SEVENTH FRAMEWORK PROGRAMME

GRANT AGREEMENT No 288048

Enabling information re-Use by linking clinical REsearch and CAre

Collaborative Project

The **European Union** (the "*Union*"), represented by the **European Commission** (the "*Commission*"),

of the **one part**,

and PHILIPS ELECTRONICS NEDERLAND B.V., established in Boschdijk 525, 5621JG EINDHOVEN - THE NETHERLANDS, represented by Mr Paul PUT, Head of Research NL - UK & Division Head and/or Mr Henk VAN HOUTEN, General Manager Philips Research, or their authorised representative, the *beneficiary* acting as *coordinator* of the *consortium* (the *"coordinator"*), (*"beneficiary n° 1"*),

of the **other part**

HAVE AGREED to the following terms and conditions including those in the following annexes, which form an integral part of this *grant agreement* (the "*grant agreement*").

Annex I	- Description of Work
Annex II	- General conditions
Annex III	- Non applicable
Annex IV	- Form A – Accession of *beneficiaries* to the *grant agreement*
Annex V	- Form B – Request for accession of a new *beneficiary* to the *grant agreement*
Annex VI	- Form C – Financial statement per funding scheme
Annex VII	- Form D – Terms of reference for the certificate on the financial statements and Form E - Terms of reference for the certificate on the methodology

Article 1 – Accession to the *grant agreement* of the other *beneficiaries*

1. The *coordinator* shall endeavour to ensure that each legal entity identified below accedes to this *grant agreement* as a *beneficiary,* assuming the rights and obligations established by the *grant agreement* with effect from the date on which the *grant agreement* enters into force, by signing Form A in three originals, countersigned by the *coordinator*.

- **FOUNDATION FOR RESEARCH AND TECHNOLOGY HELLAS** established in N PLASTIRA STR 100, 70013 HERAKLION - GREECE, represented by Mr Vasilios DOUGALIS, Chairman of the Board of Directors, or his authorised representative (*"beneficiary n° 2"*),

- **Institut Jules Bordet** established in Héger-Bordet 1, 1000 Brussels - BELGIUM, represented by Ms Dominique DE VALERIOLA, General Medical Director and/or Mr Olivier VAN TIGGELEN, General Director, or their authorised representative (*"beneficiary n° 3"*),

- **CUSTODIX NV** established in KORTRIJKSESTEENWEG 214 b3, 9830 SINT-MARTENS-LATEM - BELGIUM, represented by Mr Louis SCHILDERS, CEO, or his authorised representative (*"beneficiary n° 4"*),

- **UNIVERSITAET DES SAARLANDES** established in Campus 15, 66123 SAARBRUECKEN - GERMANY, represented by Mr Volker LINNEWEBER, University

President and/or Mr Matthias HANNIG, Vice President for Research and Technology Transfer, or their authorised representative (*"beneficiary n° 5"*),

- **THE CHANCELLOR, MASTERS AND SCHOLARS OF THE UNIVERSITY OF OXFORD** established in Wellington Square, OX1 2JD OXFORD - UNITED KINGDOM, represented by Mr Stephen CONWAY, Associate Director and/or Mr Phil CLARE, Associate Director, or their authorised representative (*"beneficiary n° 6"*),

- **FRAUNHOFER-GESELLSCHAFT ZUR FOERDERUNG DER ANGEWANDTEN FORSCHUNG E.V** established in Hansastrasse 27C, 80686 MUNCHEN - GERMANY, represented by Ms Sabine MAYER, EU Projects Officer and/or Ms Elke RUPP, EU Projects Officer, or their authorised representative (*"beneficiary n° 7"*),

- **VERENIGING VOOR CHRISTELIJK HOGER ONDERWIJS WETENSCHAPPELIJK ONDERZOEK EN PATIENTENZORG** established in De Boelelaan 1105, 1081 HV AMSTERDAM - THE NETHERLANDS, represented by Ms Dirkje SCHINKELSHOEK, Managing Director Faculty of Sciences, or her authorised representative (*"beneficiary n° 8"*),

- **BREAST INTERNATIONAL GROUP - AISBL** established in RUE HEGER BORDET 1, 1000 BRUXELLES - BELGIUM, represented by Ms MARTINE PICCART, CHAIR and/or Mr ARON GOLDHIRSCH, VICE CHAIR, or their authorised representative (*"beneficiary n° 9"*),

