



BOARD OF MEMBER STATES ON ERNS

26 JUNE 2018, 10:00-17:00

VENUE: PERMANENT REPRESENTATION OF POLAND TO THE EU

Rue Stevin 139, 1000, Brussels

MINUTES

CHAIRS: ANDRZEJ RYS & TILL VOIGTLAENDER (Co-Chairs)

1. Welcome and approval of the agenda and of past meeting minutes (*Chair AR*)

DG SANTE B Director Andrzej Rys welcomed all participants and opened the meeting. All EU Member States (except Croatia, Czech Republic, France, Italy and Romania) and Norway were represented.

The Board discussed the minutes of the last meeting. Two members of the Board of Member States (BoMS) argued that they were missing certain aspects of their interventions, namely, the importance of having the Network specific criteria available prior to further enlargement of the Networks. The Chair agreed to amend the minutes accordingly and as for the practical implementation, the Chair committed to do the necessary to extract the information related to the Network specific criteria as soon as possible, latest by end of September, from the 2016 applications for the establishment of the Networks and make it publically available on SANTE's website. The Board then approved the minutes¹.

The Board considered the agenda prepared by the Secretariat and approved it as proposed. One member reminded the Secretariat of the deadlines to be respected when circulating documents to prepare the meetings.

Affiliated Partners

The Chair reminded the Board that following the debate at the last BoMS meeting, the Secretariat amended both proposals on Affiliated Partners – Statement on Timeline for designation and Rules of Termination –, and then circulated them for approval in written procedure. The revised documents reflect the comments made during the last BoMS meeting. A clean version and a comparison in track changes to the text discussed in March for both proposals were disseminated. The written procedure lasted from 7 June

¹ https://ec.europa.eu/health/ern/events_en#anchor0

until 21 June 2018. Within the deadline of the written procedure the Secretariat received one request for clarification and two comments:

- One member reminded us that in the March meeting we had decided to replace the "invites" on page 3 addressed to the ERNs with "requests". An updated version of the Timeline reflecting that comment had been circulated (12 June 2018).
- Another member drew our attention to the possibility of simplifying the text of the Timeline proposal. The Commission services took this suggestion too on board and circulated the new version to the Board (21 June 2018).

One member expressed dissatisfaction with the fact that the delivery of the integration strategies by the Networks (initially intended to be approved by the BoMS in June 2018), was postponed to the Board meeting of November 2018. As it is important to have these documents approved by the BoMS before the designation of Affiliated Partners, it was proposed to amend the text accordingly.

The Commission services explained that the deadlines across the whole document were postponed as the original ones had been drafted assuming an approval of the proposal in March. Moreover, it was argued that the Networks integration strategies were not needed for the designation of Affiliated Partners. It was also noted that the Network specific criteria should only serve as an orientation for Member States, as the thresholds do not apply to Affiliated Partners.

Finally the Board agreed to further align the deadlines in the Timeline proposal. It was decided that Member States will designate Affiliated Partners *in the next months and possibly at the latest by December 2018*. And that the Networks will develop *by end of February 2019* their integration strategies which will be presented to the Board in its *first meeting of 2019*.

With these changes the Board approved both proposals. The Secretariat will proceed with the publication of the finalised Statements on SANTE's website².

2. Amendment of the Implementing Decision 2014/287/EU (Chair AR)

The members of the Board received an informal text with the amendments that Commission services are currently considering. The Deputy Head of DG SANTE Policy Unit summarised the main outcomes of the phone calls that DG SANTE had with many BoMS representatives (24/29) to seek their opinions and comments on the proposed text. The proposed amendments aim to clarify the role of the Board in steering the ERN initiative and to modify the procedure concerning the application for membership in existing ERNs. The new draft already reflected the input received by the members of the Board.

² https://ec.europa.eu/health/sites/health/files/ern/docs/2018_statementtimeline_ap_en.pdf

https://ec.europa.eu/health/sites/health/files/ern/docs/2018_rulestermination_ap_en.pdf

As for the role of the Board (Article 6), it was proposed to expand the Board tasks which are currently limited to the approval of proposals for Networks, their membership and their termination, and establish that the Board shall steer the development of the ERNs, provide guidance to the Networks, as well as to the Member States, and advise the Commission on matters related to the implementation of Article 12 of Directive 2011/24/EU. These are in any event activities that the Board is already carrying out.

