



AGENDA
BOARD OF MEMBER STATES ON ERNS
4TH OF APRIL 2022, 9:00-16:00
VIDEO-CONFERENCING VIA WEBEX

8:50 – 9:00 Dial-in		
1	9:00 – 9:05	Opening of the meeting
2	9:05 – 9:20	Update from the BoMS co-Chair
3	9:20 – 9:40	Update from the ERN Coordinators Group
4	9:40 – 9:50	ERNs' support for Ukraine
5	9:50 – 10:10	ERNs funding
6	10:10 – 11:10	Changes in the scope of expertise of ERN members
7	11:10 – 11:30	Draft Protocol for creation of consortia with an existing ERN member
11:30 – 11:40 Coffee Break		
8	11:40 – 12:00	Joint Action on integration of ERNs into national health systems
9	12:00 – 12:15	Report from Working group on ERN integration
10	12:15 – 12:30	Report from Working group on monitoring
11	12:30 – 12:45	Report from Working group on knowledge generation
12	12:45 – 13:00	Report from Working group on Legal and Ethical issues
13	13:00 – 13:20	Report from ERNs IT Advisory Group (ITAG) and on ERN IT related issues (including update on new CPMS)
13:20 – 14:20 Lunch Break		
14	14:20 – 14:35	ERN Research activities
15	14:35 – 15:15	Follow-up of AMEQUIS and preparations for ERN Evaluation
16	15:15 – 15:25	Update on the onboarding of new members of ERNs
17	15:25 – 16:00	Any Other Business
16:00 End of the meeting		

1 | 9:00 – 9:05 | Opening of the meeting

The EC's Co-chair of BoMS opened the meeting and welcomed all participants. The agenda and the minutes of the past meetings were approved, and the Co-chair expressed the wish to meet face-to-face in October. He explained that there were 3 topics planned for the Any Other Business (AOB) and no comments to agenda were made by the Member States (MS).

2 | 9:05 – 9:20 | Update from the BoMS co-Chair

The MS's Co-chair presented the different meetings that have taken place in the context of the new communication strategy between the BoMS, EC and ERN Coordinators and reiterated its usefulness. The Co-chair reiterated the need to have more participation of MS in the working groups because it demonstrates interest, reassures coordinators of their work and helps understand, participate and guide their work.

He explained that the amendment of the rules of procedure to allow the BoMS Co-chair to have a dual role will not be pursued as this would set a precedent for all the other groups of the Commission. It was also explained that the future meetings will most probably be hybrid and therefore the need for a dual role will no longer be justified.

3 & 4 | 9:20 – 9:50 | Update from the ERN Coordinators Group & ERNs' Support for Ukraine

The ERN-CG Co-chair explained that points 3 and 4 of the agenda (update from the ERN Coordinators and ERN's support for Ukraine) would be presented together. She gave an overview of the work that has been carried by the coordinators in the last months, stressing the points that will be discussed at the meeting of today, particularly: ERN integration into national healthcare systems, Conflict of Interest forms (COI) & partnership with industry, AMEQUIS, monitoring exercise, and the new CPMS. In addition, the Co-chair asked for a 2nd wave of expansion of expertise at HCP level as many coordinators could not process all the requests. Next, the Co-chair explained the actions carried out by ERNs with regard to the Ukrainian crisis.

ERNs estimated that about 2M patients with rare diseases may be in need of help. The main difficulties identified were related to diagnosis and the most urgent needs corresponded to therapies, rare cancers, dialysis, epilepsies, drug access, etc. ERNs had identified 2 levels of support for Ukrainian refugees, direct interaction case-by-case and via medical hubs for rare diseases (in collaboration with EU & national public health authorities). She explained that ERNs could help in various ways, for instance in the medical triage phase, diagnosis, and treatment; and that ERNs were ready to liaise directly with Ukrainian colleagues and help with lexicon in translations of medical terms.

A survey within the ERNs showed that 120 patients had been taken care of by ERNs. Many of them involving full hospitalisation and provision of complex treatments like chemotherapy.

Regarding drug shortage in Ukraine, some ERNs were contacted to help in the supply of some drugs (e.g. antiepileptic drugs), special diet milk, etc. She explained that some of the ERNs were in contact with pharma companies to facilitate the supply of drugs.

5 | 9:50 – 10:10 | ERNs' funding

The EC presented the state of play of the funding of ERNs and explained that the new Direct grants that will start on 2023 will be based on a simplified system named Financing Not Linked to Costs (FNLC). The EC explained that the introduction of this simplified system followed the recommendation of the audit performed by the European Court of Auditors and that an expert was carrying out a study to evaluate the best way to implement FNLC for ERNs. The expert was introduced to the ERNs to explain the FNLC.

The expert explained the basis of FNLC and highlighted its pros and cons. The advantages are mainly the reduction of administrative burden and costs both for ERNs and also EC. He explained that FNLC puts emphasis on the achievement of objectives and results rather than on administrative procedures. The reporting of FNLC is simplified and payments are linked to the achievement of certain objectives. The cons are mainly related to the difficulties associated with the change of the system and to the risk of oversimplifications as they may result in perverse incentives and unfair financing. Strategies to mitigate this undesirable effects were presented and assured that they will be considered from early stages.

6 | 10:10 – 11:10 | Changes in the scope of expertise of ERN members

The EC explained that ERNs had asked for an update of the expertise of its members as their expertise was defined back in 2016, and this may have changed during this time.

The EC showed that 79 HCPs had applied for the expansion of diseases, summing up to 211 diseases from 12 ERNs and 14 MS. A few problems were identified during the compilation of applications:

- Some ERNs had started the application before the protocol had been adopted and they had used different templates. To avoid duplication of efforts, EC decided to allow the use of different templates in this occasion, although it was noted that the use of different templates may hinder the evaluation procedure.
- EC noticed that some of the applications were missing the compulsory notification to the national competence authority (NCA), or that in some cases 30 days had not passed since the notification, which implied that the NCA could still reject the application at the date of approval. The applications with this problem were highlighted in the summary file and it was proposed to the BoMS to take a decision of whether these had to be accepted.

After a short discussion, BoMS agreed by consensus to approve the applications that were not highlighted in the summary file (the ones without problems detected), which sum up to 115 new areas of expertise. EC explained that the table would be finalised after the meeting and that the final version would be shared with the BoMS. EC explained that the individual HCPs would also be notified of the expansion of diseases.

Following the request of the ERN-CG, the BoMS approved by consensus the possibility of having a 2nd wave for expansion of diseases later this year.

EC explained to the BoMS the request of the ERNs to expand the list of diseases at the ERN level. EC commented that this would be a good opportunity as the ERN evaluation will start later this year and the independent body that will carry out the evaluation could also assess the applications for new diseases. The EC added that it will be unlikely to have another independent body to assess applications in the near future.

It was agreed to discuss the expansion of diseases at the ERN level later this year. Tomorrow, at the ERN-CG meeting, the EC will assess the real interest of ERNs in this expansion and will also collect more information on their needs.

7 | 11:10 – 11:30 | Draft Protocol for creation of consortia with an existing ERN member

EC explained the protocol for creation of consortia with an existing ERN member. The draft protocol had been submitted in advance to the meeting and is analogous to the one of the expansion of diseases. A few issues were put forward to the MS for consideration, but the most important one was whether an endorsement letter from the MS was required.

There was general agreement within MS that a notification of a creation of consortium to the national authority was not enough and that an endorsement letter should be necessary. It was commented that new members have to be subject to at least the same level of scrutiny as the previous ones, and MS should hold the responsibility of the evaluation and endorsement of new members.

NL commented that it is not clear what a consortium is or what a consortium can do (apply for grants, use logos, etc).

MT asked if consortiums can be multinational and NL commented that they had checked this possibility but they found difficulties in endorsing the part of the consortium that belongs to another country. AT mentioned that the original idea of consortia was to have close collaboration and that, for this reason, consortia of members that are physically distant are not created in AT.

EC recommended to start the discussion about creation of consortia with the easy cases, i.e. consortiums within national territory, and once experience will be gained start exploring more complex cases like the cross-border generation of consortia.

All MS were encouraged to send their comments to the protocol in writing. The draft protocol for creation of consortia will also be presented to the ERN-CG for their comments.

8 | 11:40 – 12:00 | Joint Action on integration of ERNs into national health systems

The EC explained the policy objectives of the Joint Action, which links to the statement of the BoMS in 2019 and is now reflected in the WP2022. The JA has a budget of 11.2Meur over a period of 3 years.

HaDEA presented the basic characteristics and timelines of the Joint Action, clarified which entities can be eligible and gave a quick overview of the type of work packages that will be considered in the JA. JAs are funded by EC up to 60% of eligible costs but in case of exceptional utility the funding can go up to 80%. HaDEA explained that there will be an info day on 17/5/2022 and a hands-on workshop on 15 September. The deadline for the nomination of competent authorities is 1/9/2022.

HaDEA presented the outcome of a review carried out on past Joint Actions. The review showed that choosing the right competent authority for the Joint Action is crucial for the success of the project. The competent authority must have competences, not only on the topic (e.g. health) but also on project management, financial management, and international cooperation.

9 | 12:00 – 12:15 | Report from Working group on ERN integration

The Co-chair of the WG gave an overview of the activities carried out by the WG on integration and highlighted the need to organise the preparatory work well in advance as indicated by HaDEA. She expressed the need that BoMS pursue the participation of their MS into the JA and contact the members of their own ministry to ensure the success of the JA.

The Co-chair commented that it will be important to list the stakeholders that can participate as affiliated partners as they will be key for the success of the JA (e.g. hospital managers, ePAGs, TEHDAS, experts of data management, etc.).

It will be important to collect the needs of every MS even though they do not participate in the JA. There should be a direct channel of communication between BoMS and the JA, and this could be a task for the WG on integration. One way of doing it could be to temporarily transfer the missions of the WG on integration to the JA.

EE commented that the participation to the JA will depend on the communication of BoMS with their respective ministries as there are competing JA. EE mentioned that it could be beneficial to have a common text from BoMS to send to the health attachee. EC commented that could prepare a draft letter for BoMS to send to the health attachee.

EC explained that there will be an extraordinary meeting of the BoMS to discuss the JA but clarified that this meeting should be open so that other representatives from the ministries can also participate. EC encouraged BoMS to invite the relevant members from the ministries to this meeting.

10 | 12:15 – 12:30 | Report from Working group on monitoring

EC explained that the WG is currently working on the recommendations of AMEQUIS regarding monitoring, which cover topics like the efficiency and sustainability of the monitoring exercise, the review of indicators and monitoring manual and publication of results. To address some of these recommendations, it was decided to reduce the collection exercises to one per year and allow a data entry period of 2 months. The other recommendations are still being discussed. It was also mentioned that one of the goals for 2022 was to reach a 100% of participation of HCPs in the monitoring exercise.

The Co-chair mentioned that the WG on monitoring would benefit from participation of more MS.

11 | 12:30 – 12:45 | Report from Working group on knowledge generation

The Co-chair of the WG explained the objectives of the WG and of ERNs in terms of knowledge generation putting special emphasis on the training of physicians and patients. He explained that there is the aim to develop a postgraduate training on rare & complex diseases, as well as developing an education program for patient representatives focusing on understanding complex diagnostic procedures. Another action proposed was the development of pre-graduate training on rare diseases and implement it in the medical curricula at EU as one of the limitations of rare diseases is the low awareness, even within the medical community. So it is necessary that all doctors have some notions of rare diseases.

In addition, the Co-chair mentioned that the WG was planning to organise an event at the European Parliament in order to find political support for the objectives mentioned above.

The current Chair and Co-chair explained that WG had been running for 5 years and that they wanted to discuss a renovation with the ERN-CG at the next meeting as well as setting new objectives.

12 | 12:45 – 13:00 | Report from Working group on Legal and Ethical issues

The Co-chair presented the activities carried out by the WG. He mentioned that after the last call, there had been an increase in the number of participants in the meetings. He showed his gratitude to the new members and asked for others to join, particularly those with legal expertise. He explained that the last efforts were dedicated to the form for conflict of interest and that there will be a pilot study using the Vascern COI form. The members will sign the form in a paper version and will be scanned and stored. The coordination team of the ERN will be responsible for checking its completeness. He explained that there is no legal responsibility for ERNs as they are not legal entities and that EC will look for possibilities that are compliant with GDPR to store the COI.

The Co-chair explained that one important topic for discussion is the statement of the BoMS regarding interactions of ERNs with industry, and the need to modify it to allow funding for ERNs as it is currently hindering interaction with industry. He explained that direct funding of

registries is essential for the sustainability of ERNs and that the statement should be reworded to allow it.

The Co-chair explained that the Together for Rare Diseases meeting is an effort to foster collaboration between ERNs and industry and this could provide examples of successful collaborations like the Epicare clinical trial platform.

The Co-chair of the BoMS commented that this was a very important point that needs to be solved as there have been developments in the recent years and there will also be EHDS coming into place. He committed to work in the coming months to find a solution to this.

13 | 13:00 – 13:20 | Report from ERNs IT Advisory Group

EC presented the results of a survey carried out to determine the needs of ERNs regarding the priorities and ways of working for the new CPMS. The results showed wide consensus on CARE. Easy access, performance and reliability were among the first mentioned points in every interview. Easy entry of cases and access to international guests were also among the top priorities. All these results were considered when writing the call for tenders, which is now under evaluation and expecting to go live on Q4 2023.

The kick-off of the new CPMS is expected for Q3 2022, and the subsequent versions will gradually include more and more functionalities.

Other objectives of the CPMS are for instance multi-language interface, which will require involvement of MS to help with translations. The new CPMS will also include targeted dashboards for MS (Hospital, Network, Member State) in order to monitor its use.

MS may also be involved in governance of CPMS, as it will be open source with no user fees, what means that MS will be able to use and adapt it to their national needs.

EC also invited MS to participate in the working group that will interact with the developers in order to understand better what will be developed and the possibilities it will offer at a later stage for the MS.

EC explained that the Virtual Academy will finally be hosted on the EU Academy, which is moodle-based and is readily available. The agreement will be signed in Q2 2022 and the pilot phase with 10 courses offered by ERNs will be carried out during Q3 2022. On Q1 2023, the platform will be opened to all ERNs.

Finally the EC raised the issue of updating the mandate of the ITAG group as it is now outdated. This will be discussed tomorrow with the ERNs.

There is the need to appoint a Co-chair, and also change the name in order to reduce the bureaucratic burden that this group represents.

CZ asked if there are any news regarding patient participation. EC explained that the new CPMS is mainly a tool for clinicians and that it is not in the plans to allow patients to participate in the clinical discussions. Regarding the participation of non-EU experts, they can be invited to provide clinical advice if a network decides to do so, but for the time being non-EU experts cannot enroll patients nor receive advice. The new CPMS will be highly configurable so, in the future, this will be easy to configure.

14 | 14:20 – 14:35 | ERN Research activities

EC presented an overview of the activities funded by the EC on rare diseases and introduced the Rare Disease Partnership. The partnership was developed hand in hand with

representatives of the MS and ERNs and will be funded with 100 million eur from Horizon2020 programme and will start on 2024.

The ERKNet coordinator provided an update on the development of registries. A survey showed that 10 ethics committees had been approved and 9 were in preparation. In terms of patient enrolment, 4 registries had more than 1000 patients, 5 <1000 and the rest <100 or were still in construction.

The coordinator explained that ERICA is starting to work on the sharing of data. The first question is to determine what data can be shared with stakeholders. They have drawn a data sharing principle matrix to determine the type of data that can be shared with what level of granularity, and when to share it (immediately after collection, after certain time). In general, there is agreement on sharing aggregated tabulated data and the existence of data accession committees.

Next, he explained the progress made in ERICA which is developing agreements and guidelines for data collection, integration, and sharing. The project has several WPs that are dedicated to different topics such as patient centred research, clinical trial support, dissemination activities, etc. The project has been running for 1 year and will end in 2024.

15 | 14:35 – 15:15 | Follow-up of AMEQUIS and preparations for ERN Evaluation

EC gave an overview of the main elements and recommendations of AMEQUIS regarding the assessment and evaluation process for ERNs. The process and actors involved in the evaluation were explained as well as the expected timelines. It is planned that the evaluation starts on Sep 2022 and finishes on August 2023.

16 | 15:15 – 15:25 | Update on the onboarding of new members

EC gave a summary of the onboarding of the new members of ERNs. The process started in January. In March, 20 out of 24 ERNs had replied to the onboarding and 500 out of 620 HCPs had provided the data. However, some centres are still blocked because the information provided was not complete, some of them due to not providing an adequate email address for data protection. In parallel, the EC is identifying the affiliated partners that need to be terminated. The next steps will be to remind ERNs to send the data and generate logos for the new members.

LT explained that they are having some problems as they are trying to harmonise the names of all ERN members. EC explained that first the centres have to be included in the service directory (database) and only then, the names can be modified.

17 | 15:25 – 16:00 | Any Other Business

In the interest of time the AOB were not covered. The MS BoMS Co-chair stressed the importance and potential that ERNs have shown in reacting in the crisis of Ukraine and wanted to highlighted the value provided by ERNs. The EC Co-chair also highlighted the

importance of ERNs and the work carried out by the BoMS. He commented that it is important to keep the engagement and efforts now that ERNs are in an stable path.

Meeting participants:

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

European Commission: DG SANTE, DG RTD, HADEA