- **GOTTFRIED WILHELM LEIBNIZ UNIVERSITAET HANNOVER** established in Welfengarten 1, 30167 HANNOVER - GERMANY, represented by Mr Henning HOWIND, Department Head of Finances and/or Ms Silke MEYER, Assistant Department Head of Finances, or their authorised representative (*"beneficiary n° 10"*),

- **XEROX SAS** established in Avenue du President Wilson, Immeuble Le Jade 253/255, 93200 LA PLAINE SAINT-DENIS CEDEX - FRANCE, represented by Ms Monica BELTRAMETTI, VP Director XRCE, or her authorised representative (*"beneficiary n° 11"*),

- **UNIVERSIDAD POLITECNICA DE MADRID** established in Calle Ramiro de Maeztu 7, 28040 MADRID - SPAIN, represented by Mr Gonzalo LEÓN, Vice-rector for research, or his authorised representative (*"beneficiary n° 12"*),

- **STICHTING MAASTRICHT RADIATION ONCOLOGY MAASTRO CLINIC** established in Dr. Tanslaan 12, 6229 ET Maastricht - THE NETHERLANDS, represented by Mr Philippe LAMBIN, Board of directors , or his authorised representative (*"beneficiary n° 13"*),

- **ecancermedicalscience AG** established in c/o Bruno Wanner Management, Gotthardstrasse 20, 6300 Zug - SWITZERLAND, represented by Mr Gordon MCVIE, Chairman and/or Ms Susi BURKE, CEO, or their authorised representative (*"beneficiary n° 14"*),

- **EUROPEAN INSTITUTE FOR HEALTH RECORDS** established in RUE DU MARECHAL DE LATTRE DE TASSIGNY 8, 59000 LILLE - FRANCE, represented by Mr Georges DE MOOR, President, or his authorised representative (*"beneficiary n° 15"*),

- **STONEROOS B.V.** established in SUMATRALAAN 45, 1217 GP HILVERSUM - THE NETHERLANDS, represented by Ms Annelies KAPTEIN, CEO, or her authorised representative (*"beneficiary n° 16"*),

- **GBG FORSCHUNGS GMBH** established in MARTIN BEHAIM STRASSE 12, 63263 NEU-ISENBURG - GERMANY, represented by Mr Gunter VON MINCKWITZ, CEO and/or

Ms Sibylle LOIBL, Head Medicine and Research, or their authorised representative (*"beneficiary n° 17"*),

- **NATIONAL RESEARCH COUNCIL CANADA** established in Montreal Road 1200, K1A 0R6 Ottawa, ON - CANADA, represented by Mr Andrew REDDICK, Director General (acting), or his authorised representative (*"beneficiary n° 18"*),

All the *beneficiaries* together form the *consortium (the "consortium").*

2. The *coordinator* shall send to the *Commission* one duly completed and signed Form A per *beneficiary* at the latest 45 calendar days after the entry into force of the *grant agreement*. The two remaining signed originals shall be kept, one by the *coordinator* to be made available for consultation at the request of any *beneficiary*, and the other by the *beneficiary* concerned.

3. Should any legal entity identified above, fail or refuse to accede to the *grant agreement* within the deadline established in the previous paragraph, the *Commission* is no longer bound by its offer to the said legal entity(ies). The *consortium* may propose to the *Commission*, within the time-limit to be fixed by the latter, appropriate solutions to ensure the implementation of the *project.* The procedure established in Annex II for amendments to this *grant agreement* will apply.

4. The *beneficiaries* are deemed to have concluded a *consortium agreement* (the "*consortium agreement*") regarding the internal organisation of the *consortium.*

Article 2 – Scope

The *Union* has decided to grant a financial contribution for the implementation of the *project* as specified in Annex I, called **"Enabling information re-Use by linking clinical REsearch and CAre *(EURECA)*"** (the "*project*") within the framework of the Specific Programme **"Cooperation"** and under the conditions laid down in this *grant agreement.*

Article 3 – Duration and *start date* of the *project*

The duration of the *project* shall be **42** months from **01 February 2012** (hereinafter referred to as the "*start date*").

