specific self-management platform designed according to the needs of patient groups and focusing on the wellbeing of the cancer patient with special emphasis on psycho-emotional evaluation and self-motivated goals. The access to and joining of patient data are needed to evaluate and validate the platform before it can be part of future clinical practice.

As a result, the platform will be primarily used by the patients themselves, but also by physicians in their routine care for patients. This will result in increasing the efficiency and effectiveness of treatment for patients.

All patients with cancer (children and adults) are facing an existential threatening disease causing mortal or terrible fear and they are depending on the health care team to cure them, a health care team they do not know and they have to trust. It is the intention of the iManageCancer project to address patient empowerment and to encourage patients to take responsibilities in the management of their disease and to fight against their cancer. This will strengthen them and put them in an active role. In this respect cancer patients will get less vulnerable.

The merging of health data collected for self-management of disease aspects or therapeutic and diagnostic purposes within or without clinical trials on the one hand and health data collected for research purposes on the other raises ethical and legal issues. For ethical reasons this will be addressed in the context of the patients' informed consent, particularly their right of withdrawal. From a legal point of view, this variation in the purpose of data use is generally prohibited. Therefore the **iManageCancer** project will adhere to the corresponding European legal and ethical regulations.

Pilot trials for adult cancer patients serve as use cases to test and validate the developed tools in iManageCancer. This will include the collection of blood samples for the development and validation of predictive models for advanced chemotherapy monitoring. Pilot trials will not be conducted unless approval by local/national ethical review committees. For approval informed consent is mandatory. Collection of data will follow the rules in the different countries. The consortium management will ensure that all processes for handling personal data conform to relevant standards and that proper anonymity or confidentiality procedures are in place. Informed consent will be obligatory in the prospective collection of data. All studies, also those built on previously collected data will be the subject of ethical reviews. There will be a transport of data across national borders. Personal identifiers of data will be protected by pseudonymization, meaning that the providing centre always can go back and identify the patient, if new information is expected to be of benefit for the patient.

2.3.6.1.1 Patient recruitment and patient informed consents

The participation of a patient in **iManageCancer** is always voluntary. Extraordinary care will be taken to receive appropriate and legally valid informed consent to the collection of, access to, joining of and analysing the patients' health data. In particular, such research will only be carried out with the prior, free, informed and expressed consent of the person concerned. This will be done in accordance with all applicable international laws and ethical guidelines related to the protection of personal data as well as internationally accepted rules on bioethics and human rights. For ethical reasons it is vital that each participant of this project is informed and is able to decide what is done with his or her data according to the principle that autonomy needs consent. All decisions and/or interventions to be made will be made with respect to the privacy of the persons concerned and the confidentiality of such personal data subject to applicable national and international data protection laws. Data of patients coming from data sources

already existing will be analysed in terms of the validity of existing consent. Such patients will be asked to give their consent again where appropriate. If refreshing consent is not possible, for reasons of the patient's death, a lack of contact details or otherwise, data will only be used if the existing consent is valid. Clinicians involved in **iManageCancer** will always handle all informed consent issues. Results from the FP7 project CONTRACT[97] of the EU will be taken into account. Templates of informed consents will be provided in the respective deliverables of WP9 (D9.1 and D9.2).

USAAR, CI-eCANCER and IEO are the responsible partners for patient recruitment. Recruitment of patients with childhood cancer will be done by USAAR and for adult cancer by CI-eCancer and IEO. At these centres patients - in case of children their parents – will be informed about the 'iManageCancer' project by the treating physician and asked to voluntarily participate in the pilots that are developed within the project. It will be asked for the participation of all members of the family.

The pilot for children with cancer will include all cancer patients treated at USAAR, independent of the diagnosis and age, and their parents, if the parents give informed consent. In case the children are younger than 6 years, only parents are asked to participate in the pilots to use the iManageCancer platform. Not only children with cancer but also their siblings are encouraged to use the platform.

The pilots for adults will include patients with prostate, lung and breast cancer who are treated at IEO and who can give informed consent by their own. The recruitment process will start with a presentation of the project to physicians during the meetings of the Division of Urology, Thoracic Oncology and Senology. Together with the physicians, patients' eligibility criteria will be discussed. Stratification criteria will be based on socio-demographic and clinical variables (e.g., age, gender, education, stage of disease). The treating physician will inform eligible patients about the possibility to participate in the pilots and will ask them to voluntarily take part in the study. All of these patients giving informed consent after elucidating the 'iManageCancer' project will be included in the adult pilots. A member of the Applied Research Unit for Cognitive and Psychological Science will be available for further information and to explain details about the use of the platform.

As these pilots will be developed during the project, information and consent sheets for the different pilots need to be written and will be provided with all detailed information for each specific pilot so that patients/legal representatives (parents) can give informed consent.

The procedures for informed consent and patient recruitment will be further detailed during the project in the context of WP9 and D9.1 when the trial outline is defined. As soon as the protocols of the clinical pilots are finalized, these protocols together with the templates for informed consent including data protection issues will be submitted to the local ethical committees. This will be done during the second year two of the project. In the case of the trial for children and adolescents it will be the Ethical Committee of the 'Ärztekammer des Saarlandes' located in Saarbrücken, Germany. For the adult pilots it will be the Ethical Committee of the European Institute of Oncology located in Milan, Italy.

2.3.6.1.2 Right of withdrawal

The **iManageCancer** consortium acknowledges the international debate underpinning the importance of a transparent system for withdrawing consent in biomedical research. For this purpose, patients and participants, having given their consent to the processing of their data, shall be able to withdraw such consent at any time and for any reason without any disadvantage or penalty on the same basis as proposed by other large-scale research undertakings. **iManageCancer** will adhere to the guidelines given by CONTRACT.

Participation in the pilots is completely voluntary and patients can withdraw their consent at any time without explanation. Participation, non-participation or withdrawal from the pilot has no impact of clinical care they receive.

[97] http://contract-fp7.eu/

2.3.6.1.3 Patients not able to give consent

The pilot for adults will only include patients who can give informed consent by their own. For patients unable to give consent, due to their age, **iManageCancer** will provide information sheets and obtain consent from their legal representatives. For patients who are minors at the time of obtaining consent, agreements will be provided, informing them about their rights upon reaching majority and asking them for additional ascent whenever they are sufficiently able to understand the implications of their declaration. Children with cancer will be enrolled in the project, after their parents have given informed consent as further described under 2.3.6.1.1.

iManageCancer will take into account that children of different age groups will be enrolled in the pilot of the project. For that reason children will only be able to participate together with their parents. In case the child is younger than 6 years, only parents will be addressed to take part in the pilot.

From the available tools and services of the iManageCancer platform only those will be provided to children they can deal with. This includes serious games for their age group, or specific test scenarios for measuring their mood, pain, and further psychological items. Such test scenarios will be selected during WP2 Task 2.2. Parents of the children are advised to supervise their children when they are using the platform. Siblings of the child with cancer are also encouraged to use the platform to register their mood, needs and to use supportive tools to help them in coping with the fact that their brother/sister has cancer. The parents themselves will have full access to the iManageCancer platform and e.g. the diary function of the platform allows them to give also information about the child's behaviour, complaints, mood, etc. The shared usage of the platform by the child and the family will be evaluated at the end of the project.

Assent for minors is primarily given by the parents or legal representatives to take part in the pilot. In addition, children above the age of 6 years will be informed about the iManageCancer project, how to use tools and what benefits they offer to them. The treating physician together with the parents will do this in an age dependant manner. Specific teaching material for children will be developed during the project before the pilots start. If parents give informed consent, but the child refuses to use the platform, the decision of the child will always be respected. Nobody and nothing will force a child to participate in the pilot and to use tools from the iManageCancer platform. In such a case parents can still participate in using the tools of the platform.

The **iManageCancer** consortium is fully aware of and acknowledges the ethical and legal difficulties of conducting research with patients unable to give consent and will reduce such research as much as possible and adhere to internationally accepted standards in relation to such research. In any doubtful cases the **iManageCancer** consortium will not include such participants in their research. Children will only be enrolled if either parents or all legal representatives have given prior and freely their informed consent. The informed consent for taking part in **iManageCancer** has to be separated from the informed consent of taking part in corresponding prospective pilot trials. Criteria to accept legal representatives are specified in the respective clinical trials and will be accepted by **iManageCancer**.

2.3.6.1.4 Protection of privacy and data management in pilots

Collecting and sharing personal data can be a threat to personal integrity, which shall be minimised. A fundamental principle underlying the iManageCancer Platform is that the patients control the access of others to their data. They will grant health professionals and family members access rights to their data. Analysis services for research on the data will use only de-identified or anonymized datasets. Consent must be given by the patient. Data collected during the pilots will be pseudomised, analysed and preserved in compliance with the national laws. Privacy will also be protected when results or data are presented. Again, the general rule will be to restrict all presentation of data to aggregations, or to line listings deprived of personal identifiers so that the identity of the study subject cannot be deduced (no backward identification). After completion of the project, all assembled datasets will be destroyed if the individual patient will not give an informed consent to maintain the data for further analyses in a succeeding project. This informed consent needs to provide all information about the further usage of the data. This procedure has to comply with each partner's national legal and ethical guidelines for preserving

raw data and guidelines for post-analysis (irreversible) data destruction. The production system of the iManageCancer Platform used in the pilots will be operated in compliance with good clinical practice in clinical trials. Organisational procedures will be put in place to protect the data for unauthorized access and for loss and damage in accordance with national laws. The system will allow the chairmen of the pilots to export the de-personalised pilot data for further analysis and for keeping a record of the pilot in compliance with national laws. After the end of the project the data in the production system will be destroyed.

2.3.6.1.5 The enrolment of children in clinical trials

A new Paediatric Regulation entered into force in the European Union (EU) (Regulation (EC) No 1901/2006) on 26 January 2007. We do not expect any specific impact of this regulation on **iManageCancer.**

The objective of the Paediatric Regulation is to improve the health of children in Europe by[98]:

- Facilitating the development and availability of medicines for children aged 0 to 17 years,
- Ensuring that medicines for use in children are of high quality, ethically researched, and authorised appropriately,
- Improving the availability of information on the use of medicines for children without:
  - Subjecting children to unnecessary trials,
  - Or delaying the authorisation of medicines for use in adults.

The Paediatric Regulation dramatically changes the regulatory environment for paediatric medicines in Europe. The new legislation comprises:

- Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use[99]
- Regulation (EC) No 1902/2006 an amending regulation in which changes to the original text were introduced relating to decision procedures for the European Commission[100]

The main elements of the finalised Regulation include:

- The establishment of a new body, the Paediatric Committee, sited at the European Medicines Agency (EMEA)
- For new products and certain changes to the marketing authorisation for products still covered by patent protection
  - A requirement for paediatric data based on a paediatric investigation plan (PIP)
  - A six-month extension of the supplementary protection certificate (SPC) if information arising from a completed PIP is incorporated into the Summary of Product Characteristics (SmPC)
- For orphan medicinal products
  - A two-year extension of market exclusivity if information arising from a completed PIP is incorporated into the Summary of Product Characteristics (SmPC)
- For off-patent products
  - A new category of marketing authorisation called the paediatric use marketing authorisation which will be associated with a ten-year period of data and market protection

[98] http://www.ema.europa.eu/htms/human/paediatrics/regulation.htm
[99] http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2006_1901/reg_2006_1901_en.pdf
[100] http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2006_1902/reg_2006_1902_en.pdf

- A European database of paediatric clinical trials, part of which will be publicly accessible
- A requirement to submit data from paediatric clinical trials to the regulatory authorities
- Coordination of a European Paediatric Clinical Trials Network.
- Funding for the study of off-patent medicines provided through the Community framework programmes
- An identifying symbol on the package of all products authorised for use in children.

2.3.6.1.6 Processing of personal data

The **iManageCancer** project will deal with highly sensitive healthcare data. Personal data processing requires a higher level of protection and is subject to numerous regulations. Furthermore, because of the therapeutic or scientific implications, such data processing has to absolutely minimise the potential of medical errors or erroneous scientific results. All relevant legal sources (legislation, case law, studies, surveys prior to legislation) at National and International level will be reviewed and examined thoroughly to identify the applicable policies and rules to be adopted. The sources considered for the purposes of this exercise include, but are not limited to:

European level:

- Art. 3, 7, 8 of the Charter of Fundamental Rights of the European Union
- The Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data
- Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use
- Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorisation of the manufacturing or importation of such products
- Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells
- Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices
- Art. 8 of the Convention of the Council No. 5 for the protection of human rights and fundamental freedoms
- Convention No. 108 of the Council of Europe for the protection of individuals with regard to automatic processing of personal data

Recommendations:

- Council of Europe, Recommendation No. R(97)5 on the protection of medical data adopted of 13 February 1997
- Council of Europe, Recommendation on human rights and biomedicine, concerning biomedical research, Strasbourg 25th of January 2005

Relevant International Instruments and Documents:

- World Medical Association Declaration of Helsinki
- Convention No. 164 of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine (Convention on Human Rights and Biomedicine). Additional Protocol to the Convention on human rights and biomedicine concerning biomedical research
- UNESCO Universal Declaration on Human Genome and Human Rights
- UNESCO International Declaration of Human Genetic Data
- UNESCO Declaration on Bioethics and Human Rights

Article 29 Data Protection Working Party:

- Working Document on Genetic Data (WP 91)
- Opinion 6/2000 on the Human Genome and Privacy
- Opinion 4/2007 on the concept of personal data
- Working Document 1/2008 on the protection of children's personal data

Other relevant documents:

- Opinion of the European Group on Ethics in science and new technologies to the European Commission, No. 11, 21 July 1998
- International Guidelines for biomedical research involving human subjects (prepared by the Council for International Organizations of Medical Sciences in collaboration with the World Health Organization)

The **iManageCancer** consortium knows that a new Data Protection Regulation is under debate in Europe. If this comes into place **iManageCancer** will adhere to this new regulation.

