# PROJECT PERIODIC REPORT

**Grant Agreement number: FP7-ICT-2011-270253**

**Project acronym: INTEGRATE**

**Project title:** Driving excellence in Integrative Cancer Research through Innovative Biomedical Infrastructures

**Funding Scheme: Collaborative project**

**Date of latest version of Annex I against which the assessment will be made:**

**Periodic report:** **1st** ☐ **2nd** ■ **3rd** ☐ **4th** ☐

**Period covered:** **from 1 February 2012 to 31 January 2013**

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[1] Usually the contact person of the coordinator as specified in Art. 8.1. of the Grant Agreement .

[2] The home page of the website should contain the generic European flag and the FP7 logo which are available in electronic format at the Europa website (logo of the European flag: http://europa.eu/abc/symbols/emblem/index_en.htm logo of the 7th FP: http://ec.europa.eu/research/fp7/index_en.cfm?pg=logos). The area of activity of the project should also be mentioned.

## Declaration by the scientific representative of the project coordinator

I, as scientific representative of the coordinator of this project and in line with the obligations as stated in Article II.2.3 of the Grant Agreement declare that:

- The attached periodic report represents an accurate description of the work carried out in this project for this reporting period;
- The project (tick as appropriate) [3]:

  ■ has fully achieved its objectives and technical goals for the period;

  ☐ has achieved most of its objectives and technical goals for the period with relatively minor deviations.

  ☐ has failed to achieve critical objectives and/or is not at all on schedule.

- The public website, if applicable

  ■ is up to date

  ☐ is not up to date

- To my best knowledge, the financial statements which are being submitted as part of this report are in line with the actual work carried out and are consistent with the report on the resources used for the project (section 3.4) and if applicable with the certificate on financial statement.
- All beneficiaries, in particular non-profit public bodies, secondary and higher education establishments, research organisations and SMEs, have declared to have verified their legal status. Any changes have been reported under section 3.2.3 (Project Management) in accordance with Article II.3.f of the Grant Agreement.

Name of scientific representative of the Coordinator: Anca Bucur

Date: 18/ 04/ 2013

For most of the projects, the signature of this declaration could be done directly via the IT reporting tool through an adapted IT mechanism.

[3] If either of these boxes below is ticked, the report should reflect these and any remedial actions taken.

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# 1 Publishable summary

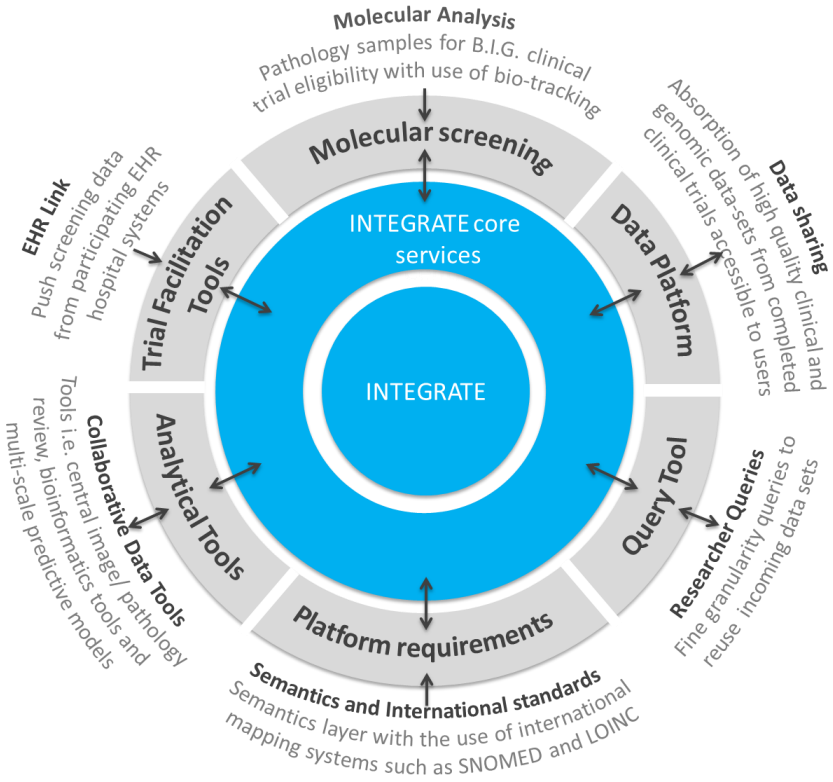
The collaborative INTEGRATE project aims to support a novel research approach in oncology through the development of innovative biomedical infrastructures enabling multidisciplinary collaboration, management and large-scale sharing of multi-level data, and the development of new methodologies and of predictive multi-scale models in cancer. The INTEGRATE infrastructure will bring together heterogeneous multi-scale biomedical data generated through standard and novel technologies within post-genomic clinical trials and seamlessly link to existing research and clinical infrastructures, such as clinical trial systems, eCRFs, and hospital EHRs, in order to enable a range of innovative applications.

INTEGRATE delivers 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. Moving away from empirical medicine, towards evidence-based personalized care has the potential to both dramatically improve patient outcome and to reduce costs.

The project also aims to make relevant steps towards semantic interoperability. To be able to reuse previous efforts in data sharing, modeling and knowledge generation, and to access relevant external sources of data and knowledge it is beneficial to adhere whenever possible to widely-accepted standards and ontologies. The use of standards will also support wide scale adoption of our solutions. A first version of our semantic interoperability layer has been implemented based on the HL7 v3 standard and on relevant medical ontologies/terminologies: SNOMED-CT, MEDDra, LOINC. The BRIDG standard has been used to represent the clinical trial information in our environment.

An important objective of this project is to build tools that facilitate efficient the execution of post-genomic multi-centric clinical trials in breast cancer. A range of such tools aim to support recruitment through the automatic evaluation of the eligibility of patients for trials based on matching the characteristics of the patient population required by the trial to the patient data available for instance in the hospital EHR. Other range of tools focus on central review of pathology images and on the INTEGRATE Analysis Platform enabling both statistical and prediction analysis. To facilitate the use of the datasets in the INTEGRATE environment for future research, we build a flexible and intuitive cohort selection application that enables users to define, select and retrieve cohorts of patient datasets that suit their research questions. First versions of these tools have been implemented and are currently being evaluated with clinical users.

The INTEGRATE consortium focuses on sustainability beyond the scope of the research project, building a long lasting translational research infrastructure that will promote scientific collaboration among European cancer research centres, pharmaceutical companies, and biomedical research communities well beyond the FP7 funding period. While the core users of the project outcomes are members of the Breast International Group network, we will also actively promote our approach and solutions in wide user communities and in other disease domains.




## 1.1 *Highlighted results*

**Moving towards Computer Aided Patient Recruitment**

The patient screening prototype fits within the wider setting of how the Breast International Group (BIG) expects to screen patients for many of its trials in the future. When physicians participating in a BIG clinical trial believe that one of their patients may be eligible, they need to formally verify whether the patient meets all of the trial's eligibility criteria. For this, physicians must acquire all necessary clinical information and check that the criteria are fulfilled. For an increasing number of trials (e.g. those involving drugs that target specific oncogenic molecular aberrations present in sub-groups of patients), checking eligibility is a multistage process that also involves the molecular testing of tumour tissue.

Identifying patients who meet all the criteria of a given trial is today still a largely manual process. It fully relies on physicians being aware of which clinical trials are open to patient recruitment and having a fairly detailed idea of the respective eligibility criteria of each one.

One of the objectives of INTEGRATE is to facilitate the patient recruitment process by maintaining a trial registry for BIG (containing all open protocols and trial eligibility criteria) and providing computer assistance for streamlining the eligibility criteria testing (i.e. automating, the criteria testing). The patient screening application built in INTEGRATE will provide automated checking of eligibility criteria based on structured patient data present in electronic health records (EHRs) and clinical trial data management systems.

**Analytical Tools for Data Sharing**

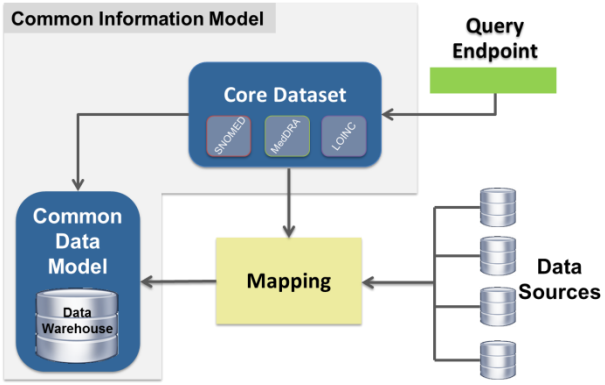
A main objective of INTEGRATE is to provide users with web-based access to a collaborative, multi-functional and easy-to-use environment for exploiting, analyzing and assessing the quality of large multi-level data. The aim is to provide physicians and other researchers with a set of web-based tools with which to easily analyse clinico-genomic data in order to get – for selected cohorts

of patients − simple statistics on selected parameters, perform survival analyses, compare regimens, and obtain genomic analysis results. INTEGRATE is being built in a way that will not require users to have any prior expertise in using such tools, or any software or libraries installed on their computers.

Because the available data are so heterogeneous – ranging from clinical and genomic to imaging information – the INTEGRATE architecture is non-monolithic. In other words, each component of INTEGRATE is responsible for implementing a specific task. A core tool is a semi-automated software platform for statistical analyses, called the INTEGRATE Analysis Platform. This is to be used together with Central Pathology Review and Predictive Modelling tools, still in development.

### INTEGRATE semantic interoperability layer

To provide homogeneous access to different data sources, the semantic interoperability layer should provide a Common Information Model (CIM) to represent the information. Thus, a common query endpoint can be provided to retrieve semantically uniform data. Components required for this task are shown in the figure below.




The CIM proposed for the INTEGRATE platform semantic layer comprises two components: (i) the core dataset and (ii) the Common Data Model (CDM). CDM refers to the schema of the data warehouse and core dataset is the domain vocabulary of the INTEGRATE platform. This vocabulary, previously transformed into an XML-based ontology representation language, is stored in a semantic web repository. The core dataset will be used to extract domain knowledge to retrieve data stored within the CDM.

### BIG's molecular screening feasibility study

In the context of INTEGRATE, BIG and the other INTEGRATE partners are developing a molecular screening infrastructure – the "INTEGRATE Prototype Platform" – which will be tested in the coming months in a pilot study, prior to implementation in future BIG clinical trials. This pilot, also referred to as the BIG Molecular Screening Feasibility Study, is detailed in a protocol prepared by BIG and the Institut Jules Bordet (IJB, legal sponsor of the study), and will involve, besides the IJB, three hospitals around Europe: the University of Dundee (UK), the Vall d'Hebron Hospital (Spain) and the Klinikum Offenbach (Germany). This study will be conducted using biopsies collected from 30 patients with invasive recurrent or metastatic breast cancer. The pilot study is supported in part by a grant from the Breast Cancer Research Foundation.

## 1.2 *Expected impact*

Our vision is to drive research excellence in oncology through a unique accessible biomedical infrastructure integrating diverse mega-datasets, building predictive bionetworks and offering advanced tools to guide the development of effective human therapeutics and diagnostics. These

comprehensive datasets will also become available to the biomedical research community through the INTEGRATE infrastructure.

**Towards personalized medicine: support for molecular screening**

We are quickly moving towards an era of personalized medicine in breast cancer, with the ultimate goal of making tumour-specific “molecular fingerprints” possible. This fingerprint would consist of distinct genetic markers obtained from a simple blood draw or tumour sample, and it would allow the physician to refine a patient’s prognosis and select the best possible therapeutic options, maximizing response and minimizing toxicity. Because these distinct genetic markers are present in relatively small sub-groups of patients, the realization of this goal requires the implementation of smaller and smarter molecularly-defined clinical trials. The Breast International Group (BIG) has recognized this essential need, both for academic and pharmaceutical research, and the subsequent necessity for a molecular screening structure to support it. This platform will ultimately facilitate the efficient development of new molecules and help overcome the current hurdles of biomarker discovery.

**The need for data sharing and integration**

At the centre of INTEGRATE is an environment bringing together clinical, genomic, pathology and radiology imaging data, originating from multiple oncology clinical trials. Researchers will be able to select subsets of patients from the INTEGRATE repository through sophisticated queries and retrieve their data. By accessing data from multiple trials, researchers will be able to build predictive models, identify biomarkers and answer other research questions faster and with more confidence. Finally, fine-grained access control for differential access to subsets of the data by different user groups will enable flexible patterns of collaboration. But sharing of raw, unprocessed data is not sufficient. The lack of standardised medical terminology poses another challenge for the integration of data from multiple trials. Often, the same concept, such as a cancer subtype, a gene, or a medical condition, will be referenced in different ways in different studies, making meta-analyses very difficult. Thus, an important part of INTEGRATE is the identification of a core data set, i.e. a set of concepts that covers the subject domain of breast cancer clinical trials. These core concepts are then mapped by a team of information specialists and oncologists to controlled terminologies and ontologies such as SNOMEDCT for clinical terms, LOINC for laboratory and clinical observations, and MedDRA for drug safety data. INTEGRATE also extends controlled terminologies and ontologies when critical concepts in the field of breast cancer clinical trials are missing.

