



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Unit B3 European Reference Networks and digital health

MINUTES OF MEETINGS: BOARD OF MEMBER STATES ON ERNs

DATE: 05 OCT 2022, / LOCATION: (HYBRID) BRUSSELS, BE + ONLINE

PARTICIPANTS:

Commission Units: DG SANTE, HADEA

Member States: Austria, Belgium, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain, Sweden.

Invited: Contractor (infeurope & Mercury-97)

AGENDA

CO-CHAIRS: ANDRZEJ RYS AND TILL VOIGTLÄNDER		
1	9:15 – 9:45	Opening of the meeting <ul style="list-style-type: none"> - <i>Welcome</i> - <i>Reorganisation of DG SANTE and introduction of the new ERN team</i> - <i>Approval of the agenda and minutes of the last meeting</i>
2	9:45 – 10:00	Update from the Commission <ul style="list-style-type: none"> - <i>Funding of ERNs</i> - <i>Evaluation of ERNs (AMEQUIS)</i> - <i>Discussion</i>
3	10:00 – 10:15	Update from the BoMS co-Chair <ul style="list-style-type: none"> - <i>Presentation (Till Voigtländer, MS Co-chair of BoMS)</i> - <i>Discussion</i>
4	10:15 – 10:40	Update from the ERN Coordinators Group <ul style="list-style-type: none"> - <i>Presentation (Alexis Arzimanoglou, Co-chair of ERN CG)</i> - <i>Reimbursement of CPMS panels - lessons learnt</i> - <i>Discussion</i>
5	10:40 – 11:05	Changes in Working Groups <ul style="list-style-type: none"> - <i>Proposal for creation of a WG for managing ERN activities</i> - <i>Future of the WG on Integration</i> - <i>Presentation (ERN Project Managers representative)</i>



		- <i>Discussion</i>
6	11:30 – 13:00	Joint Action on integration of ERNs into national health systems <ul style="list-style-type: none">- <i>Presentation (Commission + Till Voigtländer)</i>- <i>Discussion</i>
7	14:00 – 14:30	Changes in the scope of expertise at ERN level <ul style="list-style-type: none">- <i>Approval by BoMS of applications for changes in the scope of disease coverage at ERN level</i>- <i>Presentation (Commission)</i>- <i>Discussion and Decision</i>
8	14:30 – 15:00	Report from Working group on monitoring, ITAG and new CPMS <ul style="list-style-type: none">- <i>Presentation (WG Chair & Commission)</i>- <i>Discussion</i>
9	15:00 – 15:15	Report from Working group on knowledge generation <ul style="list-style-type: none">- <i>Presentation (WG Chair)</i>- <i>Discussion</i>
10	15:15 – 15:45	Report from Working group on Legal and Ethical issues <ul style="list-style-type: none">- <i>Presentation (WG Chair)</i>- <i>Discussion</i>
11	15:45 – 16:10	ERN Research activities <ul style="list-style-type: none">- <i>EU RD Platform</i>- <i>Presentation (JRC)</i>- <i>Discussion</i>- <i>Preparations of Rare Disease Partnership</i>- <i>Presentation (Commission)</i>- <i>Discussion</i>
12	16:10 – 16:15	Any Other Business

1. Opening of the meeting

Welcome

The Chair opened the meeting, and all participants were welcomed. Technical information followed as this was a hybrid meeting. (10 Member States and Norway present in the room and 14 Member States online).

Reorganisation of DG SANTE and introduction of the new ERN team

The Chair announced that a reorganisation had taken place at DG SANTE and that it entered into force on 1 October. The most relevant aspect of the reorganisation for the ERN file is its transfer to a unit in Luxembourg (called B3), which will be in charge of health networks and also the policies on rare diseases, among others. The Chair then presented the new team in charge of ERNs, who introduced themselves and shared previous experience and expectations. The Director General of the Directorate of the new unit in charge of ERNs addressed the attendees and spoke about the upcoming investments of the Commission and its commitment to better structure and streamline the ERNs to assure the ERN Reference Network project is taken forward.

