EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Unit B3 European Reference Networks and digital health

BOARD OF MEMBER STATES ON ERNS

28 OCTOBER 2021, 9:30-16:30

VIDEO-CONFERENCING VIA WEBEX

DRAFT MINUTES

CO-CHAIRS: EUROPEAN COMMISSION AND AUSTRIA		
9:20 – 9:30 Dial-in		
1	**9:30 – 9:35**	**Opening of the meeting** - *Welcome* - *Approval of the agenda and minutes of the last meeting*
2	**9:35 – 9:45**	**Working methods of the Board of Member States** Presentation (MS Co-chair of BoMS) + Discussion
3	**9:45 – 10:05**	**Update from the ERN Coordinators Group** Presentation (ERN CG co-chair) + Discussion
4	**10:05 – 10:25**	**Future direct ERN grants** Presentation (Commission) + Discussion
5	**10:25 – 10:45**	**Enlargement of ERNs and integration of new members in the ERNs** Presentation (Commission) + Discussion
6	**10:45 – 10:55**	**Changes in the scope of expertise of ERN members** Presentation (Commission) + Discussion
10:55 – 11:10 Coffee Break		
7	**11:10 – 11:25**	**ERN Working Groups and their reporting – general issues** Presentation: Commission
8	**11:25 – 11:35**	**Report from Working group on ERN integration** Presentation: WG Co-Chair & Commission
9	**11:35 – 11:50**	**Report from Working group on monitoring** Presentation: WG Chair and Commission - *Update of the publication of results 2020 & 2021*
10	**11:50 – 12:50**	**Report from Working group on knowledge generation** Presentations + Discussion - *Update form WG Co-chair (11:50-12:00)* - *ERN Professional Exchange mobility program (Ecorys) (12:00-12:15)* - *Clinical Practice Guidelines Programme (AETSA) (12:15-12:35)*

		- *Education and training strategy (report on meeting 28/9) (12:35-12:50)*
11	**12:50 – 13:00**	**Report from Working group on legal and ethical issues** Presentation (WG Chair) + Discussion
13:00 – 14:00 Lunch Break		
12	**14:00 – 14:30**	**Report from ERNs IT Advisory Group (ITAG)** Presentation (Commission) + Discussion - *Update on the New CPMS*
13	**14:30 – 14:40**	**CPMS activity report (current CPMS)** Presentation (Commission) + Discussion
14	**14:40 – 15:00**	**Report on ERN registry activities (including ERICA/EJP-RD)** Presentation (Task Force representative & Commission) + Discussion
15:00 – 15:15 Coffee Break		
15	**15:15 – 15:30**	**European Health Data Space and ERN registries** Presentation (Commission) + Discussion
16	**15:30 – 15:50**	**Evaluation of Cross-border healthcare directive and ERN policy** Presentation (Commission) + Discussion
17	**15:50 – 16:10**	**Updates on other ERN related activities** - *Hospital Managers event debrief* - *Update on AMEQUIS project*
18	**16:10 – 16:30**	**Any Other Business**
16:30 End of the meeting		

1. Welcome, approval of the agenda and minutes of the past meeting

The Commission co-chair welcomed all participants and opened the meeting. The minutes of the last meeting of 29 April 2021 had already been approved by written procedure. New members of the Board were introduced to the Board of Member States (BoMS). The representative of Finland, who will retire at the end of the year, was congratulated for her dedication to the ERN project. Due to availability of the speakers, point 8 of the agenda was postponed after the lunch break. The Board accepted the change in the agenda.

2. Working methods of the Board of Member States

The Member State (MS) co-chair presented an initiative to the BoMS with the aim to strengthen the collaboration within the BoMS and between the BoMS and the ERN Coordinators Group (ERN-CG).

The co-chair suggested having additional virtual meetings within the BoMS to discuss specific questions. These meetings would have a duration of 2-3 hours maximum and would be targeted to 1 or 2 topics. The meetings would take place at least 1 month ahead of time of the next BoMS meeting.