In consequence, the consortiums will also develop a data management plan for the clinical data collected in the pilots. The data management plan that details also how data protection is ensured will be subject to approval by the competent University Data Protection Officers. ***2.3.6.1.7 The iManageCancer legal and ethical framework***

In case a problem arises with new legislation relating to health/genetic data collection, data access or patients' rights, the management of **iManageCancer** will evaluate the situation and take appropriate actions. The legal responsibility will always remain within the consortium. Special attention will be given to the following legal and ethical issues directly related to the research performed by **iManageCancer**:

- Patient's prior, free, express and informed consent
- Evaluation, analysis and renewal where appropriate of the informed consent of already existing patient data that will be made available
- Procedures of withdrawal in case a patient wishes to quit at any time
- Design and implementation of legally compliant anonymisation and pseudonymisation tools
- Lawful process, transfer, transmission and storage of health data codified in the **iManageCancer** ethical and legal policies
- A feedback procedure to the patient where necessary and agreed on in the informed consent

2.3.6.1.8 Feedback procedure

The medical manager will be the central contact point for patients and participants with respect to rights resulting from the processing of their data within iManageCancer. In case there is a need to give feedback to patients, and the patient concerned agreed to receiving feedback as part of the consent provided, the procedure to be followed will be:

1. The medical manager is to be informed.
2. The medical manager with the help of Steering Committee and supported by the appropriate WP will be able to assign the data set to the treating physician or hospital, who is in the best position to assess and divulge the clinical data as well as to decide on further action, if necessary.
3. The treating physician or hospital thereafter gives feedback to the patient.

This procedure will also take place in case of incidental findings in patients. The local physician is responsible to inform the patient about the incidental finding, as he is the only person in charge for the patient.

2.3.6.1.9 Animal experimentation

There will be no data from animal experiments used in **iManageCancer**.

2.3.6.1.10 Practical management of iManageCancer legal and ethical issues

The **iManageCancer** consortium acknowledges that many other ethical issues that are not foreseeable at this moment may arise as a result of the innovative design of the project. To ensure that at any point in time throughout the project, all ethical, legal, social and safety issues raised by any of the activities of **iManageCancer** are evaluated in a timely, accurate and careful fashion from the perspective of all stakeholders involved. In any case privacy of clinical data will be ensured building on the guidelines developed in ACGT, p-medicine and CONTRACT. The deliverables of WP11 of ACGT and of WP5 of p-medicine will serve as a master for the technical security infrastructure.

Secondly, the clinical beneficiaries' institutional ethics committees will be contacted and involved to provide the maximum available safety.

Finally, an External Advisory Panel will be formed from independent experts including an independent ethical advisor, providing a consultative function. Their members will be invited to consortium meetings and be contacted for advice as and when needed. The ethical adviser is appointed to monitor that ethical issues are adequately addressed by the consortium and will provide a regular report on this that is made available to the Commission. In summary, the **iManageCancer** platform will be built according to the European legal and ethical requirements that will guarantee the compliance of researchers with the European Legal framework. This is based on contracts between providers and users of data, tools and services, informed consent and respective tools for anonymisation of data. The access to the **iManageCancer** platform will be regulated by a roles and rights management system. As a fundamental principle underlying the iManageCancer Platform access for others to the data of the patient is granted by the patient himself who is the owner of his data.

2.3.6.1.11 Consideration of gender aspects

All partners in the consortium are committed to a work environment in which all individuals are treated with respect and dignity. It is believed that each person has the right to work in a professional atmosphere that promotes equal employment opportunity and prohibits discriminatory practices, including harassment. Equal Employment Opportunity (EEO) and non-discrimination has been – and will continue to be – a fundamental principle within the consortium, where assignments and advancement are based upon personal capabilities and qualifications, without regard to race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status. The consortium recognizes the need to attract and retain talent, and that must encompass doing a better job of recruiting and developing women - traditionally less visible in the technology sector. In view of the low percentage of women active in technical jobs, it is the consortium's policy to strive for women working in the

project. The type of work is equally suited for women and men. In **iManageCancer** several women are already active at key positions:

- Prof **Gabriella Pravettoni** (IEO) is a Full Professor of Cognitive Psychology at University of Milan and is Director of the Applied Research Unit for Cognitive and Psychological Science and Director of Anti-Smoking Centre, at the European Institute of Oncology (IEO).

- **Anca Bucur** M.Sc., PhD, is a senior scientist for PHILIPS.

- Dr. **Gabriele Weiler** is a senior scientist at FRAU, leading FRAU's activities in FP7 ICT projects related to cancer.

- **Barbara Alicja Jereczek-Fossa** M.D., Ph.D. is a Senior Deputy Director of the Division of Radiotherapy&Advanced Radiotherapy Center at the European Institute of Oncology (IEO) in Milan and Assistant Professor of Radiation Oncology at the University of Milan, Italy.

- Dr. **Ketti Mazzocco** (IEO) has a position as senior researcher at the Department of Health Science, at the University of Milan.

At the scientific level the project will be even more gender balanced, since among the younger research community in this field there is a strong involvement of female students and PhD students. The project leader Stephan Kiefer will monitor any related issues in the **iManageCancer** project.

Actions to be taken

Within **iManageCancer** we will promote gender equality in several ways. Education is in this respect important.

- When publishing project job vacancies, urge women to apply, especially in fields where males usually dominate. Aim should be that the project is comprised of at least 40% women

- To make projects even more attractive to women, offer part-time positions whenever possible.

- Offer the opportunity for parental leave

- Positively encourage women to become involved in management roles in the Consortium. One possibility is to substitute single managers with a management group, with equal numbers of females and males represented. The aim should be that at least 40% of project staff, including Principal Investigators are female

- Offer specialised vocational training and gender training for females, including career management, communication, rhetoric techniques, and conflict management

- Create a network of women scientists within the project linked to other European networks of female scientists

- At consortium conferences, the number of sessions chaired by women should equal the numbers chaired by men

- Women scientists should be encouraged to be responsible for dissemination of results and in communication activities

- Workshops and conferences within the project should preferably be short and intensive and held during weekdays. Overnight stays should be minimised. Evening and weekend meetings should be avoided when feasible for family and economic reasons. Video conferencing should be encouraged. Offer conference child care if possible and necessary

2.3.6.2 Security [101]

Please indicate if your project will involve:

- activities or results raising security issues: NO (YES/NO)
- 'EU-classified information' as background or results: NO (YES/NO)

The project does not involve 'EU-classified information' as background or results. Security issues raised by the project are the protection of sensible health care data and privacy of patients. The project takes several measures to address these issues as described in Chapter 2.3.6.1.

[101] Article 37.1 of Model Grant Agreement. *Before disclosing results of activities raising security issues to a third party (including affiliated entities), a beneficiary must inform the coordinator — which must request written approval from the Commission/Agency;* Article 37. *Activities related to 'classified deliverables' must comply with the 'security requirements' until they are declassified; Action tasks related to classified deliverables may not be subcontracted without prior explicit written approval from the Commission/Agency.; The beneficiaries must inform the coordinator — which must immediately inform the Commission/Agency — of any changes in the security context and — if necessary —request for Annex 1 to be amended (see Article 55)*

ESTIMATED BUDGET FOR THE ACTION (page 1 of 3)

	Estimated eligible* costs (per budget category)								
	A. Direct personnel costs				B. Direct costs of subcontracting	[C. Direct costs of fin. support]	D. Other direct costs	E. Indirect costs	Total costs
	A.1 Personnel A.2 Natural persons under direct contract A.3 Seconded persons [A.6 Personnel for providing access to research infrastructure]		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services D.4 Costs of large research infrastructure		
Form of costs****	Actual	Unit (1)	Unit (2) EUR/hour		Actual	Actual	Actual	Flat-rate (3) 25%	
	(a)	Total (b)	No hours	Total (c)	(d)	(e)	(f)	(g)=0,25x ((a)+(b)+ (c)+(f)-(m))	(i)= (a)+(b)+(c)+ (d)+(e)+(f)+ (g)
1. Fraunhofer	.00	670000.00			100000.00	.00	94600.00	191150.00	1055750.00
2. FORTH	540000.00	.00			.00	.00	58000.00	149500.00	747500.00
3. USAAR	264600.00	.00			.00	.00	35000.00	74900.00	374500.00
4. PHILIPS ELECTRONICS NEDERLAND B.V.	534419.20	.00			.00	.00	25000.00	139854.80	699274.00
5. Cancer Intelligence Ltd	265000.00	.00			.00	.00	91000.00	89000.00	445000.00
6. BED	451000.00	.00			.00	.00	32000.00	120750.00	603750.00
7. ISTITUTO EUROPEO DI ONCOLOGIA SRL	261250.00	.00			.00	.00	110070.00	92830.00	464150.00
8. SGS	357000.00	.00			.00	.00	16000.00	93250.00	466250.00
Total Consortium	2673269.20	670000.00			100000.00	.00	461670.00	951234.80	4856174.00

ESTIMATED BUDGET FOR THE ACTION (page 2 of 3)

		EU contribution			Additional information	
	Total costs	Reimbursement rate %	Maximum EU contribution ***	Maximum grant amount	Information for indirect costs	Information for auditors
					Costs of in-kind contributions not used on premises	Declaration of costs under Point D.4
	(i)= (a)+(b)+(c)+ (d)+(e)+(f)+ (g)+(h1)+(h2)	(j)	(k)	(l)	(m)	Yes/No
1. Fraunhofer	1055750.00	100.00	1055750.00	1055750.00	.00	No
2. FORTH	747500.00	100.00	747500.00	747500.00	.00	No
3. USAAR	374500.00	100.00	374500.00	374500.00	.00	No
4. PHILIPS ELECTRONICS NEDERLAND B.V.	699274.00	100.00	699274.00	699274.00	.00	No
5. Cancer Intelligence Ltd	445000.00	100.00	445000.00	445000.00	.00	No
6. BED	603750.00	100.00	603750.00	603750.00	.00	No
7. ISTITUTO EUROPEO DI ONCOLOGIA SRL	464150.00	100.00	464150.00	464150.00	.00	No
8. SGS	466250.00	100.00	466250.00	466250.00	.00	No
Total Consortium	4856174.00		4856174.00	4856174.00	.00	

ESTIMATED BUDGET FOR THE ACTION (page 3 of 3)

* See Article 6 for conditions for costs to be eligible
** Depending on its type, this cost will or will not include indirect costs.
Costs that include indirect costs are: costs of energy efficiency measures in buildings, costs of providing trans-national access to research infrastructure and costs of clinical studies.
*** This is the theoretical amount of EU contribution if the reimbursement rate is applied to all the budgeted costs. The theoretical amount of EU contribution for the action is capped by the maximum grant amount.
**** See Article 5 for forms of costs
(1) unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice
(2) unit : hours worked on the action; cost per unit : XX EUR
(3) flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under Point F if they include indirect costs
(4) unit : … ; costs per unit : XX EUR
(5) unit : ….. costs per unit …… (the units,the costs per unit and the estimated number of units will be agreed with the beneficiaries in a separate document that becomes part of Annex 2 of their grant agreement)
(6) only unit costs not including indirect costs to be added

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS (FORTH), PD432/87, established in N PLASTIRA STR 100, HERAKLION 70013, Greece, EL090101655, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary (‘2’)

in Agreement No 643529 (‘the Agreement’)

between FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V **and** *the European Union ('the EU', represented by the European Commission ('the Commission') ,*

for the action entitled ‘iManageCancer - Empowering patients and strengthening self-management in cancer diseases (iManageCancer)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

COSTAS FOTAKIS with ECAS id ncostafs signed in the Participant Portal on 11/12/2014 at 12:16:56 (transaction id SigId-12220-LLUKvxfjtd9Uzga0T6bd04Ra0JzkZ19RN1lMrWuYi5rbBg5IUuHKrcSn3AzkJubUjhCgDsKC6EG8wYCNK3wBW20-PHslUMVSXYCxZAW3OHozsk-OMAo7e0WcmzI9UaZSOZ0JXPeFTdCvGVeXMc20KvMIhr). Timestamp by third party at Thu Dec 11 12:17:01 CET 2014