Article 4 – Reporting periods and language of reports

The *project* is divided into reporting periods of the following duration:

- **P1**: from month **1** to month **12**
- **P2**: from month **13** to month **24**
- **Final**: from month **25** to the last month of the *project*

Any report and deliverable, when appropriate, required by this *grant agreement* shall be in **English.**

Article 5 – Maximum financial contribution of the *Union*

1. The maximum financial contribution of the *Union* to the *project* shall be **EUR 9,651,000 (NINE MILLION SIX HUNDRED FIFTY-ONE THOUSAND *EURO*)**. The actual financial contribution of the *Union* shall be calculated in accordance with the provisions of this *grant agreement.*

2. Details of the financial contribution of the *Union* are contained in Annex I to this *grant agreement* which includes:

- a table of the estimated breakdown of budget and financial contribution of the *Union* per activity to be carried out by each of the *beneficiaries* under the *project. Beneficiaries* are allowed to transfer budget between different activities and between themselves in so far as the work is carried out as foreseen in Annex I.

3. The bank account of the *coordinator* to which all payments of the financial contribution of the *Union* shall be made is:

Name of account holder:	Philips Electronics Nederland B.V./Research Lab. F&A
Name of bank:	THE ROYAL BANK OF SCOTLAND
Account reference:	NL44RBOS0532406338

Article 6 – *Pre-financing*

A *pre-financing* of **EUR 5,147,200 (FIVE MILLION ONE HUNDRED FORTY-SEVEN THOUSAND TWO HUNDRED *EURO*)** shall be paid to the *coordinator* within 45 days following the date of entry into force of this *grant agreement*. The *coordinator* shall distribute the *pre-financing* only to the *beneficiaries* who have acceded to the *grant agreement* and after the minimum number of *beneficiaries* required by the *Rules for Participation* as detailed in the call for proposals to which the *project* is related, have acceded to the *grant agreement*.

Beneficiaries hereby agree that the amount of **EUR 482,550 (FOUR HUNDRED EIGHTY-TWO THOUSAND FIVE HUNDRED FIFTY *EURO*)**, corresponding to the *beneficiaries*' contribution to the Guarantee Fund referred to in Article II.20 and representing 5% of the maximum financial contribution of the *Union* referred to in Article 5.1, is transferred in their name by the *Commission* from the *pre-financing* into the Guarantee Fund. However, *beneficiaries* are deemed to have received the full *pre-financing* referred to in the first indent and will have to justify it in accordance with the *grant agreement*.

Article 7 – Special clauses

The following special clauses apply to this *grant agreement*:

7.1 Special clause n°6 - LATE PAYMENT OF THE *PRE-FINANCING*

Notwithstanding the provisions of Article 6, the *pre-financing* shall be paid not earlier than 45 days before the *start date* of the *project*.

7.2 Special clause n°15 - ETHICAL REVIEW

1. The *beneficiaries* shall provide the *Commission* with a written confirmation that it has received favourable opinions of the relevant ethics committees and, if applicable, the regulatory approvals of the competent national or local authorities in the country in which the research is to be carried out before beginning any *Commission* approved research requiring such opinions or approvals. The copy of the official approval from the relevant national or local ethics committees must also be provided to the *Commission*.

2. The *beneficiaries* shall ensure that, where an ethical review has been carried out by the *Commission*, the research carried out under the *project* fully complies with the following additional requirements resulting from the ethical review:

1. Prior to the commencement of each relevant WP, and where applicable, copies of ethical approvals/opinions/notifications by the competent legal local/national Ethics Bodies/administrations must be submitted to the European *Commission* and reported as a deliverable.

2. Detailed information must be provided on the procedures that will be used for the recruitment of participants (e.g. number of participants, inclusion/exclusion criteria, direct/indirect incentives for participation, the risks and benefits for the participants etc) and the nature of the material that will be collected (e.g. sensitive or personal data, etc). It must be explicitly stated if children or adults unable to give informed consent will be involved and, if so, full justification for their participation must be provided.

3. Prior to the start of the *project*, detailed information must be provided to the European *Commission* on the informed consent procedures that will be implemented. Copies of examples/templates of Informed Consent Forms and Information Sheets must be included. Applicants must also confirm that they will provide material to potential participants in language understandable to them, and that proper translation of consent forms and information sheets will be made available to them.

4. The proposed Ethics Board must include independent, external members with relevant experience in ethics. A report by the Ethics Board must be submitted to the *Commission* with the Periodic Reports. The first report must include an in depth analysis of the ethical and legal framework of the *project* which can be used as a basis for an ethical follow up audit.

5. Applicants must provide a detailed description of security measures that will be implemented to prevent improper use, improper data disclosure scenarios and 'mission creep' (i.e.: unforeseen usage of data by any third party). It is required that the potential "unforeseen usage" implications of this *project* be examined and reported to the European *Commission*.

