How EHRA/ESC ventures into Horizon2020 funded trials

Nikos Dagres

Chair of EHRA Scientific Initiatives Committee

EHRA involvement in Horizon2020

- **Importance**
- **Current status**
- **Obstacles**
- **Perspectives**

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EHRA involvement in Horizon2020

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EHRA Strategic Goals

- **Congress**
- **Education**
- **Research**
- **Members**
- **Advocacy**

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EHRA involvement in Horizon2020

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Recent initiatives

1. **Horizon 2020 call:**
   ESCAPE-NET: European Sudden Cardiac Arrest network towards Prevention, Education and NEw Treatment

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ESCAPE-NET

- **Total budget: approx. 10 mio Euro**
- **Successful with the highest score (15 out of 15)**
- **EHRA involvement:**
  Co-leader (together with European Resuscitation Council and P. Schwartz) in Work Package on dissemination, communication, education
- **Current stage: Has started**

www.escardio.org/EHRA

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ESCAPE-NET

Participant Number	Participant Organisation Name	Country
1 (Coordinator)	Academic Medical Center (AMC)	NL
2	University of Copenhagen (UC-REGIONH)	DK
3	Unisersite Paris Descartes, Inserm (UP)	FR
4	University of Pavia (UPAV)	IT
5	IRCCS Istituto Auxologico Italiano (AUXO)	IT
6	VU University Medical Center	NL
7	European Society of Cardiology (ESC)*	FR
10	Emergency Medical Services of the Hradec Kralove Region (EMS)	CZ
11	European Rescucitation Council (ERC)	BE
12	Istituto di Ricerche Farmacologiche "Mario Negri" (IRFMN)	IT
13	Panaxea (PAN)	NL
14	Fundacio Institut Mar d'Investigacions Mediques (IMIM)	ES
15	Catalyze (CAT)	NL
16	Helmholtz Zentrum Munchen (HZM)	DE

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Current projects in Horizon2020

1. **Horizon 2020 call:**
   ESCAPE-NET: Sudden Cardiac Arrest Network

2. **Innovative Medicines Initative 2 call:**
   Big data in cardiovascular medicine

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Big data in ACS, AF and HF

BigData@Heart
Big Data for Better Hearts

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BigData@Heart

- Consortium consisting of academia, pharmaceutical companies, patient networks, learned societies, SMEs

- It aims at delivering clinically relevant disease phenotypes, scalable insights from realworld evidence through advanced analytics, and innovative insights for driving drug development and personalised medicine.

- The platform comprises rich biomedical and omics-data on over 25 million subjects across Europe

EHRA involvement

Table 1.3.a: highlights of the BigData@Heart scientific leadership

Prof. dr. Rick Grobbee (UMCU): President of European Association for Cardiovascular Prevention and Rehabilitation, Academic Lead IMI Get Real; Expertise: clinical and cardiovascular epidemiology (co-chair; WP-lead WP1 & WP5)

Prof. dr. Stefan Anker (UMG): Professor Innovative Clinical Trials in chronic and acute HF and wasting disorders. Past president of ESC HF association, councillor of the ESC board (co-chair; WP-lead WP2 & WPX and HF-lead)

Dr. Jason Arora (ICHOM): Director at ICHOM. Expertise in outcomes, public health, international datasets, patient reported outcomes, and value-based healthcare. (WP-lead WP2)

Prof. dr. Nikolaos Maniadakis (ESC): Chair of Department of Health Services Management. Expertise: health services research, health systems performance measurement, economic evaluation and HTA, health policy. (WP-lead WP3)

Prof. Richard Dobson (UCL): Professor of Bio and Health Informatics, IMI Radar, EMIF; Expertise: bioinformatics and health informatics; structured and unstructured data; googleizing elastic searchs of entire hospital diverse records. (WP-lead WP3)

Prof. dr. Harry Hemingway (UCL): Director of Farr Institute; Expertise: linked health records and disease registries; Impact: ACS outcomes (Lancet 2014a), CVD risk factors (Lancet 2014b), and records and genomics (Science 2016) (WP-lead WP4)

Dr. Aldo Maggioni (ESC): Director, Research Center Italian Association of Hospital Cardiologists; Scientific Coordinator of the EUObservational Research program of the European Society of Cardiology (WP-lead WP4)

Prof. dr. John Danesh (CAM): European Research Council Senior Investigator, Principal Investigator of EU-FP7 EPIC-CVD. Expertise: CVD target validation (Science 2016, NEJM 2016), large-scale epidemiology (Lancet 2012, 2013) (WP-lead WP5)

Prof. dr. Panos E. Vardas (ESC): Past president ESC, professor of cardiology, chairman European Heart Agency (ESC) (WP-lead WP6)

Susanne Løgstrup (EHN): Director; 20 years' experience in policies to prevent CVD and promote CV health; ESC Fellow; in charge of EHN's, advocacy strategy, research and coordination of EHN's patients' group (WP-lead WP6)

Prof. dr. Hans van Delden (UMCU): Professor medical ethics, president of CIOMS, Chair of the International Bioethics committee, Unesco. Expertise: responsible innovation in drug development and end-of-life(WP-lead WP7)

Prof. dr. Paulus Kirchhof (BHAM): Deputy Director Institute of Cardiovascular Sciences BHAM. Chair, AFNET. Coordinator, CATCH ME. Expertise in identifying disease mechanisms in AF and HF for clinical evaluations and guideline writing (AF-lead)

Prof. dr. Gerhard Hindricks (ESC): Director of the Department of Electrophysiology at the University Leipzig, Heart Centre; President European Heart Rhythm Association (AF-lead)

Prof. dr. Stefan Blankenberg (UKE): Director of the Clinic for General and Interventional Cardiology; Steering Committee member "Functional Genomics" of the American Heart Association. (ACS-lead)

Prof. dr. Josep Redon (INCLIVA): Professor of Medicine. Scientific Director INCLIVA, Research Institute, University of Valencia. Expertise: Clinical and cardiovascular research. (ACS-lead)

Dr. Lars Lund (KI): Assoc. Director SwedeHF Research Program; Assoc. Director the International Society for Heart & Lung Transplantation Registry. Expertise: HF big data and registry comparative effectiveness and pragmatic trials, biomkarers and proteomics. (HF-lead)

Prof. dr. Folkert Asselbergs (UMCU-UCL): Professor of Cardiovascular Genetics, CSO Durrer Center for Cardiovascular Disease; Expertise Translational genomics, Pharmacogenomics, Clinical Cardiology, Biobanking (Scientific coordinator)

Dr. Pieter Stolk (UMCU): Experienced project manager for public private partnerships (incl. IMI GetReal). Expertise: EU pharma policy (incl. HTA/marketing authorization) (Executive coordinator)

Isabel Bardinet (ESC): ESC CEO since 2009 (ESC representative in BigData@Heart operational management team)

Prof. dr. Spiros Denaxas (UCL): Senior Lecturer in Biomedical Informatics; clinical epidemiology; biomedical informatics; semantic technologies; CALIBER; machine learning and data mining (WP3 nucleus)

Dr. Ghislaine van Thiel (UMCU): Medical ethicist. Expertise in ethics of drug development, governance and research ethics. IMI Get Real (WP7 nucleus member)

Prof. dr. Alan John Camm (ESC): Professor of Clinical Cardiology at St. George's University of London and President-elect of European Heart Rhythm Association (AF nucleus member)

Prof. dr. René Eijkemans (UMCU): Professor in biostatistics; Expertise: tatistical methods for prediction and classification in high dimensional data, Survival analysis, clincial trial (WP5 nucleus member)

Prof. dr. Tanja Zeller (UKE): Professor for Genomics and Systems Biology; expertise: molecular biomarkers in the field of cardiovascular diseases, bioinformatics and biostatistics (WP4 & WP5 nucleus member)

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Current projects in Horizon2020

1. **Horizon 2020 call:**
    ESCAPE-NET: Sudden Cardiac Arrest Network

2. **Innovative Medicines Initative 2 call:**
    Big data in cardiovascular medicine

3. **Horizon 2020:**
    CATCH ME

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CATCH ME

Aims: improve the prevention and treatment of Atrial Fibrillation

Develop and validate better disease management strategies based on the improved understanding of the main health modifiers

- Identify the major health modifiers causing AF
- Develop clinical tools to personalise the AF patients management
- Guide and strengthen future strategies to prevent, diagnose, and treat AF

- More info: http://www.catch-me.info/

Current projects in Horizon2020

1. **Horizon 2020 call:**
   ESCAPE-NET: Sudden Cardiac Arrest Network
2. **Innovative Medicines Initative 2 call:**
   Big data in cardiovascular medicine
3. **Horizon 2020:**
   CATCH ME
4. **Horizon 2020 call:**
   RESET SCD Trial

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RESET SCD - Background

- **Main guideline relevant trials 15-20 years old**
- **MADIT II Trial begin July 1997, published 2002**
- **Since then significant changes in therapy reducing mortality:**
- **New drugs, e.g. eplerenone, ARNI**
- **Wider beta blocker use (MADIT II baseline 60%, last follow up 72%) and statin use**
- **Improved revascularization strategies**

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RESET SCD – Trial design

- **Patients with ischemic cardiomyopathy eligible for ICD indication for primary prevention**
- **Randomization: ICD vs optimal medical treatment**
- **Sample size: 3.500 patients**

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- **Two-stage application**
- **Successful in the first stage (10%, threshold 9.5 of 10)**
- **Preparing the full application**
- **Deadline: April 2017**

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- **Importance**
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Complex structure

Societal Challenges
Horizon Prize - Birth Day

H2020-BirthDayPrize-2016

Publication date:28 April 2016

Societal Challenges
H2020-JTI-IMI2-2016-10-two-stage

H2020-JTI-IMI2-2016-10-two-stage

Publication date:21 December 2016

Societal Challenges
H2020-JTI-IMI2-2015-08-single-stage

H2020-JTI-IMI2-2015-08-single-stage

Publication date:18 December 2015

Societal Challenges
Personalised Medicine

H2020-SC1-2016-2017

Publication date:14 October 2015

Industrial Leadership
Horizon 2020 dedicated SME Instrument 2016-2017

H2020-SMEInst-2016-2017

Publication date:14 October 2015

Industrial Leadership
Internet of Things

H2020-IOT-2016-2017

Publication date:14 October 2015

Societal Challenges
Digital Security Focus Area

H2020-DS-2016-2017

Publication date:14 October 2015

In addition to the search facilities, the full list of H2020 Calls can be found here.

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Very competitive

The Commission has now completed the evaluation of the proposals submitted to the above-mentioned call.

The following overall thresholds were applied:

Topic code	Topic short name	Overall threshold applied
SC1-PM-02-2017	New concepts in patient stratification	9.0
SC1-PM-07-2017	Promoting mental health and well-being in the young	8.0
SC1-PM-08-2017	New therapies for rare diseases	8.5
SC1-PM-10-2017	Comparing the effectiveness of existing healthcare interventions in the adult population	9.5

The results of the evaluation are as follows:

Number of proposals submitted (including proposals transferred from or to other calls): 668
Number of inadmissible proposals: 0
Number of ineligible proposals: 0
Number of above-threshold proposals: 101
Total budget requested for above-threshold proposals: EUR 560.480.405,00

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EHRA involvement in Horizon2020

- **Important!**
- **Opportunities for funding big, relevant projects**
- **Difficult, but doable**

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