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITAET DES SAARLANDES (USAAR), established in CAMPUS, SAARBRUCKEN 66041, Germany, DE138117521, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary (‘3’)

in Agreement No 643529 (‘the Agreement’)

between FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V **and** *the European Union ('the EU', represented by the European Commission ('the Commission') ,*

for the action entitled ‘iManageCancer - Empowering patients and strengthening self-management in cancer diseases (iManageCancer)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Volker LINNEWEBER with ECAS id nlinnevo signed in the Participant Portal on 18/12/2014 at 09:54:10 (transaction id SigId-22007-bQg2exJwqk4SF7qdkOdkRihbxiTZybyevj6T9pqacp2GLbrrQrIPHa5enuxjNhbR7E1ZENkmgTt9e415BYg8zu-PHslUMVSXYCxZAW3OHozsk-tD1qShbDD4nzGn2jPdHOiAPmQTDLQi29XdQs2chAajzW).
Timestamp by third party at
Thu Dec 18 09:54:15 CET 2014

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

PHILIPS ELECTRONICS NEDERLAND B.V. (PHILIPS ELECTRONICS NEDERLAND B.V.) BV, 17008551, established in Boschdijk 525, EINDHOVEN 5621JG, Netherlands, NL001902106B01, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary (‘4’)

in Agreement No 643529 (‘the Agreement’)

between FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V **and** *the European Union ('the EU', represented by the European Commission ('the Commission') ,*

for the action entitled ‘iManageCancer - Empowering patients and strengthening self-management in cancer diseases (iManageCancer)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Henk VAN HOUTEN with ECAS id nhoutehe signed in the Participant Portal on 15/12/2014 at 14:54:22 (transaction id SigId-16415-ZCTWDuyQLkAdYzJsiA1NtsGQYJHreVNzlwPkfBtXHc99NtlGQIa6yvS2EdiSOkBRnxdR29vJKbJbbpeK8cjgszm-PHslUMVSXYCxZAW3OHozsk-IztYJsQRZIVhl1r989OvA1ezfTTzkAa6l9QFouS9jONq). Timestamp by third party at
Mon Dec 15 14:54:28 CET 2014

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

CANCER INTELLIGENCE LIMITED (Cancer Intelligence Ltd) LTD, 04595666, established in Alma Vale Road 11, Bristol BS8 2HL, United Kingdom, GB811051486, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary (‘5’)

in Agreement No 643529 (‘the Agreement’)

between FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V **and** *the European Union ('the EU', represented by the European Commission ('the Commission') ,*

for the action entitled ‘iManageCancer - Empowering patients and strengthening self-management in cancer diseases (iManageCancer)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Gordon MCVIE with ECAS id nvievigo signed in the Participant Portal on 09/12/2014 at 13:19:07 (transaction id SigId-9347-nYVbNYQ7DjSRGCXTdQ0LgSy0hbzIC3Vcr2d6lKcI7iR12zrp6ojZiT5tztWbpGvcYnv3qSRIpfRcmdmL8AFRzZG-PHslUMVSXYCxZAW3OHozsk-yXJVXPSq9YtMlCk6lSOV9zcLMlG3EkkOmsqeS74rg1p). Timestamp by third party at
Tue Dec 09 13:19:13 CET 2014

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITY OF BEDFORDSHIRE (BED), , established in PARK SQUARE, LUTON LU1 3JU, United Kingdom, GB600498850, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary (‘6’)

in Agreement No 643529 (‘the Agreement’)

between FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V **and** *the European Union ('the EU', represented by the European Commission ('the Commission') ,*

for the action entitled ‘iManageCancer - Empowering patients and strengthening self-management in cancer diseases (iManageCancer)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Mary MALCOLM with ECAS id nmalcolm signed in the Participant Portal on 10/12/2014 at 09:10:16 (transaction id SigId-10185-zN7Z9PJuAROMKjWe2WVtJyNWM0DiFgzis5LNa38zkch813GLOPD1TB1PsI4gBicPYQsfOTN0oV3lNWtRIGFBbBm-PHslUMVSXYCxZAW3OHozsk-ApCu4szr7dJMycM0mTzte5LiNrlr2CRU5hexjVoKnDSW). Timestamp by third party at
Wed Dec 10 09:10:23 CET 2014

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ISTITUTO EUROPEO DI ONCOLOGIA SRL (ISTITUTO EUROPEO DI ONCOLOGIA SRL) SRL, 1243795, established in Via Filodrammatici 10, MILANO 20121, Italy, IT08691440153, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary (‘7’)

in Agreement No 643529 (‘the Agreement’)

between FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V **and** *the European Union ('the EU', represented by the European Commission ('the Commission') ,*

for the action entitled ‘iManageCancer - Empowering patients and strengthening self-management in cancer diseases (iManageCancer)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Mauro MELIS with ECAS id nmelimur signed in the Participant Portal on 19/12/2014 at 16:43:05 (transaction id SigId-25575-2D6rvgr7vQ632rp9jvqYXpZzhvtrF1aMMWw4087srFdzb1d59ydYBUNTHuRYvuzlf3PS4vjlZtPeoLMzzJQDa7zW-PHslUMVSXYCxZAW3OHozsk-YtTlpzvuyERiijfjR3SGA6j5E6awqkqFJZ9GMzWCchV0). Timestamp by third party at
Fri Dec 19 16:43:12 CET 2014

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

SERIOUS GAMES SOLUTIONS GMBH (SGS) GMBH, HRB22627P, established in AUGUST BEBEL STRASSE 27, POTSDAM 14482, Germany, DE268028228, ('the beneficiary'), represented for the purpose of signing this Accession Form by the undersigned,

hereby agrees

to become beneficiary (‘8’)

in Agreement No 643529 (‘the Agreement’)

between FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V **and** *the European Union ('the EU', represented by the European Commission ('the Commission') ,*

for the action entitled ‘iManageCancer - Empowering patients and strengthening self-management in cancer diseases (iManageCancer)’.

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 55.

By signing this Accession Form, the beneficiary accepts the grant and agrees to implement the action in accordance with the Agreement, with all the obligations and conditions it sets out.

SIGNATURE

For the beneficiary

Ralph STOCK with ECAS id nstockrp signed in the Participant Portal on 08/12/2014 at 23:44:07 (transaction id SigId-8675-4WcQ8f33AwsUMuzbLcSxVgjoMQR2Ze0GojquSAYhzWBKwqRVpcFeR0YgnMeUOzcEpgdv3qLMA77DExzKfcbTama-PHslUMVSXYCxZAW3OHozsk-oSwaXvMxpteOJFrsY6nFQzVoM9VWtmfLKeB9knGZKTD). Timestamp by third party at
Mon Dec 08 23:44:14 CET 2014

ⓘ print format A4 landscape

MODEL ANNEX 4 FOR GENERAL MGA - MULTI-BENEFICIARY

FINANCIAL STATEMENT FOR *[BENEFICIARY [name]/ LINKED THIRD PARTY [name]]*

	Eligible* costs (per budget category)												Receipts	EU contribution			Additional information
	A. Direct personnel costs				B. Direct costs of subcontracting	*[C. Direct costs of fin. support]*	D. Other direct costs		E. Indirect costs	*[F. Costs of …]*		Total costs	Receipts	Reimbursement rate %	Maximum EU contribution ***	Requested EU contribution	Information for indirect costs :
	A.1 Personnel A.2 Natural persons under direct contract A.3 Seconded persons *[A.6 Personnel for providing access to research infrastructure]*		A.4 SME owners without salary A.5 Beneficiaries that are natural persons without salary				D.1 Travel D.2 Equipment D.3 Other goods and services	D.4 Costs of large research infrastructure		*[F.1 Costs of …] **	*[F.2 Costs of …]**		Receipts of the action, to be reported in the last reporting period, according to Article 5.3.3				Costs of in-kind contributions not used on premises
Form of costs**	Actual	Unit ①	Unit ②		Actual	Actual	Actual	Actual	Flat-rate ③	Unit ④		Unit ⑤					
			XX EUR/hour						25%	XX EUR/unit							
	(a)	Total (b)	No hours	Total (c)	(d)	(e)	(f)	(g)	(h)=0,25x((a)+(b)+(c)+(f)+ (g)+ [(i1)]⑥+[(i2)]⑥- (o))	No units	Total (i1)	Total (i2)	(j) = (a)+(b)+(c)+(d)+(e)+(f)+(g)+(h)+(i1)+(i2)	(k)	(l)	(m)	(n)	(o)

The beneficiary/linked third party hereby confirms that:
The information provided is complete, reliable and true.
The costs declared are eligible (see Article 6).
The costs can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 17, 18 and 22).
For the last reporting period: that all the receipts have been declared (see Article 5.3.3).

ⓘ The beneficiary/linked party must declare all eligible costs, even if - for actual costs, unit costs and flat-rate costs - they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts not declared in the individual financial statement will not be taken into account by the *[Commission][Agency]*

* See Article 6 for conditions for costs to be eligible
** Depending on its type, this cost will or will not include indirect costs.
Costs that include indirect costs are: costs of energy efficiency measures in buildings, costs of providing trans-national access to research infrastructure and costs of clinical studies.
*** This is the theoretical amount of EU contribution if the reimbursement rate is applied to *all* the reported costs. At the payment of the balance, the theoretical amount of EU contribution for the action is capped by the maximum grant amount.
**** See Article 5 for forms of costs
① unit : hours worked on the action; costs per unit (hourly rate) : calculated according to beneficiary's usual accounting practice
② unit : hours worked on the action; cost per unit : XX EUR
③ flat rate : 25% of eligible direct costs, from which are excluded: direct costs of subcontracting, costs of in-kind contributions not used on premises, direct costs of financial support, and unit costs declared under Point F if they include indirect costs
④ unit : … ; costs per unit : XX EUR
⑤ unit : ….. costs per unit …… (the units and the costs per unit are set out in Annex 2 of the grant agreement)
⑥ only unit costs **not including indirect costs** to be added

ANNEX 5

MODEL FOR THE CERTIFICATE ON THE FINANCIAL STATEMENTS

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data**

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TERMS OF REFERENCE FOR AN INDEPENDENT REPORT OF FACTUAL FINDINGS ON COSTS DECLARED UNDER A GRANT AGREEMENT FINANCED UNDER THE HORIZON 2020 RESEARCH FRAMEWORK PROGRAMME..... 2

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Terms of Reference for an Independent Report of Factual Findings on costs declared under a Grant Agreement financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the Financial Statement(s)[47] drawn up by the *[Beneficiary] [Linked Third Party]* for the Horizon 2020 grant agreement [insert number of the grant agreement, title of the action, acronym and duration from/to] ('the Agreement'), and

to issue a Certificate on the Financial Statements' ('CFS') referred to in Article 20.4 of the Agreement based on the compulsory reporting template stipulated by the Commission.

The Agreement has been concluded under the Horizon 2020 Research and Innovation Framework Programme (H2020) between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union][Euratom][Agency]* is not a party to this engagement.

1.1 Subject of the engagement

The coordinator must submit to the *[Commission][Agency]* the final report within 60 days following the end of the last reporting period which should include, amongst other documents, a CFS for each beneficiary and for each linked third party that requests a total contribution of EUR 325 000 or more, as reimbursement of actual costs and unit costs calculated on the basis of its usual cost accounting practices (see Article 20.4 of the Agreement). The CFS must cover all reporting periods of the beneficiary or linked third party indicated above.

The Beneficiary must submit to the coordinator the CFS for itself and for its linked third party(ies), if the CFS must be included in the final report according to Article 20.4 of the Agreement..

The CFS is composed of two separate documents:

- The Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

[47] By which costs under the Agreement are declared (see template 'Model Financial Statements' in Annex 4 to the Grant Agreement).

- The Auditor's Independent Report of Factual Findings ('the Report') to be issued on the Auditor's letterhead, dated, stamped and signed by the Auditor (or the competent public officer) which includes the agreed-upon procedures ('the Procedures') to be performed by the Auditor, and the standard factual findings ('the Findings') to be confirmed by the Auditor.

If the CFS must be included in the final report according to Article 20.4 of the Agreement, the request for payment of the balance relating to the Agreement cannot be made without the CFS. However, the payment for reimbursement of costs covered by the CFS does not preclude the *[Commission,][Agency,]* the European Anti-Fraud Office and the European Court of Auditors from carrying out checks, reviews, audits and investigations in accordance with Article 22 of the Agreement.

1.2 Responsibilities

The *[Beneficiary] [Linked Third Party]:*

- must draw up the Financial Statement(s) for the action financed by the Agreement in compliance with the obligations under the Agreement. The Financial Statement(s) must be drawn up according to the *[Beneficiary's] [Linked Third Party's]* accounting and book-keeping system and the underlying accounts and records;
- must send the Financial Statement(s) to the Auditor;
- is responsible and liable for the accuracy of the Financial Statement(s);
- is responsible for the completeness and accuracy of the information provided to enable the Auditor to carry out the Procedures. It must provide the Auditor with a written representation letter supporting these statements. The written representation letter must state the period covered by the statements and must be dated;
- accepts that the Auditor cannot carry out the Procedures unless it is given full access to the *[Beneficiary's] [Linked Third Party's]* staff and accounting as well as any other relevant records and documentation.

