

Friday 26 January 2018



GUARD-Heart

Gateway to Uncommon And Rare Diseases of the Heart



ERN GUARD-HEART BIMONTHLY NEWSLETTER

YEAR 2018 NUMBER 1



Third Meeting of the ERN GUARD-Heart Board

20 December 2017 – Amsterdam, Netherlands

The third official Board Meeting of ERN GUARD-Heart was held on Wednesday 20 December 2017 in Amsterdam, the Netherlands.

The meeting was attended by representatives of 18 ERN members: Anwar Baban (Rome), Cristina Basso (Padua), Elijah Behr (London), Connie Bezzina (Amsterdam), Alida Caforio (Padua), Philippe Charron (Paris), Philippe Chevalier (Lyon), Lia Crotti (Milan), Juan Gimeno (Murcia), Ruxandra Jurcut (Bucharest), Juan Kaski (London), Daniele Masarone (Napels), Jaana Pihkala (Helsinki), Silvia Priori (Pavia), Victori Fiol Ramis (Barcelona), Georgia Sarquella-Brugada (Barcelona), Eric Schulze-Bahr (Munster), Jacob Tfelt-Hansen (Copenhagen), Aurelie Thollet (Nantes), Patricia Vlasman (Patient Advocacy Board), Arthur Wilde (Amsterdam), Rik Willems (Leuven), and Nynke Hofman and Ahmad Amin(project management office).

Among others, the following topics were discussed: the Clinical Patient Management System (CPMS), the IT platform, research and registries, education strategy and plans, extension of the ERN GUARD-Heart in 2018, and external communication strategy and tools. The thematic area leaders provided an update of the activities of their groups. In addition, Patricia Vlasman provided a presentation behalf of the Patient Advocacy Board of the Network (*see photo below*). During parallel Sessions, the cross-cutting action groups discussed subjects that are important for all thematic areas. The notes of the meeting are available at the IT Platform. To visit the Platform, go to: <https://webgate.ec.europa.eu/ern/> ♥





Procedure for extension of the ERN

13 December 2017 – Brussels, Belgium

In 2018 there will be a new opportunity for highly specialised healthcare providers to join the existing ERNs, in particular to complete their coverage and clinical capacity. Independent assessment bodies will evaluate membership applications as provided for in the Commission Implementing Decision of 10 March 2014 (2014/287/EU). In particular, the assessment bodies will verify:

- whether the contents of membership application are complete, in line with the requirements in the Commission Implementing Decision,
- whether the healthcare provider concerned fulfils the criteria and conditions in Annex II to Delegated Decision (2014/286/EU9) and detailed in the assessment manual developed by the European Commission ('operational criteria'). The assessment should include the specific criteria further developed by the ERNs.

The assessment reports will provide the basis for the ERN Board of Member States to decide on the approval of the new ERN members.

The indicative timeframe for launching the procedure is the second half of 2018. The Call will be published by the European Commission DG SANTE.

For the ERN GUARD-Heart this will lead to increased numbers of healthcare providers per thematic area and to the establishment of new thematic areas, e.g., for the congenital heart defects. ♥

EU Health Programme (2014-2020)

Annual work plan for 2018

13 December 2017 – Brussels, Belgium

The 2018 work plan for the EU Health Programme has been published and can be found here:

https://ec.europa.eu/health/sites/health/files/programme/docs/wp2018_annex_en.pdf

There are a number of calls of specific applicability for the ERNs and that are of interest to the rare disease field. These calls (and their numbers) are listed below:

2.13 Orpha code Project

2.1.4 Multiannual specific agreements for ERNs

2.5.1 Orphanet

4.13 Assessment of HCPs wishing to join existing ERNs

4.14 Implementation of the ERN

5.1 Direct agreement with the Joint Research Centre ♥

**IMPORTANT
NOTICE**

Clinical Patient Management System

The European Commission has released the Clinical Patient Management System (CPMS), a secure online consultation system for second opinion service within the ERNs. CPMS is part of the clinical care and therefore approval of medical ethical committee for research is not required. Using CPMS, ERN experts can discuss their patients within the ERN, and can be invited to provide second opinion advice within the ERN.

Each participating centre within ERN GUARD-Heart will be assessed by the European Commission (EC) with regard to its activities within the CPMS.

It is of extreme importance that all ERN GUARD-Heart members have an CPMS account. The project management office of ERN GUARD-Heart will request the European Commission Helpdesk to create an CPMS account for all the representative members of the 24 centres within the ERN GUARD-Heart. However, for this, an EU Login is required.

Members who have an EU Login will be contacted by EU Helpdesk soon. Members who still do not have an EU Login are urgently requested to create an EU Login here: <https://webgate.ec.europa.eu/cas/>

ERN members can also create an CPMS account by themselves. To do this, please visit the IT Platform (<https://webgate.ec.europa.eu/ern/>) and download the user manual with instructions how to create an account and how to use the CPMS.

There is a CPMS training area. To use this area visit: <https://cpms-training.ern-net.eu/login/> For logging in to the training environment for CPMS, you need to use one of the following training accounts:

guardheartpuser1
guardheartpuser2
guardheartpuser3
guardheartpuser4
guardheartpuser5
guardheartpuser6
guardheartpuser7
guardheartpuser8

The password for all the accounts is **cpmsern**. On the login page for the training area you need to select the option: non-eulogin users (test only). ♥



ERN GUARD-Heart Registries

20 December 2017 – Amsterdam, Netherlands

The EU requests the ERN GUARD-Heart has to deliver links to registries before end of February 2018. In addition, evidence that patients have are being enrolled into the registries should be provided.

After discussing this topic at the second meeting of the ERN GUARD-Heart Board, the following registries will be delivered to the European Commission:

- *CALM* genes. Coordinators: Peter Schwartz and Lia Crotti (RedCap)
- CPVT. Coordinator Arthur Wilde (OpenClinica)
- *FLNC*. Coordinator Perry Elliott
- LQTS. Coordinator Connie Bezzina (RedCap)
- *PRKAG2*. Coordinator Philippe Charron & G. Laurent (RedCap)
- LQT8 (*CACNA1C*). Coordinator Georgia Sarquella-Brugada (RedCap)
- SQTs. Coordinator Silvia Priori (RedCap)

At future ERN Board meeting, other registries will be discussed, including the Brugada syndrome registry, *LMNA* gene registry, and Danon disease registry. ♥

Disease-specific patient materials

10 January 2018 – Amsterdam, Netherlands

In collaboration with the Patient Advocay Board of the ERN GUARD-Heart, with the expert assistance of Elijah Behr (St George's Healthcare NHS trust), and thanks to all members of the ERN GUARD-Heart who provided their institutional patient materials to the ERN, the project management office has produced six patient information folders for patients and families with the following inheritable cardiac diseases:

- Brugada syndrome
- catecholaminergic polymorphic tachycardia
- Long QT syndrome
- Arrhythmogenic right ventricular cardiomyopathy
- Dilated cardiomyopathy
- Hypertrophic cardiomyopathy

The folders have been published on the website of the ERN (<http://guardheart.ern-net.eu/disease-specific-brochures/>). The folders are currently only available in English, and will be translated to native European languages in the future. ♥

ERN Participation in LQT5 Registry

ERN GUARD-Heart has been invited to participate in the international LQT5 (*KCNE1*) registry, which is coordinated by Jason Roberts (London Health Sciences Centre, Ontario, Canada). Members of the ERN GUARD-Heart may be approached by Jason Roberts for participation and/or can contact the ERN project management office for information on how to participate in this Registry. ♥

Spreadsheet for next ERN meetings

The ERN management office aim to plan meetings for the ERN Board and the thematic areas. To do this, all ERN members are requested to fill in their availability at the 2018 EHRA, HRS, and ESC meetings in the Google spreadsheet available at : <https://docs.google.com/spreadsheets/d/1cCSgepssKAjNoEeC0DagnRC4vzic6Ms5uLTemyQti48/edit> ♥

Deliverables of the ERN GUARD-Heart project for 28 February 2018

According the annual work plan of the ERN GUARD-Heart. The Network must deliver 10 deliverables before the end of February 2018.

The deliverables are:

1. Update list of Network healthcare providers
2. Annual work programme for 2018/2019
3. Patient Registries
4. Quality and Safety Framework
5. Benchmark studies
6. Collaborative strategy with ERNs and public or private institutions
7. Annual report on research projects & trials
8. Network activity evaluation report
9. Annual Network Newsletter
10. Policy on the declaration of conflict of interest



The First ERN GUARD-Heart Publications on PubMed

26 January 2018 – Amsterdam, Netherlands

Official membership of ERN GUARD-Heart can be stated in scientific publications as a separate affiliation using the following text: *Member of the European Reference Network for rare, low prevalence and complex diseases of the heart - ERN GUARD-Heart*. However, according to EU regulations, a scientific publication is considered as an ERN article if members from at least 2 or more ERN centres are co-authoring on the paper. Based on this regulation, the next PubMed items are considered as ERN GUARD-Heart publications:

Empana JP, Blom MT, Böttiger BW, Dagnes N, Dekker JM, Gislason G, Jouven X, Meitinger T, Ristagno G, Schwartz PJ, Jonsson M, Tfelt-Hansen J, Truhlar A, Tan HL; ESCAPE-NET Investigators. Determinants of occurrence and survival after sudden cardiac arrest - A European perspective: The ESCPAE-NET project. Resuscitation. 2017;124:7-13.

O'Mahony C, Jichi F, Ommen SR, Christiaans I, Arbustini E, Garcia-Pavia P, Cecchi F, Olivotto I, Kitaoka H, Gotsman I, Carr-White G, Mogensen J, Antoniadis L, Mohiddin S, Maurer MS, Tang HC, Geske JB, Siontis KC, Mahmoud K, Vermeer A, Wilde A, Favalli V, Guttman O, Gallego-Delgado M, Dominguez F, Tanini I, Kubo T, Keren A, Bueser T, Waters S, Issa IF, Malcolmson J, Burns T, Sekhri N, Hoeger CW, Omar RZ, Elliott PM. An international external validation study of the 2014 European Society of Cardiology Guideline on Sudden Cardiac Death Prevention in Hypertrophic Cardiomyopathy (Evidence from HCM). Circulation. 2017. pii: CIRCULATIONAHA.117.030437.



EUROPEAN REFERENCE NETWORKS
FOR RARE, LOW-PREVALENCE AND COMPLEX DISEASES

Share. Care. Cure.



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