In order to improve communication between ERN-CG and BoMS, the co-chair proposed having regular short virtual meetings between the chairs of the two groups, to which 1-2 volunteers from the BoMS were welcomed to participate. The main aim of these meetings would be to exchange questions or important information ahead of the regular meetings of the BoMS and ERN-CG. These meetings between the chairs of the two groups would be held close to the virtual meetings of the BoMS.

The co-chair also expressed the will to improve the communication between the main players of the ERNs community: BoMS, ERN-CG, European Commission, and Hospital Managers.

EC clarified that the virtual meetings would be, in principle, dedicated to discussing topics put forward by the BoMS or ERN-CG and that the EC will only give secretarial support to it.

The proposal was well received, and several members volunteered to participate in the meetings between the BoMS and ERN-CG.

3. Update from the ERN Coordinators Group

The current ERN-CG co-chair provided an overview of the composition of the ERN-CG group and their activities. Some of the challenges faced by the ERNs were mentioned, including Brexit, expected doubling in size following the ERN enlargement in 2022, and keeping a strong and successful partnership with patients. The co-chair shared what the Coordinators consider the key points of the near and mid-term future of ERNs, showing particular concern on the budget tensions that may occur in 2022 when the current SGA grants will finish and the new Direct Grants start. The Coordinators expressed their support for a simplified future version of CPMS, but which would still cover the heterogeneous use given by the ERNs. The Coordinators acknowledged the need of the monitoring exercise but expressed concerns about the resources currently needed to provide the data.

The ERN-CG co-chair admitted that the engagement of some HCPs is challenging and that they need to find a way to improve it. ERN-CG expressed their support to all actions to better integrate the ERNs into the national systems.

Some Member States commented that the monitoring and evaluation processes are necessary and need to be performed thoroughly in order to assure the continuity of ERNs.

4. Future direct ERN grants

The Commission presented the plans for future funding schemes for the ERNs, which will consist of new “bridging” direct grants for the ERN in 2022 followed by new, possibly multiannual, funding scheme based on financing not linked to cost bringing all existing ERN funding streams together from 2023 onward.

The plan for future funding aims for simplification, in the form of direct grants, with a single funding channel that will include all the current activities. This will provide predictability of funding and reduced bureaucracy as the new grants will cover 100% of eligible costs. The direct grant of 2022 will be used as a “bridge” grant to align the funding of ERNs as the current grants (e.g. coordination, IT, registries, etc) expire in different months of 2022. In March 2023 the new multiannual grants should start.

The Commission shared a tentative timeline of the funding scheme process for the 2022 bridging direct grants. It was clarified that the call will only be launched once the Work Programme of 2022 will be approved. The Commission clarified that the new grants will provide for retroactive payments of the costs incurred after the existing grants expire and these costs will be fully reimbursed once the signature of the new grant agreements takes place. This will provide business continuity for the ERNs.

The Commission explained that the monitoring activity has identified certain underuse of the CPMS. It seems that one of the main reasons for the underuse is the fact that experts are not being compensated for the time spent on virtual consultations. In order to improve the use of CPMS, the Commission is planning to introduce a "pilot scheme" and to include as eligible cost the time spent on virtual consultation via CPMS.

The Commission also clarified that it is planned that the new grants starting in 2023 will be slightly different in format as a single instrument will cover all the expenses, and the payments will be linked to the fulfilment of the objectives included in the grant agreement and it will not be necessary to present separate invoices for specific costs incurred.

Some Member States raised a possible funding issue for some ERNs, as the hospitals hosting the coordinating centers may not accept to renew the contracts of their project managers unless the funding is actually available, i.e. 2022 bridging grant is signed. The Commission explained that this situation has happened before and that it was solved by the Commission providing a letter to the hospitals confirming the availability of the money. The Commission agreed to provide support to the ERNs in this matter and issuing such letter as soon as it will be legally possible.

5. Enlargement of ERNs and integration of new members in the ERNs

The Commission gave an overview of the assessment process of the applicants for new members of ERNs that ran from 3/2021 to 10/2021. The results showed different levels of submission per Member State ranging from 0 submissions to 145. Only 10 applicants had received a negative assessment, some of which were due to the application had been withdrawn during the assessment period.

The approval of the applications will take place on 26/11/2021 on a dedicated meeting of the BoMS. The next step after approval will be the notification to the new members and the update of the Service Directory. The new members will become officially members of the ERNs on 1/1/2022, however access to all the tools and activities of ERNs will only be granted once the new members are uploaded to the Service Directory. This step requires some manual checking of the data and will take place gradually during the first days and weeks of 2022.

The Commission also explained that the affiliated partners of countries with new full members will lose membership as stated in the Rules of Termination for affiliated partners.

In the last meeting of the BoMS, BE raised the issue of the need for a protocol for consortiums that already have an HCP that is a full member of an ERN. The Commission is preparing a draft protocol similar to that of managing diseases areas within current ERN HCPs.

6. Changes in the scope of expertise of ERN members

The Commission gave an overview of the protocol for managing disease areas within current ERN HCPs, which was discussed at the last meeting and approved by written procedure and announced that a template for applications will be circulated soon. ERNs will continuously collect applications and, once a year, ERNs should submit a package with all applications to the EC for their approval by the BoMS. The next

package will need to be submitted to the Commission by 31/01/2022 as it is planned that the applications be approved at the BoMS meeting that will take place on Spring 2022.

The Netherlands presented the changes that will be introduced in their national system to endorse HCPs. The aim is to endorse centres or networks of centres at the level of the Main Thematic groups instead of at the speciality. Using the simile of hands for main thematic groups and fingers for specialities, this can be described as endorsing a centre as expert on "hand" instead of endorsing the centre as expert in the index and small finger. This implies that if a centre is not an expert in "all" the fingers, it will not be endorsed as expert in the "hand". The aim of this stricter criterion is to stimulate the formation of national networks at the level of the Main Thematic groups, which would increase expertise and reduce burden on the ERNs side. The change of endorsement protocol will take place on December 2022. The Netherlands asked whether they could use the procedure for changes in the scope of expertise to communicate the changes that will take place after the new endorsement protocol is applied.

The Commission clarified that the current protocol is to extend the expertise of HCPs and is probably not fit to accommodate the Dutch case. The Commission will reflect on the possibility to adapt the current protocol to include this possibility or decide to create a new protocol for this case.

7. ERN Working Groups and their reporting – general issues

The Commission presented a document laying down general working principles for the Working Groups, including chairing of the groups, participation, reaching agreement, secretariat support, etc. The document had been circulated to the BoMS and will also be circulated to the ERN-CG with the aim to agree by written procedure.

9. Report from Working group on monitoring

The Commission, on behalf of the WG chair, presented the activities of the Monitoring WG and the goals for the coming months. Since the data collection exercise of 2021 was still in progress, the Commission presented the results and conclusions of the data collection of 2020.

The results of 2020 show that about 88% of the hospitals participated in the data collection, the total population referred to the ERNs is approaching 1.7 million patients, and that there is an increasing number of learning, training, and research activities. No significant advancements were observed in the development of important indicators such as the integration process. For the coming months, the work will concentrate on the cooperation with the AMEQUIS initiative and with the Integration WG. The importance of having a joint meeting between the WG on monitoring and AMEQUIS was stresses by LT in the discussion that followed the presentation. CZ commented that the AMEQUIS exercise has represented a huge effort and that more clarification is needed in the definition and purpose in order to get the most out of it.

10. Report from Working group on knowledge generation

The contractors in charge of the ERN Professional Exchange mobility (Ecorys) programme and the Clinical Practice Guidelines Programme (AETSA) presented the state of play of the two projects. Ecorys explained that the exchange programme has significantly suffered from the COVID related restrictions as ERNs have not been able to engage fully until summer. The situation is improving as the number of

exchanges planned in the last months have doubled. However, some ERNs have not started yet, and are waiting for more certainty on the pandemic situation. Some Member States asked about a possible extension of the programme and the Commission explained that there is no decision taken now but that this option can be considered.

The Commission asked Ecorys to prepare a further analysis for the next BoMS meeting on the current programme and see how it could be improved, e.g. length of visits, type of visitor, countries involved, etc.

AETSA gave an overview of the Clinical Practice Guidelines project; explained that the methodological handbooks have been updated and improved, that more than 100 participants followed the course that took place between April and July, and that the participants will soon receive the certificates. The documents of the training will be available to the ERNs in the virtual academy.

AETSA explained that is considering together with the Advisory Body how the clinical practice guidelines produced in the project can be formally endorsed. The co-chair of the WG considered that it is important to be in contact with the European Union of Medical Specialists and other medical associations, otherwise will be difficult to get these CPG used at a broader level.

The Commission gave an overview on the activity of the WG, whose next steps will be to consult the ERN-CG about the needs and difficulties they find in terms of education and incorporate this topic in the next meeting. The co-chair of the WG commented that, for its success, the rare diseases programme should be useful for young professionals, so that they can incorporate it in their PhD programs. LT explained that, within the context of EJPRD, there had recently been a workshop with the association of medical schools in Europe and that there is a plan to develop a strategy to foster and encourage rare disease education in European universities and medical schools.

11. Report from Working group on legal and ethical issues

The Commission announced that there will be a new legislation that will facilitate international clinical trials within the EU level and that it can be an opportunity for ERNs to benefit from this.

The WG co-chair gave an overview of the tasks of the WG and identified several problems of the WG. There has been a declining representation of Member States in the WG, although a few new Member States have joined the last meeting. The WG needs more legal expert advice to deal with issues like Conflict-of-Interest forms. Another problem, which has been discussed at length, is point 5 of the statement of the ERN Board of Member States on ERNs & Industry relations, which prohibits the funding of registries by industry. The WG wonders if the wording may be changed to allow some type of direct or indirect funding or activity to promote registries. In the discussion, it was also mentioned that an additional difficulty that ERNs may face regarding funding is the fact that they are not legal entities.

8. Report from Working group on ERN integration

The WG Chair gave an overview of the work carried out by the group and shared the first results from the ERN integration questionnaire. Good practices in MS were identified in governance, patient care pathways, referral systems to the ERNs, education and awareness raising on ERNs at national level, and sustainability at HCP level. The overall conclusion is that some countries have good examples, but that in general countries need to do better. The Joint Action on Integration of ERNs into national healthcare systems will be a very important topic for 2022 and the WG will have dedicate meetings to this in 2022.

The Commission explained that the formal adoption of the Annual Work Programme 2022 will be the preamble of the Joint Action and that there will not be a lot of time to prepare once the programme starts. There will be a call for interest for MS and once a pool of MS will be identified, MSs will need to nominate a leader and make a proposal. The whole proposal will take several months, but it would be good that MS started preparing for the Joint Action so that more MSs participate.

12. & 13. Report from the ERN IT Advisory Group (ITAG) and ERN CPMS activity report (current CPMS)

IT related activities

The Commission presented the activities of the IT Advisory Group and the state of play of current IT tools. Special focus was given to the new CPMS.

After presenting the genesis of the ITAG and an overview of the activities of the group, the Commission regretted the fact that some official members of the group decreased their participation to a vestigial level and encouraged all members to review their availability and interest in participating; at the same time invited MSs, who are willing to participate, to make a step forward and actively engage with the group. The Commission also reported that most of the work is done in ad-hoc informal meetings and not on the regular ones.

The Commission gave an overview on the state of play of the ERN IT tools. All tools are currently stable, and some are undergoing improvements:

- Service directory – configurable interactive maps and External editor role. Once this last improvement is in production members will be responsible to verify and update their contact details. Will soon be updated to reflect the results of the expansion of new members.
- Indicators – extension to HCP level and different timings are under discussion in the ITAG and the Monitoring WG.
- HCP Applications – data is being prepared to be migrated to the Service Directory.
- Academy – the development of this new tool has been delayed due to a change of the agency that will manage the tool (CHAFEA was closed and HaDEA launched) and to the added workload on the new CPMS. Two important points need to be discussed: the future enrolment process and whether there will be tuition fees.

The activity of the current CPMS was also presented. The results show that more than 2000 patient cases have been discussed and there is a substantial diversity in the use of the tool among ERNs because the tool is not well adapted to the working methods of many networks.

The CPMS has a new contract for 2 years with the possibility of extension for an additional one and is also undergoing several improvements, e.g. Expert Groups, improved GDPR-compliant VCS (video conferencing system), enhanced functionality, new custom datasets. The Commission explained that because of lack of adequate European cloud storage alternatives, the CPMS was recently migrated to a new Microsoft Azure Global data centre. State of the art encryption technology, independent of Microsoft, is used.

The new CPMS was presented as a “flexible, user-friendly CPMS, to facilitate cross border medical discussions and integration into the national healthcare systems”. It will be secure, GDPR compliant and

compatible with the current CPMS. The call for tenders will probably be launched before the end of the year, which would allow to sign the contract in the first half of 2022 and immediately start the development, testing and deployment of the new system with the goal of having a first go live event by Q2 2023.

TOne important aspect is the need that ERNs and MS also act as project owners of the CPMS and not only the Commission. The new CPMS will be useful not only to clinicians but also to Hospital Managers and National Health Authorities - dashboards at Hospital level and at Member State Level will be available allowing for better informed decisions to be taken based on the consolidated data extracted from the new CPMS activity dashboards. Other requirements are a multi-channel and multilingual user interface (desktop and mobile), secure instant messaging system for quick informal consultations between clinicians and a structured and smart free text data entry. The new CPMS will be open source, so any external stakeholder (e.g. ERN, Hospital, MS) will be able to access the source code of the system, study it, modify it, improve it, as long as the work stays open source. This will give the interested Member States an already very advanced base to develop their own national Systems and will facilitate interoperability with the European CPMS.

From the discussion that followed, the need for interoperability among systems was again underlined. Previously, in the context of the Integration WG several initiatives regarding national CPMS-like systems had been related, for example a national CPMS will be operated in Germany, France has already a CPMS-like system up and running, the Flemish Region intends to develop a regional network in Belgium.

Norway explained that has not adopted CPMS in wait for the Data Protection Impact Assessment of CPMS. The Commission explained that the DPIA was finalised a few months ago, and that the only comments made were regarding the clarity of the consent forms. The Commission will share the DPIA in the following weeks.

14. Report on ERN registry activities (including ERICA/EJP-RD)

The Coordinator of the ErkNET ERN gave an update on the process of setting up the ERN-wide patient registries, which is ongoing for the 24 ERNs. The funding provided by EU programs to design and roll-out the registries since 2019 is now complemented by the research programs of EJP-RD and ERICA and will run until 2024 and 2025, respectively.

Two type of data registries co-exist, federated and centralised. Both registry architectures share the difficulties in extracting data from electronic health records due to their heterogeneity and non-interoperability. The only solution that has been found to capture and transfer data has been to do it manually, which is not an ideal approach although experience has shown that it works. In terms of cost, it is estimated to be 1/10 of the full-time cost of a research coordinator and, thus, seems a viable solution for ERNs.

Regarding ERN registries development, it was estimated that 2/3 of ERNs have finalised the data dictionaries, and 1/2 have finished the programming. It was explained that a common template for the ethics committee review has just been made available and that the ERNs will now start filling it in.

ERICA and EJP-RD are helping the setting-up of registries through the creation of several Working Groups (data collection, legal aspects, interoperability, secondary use of data). Several standardised forms

have also been developed (e.g. consent form, collaboration and data transfers agreements, data access policy).

Currently there are discussions on what contents of the registries will be shared (e.g. common data or disease specific), how detailed (e.g. aggregated, anonymised patient level data), when (e.g. upon collection, after grace period), and to whom (e.g. within ERN, industry, EMA, patient organisations). Each data access committee will share their preferences on these options and will be implemented in the EJP-RD virtual platform, which should serve as a test case for the European Health Data Space.

