

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR RESEARCH & INNOVATION

SP1-Cooperation

Collaborative project

Small or medium-scale focused research project

FP7-HEALTH-2013-INNOVATION-1

Grant Agreement Number 603266

DISCHARGE

Diagnostic Imaging Strategies for Patients with Stable Chest Pain and
Intermediate Risk of Coronary Artery Disease: Comparative
Effectiveness Research of Existing Technologies

HEALTH-F2-2013-603266

SEVENTH FRAMEWORK PROGRAMME

GRANT AGREEMENT No 603266

PROJECT TITLE DISCHARGE

Collaborative project

Small or medium-scale focused research project

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

and CHARITE - UNIVERSITAETSMEDIZIN BERLIN, established in Chariteplatz 1, BERLIN, 10117, Germany represented by Gerrit Fleige, Financial Director and/or Karl Max Einhäupl, Chairman of the Executive Board or their authorised representative, the *beneficiary* acting as "*coordinator*" of the *consortium* (the "*coordinator*"), ("*beneficiary no. 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*.

- **MEDIZINISCHE UNIVERSITAET INNSBRUCK**, established in Christoph-Probst Platz 1, INNSBRUCK, 6020, Austria represented by Helga Fritsch, Dean and/or Werner Jaschke, Chairmen or their authorised representative ("*beneficiary no. 2*"),
- **UNIVERSITAIR ZIEKENHUIS ANTWERPEN**, established in WILRIJKSTRAAT 10, EDEGEM, 2650, Belgium represented by Johnny Van der Straeten, Managing Director and/or Erlend Van Breusegem, Financial director or their authorised representative ("*beneficiary no. 3*"),
- **FAKULTNI NEMOCNICE V MOTOLE**, established in V UVALU 84, PRAHA 5, 150 06, Czech Republic represented by Miloslav Ludvík, Director and/or Anna Šedivá, Head of Scientific Council or their authorised representative ("*beneficiary no. 4*"),

- **REGION HOVEDSTADEN**, established in KONGENS VAENGE 2, HILLEROD, 3400, Denmark represented by Jannik Hilsted, Medical Director and/or Torben Stentoft, Hospital Director or their authorised representative ("*beneficiary no. 5*"),
- **KLINIKEN DES LANDKREISES GOPPINGEN GGMBH**, established in EICHERTSTRASSE 3, GOPPINGEN, 73035, Germany represented by Wolfgang Schmid, Geschäftsführer or his authorised representative ("*beneficiary no. 6*"),
- **UNIVERSITAET LEIPZIG**, established in RITTERSTRASSE 26, LEIPZIG, 04109, Germany represented by Frank Nolden, Chancellor and/or Fritz König, Deputy Chancellor or their authorised representative ("*beneficiary no. 7*"),
- **SEMMELWEIS EGYETEM**, established in ULLOI UTCA 26, BUDAPEST, 1085, Hungary represented by Agoston SZEL, Rector and/or Iren BAUMGARTNERNE HOLLO, Head of Economic and Technical Directorate or their authorised representative ("*beneficiary no. 8*"),
- **SOUTH EASTERN HEALTH AND SOCIAL CARE TRUST NHS**, established in UPPER NEWTOWNARDS ROAD ULSTER, BELFAST, BT16 1RH, United Kingdom represented by David Hill, Associate Medical Director R&D and/or Paul Carlin, Research and Development Manager or their authorised representative ("*beneficiary no. 9*"),
- **UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN**, established in Belfield Campus, DUBLIN, 4, Ireland represented by Donal DOOLAN, Head of Financial Management and/or John KENNY, Operations Accountant or their authorised representative ("*beneficiary no. 10*"),
- **UNIVERSITA DEGLI STUDI DI CAGLIARI**, established in VIA UNIVERSITA 40, CAGLIARI, 09124, Italy represented by Giovanni Melis, Rector and/or Francesco Pigliaru, Vice-Chancellor for Scientific Research or their authorised representative ("*beneficiary no. 11*"),
- **UNIVERSITA DEGLI STUDI DI ROMA LA SAPIENZA**, established in Piazzale Aldo Moro 5, ROMA, 00185, Italy represented by Vincenzo Tombolini, Head of Department or his authorised representative ("*beneficiary no. 12*"),
- **PAULA STRADINA KLINISKA UNIVERSITATES SLIMNICA AS**, established in PILSONU IELA 13, RIGA, 1002, Latvia represented by Ruta Valtere, Chairman of the Board and/or Eva Strike, Member of the Board or their authorised representative ("*beneficiary no. 13*"),
- **LIETUVOS SVEIKATOS MOKSLU UNIVERSITETAS**, established in A MICKEVICIAUS GATVE 9, KAUNAS, 44307, Lithuania represented by Remigijus Zaliunas, Rector of LSMU or his authorised representative ("*beneficiary no. 14*"),
- **WOJEWODZKI SZPITAL SPECJALISTYCZNY WE WROCLAWIU**, established in UL. HENRYKA MICHALA KAMIENSKIEGO 73 A, WROCLAW, 51 124, Poland represented by Wojciech Witkiewicz, Director or his authorised representative ("*beneficiary no. 15*"),
- **CENTRO HOSPITALAR DE VILA NOVA DE GAIA/ESPINHO EPE**, established in RUA CONCEICAO FERNANDES S/N, VILA NOVA DE GAIA, 4434 502, Portugal represented by Álvaro Monteiro, President of the administration board and/or António Alves, Member of the administration board or their authorised representative ("*beneficiary no. 16*"),

- **CARDIO MED SRL**, established in 22 DECEMBRIE 1989 STRADA 76 AP 1, TARGU MURES, 540124, Romania represented by Theodora Benedek, head of cardiac imaging and/or Imre Benedek, head of the clinic of cardiology or their authorised representative ("*beneficiary no. 17*"),
- **INSTITUT ZA KARDIOVASKULARNE BOLESTI VOJVODINE**, established in PUT DOKTORA GOLDMANA 4, SREMSKA KAMENICA, 21204, Serbia represented by Petar Gabric, Financial Director and/or Nada Cemerlic Adjic, General Director or their authorised representative ("*beneficiary no. 18*"),
- **INSTITUT CATALA DE LA SALUT**, established in GRAN VIA DE LES CORTS CATALANES 587, BARCELONA, 08007, Spain represented by José Jerónimo Navas Palacios, Manager or his authorised representative ("*beneficiary no. 19*"),
- **OSTERGOTLANDS LAN**, established in Smedstadvagen, Linköping, 58185, Sweden represented by Stefan Franzen, Chief executive officer and/or Jan Kåredal, Chief executive officer or their authorised representative ("*beneficiary no. 20*"),
- **KANTONSSPITAL ST. GALLEN**, established in Rorschacherstrasse 95, ST. GALLEN, 9007, Switzerland represented by Simon Wildermuth, Assistant Executive Director and/or René Thurnheer, Head of the Financial Department or their authorised representative ("*beneficiary no. 21*"),
- **UNIVERSITY OF GLASGOW**, established in University Avenue, GLASGOW, G12 8QQ, United Kingdom represented by Joe Galloway, Contracts Manager and/or Paul Ellis, Senior Contracts Manager or their authorised representative ("*beneficiary no. 22*"),
- **AINTREE UNIVERSITY HOSPITAL NHS FOUNDATION TRUST**, established in LONGMOOR LANE, LIVERPOOL, L9 7AL, United Kingdom represented by Michelle Mossa, Deputy Director, R&D and/or Anne Ainscough, Head of Management Accounts or their authorised representative ("*beneficiary no. 23*"),
- **INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM)**, established in 101 Rue de Tolbiac, PARIS, 75654, France represented by Nicolas Jeanjean, Délégué Régional and/or Lyddie Laaland, Gestionnaire Ressources Externes or their authorised representative ("*beneficiary no. 24*"),
- **ACADEMISCH ZIEKENHUIS LEIDEN - LEIDS UNIVERSITAIR MEDISCH CENTRUM**, established in Albinusdreef 2, LEIDEN, 2333 ZA, Netherlands represented by Paul Bilars, Manager and/or Koos van Rossum, Consultant division 2 or their authorised representative ("*beneficiary no. 25*"),
- **FUNDACION VASCA DE INNOVACION E INVESTIGACION SANITARIAS**, established in PLAZA ASUA 1, SONDIKA, 48150, Spain represented by Roberto Nuño, Director or his authorised representative ("*beneficiary no. 26*"),
- **CESKE VYSOKE UCENI TECHNICKE V PRAZE**, established in ZIKOVA 4, PRAHA, 166 36, Czech Republic represented by Havlicek Vaclav, Rector or his authorised representative ("*beneficiary no. 27*"),
- **Universitätsklinikum Jena**, established in Bachstraße 18, Jena, 07743, Germany represented by Klaus Benndorf, Dean of Medical Faculty or his authorised representative ("*beneficiary no. 28*"),

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 *Diagnostic Imaging Strategies for Patients with Stable Chest Pain and Intermediate Risk of Coronary Artery Disease: Comparative Effectiveness Research of Existing Technologies (DISCHARGE)* (the "*project*") within the framework of the *SP1-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 60 months from 1st February 2014 (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 18
- P2: from month 19 to month 36
- P3: from month 37 to month 54
- P4: from month 55 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 5,999,995.00 (*five million nine hundred and ninety nine thousand nine hundred and ninety five 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: Charite - Universitätsmedizin Berlin

Name of bank: Berliner Sparkasse

Account reference: DE53100500001270005550

Article 6 - Pre-financing

A *pre-financing* of EUR 1,949,998.00 (*one million nine hundred and forty nine thousand nine hundred and ninety eight EURO*) shall be paid to the *coordinator* within 30 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 299,999.75 (*two hundred and ninety nine thousand nine hundred and ninety nine EURO and seventy five cents*), 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*:

Special clause 6

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

Special clause 10

1. The following third parties are linked to FUNDACION VASCA DE INNOVACION E INVESTIGACION SANITARIAS:

- EUSKO JAURLARITZA-GOBIERNO VASCO.

2. This *beneficiary* may charge costs incurred by the above mentioned third parties in carrying out the *project*, in accordance with the provisions of the *grant agreement*. These contributions shall not be considered as receipts of the *project*.

The third parties shall identify the costs to the *project* mutatis mutandis in accordance with the provisions of part B of Annex II of the *grant agreement*. Each third party shall charge its eligible costs in accordance with the principles established in Articles II.14 and II.15. The *beneficiary* shall transmit to the *coordinator* using the electronic exchange system set up by the *Commission*:

- an individual financial statement from each third party in the format specified in Form C. These costs shall not be included in the *beneficiary's* Form C.
- certificates on the financial statements and/or on the methodology from each third party in accordance with the relevant provisions of this *grant agreement*.

The beneficiary shall keep the originals of the Forms C and the certificates of the third parties according to Article II.22.3.

When submitting reports referred to in Article II.4, the *consortium* shall identify work performed and resources deployed by each third party linking it to the corresponding *beneficiary*.

3. The eligibility of the third parties' costs charged by the *beneficiary* is subject to controls and audits of the third parties, in accordance with Articles II.22 and 23.

4. The *beneficiary* shall retain sole responsibility towards *the Union* and the other *beneficiaries* for the third parties linked to it. The *beneficiary* shall ensure that the third parties abide by the provisions of the *grant agreement*.

Special clause 16

1. The *beneficiary(ies)* shall provide the *Commission* with a statement confirming that it has received (a) favourable opinion(s) of the relevant ethics committee(s) and, if applicable, the regulatory approval of the competent national authority(ies) 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.

Special clause 39

In addition to Article II.30.4, *beneficiaries* shall deposit an electronic copy of the published version or the final manuscript accepted for publication of a scientific publication relating to *foreground* published before or after the final report in an institutional or subject-based repository at the moment of publication.

Beneficiaries are required to make their best efforts to ensure that this electronic copy becomes freely and electronically available to anyone through this repository:

- immediately if the scientific publication is published "open access", i.e. if an electronic version is also available free of charge via the publisher, or
- within 6 months of publication.

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
Directorate-General for Research & Innovation
F2
B-1049 Brussels, Belgium

For the *coordinator*: Dr. Marc Dewey
CHARITE - UNIVERSITAETSMEDIZIN BERLIN
Radiology
Chariteplatz 1
BERLIN 10117
GERMANY

2. Reports and deliverables shall be transmitted to the *Commission* according to Article II.4.5.
3. For information or documents to be transferred by e-mail, the following addresses shall be used:
For the *Commission*: RTD-FP7-Health-Medical-research@ec.europa.eu
For the *coordinator*: marc.dewey@charite.de

4. 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 3 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.

5. 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 3, to the controller responsible for the processing: Head of Unit of F2.

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 of *the Union* and its *Rules of Application* 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 BERLIN

For the *Commission* done at Brussels

Charité - Universitätsmedizin Berlin

Name of the legal entity

Dr. Gerrit Fleige

Name of the legal representative

CHARITÉ

UNIVERSITÄTSMEDIZIN BERLIN
Dr. Gerrit Fleige, MBA
Kaufmännischer Leiter Fakultät
Charitéplatz 1 | D-10117 Berlin

Stamp of the organisation (if applicable)

[Handwritten signature]

Signature of legal representative

CHARITÉ
UNIVERSITÄTSMEDIZIN BERLIN
Dr. Gerrit Fleige, MBA
Kaufmännischer Leiter Fakultät
Charitéplatz 1 | D-10117 Berlin

Date

02. Sep. 2013

D. Gaubert for R. Dreyfus, Akle

Name of the legal representative

[Handwritten signature]

Signature of legal representative

26 SEP. 2013

Date

CHARITÉ
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