[redacted]

FP7 GRANT AGREEMENT
ANNEX IV - FORM A - ACCESSION OF BENEFICIARIES TO THE GRANT AGREEMENT

SLOVENSKA ZDRAVOTNICKA UNIVERZITA V BRATISLAVE, represented for the purpose hereof by Dana FARKAŠOVÁ, Rector, and/or Martin GAJDOŠ, Vice-rector for research and science, or her/his/their authorised representative, established in LIMBOVA 12, BRATISLAVA, 83303, Slovakia acting as its legal authorised representative, hereby consents to become a *beneficiary* ("*beneficiary no. 7*") to *grant agreement* N° 602299 (relating to *project* "*Comparative Effectiveness Research to Assess the Use of Primary ProphylacTic Implantable Cardioverter Defibrillators in EUrope*") concluded between the European Commission and UNIVERSITAETSMEDIZIN GOETTINGEN - GEORG-AUGUST-UNIVERSITAET GOETTINGEN - STIFTUNG OEFFENTLICHEN RECHTS established in Robert-Koch-Strasse - 40, GOETTINGEN, 37075, Germany and accepts in accordance with the provisions of the aforementioned *grant agreement* all the rights and obligations of a *beneficiary*.

Done in 3 copies, of which one shall be kept by the *coordinator* and one by **SLOVENSKA ZDRAVOTNICKA UNIVERZITA V BRATISLAVE**, the third being sent to the *Commission* by the coordinator in accordance with Articles 1.1 and 1.2 and Article 8 of the grant agreement.

SLOVENSKA ZDRAVOTNICKA UNIVERZITA V BRATISLAVE

Dr.h.c. prof. PhDr. Dana Farkašová, PhD.
Name of legal representative(s)

[redacted]
Signature of legal representative(s)

[redacted]

23. 09. 2013
Date

[redacted]
Stamp of the organisation

UNIVERSITAETSMEDIZIN GOETTINGEN - GEORG-AUGUST-UNIVERSITAET GOETTINGEN - STIFTUNG OEFFENTLICHEN RECHTS

Christiane Hennecke, M.A.
Name of legal representative(s)

[redacted]
Signature of legal representative(s)

Sept. 19, 2013
Date

[redacted]
Stamp of the

[redacted]

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 602299

EU-CERT-ICD

Comparative Effectiveness Research to Assess the Use of Primary ProphylacTic Implantable Cardioverter Defibrillators in EUrope

HEALTH-F2-2013-602299

SEVENTH FRAMEWORK PROGRAMME

GRANT AGREEMENT No 602299

PROJECT TITLE EU-CERT-ICD

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 UNIVERSITAETSMEDIZIN GOETTINGEN - GEORG-AUGUST-UNIVERSITAET GOETTINGEN - STIFTUNG OEFFENTLICHEN RECHTS, established in Robert-Koch-Strasse 40, GOETTINGEN, 37075, Germany represented by Christiane Hennecke, Director International Relations or her 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*.

- **UNIVERSITAIR MEDISCH CENTRUM UTRECHT,** established in HEIDELBERGLAAN 100, UTRECHT, 3584 CX, Netherlands represented by Karin Krol-Simons, Manager of Finance & Operation and/or Pieter Doevendans, Manager Healthcare or their authorised representative ("*beneficiary no. 2*"),

- **EBERHARD KARLS UNIVERSITAET TUEBINGEN,** established in GESCHWISTER-SCHOLL-PLATZ, TUEBINGEN, 72074, Germany represented by Andreas Rothfuss, Chancellor and/or Jürgen Rottenecker, Deputy Chancellor or their authorised representative ("*beneficiary no. 3*"),

• **KAROLINSKA INSTITUTET,** established in Nobels Vag 5, STOCKHOLM, 17177, Sweden represented by Björn Kull, Head of Unit Grants Office and/or Eva Björndal, Compliance coordinator or their authorised representative ("*beneficiary no. 4*"),