2. Update from the Commission

Funding of ERNs

The Commission gave a brief overview of the funding of ERNs and explained that the grant proposals that will fund ERNs from March 2022 to August 2023 were evaluated by HADEA during the summer of 2022 and explained that almost all ERNs had already signed the grant agreements. The Commission explained that there would be a new call in 2023 for the funding of ERNs from September 2023 onwards. This call was conceived to be multiannual and with a higher budget. However, the duration and final budget remain under discussion until the approval of the WP2023.

The Commission explained that it is carrying out a study to determine the feasibility to introduce a simplified funding scheme based on Financing Not Linked to Costs, which would ease the bureaucratic burden.

Evaluation of ERNs (AMEQUIS)

The Commission explained that the 5-year evaluation of ERNs will start later this year by an independent assessment body, whose contract has just been signed. The evaluation will follow the recommendations of the AMEQUIS project. A total of 835 units from all twenty-four networks will be evaluated as the new members of ERNs (the ones that joined the ERN system on 2022) will not be evaluated.

The Commission commented that the objective of the evaluation will be to determine if ERNs and HCPs have achieved the objectives for which ERNs were created. In case of weak results, improvement strategies will be proposed and their effectiveness will be re-evaluated in 1 year time.

The Commission explained that the evaluation will start beginning of November at the latest. An IT platform will provide exchange of documents and a Help Desk. Deadline for the final evaluation reports for each ERN / HCP was set for September 2023.

3. Update from the BoMS Co-Chair

The Chair presented the first conclusions of the Co-Chair period from 2021-2022. Two main activities were addressed: (1) implementing new communication and reflection strategies



between members of BoMS, the co-chairs of the ERN CG, and EC; and (2) the increased participation of the BoMS in Working Groups (WG).

He gave a positive opinion on the new communication and reflection strategies, which involved holding: (a) virtual reflection meetings of the BoMS; (b) preparatory meetings between the ERN CG and BoMS Co-Chairs along with some BoMS representatives; and (c) regular meetings between EC and BoMS Co-Chairs.

Within virtual reflections meetings of the BoMS, the topic of AMEQUIS and the Joint Action (JA) on Integration were addressed. Five meetings were dedicated on the latter with most MS participating. The final document shaping the structure and main elements of the JA was sent to the Consortium members.

In the preparatory meetings between ERN CG and BoMS Co-Chairs, topics were discussed which related to the New Orphanet project D4RD, the upcoming monitoring process, the Direct Action Grant on Integration, the ERN CG Participation at Stakeholders event on EU4Health funding call, timelines and stipulation for next ERN HaDEA Call, nomination of a new LES BoMS Co-Chair, the imminent transfer of ERN File to DG SANTE in Luxembourg, ongoing procedures and evaluations of the past 5 years, as well as bridging grants for ERNs.

A total of 7 meetings were held between EC and the BoMS Co-Chairs, which helped to clarify internally selected urgent or general strategic issues.

Overall, the outcome of these various meetings was considered a success because these meetings led to improved communication and brought forth different perspectives on specific issues.

Of important note, however, is that there currently exists a deficiency in communication with the hospital managers, as there is currently no official group of hospital manager representatives.

Regarding the second activity – the increased participation of MS in WG – the BoMS Co-Chair stated that more MS participation is needed, specifically within the Monitoring WG, Legal and Ethical Issues (LES) WG, and the IT WG (ITWG).

As the Monitoring WG was created by the request of MS, their participation is key in order to address the monitoring process and any deficits analysed by ERN Coordinators. Their working profile is to hold ongoing discussions as well as perform strict quality assurance on the monitoring processes. Analysis must be made on the deficits –misunderstanding of indicators, wrong data and variation on data granularity across ERNs. All this information is crucial for MS.

For the LES WG, the position of MS BoMS Co-Chair remains vacant and a critical topic for discussion – the collaboration between ERNs and industry – needs to be addressed. Due to the fact that this issue goes legally beyond ERNs and their Coordinator's competency, it is critical that MS get involved and partake in these discussions so a solution can be found. The BoMS Co-Chair stated that action must be taken to fill the vacant position of BoMS Co-Chair in LES WG and proposed to solve the issue later this year once the transfer of the ERN file to DG SANTE in Luxemburg is completed.

ITAG holds pertinent discussions regarding all relevant aspects of the IT infrastructure for the old and new CPMS, the ERN Academy, and communication platforms.

New activities and strategies for the BoMS were proposed, one of which was for conducting 2-3 regular meetings per year: spring, summer and autumn. Several BoMS agreed on changing the structure of meetings as currently, little room is left for discussions.

When reviewing the planned activities on the transfer of the ERN file from BRU to LUX, the BoMS Co-Chair commented that there is a risk of complete loss of physical memory on the side of the EC as only one member is transferring from Brussels to Luxembourg. He mentioned that the participation of MS will be now even more important than before as there are great challenges ahead and MS have the co-responsibility and co-governance of the ERN file.

The Commission iterated that the transfer of the file is being done calmly and that all the knowledge is being transferred to the new location. The Commission also explained that colleagues that had been working on the file will meet regularly with the new unit to discuss ERN issues, and that they will be available to answer questions so as to ensure a smooth transition. The BoMS Co-Chair expressed gratitude towards all colleagues, MS, doctors and patients for all the help and work done.

4. Update from the ERN Coordinators Group

The ERN-CG Co-chair gave an overview of how challenging for the coordinators had been the task of setting up ERNs. Coordinators accepted the challenge and worked to the best of their possibilities, for which they are very proud. However, there are aspects that are out of their hands, for instance the disparity in costs and availability of genetic tests which are essential to diagnose some rare diseases. A recent survey showed only 55% of the population have access to genetic tests. Price ranges from EUR 0 to EUR 6,000 with waiting times from 1 week to 52 weeks. Co-Chair stated this issue is of great relevance and needs urgent actions and further discussions.

The ERN-CG Co-Chair stressed the effort that the volume of administrative and reporting procedures represent, particularly in the last period March-October 2022 during which the submission of the “Bridging Grant” and the reporting of the previous grants have overlapped.

The wish was expressed that the rest of the bridging grant period should be used constructively and more effectively.

Proposals were made on the following topics:

- A transition period to be provided and a working group to be created knowing the ERNs should work on a consensus for adapting ERN development processes to discuss and address critical issues. Work on a model that will allow easier inclusion of the ERN members as third parties to the Grant Agreement; whenever needed the WG to make innovative proposals on changes in regulations to better serve the patient’s needs.
- Collaboration between different counterparts to share ideas. As different counterparts know things others may not know – collaboration is needed.
- Before the launching of the new evaluation process, an informational meeting is to be organised between the Independent Evaluation Body, representative from DG SANTE, BoMS, HADEA and the Chair of CG’s.
- Request an annual management budget of one million euro (corresponding to less than 1 euro per year for each patient with rare disease) for the stability of human resources, communication, networking, Guidelines production, and for the support of local registries and CPMS activities.

Reimbursement of CPMS panels



The ERN-CG Co-chair gave a short overview of the pilot project for the reimbursement of CPMS panels.

A comparison of the results of a short survey of answers given by 11 ERNs (one ERN did not participate in the study) was provided:

- 5 ERNs plan to use the 200 € per panel to compensate the one HCP which has an expert assigned as the lead of panel (for some ERNs the same health provider who upload the case is the one that is funded; expert from other HPC's will not receive compensation).
- 2 ERNs plan to share the amount between the leader of the panel and the HCP uploading the case.
- EYE plan 50€ for the HCP and 150 € for the HCP of the panel leader who delivers a recommendation on the case.
- ERNICA plan 100€ for the panel lead namely uploading and presenting the case and 100€ for the CPMS Chairman.
- 3 ERNs plan to share the 200€ between all HCP presented at a panel.
- EURACAN will share the 200 € per panel among different HCPs represented by the expert giving advice.

The Co-chair concluded that the financing model of CPMS panels appears to be ERN dependant and that in general it is better to compensate the hospital who took the time to upload the case. He also commented that CPMS has been open to other medical fields – now more specialists from various areas are needed which impacts the support needed. A reminder was made to the BoMS that other countries (outside the EU) keep turning for help and free treatment in Europe.

The Commission explained that the experience gained from this pilot program was very important as it would inform future policy options that go beyond ERNs.

5. Changes in Working Groups

Proposal for Creation of a WG for managing ERN Activities:

A proposal was presented to the BoMS regarding the creation of a WG to track the management activities of ERNs. Informal meetings have been held since 2018, with each ERNs taking turns to organise and run each meeting. The proposed governance structure is to mirror the ERN CG, with it being a free group open for all stakeholders and ad hoc experts. There are many possible projects to address, such as coordination with Patient Associations or Grant Management (Financing not linked to costs). The added value of having this WG would be enhanced communication between ERN Project Managers and Coordinators with DG SANTE, HaDEA, ERN CG, the BoMS, and with stakeholders. It would also add harmonisation in the work being done by Project Managers, enabling them to share good practices and build on the knowledge gained. Furthermore, the WG could be a contact point for all ERN Stakeholders.

Discussion

The Commission and the ERN CG supported the idea of having a WG on Management Activities.

ES mentioned that the representation of Project Managers has shown that they are not only important, but also key in what is being developed with ERNs.

FR suggested that the grouper CG create a link between the ERN Project Managers and physicians. Clarification was provided that the idea is for this to be a multi-stakeholder WG where things can be addressed together for avoiding additional efforts and simplify the work for everyone.

The EC Co-Chair clarified that there remains final decisions to be made about the leadership of the WG, the participation of HaDEA, BoMS, ERN CG, and other stakeholders which should be integrated.

Following no objections, the BoMS agreed to formalise the ERN WG on Management Activities.

Future of the WG on Integration

With the imminence of the JA fast approaching, questions were being raised about the future of the ERN WG on Integration. Since this group focused on compiling much of the preparatory work necessary for the JA, there is a concern regarding the possibility of creating redundant work. In order to avoid doing so, two options for the future of the WG on Integration were proposed: (1) disbanding the WG; (2) pausing its activities for the time being and reviving it, if necessary, following the mandate of the JA.

There was an overall agreement to suspend the activities of the WG on Integration for the time being, with the possibility to revive it. LT mentioned the practical need for the WG due to it being a body which produces draft documents and proposal for wider discussions. PL also suggested that should the activity of the WG on Integration be required within the work of the JA, it could be included in the WP on Sustainability.

6. Joint Action on integration of ERNs into national health systems

The BoMS Co-Chair gave an overview of the objectives of the Joint Action and of its structure. Joint Action 05 supports ERN integration into national healthcare systems of Member States, and primarily concerns national authorities as it addresses high policy level demands and challenges to provide solution with high public interest within the EU. He explained that the primary objective is for Member States authorities to develop their national strategies, solutions, and infrastructures, so that a successful implementation of on key element can be had. There are four principal modes of participation: (1) Competent Authority – the deadline of application having passed (01 Sept. 2022); (2) Affiliated Entity – the deadline for which is on 17 Jan 2023; (3) Subcontracting of well-defined activities; (4) in kind contributions. The current maximum funding is EUR 11.2 million with two possible options of co-funding – 60% or 80%. Due to the total of 28 MS (26 MS plus Norway and Ukraine) participating in the JA 05, the co-funding rate of exception utility of 80% will be applicable. The maximum budget is set at EUR 14 million for three years. Of the 26 participating EU Member States, at least 9 institutions hosting members of ERNs, which ensured a high representativity of ERNs in the JA.

There are a total of 9 Work Packages (WPs), the first four of which are obligatory. Member States have also expressed their wish to lead certain WPs.

1. Coordination (AT)
2. Dissemination & ERN Dissemination (ES)
3. Evaluation (HR)
4. Sustainability & National Plan Capacity (CZ, LT)



5. National governance and quality assurance models (IT, (PL))
6. National care pathways and ERN referral systems (IT, LT, IR)
7. National reference networks and undiagnosed disease programmes (DE, AT)
8. Data management (FR, CZ)
9. National support options for ERN-HCP (CZ, FR)

The tasks at hand remain to define the tasks, deliverables, milestones, indicators, etc., of each respective WP. An overview of the general and specific objectives for each WP was also shared. The recommended workflow is to have a meeting a week between October and November, one for every WP, with WP2 starting on 13 Oct. 2022. There will also be discussions in parallel for WP1 on Coordination.

Urgent matters remaining to be addressed are the final decision on a few WP lead positions, clarifications on the status of partners (CA vs. AE), and where to store relevant documentation.

Discussion

The BoMS Co-Chair provided clarifications on the definition of Affiliated Entities, which Member States should note in their AE applications.

LT, MT, SE, CZ, IT, HU, IR all shared local methods regarding how to integrate AEs within their respective country so as to adhere to the proper WP. However, further clarifications are needed in terms of how to translate CA-AE relationship into the existing structure in Member States.

7. Changes in the scope of expertise at ERN level

The Commission gave a brief introduction of the expansion of diseases that was launched during the summer of 2022 with the aim to update and expand the coverage of thematic and sub thematic areas of ERNs.

The Commission explained that only 9 ERNs had requested for the expansion of diseases and that 11 ERNs claimed they had no need for such expansion. The requests were sent to the BoMS for approval, who noticed that some ERNs had asked for expansion of diseases that were covered by other ERNs. The Commission commented that before any expansion, there was already some overlapping between the diseases covered by the different ERNs. The BoMS concluded that this was a complex topic that needed further discussion and the involvement and guidance of the ERN Coordinators. It was agreed to have a dedicated discussion in the coming months to unblock the expansion of diseases.

8. Report from Working group on monitoring, IT Advisory Group and new CPMS

The speaker began presentation with brief introduction of the problems with data collection in the last few years due to the COVID Pandemic and the Ukraine war causing a major lack of staff in the hospitals which are responsible for data collection. Information was provided by the Networks for a lack of support on the side of MS with communicating with national hospitals.

Explanation on the data collection methodology was also given. The Speaker noted that currently the HCPs submit the information to the ERNs and there are difficulties due to the usage of different methods and tools for collecting that information. A solution for that issue is proposed- new IT platform for submitting the HCPs information so the Commission will have their perspective on the information not only the ERN's one.

The data collection issues are caused mainly from different interpretation of indicators by the ERNs. A survey about the added value of each indicator is under development.

Support needed was addressed to MS for more participants in the WG.

The Speaker introduced the vision for the new CPMS – intuitive, easy-to-use IT platform supporting medical discussions; flexible, open-sourced and GDPR secured. HCPs shall issue and submit data using this platform. IBM International is the new contractor selected. ERNs are expected to provide practical help so Business Implementation Group (BIG) would provide it. The main goal is the first meeting of BIG to be on 25.10.22 to clarify the goal of the CPMS.

The **ERN EU Academy platform** (developed in partnership with the IRC) was presented as well. Currently, it does not support medical imaging, and this is one of the additional functionalities to be further developed.

9. Report from working group on knowledge generation

Presentation started with a short report on the work done by the group around care of patients with rare diseases. The WG Chair started by summarising the achievements in the previous months regarding the Rare Disease education and training. The knowledge on RDs among health care professionals needs to be improved to shorten the path to correct diagnosis. Chair states a Do Decalogue has been designed to develop a curriculum on the RD (Rare Diseases), open for registration to postgraduate physicians both from ERN and Affiliated member centres (further details should be defined by ERNs). An effort should be made, and the educational programmes should be expanded.

Several key points were agreed –Identifying who this EU Educational program on RD should be targeted to. The focus to be on spreading awareness of rear diseases with involvement of scientific societies.

The ERNs need to build up on what was already created the last 5 years identify the key elements that could ignite suspicion of RD for non-expert doctors- the focus to be on symptoms rather than on specific diseases.

Another topic importance was highlighted – challenges in transitions form Childhood do Adult Care in rear metabolic diseases.

Discussion

Conclusion of the group is that education and training beneficial should be PhDs, postdocs, clinicians, nurses, students etc. - On the other side providers of education and training should be Universities, University hospitals/ERNs, Patient organisations and NGOs.

Plan of actions of the WG is preparation of surveys, drafting guidelines, use the ERN Academy to generate courses, organisation of webinar to involve stakeholders, organisation of a Parliament Event on the need of education in rear diseases.

Discussions included comments made by HU (a need to attract young specialists) and LT (two initiatives have been developed: appointment of nurse coordinators and education provided to GPs on rare diseases).

10. Report from working group on Legal and Ethical issues

The Chair presented activities of the Working group regarding composition of the WG, short form for conflict of interest (COI), ERN policy for management of conflict of interests and request of legal advice.

The ERN policy for management of conflict of interest was analysed further in the presentation and specifically how COI would be handled after being declared. Question was asked –who is responsible for uploading, monitoring and access to conflict of interest forms when ERNs are not legal entities? The need of statement of the BoMS regarding collaboration between ERMs and the Industry. An example was given with the unique possibility companies to be addressed directly to the patients for clinical trials that will also speed up the clinical trials. Advisory boards can be created. A strong comment was made - urgent need of answer about the process of collaboration with the companies especially on legal entities issues. Chair confirmed an enquiry was made regarding authorization of the ERNs for direct funding to registries.

NL shared opinion that as public-private partnerships are reviewed in different terms, multi-stakeholder initiatives should be better clarified. In addition, it was clarified that solutions will be discussed further on-Board level.

11. ERN Research activities

EU RD Platform

The WG explained there is a platform developed for Rare Disease registries – in support of the work carried out by the ERNs on de-fragmenting data sources and collecting a critical number of patients for studies. All the advantages of it were listed: the platform is open to all ERNs, free of charge, it stores patient cohorts, enhances data discovery, it has a central metadata repository. First trainings on the ERDRI shall be organized in October 2022 and are available for ERN members.

Preparations of Rare Disease Partnership

Recent policy actions have catalysed research on RD, actions and funding, resulting in the following figures:

- 2007-2020 = EUR 2.4 billion of available funds, 440 multinational projects on cross disciplinary research.
- 2024-2030 = EUR 95.9 billion of available funds.

The Chair stated the main goal of the partnership is to improve the health and wellbeing of some thirty million people living with a rare disease (RD) in Europe, support research and coordination, develop new pathways and utilize RD innovations. Public discussions are foreseen for 2023.



12. Any Other Business

BE raised question on continuing the procedure of creating consortia. The Chair noted this will be added to the agenda of future meetings.

The Chair notes the Brochure for the ERNs is updated and finalised in twenty-four languages – text reviewed and presented in a new format, it is now uploaded and ready for download/use. BoMS are encouraged to circulate it. Permission needs to be obtained if one wants to use it on copyrights.

The Chair states a Clinical Practice Guideline has been developed which is ready and uploaded. An additional online course has also been developed as a module and open to access. The new course (starting in spring 2023) will be dedicated to new members.

At the end of the meeting, the Chair thanked all participants for their participation and closed the session.