As for the membership application procedure (Articles 8-10), it is was proposed that each membership application shall be accompanied by a favourable opinion from the Board of the Network that the healthcare provider wishes to join.

The following points were raised by the members of the Board:

- It was suggested that the steering role of the Board is extended also to the preparation of the assessment and evaluation manuals (Articles 13 and 15).
- A question was asked about the decision making process within the Boards of the ERN Networks which shall issue the opinion on the membership application. It was clarified that the Boards of the Networks are composed by representatives of each hospital member of the Network in line with the Commission Delegated Decision 2014/286/EU setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil (Recital 3 and point 1)(b)(ii) in Annex I).
- Concerns were expressed on the workload of the BoMS and on the feasibility for the BoMS to overrule a negative opinion of the Board of the Network.
- It was highlighted that the opinion of the Board of the Network should not be an excluding step but a peer review in a quality assurance framework.
- It was clarified that the Assessment Manual will provide the details of the procedures and notably the deadlines for each step.
- The following aspects of the proposed approach were appreciated:
 - that the endorsement of the Member State of establishment is the first step;
 - that the opinion of the Network is issued by its Board;
 - that only the Member State of establishment can appeal to the BoMS in case of negative opinion by the Board of the Network;
 - that the final say on the applications remains with the BoMS.

As for the procedure, some BoMS members expressed their concern for the series of phone calls that DG SANTE had organised. They were arguing that this kind of discussions should take place during Board meetings in a form of open debate allowing to know each Member State's opinion. One Member State encouraged members of the Board to actively participate in the Board debates.

The Chair underlined that after the last meeting it was clear that there was a need to deepen the discussion with Member States to understand their views.

The Chair also reminded that the text was to be discussed in the Cross-border Healthcare Committee, on July 9.

Finally the Commission services explained that they were considering introducing in the amendment rules on co-controllership of patient data in the CPMS due to the entry into force of the General Data Protection Regulation (GDPR): these changes would avoid the administrative burden of signing agreements with the 300 Hospitals which are ERN Members.

3. Feedback on the activities of the ERN Coordinators Group (*Chair AR*)

The Chair informed the Board that as of June 2018 the term of the ERN Coordinator Group (ERN-CG) Chair expired and, therefore, Prof Maurizio Scarpa handed over his tasks as Chair to Prof Franz Schaefer, former Vice-Chair.

Prof Scarpa assessed the first year of activity of ERN-CG. The first year was dedicated to put in place the concept of ERNs. The established governance structure including details on the existing working groups was presented. The comprehensive amount of achievements to which the ERN-CG in collaboration with the BoMS contributed were presented. It was underlined that the ERNs are not virtual any longer, all Networks have a solid structure and a governance and they are all committed to continue to implement and expand their activities. The ERN-CG has become a homogenous group and it is not just an expert group, but also a “tool” to be consulted. The Networks need support in order to be fully integrated into the national health systems and sustained as a new concept of medicine.

Then Prof Schaefer summarised the discussions that took place at the ERN-CG meeting held the day before the Board meeting. The Board was also updated on activities being carried out by the different ERN-CG working groups (WGs).

- The ERN-CG elected its new vice-chair for 2018/19, Mrs Matthijssen (Coordinator of ERN CRANIO).
- Prof Schaefer proposed to the Board that the working groups of the BoMS and of the ERN-CG were merged, to create synergies and align work.
- Report from the WGs activities:
 - WG on Monitoring – the working group finalised the first set of 18 core indicators. The aim is to provide a conceptual framework to carry out continuous monitoring and periodical self-assessment of ERNs by identifying common indicators to all the networks.
 - WG on Research – a debrief of the RD-ACTION workshop on ERNs & Clinical Research at EMA (29-30 May) was given. The aim of the workshop was to:
 - share the state of the art of tools and resources which exist in 2018 to streamline and optimise each ‘point’ in the clinical research pipeline;
 - better understand the priorities and needs of the ERN community specific to clinical research;
 - clarify the services and opportunities offered by EMA which are of relevance to clinical research in rare and highly specialised domains;