The Auditor:

- *[Option 1 by default:* is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations*]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer:* is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary*]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation:* is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation*]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the *[Beneficiary's] [Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with this ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commissionsets out the Procedures to be carried out by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement, the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[48]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Federation of Accountants (IFAC);
- the *Code of Ethics for Professional Accountants* issued by the IFAC. Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the [*Commission*] [*Agency*] requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there is no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]*, and must specify - if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7).

Under Article 22 of the Agreement, the [*Commission*] [*Agency*], the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are declared from [*the European Union*] [*Euratom*]. This includes work related to this engagement. The Auditor must provide access to all working papers (e.g. recalculation of hourly rates, verification of the time declared for the action) related to this assignment if the *[Commission] [Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by *[*dd Month yyyy*]*.

1.6 Other terms

[*The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.*]

[legal name of the Auditor]	[legal name of the *[Beneficiary][Linked Third Party]*]
[name & function of authorised representative]	[name & function of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor	Signature of the *[Beneficiary][Linked Third Party]*

[48] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IFAC.

Independent Report of Factual Findings on costs declared under Horizon 2020 Research and Innovation Framework Programme

(To be printed on the Auditor's letterhead)

To
[name of contact person(s)], [Position]
[[*Beneficiary's*] [*Linked Third Party's*] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the procedures agreed with you regarding the costs declared in the Financial Statement(s)[49] of the *[Beneficiary] [Linked Third Party]* concerning the grant agreement [insert grant agreement reference: number, title of the action and acronym] ('the Agreement'),

with a total cost declared of

[total amount] EUR,

and a total of actual costs and 'direct personnel costs declared as unit costs calculated in accordance with the [*Beneficiary's*] [*Linked Third Party's*] usual cost accounting practices' declared of

[sum of total actual costs and total direct personnel costs declared as unit costs calculated in accordance with the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practices] EUR

and **hereby provide our Independent Report of Factual Findings ('the Report')** using the compulsory report format agreed with you.

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') examined.

[49] By which the Beneficiary declares costs under the Agreement (see template 'Model Financial Statement' in Annex 4 to the Agreement).

The Procedures were carried out solely to assist the [*Commission*] [*Agency*] in evaluating whether the [*Beneficiary's*] [*Linked Third Party's*] costs in the accompanying Financial Statement(s) were declared in accordance with the Agreement. The *[Commission] [Agency]* draws its own conclusions from the Report and any additional information it may require.

The scope of the Procedures was defined by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence. Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, the Auditor does not give a statement of assurance on the Financial Statements.

Had the Auditor carried out additional procedures or an audit of the *[Beneficiary's] [Linked Third Party's]* Financial Statements in accordance with International Standards on Auditing or International Standards on Review Engagements, other matters might have come to its attention and would have been included in the Report.

Not applicable Findings

We examined the Financial Statement(s) stated above and considered the following Findings not applicable:

Explanation (to be removed from the Report):

*If a Finding was not applicable, it must be marked as '**N.A.**' ('Not applicable') in the corresponding row on the right-hand column of the table and means that the Finding did not have to be corroborated by the Auditor and the related Procedure(s) did not have to be carried out.*

The reasons of the non-application of a certain Finding must be obvious i.e.

i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable;

ii) if the condition set to apply certain Procedure(s) are not met the related Finding(s) and those Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than euro' the Procedure and Finding related to 'beneficiaries with accounts established in euro' are not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

List here all Findings considered not applicable for the present engagement and explain the reasons of the non-applicability.

….

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

Explanation (to be removed from the Report):

- *If the Auditor was not able to successfully complete a procedure requested, it must be marked as '**E**' ('Exception') in the corresponding row on the right-hand column of the table. The reason such as the inability to reconcile key information or the unavailability of data that prevents the Auditor from carrying out the Procedure must be indicated below.*
- *If the Auditor cannot corroborate a standard finding after having carried out the corresponding procedure, it must also be marked as '**E**' ('Exception') and, where possible, the reasons why the Finding was not fulfilled and its possible impact must be explained here below.*

List here any exceptions and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, include the corresponding amount.

….

Example (to be removed from the Report):

1. *The Beneficiary was unable to substantiate the Finding number 1 on … because ….*
2. *Finding number 30 was not fulfilled because the methodology used by the Beneficiary to calculate unit costs was different from the one approved by the Commission. The differences were as follows: …*
3. *After carrying out the agreed procedures to confirm the Finding number 31, the Auditor found a difference of _____ EUR. The difference can be explained by …*

Further Remarks

In addition to reporting on the results of the specific procedures carried out, the Auditor would like to make the following general remarks:

Example (to be removed from the Report):

1. *Regarding Finding number 8 the conditions for additional remuneration were considered as fulfilled because …*
2. *In order to be able to confirm the Finding number 15 we carried out the following additional procedures: ….*

Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the *[Beneficiary] [Linked Third Party]* and the [*Commission*] [*Agency*], and only to be submitted to the [*Commission*] [*Agency*] in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the *[Beneficiary] [Linked Third Party]* or by the [*Commission*] [*Agency*] for any other purpose, nor may it be distributed to any other parties. The [*Commission*] [*Agency*] may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the *[Commission] [Agency]* by the *[Beneficiary] [Linked Third Party]* for the Agreement. Therefore, it does not extend to any other of the [*Beneficiary's*] [*Linked Third Party's*] Financial Statement(s).

There was no conflict of interest[50] between the Auditor and the Beneficiary *[and Linked Third Party]* in establishing this Report. The total fee paid to the Auditor for providing the Report was EUR _____ (including EUR_____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance.

[legal name of the Auditor]
[name and function of an authorised representative]
[dd Month yyyy]
Signature of the Auditor

[50] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Agreed-upon procedures to be performed and standard factual findings to be confirmed by the Auditor

The European Commission reserves the right to i) provide the auditor with additional guidance regarding the procedures to be followed or the facts to be ascertained and the way in which to present them (this may include sample coverage and findings) or to ii) change the procedures, by notifying the Beneficiary in writing. The procedures carried out by the auditor to confirm the standard factual finding are listed in the table below.

If this certificate relates to a Linked Third Party, any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

The 'result' column has three different options: 'C', 'E' and 'N.A.':

- 'C' stands for 'confirmed' and means that the auditor can confirm the 'standard factual finding' and, therefore, there is no exception to be reported.
- 'E' stands for 'exception' and means that the Auditor carried out the procedures but cannot confirm the 'standard factual finding', or that the Auditor was not able to carry out a specific procedure (e.g. because it was impossible to reconcile key information or data were unavailable),
- 'N.A.' stands for 'not applicable' and means that the Finding did not have to be examined by the Auditor and the related Procedure(s) did not have to be carried out. The reasons of the non-application of a certain Finding must be obvious i.e. i) if no cost was declared under a certain category then the related Finding(s) and Procedure(s) are not applicable; ii) if the condition set to apply certain Procedure(s) are not met then the related Finding(s) and Procedure(s) are not applicable. For instance, for 'beneficiaries with accounts established in a currency other than the euro' the Procedure related to 'beneficiaries with accounts established in euro' is not applicable. Similarly, if no additional remuneration is paid, the related Finding(s) and Procedure(s) for additional remuneration are not applicable.

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A	**ACTUAL PERSONNEL COSTS AND UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICE**		
	The Auditor draws a sample of persons whose costs were declared in the Financial Statement(s) to carry out the procedures indicated in the consecutive points of this section A. (*The sample should be selected randomly so that it is representative. Full coverage is required if there are fewer than 10 people (including employees, natural persons working under a direct contract and personnel seconded by a third party), otherwise the sample should have a minimum of 10 people, or 10% of the total, whichever number is the highest)* The Auditor sampled _____ people out of the total of _____ people.		

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.1	**PERSONNEL COSTS** <u>For the persons included in the sample and working under an employment contract or equivalent act (general procedures for individual actual personnel costs and personnel costs declared as unit costs)</u> To confirm standard factual findings 1-5 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o a list of the persons included in the sample indicating the period(s) during which they worked for the action, their position (classification or category) and type of contract; o the payslips of the employees included in the sample; o reconciliation of the personnel costs declared in the Financial Statement(s) with the accounting system (project accounting and general ledger) and payroll system; o information concerning the employment status and employment conditions of personnel included in the sample, in particular their employment contracts or equivalent; o the Beneficiary's usual policy regarding payroll matters (e.g. salary policy, overtime policy, variable pay); o applicable national law on taxes, labour and social security and o any other document that supports the personnel costs declared. The Auditor also verified the eligibility of all components of the retribution (see Article 6 GA) and recalculated the personnel costs for employees included in the sample.	1) The employees were i) directly hired by the Beneficiary in accordance with its national legislation, ii) under the Beneficiary's sole technical supervision and responsibility and iii) remunerated in accordance with the Beneficiary's usual practices.	
		2) Personnel costs were recorded in the Beneficiary's accounts/payroll system.	
		3) Costs were adequately supported and reconciled with the accounts and payroll records.	
		4) Personnel costs did not contain any ineligible elements.	
		5) There were no discrepancies between the personnel costs charged to the action and the costs recalculated by the Auditor.	
	Further procedures if 'additional remuneration' is paid To confirm standard factual findings 6-9 listed in the next column, the Auditor: o reviewed relevant documents provided by the Beneficiary (legal form, legal/statutory	6) The Beneficiary paying "additional remuneration" was a non-profit legal entity.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	obligations, the Beneficiary's usual policy on additional remuneration, criteria used for its calculation…); o recalculated the amount of additional remuneration eligible for the action based on the supporting documents received (full-time or part-time work, exclusive or non-exclusive dedication to the action, etc.) to arrive at the applicable FTE/year and pro-rata rate (see data collected in the course of carrying out the procedures under A.2 'Productive hours' and A.4 'Time recording system'). *IF ANY PART OF THE REMUNERATION PAID TO THE EMPLOYEE IS NOT MANDATORY ACCORDING TO THE NATIONAL LAW OR THE EMPLOYMENT CONTRACT ("ADDITIONAL REMUNERATION") AND IS ELIGIBLE UNDER THE PROVISIONS OF ARTICLE 6.2.A.1, THIS CAN BE CHARGED AS ELIGIBLE COST TO THE ACTION UP TO THE FOLLOWING AMOUNT:* *(A) IF THE PERSON WORKS FULL TIME AND EXCLUSIVELY ON THE ACTION DURING THE FULL YEAR: UP TO EUR 8 000/YEAR;* *(B) IF THE PERSON WORKS EXCLUSIVELY ON THE ACTION BUT NOT FULL-TIME OR NOT FOR THE FULL YEAR: UP TO THE CORRESPONDING PRO-RATA AMOUNT OF EUR 8 000, OR* *(C) IF THE PERSON DOES NOT WORK EXCLUSIVELY ON THE ACTION: UP TO A PRO-RATA AMOUNT CALCULATED IN ACCORDANCE TO ARTICLE 6.2.A.1.*	7) The amount of additional remuneration paid corresponded to the Beneficiary's usual remuneration practices and was consistently paid whenever the same kind of work or expertise was required. 8) The criteria used to calculate the additional remuneration were objective and generally applied by the Beneficiary regardless of the source of funding used. 9) The amount of additional remuneration included in the personnel costs charged to the action was capped at EUR 8,000 per FTE/year (up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).	
	Additional procedures in case "unit costs calculated by the Beneficiary in accordance with its usual cost accounting practices" is applied: Apart from carrying out the procedures indicated above to confirm standard factual findings 1-5 and, if applicable, also 6-9, the Auditor carried out following procedures to confirm standard	10) The personnel costs included in the Financial Statement were calculated in accordance with the Beneficiary's usual cost accounting practice. This methodology was consistently	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	factual findings 10-13 listed in the next column: o obtained a description of the Beneficiary's usual cost accounting practice to calculate unit costs;. o reviewed whether the Beneficiary's usual cost accounting practice was applied for the Financial Statements subject of the present CFS; o verified the employees included in the sample were charged under the correct category (in accordance with the criteria used by the Beneficiary to establish personnel categories) by reviewing the contract/HR-record or analytical accounting records; o verified that there is no difference between the total amount of personnel costs used in calculating the cost per unit and the total amount of personnel costs recorded in the statutory accounts; o verified whether actual personnel costs were adjusted on the basis of budgeted or estimated elements and, if so, verified whether those elements used are actually relevant for the calculation, objective and supported by documents.	used in all H2020 actions. 11) The employees were charged under the correct category. 12) Total personnel costs used in calculating the unit costs were consistent with the expenses recorded in the statutory accounts. 13) Any estimated or budgeted element used by the Beneficiary in its unit-cost calculation were relevant for calculating personnel costs and corresponded to objective and verifiable information.	
	<u>For natural persons included in the sample and working with the Beneficiary under a direct contract other than an employment contract, such as consultants (no subcontractors).</u> To confirm standard factual findings 14-18 listed in the next column the Auditor reviewed following information/documents provided by the Beneficiary: o the contracts, especially the cost, contract duration, work description, place of work, ownership of the results and reporting obligations to the Beneficiary; o the employment conditions of staff in the same category to compare costs and; o any other document that supports the costs declared and its registration (e.g. invoices,	14) The natural persons reported to the Beneficiary (worked under the Beneficiary's instructions). 15) They worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary). 16) The results of work carried out belong to the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	accounting records, etc.).	17) Their costs were not significantly different from those for staff who performed similar tasks under an employment contract with the Beneficiary.	
		18) The costs were supported by audit evidence and registered in the accounts.	
	<u>For personnel seconded by a third party and included in the sample (not subcontractors)</u> To confirm standard factual findings 19-22 listed in the next column, the Auditor reviewed following information/documents provided by the Beneficiary: o their secondment contract(s) notably regarding costs, duration, work description, place of work and ownership of the results; o if there is reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution against payment): any documentation that supports the costs declared (e.g. contract, invoice, bank payment, and proof of registration in its accounting/payroll, etc.) and reconciliation of the Financial Statement(s) with the accounting system (project accounting and general ledger) as well as any proof that the amount invoiced by the third party did not include any profit; o if there is no reimbursement by the Beneficiary to the third party for the resource made available (in-kind contribution free of charge): a proof of the actual cost borne by the Third Party for the resource made available free of charge to the Beneficiary such as a statement of costs incurred by the Third Party and proof of the registration in the Third Party's accounting/payroll; o any other document that supports the costs declared (e.g. invoices, etc.).	19) Seconded personnel reported to the Beneficiary and worked on the Beneficiary's premises (unless otherwise agreed with the Beneficiary).	
		20) The results of work carried out belong to the Beneficiary.	
		If personnel is seconded against payment: 21) The costs declared were supported with documentation and recorded in the Beneficiary's accounts. The third party did not include any profit.	
		If personnel is seconded free of charge: 22) The costs declared did not exceed the third party's cost as	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
		recorded in the accounts of the third party and were supported with documentation.	
A.2	**PRODUCTIVE HOURS** To confirm standard factual findings 23-28 listed in the next column, the Auditor reviewed relevant documents, especially national legislation, labour agreements and contracts and time records of the persons included in the sample, to verify that: o the annual productive hours applied were calculated in accordance with one of the methods described below, o the full-time equivalent (FTEs) ratios for employees not working full-time were correctly calculated. If the Beneficiary applied method B, the auditor verified that the correctness in which the total number of hours worked was calculated and that the contracts specified the annual workable hours. If the Beneficiary applied method C, the auditor verified that the 'annual productive hours' applied when calculating the hourly rate were equivalent to at least 90 % of the 'standard annual workable hours'. The Auditor can only do this if the calculation of the standard annual workable hours can be supported by records, such as national legislation, labour agreements, and contracts. *BENEFICIARY'S PRODUCTIVE HOURS' FOR PERSONS WORKING FULL TIME SHALL BE ONE OF THE FOLLOWING METHODS:* ***A.*** *1720 ANNUAL PRODUCTIVE HOURS (PRO-RATA FOR PERSONS NOT WORKING FULL-TIME)* ***B.*** *THE TOTAL NUMBER OF HOURS WORKED BY THE PERSON FOR THE BENEFICIARY IN THE YEAR (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL NUMBER OF HOURS WORKED' IN THE NEXT COLUMN). THE CALCULATION OF THE TOTAL NUMBER OF HOURS WORKED WAS DONE AS*	23) The Beneficiary applied method [*choose one option and delete the others*] [**A**: 1720 hours] [**B**: the 'total number of hours worked'] [**C**: 'annual productive hours' used correspond to usual accounting practices]	
		24) Productive hours were calculated annually.	
		25) For employees not working full-time the full-time equivalent (FTE) ratio was correctly applied.	
		If the Beneficiary applied method B. 26) The calculation of the number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	FOLLOWS: ANNUAL WORKABLE HOURS OF THE PERSON ACCORDING TO THE EMPLOYMENT CONTRACT, APPLICABLE LABOUR AGREEMENT OR NATIONAL LAW PLUS OVERTIME WORKED MINUS ABSENCES (SUCH AS SICK LEAVE OR SPECIAL LEAVE). ***C.** THE STANDARD NUMBER OF ANNUAL HOURS GENERALLY APPLIED BY THE BENEFICIARY FOR ITS PERSONNEL IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES (THIS METHOD IS ALSO REFERRED TO AS 'TOTAL ANNUAL PRODUCTIVE HOURS' IN THE NEXT COLUMN). THIS NUMBER MUST BE AT LEAST 90% OF THE STANDARD ANNUAL WORKABLE HOURS.* *'ANNUAL WORKABLE HOURS' MEANS THE PERIOD DURING WHICH THE PERSONNEL MUST BE WORKING, AT THE EMPLOYER'S DISPOSAL AND CARRYING OUT HIS/HER ACTIVITY OR DUTIES UNDER THE EMPLOYMENT CONTRACT, APPLICABLE COLLECTIVE LABOUR AGREEMENT OR NATIONAL WORKING TIME LEGISLATION.*	*If the Beneficiary applied method C.* 27) The calculation of the number of 'standard annual workable hours' was verifiable based on the documents provided by the Beneficiary.	
		28) The 'annual productive hours' used for calculating the hourly rate were consistent with the usual cost accounting practices of the Beneficiary and were equivalent to at least 90 % of the 'annual workable hours'.	
A.3	**HOURLY PERSONNEL RATES** <u>I) For unit costs calculated in accordance to the Beneficiary's usual cost accounting practice (unit costs):</u> If the Beneficiary has a "Certificate on Methodology to calculate unit costs " (CoMUC) approved by the Commission, the Beneficiary provides the Auditor with a description of the approved methodology and the Commission's letter of acceptance. The Auditor verified that the Beneficiary has indeed used the methodology approved. If so, no further verification is necessary. If the Beneficiary does not have a "Certificate on Methodology" (CoMUC) approved by the Commission, or if the methodology approved was not applied, then the Auditor:	29) The Beneficiary applied [*choose one option and delete the other*]: [Option I: "Unit costs (hourly rates) were calculated in accordance with the Beneficiary's usual cost accounting practices"] [Option II: Individual hourly rates were applied]	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the unit costs (hourly rates) of staff included in the sample following the results of the procedures carried out in A.1 and A.2. II) For individual hourly rates: The Auditor: o reviewed the documentation provided by the Beneficiary, including manuals and internal guidelines that explain how to calculate hourly rates; o recalculated the hourly rates of staff included in the sample following the results of the procedures carried out in A.1 and A.2. *"UNIT COSTS CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH ITS USUAL COST ACCOUNTING PRACTICES":* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF THE CATEGORY TO WHICH THE EMPLOYEE BELONGS VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF FTE AND THE ANNUAL TOTAL PRODUCTIVE HOURS OF THE SAME CATEGORY CALCULATED BY THE BENEFICIARY IN ACCORDANCE WITH PROCEDURE A.2.* *HOURLY RATE FOR INDIVIDUAL ACTUAL PERSONAL COSTS:* *IT IS CALCULATED BY DIVIDING THE TOTAL AMOUNT OF PERSONNEL COSTS OF AN EMPLOYEE VERIFIED IN LINE WITH PROCEDURE A.1 BY THE NUMBER OF ANNUAL PRODUCTIVE HOURS VERIFIED IN LINE WITH PROCEDURE A.2.*	*For option I concerning unit costs and if the Beneficiary applies the methodology approved by the Commission (CoMUC):* 30) The Beneficiary used the Commission-approved methodology to calculate hourly rates. It corresponded to the organisation's usual cost accounting practices and was applied consistently for all activities irrespective of the source of funding. *For option I concerning unit costs and if the Beneficiary applies a methodology not approved by the Commission:* 31) The unit costs re-calculated by the Auditor were the same as the rates applied by the Beneficiary. *For option II concerning individual hourly rates:* 32) The individual rates re-calculated by the Auditor were the same as the rates applied by the Beneficiary.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
A.4	**TIME RECORDING SYSTEM** To verify that the time recording system ensures the fulfilment of all minimum requirements and that the hours declared for the action were correct, accurate and properly authorised and supported by documentation, the Auditor made the following checks for the persons included in the sample that declare time as worked for the action on the basis of time records: o description of the time recording system provided by the Beneficiary (registration, authorisation, processing in the HR-system); o its actual implementation; o time records were signed at least monthly by the employees (on paper or electronically) and authorised by the project manager or another manager; o the hours declared were worked within the project period; o there were no hours declared as worked for the action if HR-records showed absence due to holidays or sickness (further cross-checks with travels are carried out in B.1 below) ; o the hours charged to the action matched those in the time recording system. *ONLY THE HOURS WORKED ON THE ACTION CAN BE CHARGED. ALL WORKING TIME TO BE CHARGED SHOULD BE RECORDED THROUGHOUT THE DURATION OF THE PROJECT, ADEQUATELY SUPPORTED BY EVIDENCE OF THEIR REALITY AND RELIABILITY (SEE SPECIFIC PROVISIONS BELOW FOR PERSONS WORKING EXCLUSIVELY FOR THE ACTION WITHOUT TIME RECORDS).*	33) All persons recorded their time dedicated to the action on a **daily/ weekly/ monthly** basis using a **paper/computer-based** system. (*delete the answers that are not applicable)*	
		34) Their time-records were authorised at least monthly by the project manager or other superior.	
		35) Hours declared were worked within the project period and were consistent with the presences/absences recorded in HR-records.	
		36) There were no discrepancies between the number of hours charged to the action and the number of hours recorded.	
	<u>If the persons are working exclusively for the action and without time records</u> For the persons selected that worked exclusively for the action without time records, the Auditor verified evidence available demonstrating that they were in reality exclusively dedicated to the action and that the Beneficiary signed a declaration confirming that they have worked exclusively for the action.	37) The exclusive dedication is supported by a declaration signed by the Beneficiary's and by any other evidence gathered.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
B	**COSTS OF SUBCONTRACTING**		
B.1	**The Auditor obtained the detail/breakdown of subcontracting costs and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). To confirm standard factual findings 38-42 listed in the next column, the Auditor reviewed the following for the items included in the sample: o the use of subcontractors was foreseen in Annex I; o subcontracting costs were declared in the subcontracting category of the Financial Statement; o supporting documents on the selection and award procedure were followed; o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the subcontract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment). In particular, i. if the Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the subcontracting complied with the Terms and Conditions of the Agreement. ii. if the Beneficiary did not fall under the above-mentioned category the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and	38) The use of claimed subcontracting costs was foreseen in Annex I and costs were declared in the Financial Statements under the subcontracting category. 39) There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. Subcontracts were awarded in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	Conditions of the Agreement.. For the items included in the sample the Auditor also verified that: o the subcontracts were not awarded to other Beneficiaries in the consortium; o there were signed agreements between the Beneficiary and the subcontractor; o there was evidence that the services were provided by subcontractor;	40) The subcontracts were not awarded to other Beneficiaries of the consortium.	
		41) All subcontracts were supported by signed agreements between the Beneficiary and the subcontractor.	
		42) There was evidence that the services were provided by the subcontractors.	
C	**COSTS OF PROVIDING FINANCIAL SUPPORT TO THIRD PARTIES**		
C.1	**The Auditor obtained the detail/breakdown of the costs of providing financial support to third parties and sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). The Auditor verified that the following minimum conditions were met: a) the maximum amount of financial support for each third party did not exceed EUR 60 000, unless explicitly mentioned in Annex I; b) the financial support to third parties was agreed in Annex I of the Agreement and the other provisions on financial support to third parties included in Annex I were respected.	43) All minimum conditions were met	
D	**OTHER ACTUAL DIRECT COSTS**		
D.1	**COSTS OF TRAVEL AND RELATED SUBSISTENCE ALLOWANCES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there*	44) Costs were incurred, approved and reimbursed in line with the	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest). The Auditor inspected the sample and verified that: o travel and subsistence costs were consistent with the Beneficiary's usual policy for travel. In this context, the Beneficiary provided evidence of its normal policy for travel costs (e.g. use of first class tickets, reimbursement by the Beneficiary on the basis of actual costs, a lump sum or per diem) to enable the Auditor to compare the travel costs charged with this policy; o travel costs are correctly identified and allocated to the action (e.g. trips are directly linked to the action) by reviewing relevant supporting documents such as minutes of meetings, workshops or conferences, their registration in the correct project account, their consistency with time records or with the dates/duration of the workshop/conference; o no ineligible costs or excessive or reckless expenditure was declared.	Beneficiary's usual policy for travels. 45) There was a link between the trip and the action. 46) The supporting documents were consistent with each other regarding subject of the trip, dates, duration and reconciled with time records and accounting. 47) No ineligible costs or excessive or reckless expenditure was declared.	
D.2	**DEPRECIATION COSTS FOR EQUIPMENT, INFRASTRUCTURE OR OTHER ASSETS** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is the highest*). For "equipment, infrastructure or other assets" [from now on called "asset(s)"] selected in the sample the Auditor verified that: o the assets were acquired in conformity with the Beneficiary's internal guidelines and procedures; o they were correctly allocated to the action (with supporting documents such as delivery	48) Procurement rules, principles and guides were followed. 49) There was a link between the grant agreement and the asset charged to the action. 50) The asset charged to the action was traceable to the accounting records and the underlying documents.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	note invoice or any other proof demonstrating the link to the action) o they were entered in the accounting system; o the extent to which the assets were used for the action (as a percentage) was supported by reliable documentation (e.g. usage overview table); The Auditor recalculated the depreciation costs and verified that they were in line with the applicable rules in the Beneficiary's country and with the Beneficiary's usual accounting policy (e.g. depreciation calculated on the acquisition value). The Auditor verified that no ineligible costs such as deductible VAT, exchange rate losses, excessive or reckless expenditure were declared (see Article 6.5 GA).	51) The depreciation method used to charge the asset to the action was in line with the applicable rules of the Beneficiary's country and the Beneficiary's usual accounting policy. 52) The amount charged corresponded to the actual usage for the action. 53) No ineligible costs or excessive or reckless expenditure were declared.	
D.3	**COSTS OF OTHER GOODS AND SERVICES** **The Auditor sampled _____ cost items selected randomly** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest*). For the purchase of goods, works or services included in the sample the Auditor verified that: o the contracts did not cover tasks described in Annex 1; o they were correctly identified, allocated to the proper action, entered in the accounting system (traceable to underlying documents such as purchase orders, invoices and accounting); o the goods were not placed in the inventory of durable equipment;	54) Contracts for works or services did not cover tasks described in Annex 1. 55) Costs were allocated to the correct action and the goods were not placed in the inventory of durable equipment. 56) The costs were charged in line with the Beneficiary's accounting policy and were adequately supported.	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	o the costs charged to the action were accounted in line with the Beneficiary's usual accounting practices; o no ineligible costs or excessive or reckless expenditure were declared (see Article 6 GA). In addition, the Auditor verified that these goods and services were acquired in conformity with the Beneficiary's internal guidelines and procedures, in particular: o if Beneficiary acted as a contracting authority within the meaning of Directive 2004/18/EC or of Directive 2004/17/EC, the Auditor verified that the applicable national law on public procurement was followed and that the procurement contract complied with the Terms and Conditions of the Agreement. o if the Beneficiary did not fall into the category above, the Auditor verified that the Beneficiary followed their usual procurement rules and respected the Terms and Conditions of the Agreement. For the items included in the sample the Auditor also verified that: o the Beneficiary ensured best value for money (key elements to appreciate the respect of this principle are the award of the contract to the bid offering best price-quality ratio, under conditions of transparency and equal treatment. In case an existing framework contract was used the Auditor also verified that the Beneficiary ensured it was established on the basis of the principle of best value for money under conditions of transparency and equal treatment); *SUCH GOODS AND SERVICES INCLUDE, FOR INSTANCE, CONSUMABLES AND SUPPLIES, DISSEMINATION (INCLUDING OPEN ACCESS), PROTECTION OF RESULTS, SPECIFIC EVALUATION OF THE ACTION IF IT IS REQUIRED BY THE AGREEMENT, CERTIFICATES ON THE FINANCIAL STATEMENTS IF THEY ARE REQUIRED BY THE AGREEMENT AND CERTIFICATES ON THE METHODOLOGY, TRANSLATIONS, REPRODUCTION.*	57) No ineligible costs or excessive or reckless expenditure were declared. For internal invoices/charges only the cost element was charged, without any mark-ups.	
		58) Procurement rules, principles and guides were followed. There were documents of requests to different providers, different offers and assessment of the offers before selection of the provider in line with internal procedures and procurement rules. The purchases were made in accordance with the principle of best value for money. *(When different offers were not collected the Auditor explains the reasons provided by the Beneficiary under the caption "Exceptions" of the Report. The Commission will analyse this information to evaluate whether these costs might be accepted as eligible)*	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
D.4	**AGGREGATED CAPITALISED AND OPERATING COSTS OF RESEARCH INFRASTRUCTURE** The Auditor ensured the existence of a positive ex-ante assessment (issued by the EC Services) of the cost accounting methodology of the Beneficiary allowing it to apply the guidelines on direct costing for large research infrastructures in Horizon 2020. ***In the cases that a positive ex-ante assessment has been issued*** *(see the standard factual findings 59-60 on the next column)**,*** The Auditor ensured that the beneficiary has applied consistently the methodology that is explained and approved in the positive ex ante assessment; ***In the cases that a positive ex-ante assessment has NOT been issued*** *(see the standard factual findings 61 on the next column),* The Auditor verified that no costs of Large Research Infrastructure have been charged as direct costs in any costs category; ***In the cases that a draft ex-ante assessment report has been issued with recommendation for further changes*** *(see the standard factual findings 61 on the next column),* • The Auditor followed the same procedure as above (when a positive ex-ante assessment has NOT yet been issued) and paid particular attention (testing reinforced) to the cost items for which the draft ex-ante assessment either rejected the inclusion as direct costs for Large Research Infrastructures or issued recommendations.	59) The costs declared as direct costs for Large Research Infrastructures (in the appropriate line of the Financial Statement) comply with the methodology described in the positive ex-ante assessment report. 60) Any difference between the methodology applied and the one positively assessed was extensively described and adjusted accordingly. 61) The direct costs declared were free from any indirect costs items related to the Large Research Infrastructure.	
E	**USE OF EXCHANGE RATES**		
E.1	a) For Beneficiaries with accounts established in a currency other than euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number*	62) The exchange rates used to convert other currencies into Euros were in accordance with the rules established of the Grant Agreement and there was no difference in the final	