## 1.3 *General information*

| General Info | |
|---|---|
| Acronym | INTEGRATE |
| Name | Driving excellence in Integrative Cancer Research through Innovative Biomedical Infrastructures |
| Web page | www.fp7-integrate.eu |
| Reference | FP7-ICT-2009-6-270253 |

| Participants | | | |
|---|---|---|---|
| No. | Name | Short name | Country |
| 1 | Philips Electronics Nederland BV | PENB | NL |
| 2 | Breast International Group | BIG | B |
| 3 | Foundation for research and technology Hellas | FORTH | GR |
| 4 | Custodix | CUSTODIX | B |
| 5 | Institut Jules Bordet | IJB | B |
| 6 | Universidad Politecnica de Madrid | UPM | SP |

# 2 Core of the report for the period: Project objectives, work progress and achievements, project management

## 2.1 *Project objectives for the period*

The main tasks during the second year of the INTEGRATE project (February 1st, 2012 – January 31st, 2013) have focused on the following objectives:

- Consolidation of the user needs, refinement/second iteration of user scenarios
- Elaboration of the integration guidelines, refinement of the system architecture, security framework definition
- Implementation of the initial semantic interoperability layer
- Initial demonstrators of new tools according to the defined user scenarios, focusing on enhancing collaboration and data sharing
- Refined implementations of tools implemented in year 1 and integration with the semantic interoperability and security framework.
- Preparation of the deployment and definition of the verification steps for the project tools
- Final dissemination plan and further investigation into sustainability

All the objectives for the second year have been achieved in this reporting period. An overview of the progress is presented in the next section. Further, the document details the achievements per each work package of the project.

**Recommendations from previous reviews**

A closer collaboration with related projects (P-Medicine, VPH NoE) and a better description of the needs of our clinical users were recommended during the first review. These recommendations were addressed as follows:

- In the updated progress report of year 1, our clinical users extensively described their needs and the rationale behind the prioritization of the selected scenarios and demonstrators. They also focused on describing the process of gathering requirements that involved a large number of clinical users.
- For the evaluation and validation of the project outcomes we have selected several additional clinical sites and we are currently finalizing the details of the collaboration. They will be introduced during the next project review. The selected new partners are important clinical sites in the EU and beyond.
- We have organized an alignment meeting with the closely-related P-Medicine project and agreed on future close collaboration that includes sharing of tools between the two projects and shared meetings with the user groups of the two projects.
- We have participated with presentations and demonstrators in the VPH NoE event to set up new collaborations.
- We have been accepted to hold a session in a large European cancer conference (ECCO) in 2013. This will enable us to have access to a wider community of clinical users.
- We have organized meetings with several Pharmaceutical companies to collect requirements and feedback on our solutions.

**Overview of progress in the reporting period in line with the objectives**

- The user scenarios have been refined. Additionally, to establish and validate the methodology and the clinical workflow for the patient screening program BIG has set up a pilot study. The patient data collected in the pilot study will also be used when available in the INTEGRATE context for development and validation of the environment and tools.

- The architecture has been refined, the integration guidelines are available, the privacy and security framework is in place. Security has been integrated in the first year demonstrators.
- Prototypes for new tools required by the user scenarios have been implemented. These focus on collaboration (pathology review) and data sharing (cohort selection application).
- The demonstrators of year 1 have been evaluated with users (in INTEGRATE and outside) and refined. A usability study for the patient screening application was also carried out.
- The interoperability layer has been defined and implemented, tools for data transformation have been implemented or existing tools reused when available. A process for data transformation has been defined.
- The final dissemination plan has been finalized, several dissemination events were planned, we participated in international events, gave presentations, published several research papers, published 2 newsletters including progress articles, user articles, and interviews with hey opinion leaders in the relevant fields.
- Plans, procedures and guidelines for deployment and validation are available. We have reached out to the community and propose new centres to participate in the validation activities. These will join after approval by the EC.

## 2.2 *Work progress and achievements during the period*

### 2.2.1 WP1 – User needs & requirements (IJB)

### 2.2.2 Objectives (of the reporting period)

The main goals of the WP1 for the 18-24 months period was to collaborate with the technical partners in order to refine and conclude on the user requirements, clinical scenarios and use cases from a clinical point of view. The WP1 provided end-users input to the development and evaluation of the INTEGRATE environment. On top of that, WP1 partners progressed on the set-up of the molecular screening scenario for which the technical partners built different prototype components in order to support the screening pilot project.

### 2.2.3 Status/progress towards objectives WP1

**Task 1.1 Identification of the users and their needs**

The panel of users, including but not restrictive to clinicians, researchers and pathologists, were consulted through several meetings in order to validate the user requirements and clinical scenarios elaborated during the last months.

**Task 1.2 Definition of user scenarios**

The user scenarios were not altered but were refined in order to complete them. Especially, the clinical partner in WP1 continued to help the technical partners in order to implement the molecular screening scenario. The protocol for the molecular screening pilot project has been finalized and was circulated to the different participating clinical centres (which are the Jules Bordet Institute in Brussels, the Vall d'Hebron Institute in Barcelona, The Offenbach clinic in Frankfurt and the University of Dundee in UK) as well as to the different laboratories (detailed in previous progress report). The protocol is being approved by the different Ethics Committee in each country. The patient recruitment will start soon. The molecular screening pilot will help the technical partners together with the clinical partners in evaluating the different modules of the INTEGRATE platform (which are part of scenario 1: molecular testing, biotracking and eligibility criteria matching as well as part of scenarios 4 and 5).

**Task 1.3 Legal and regulatory compliance requirements**

In order to conduct the molecular screening pilot study, the legal team part of the WP1 put in place a 1) Study site Agreement, and a 2) Central laboratory agreement. The legal team also participated

to the development of the patient information sheet and informed consent. The study site agreement and central laboratory agreement are being reviewed by the different concerned parties. It should be noted that the Jules Bordet Institute already approved the project protocol and informed consent form.

**Task 1.4 Definition of the relevant use cases and requirements analysis**
The use cases are being finalized and approved together with the technical partners. Regarding the analysis, the clinical partners have been solicited in the refinement of the definition of genetic and imaging biomarkers and of a modeling methodology as well as in the virtual collaborator tools and services.

### 2.2.4 Deviations from the DOW and corrective actions
The finalization of the D1.4: Consolidation of the user needs, use-case development and requirements analysis has been delayed and is postponed to end of March.

### 2.2.5 Planning next period
The molecular screening pilot will take place and the different modules supporting it will be tested and validated throughout the project period. Results and raw data are going to be uploaded and stored using INTEGRATE tools. This pilot project will help the clinical and technical partners to further refine and complete the user requirements and related use cases if needed.

## 2.3 *WP2 – Architecture & integration (Custodix)*

### 2.3.1 Objectives (of the reporting period)
- Implement, deploy and present the demonstrators in line with the specifications that were defined in the initial architecture document of year 1 (in cooperation with WP6 - Pilots, evaluation and validation).
- Write integration guidelines, focusing on on the technical aspects of integration, describing the guidelines for adding new models and tools, new (functional) services and new data sources.
- Start of implementation of the INTEGRATE demonstrators of year 2, specified in the next iteration of the architectural document (year 2).
- Finish the next iteration of the architecture, including the status of the INTEGRATE security framework
- The specification and development of the INTEGRATE security services should be further elaborated.

### 2.3.2 Status/progress towards objectives WP2

**Task 2.1 Identification and evaluation of relevant standards**
- This task was finished in month 9

**Task 2.2 Inventory of re-useable/available relevant solutions and components**
- This task was finished in month 9

**Task 2.3 Design and implementation of the INTEGRATE reference architecture**
- Brainstorm technical meetings were held, defining the scope of the different demonstrators for year 1 and year 2
- Two demonstrators (‘patient screening demonstrator’ and ‘analytical tools demonstrator’) were implemented, deployed and presented at the review meeting of year 1, mainly

coordinated by WP2, which has dealt with task assignment, load distribution and resources allocation.
- A next iteration of the ‘patient screening demonstrator’ was started, including a GUI update
- The implementation of two new demonstrators was started (‘cohort selection demonstrator’ and the ‘pathology demonstrator’) for review year 2.
- The next iteration of the architecture was started

**Task 2.4 Security for dynamic collaborative environments**

- Implementation was started of the initial INTEGRATE security framework services, in the first iteration the STS/IDP and identity management framework were developed and deployed.
- Integration of the authentication infrastructure in the demonstrators of year 1 has been started.
- A scientific paper about the concept of contextual attributes was submitted for HEALTHINF 2013 in Barcelona.

**Task 2.5: Component integration and interfacing with external systems**

- Within this task effort has dedicated during component implementation that component interactions was loosely coupled and interfaces were implemented as agreed (conformance to the architecture). Several telco’s have been held for coordination.
- Interfaces have been validated during component integration on the demonstration platform.
- Integration guidelines were specified in Deliverable 2.5

## 2.3.3 Deviations from the DOW and corrective actions

- Deliverable D2.5 integration guidelines was merged with D4.3 initial specification of privacy enhancing services and the deadline has been moved to January 2013. We have proposed to merge deliverables "D2.5 Integration Guidelines" and "D4.3 Initial specification of Privacy Enhancing Services" because of the following:

  - At this stage of the project, the content of D4.3 is rather limited. The privacy enhancing services come mainly into play into the last stage of the project, where all services are integrated and there is dataflow from the "care domain" into the "trial domain" (year 3).

  - More importantly, these services (of D4.3) are for a large part "glue logic" that supports the integration of the different application services (in different legal domains) defined in INTEGRATE. In this respect, their description fits the content of "D2.5 Integration Guidelines". At the same time we felt that describing the services in a separate deliverable "D4.3" would cause unnecessary repetition of context of the overall framework (cf. the integrating nature).

  Note that the description of Privacy Enhancing Services also fits "D2.6 System architecture refinement, security framework and implementation status" (scheduled T0+24). These services were already introduced in the previous iteration of this deliverable. Hence D4.3 could also have been merged with D2.6.

- Deliverable D2.6 was delayed to March 2013

## 2.3.4 Planning next period

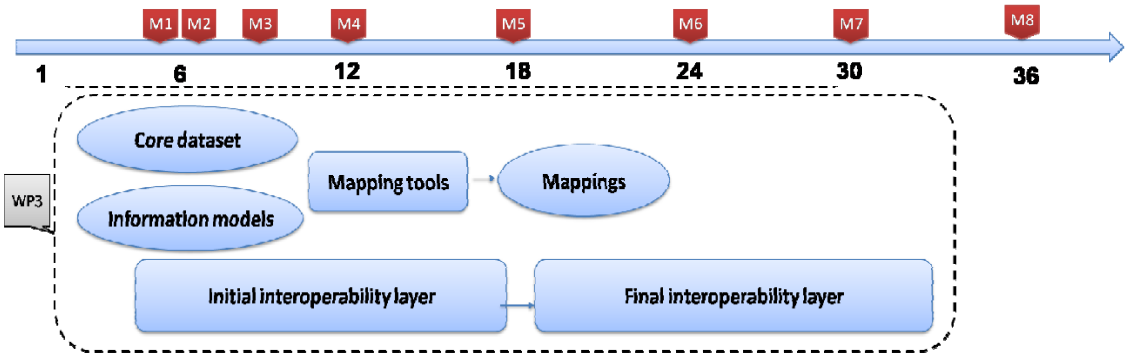
- Finishing the next iteration of the architecture (year 2), including detailing of the high-level view of the current specified architecture as requested in the first annual review.
- Write and define the final version of the architecture and security framework

- Further specification, integration and deployment of the next iteration of the security framework services.
- Further integration of the security environment in the demonstrators of year 1 and 2
- Decide which demonstrators will be implemented (or updated) and presented in year 3 of the INTEGRATE project

## 2.4 *WP 3 Data Models and Interoperability (UPM)*

### 2.4.1 Objectives (of the reporting period)

The main objective in WP 3 is to facilitate a common access to clinical data for applications of the INTEGRATE platform. Common information models, vocabularies and mappings mechanisms are required to homogenize data repositories. From month 12 to month 24, tasks have been mainly focused on the mapping formalism (Task 3.3) and the semantic interoperability layer (Task 3.4), while the core dataset (Task 3.1) and common information models (Task 3.2) have been iteratively refined.




During the reporting period, the following objectives should be achieved: (i) identification of the initial proposals for the core dataset (common vocabulary), (ii) mapping formalisms and mappings between the core dataset and the common data model (CDM), (iii) an initial prototype of the semantic interoperability layer to facilitate homogeneous access to data sources and (iv) a homogeneous solution to access external sources.