• **CONSORCI INSTITUT D'INVESTIGACIONS BIOMEDIQUES AUGUST PI I SUNYER,** established in Villarroel 170, BARCELONA, 08036, Spain represented by Pastora Martinez Samper, Managing Director and/or Ramon Gomis, Director General or their authorised representative ("*beneficiary no. 5*"),

• **PANEPISTIMIAKO GENIKO NOSOKOMEIO ATTIKON,** established in ODOS RIMINI 1, ATHINA CHAIDARI, 12462, Greece represented by Elias Lambiris, President of Hospital Board and/or Ioannis Evdokimidis, President of 2nd Health Care Region or their authorised representative ("*beneficiary no. 6*"),

• **SLOVENSKA ZDRAVOTNICKA UNIVERZITA V BRATISLAVE,** established in LIMBOVA 12, BRATISLAVA, 83303, Slovakia represented by Dana FARKAŠOVÁ, Rector and/or Martin GAJDOŠ, Vice-rector for research and science or their authorised representative ("*beneficiary no. 7*"),

• **OULUN YLIOPISTO,** established in Pentti Kaiteran Katu 1, OULU, 90014, Finland represented by Taina Pihlajaniemi, Vice Rector for Research and/or Pirjo Kytosalmi, Chief Financial Officer or their authorised representative ("*beneficiary no. 8*"),

• **LUDWIG-MAXIMILIANS-UNIVERSITAET MUENCHEN,** established in Geschwister-Scholl-Platz 1, MUENCHEN, 80539, Germany represented by Frank Spiekermann, Financial Officer and/or Willibald Seitz, Deputy Financial Officer or their authorised representative ("*beneficiary no. 9*"),

• **UNIVERSYTET MEDYCZNY W LODZI.,** established in Al. Kosciuszki, 4, LODZ, 90419, Poland represented by Pawel Gorski, Rector and/or Lucyna Wozniak, Vice-Rector for Research or their authorised representative ("*beneficiary no. 10*"),

• **ST. PAUL'S CARDIAC ELECTROPHYSIOLOGY LLP,** established in VERULAM AVENUE 16, PURLEY, CR8 3NQ, United Kingdom represented by Katerina Hnatkova, Director & Principal Partner and/or Marek Malik, Principal Partner or their authorised representative ("*beneficiary no. 11*"),

• **SEMMELWEIS EGYETEM,** established in ULLOI UTCA 26, BUDAPEST, 1085, Hungary represented by Agoston SZEL, Director and/or Iren BAUMGARTNERNE HOLLO, Head of Economic and Technical Directorate or their authorised representative ("*beneficiary no. 12*"),

• **KLINIKUM RECHTS DER ISAR DER TECHNISCHEN UNIVERSITAT MUNCHEN,** established in ISMANINGER STRASSE 22, MUENCHEN, 81675, Germany represented by Inge Linder, Legal Representative & Head of Dept. and/or Daniel Lahne, Vice Head of Department or their authorised representative ("*beneficiary no. 13*"),

• **UNIVERSITAETSSPITAL BASEL,** established in Hebelstrasse 34, BASEL, 4031, Switzerland represented by Werner Kuebler, Director and/or Christian Sticherling, Director of Electrophysiology or their authorised representative ("*beneficiary no. 14*"),

• **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. 15*"),

• **KATHOLIEKE UNIVERSITEIT LEUVEN,** established in Oude Markt 13, LEUVEN, 3000, Belgium represented by Paul Van Dun, General Manager and/or Elke Lammertyn, Head of European Projects or their authorised representative ("*beneficiary no. 16*"),

• **CHARITE - UNIVERSITAETSMEDIZIN BERLIN,** established in Chariteplatz 1, BERLIN, 10117, Germany represented by Gerrit Fleige, Executive Director Finance & Administration and/or Annette Grüters-Kieslich, Dean or their authorised representative ("*beneficiary no. 17*"),

