

Saturday 28 July 2018



# GUARD-Heart

Gateway to Uncommon And Rare Diseases of the Heart



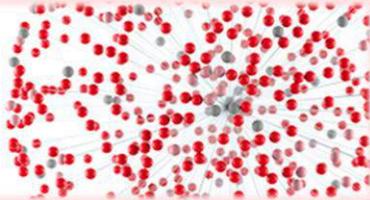
ERN GUARD-HEART BIMONTHLY NEWSLETTER

YEAR 2018 NUMBER 4

**ESC Congress  
Munich 2018**

25-29 August

Where the world of  
cardiology comes together



## 4<sup>th</sup> meeting of ERN GUARD-Heart Board

**Tuesday, 28 August 2018**

**9:00-12:30 (followed by lunch)**

**Hotel Prinzregent (Riemer Straße 350)**

**Munich, Germany**

*(walking distance from ESC Congress venue)*



ERN members who wish to discuss a topic or provide a presentation can contact the project management office.

The agenda of the meeting will be disseminated among the members around mid August 2018.

## CPMS Workshop

*during the 4<sup>th</sup> Board Meeting*

CPMS is a secure online consultation system for 2<sup>nd</sup> opinion service within ERNs. Each healthcare provider (HCP) in ERN GUARD-Heart will be assessed by the European Commission with regard to its activities in the CPMS.

During the 4<sup>th</sup> ERN GUARD-Heart Board meeting, a workshop will be held on how to use the CPMS to discuss cases & provide expert comments on request.

For the purpose of this workshop, HCP leaders are requested to introduce a case from their practice in CPMS prior to the meeting. For assistance, please contact the project management office.



Co-funded by  
the European Union





## ERN News



### Assessment of ERN GUARD-Heart Members by the European Commission

Brussels, 28 June 2018

As anticipated in the Newsletter of March 2018, DG SANTE and Consumers, Health, Agriculture and Food Executive Agency (CHAFAEA) of the European Commission (EC) will carry out, on annual basis, a technical assessment of a sample of ERN members' applications received under the framework of the call for interest for ERN in 2016. On 28 June, DG SANTE published the list of the ERN GUARD-Heart members that will be assessed by the Andalusian Agency for Healthcare Quality (ACSA). The centres that are selected for the 2018 assessment exercise are "*Emergency Institute for cardiovascular disease: Prof dr. C. C. Iliescu*" (Bucharest) for technical assessment and on-site visit, & "*University Hospital Virgen de la Arrixaca*" (Murcia, Spain) for technical assessment. DG SANTE has reassured ERNs that their members have been selected in an objective way respecting a ratio between the magnitude of the Networks and a geographical balance.

On 11 July 2018, ERN GUARD-Heart management office had a teleconference with the representative members of the selected centres (Ruxandra Jurcut and Juan R. Gimeno) to discuss some preparatory work with regard to the planned assessment. ♥

### 2<sup>nd</sup> Year ERN Specific Grant Agreement Approved by EU

Amsterdam, 26 July 2018

The Specific Grant Agreement (SGA) for the ERN GUARD-Heart for the years 2018-2019 has been approved by the European Commission (EC). The content of the SGA was fully in line with the 5-year-work programme 2017-2021 for the Framework Partnership Agreement (FPA) for ERN. The approved version of the SGA is available at the [IT-platform](#). ♥

### GDPR & Patient Data



Brussels, 25 May 2018

The General Data Protection Data Regulation (GDPR) of the EU has come into force on May 25, 2018. GDPR governs the storage and processing of data, & introduces an obligation on organisations to notify relevant authorities of any personal data breach likely to result in a risk to the rights and freedom of EU subjects. In order for healthcare providers to comply with GDPR, there are a number of requirements that must be adhered to. One of these requirements is that personal data are processed in a lawful, fair, transparent and secure manner. To prompt health organisations to ensure they comply with GDPR, penalties up to €20 million or 4% of global turnover have been introduced for breaching the Regulation.

Sharing patient data by email or currently available online tools increases the risk of data breaches. It is for this reason that, before using email or online tools for data transfer, each healthcare provider is required to conduct a data protection impact assessment (DPIA) to identify and reduce the data protection risk, and thereby reduce the likelihood of privacy harms to patients. DPIAs should be stored and be available for review and assessment by authorities in case of data breaches.

In daily practice, this implicates that healthcare providers may not be allowed to share patient data anymore by email or tools such as Wetransfer and Dropbox. However, it is important to note that the Clinical Patient Management System (CPMS) and the official CPMS patient consent form fully comply with GDPR, and can be used within ERNs to share data, for online consultation, and for 2<sup>nd</sup> opinion service. ♥



## Conferences & Meetings

### ERNs and Clinical Research

Workshop by RD-ACTION, DG SANTE & European Medical Agency

London, 29 May 2018

On 29&30 May, RD-ACTION, in collaboration with the DG SANTE and the European Medical Agency (EMA) organized a workshop on “How can ERNs add value to clinical research in rare diseases and highly specialised domains?” at the EMA in London. ERN GUARD-Heart was represented by Andrea Mazzanti, cardiologist from the Clinical Scientific Institutes Maugeri IRCCS (Pavia, Italy). At the workshop, current ways in which the European Commission (EC), ERNs, EMA and other European partners add value to research were discussed.

The EC funds clinical research in several forms, e.g., through co-funding ERNs, “Research and Innovation” ([website](#)), E-RARE ([website](#)), and International Rare Disease Research Consortium (IRDRC; [website](#)). The Horizon 2020 work programme for 2018-2020 will form a new opportunity for the EC to fund research (deadline to present projects will be April 2019).

ERNs, on the other hand, aim to add value to clinical research by establishing an ERN **Working Group on Research** (*ERN GUARD-Heart is a member of this Working Group*). This **Working Group on Research** aims to potentiate the research capabilities of individual ERNs by means of cooperation and mutual reinforcement in common strategic areas and activities, building up on existing resources and capabilities, and promoting new developments in a harmonized and integrative way. In addition, ERNs have in recent past collaborated to participate in the writing of the European Joint Programma Co-fund proposal.

An important group that links scientific partners and networks across the EU to facilitate multinational clinical research is the European Clinical Research Infrastructure Network (ECRIN). ECRIN, a public, non-profit organisation, provide sponsors and investigators with advice, management services and tools to overcome hurdles to multinational trials and enhance collaboration ([website](#)).



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

The EMA supports research by providing scientific advice (but does not contribute in designing trials) and is responsible for the databases. In addition, the role of EMA is crucial in supporting the development of medicines (e.g., orphan drugs) and new diagnostic methodologies, and their approval. Importantly, application for orphan drugs may be sent for evaluation directly to the EMA (instead to national authorities), and if accepted by EMA, they are automatically accepted in all EU Member States. Moreover, EMA is interested in the creation and maintenance of registries, especially for the natural history of rare disorders. EMA maintains a [website](#) to track all clinical trials produced in Europe.

At the workshop., attendees suggested some ideas on how to work together to add value to clinical research in the EU. Such ideas included designing a survey to prioritise research topics, creating a registry of trial sites for patients to facilitate their participation, and future activities to centralize and harmonize the process for the approval of a clinical trial. ♥



## Conferences & Meetings

# EU Conference on the ERNs “ERNs in Action”

**European Commission, Brussels, 6 June 2018**

Since the first conceptualisation of the ERNs system, many challenges have been addressed and actions developed that have made ERNs a reality today. It is important to keep in mind that the complexity and ambition of the ERN model implies a continuous and proactive analysis of the many challenges that ERNs are facing in the current deployment phase and those that will arise in the future.

On 21 & 22 November, an event called “ERNs in Action” will be organized by the EU. This events will provide the opportunity to gather all the actors involved in the ERNs system in order to learn about the experience so far and find ways and ideas to address the future of the ERNs in the EU.

ERN GUARD-Heart will be represented by: Philippe Charron, Silvia Priori, Georgia Sarquella-Brugada, Jacob Tfelt-Hansen, Carlo de Asmundis, Jaana Pihkala, & Arthur Wilde (HCP representatives), Patricia Vlasman & Dayenne Zwaagman (patient representatives), Nynke Hofman & Ahmad Amin (project management). ♥

## ERN Activities

# IT Helpdesk for ERN GUARD-Heart Members

**Amsterdam, 25 July 2018**

From 1<sup>st</sup> September 2018, ERN GUARD-Heart will set up an IT Helpdesk to facilitate & ensure adequate and efficient use of the information systems for the ERNs: i.e., the Clinical Patient Management System (CPMS) and the IT Collaborative Platform. CPMS is a secure online consultation system for 2<sup>nd</sup> opinion service within ERNs. The IT Collaborative Platform is a restricted online space for ERN communications and administrative document management. Each healthcare provider (HCP) in ERN GUARD-Heart will be assessed by the European Commission with regard to its activities in CPMS and the IT Platform.

The IT Help desk will consist of two staff members: Ms. Evelien van der Schaaf (Medical Informatics) and Mr. Hidde Bleijendaal (Medicine). The IT Helpdesk will be responsible for training the ERN members to use the information systems of the ERN, assisting the ERN members in introducing patients data into the CPMS and create discussion panels, provide support for local hardware and/or software, and provide phone (or if necessary face-to-face) support for all the ERN members. Further details on how to contact the IT Helpdesk for support will be provided at the 4<sup>th</sup> ERN Board Meeting on 28 August 2018. ♥



**European  
Reference  
Network**

for rare or low prevalence  
complex diseases

**Network**  
Heart Diseases  
(ERN GUARD-HEART)

Co-funded by  
the European Union



# SAVE THE DATE

**Educational Course on  
Sudden Cardiac Death  
& Familial Electrical Diseases**

**6 December 2018 – London, UK**

**ERN GUARD-Heart  
Project  
Management  
Office**



**Arthur A.M. Wilde**  
Network Coordinator  
Academic Medical Center  
Amsterdam, Netherlands  
Email: a.a.wilde@amc.nl  
Phone: +31205662904



**Nynke Hofman**  
Research Manager  
Academic Medical Center  
Amsterdam, Netherlands  
Email: n.hofman@amc.nl  
Mobile: +31622046435



**Ahmad S. Amin**  
Project Manager  
Academic Medical Center  
Amsterdam, Netherlands  
Email: a.s.amin@amc.nl  
Mobile: +31614471713