### 2.4.2 Status/progress towards objectives WP 3

**Task 3.1 Definition of the semantic core dataset**

The core dataset have been refined by identifying a subset of SNOMED and LOINC terms. Concepts that would be included within the INTEGRATE “lingua franca” have been extracted by:

- Automatic analysis of public clinical trials
- Automatic identification within EHRs from data sources
- Manually identified by domain experts

We have included new terms as SNOMED CT extensions for clinical trial eligibility criteria classification, since there is a lack of standardized taxonomy in this field. Deliverable 3.2 provided a detailed description of such process. The core dataset vocabularies have been stored using the OWL ontology representation language and loaded into a SESAME server to facilitate semantic reasoning.

### Task 3.2 Definition of the information models of the clinical and research infrastructures

After analyzing a set of common data models candidates from previous projects, a first version of the common data model for the INTEGRATE platform was developed during the past period based on HL7 RIM. As described in D3.1, HL7 RIM provided powerful capabilities of representation for any kind of clinical data and it is widely used to be used together with SNOMED (which INTEGRATE core dataset is mainly based). During the current reporting period, further refinement has been carried out to homogenize data types, one of the main challenges of HL7 RIM models.

The INTEGRATE CDM implemented with a relations database plus a D2R server to provide an SPARQL template, and it was adapted to normalize data sources by using the SNOMED normal form and the terminology binding between HL7 RIM and SNOMED. These issues and performance test has been described within a publication recently accepted for the MEDINFO 2013 conference "The 14th World Congress on Medical and Health Informatics".

### Task 3.3 Semantic formalism, mapping tools and mapping implementations

Three different mappings have been identified within the INTEGRATE platform (a detailed description has been reported at deliverable 3.4):

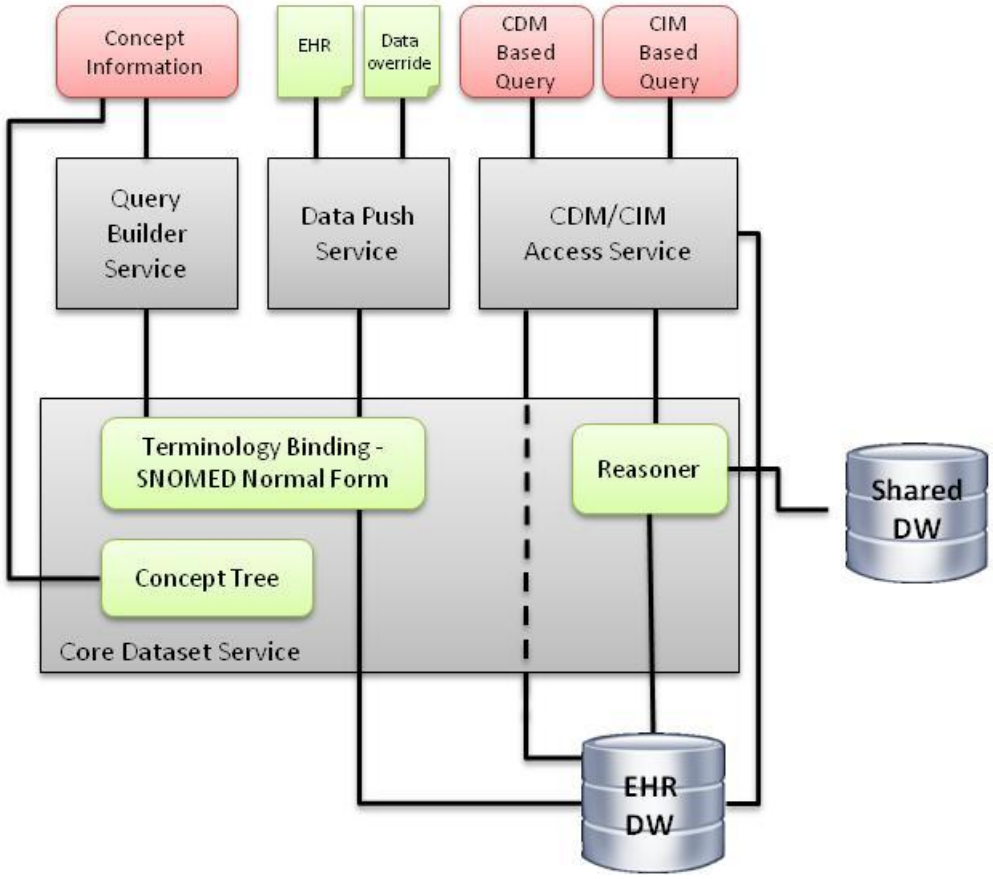
- Links between core dataset concepts and the common data model (also called terminology binding)
- Links among vocabularies composing the core dataset, identifying overlapping among them concepts
- Links between data sources and the INTEGRATE common data model (ETL tools)

The terminology binding is mainly used to automatically build queries extracting data from the core dataset. An analysis for breast cancer clinical trials have been described within a publication recently accepted for the MEDINFO 2013 conference "The 14th World Congress on Medical and Health Informatics".

Links among ontologies have been analyzed from previous works to identify links among SNOMED, LOINC and MedDra. While Pentaho Kettle open source ETL suite have been used to store information from data sources within the INTEGRATE common data model.

### Task 3.4 Design and implementation of the semantic interoperability layer

A first version of the query mechanism has been implemented to homogeneously retrieve data integrated through the platform. Core dataset concepts are used within SPARQL queries to retrieve through the mapping to the common data model, the required information homogeneously integrated. Reasoning capabilities were included to improve query building, increase the semantic potential of the INTEGRATE platform and improve sustainability when new sources are included. Performance issues were also solved by improving the SPARQL to SQL rewriting mechanism of the D2R server.




An additional component to facilitate the construction of Common Information Model-based queries has been also developed during the reporting period. The so called “query builder” receives a concept or a pair of concept and HL7 class, and return an SPARQL query template to retrieve information from the CIM based on such concept.

The initial proposal of the semantic interoperability layer is described at Deliverable 3.5.

**Task 3.5 Standards-based uniform access to external sources**

External repositories have been analyzed to enable access, through the same homogeneous mechanism, to complementary data within the INTEGRATE platform. A solution based on uniform interfaces and existing standards is being developed, to enable that INTEGRATE tools and services can access information from external repositories. EHR data sources have been the main external source identified at the moment, exporting data through standard built-in HL7 interfaces. Information encoded using HL7 version 2 and version 3 (XML-based) is then loaded into the common data model using ETL tools and the mapping formalisms. Simple information extraction has been carried out within free text field of data to provide a homogeneous structure. Molecular information from samples has being also linked to the common data model.

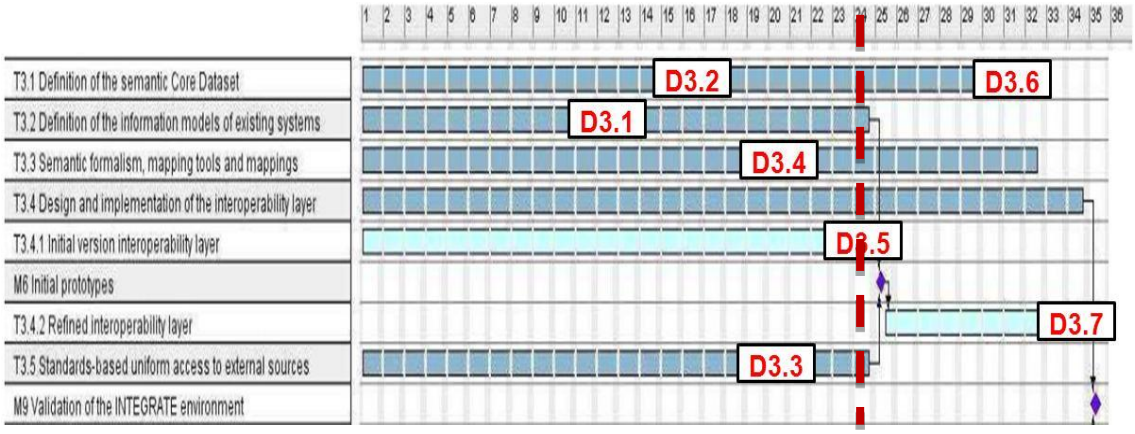
## 2.4.3 Deviations from the DOW and corrective actions

There are not significant deviations from the DoW. WP3 have been mainly focused on Task 3.3 and 3.4 during months 12 to 24.

### 2.4.4 Planning next period

A second version of the semantic interoperability layer has been designed and implemented to provide a method to retrieve a set of patients within a cohort selection tool. Although previous developments from the first version were reused, new components were required to generate queries based on core dataset concepts (i.e. the “query builder”).

Within the next period, the CDM of INTEGRATE is not expected to be modified, while the core dataset should be extended to other domains beyond clinical trials on breast cancer. Such expansion will be reported in Deliverable 3.6 “Study on the extension of the core dataset”. Due to the complexity of the knowledge represented in the area, other types of cancer will be the main focus of the core dataset extensions.




The ETL process will be adapted to automatically normalize data source with SNOMED CT Normal Forms and the terminology binding between HL7 and SNOMED. The semantic interoperability layer will be refined to deal with other data sources, keeping track of original and normalized repositories.

## 2.5 *WP4 – Sharing and collaborating tools and services (FORTH)*

For the 2nd year WP4, the main effort had been focused in the design and the materialization of a flexible platform for allowing central review of pathology images between many reviewers, which is easily accessible from the web and operates as a virtual microscope.
In the section below there is a detailed description for all the activities related to the platform of Central Review of pathology images.

#### 2.5.1.1 Summary of Technical Progress

The following objectives had been set for the reporting period:

1. Finalization of all user requirements, scenarios and test cases.
2. Definition and finalization of workflows, verified by the stakeholders.
3. Creation of the initial version of the virtual collaboratory and its services. This objective is compiled by a set of subcases, as described below:
   a. Process the retrieved from the Common Data Warehouse pathology images, in order to generate images in a format appropriate for displaying through a browser
   b. Connect to the Common Data Warehouse (CDW) in order to retrieve the pathology images which should be reviewed and to publish back to the CDW the produced reports from the reviewing protocols. .

c. Implement the Single Sign On (SSO) functionality, to handle user creation and user authentication.

4. Provision of tools for configuring the platform through a web interface, without the need to manually edit configuration files.
5. Definition and implementation of a powerful mechanism for dynamic report generation, as flexible as possible, which can be set to serve any kind of medical image type with almost no modifications.

## 2.5.2 Status/progress towards objectives

### 2.5.2.1 Task 4.1: Model, data and annotation repositories

According to this task the Central Review Platform (CRP) is using SOAP requests in order to access and retrieve the imaging data and their metadata from the CDW, as an XML response. A moderator[4] can then define a dynamic model perfectly adapted to the current needs, and then create Reviewing Protocols in which everything is controlled (images to be reviewed, reviewers, features of interest, etc.) and described (any kind of information can be used in order to complete a reviewing protocol as rich text, and URLs to documentation or other fountains of information).

### 2.5.2.2 Task 4.2: Tools enabling data and knowledge sharing

According to the task the CRP provides tools enabling the clinical research community of BIG to collaboratively define research protocols and carry out all the necessary regulatory and administrative steps to carry on the success of a clinical trial. The CRP provides wizard driven procedures and intuitive interfaces in order for the clinicians to successfully identify which patients are eligible to be included in the trial, resulting in rapid reviewing process among multiple reviewers. The protocols are dynamically defined by the administrator/moderator of the platform, using secure mechanisms to share data among the appropriate reviewers.

### 2.5.2.3 Task 4.3: Tools enabling collaboration

The concept of a centralized reviewing platform is based upon the spirit of collaboration among the reviewers who are called to review a pathology image. A review is characterized as successful only when there are no conflicts among the results of the reviewers. Thus the CRP provides means to resolve conflicts upon sharing the information available among the appropriate reviewers and by providing a seamless interface which assists the reviewers to isolate any issues appearing during a reviewing protocol. The collaboration features of the CRP include automatic notifications send by the platform, reminders and discussion like procedures until a conflict is resolved and the final status of an image under review is set.
A brief listing of the collaboration tools provided by the CRP is:

1. Listing of pending reviewing protocols.
2. History of the images reviewed.
3. Listing of all the notifications (with history) sent by the platform to the reviewers.
4. Listing of all the pathology images available to the reviewers.
5. Medical image viewer which successfully simulates a virtual microscope.
6. Metadata viewer for a selected pathology image.
7. Report editor with export to PDF functionality.
8. Graphical editor for the configuration of the model used in the reviewing protocols and for the reports.
9. Wizard driven interface for the creation of a reviewing protocol.

[4] The CRP supports two distinct roles: moderators and reviewers.

10. Conflict editor for the moderator, which assists in the resolution of conflicts among the reports of the reviewers.

#### 2.5.2.4 Task 4.4: Privacy Enhancing Processes and Services

The CRP implements SSO functionality, for the creation and the authentication of the users. All the data pushed to the platform are anonymized, while the reviewers have no access to any crucial information (regarding the identity of the patient).

#### 2.5.2.5 Deviations from the Annex 1

No deviations

### 2.5.3 Planning next period

The planning of activities for the upcoming period is focused on the following:

- Complete the prototype of the CRP, in order to provide all the necessary functionality described in the DOW.
- Evaluate the performance and the usability of the platform in close collaboration with the clinical partners.

## 2.6 *WP5 – Support for predictive modelling & validation (FORTH)*

WP5 has focused on providing users with a web-based multi-functional and easy-to-use platform for analyzing large multi-level datasets using a pool of statistical tools and predictive models.

#### 2.6.1.1 Summary of Technical Progress

Our effort for this reporting period has been generally directed to the following aspects:

1. Optimizing the existed software (statistical analysis software, platform's code, on-the-fly report generators, single-sign-on authentication mechanisms, etc.), defined in the Periodic Progress report #1 outcome.
2. Adding new functionalities for predictive analysis.
3. Establishing the connectivity between the platform and the common data-warehouse (CDW), allowing data retrieval directly from the CDW.
4. Providing mechanisms for scheduling automatically periodic controls for any changes occurred to the data in the data-warehouse.
5. Building the platform's metadata repository in which users can access and edit the entire history of their executed analysis.
6. Evaluate the functionality of the platform using several datasets.

### 2.6.2 Status/progress towards objectives WP5

**Task 1.1 Definition of clinical scenario (questions) for the INTEGRATE VPH use case**

This task uses as input the clinical scenarios elaborated in WP1 (D.1.2), based on which will develop VPH-focused scenarios. A refinement in these user needs has led to additional new tools for statistical analysis using genomic data, extending the functionality for survival analysis, and allowing the predictive models to perform on outcomes defined by the user (i.e. the user selects a clinical variable related to the efficacy of a specific regimen, the clinical outcome, etc. for prediction).

**Task 1.2 Definition of genetic and imaging biomarkers and of a modelling methodology**
Public available data for breast cancer prognosis and treatment comprising of survival, gene expression, SNP data, and clinical covariates are available through the Synapse Commons Repository (https://synapse.sagebase.org/Portal.html#BCCOverview:0). This multi-modal dataset, along with the BIG data from the TOP trial are already available for the needs of the analysis platform. A data model for both the TOP trial and the public dataset has been constructed and widely used health terminology standards like SNOMED (http://www.ihtsdo.org/snomed-ct/) enable consistent transmission and retrieval of data from the common data-warehouse to the platform.

**Task 1.3 Development of predictive models of response to therapy and of the modelling framework**
According to the definition of clinical scenarios for the INTEGRATE VPH use, a number of statistical analysis tools in conjunction with the predictive models comprise the overall analysis framework. A significant progress has been achieved during the second year of the project in the optimization of the existed code, the design of the predictive models, the enhancement of the platform's functionality in communicating with external data-warehouses and retrieving data, the storage of the metadata information of an analysis performed, and the evaluation of the analysis results in a simple and efficient way. Summarizing, the progress in developing a consistent multi-functional platform for statistical and predictive analysis is depicted in the following list:

- A multi-user web-based environment has been established and tested successfully where users can login the platform and run simultaneously various tools and models.
- Single-sign-on (SSO) authentication mechanisms where users log in once and have access to all services without being prompted to login again, are used as a log-in process.
- The platform can interact with the common data-warehouse (CDW) and displays the name of all the available datasets stored in the CDW and the user's exploitation permissions to them.
- The user can select from the platform's settings which of the available dataset(s) in the CDW will use for analysis, and schedule periodic controls for any changes occurred to the dataset(s).
- The platform is coupled with an intuitive clinical browser that interacts with the common data-warehouse, using web services, and retrieves the data for examination.
- Filtering mechanisms for generating cohorts from the entire dataset are available through the clinical browser.
- Processing techniques for parallel computations in the analysis tools and models using multiple cores have been applied to our software, reducing the computational cost and time.
- The statistical analysis tools, addressing the statistical research questions in the "Definition of clinical scenario (questions) for the INTEGRATE VPH use case", have been implemented and embedded to the platform.
- Code for the predictive models has been written and the models are running locally in our software platform.
- On the fly automatically generated HTML reports are available, providing a flexible way of assessing, editing and comparing different analysis results.
- The platform provides an internal database where a full analysis record of an executed analysis is stored. These records include:
    - Metadata information such as timestamp information, tool/model authorship, type of the analysis, examined data, any memory constraints, the analysis progress (complete or pending), etc.
    - The automatically generated reports in both *.pdf and *.html format.
- User-friendly functionality is made available for accessing, modifying, comparing, and downloading several analysis scenarios.

#### 2.6.2.1 Deviations from the Annex 1

No deviations

### 2.6.3 Planning next period

The planning of activities for the upcoming period is mainly focused on the following fields:

- Complete the implementation of the predictive models software and embed them to the analysis platform.
- Evaluate the performance of the platform by getting feedback from clinical users
- Enhance collaboration with p-medicine and share this tool with clinicians from p-medicine and other relevant projects.
- Look for additional, external datasets for assessing the value of the tool.
- Disseminate this work through publications (conferences and journals).

## 2.7 *WP 6 Pilots, evaluation and validation (Philips)*

### 2.7.1 Objectives (of the reporting period)

Considering the user needs as described in WP2 and the corresponding intended pilots, this work package identified specific application objectives to be tested and defined the evaluation criteria. A special focus was to involve the clinical end-user community in the evaluation and validation effort and to choose evaluation and validation sites.

In this period we have formulated evaluation criteria, validation procedures, and feedback report guidelines and the specifications of test (validation) cases and demonstrators.

A crucial objective of WP6 is to coordinate the efforts with the technical staff and the IT departments of the pilot sites, so that the Consortium receives all information required for developing the information models of the existing infrastructures, and all the data necessary for the testing and validation of the INTEGRATE infrastructure components and tools.

Another objective of the WP is to prepare the technical and procedural infrastructure – in compliance with the defined security framework of the project – for the installation of the INTEGRATE software solutions for their extensive evaluation and validation.

### 2.7.2 Status/progress towards objectives WP 6 (per Task)

The tasks were to define on one hand, the evaluation methods of the various components, and particularly, in the case of EHR connectivity with clinical centers (e.g. formats compliance, exported data verification) and on other hand, the validation procedures of different services (each one being the subject of a demonstrator) in an operating environment. These procedures cover also the technical aspects of the ETL (extraction of data from medical records) as well as legal impact implied by data exchange.

**Task 6.1 Building the INTEGRATE development and testing environment**
For this task, all partners in the project cooperated so that sufficient and suitable clinical data was available for the development of the INTEGRATE tools and semantic interoperability environment. This required close collaboration between the clinical and technical partners to define the needs of the scenarios and the requirements with respect to data and information. The clinical partners provided a wealth of data and information that enabled the development of the functionality. Public

data (such as the clinical trial criteria available on the clinicaltrials.gov site) were also used in the development of our solutions.

**Task 6.2 Formulate evaluation criteria, validation procedures and feedback report guidelines**
In this task the procedures for the evaluation and validation activities were established (topic of D6.2). In general evaluation criteria will be continuously adapted to the current state of development of the environment, considering the end-user scenarios and clinical pilots as general guideline. Usability, user-friendliness, speed and robustness will be key criteria in the evaluation process. Quantitative measures of the benefits of the project as a whole were also defined. The validation of the platform will essentially be conducted by the design of and execution of test cases with known results, those will adapted to the specificities of the software issued in each work package.

**Task 6.3 Coordinate specifications of test scenarios and demonstrators**
This task consisted in the definition of methods for the evaluation of components developed in the context of EHR connectivity with medical centers. These methods estimate the modules through different aspects: performance, maintenance, reliability, *etc.*

**Task 6.4 Deployment Environment**
This task consisted in definition of validation procedures for the system running in operational environment. These procedures covering legal, technical and functional aspects are formalized through different protocols and guidelines.

### 2.7.3 Deviations from the DOW and corrective actions
The finalization of D6.4 was delayed due to the need to identify new pilot sites and discuss with the sites our requirements and their expectations from the project (agreements from the sites also included administrative processes), it was submitted at the end of March.

### 2.7.4 Planning next period
The next steps will be to implement the procedures defined previously in an operating environment during the pilot phase (step during which end users have the opportunity to test the modules offered by the platform). This task will test various implemented software components and therefore validate the work. The results will help to define the changes and improvements to bring to the platform.
Several pilot sites will be included and the tools will be deployed and validated with users in those sites.

## 2.8 *WP 7 Knowledge management (BIG)*

The objectives of the work package WP7 are:

- To exchange information within the project consortium
- To exploit and disseminate the results of the project
- To manage the generation of intellectual property and to contribute to standardization activities

### 2.8.1 Objectives (of the reporting period)

The main objectives of this WP for this reporting period were to produce the first three INTEGRATE Newsletters (D7.5, D7.6, D7.8) to reach out to the INTEGRATE stakeholders and to prepare the final dissemination plan (D7.7).

## 2.8.2 Status/progress towards objectives WP7 (per Task)

The required tasks for this reporting period (as described in the DoW document) were elaborated and successfully carried out by good interdisciplinary collaboration.

Task 7.1 Dissemination

The INTEGRATE Newsletters (five in total throughout the duration of the project) describe aspects of the research problems in focus, inform readers about challenges encountered and progress made towards overcoming them, and refer to relevant project deliverables. The aim is to engage readers in discussions about data sharing and collaboration in the biomedical domain, as well as the scientific issues around information integration and interoperability. The first three newsletters were produced in this reporting period (April and August 2012, January 2013) and distributed among consortium partners, on the INTEGRATE (www.fp7-integrate.eu) and BIG (www.breastinternationalgroup.org) websites. Articles published in the INTEGRATE Newsletter were also published in the BIG Newsletter.

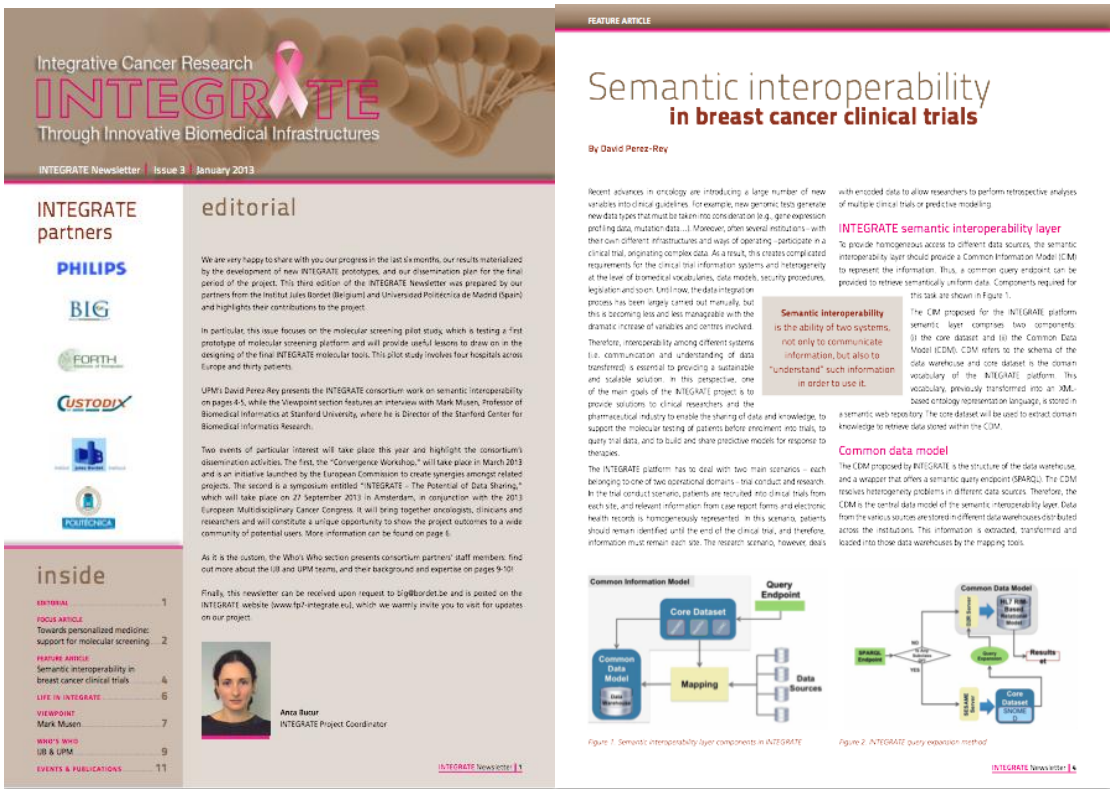

Integrative Cancer Research
INTEGRATE
Through Innovative Biomedical Infrastructures
INTEGRATE Newsletter | Issue 3 | January 2013
INTEGRATE partners
editorial
inside
FEATURE ARTICLE
Semantic interoperability
in breast cancer clinical trials
By David Perez-Rey
Semantic interoperability is the ability of two systems, not only to communicate information, but also to "understand" such information in order to use it.
INTEGRATE semantic interoperability layer
Common data model
Common Information Model
Query Endpoint
Core Dataset
Common Data Model
Mapping
Data Sources
Figure 1. Semantic interoperability layer components in INTEGRATE
Figure 2. INTEGRATE query expansion method

Figure: Excerpt from the third INTEGRATE newsletter

The final dissemination plan is a revision of the initial dissemination plan (D7.3). It provides an update on the consortium dissemination efforts. Together, these two plans provide a “road-map” for dissemination of information and knowledge generated by the project.