• **GABO:MI GESELLSCHAFT FUR ABLAUFORGANISATION:MILLIARIUM MBH & CO KG,** established in OSKAR VON MILLER RING 29, MUENCHEN, 80333, Germany represented by Hans-Dieter Schuster, Managing Director and/or Birgit Fuchs, Managing Director or their authorised representative ("*beneficiary no. 18*"),

• **MAGDALENA - KLINIKA ZA KARDIOVASKULARNE BOLESTI MEDICINSKOG FAKULTETASVEUCILISTA J.J. STROSSMAYERA U OSIJEKU USTANOVA,** established in LJUDEVITA GAJA 2, KRAPINSKE TOPLICE, 49000, Croatia represented by Mihajlo Šesto, Director and/or Zvonimir Ante Korda, Deputy director or their authorised representative ("*beneficiary no. 19*"),

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 *Comparative Effectiveness Research to Assess the Use of Primary ProphylacTic Implantable Cardioverter Defibrillators in EUrope (EU-CERT-ICD)* (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 48 months from 1st October 2013 (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 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 5,999,562.00 (*five million nine hundred and ninety nine thousand five hundred and sixty two 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 1 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: Universitaetsmedizin Goettingen
Name of bank:
Account reference:

Article 6 - Pre-financing

A *pre-financing* of EUR 2,599,810.00 (*two million five hundred and ninety nine thousand eight hundred and ten 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 *299,978.10* (*two hundred and ninety nine thousand nine hundred and seventy eight EURO and ten 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 UNIVERSITAETSMEDIZIN GOETTINGEN - GEORG-AUGUST-UNIVERSITAET GOETTINGEN - STIFTUNG OEFFENTLICHEN RECHTS:

- IFS INSTITUT FUR ANWENDUNGSORIENTIERTE FORSCHUNG UND KLINISCHE STUDIEN GMBH

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*: Mrs. Christiane Hennecke
UNIVERSITAETSMEDIZIN GOETTINGEN -
GEORG-AUGUST-UNIVERSITAET GOETTINGEN - STIFTUNG
OEFFENTLICHEN RECHTS
Dept. International Relations
Robert-Koch-Strasse 40
GOETTINGEN 37075
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*: christiane.hennecke@med.uni-goettingen.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 GOETTINGEN

[redacted]

.....

Name of the legal entity

Christiane Hennecke, M.A.

.....

Name of the legal representative

[redacted]

.....

Stamp of the organisation (if applicable)

[redacted]

.....

Signature of legal representative

July 29, 2013

.....

Date

For the *Commission* done at Brussels

Ruxandra DRAGHIA-AKLI
Director

.....

Name of the legal representative

[redacted]

.....

Signature of legal representative

.....

Date 0 2 SEP. 2013

[redacted]

Participant 07: Slovak Medical University, SMU, Bratislava, Slovakia

Main tasks attributed in the project

SMU will participate in **WP 01** (Prospective Study) as well as in **WP02** (ICD Registry) with enrolment of patients. SMU will also actively participate in **WP11** (Dissemination). The centre will actively disseminate the results of the project among a wide community of specialty and primary care physicians. SMU is a leading consultant for health/care administrators and insurance companies in Slovakia. The results can directly impact the health policy related to prevention of sudden cardiac death in the country.
In WP01, SMU expects to enroll 187 patients.

Brief description of the organisation and summary of experience relevant to the project

The Division of Cardiology and Angiology of the School of Medicine at the Slovak Medical University is a joint institution with the National Cardiovascular Institute in Bratislava. It is the leading tertiary care centre in the field of cardiovascular medicine in the Slovak republic. Its Department of Arrhythmias and Cardiac Pacing (further DACP) is involved in all aspects of diagnosis and therapy of cardiac arrhythmias. With its 16 fully monitored beds dedicated entirely to patients with all types of arrhythmias, DACP hospitalised in 2012 over 1500 pts with cardiac arrhythmias in whom over 2000 antiarrhythmic interventions were performed. DACP has access to all relevant invasive and non-invasive diagnostic and therapeutic technologies used in contemporary arrhythmia management. Furthermore, with its 3 outpatient clinics DACP has the necessary infrastructure for long term follow-up and over 14 000 patients are seen here annually. In the field of device therapy DACP implants up to 300 implantable defibrillators (ICD) annually, with two thirds in primary prevention indications (first ICD implant was performed at the DACP in 1990). All patients with an ICD implanted at DACP are also followed by the centre, partially using remote GSM and web based monitoring technologies. An ICD registry is systematically conducted in the Slovak republic since 1993, since 2011 in the form of electronic on-line CRF. The structure of the registry will be adapted to the requirement of the project.
Prof. Robert Hatala (Ph.D.), is the head of Dept. of Cardiology and Angiology since 2008 and Director of the DACP since its establishment in 1995. He participated in 3 important randomised clinical trials focused on primary prevention of sudden cardiac death with the ICD in patients after myocardial infarction: in the DINAMIT trial as a member of the steering-committee; in the IRIS trial as investigator; and he is lead principal investigator of the currently conducted SPIRIT-ICD trial. He serves as an active board member of the European Heart Rhythm Association responsible for cooperation among arrhythmia national societies and working groups within Europe.
Dr. Peter Hlivak (Ph.D.), Dr. Martin Svetlosak (Ph.D.) and Dr. Michal Sasov are all staff members of the DACP and board certified cardiologists with relevant experience in arrhythmia management. Prof. Eva Goncalvesova (Ph.D.) is director of the heart failure program at the National Cardiovascular Institute in Bratislava, board certified internist and cardiologist with extensive experience in all aspects of management of chronic heart failure. This program guarantees a high volume of heart failure patients referred for screening for eligibility for for specialised therapeutic options including CRT and ICD implantation. Maria Cisarova and Zuzana Husekova are in the working group as technical personnel. A study nurse (N.N.) will be added for the project.

Recent publications relevant to the project

- Hohnloser SH, Kuck KH, Dorian P, Roberts RS, Hampton JR, **Hatala R**, Fain E, Gent M, Connolly SJ; DINAMIT Investigators: Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. *N Engl J Med.* 2004;351:2481-8.
- Braunschweig F, Boriani G, Bauer A, **Hatala R,** Herrmann-Lingen C, Kautzner J, Pedersen SS, Pehrson S, Ricci R, Schalij MJ. Management of patients receiving implantable cardiac defibrillator shocks: Recommendations for acute and long-term patient management. *Europace.* 2010;12:1673-1690
- Merkely B, Kautzner J, Milasinovic G, **Hatala R,** Taborsky M, Lubinski A, Dan GA, Zima E, Milicic D, Auricchio A, Camm AJ, Wolpert C, Vardas P, Summit E. Summary statement: EHRA summit 2010 with the participation of central-eastern european countries: 'ICD for life' initiative--fighting against sudden cardiac death in emerging economies. *Europace.* 2011;13:1209-1210

- **Hatala R.**, Wollmann C., et al. on behalf of the SPIRIT-ICD Investigators: Survival of Patients with Primary Prophylactic Implantable Cardioverter DefibrillatoR (ICD) Indication Provided with Intensified Care after 1st ICD Therapy (SPIRIT-ICD trial) – Rationale and Design. Europace submitted (Nov 12, 2012)

2.4 Resources to be committed

The total cost of the project will amount to 8.021.762,66 € of which 5.999.562,-€ are asked to be funded by the EC. This leads to an own contribution equal to 23%. The consortium commits itself to bringing in additional 23% own, non-funded staff. The scientific consortium partners will provide the necessary infrastructure for the researchers involved in the project to fulfill their related tasks including office spaces, information technology, and theoretical and practical support by study group members. All recruiting centres will provide an infrastructure for the assessment and treatment of patients. The requested budget reflects the costs for patient recruitment (700 € patient fee/patient in Western Europe and 500 € in Eastern Europe).

	WP01: Observational Prospective Study	WP02: Combined ICD Registry	WP03: Health Economics and Quality of Life	WP04: Gender Issues	WP05: Beat-to-Beat variability	WP06: T-wave morphology	WP07: Fractionization and repolarization	WP08: Heart rate variability	WP09: Biobanking	WP10: Statistics and Metaanalyses	WP11: Dissemination	WP12: Prospective Study management	WP13: Project Management	Total per participant
01: UMG (EU-CERT-ICD)	555.280 €	39.640 €	39.640 €	39.640 €	39.640 €	13.200 €	0 €	224.400 €	0 €	0 €	79.360 €	194.843 €	79.380 €	**1.305.023 €**
01.1: IFS (third partyUMG)	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	388.500 €	1.500 €	**390.000 €**
02: UMCU (EU-CERT-ICD)	131.491 €	16.320 €	0 €	7.680 €	219.162 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	1.500 €	**376.153 €**
03: EKUT (EU-CERT-ICD)	208.296 €	6.600 €	0 €	0 €	0 €	0 €	0 €	35.592 €	0 €	0 €	0 €	0 €	0 €	**250.488 €**
04: KI (EU-CERT-ICD	126.576 €	32.987 €	38.831 €	7.766 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	**206.160 €**
05: IDIBAPS (EU-CERT-ICD	146.662 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	2.310 €	55.168 €	0 €	0 €	**204.140 €**
06: AUH (EU-CERT-ICD)	93.016 €	21.359 €	0 €	11.241 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	**125.616 €**
07: SMU (EU-CER-ICD)	116.791 €	24.684 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	941 €	0 €	0 €	**142.416 €**
08: UOULU (EU-CERT-ICD)	112.573 €	43.587 €	0 €	2.688 €	12.149 €	12.149 €	103.677 €	9.461 €	0 €	0 €	0 €	0 €	0 €	**296.284 €**
09: LMU (EU-CERT-ICD)	17.495 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	180.582 €	0 €	0 €	0 €	0 €	**198.077 €**
10: MUL (EU-CERT-ICD)	96.452 €	36.874 €	28.063 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	**161.389 €**
11: SPCE (EU-CERT-ICD)	0 €	0 €	0 €	0 €	33.640 €	95.127 €	6.124 €	6.124 €	0 €	0 €	0 €	0 €	0 €	**141.015 €**
12: SUHC (EU-CERT-ICD)	189.812 €	30.964 €	0 €	0 €	0 €	0 €	0 €	0 €	4.078 €	0 €	28.080 €	0 €	0 €	**252.934 €**
13: TUM-Med (EU-CERT-ICD	68.881 €	0 €	0 €	0 €	0 €	7.724 €	7.724 €	245.847 €	0 €	0 €	0 €	0 €	0 €	**330.176 €**
14: UHBS (EU-CERT-ICD)	0 €	188.756 €	0 €	68.994 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	**257.750 €**
15: RHC (EU-CERT-ICD)	169.197 €	70.018 €	0 €	47.978 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	1.900 €	0 €	**289.093 €**
16: KUL (EU-CERT-ICD	130.436 €	32.082 €	19.018 €	0 €	0 €	0 €	0 €	0 €	960 €	0 €	0 €	0 €	0 €	**182.496 €**
17: Charité (EU-CERT-ICD	59.040 €	0 €	338.100 €	0 €	0 €	0 €	0 €	0 €	0 €	18.900 €	46.080 €	0 €	3.000 €	**465.120 €**
18: GABO:mi (EU-CERT-ICD	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	48.932 €	0 €	346.300 €	**395.232 €**
19: Magdalena (EU-CERT)	30.000 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	0 €	**30.000 €**
Total	**2.251.998 €**	**543.871 €**	**463.652 €**	**185.987 €**	**304.591 €**	**128.200 €**	**117.525 €**	**521.424 €**	**185.620 €**	**21.210 €**	**258.561 €**	**585.243 €**	**431.680 €**	**5.999.562 €**
% of budget per WP	**37,54%**	**9,07%**	**7,73%**	**3,10%**	**5,08%**	**2,14%**	**1,96%**	**8,69%**	**3,09%**	**0,35%**	**4,31%**	**9,75%**	**7,20%**	**100,00%**

PARTNER 06 (AUH (EU-CERT-ICD)): WP 01; 02; 04; 09; 13	
Cost Category RTD	
Personnel : Nurse WP1 8 PM; Junior Doctor WP1(6 PM);	€ 23,480
Travel : Travel to conferences / stakeholders; Travel to project meetings;	€ 11,000
Other costs ('the rest') : Patient fees (117);	€ 70,200
Indirect costs	€ 62,808
Total	€ 167,488
EC Contribution	€ 125,616

PARTNER 07 (SMU (EU-CER-ICD)): WP 01; 02; 09; 11; 13	
Cost Category RTD	
Personnel : Researcher WP1 (5.76 PM)	€ 13,396
Travel : Travel to conferences/stakeholder; Travel to project meetings;	€ 11,000
Other costs ('the rest') : Patient fee (187);	€ 93,500
Cost Category Others	
Personnel : Researcher WP11 0.24 PM	€ 588
Indirect costs	€ 71,090
Total	€ 189,574
EC Contribution	€ 142,416

PARTNER 08 (UOULU (EU-CERT-ICD)): WP 01; 02; 04; 05; 06; **07**; 08; 09; 10; 11; 13	
Cost Category RTD	
Personnel : Research nurse WP1,2,7 (35PM)	€ 131,403
Travel : Travel to conferences/stakeholders; Travel to project meeting;	€ 11,200
Other costs ('the rest') : Patient fee (149);	€ 104,300
Indirect costs	€ 148,142
Total	€ 395,045
EC Contribution	€ 296,284

PARTNER 09 (LMU (EU-CERT-ICD)): WP 01; 02; 07; **09**; 11; 13	
Cost Category RTD	
Personnel : Lab technician WP1,2,9 (6 PM); Documentist/Study nurse WP 1,2,9 (6 PM);	€ 55,798
Consumables: Kits + Shipment (Kits);	€ 73,167
Travel : Travel to project meetings; Travel to conferences / stakeholders;	€ 10,900
Other costs ('the rest') : Patient fee (36);	€ 25,199
Indirect costs	€ 99,039
Total	€ 264,103
EC Contribution	€ 198,077

PARTNER 10 (MUL (EU-CERT-ICD)): WP 01; 02; 03; 09; 11; 13	
Cost Category RTD	
Personnel : 2 Researchers WP 1,2,3 (12PM); 1 Senior researcher (professor) WP 1,2,3 (5PM); 1 Researcher (adjunct) WP1,2,3 (6PM); 1 technician (statistics specialist) WP 1,2,3 (6 PM); 2 laboratory technicians WP1,2,3 (10 PM);	€ 77,119
Travel : Travel to conferences/stakeholder; Travel to project meetings;	€ 10,372
Other costs ('the rest') : Patient fee (94);	€ 47,000
Indirect costs	€ 80,695
Total	€ 215,185
EC Contribution	€ 161,389

PARTNER 11 (SPCE (EU-CERT-ICD)): WP 01; 02, 05; **06**; 07; 08; 10; 11	
Cost Category RTD	
Personnel : Biomedical engineer WP 5,6,7,8 (8PM); Data Analyst WP6 (11PM);	€ 94,582
Travel : Travel to conferences / stakeholders; Travel to project meetings;	€ 10,430
Equipment : High Capacity disc array;	€ 12,500
Indirect costs	€ 70,508
Total	€ 188,020
EC Contribution	€ 141,015

PARTNER 12 (SUHC (EU-CERT-ICD)): WP 01; 02; 09; 11	
Cost Category RTD	
Personnel : 1 Post Doc WP1,2,9 (4PM); 1 Lab technician WP1,2,9 (4PM);	€ 18,400
Travel : Travel to conferences / stakeholders; Travel to project meetings;	€ 11,028
Other costs ('the rest') : Patient Fee (351);	€ 175,500
Indirect costs	€ 122,957
Total	€ 327,885
EC Contribution	€ 252,934