Ref	Procedures	Standard factual finding	Result (C / E / N.A.)
	is highest): *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO AT THE AVERAGE OF THE DAILY EXCHANGE RATES PUBLISHED IN THE C SERIES OF OFFICIAL JOURNAL OF THE EUROPEAN UNION (https://www.ecb.int/stats/exchange/eurofxref/html/index.en.html), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.* *IF NO DAILY EURO EXCHANGE RATE IS PUBLISHED IN THE OFFICIAL JOURNAL OF THE EUROPEAN UNION FOR THE CURRENCY IN QUESTION, CONVERSION SHALL BE MADE AT THE AVERAGE OF THE MONTHLY ACCOUNTING RATES ESTABLISHED BY THE COMMISSION AND PUBLISHED ON ITS WEBSITE (http://ec.europa.eu/budget/contracts_grants/info_contracts/inforeuro/inforeuro_en.cfm), DETERMINED OVER THE CORRESPONDING REPORTING PERIOD.*	figures.	
	b) For Beneficiaries with accounts established in euros **The Auditor sampled _____ cost items selected randomly and verified that the exchange rates used for converting other currencies into euros were in accordance with the following rules established in the Agreement** (*full coverage is required if there are fewer than 10 items, otherwise the sample should have a minimum of 10 item, or 10% of the total, whichever number is highest)*: *COSTS INCURRED IN ANOTHER CURRENCY SHALL BE CONVERTED INTO EURO BY APPLYING THE BENEFICIARY'S USUAL ACCOUNTING PRACTICES.*	63) The Beneficiary applied its usual accounting practices.	

[legal name of the audit firm]
[name and function of an authorised representative]
[dd Month yyyy]
<Signature of the Auditor>

ANNEX 6

MODEL FOR THE CERTIFICATE ON THE METHODOLOGY

- **For options [*in italics in square brackets*]: choose the applicable option. Options not chosen should be deleted.**
- **For fields in [grey in square brackets]: enter the appropriate data.**

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INDEPENDENT REPORT OF FACTUAL FINDINGS ON THE METHODOLOGY CONCERNING GRANT AGREEMENTS FINANCED UNDER THE HORIZON 2020 RESEARCH AND INNOVATION FRAMEWORK PROGRAMME …….. 5

Terms of reference for an audit engagement for a methodology certificate in connection with one or more grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

This document sets out the '**Terms of Reference (ToR)**' under which

[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]

agrees to engage

[**insert legal name of the auditor**] ('the Auditor')

to produce an independent report of factual findings ('the Report') concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and claiming direct personnel costs declared as unit costs ('the Methodology') in connection with grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme.

The procedures to be carried out for the assessment of the methodology will be based on the grant agreement(s) detailed below:

[title and number of the grant agreement(s)] ('the Agreement(s)')

The Agreement(s) has(have) been concluded between the Beneficiary and *[OPTION 1: the European Union, represented by the European Commission ('the Commission')][OPTION 2: the European Atomic Energy Community (Euratom,) represented by the European Commission ('the Commission')][OPTION 3: the [Research Executive Agency (REA)] [European Research Council Executive Agency (ERCEA)] [Innovation and Networks Executive Agency (INEA)] [Executive Agency for Small and Medium-sized Enterprises (EASME)] ('the Agency'), under the powers delegated by the European Commission ('the Commission').]*.

The *[Commission] [Agency]* is mentioned as a signatory of the Agreement with the Beneficiary only. The *[European Union] [Euratom] [Agency]* is not a party to this engagement.

1.1 Subject of the engagement

According to Article 18.1.2 of the Agreement, beneficiaries *[and linked third parties]* that declare direct personnel costs as unit costs calculated in accordance with their usual cost accounting practices may submit to the *[Commission] [Agency]*, for approval, a certificate on the methodology ('CoMUC') stating that there are adequate records and documentation to prove that their cost accounting practices used comply with the conditions set out in Point A of Article 6.2.

The subject of this engagement is the CoMUC which is composed of two separate documents:

- the Terms of Reference ('the ToR') to be signed by the *[Beneficiary] [Linked Third Party]* and the Auditor;

- the Auditor's Independent Report of Factual Findings ('the Report') issued on the Auditor's letterhead, dated, stamped and signed by the Auditor which includes; the standard statements ('the Statements') evaluated and signed by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') performed by the Auditor and the standard factual findings

('the Findings') assessed by the Auditor. The Statements, Procedures and Findings are summarised in the table that forms part of the Report.

The information provided through the Statements, the Procedures and the Findings will enable the Commission to draw conclusions regarding the existence of the *[Beneficiary's] [Linked Third Party's]* usual cost accounting practice and its suitability to ensure that direct personnel costs claimed on that basis comply with the provisions of the Agreement. The Commission draws its own conclusions from the Report and any additional information it may require.

1.2 Responsibilities

The parties to this agreement are the *[Beneficiary] [Linked Third Party]* and the Auditor.

The *[Beneficiary] [Linked Third Party]:*

- is responsible for preparing financial statements for the Agreement(s) ('the Financial Statements') in compliance with those Agreements;
- is responsible for providing the Financial Statement(s) to the Auditor and enabling the Auditor to reconcile them with the *[Beneficiary's] [Linked Third Party's]* accounting and bookkeeping system and the underlying accounts and records. The Financial Statement(s) will be used as a basis for the procedures which the Auditor will carry out under this ToR;
- is responsible for its Methodology and liable for the accuracy of the Financial Statement(s);
- is responsible for endorsing or refuting the Statements indicated under the heading 'Statements to be made by the Beneficiary/ Linked Third Party' in the first column of the table that forms part of the Report;
- must provide the Auditor with a signed and dated representation letter;
- accepts that the ability of the Auditor to carry out the Procedures effectively depends upon the *[Beneficiary] [Linked Third Party]* providing full and free access to the *[Beneficiary's] [Linked Third Party's]* staff and to its accounting and other relevant records.

The Auditor:

- *[Option 1 by default: is qualified to carry out statutory audits of accounting documents in accordance with Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts, amending Council Directives 78/660/EEC and 83/349/EEC and repealing Council Directive 84/253/EEC or similar national regulations]*.
- *[Option 2 if the Beneficiary or Linked Third Party has an independent Public Officer: is a competent and independent Public Officer for which the relevant national authorities have established the legal capacity to audit the Beneficiary]*.
- *[Option 3 if the Beneficiary or Linked Third Party is an international organisation: is an [internal] [external] auditor in accordance with the internal financial regulations and procedures of the international organisation]*.

The Auditor:

- must be independent from the Beneficiary *[and the Linked Third Party]*, in particular, it must not have been involved in preparing the Beneficiary's *[and Linked Third Party's]* Financial Statement(s);
- must plan work so that the Procedures may be carried out and the Findings may be assessed;
- must adhere to the Procedures laid down and the compulsory report format;
- must carry out the engagement in accordance with these ToR;
- must document matters which are important to support the Report;
- must base its Report on the evidence gathered;
- must submit the Report to the *[Beneficiary] [Linked Third Party]*.

The Commission sets out the Procedures to be carried out and the Findings to be endorsed by the Auditor. The Auditor is not responsible for their suitability or pertinence. As this engagement is not an assurance engagement the Auditor does not provide an audit opinion or a statement of assurance.

1.3 Applicable Standards

The Auditor must comply with these Terms of Reference and with[52]:

- the International Standard on Related Services ('ISRS') 4400 *Engagements to perform Agreed-upon Procedures regarding Financial Information* as issued by the International Federation of Accountants (IFAC);
- the *Code of Ethics for Professional Accountants* issued by the IFAC. Although ISRS 4400 states that independence is not a requirement for engagements to carry out agreed-upon procedures, the Commission requires that the Auditor also complies with the Code's independence requirements.

The Auditor's Report must state that there was no conflict of interests in establishing this Report between the Auditor and the Beneficiary *[and the Linked Third Party]* that could have a bearing on the Report, and must specify – if the service is invoiced - the total fee paid to the Auditor for providing the Report.

1.4 Reporting

The Report must be written in the language of the Agreement (see Article 20.7 of the Agreement).

Under Article 22 of the Agreement, the Commission, *[the Agency]*, the European Anti-Fraud Office and the Court of Auditors have the right to audit any work that is carried out under the action and for which costs are claimed from [*the European Union*] [*Euratom*]. This includes work related to this engagement. The Auditor must provide access to all working papers related to this assignment if the Commission, *[the Agency]*, the European Anti-Fraud Office or the European Court of Auditors requests them.

1.5 Timing

The Report must be provided by [dd Month yyyy].

1.6 Other Terms

[The [Beneficiary] [Linked Third Party] and the Auditor can use this section to agree other specific terms, such as the Auditor's fees, liability, applicable law, etc. Those specific terms must not contradict the terms specified above.]

[legal name of the Auditor]	[legal name of the [Beneficiary] [Linked Third Party]]
[name & title of authorised representative]	[name & title of authorised representative]
[dd Month yyyy]	[dd Month yyyy]
Signature of the Auditor Signature	Signature of the *[Beneficiary] [Linked Third Party]*

[52] Supreme Audit Institutions applying INTOSAI-standards may carry out the Procedures according to the corresponding International Standards of Supreme Audit Institutions and code of ethics issued by INTOSAI instead of the International Standard on Related Services ('ISRS') 4400 and the Code of Ethics for Professional Accountants issued by the IFAC.

Independent report of factual findings on the methodology concerning grant agreements financed under the Horizon 2020 Research and Innovation Framework Programme

(To be printed on letterhead paper of the auditor)

To
[name of contact person(s)], [Position]
[[Beneficiary's] [Linked Third Party's] name]
[Address]
[dd Month yyyy]

Dear [Name of contact person(s)],

As agreed under the terms of reference dated [dd Month yyyy]

with *[OPTION 1: [insert name of the beneficiary] ('the Beneficiary')] [OPTION 2: [insert name of the linked third party] ('the Linked Third Party'), third party linked to the Beneficiary [insert name of the beneficiary] ('the Beneficiary')]*,

we

[name of the auditor] ('the Auditor'),

established at

[full address/city/state/province/country],

represented by

[name and function of an authorised representative],

have carried out the agreed-upon procedures ('the Procedures') and provide hereby our Independent Report of Factual Findings ('the Report'), concerning the *[Beneficiary's] [Linked Third Party's]* usual accounting practices for calculating and declaring direct personnel costs declared as unit costs ('the Methodology').

You requested certain procedures to be carried out in connection with the grant(s)

[title and number of the grant agreement(s)] ('the Agreement(s)').

The Report

Our engagement was carried out in accordance with the terms of reference ('the ToR') appended to this Report. The Report includes: the standard statements ('the Statements') made by the *[Beneficiary] [Linked Third Party]*, the agreed-upon procedures ('the Procedures') carried out and the standard factual findings ('the Findings') confirmed by us.

The engagement involved carrying out the Procedures and assessing the Findings and the documentation requested appended to this Report, the results of which the Commission uses to draw conclusions regarding the acceptability of the Methodology applied by the *[Beneficiary] [Linked Third Party]*.

The Report covers the methodology used from [dd Month yyyy]. In the event that the *[Beneficiary] [Linked Third Party]* changes this methodology, the Report will not be applicable to any Financial Statement[53] submitted thereafter.

[53] Financial Statement in this context refers solely to Annex 4 of the Agreement by which the Beneficiary declares costs under the Agreement.

The scope of the Procedures and the definition of the standard statements and findings were determined solely by the Commission. Therefore, the Auditor is not responsible for their suitability or pertinence.

Since the Procedures carried out constitute neither an audit nor a review made in accordance with International Standards on Auditing or International Standards on Review Engagements, we do not give a statement of assurance on the costs declared on the basis of the *[Beneficiary's] [Linked Third Party's]* Methodology. Had we carried out additional procedures or had we performed an audit or review in accordance with these standards, other matters might have come to its attention and would have been included in the Report.

Exceptions

Apart from the exceptions listed below, the *[Beneficiary] [Linked Third Party]* agreed with the standard Statements and provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and corroborate the standard Findings.

List here any exception and add any information on the cause and possible consequences of each exception, if known. If the exception is quantifiable, also indicate the corresponding amount.

…..

Explanation of possible exceptions in the form of examples (to be removed from the Report):

i. the [Beneficiary] [Linked Third Party] did not agree with the standard Statement number … because…;

ii. the Auditor could not carry out the procedure … established because …. (e.g. due to the inability to reconcile key information or the unavailability or inconsistency of data);

iii. the Auditor could not confirm or corroborate the standard Finding number … because ….

Remarks

We would like to add the following remarks relevant for the proper understanding of the Methodology applied by the [Beneficiary] [Linked Third Party] or the results reported:

Example (to be removed from the Report):

Regarding the methodology applied to calculate hourly rates …

Regarding standard Finding 15 it has to be noted that …

The [Beneficiary] [Linked Third Party] explained the deviation from the benchmark statement XXIV concerning time recording for personnel with no exclusive dedication to the action in the following manner: …

Annexes

Please provide the following documents to the auditor and annex them to the report when submitting this CoMUC to the Commission:

1. Brief description of the methodology for calculating personnel costs, productive hours and hourly rates;
2. Brief description of the time recording system in place;
3. An example of the time records used by the [*Beneficiary] [Linked Third Party*];
4. Description of any budgeted or estimated elements applied together with an explanation as to why they are relevant for calculating the personnel costs, why they are reasonable and how they are based on objective and verifiable information;

5. A summary sheet with the hourly rate for direct personnel declared by the [*Beneficiary*] [*Linked Third Party*] and recalculated by the Auditor for each staff member included in the sample (the names do not need to be reported);
6. A comparative table summarising for each person selected in the sample a) the time claimed by the [*Beneficiary*] [*Linked Third Party*] in the Financial Statement(s) and b) the time according to the time record verified by the Auditor;
7. A copy of the letter of representation provided to the Auditor.

Use of this Report

This Report has been drawn up solely for the purpose given under Point 1.1 Reasons for the engagement.

The Report:

- is confidential and is intended to be submitted to the Commission by the [*Beneficiary*] [*Linked Third Party*] in connection with Article 18.1.2 of the Agreement;
- may not be used by the [*Beneficiary*] [*Linked Third Party*] or by the Commission for any other purpose, nor distributed to any other parties;
- may be disclosed by the Commission only to authorised parties, in particular the European Anti-Fraud Office (OLAF) and the European Court of Auditors.
- relates only to the usual cost accounting practices specified above and does not constitute a report on the Financial Statements of the [*Beneficiary*] [*Linked Third Party*].

No conflict of interest[54] exists between the Auditor and the Beneficiary *[and the Linked Third Party*] that could have a bearing on the Report. The total fee paid to the Auditor for producing the Report was EUR _____ (including EUR _____ of deductible VAT).

We look forward to discussing our Report with you and would be pleased to provide any further information or assistance which may be required.

Yours sincerely

[legal name of the Auditor]
[name and title of the authorised representative]
[dd Month yyyy]
Signature of the Auditor

[54] A conflict of interest arises when the Auditor's objectivity to establish the certificate is compromised in fact or in appearance when the Auditor for instance:
- was involved in the preparation of the Financial Statements;
- stands to benefit directly should the certificate be accepted;
- has a close relationship with any person representing the beneficiary;
- is a director, trustee or partner of the beneficiary; or
- is in any other situation that compromises his or her independence or ability to establish the certificate impartially.

Statements to be made by the Beneficiary/Linked Third Party ('the Statements') and Procedures to be carried out by the Auditor ('the Procedures') and standard factual findings ('the Findings') to be confirmed by the Auditor

The Commission reserves the right to provide the auditor with guidance regarding the Statements to be made, the Procedures to be carried out or the Findings to be ascertained and the way in which to present them. The Commission reserves the right to vary the Statements, Procedures or Findings by written notification to the Beneficiary/Linked Third Party to adapt the procedures to changes in the grant agreement(s) or to any other circumstances.

If this methodology certificate relates to the Linked Third Party's usual accounting practices for calculating and claiming direct personnel costs declared as unit costs any reference here below to 'the Beneficiary' is to be considered as a reference to 'the Linked Third Party'.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
A. Use of the Methodology I. The cost accounting practice described below has been in use since *[*dd Month yyyy*]*. II. The next planned alteration to the methodology used by the Beneficiary will be from [dd Month yyyy*]*.	**Procedure:** ✓ The Auditor checked these dates against the documentation the Beneficiary has provided. **Factual finding:** 1. The dates provided by the Beneficiary were consistent with the documentation.
B. Description of the Methodology III. The methodology to calculate unit costs is being used in a consistent manner and is reflected in the relevant procedures. *[Please describe the methodology your entity uses to calculate <u>personnel</u> costs, productive hours and hourly rates, present your description to the Auditor and annex it to this certificate]* *[If the statement of section "B. Description of the methodology" cannot be endorsed by the Beneficiary or there is no written methodology to calculate unit costs it should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *…]*	**Procedure:** ✓ The Auditor reviewed the description, the relevant manuals and/or internal guidance documents describing the methodology. **Factual finding:** 2. The brief description was consistent with the relevant manuals, internal guidance and/or other documentary evidence the Auditor has reviewed. 3. The methodology was generally applied by the Beneficiary as part of its usual costs accounting practices.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
C. **Personnel costs** General IV. The unit costs (hourly rates) are limited to salaries including during parental leave, social security contributions, taxes and other costs included in the remuneration required under national law and the employment contract or equivalent appointing act; V. Employees are hired directly by the Beneficiary in accordance with national law, and work under its sole supervision and responsibility; VI. The Beneficiary remunerates its employees in accordance with its usual practices. This means that personnel costs are charged in line with the Beneficiary's usual payroll policy (e.g. salary policy, overtime policy, variable pay) and no special conditions exist for employees assigned to tasks relating to the European Union or Euratom, unless explicitly provided for in the grant agreement(s); VII. The Beneficiary allocates its employees to the relevant group/category/cost centre for the purpose of the unit cost calculation in line with the usual cost accounting practice; VIII. Personnel costs are based on the payroll system and accounting system. IX. Any exceptional adjustments of actual personnel costs resulted from relevant budgeted or estimated elements, were reasonable and were based on objective and verifiable information. *[Please describe the 'budgeted or estimated elements' and their relevance to personnel costs, and explain how they were reasonable and based on objective and verifiable information, present your explanation to the Auditor and annex it to this certificate]*. X. Personnel costs claimed do not contain any of the following ineligible costs: costs related to return on capital; debt and debt service charges; provisions for future losses or debts; interest owed; doubtful debts; currency exchange losses; bank costs charged by the Beneficiary's bank for transfers from the Commission/Agency; excessive or reckless expenditure; deductible VAT or costs incurred during suspension of the implementation of the action. XI. Personnel costs were not declared under another EU or Euratom grant (including grants awarded by a Member State and financed by the EU budget and grants awarded by bodies other than the Commission/Agency for the	**Procedure:** *The Auditor draws a sample of employees to carry out the procedures indicated in this section C and the following sections D to F.* *[The Auditor has drawn a random sample of 10 full-time equivalents made up of employees assigned to the action(s). If fewer than 10 full-time equivalents are assigned to the action(s), the Auditor has selected a sample of 10 full-time equivalents consisting of all employees assigned to the action(s), complemented by other employees irrespective of their assignments.]*. For this sample: ✓ the Auditor reviewed all documents relating to personnel costs such as employment contracts, payslips, payroll policy (e.g. salary policy, overtime policy, variable pay policy), accounting and payroll records, applicable national tax , labour and social security law and any other documents corroborating the personnel costs claimed; ✓ in particular, the Auditor reviewed the employment contracts of the employees in the sample to verify that: i. they were employed directly by the Beneficiary in accordance with applicable national legislation; ii. they were working under the sole technical supervision and responsibility of the latter; iii. they were remunerated in accordance with the Beneficiary's usual practices; iv. they were allocated to the correct group/category/cost centre for the purposes of calculating the unit cost in line with the Beneficiary's usual cost accounting practices; ✓ the Auditor verified that any ineligible items or any costs claimed under other costs categories or costs covered by other types of grant or by other grants financed from the European Union budget have not been taken into account when calculating the personnel costs; ✓ the Auditor numerically reconciled the total amount of personnel costs used to calculate the unit cost with the total amount of personnel costs recorded in the statutory accounts and the payroll system. ✓ to the extent that actual personnel costs were adjusted on the basis of

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
purpose of implementing the EU budget). <u>If additional remuneration as referred to in the grant agreement(s) is paid</u> XII. The Beneficiary is a non-profit legal entity; XIII. The additional remuneration is part of the beneficiary's usual remuneration practices and paid consistently whenever the relevant work or expertise is required; XIV. The criteria used to calculate the additional remuneration are objective and generally applied regardless of the source of funding; XV. The additional remuneration included in the personnel costs used to calculate the hourly rates for the grant agreement(s) is capped at EUR 8 000 per full-time equivalent (reduced proportionately if the employee is not assigned exclusively to the action). *[If certain statement(s) of section "C. Personnel costs" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor in the main Report of Factual Findings:* - *…]*	budgeted or estimated elements, the Auditor carefully examined those elements and checked the information source to confirm that they correspond to objective and verifiable information; ✓ if additional remuneration has been claimed, the Auditor verified that the Beneficiary was a non-profit legal entity, that the amount was capped at EUR 8 000 per full-time equivalent and that it was reduced proportionately for employees not assigned exclusively to the action(s). ✓ the Auditor recalculated the personnel costs for the employees in the sample. **Factual finding:** 4. All the components of the remuneration that have been claimed as personnel costs are supported by underlying documentation. 5. The employees in the sample were employed directly by the Beneficiary in accordance with applicable national law and were working under its sole supervision and responsibility. 6. Their employment contracts were in line with the Beneficiary's usual policy; 7. Personnel costs were duly documented and consisted solely of salaries, social security contributions (pension contributions, health insurance, unemployment fund contributions, etc.), taxes and other statutory costs included in the remuneration (holiday pay, thirteenth month's pay, etc.); 8. The totals used to calculate the personnel unit costs are consistent with those registered in the payroll and accounting records; 9. To the extent that actual personnel costs were adjusted on the basis of budgeted or estimated elements, those elements were relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information. The budgeted or estimated elements used are: — (indicate the elements and their values). 10. Personnel costs contained no ineligible elements; 11. Specific conditions for eligibility were fulfilled when additional remuneration was paid: a) the Beneficiary is registered in the grant agreements as a non-profit legal entity; b) it was paid according to

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
	objective criteria generally applied regardless of the source of funding used and c) remuneration was capped at EUR 8 000 per full-time equivalent (or up to up to the equivalent pro-rata amount if the person did not work on the action full-time during the year or did not work exclusively on the action).
D. Productive hours XVI. The number of productive hours per full-time employee applied is *[delete as appropriate]*: A. 1720 productive hours per year for a person working full-time (corresponding pro-rata for persons not working full time). B. the total number of hours worked in the year by a person for the Beneficiary C. the standard number of annual hours generally applied by the beneficiary for its personnel in accordance with its usual cost accounting practices. This number must be at least 90% of the standard annual workable hours. <u>If method B is applied</u> XVII. The calculation of the total number of hours worked was done as follows: annual workable hours of the person according to the employment contract, applicable labour agreement or national law plus overtime worked minus absences (such as sick leave and special leave). XVIII. 'Annual workable hours' are hours during which the personnel must be working, at the employer's disposal and carrying out his/her activity or duties under the employment contract, applicable collective labour agreement or national working time legislation. XIX. The contract (applicable collective labour agreement or national working time legislation) do specify the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> XX. The standard number of productive hours per year is that of a full-time equivalent; for employees not assigned exclusively to the action(s) this	**Procedure (same sample basis as for Section C: Personnel costs):** ✓ The Auditor verified that the number of productive hours applied is in accordance with method A, B or C. ✓ The Auditor checked that the number of productive hours per full-time employee is correct and that it is reduced proportionately for employees not exclusively assigned to the action(s). ✓ If method B is applied the Auditor verified i) the manner in which the total number of hours worked was done and ii) that the contract specified the annual workable hours by inspecting all the relevant documents, national legislation, labour agreements and contracts. ✓ If method C is applied the Auditor reviewed the manner in which the standard number of working hours per year has been calculated by inspecting all the relevant documents, national legislation, labour agreements and contracts and verified that the number of productive hours per year used for these calculations was at least 90 % of the standard number of working hours per year. **Factual finding:** <u>General</u> 12. The Beneficiary applied a number of productive hours consistent with method A or B detailed in the left-hand column. 13. The number of productive hours per year per full-time employee was accurate and was proportionately reduced for employees not working full-time or exclusively for the action. <u>If method B is applied</u> 14. The number of 'annual workable hours', overtime and absences was verifiable based on the documents provided by the Beneficiary and the

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
number is reduced proportionately. XXI. The number of productive hours per year on which the hourly rate is based i) corresponds to the Beneficiary's usual accounting practices; ii) is at least 90% of the standard number of workable (working) hours per year. XXII. Standard workable (working) hours are hours during which personnel are at the Beneficiary's disposal preforming the duties described in the relevant employment contract, collective labour agreement or national labour legislation. The number of standard annual workable (working) hours that the Beneficiary claims is supported by labour contracts, national legislation and other documentary evidence. *[If certain statement(s) of section "D. Productive hours" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	calculation of the total number of hours worked was accurate. 15. The contract specified the working time enabling to calculate the annual workable hours. <u>If method C is applied</u> 16. The calculation of the number of productive hours per year corresponded to the usual costs accounting practice of the Beneficiary. 17. The calculation of the standard number of workable (working) hours per year was corroborated by the documents presented by the Beneficiary. 18. The number of productive hours per year used for the calculation of the hourly rate was at least 90% of the number of workable (working) hours per year.
E. Hourly rates The hourly rates are correct because: XXIII. Hourly rates are correctly calculated since they result from dividing annual personnel costs by the productive hours of a given year and group (e.g. staff category or department or cost centre depending on the methodology applied) and they are in line with the statements made in section C. and D. above. *[If the statement of section 'E. Hourly rates' cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor:* - *…]*	**Procedure** ✓ The Auditor has obtained a list of all personnel rates calculated by the Beneficiary in accordance with the methodology used. ✓ The Auditor has obtained a list of all the relevant employees, based on which the personnel rate(s) are calculated. For 10 full-time equivalent employees selected at random (same sample basis as Section C: Personnel costs): ✓ The Auditor recalculated the hourly rates. ✓ The Auditor verified that the methodology applied corresponds to the usual accounting practices of the organisation and is applied consistently for all activities of the organisation on the basis of objective criteria irrespective of the source of funding. **Factual finding:** 19. No differences arose from the recalculation of the hourly rate for the employees included in the sample.

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
F. Time recording XXIV. Time recording is in place for all persons with no exclusive dedication to one Horizon 2020 action. At least all hours worked in connection with the grant agreement(s) are registered on a **daily/weekly/monthly** basis *[delete as appropriate]* using a **paper/computer-based system** *[delete as appropriate]*; XXV. For persons exclusively assigned to one Horizon 2020 activity the Beneficiary has either signed a declaration to that effect or has put arrangements in place to record their working time; XXVI. Records of time worked have been signed by the person concerned (on paper or electronically) and approved by the action manager or line manager at least monthly; XXVII. Measures are in place to prevent staff from: i. recording the same hours twice, ii. recording working hours during absence periods (e.g. holidays, sick leave), iii. recording more than the number of productive hours per year used to calculate the hourly rates, and iv. recording hours worked outside the action period. XXVIII. No working time was recorded outside the action period; XXIX. No more hours were claimed than the productive hours used to calculate the hourly personnel rates. *[Please provide a brief description of the time recording system in place together with the measures applied to ensure its reliability to the Auditor and annex it to the present certificate[55]].*	**Procedure** ✓ The Auditor reviewed the brief description, all relevant manuals and/or internal guidance describing the methodology used to record time. The Auditor reviewed the time records of the random sample of 10 full-time equivalents referred to under Section C: Personnel costs, and verified in particular: ✓ that time records were available for all persons with not exclusive assignment to the action; ✓ that time records were available for persons working exclusively for a Horizon 2020 action, or, alternatively, that a declaration signed by the Beneficiary was available for them certifying that they were working exclusively for a Horizon 2020 action; ✓ that time records were signed and approved in due time and that all minimum requirements were fulfilled; ✓ that the persons worked for the action in the periods claimed; ✓ that no more hours were claimed than the productive hours used to calculate the hourly personnel rates; ✓ that internal controls were in place to prevent that time is recorded twice, during absences for holidays or sick leave; that more hours are claimed per person per year for Horizon 2020 actions than the number of productive hours per year used to calculate the hourly rates; that working time is recorded outside the action period; ✓ the Auditor cross-checked the information with human-resources records to verify consistency and to ensure that the internal controls have been effective. In addition, the Auditor has verified that no more hours were charged to Horizon 2020 actions per person per year than the number of

[55] The description of the time recording system must state among others information on the content of the time records, its coverage (full or action time-recording, for all personnel or only for personnel involved in H2020 actions), its degree of detail (whether there is a reference to the particular tasks accomplished), its form, periodicity of the time registration and authorisation (paper

Please explain any discrepancies in the body of the Report.	
Statements to be made by Beneficiary	**Procedures to be carried out and Findings to be confirmed by the Auditor**
[If certain statement(s) of section "F. Time recording" cannot be endorsed by the Beneficiary they should be listed here below and reported as exception by the Auditor: *- …]*	productive hours per year used to calculate the hourly rates, and verified that no time worked outside the action period was charged to the action. **Factual finding:** 20. The brief description, manuals and/or internal guidance on time recording provided by the Beneficiary were consistent with management reports/records and other documents reviewed and were generally applied by the Beneficiary to produce the financial statements. 21. For the random sample time was recorded or, in the case of employees working exclusively for the action, either a signed declaration or time records were available; 22. For the random sample the time records were signed by the employee and the action manager/line manager in reasonable time. 23. Working time claimed for the action occurred in the periods claimed; 24. No more hours were claimed than the number productive hours used to calculate the hourly personnel rates; 25. There is proof that the Beneficiary has checked that working time has not been claimed twice, that it is consistent with absence records and the number of productive hours per year, and that no working time has been claimed outside the action period. 26. Working time claimed is consistent with that on record at the human-resources department.

[official name of the** [Beneficiary] [Linked Third Party]**]
[name and title of authorised representative]
[dd Month yyyy]
<***Signature of the** [Beneficiary] [Linked Third Party]*>

[official name of the Auditor]
[name and title of authorised representative]
[dd Month yyyy]
<***Signature** of the Auditor*>

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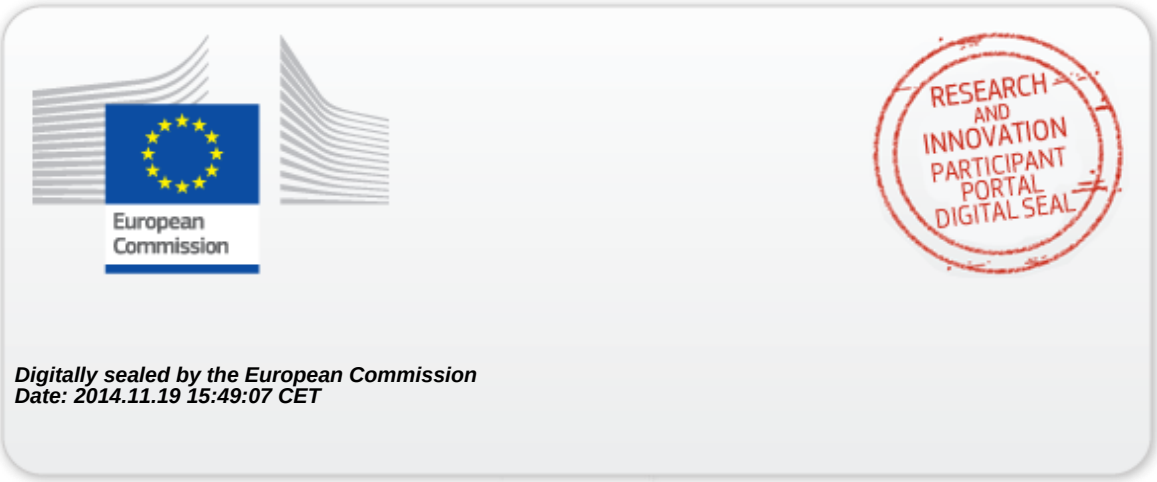
or a computer-based system; on a daily, weekly or monthly basis; signed and countersigned by whom), controls applied to prevent double-charging of time or ensure consistency with HR-records such as absences and travels as well as it information flow up to its use for the preparation of the Financial Statements.



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