As part of the dissemination effort, an INTEGRATE micro-symposium on data-sharing in oncology will also take place on September 27, 2013 (tentative title "INTEGRATE - The potential of data sharing"). This is will happen just before the prestigious ECCO-ESMO-ESTRO oncology conference 2013 and will appear in the printed program of the conference. Five talks are planned on the topics of the need for data sharing in oncology, the challenges of data

sharing, semantics, legal and ethical issues, security issues and the presentation of the INTEGRATE project itself. External speakers for the event have been approached.

Dissemination of information has also been ensured by the participation of consortium members in several meetings, where they presented the INTEGRATE project.

Task 7.2 Exploitation

T7.2.1 Adoption of the INTEGRATE Solutions

In order to ease the adoption of the INTEGRATE solution by clinical partners, discussions were held to make sure that the developed software components are still in line with clinical requirements. To this end, the requirements for a proof-of-principle real-world deployment of a data sharing platform hosting data from BIG (and associates) clinical trials were also discussed. This proof-of-concept real-world platform will be deployed before the end of the project, and will be a showcase for the capabilities of the INTEGRATE solution. This should facilitate the adoption of INTEGRATE beyond the consortium clinical partners.

T7.2.3 Educational activities
INTEGRATE will join the 2nd Summer School on Computational Oncology organized by p-medicine project with presentations and demonstrators.

## 2.8.3 Deviations from the DOW and corrective actions

No significant deviations from the DoW to report.

## 2.8.4 Planning next period

The main activities for the next period are:

- To continue engaging project stakeholders through the INTEGRATE Newsletter
- To organize the event “INTEGRATE – The potential of data sharing” on 27 September 2013 to disseminate information about the project
- To start preparing a launching event
- To prepare the final exploitation plan
- To help securing the sustainability of the platform

# 3 Achievements per individual partner

**Partner 1 Philips**

In this reporting period Philips contributed to a range of activities in the project

- Attended technical, review and consortium meetings
- Contribution to the elaboration of the solution for the semantic interoperability layer of the project.
- Contributed to the preparation of demonstrators for the second review meeting
- Carried out an usability study of the patient screening application, organized interviews and feedback sessions with clinicians
- Build the improved, advanced UI of the patient screening demonstrator, the trial metadata repository and contributed to the development of the matching scripts.
- Lead the elaboration of deliverables D3.2 and D2.5 and contributed to several other deliverables: D3.3, D3.5, D6.3, D6.4, D1.5.
- Contributed to the content of the second newsletter.
- Designed User Interfaces for the cohort selection application
- Contributed to and reviewed D7.3 initial dissemination plan and D7.4 Initial exploitation plan
- Lead the writing of a scientific paper about the selection of the core dataset based on widely-used medical ontologies and presented the paper (accepted in BIBE 2012).
- Preparation of a journal paper submitted to IEEE Journal of Biomedical and Health Informatics.
- Participation and presentation in the 3rd VPH NoE working group in Barcelona, May 2012.
- Participation in the convergence meetings on interoperability (Basel Nov. 2012, Brussels March 2013)

**Partner 2 BIG**

During this reporting period, the main work of BIG was carried out in relation to WP7. The main achievements were:

- Producing the first three INTEGRATE Newsletters (D7.5, D7.6, D7.8) to reach out to the INTEGRATE stakeholders
- Delivering the final dissemination plan (D7.7)
- Starting the preparation of an INTEGRATE micro-symposium on data sharing in oncology that will be held at the prestigious ECCO-ESMO-ESTRO oncology conference
- BIG also played a role in securing the future adoption and sustainability of the INTEGRATE software solutions by specifying the requirements for a real-world deployment of a clinic-genomic data sharing platform that will be deployed before the end of the project and will be a showcase for the capabilities of the INTEGRATE solution.
- Implementation of a data acquisition and management tool to support the pilot study for establishing the methodology of the molecular screening program.

**Partner 3 FORTH**

- For the 2nd year FORTH has extensively work in WP4 for developing a flexible platform for remote review of pathology images by a group of experts, which is easily accessible from the web and operates as a virtual microscope.
- The Central Review Platform (CRP) implements SSO functionality, for the creation and the authentication of the users. All the data pushed to the platform are anonymized, while the reviewers have no access to any crucial information (regarding the identity of the patient).
- In WP5, FORTH has focused on providing a web-based multi-functional and easy-to-use platform for analyzing large multi-level datasets using a pool of statistical tools and predictive models.

- Functionalities such as Single-sign-on (SSO) authentication mechanisms and interaction with the common data-warehouse (CDW) have been incorporated through a close collaboration with all INTEGRATE partners.

**Partner 4 Custodix**

Main contributions for Custodix:

- Attended telco's and technical, review and consortium meetings
- Led and contributed to the next iteration of the architectural document
- Contribution in discussions about semantic approaches, data sources and common and local information models
- Discussed the scope of the demonstrators for the first and second review meeting
- Worked out the technical specification of the patient screening demonstrator and cohort selection demonstrator
- Devised the innovative DSL Query engine core for the cohort selection application
- Collaborated to the implementation and deployment of the patient screening demonstrator and cohort selection demonstrator
- Wrote sections in the INTEGRATE newsletter
- Contributed to the report on preparation of the deployment environment for the clinical pilots
- Contributed to and reviewed the final iteration of the technical use cases
- Specified the initial version of the privacy enhancing services
- Discussed an provided input for the scope of the INTEGRATE demonstrators in year 2
- Contributed and reviewed D7.3 initial dissemination plan and D7.4 Initial exploitation plan
- Written a scientific paper about contextual attributes for presentation at HEALTHINF 2013
- Integrated authentication security in the INTEGRATE demonstrators of year 1
- Started with implementation of the INTEGRATE security framework services (authentication services)
- Organised several meetings with representatives of pharmaceutical companies to gather feedback on the patient screening demonstrator

**Partner 5 IJB**

Main contributions of IJB

- Building of a dataset including pathology data and results of laboratory tests from the medical records of patients enrolled in the TOP trial. This data extraction was the basis for the implementation of the first modules of the platform Integrate (especially in the case of the first demonstrator).
- Finding solutions and approaches to solve the problem in mapping different medical terminologies (MedDRA, SNOMED CT and LOINC) in the context of the definition of the core dataset. These investigations allowed us to measure the scope of the problem posed by the integration of different medical terminologies into the platform.
- Definition of software components evaluation involved in the context of EHR connectivity with clinical centers (including also technical issues in relation with the exchange of data from medical records).
- Definition of validation procedure models regarding different parts of the platform as well as legal issues involved in the medical data exchange. This work covers the issue of the installation and the use of software modules in operating environment.
- The molecular screening pilot protocol was finalized and approved. It has been sent to the different participating clinical centres and central laboratories. The protocol and the ICF are being approved by the respective EC. It should be noted that IJB has already approved both of them and patient recruitment will start soon. Study site and central laboratory agreements are also under review.
-

**Partner 6 UPM**

Main contributions for UPM

- Collaboration on user requirements extension
- Collaboration to provide architectural principles and design
- Analysis of core dataset concepts from EHR data
- Implementation of a HL7-based Common Data Model for INTEGRATE
- Implementation of ETL tools to load data sources into the Common Data Model
- Implementation of the reasoning mechanism of the semantic interoperability layer
- Collaboration with the INTEGRATE 3rd Newsletter, including an interview on semantic interoperability issues with Prof. Mark Musen

# 4 Project management during the period

## 4.1 *Consortium Management*

The project has proceeded according to plan. The focus of the WP in the reporting period was to support the activities of the WPs so that the necessary work is carried out efficiently and the project objectives are reached. The project website was regularly updated with the new results. The work in the project was coordinated using the project wiki.

There were no changes in the consortium. According to the initial plans, several potential new clinical partners were selected and proposed. Their role will be to participate in the validation of the project results.

## 4.2 *Project Meetings*

### 4.2.1 Project Management Team Meetings

| When | Where | Organising Partner or Work Package | Participants |
|---|---|---|---|
| 1st February 2012 | Demonstrator Telco | Philips-IJB-Custodix-UPM<br>Gent / Custodix | -<br>Belgium |
| 6th – 8th February 2012 | 3rd Workshop | | |
| 16th March 2012 | Demonstrator Telco | Philips-IJB-Custodix-UPM | - |
| 28th March 2012 | Demonstrator Telco | Philips-Custodix-UPM | - |
| 4th April 2012 | Demonstrator Telco | Philips-Custodix-UPM | - |
| 10th April 2012 | Demonstrator Telco | Philips-Custodix-UPM | - |
| 20th April 2012 | Demonstrator Telco | Philips-Custodix-UPM | - |
| 1st – 4th May 2012 | 1st Annual Review (and rehearsal) | Philips-Custodix-IJB-BIG-FORTH-UPM | Belgium |
| 24th – 25th May 2012 | Technical Meeting | Gent / Custodix | Belgium |
| 15th June 2012 | Dissemination Telco | Philips-Custodix-UPM | - |
| 26th – 27th June 2012 | 4th Workshop | Brussels / BIG | Belgium |
| 17th July 2012 | BIG pilot Telco | Philips-BIG-UPM | - |
| 13th August 2012 | BIG pilot Telco | Philips-BIG-UPM | - |
| 1st – 2nd October 2012 | 5th Workshop | Madrid / UPM | Spain |
| 5th October 2012 | Collaboration tools integration Telco | FORTH-UPM | - |
| 18th October 2012 | Technical Meeting | Heraklion / FORTH | Greece |
| 11th – 12th December 2012 | Technical Meeting | Madrid / UPM | Spain |
| 25th January 2013 | Architecture Telco | Custodix-UPM | - |

**Table 1 – Project Management Team Meetings**

### 4.2.2 Work Packages Meetings

| When | Where | Subject | Organising Partner or Work Package | Participating Partners |
|---|---|---|---|---|
| 01/02/2012 | Technical telco | Sint-Martens Latem/Custodix | Belgium | |
| 03/02/2012 | Monthly telco | Sint-Martens Latem /Custodix | Belgium | |
| 06/02/2012 | Technical meeting | Sint-Martens Latem/Custodix | Belgium | |
| 07-08/02/2012 | Consortium meeting | Ghent/Custodix | Belgium | |
| 02/03/2012 | Monthly telco | Sint-Martens Latem/Custodix | Belgium | |
| 10/04/2012 | WP6 meeting | Eindhoven/Philips | Netherlands | |
| 02-03/05/2012 | Pre-review meeting | Brussels/UPM | Belgium | |
| 04/05/2012 | Review meeting | Brussels/EC | Belgium | |
| 07-09/05/2012 | WoHIT 2012 | Copenhagen/WoHIT | Denmark | |
| 24/05/2012 | Technical meeting | Sint-Martens Latem/Custodix | Belgium | |
| 29/05/2012 | Meeting Jansens | Sint-Martens Latem/Custodix | Belgium | |
| 31/05/2012 | Meeting Merck | Sint-Martens Latem/Custodix | Belgium | |
| 01/06/2012 | Monthly telco | Sint-Martens Latem/Custodix | Belgium | |
| 26-27/06/2012 | Consoritum meeting | Brussels/IJB, BIG | Belgium | |
| 06/07/2012 | Technical meeting | Eindhoven/Philips | Netherlands | |
| 03/08/2012 | Monthly PMT Telco | Sint-Martens Latem/ Custodix | Belgium | |
| 13/08/2012 | Pilot Telco | Sint-Martens Latem/Custodix | Belgium | |
| 20-21/08/2012 | Technical Meeting Cohort Selection | Sint-Martens Latem/ Custodix | Belgium | |
| 07/09/2012 | Monthly PMT Telco | Sint-Martens Latem/ Custodix | Belgium | |
| 21/09/2012 | WP4 Telco | Sint-Martens Latem/ Custodix | Belgium | |
| 01-02/10/2012 | Consortium Meeting | Madrid/ UPM | Spain | |
| 05/10/2012 | WP4 Telco | Sint-Martens Latem/ Custodix | Belgium | |
| 18/10/2012 | Demonstrator Meeting | Heraklion/ FORTH | Greece | |
| 31/10/2012 | Monthly PMT Telco | Sint-Martens Latem/ Custodix | Belgium | |
| 16/11/2012 | WP3 Telco | Sint-Martens Latem/ Custodix | Belgium | |
| 22/11/2012 | Evaluation Meeting, patient screening tool | Homburg/ UdS | Germany | |
| 07/12/2012 | Monthly PMT Telco | Sint-Martens Latem/ Custodix | Belgium | |

| When | Where | Subject | Organising Partner or Work Package | Participating Partners |
|---|---|---|---|---|
| 11-12/12/2012 | Technical Meeting | Madrid/ UPM | Spain | |
| 11/01/2013 | Monthly PMT Telco | Sint-Martens Latem/Custodix | Belgium | |
| 31/01/2013 | BIG Pilot & Dissemination Meeting | Brussels/ BIG | Belgium | |

**Table 2 – Work Packages and Working Group Meetings**

## 4.3 *Dissemination activities*

The information reported in this section is delineated in the Final Dissemination Plan which was finalized this year of the project and which underlies the INTEGRATE approach to dissemination.