- identify concretely *how* and *where* ERNs could make a positive difference, including points of engagement specifically with the EMA, to agree a ‘roadmap’ to a more strategic and streamlined collaboration in future.
 - WG on Ethical issues – the WG prepared a new version (V2.3) of the Policy of Conflict of Interest. It was reviewed by the ERN-CG and DG SANTE.
 - The WG is now proposing to re-open the discussion on the Statement of the BoMS on *ERNs and Industry* as according to the current wording, ERNs would not be allowed to receive industry funding for any ERN operational activity. However, the objectives that the Networks are asked to fulfil require more funding than the EU is currently providing.
 - The WG needs legal advice and requested help from DG SANTE.
 - The WG is proposing:
 - rules for independency from industry on content;
 - balance of funding ERN activities (e.g. guidelines, meetings);
 - clarification of roles and tasks between ERN-CG and DG SANTE.
- Other activities in which the ERN-CG is involved:
 - The methodology used in the mapping exercise in view of analysing the needs for the ERNs in terms of geographical spread and expertise – Prof Schaefer underlined that the mapping is based on an online survey sent to all ERN Coordinators in March 2018. The survey was completed by 22 Coordinators. The outcome of the survey is available per ERN and per country. Unfortunately, some data suggests that one should be cautious when interpreting the results.
 - European Joint Programme for Rare Disease Research – the proposals were submitted on 15 April 2018 and the funding is expected January 2019. ERNs will be part of many Work Packages.
 - Innovative Medicines Initiative – the Connect 4 Children is a collaborative network for European clinical trials for children, which will last from 2018 to 2023. It has 41 members, including ERKNet, MetabERN, EpiCare and PaedCan.

The presentation was followed by a discussion.

Several members of the Board agreed to discuss again industry funding while underlining the importance of full transparency. One member proposed to have this topic as an agenda item at next Board meeting.

The Chair committed to provide legal support on the final version of the Policy document and requested the Working Group on Industry of the Board to review the Policy on Conflict of Interest. The role of private funding in the development of guidelines, registries (disease and not drug-specific) and supporting educational activities as well as the type of instruments will further be discussed by the BoMS.

Finally, the Board agreed with the proposal to merge the Industry WG of the Board together with the WG on Ethical issues of the ERN-CG.

4. Integration of ERNs into the national health system of the Member States *(Chair AR)*

Paul Boom, Chair of the WG on Integration, presented to the Board the draft position paper, which was prepared based on the outcome of a survey addressed to Member States and covering all the aspects of Integration.

The Chair of the WG underlined that the draft was a preliminary paper of the progress made by the WG. It reflects on all the themes falling under the scope of the WG, notably on the national plans on rare diseases, patient pathways, referral of patients to the ERNs, reimbursement in case of patient mobility, support by Member States to the ERN structure and awareness raising. The most important part of the progress made was the identification of the strategic issues that need to be addressed and challenges to be overcome to ensure a proper integration of the ERNs into the health systems of the Member States and thus the delivery of the expected benefits. The paper describes in details the current state of play for each strategic area and formulates recommendations for the Member States to address these issues. In relation to referral of patients to the ERNs, the paper requests information from ERN-CG on the type of patients to be treated by each Network and the requirements to be met for a patient's case to be eligible for referral to each ERN. As for the reimbursement in case of cross-border mobility, it has been suggested to take this area out of the scope of the WG.

In the discussion following the presentation one member underlined the need to reflect on the criteria to be met for a patient's case to be eligible for referral to each Network. Another member raised the importance of involving patients' representatives. The Chair concluded that once the paper will be more mature we could, for specific elements, consult hospital managers and/or patient organisations.

Finally, it has been decided the Birute Tumiene, representative of Lithuania, will take over as chair of the WG from Paul Boom, representative of the Netherlands, who has been assigned a new job.