6. Applicants must provide detailed information on privacy/confidentiality and the procedures that will be implemented for data collection, storage, access, sharing policies especially when third party countries are concerned, protection, retention and destruction. Confirmation that third party countries will comply with national and EU legislation should also be included. A procedure must be implemented by the applicants in order to tackle all processed data that might fall under Article 8 of the Data Protection Directive.

7. In compliance with Directive 95/46/EC and with article 29 working group 8/2010 opinion, a data controller dedicated to the *project* must be designated. Applicants need to specify how they intend to manage potential conflicts of interest. More specifically, applicants need to document how they will guarantee autonomy towards the commercial third party behind Custo

7.3 Special clause n°16 - CLINICAL RESEARCH

1. The *beneficiaries* shall provide the *Commission* with a statement confirming that it has received favourable opinions of the relevant ethics committees and, if applicable, the regulatory approval of the competent national authorities in the country concerned before beginning any biomedical research involving human beings.

2. The *Commission* shall never be considered as a sponsor for clinical trials in the sense of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the

approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

Annex I shall indicate the name(s) of any such sponsor(s).

For trials not covered by Directive 2001/20/EC, Annex I shall indicate the name of the person or organisation that is responsible for the initiation, co-ordination and monitoring of the trial.

Article 8 – Communication

1. Any communication or request concerning the *grant agreement* shall identify the *grant agreement* number, the nature and details of the request or communication and be submitted to the following addresses:

For the *Commission*: European Commission
Information Society and Media Directorate-General
B-1049 Brussels
Belgium

For the *coordinator*: Mr. Patrick Keur
High Tech Campus 34
5656AE Eindhoven
The Netherlands

2. For information or documents to be transferred by electronic means, the following addresses shall be used:

For the *Commission*: INFSO-ICT-288048@EC.EUROPA.EU

For the *coordinator*: patrick.keur@philips.com

3. In case of refusal of the notification or absence of the recipient, the *beneficiary* or the *consortium,* as the case may be, is deemed to have been notified on the date of the latest delivery, if notification to the *coordinator* has been sent to one of the addresses mentioned in paragraphs 1 and 2 and to their legal representative. Other *beneficiaries* are deemed to have been notified if notification has been sent to the address mentioned in Article 1.1.

4. Any communication or request relating to the processing of personal data (Article II.13) shall be submitted, using the address(es) for the *Commission* identified in paragraphs 1 and 2, to the Controller responsible for the processing: Head of *IST Operations* Unit.

Article 9 – Applicable law and competent court

The financial contribution of the *Union* is a contribution from the *Union* research budget with the aim to implement the 7th Research Framework Programme (FP7) and it is incumbent on the *Commission* to execute FP7. Accordingly, this *grant agreement* shall be governed by the terms of this *grant agreement,* the European Community and European Union acts related to FP7, the Financial Regulation applicable to the general budget and its implementing rules and other European Community and European Union law and, on a subsidiary basis, by the law of Belgium.

Furthermore, the *beneficiary* is aware, and agrees, that the *Commission* may take a decision to impose pecuniary obligations, which shall be enforceable in accordance with Article 299 of the Treaty on the

Functioning of the European Union and Articles 164 and 192 of the Treaty establishing the European Atomic Energy Community.

Notwithstanding the *Commission*'s right to directly adopt the recovery decisions referred to in the previous paragraph, the General Court, or on appeal, the Court of Justice of the European Union, shall have sole jurisdiction to hear any dispute between the *Union* and any *beneficiary* concerning the interpretation, application or validity of this *grant agreement* and the validity of the decision mentioned in the second paragraph.

Article 10 – Application of the *grant agreement* provisions

Any provision of this part of the *grant agreement*, shall take precedence over the provisions of any of the Annexes. The provisions of Annex III shall take precedence over the provisions of Annex II, and both shall take precedence over the provisions of Annex I.

The special clauses set out in Article 7 shall take precedence over any other provisions of this *grant agreement*.

Article 11 – Entry into force of the *grant agreement*

This *grant agreement* shall enter into force after its signature by the *coordinator* and the *Commission,* on the day of the last signature.

Done in two originals in **English.**

For the *coordinator* done at:

Name of the legal entity:

Name of legal representative: Paul Put / Henk van Houten

Stamp of the organisation (if applicable):

Signature of legal representative:

Date: 19-12-2011

For the *Commission* done at Brussels:

Name of legal representative:

Signature of legal representative:

Date: