`

FP7 COLLABORATIVE RESEARCH PROJECT

CONSORTIUM AGREEMENT

Version 1.0

PROJECT NO: 6032662

GRANT AGREEMENT NO: 6032662

EFFECTIVE DATE: 01-June-2013

TITLE OF PROJECT: Diagnostic Imaging Strategies for Patients with Stable Chest Pain and Intermediate Risk of Coronary Artery Disease: Comparative Effectiveness Research of Existing Technologies (DISCHARGE)

COORDINATOR: CHARITE – UNIVERSITAETSMEDIZIN BERLIN (CHARITE)

Parties:

2. MEDIZINISCHE UNIVERSITAET INNSBRUCK (MUI)

3. UNIVERSITAIR ZIEKENHUIS ANTWERPEN (UZA)

4. FAKULTNI NEMOCNICE V MOTOLE (FN Motol)

5. REGION HOVEDSTADEN (REGIONH)

6. KLINIKEN DES LANDKREISES GOPPINGEN GGMBH (KaE)

7. UNIVERSITAET LEIPZIG (ULEI)

8. SEMMELWEIS EGYETEM (SE)

9. South Eastern Health and Social Care Trust (SET)

10. UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN (St. Vincent's University Hospital, NUID UCD)

11. UNIVERSITA DEGLI STUDI DI CAGLIARI (UNICA)

12. UNIVERSITA DEGLI STUDI DI ROMA LA SAPIENZA (UNIROMA)

13. Paula Stradiņa Klīniskā universitātes slimnīca (PSKUH)

14. LIETUVOS SVEIKATOS MOKSLU UNIVERSITETAS (LSMU)

15. WOJEWODZKI SZPITAL SPECJALISTYCZNY WE WROCLAWIU (WSS)

16. Centro Hospitalar de Vila Nova de Gaia/Espinho, EPE (ESPINHO/EPE)

17. S.C.Cardio Med S.R.L (CAM)

18. Institut za kardiovaskularne bolesti Vojvodine - Sremska Kamenica (IKVBV)

19. INSTITUT CATALA DE LA SALUT (ICS-HUVH)

20. OSTERGOTLANDS LAN (OSTERGOTLANDS LAN)

21. Kantonsspital St. Gallen (KSSG)

22. University of Glasgow (Glasgow)

23. Aintree University Hospital NHS Foundation Trust (AUHT)

24. INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (on behalf of ECRIN) (INSERM/ECRIN))

25. ACADEMISCH ZIEKENHUIS LEIDEN - LEIDS UNIVERSITAIR MEDISCH CENTRUM (LUMC)

26. FUNDACION VASCA DE INNOVACION E INVESTIGACION SANITARIAS (Osteba-BIOEF)

27. Ceske Vysoke Uceni Technicke v Praze (CVUT)

28. Universitätsklinikum Jena (UKJ)

PROJECT FUNDED BY THE

EUROPEAN COMMUNITY'S SEVENTH FRAMEWORK PROGRAMME

FP7 CONSORTIUM AGREEMENT

This Consortium Agreement is made on 2013-06-01, hereinafter referred to as "Effective Date" between:

Coordinator: 1. CHARITE – UNIVERSITAETSMEDIZIN BERLIN (CHARITE)
and partners:

2. MEDIZINISCHE UNIVERSITAET INNSBRUCK (MUI)

3. UNIVERSITAIR ZIEKENHUIS ANTWERPEN (UZA)

4. FAKULTNI NEMOCNICE V MOTOLE (FN Motol)

5. REGION HOVEDSTADEN (REGIONH)

6. KLINIKEN DES LANDKREISES GOPPINGEN GGMBH (KaE)

7. UNIVERSITAET LEIPZIG (ULEI)

8. SEMMELWEIS EGYETEM (SE)

9. South Eastern Health and Social Care Trust (SET)

10. UNIVERSITY COLLEGE DUBLIN, NATIONAL UNIVERSITY OF IRELAND, DUBLIN (St. Vincent's University Hospital, NUID UCD)

11. UNIVERSITA DEGLI STUDI DI CAGLIARI (UNICA)

12. UNIVERSITA DEGLI STUDI DI ROMA LA SAPIENZA (UNIROMA)

13. Paula Stradiņa Klīniskā universitātes slimnīca (PSKUH)

14. LIETUVOS SVEIKATOS MOKSLU UNIVERSITETAS (LSMU)

15. WOJEWODZKI SZPITAL SPECJALISTYCZNY WE WROCLAWIU (WSS)

16. Centro Hospitalar de Vila Nova de Gaia/Espinho, EPE (ESPINHO/EPE)

17. S.C.Cardio Med S.R.L (CAM)

18. Institut za kardiovaskularne bolesti Vojvodine - Sremska Kamenica (IKVBV)

19. INSTITUT CATALA DE LA SALUT (ICS-HUVH)

20. OSTERGOTLANDS LAN (OSTERGOTLANDS LAN)

21. Kantonsspital St. Gallen (KSSG)

22. University of Glasgow (Glasgow)

23. Aintree University Hospital NHS Foundation Trust (AUHT)

24. INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (on behalf of ECRIN) (INSERM/ECRIN))

25. ACADEMISCH ZIEKENHUIS LEIDEN - LEIDS UNIVERSITAIR MEDISCH CENTRUM (LUMC)

26. FUNDACION VASCA DE INNOVACION E INVESTIGACION SANITARIAS (Osteba-BIOEF)

27. Ceske Vysoke Uceni Technicke v Praze (CVUT)

28. Universitätsklinikum Jena (UKJ)

- hereinafter, jointly or individually, referred to as "Parties" or "Party" - The corresponding term in the Grant Agreement is Beneficiary

Relating to the EC project entitled

"DISCHARGE"

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the European Union's Seventh Framework Programme. The Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of EC Grant Agreement (hereinafter referred to as "EC-GA").

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1. Words beginning with a capital letter shall have the meaning defined either herein or in the Rules for Participation or in the EC-GA including its Annexes without the need to replicate said terms herein. “Consortium Plan” means the description of the work and the related agreed Consortium Budget, including the payment schedule, as updated and approved by the Steering Committee. The starting point for the Consortium Plan will be the Description of Work (DoW) as laid down in Annex I of the EC-GA. “Consortium Budget” means the allocation of all the resources in cash or in kind for the activities as defined in Annex I of the Grant Agreement and in the Consortium Plan thereafter.

2. An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorised representative. This Consortium Agreement shall have effect from the Effective Date identified at the beginning of this Consortium Agreement. This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the EC-GA and under this Consortium Agreement.

3. Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations and allocated work under the EC-GA and this Consortium Agreement as may be reasonably required from it and in a manner of good faith as prescribed by Belgian law.

4. The Parties undertake to negotiate in good faith an updated version (“Version 2”) of this Consortium Agreement which shall be concluded and signed before the signature of the EC-GA. Version 2 shall be based upon and not materially deviate from the ‘DESCA’ model consortium agreement available at www.DESCA-FP7.eu, and its provisions shall extend and supersede those of this Consortium Agreement. These extended provisions shall include, but not be limited to, the identification of specific Background to which the Parties are prepared to grant Access Rights.

5. For the clinical sites, a clinical site contract is foreseen, that specifies the consortium budget, number of patients to be recruited and other formalities.

6. During the recruitment phase of DISCHARGE, all patients with suspected coronary artery disease referred to or directly presenting to the recruiting sites, fulfilling inclusion and exclusion criteria, with stable chest pain and a pretest likelihood of coronary artery disease between 10-70% will be approached by the party for participation in DISCHARGE. Patients with a pretest likelihood of 10- 70% must not be included in any other study during the DISCHARGE recruitment phase.

7. The organisational structure of the Project shall initially comprise the following consortium bodies as specified in DoW:

a) Consortium Council: The Consortium Council will meet in-person once a year in form of a general assembly at the coordinators site. The clinical sites will be evenly sorted by the regions Northern, Western, Southern, Eastern and Central Europe and each of them will have one vote to select the respective 5 regional representative.

b) Steering Committee: The Steering Committee is the major decision making body, empowered by the Consortium Council. The 5 regional representatives from the clinical sites and the 6 scientific work package leaders who are not from Charité

(INSERM/ECRIN, OSTERGOTSLAND LAN, Osteba-BIOEF, LUMC, CVUT, and UKJ) and the Coordinator (Charité) will form the Steering Committee as the ultimate decision-making body of the Project**.** The Steering Committee shall not deliberate and decide validly unless two-thirds (2/3) of its members are present or represented (quorum). Each member present or represented shall have one vote, and decisions shall be made with at least one vote difference. In case of an equality of votes, measures will be taken to come to a consensus.

c) The Coordinator: The coordinator functions as the intermediary between the EU-Commission and all beneficiaries with his project manager. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the EC-GA and this Consortium Agreement.

Additional Consortium Bodies identified in Section 2.1.1 of Part B of the EC-GA shall have their responsibilities and decision making procedures defined in Version 2.

8. Funding of costs included in the Consortium Plan will be paid to Parties after receipt from the EU-Commission in separate instalments in conformity with the decision of the Steering Committee and the Coordinator on the applicable instalment mechanism: Funding for costs accepted by the EU-Commission will be paid to the Party concerned, taking into account the amounts already paid for the reporting period concerned. The Coordinator is entitled to withhold any payments due to a Party identified by the Steering Committee to be in breach of its obligations under this Consortium Agreement or the EC-GA, or to a Beneficiary which has not yet signed Version 2.

9. Dissemination activities including but not restricted to publications and presentations shall be governed by the procedure of Article II.30.3 of the EC-GA subject to the following provisions. Prior notice of any planned publication shall be given to the other Parties concerned at least 45 days before the publication. Any objection to the planned publication shall be made in accordance with the GA in writing to the Coordinator and to any Party concerned within 30 days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted. An objection is justified if

a) the objecting Party's legitimate academic or commercial interests are compromised by the publication; or

b) the protection of the objecting Party's Foreground or Background is adversely affected.

The objection has to include a precise request for necessary modifications.

10. The Parties agree, for the duration of this Consortium Agreement and for a period of five years thereafter (in accordance with Article II.9.1 of the EC-GA), to keep secret and confidential all information marked as “confidential” or subsequently notified as confidential, whether of a technical business or commercial nature or otherwise, and whether oral, written or in electronic form ("Confidential Information"), as is disclosed from time to time by any of them to the another in connection with the Project. If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure:

a) notify the disclosing Party, and

b) comply with the disclosing Party's reasonable instructions to protect the confidentiality of the information.

11. Access rights to Foreground and Background needed for the performance of the work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed. Access rights to Foreground and Background if needed for the use of a Party's own Foreground, including for third-party research, shall be granted on fair and reasonable conditions. Access rights for internal non-commercial research activities shall be granted on a royalty-free basis.

12. Any dispute, controversy or claim arising under, out of or relating to this contract and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be submitted to mediation in accordance with the WIPO Mediation Rules. The place of mediation shall be Brussels unless otherwise agreed upon. The language to be used in the mediation shall be English unless otherwise agreed upon. If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the mediation within 60 days of the commencement of the mediation, it shall, upon the filing of a Request for Arbitration by either party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. Alternatively, if, before the expiration of the said period of 60 days, either party fails to participate or to continue to participate in the mediation, the dispute, controversy or claim shall, upon the filing of a Request for Arbitration by the other party, be referred to and finally determined by arbitration in accordance with the WIPO Expedited Arbitration Rules. The place of arbitration shall be Brussels unless otherwise agreed upon. The language to be used in the arbitral proceedings shall be English unless otherwise agreed upon.

13. Each Party shall be solely liable for any loss, damage or injury to third parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement.

14. No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damage was not caused by a wilful act or by a breach of confidentiality. A Party's aggregate liability towards the other Parties collectively shall be limited to once the Party's share of the total costs of the project as identified in the EC-GA provided such damage was not caused by a wilful act or gross negligence. The terms of this agreement shall not be construed to amend or limit any Party's statutory liability.

15. The Parties shall not be entitled to act or to make legally binding declarations on behalf of any other Party. Nothing in this agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

16. This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

17. The Parties have caused this Consortium Agreement to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written.

Signatures

A. Coordinator:

Signed on behalf of CHARITE – UNIVERSITAETSMEDIZIN BERLIN (CHARITE)

Signature _____ Date _____

Name _____ Title _____

Signature _____ Date _____

Name _____ Title _____

Organisation Stamp (if applicable)

B. Partner:

Signed on behalf of Fill in name of your institution

Signature _____ Date _____

Name _____ Title _____

Signature _____ Date _____

Name _____ Title _____

Organisation Stamp (if applicable)