ERICA is working towards a coherent data strategy for the ERNs and is organising a series of workshops to define consensus guidelines and data strategy for the ERNs.

FR asked if the registries are collecting real world evidence. The coordinator confirmed that some registries are collecting data beyond the common data elements at different levels.

15. European Health Data Space and ERN registries

The Commission explained that the EHDS legislative proposal is in preparation and that the proposal is expected to be adopted in Q1 2022.

The Joint Action TEHDAS is working on different aspects of the secondary use of data and the Commission is exploring existing solutions in Member States to promote the re-use of health data such as the French Health Data Hub and the Danish Sundheddatastyrelsen. The next steps will include making sure that ERNs become part of the EHDS infrastructure being designed at TEHDAS and explore how ERN centres are connected in the national systems.

16. Evaluation of Cross-border healthcare directive and ERN policy

According to the better regulation principles, the cross-border healthcare directive (CBHCD) needs to be evaluated 10 years after its implementation. The scope of the CBHCD covers many aspects including ERNs, and the objective of the evaluation is to determine whether the directive has been useful and effective to achieve its objectives and to see if it needs to be modified.

The Commission explained that a stakeholder consultation was carried out on May-July and the preliminary findings showed that the Directive is overall effective as ERNs have provided health care professionals with access to expertise and knowledge, critical mass of patients´ data, facilitated large clinical studies, and virtual consultation panels through CPMS. CPMS was in general considered positive. The consultation revealed that some of the aspects to improve were the presence of practical barriers to access expertise of ERNs such as IT interoperability, language, lack of awareness. The consultation also highlighted the fact that ERNs have been more successful in diagnosing rare or complex diseases rather than treating them and the importance to integrate ERNs into the national health care systems.

The Commission explained that a stakeholders' workshop is planned for the 9/11/2021 and that the BoMS and ERN-CG have already been invited. The final evaluation report will be published next year.

17. Updates on other ERN related activities

The Commission informed the BoMS on the outcomes of the recent meeting with the Hospital Managers and AMEQUIS.

One important message from the hospital managers' meeting was the need to improve communication with hospital managers as they play a crucial role in the integration of ERNS into national systems. Some MS commented that hospital managers do not have a legal entity and that they are not a established group with regular interactions, which may difficult communication. It was proposed to invite hospital managers that show interest to participate in the working groups of ERNs. The BoMS co-chair proposed that MS would convene an online meeting with the hospital managers. The Commission commented that hospital managers of the new members of ERNs must sign the form of consent for the ERNs, and that this interaction would be a good opportunity to get in contact with this group.

The Commission explained that the expected outcome of AMEQUIS is to have an integrated quality system for the ERNs, including the assessment, monitoring, and evaluation. The final report is expected by end of January 2022.

Following the proposal of the BoMS co-chair, the BoMS agreed to have a dedicated meeting to discuss the outcomes of AMEQUIS sometime between February and March 2022.

18. Any Other Business

The co-chair of the BoMS mentioned that the rules of procedure of the BoMS do not allow being co-chair and representative of a Member State at the same time. The chair argued that for physical meetings this limitation is not ideal, because small countries may not have the personnel to fulfil both positions, and that it would be good to allow for the dual function. This would require amending the rules of procedure. He argued that this duality is not intended for the cases in which there is a vote but more of a practical point of view and that it could even be limited to a speaking function only, if required.

The Commission clarified that there is no legal limitation on the options and that any proposal to address this limitation can be put forward to the BoMS for agreement.

The Commission asked the BoMS whether there was any objection in sharing the list of members of BoMS and their details to the ERN-CG as the Commission is receiving many requests for contact details of members of the BoMS. This frequency is expected to increase when the new members of ERNs will join. The Commission will check under what conditions it can legally share the contact details and will proceed accordingly.

Meeting participants:

Members: Austria, Belgium, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Ireland, Lithuania, Luxembourg, Malta, Romania, Germany, Netherlands, Norway, Poland, Italy, Spain, Cyprus, Greece, Sweden.

European Commission: DG SANTE and HaDEA

External companies: AETSA Consortium and Ecorys.