The first priority of the dissemination task was to optimise the sharing of knowledge at the project-level. To achieve this objective, the project coordinator, Philips, and the participant in charge of the knowledge management work package, BIG, have used a variety of tools (wiki, BSCW document sharing server, public website, newsletter).

The project has issued two newsletters including presentations of the project results and interviews with key opinion leaders in topics relevant to the project such as information sharing, privacy and legal issues. These newsletters were widely distributed and published on the website.

Our proposal for a session on INTEGRATE and data sharing during the ECCO (European Cancer Conference) was accepted and we are included in the conference program. We have started the preparation of this event.

We also plan a launching event with the IMPAKT 2014 clinical conference.

### 4.3.1 Publications & presentations

HealthInf 2013:

Sergio Paraiso-Medina, David Perez-Rey, Raul Alonso-Calvo, Brecht Claerhout, Kristof de Schepper, Philippe Hennebert, Jérôme Lhaut, Jasper Van Leeuwen and Anca Bucur. Semantic interoperability solution for multicentric breast cancer trials ath the INTEGRATE EU project. In proceedings of the 6th International conference on Health Informatics, HEALTHINF 2013, 11-14 Feb 2013, Barcelona.

“CONTEXTUALISATION OF ABAC ATTRIBUTES THROUGH A GENERIC XACML FUNCTIONALITY EXTENSION MECHANISM”,
Brecht Claerhout, Kristof De Schepper, David Pérez del Rey and Anca Bucur

IEEE BIBE 2012:

“Identifying the Semantics of Eligibility Criteria of Clinical Trials based on relevant Medical Ontologies”

Anca Bucur, Jasper van Leeuwen, David Perez Del Rey, Brecht Claerhout, Kristof de Schepper and Raul Alonso Calvo

3rd VPH NoE working group, May 2012, Presentation in the oncology track:
"INTEGRATE: Patient screening for clinical trials application", Anca Bucur

| When | Where | Presentation Title | Presenting Person(s) | Presenting Partner(s) |
|---|---|---|---|---|
| 11-13/02/2013 | HEALTHINF 2013 Conference | Health Informatics | International | UPM, Custodix |
| 11-13.11.2012 | BIBE 2012 Conference | IEEE 12th International Conference on BioInformaticsand BioEngineering | International | Philips |
| | | | | |
| | | | | |

## 4.3.2 Paper submissions

**Submitted papers:**
Juan M. Moratilla, Raul Alonso-Calvo, Gema Molina-Vaquero, Sergio Paraiso-Medina, David Perez-Rey, Victor Maojo. A data model based on semantically enhanced HL7 RIM for sharing patient data of breast cancer clinical trials. In proceedings of The 14th World Congress on Medical and Health Informatics, MEDINFO 2013, 20-23 August 2013, Copenhagen. (Accepted for publication)

Santiago Aso, David Perez-Rey, Raul Alonso-Calvo, Antonio Rico-Diez, Anca Bucur, Brecht Claerhout, Victor Maojo. Analyzing SNOMED CT and HL7 Terminology Binding for Semantic Interoperability on Post-Genomic Clinical Trials. In proceedings of The 14th World Congress on Medical and Health Informatics, MEDINFO 2013, 20-23 August 2013, Copenhagen. (Accepted for publication)

Anca Bucur, Jasper van Leeuwen, David Perez-Rey, Raul Alonso-Calvo, Brecht Claerhout, Kristof de Schepper, Jérôme Lhaut, Philippe Hennebert, and Alexandre Irrthum. Identifying the Semantics of Eligibility Criteria of Clinical Trials based on relevant Medical Ontologies, IEEE Journal of Biomedical and Health Informatics. (Under evaluation)

## 4.3.3 Participation in alignment and convergence events with other projects

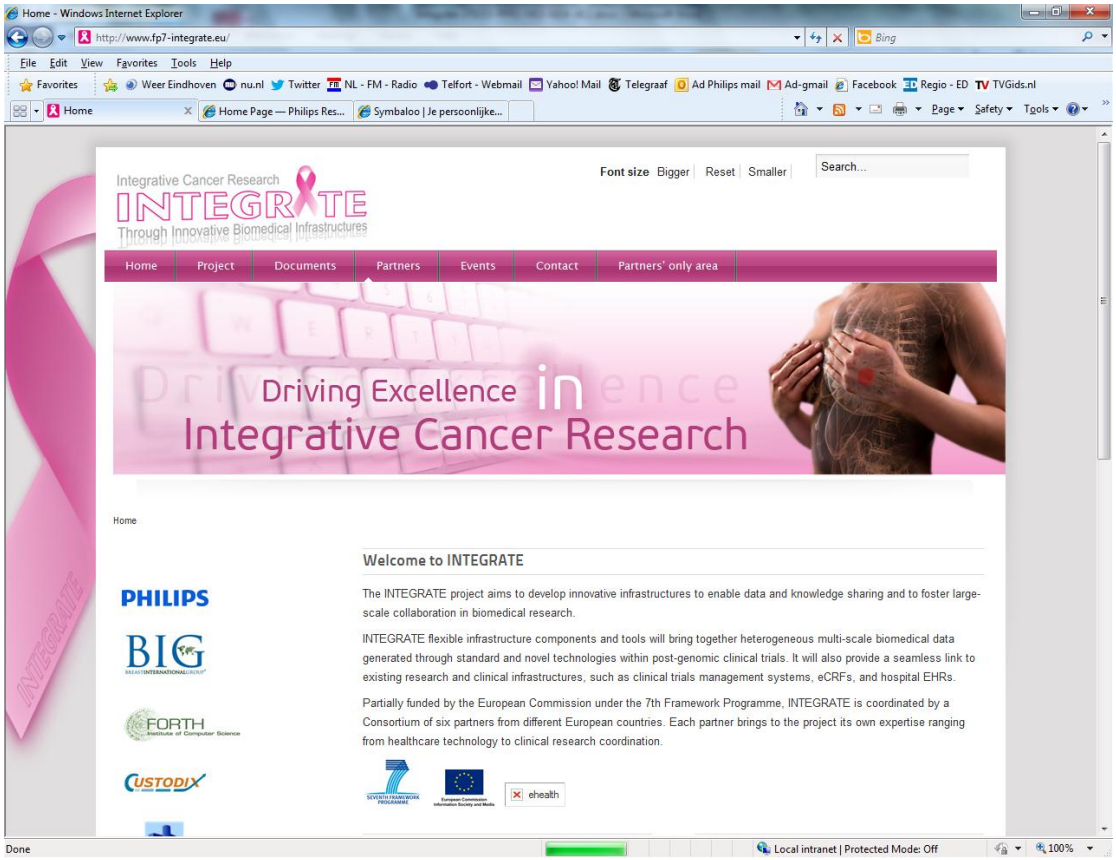
- We have reached out to other projects in the area, participating in the event of the VPH NoE with presentations and demonstrations. Additionally, as recommended during the review meeting we have organized an alignment meeting with the P_Medicine project. Together we have agreed on close collaboration and sharing of results. A common event will be planned.
- The project participated to the convergence events on interoperability:
  - Convergence round table, Basel, November 2012 – organized by EuroRec
  - Convergence workshop, Brussels, March 2013 – organized by the EC
- The project and the first demonstrators were also presented in the consortium meeting of the FP7 EURECA project and further close collaboration was agreed. Clinical partners in

EURECA expressed interest to participate in the validation of the tools developed in INTEGRATE.

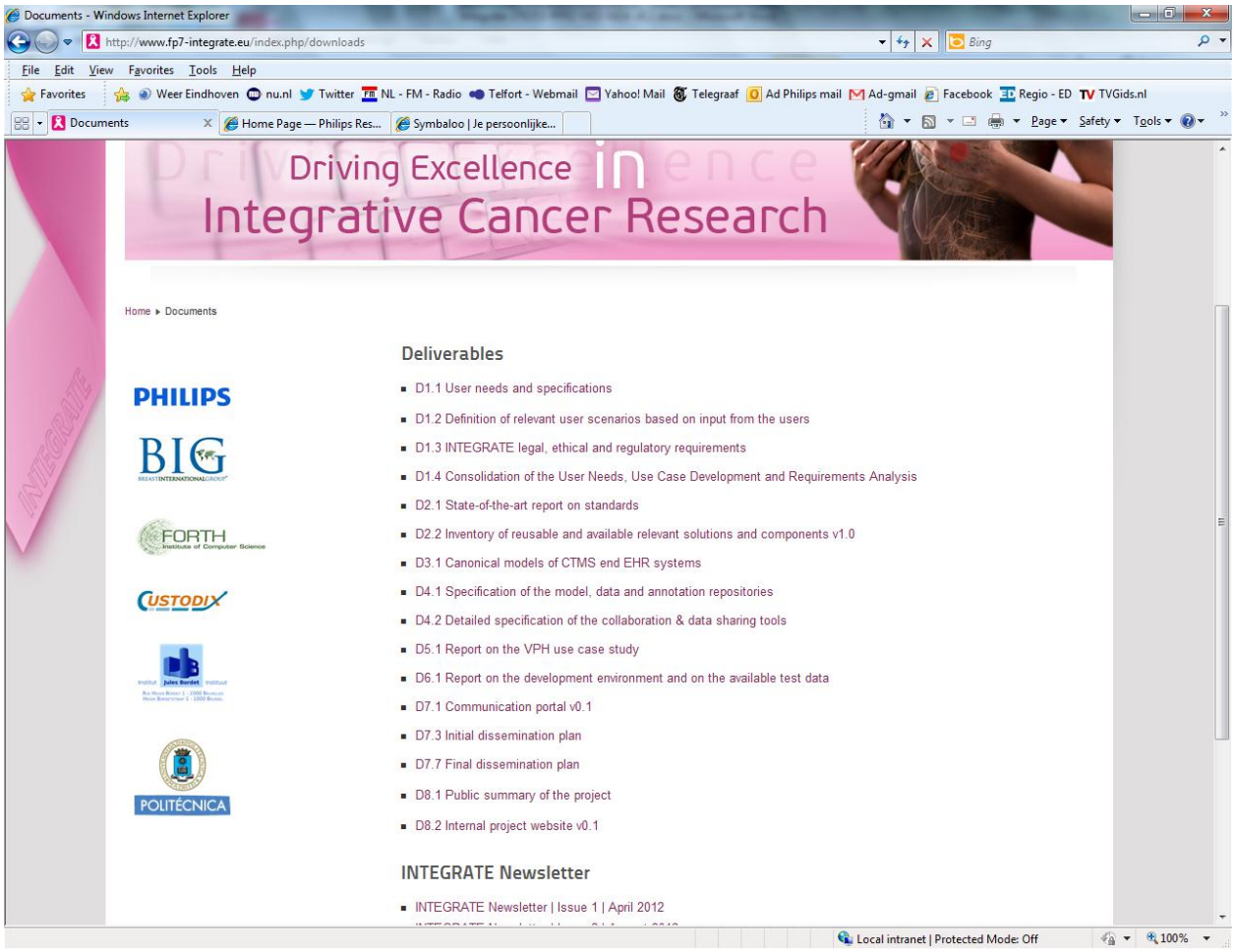
- We have discussed with several partners of the Breast International Group their participation to the validation of our results in year 3. Several partners will be selected and the amendment for budget allocation will be completed before the second INTEGRATE review.
- We have started the planning of the INTEGRATE event part of a large European oncology event in 2013.

### 4.3.4 Project web-site

This is a screenshot of the public website of the Integrate project, which can be found at the following link: http://www.fp7-integrate.eu/




Referring to the webpage where all our public documents are placed: http://www.fp7-integrate.eu/index.php/downloads


Documents - Windows Internet Explorer
http://www.fp7-integrate.eu/index.php/downloads
Driving Excellence in Integrative Cancer Research
Home ▸ Documents
Deliverables
D1.1 User needs and specifications
D1.2 Definition of relevant user scenarios based on input from the users
D1.3 INTEGRATE legal, ethical and regulatory requirements
D1.4 Consolidation of the User Needs, Use Case Development and Requirements Analysis
D2.1 State-of-the-art report on standards
D2.2 Inventory of reusable and available relevant solutions and components v1.0
D3.1 Canonical models of CTMS end EHR systems
D4.1 Specification of the model, data and annotation repositories
D4.2 Detailed specification of the collaboration & data sharing tools
D5.1 Report on the VPH use case study
D6.1 Report on the development environment and on the available test data
D7.1 Communication portal v0.1
D7.3 Initial dissemination plan
D7.7 Final dissemination plan
D8.1 Public summary of the project
D8.2 Internal project website v0.1
INTEGRATE Newsletter
INTEGRATE Newsletter | Issue 1 | April 2012
Local intranet | Protected Mode: Off
100%

# 5 Deliverables and milestones tables

**TABLE 1. DELIVERABLES[5]**

| Del. no. | Deliverable name | WP no. | Lead participant | Nature | Dissemination level | Due delivery date from Annex I | Delivered Yes/No | Actual / Forecast delivery date | Comments |
|---|---|---|---|---|---|---|---|---|---|
| 6.2 | Evaluation and validation procedures for the INTEGRATE environment | 6 | UPM | R | PU | 15 | Yes | 16 | |
| 3.2 | Initial proposal for the Core Dataset | 3 | Philips | O | RE | 16 | Yes | 19 | |
| 6.3 | Specifications of the evaluation and validation scenarios for the different components | 6 | Forth | R | PU | 18 | Yes | 22 | |
| 7.6 | Project newsletter | 7 | BIG | R | PU | 18 | Yes | 20 | |
| 8.5 | Interim Progress Report #2 | 8 | Philips | R | CO | 19 | Yes | 20 | |
| 3.3 | Solution providing uniform access to relevant external sources | 3 | Forth | P | PU | 20 | Yes | 21 | |
| 3.4 | Initial proposal for the mapping formalism and mappings | 3 | UPM | R | RE | 20 | | 21 | |
| 5.2 | Report on methodology and genetic and imaging biomarkers | 5 | IJB | R | PU | 20 | Yes | 23 | |
| 2.5 | Integration guidelines | 2 | Philips | R | PU | 21 | Yes | 25 | |
| 4.3 | Initial specification of Privacy Enhancing Services | 4 | Custodix | R | RE | 21 | Yes | 25 | Merged with 2.5 |
| 1.5 | Consolidation of the user needs, use-case development and requirements analysis (final) | 1 | Philips | R | PU | 24 | Yes | 26 | |
| 2.6 | System architecture refinement, security | 2 | Custodix | R | PU | 24 | Yes | 26 | |

**4 PU** = Public
**PP** = Restricted to other programme participants (including the Commission Services).
**RE** = Restricted to a group specified by the consortium (including the Commission Services).
**CO** = Confidential, only for members of the consortium (including the Commission Services).
**Make sure that you are using the correct following label when your project has classified deliverables.**
**EU restricted** = Classified with the mention of the classification level restricted "EU Restricted"
**EU confidential** = Classified with the mention of the classification level confidential " EU Confidential "
**EU secret** = Classified with the mention of the classification level secret "EU Secret "

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | framework and implementation status | | | | | | | | |
| 3.5 | Initial prototype of the semantic interoperability layer | 3 | Philips | P | RE | 24 | Yes | 26 | |
| 4.4 | Initial version of the virtual collaboratory and its services | 4 | Forth | P | RE | 24 | Yes | 26 | |
| 6.4 | Report on preparation of the deployment environment for the clinical pilots | 6 | IJB | R | PU | 24 | Yes | 26 | |
| 7.7 | Final dissemination plan | 7 | BIG | R | PU | 24 | Yes | 26 | |
| 7.8 | Project newsletter | 7 | BIG | R | PU | 24 | Yes | 25 | |

Milestones

Please complete this table if milestones are specified in Annex I of the Grant Agreement.
Milestones will be assessed against the specific criteria and performance indicators as defined in Annex I.

**TABLE 2. MILESTONES**

| Milestone no. | Milestone name | Due achievement date from Annex I | Achieved Yes/No | Actual / Forecast achievement date | Comments |
|---|---|---|---|---|---|
| MS5 | Availability of the evaluation and validation procedures and scenarios | M18 | Yes | Jul | |
| MS6 | Initial prototypes of the interoperability layer, of the virtual collaborator and of the modeling | M24 | Yes | Jan | |
| | | | | | |

# PROJECT PERIODIC REPORT
# Use of Resources

**Grant Agreement number: FP7-ICT-2011-270253**

**Project acronym: INTEGRATE**

**Project title:** Driving excellence in Integrative Cancer Research through Innovative Biomedical Infrastructures

**Funding Scheme: Collaborative project**

**Date of latest version of Annex I against which the assessment will be made:**

**Periodic report:** **1st** ☐ **2nd** ■ **3rd** ☐ **4th** ☐

**Period covered:** **from 1 February 2012 to 31 January 2013**

**Name, title and organisation of the scientific representative of the project's coordinator[1]:**

**Name: Anca Bucur**

**Tel: +31 40 27 49699**

**Fax:**

**E-mail: anca.bucur@philips.com**

**Project website[2] address:** http://pothos.ics.forth.gr/integrate/

[1] Usually the contact person of the coordinator as specified in Art. 8.1. of the Grant Agreement .

[2] The home page of the website should contain the generic European flag and the FP7 logo which are available in electronic format at the Europa website (logo of the European flag: http://europa.eu/abc/symbols/emblem/index_en.htm logo of the 7th FP: http://ec.europa.eu/research/fp7/index_en.cfm?pg=logos). The area of activity of the project should also be mentioned.

# Integrate

**PMR2, effort**

Planned effort is budget

Actual is effort M13 - M24

| | | WP1 | | WP2 | | WP3 | | WP4 | | WP5 | | WP6 | | WP7 | | WP8 (MA) | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual |
| 1 | PEN | 5,00 | 2,00 | 16,00 | 5,00 | 20,00 | 6,00 | 22,00 | | 6,00 | | 11,00 | 5,50 | 4,00 | 0,50 | 12,00 | 2,30 | 96,00 | 21,30 |
| 2 | Breast International | 12,00 | 3,48 | 9,00 | 1,10 | 9,00 | 2,20 | 10,00 | 2,30 | 10,00 | 1,60 | 10,00 | 2,00 | 11,50 | 5,02 | 1,50 | 1,02 | 73,00 | 18,72 |
| 3 | FORTH | 5,00 | 4,00 | 16,00 | 13,00 | 6,00 | 5,00 | 26,00 | 25,00 | 27,00 | 25,13 | 10,00 | 8,00 | 3,00 | 2,00 | 3,00 | 0,64 | 96,00 | 82,77 |
| 4 | Custodix | 4,00 | 0,35 | 28,00 | 5,05 | 6,00 | 1,15 | 20,00 | 6,31 | 2,00 | 0,46 | 9,00 | 6,71 | 2,00 | 1,36 | 1,00 | 0,51 | 72,00 | 21,90 |
| 5 | Univ. Brussel | 19,00 | 3,45 | 0,00 | 3,11 | 7,00 | | 0,00 | | 12,00 | 1,78 | 11,00 | 1,82 | 3,50 | 0,30 | 1,50 | 0,63 | 54,00 | 11,09 |
| 6 | Univ. Madrid | 4,00 | 0,93 | 12,00 | 3,94 | 26,00 | 7,70 | 14,00 | 4,40 | 2,00 | 0,31 | 10,00 | 2,51 | 2,50 | 0,63 | 1,50 | 0,29 | 72,00 | 20,71 |
| | | | | | | | | | | | | | | | | | | | |
| | Total | 49,00 | 14,21 | 81,00 | 31,20 | 74,00 | 22,05 | 92,00 | 38,01 | 59,00 | 29,28 | 61,00 | 26,54 | 26,50 | 9,81 | 20,50 | 5,39 | 463,00 | 176,49 |

**Total effort**

Actual is effort M1 - M24

| | | WP1 | | WP2 | | WP3 | | WP4 | | WP5 | | WP6 | | WP7 | | WP8 (MA) | | Total | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual | Planned | Actual |
| 1 | PEN | 5,00 | 4,00 | 16,00 | 11,00 | 20,00 | 12,60 | 22,00 | 5,00 | 6,00 | 1,00 | 11,00 | 8,50 | 4,00 | 1,50 | 12,00 | 4,30 | 96,00 | 47,90 |
| 2 | Breast International | 12,00 | 16,78 | 9,00 | 5,25 | 9,00 | 4,00 | 10,00 | 5,30 | 10,00 | 5,30 | 10,00 | 3,60 | 11,50 | 10,52 | 1,50 | 4,02 | 73,00 | 54,77 |
| 3 | FORTH | 5,00 | 6,00 | 16,00 | 16,00 | 6,00 | 6,14 | 26,00 | 30,00 | 27,00 | 32,13 | 10,00 | 8,52 | 3,00 | 2,50 | 3,00 | 1,19 | 96,00 | 102,48 |
| 4 | Custodix | 4,00 | 3,86 | 28,00 | 18,65 | 6,00 | 2,27 | 20,00 | 9,08 | 2,00 | 0,46 | 9,00 | 6,71 | 2,00 | 1,49 | 1,00 | 0,66 | 72,00 | 43,18 |
| 5 | Univ. Brussel | 19,00 | 14,25 | 0,00 | 3,11 | 7,00 | 8,10 | 0,00 | 0,00 | 12,00 | 3,08 | 11,00 | 3,02 | 3,50 | 0,70 | 1,50 | 0,63 | 54,00 | 32,89 |
| 6 | Univ. Madrid | 4,00 | 2,31 | 12,00 | 8,93 | 26,00 | 17,62 | 14,00 | 7,19 | 2,00 | 0,43 | 10,00 | 4,91 | 2,50 | 1,58 | 1,50 | 0,84 | 72,00 | 43,81 |
| | | | | | | | | | | | | | | | | | | | |
| | Total | 49,00 | 47,20 | 81,00 | 62,94 | 74,00 | 50,73 | 92,00 | 56,57 | 59,00 | 42,40 | 61,00 | 35,26 | 26,50 | 18,29 | 20,50 | 11,64 | 463,00 | 325,03 |

# Use of Resources

Period 2 (13 - 24)
(01-02-2012 - 31-01-2013)

| Project Number | 270253 | Project Acronym | INTEGRATE |
|---|---|---|---|

**Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 1 for the period.**

**PHILIPS ELECTRONICS NEDERLAND B.V.**

| Work Package | Item description | Amount in € | Explanation | Free Text |
|---|---|---|---|---|
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Personnel costs | 123,853 € | salaries of 4 researchers for 19.0 MM. | |
| WP 8 | Personnel costs | 15,874 € | salaries of 2 researchers for 2.3 MM. | |
| | Indirect costs | 269,912 € | | |
| | TOTAL COSTS | 409,639 € | | |

**Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 2 for the period.**

**BREAST INTERNATIONAL GROUP - AISBL**

| Work Package | Item description | Amount in € | Explanation | Free Text |
|---|---|---|---|---|
| WP 1 WP 3 WP 2 WP 4 WP 5 WP 6 WP 7 | Personnel costs | 135,169 € | Salaries of 8 persons including Scientific, IT, communication, Legal personnel | |
| WP 7 | Subcontracting | 1,830 € | INTEGRATE Newsletter | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Other direct cost | 1,855 € | Consortium meeting Madrid 30/09 - 05/10/12 | L. Pugliano, A. irrthum & L. Meirsman |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Other direct cost | 78 € | Technical meeting Greece 17-19/10/12 | L. Pugliano |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Other direct cost | 179 € | Consortium meeting Gent 07/02/12 | L. Meirsman, A. Irrthum & K. Saini |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Other direct cost | 1,424 € | Meeting Viena 20-24/09/12 | L. Pugliano, A. Irrthum & K. Saini |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Other direct cost | 463 € | Traning FP7 & Photos newsletter | |
| WP 8 | Personnel costs | 3,832 € | Salaries of 3 persons including financial & project management personnel | |
| | Indirect costs | 28,599 € | | |
| | TOTAL COSTS | 173,429 € | | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 3 for the period. FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Personnel costs | 154,898 € | RTD Personnel -Total P-Months 82,13 as per following Team: (1) Principal Researchers / Tsiknakis , Marias, Kafetzopoulos 6,99 P-Months (2) Researcher Sakalis Evangelos 4,68 P-months (3) Phd Technical Staff /Kondylakis, Spanakis, Giannakakis 12,25 P-Months (4) Technical Staff / Sfakianakis, Kritsotakis, Karatzanis, Genitsaridis, Maniadi , Zacharioudakis, Manikis, Pediaditis, Heliopoulos, Roniotis, Pavlidis 58,21 P-Months | RTD Personnel |
| WP 4 WP 5 | Other direct cost | 1,043 € | (1) Manikis Belgium 06.02-13.02.12 / INTEGRATE Consortium Meeting 7-8/2/2012 | RTD Travel Costs |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Other direct cost | 1,141 € | (2) Marias Belgium 06.02-09.02.12 INTEGRATE Consortium Meeting 7-8/2/2012 | RTD Travel Costs |
| WP 4 WP 5 | Other direct cost | 998 € | (3) Karatzanis Brussels Preparation Review Meeting INTEGRATE 4/5/2012 | RTD Travel Costs |
| WP 4 WP 5 | Other direct cost | 1,160 € | (4) Manikis Brussels Preparation Review Meeting INTEGRATE 4/5/2012 | RTD Travel Costs |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Other direct cost | 1,082 € | (5) Marias Brussels Preparation Review Meeting INTEGRATE 4/5/2012 | RTD Travel Costs |
| WP 4 | Other direct cost | 285 € | (6) Marias Barcelona 07.05-12.05.12 | RTD Travel Costs |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 3 for the period. FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| | | | Participation at Cancer Challenge of SG3 VPH Group | |
| WP 4 WP 5 | Other direct cost | 1,120 € | (7) Karatzanis Brussels 25.06-28.06.12 Face to Face Consortium Meeting INTEGRATE | RTD Travel Costs |
| WP 4 WP 5 | Other direct cost | 1,184 € | (8) Manikis Brussels Document: 400/22.06-02.07.12 Brussels Face to Face Consortium Meeting INTEGRATE | RTD Travel Costs |
| WP 4 WP 5 | Other direct cost | 1,066 € | (9) Manikis Madrid INTEGRATE Consortium Meeting 1-2/10/2012 | RTD Travel Costs |
| WP 4 WP 5 | Other direct cost | 1,089 € | (10) Eliopoulos Madrid INTEGRATE Consortium Meeting 1-2/10/2012 | RTD Travel Costs |
| WP 5 | Other direct cost | 1,027 € | (11) Eliopoulos Madrid Document: 793/07.12-13.12.12 | RTD Travel Costs |
| WP 5 | Other direct cost | 1,001 € | (12) Kondylakis Larnaca Cyprus 11.11-13.11.12 Participation at IEEE 12th International Conference on Bioengineering | RTD Travel Costs |
| WP 5 | Other direct cost | 1,054 € | (13) Manikis Madrid 08.12-13.12.12 Participation at the F2F Technical Meeting INTEGRATE | RTD Travel Costs |
| WP 5 | Other direct cost | 820 € | (14) Kafetzopoulos Turkey Instambull 23.08-01.09.12 Conference ITU "6th Molecular Biology and Genetics students Conference" | RTD Travel Costs |
| WP 4 WP 5 | Other direct cost | 366 € | Meeting Costs for Technical Meeting in Heraklion 18/10/2012 | RTD Other |
| WP 4 WP 5 | Other direct cost | 112 € | | RTD Other |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 3 for the period. FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| | | | Meeting Costs for Technical Meeting in Heraklion 18/10/2012 | |
| WP 5 | Other direct cost | 154 € | Various consumables for WP5 | RTD Other |
| WP 8 | Personnel costs | 3,296 € | Principal Researcher Prof. Tsiknakis for Management occupation 0,64 P-Months | Management Personnel |
| | Indirect costs | 137,628 € | | |
| | TOTAL COSTS | 310,524 € | | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 4 for the period. CUSTODIX NV | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 WP 8 | Other direct cost | 128 € | travel | Review rehearsal meeting, Brussels, BE, 2-3/5/2012 |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 WP 8 | Other direct cost | 286 € | travel | Review meeting, Brussels, BE, 4/5/2012 |
| WP 7 | Other direct cost | 189 € | meeting organisation | Tool demonstration meeting Janssen, Sint-Martens-Latem, 29/5/2012 |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 WP 8 | Other direct cost | 206 € | travel | Consortium meeting, Brussels, BE, 26-27/6/2012 |
| WP 2 WP 6 WP 3 WP 4 | Other direct cost | 7 € | travel | Technical meeting Cohort Selection, Eindhoven, NL, 5/7/2012 |
| WP 7 | Other direct cost | 61 € | meeting organisation | Tool Demonstration meeting MSD, Sint-Martens-Latem, BE, 9/7/2012 |
| WP 2 WP 3 WP 4 WP 6 | Other direct cost | 29 € | meeting organisation | Technical Meeting Cohort Selection, Sint-Martens-Latem, BE, 20-21/8/2012 |
| WP 1 WP 2 WP 4 WP 3 WP 5 WP 6 WP 7 WP 8 | Other direct cost | 560 € | travel | Consortium meeting, Madrid, ES, 1-2/10/2012 |
| WP 2 WP 3 WP 4 WP 6 | Other direct cost | 1,127 € | travel | Technical meeting Demonstrators, |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 4 for the period. CUSTODIX NV | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| | | | | Madrid, ES, 11-12/12/2012 |
| WP 6 WP 3 WP 2 | Other direct cost | 56 € | meeting organisation | Architecture / Demonstrator meeting, Sint-Martens-Latem, BE, 6/2/2012 |
| WP 3 WP 2 WP 4 WP 6 WP 7 | Personnel costs | 50,555 € | Salary Brecht Claerhout | |
| WP 2 | Personnel costs | 258 € | Salary David Voets | |
| WP 2 WP 4 | Personnel costs | 4,239 € | Salary Elias Neri | |
| WP 2 WP 4 | Personnel costs | 9,656 € | Salary Jelle Vandendriessche | |
| WP 2 WP 4 WP 6 WP 7 | Personnel costs | 14,368 € | Salary Louis Schilders | |
| WP 1 WP 4 WP 6 WP 7 WP 3 WP 2 | Personnel costs | 34,099 € | Salary Kistof De Schepper | |
| WP 4 WP 6 | Personnel costs | 14,546 € | Salary Wouter Dhaeze | |
| WP 4 WP 6 | Personnel costs | 12,266 € | Salary Ken Audenaert | |
| WP 1 WP 4 WP 2 | Personnel costs | 3,587 € | Salary Rolando Quinones | |
| WP 8 | Other direct cost | 1,780 € | Meeting Organisation | Consortium Meeting, Ghent, BE |
| WP 8 | Personnel costs | 4,765 € | Salary Brecht Claerhout | |
| WP 8 | Personnel costs | 430 € | Salary Kristof De Schepper | |
| | Indirect costs | 87,416 € | | |
| | TOTAL COSTS | 240,614 € | | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 5 for the period. Institut Jules Bordet | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| WP 1 WP 3 WP 5 WP 6 WP 7 | Personnel costs | 66,163 € | Salary costs of IT specialists and 1 PhD | |
| WP 1 WP 3 WP 5 WP 6 WP 7 | Other direct cost | 2,827 € | Integrate Consortium Meeting Brussels 26 and 27 June 2012 | |
| WP 8 | Personnel costs | 5,742 € | Salary cost administrative manager | |
| | Indirect costs | 44,839 € | | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 5 for the period. Institut Jules Bordet | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| | TOTAL COSTS | 119,571 € | | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 6 for the period. UNIVERSIDAD POLITECNICA DE MADRID | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Personnel costs | 69,874 € | TOTAL Staff effort RTD: 20,43 person-months. Prof. Victor Maojo (0,95 PM): Principal Investigator. Coordinator of UPM´s activities within the project. Coordinator of UPM´s publications within the project framework. Review of deliverables. Dr. Jose Crespo (3,8 PM): Senior investigator. Collaboration in WP2, WP4 and WP6 tasks. Review of deliverables. Dr. Jose María Barrreiro (1,06 PM): Senior investigator. Collaboration in WP2 and WP4 tasks. Review of deliverables. Dr. Andrés Silva (2,66 PM): Senior investigator. Collaboration in WP3 and WP6 tasks. Dr. David Perez (4,88 PM): Senior investigator. Participation in WP1-WP7 tasks. Designer and developer. Sergio Paraíso (4,9 PM): Junior Researcher. Participation in WP1-WP7 tasks. Designer and Developer. MSc. Diana de la Iglesia (2,17 PM): Junior Researcher (postgraduate student). | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 6 for the period. UNIVERSIDAD POLITECNICA DE MADRID | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| | | | Collaboration in WP2, WP4 and WP6 tasks. Review of deliverables. | |
| WP 1 WP 5 WP 4 WP 3 WP 2 WP 6 | Other direct cost | 1,479 € | Travel, subsistence and accomodation expenses: Travel to Ghent for the 3rd Consortium meeting, 6-8 February 2012, David Pérez del Rey, Alejandro García Ruíz | |
| WP 6 WP 5 WP 4 WP 3 WP 2 WP 1 | Other direct cost | 2,845 € | Travel, subsistence and accomodation expenses: Travel to Brussels for the 1st Project Review, 1-4 May 2012, Raúl Alonso, David Pérez del Rey | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 1,896 € | Travel, subsistence and accomodation expenses: Travel to Brussels for a project workshop, 25-27 June 2012, David Pérez del Rey, Sergio Paraíso | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 1,823 € | Travel, subsistence and accomodation expenses:Travel to Ghent for Technical Meeting, 19-21 August 2012, David Pérez del Rey, Raúl Alonso | |
| WP 6 WP 5 WP 4 WP 3 WP 2 WP 1 | Other direct cost | 849 € | Travel, subsistence and accomodation expenses:Travel to Crete for a Technical Meeting, 16-19 October 2012, David Pérez del Rey | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 494 € | Durable equipment: Depreciation costs (12 months) of two personal computers for programming tasks within WP1-WP6. | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 595 € | Congress INSTCC, Biostec 2013 Early Registration, 18 | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 6 for the period. UNIVERSIDAD POLITECNICA DE MADRID | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| | | | December 2012, David Perez del Rey | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 152 € | Coffee services during Brussels Consortium Meeting, 2-3 May 2012 | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 723 € | Coffee services and consortium dinner during Madrid Consortium Meeting, 1-3 october 2012 | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 522 € | Consortium dinners during Madrid Consortium Meeting, 11-12 December 2012 | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 8 | Other direct cost | 50 € | Express mail services to send signed Form C to the coordinator | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 10 € | Parking during consortium meeting | |
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 | Other direct cost | 242 € | Coffee services during Madrid Consortium Meeting, 14 January 2013 | |
| WP 8 | Personnel costs | 974 € | MSc. Diana de la Iglesia (0,29 PM): Junior Researcher (postgraduate student). UPM´s administrative and financial management (periodic reports, financial statements) | |
| | Indirect costs | 49,395 € | | |
| | TOTAL COSTS | 131,923 € | | |

# Use of Resources

Period 1 (1 - 12)
(01-02-2011 - 31-01-2012)

| Project Number | 270253 | Project Acronym | INTEGRATE |
|---|---|---|---|

**Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 1 for the period.**

**PHILIPS ELECTRONICS NEDERLAND B.V.**

| Work Package | Item description | Amount in € | Explanation | Free Text |
|---|---|---|---|---|
| WP 1 WP 2 WP 3 WP 4 WP 5 WP 6 WP 7 | Personnel costs | -1,115 € | recalculation of pre calculated tariffs into post calculated tariffs. | |
| WP 8 | Personnel costs | 11 € | recalculation of pre calculated tariffs into post calculated tariffs. | |
| | Indirect costs | 2,555 € | | |
| | TOTAL COSTS | 1,451 € | | |

**Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 2 for the period.**

**BREAST INTERNATIONAL GROUP - AISBL**

| Work Package | Item description | Amount in € | Explanation | Free Text |
|---|---|---|---|---|
| | Indirect costs | 0 € | | |
| | TOTAL COSTS | 0 € | | |

**Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 3 for the period.**

**FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS**

| Work Package | Item description | Amount in € | Explanation | Free Text |
|---|---|---|---|---|
| WP 5 | Personnel costs | 116 € | Payroll Settlement of Researcher Sakalis and Principal Researcher D. Kafetzopoulos P-month 0.027 | RTD Personnel /Payroll settlement |
| | Indirect costs | -3,576 € | | |
| | TOTAL COSTS | -3,460 € | | |

**Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 4 for the period.**

**CUSTODIX NV**

| Work Package | Item description | Amount in € | Explanation | Free Text |
|---|---|---|---|---|
| WP 1 WP 2 WP 4 WP 5 WP 6 WP 7 WP 8 WP 3 | Personnel costs | 6,024 € | Difference due to final calculation of salary | |
| | Indirect costs | -30 € | | |
| | TOTAL COSTS | 5,994 € | | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 5 for the period. Institut Jules Bordet | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| | Indirect costs | 0 € | | |
| | TOTAL COSTS | 0 € | | |

| Table 3.1 Personnel, subcontracting and other Major cost items for beneficiary 6 for the period. UNIVERSIDAD POLITECNICA DE MADRID | | | | |
|---|---|---|---|---|
| **Work Package** | **Item description** | **Amount in €** | **Explanation** | **Free Text** |
| | Indirect costs | 0 € | | |
| | TOTAL COSTS | 0 € | | |