5. ERN Monitoring *(Chair TV)*

The Policy Officer of DG SANTE Policy Unit presented the proposal of a core set of ERN indicators. Following the March meeting of the ERN BoMS and according to the mandate given to the Secretariat, virtual meetings of the new Working Group on ERN Continuous Monitoring and Quality Improvement System (ERN CMQS) were held in May and June. The new group is a result of merging the working groups of the Board and the ERN-CG. The integrated Working Group includes five members of the Board (AT as chair and FR, ES, UK, NO) and five ERNs (eUROGEN as chair and CRANIO, ERKnet, eUROGEN, TRANSPLANTCHILD, VASCERN). The mandate given to the integrated WG was to identify a core set of ERN indicators based on the initial proposal. The methodology took into consideration the priorities, the feasibility, utility and

appropriateness and the analysis of the resources and capacity to develop the info system together with DG SANTE IT services.

Four possible work packages have been identified; the current proposal includes the background, methodology and proposal of the set of 18 indicators for the initial monitoring of the ERNs (work package I). The other strands of the future ERN CMQS include:

- II. ERN specific set of indicators (by ERN). Including Network specificities and addressing outcomes (clinical and not clinical).
- III. ERN extended set of indicators (HCP indicators from applications 2016). Periodical self-assessment and reporting of the ERNs and HCPs.
- IV. External (MS or third parties) validation of HCP fulfilment of the criteria (specific criteria) for healthcare providers defined in the HCP membership applications (2016).

A Roadmap of the next steps related with the implementation and completeness of the ERN continuous Monitoring System was also presented to the members of the Board. The timeline foreseen will allow the 5 years evaluation.

One member complained about the late dissemination of the documents and requested more time to assess them. The importance of outcome-side data and the need to find all the patients were raised. Adjustment of the current assessment and evaluation manuals to ensure interoperability of data was also mentioned. The need for data enabling an economic analysis was stated. The lack of data on access to ERNs was mentioned as it is necessary to raise those questions which will one day show that access/quality of care for patients suffering from rare and complex diseases has improved thanks to the ERNs. The possible link with the Integration WG as well as the interlink with the discussion on registries was noted in relation to data on accessibility.

The Chair closed the discussion with the following conclusions:

- written comments should be sent to the Secretariat until the end of July;
- work to be finalised in August;
- launch written procedure for approval of the proposal at the end of August.

6. Tenders under the Health Programme to support ERNs (*Chair TV*)

The representative of DG SANTE Policy Unit informed the Board on the Tenders under the Health Programme to support ERNs. These include:

- Taxonomy and templates for ERN documents;
- Secretarial support to the ERN-CG and its working groups;
- ERN Coordinators training, methodology and tools;
- Report on ERN research capabilities;
- Animation video clip on “ERN for patients”;
- Clinical guidelines.

In relation to this it was explained that the Knowledge Generation Working Group was reactivated by the Secretariat in May and a written consultation was launched on the priorities for the Clinical Practice Guidelines Development. Based on the outcome of the survey an action on Clinical Practice Guidelines will be included in the 2018 Annual Work Programme of the Health Programme. A tender for the relevant actions is under preparation. There is a need for a strong leadership and to integrate and co-chair this WG with the ERN BoMS representatives in order to create a joint WG as in the case of monitoring. Therefore; the Secretariat launched a call for participation among the Board members. AT, HU and IE representatives expressed willingness to join. Further volunteers are welcome to join. The importance of using already existing guidelines (even national ones) was underlined by some Member States.

7. Progress on clinical patient work (CPMS pilot phase, ITAG meeting debrief (Chair TV)

The representative of DG SANTE Policy Unit updated the Board on the first user experiences and the concerns raised, and highlighted the on-going development mainly related to the joint controllership of patient data as referred to in Article 26 of the GDPR and the liability disclaimer.

In summary, 2017 was dedicated to the development of the Clinical Patient Management System (CPMS) and the European Collaborative Platform (ECP). First views from CPMS users have been collected through two surveys run by both SANTE Policy and IT units. Globally, the overall satisfaction is high. The largest barrier to use the CPMS is linked to the perceived complexity of the system. Further concerns raised are related to the legal clearance of the use of CPMS and Informed Consent Form, the time constraints and the need of support from “assisting staff”. The language versions of the Informed Consent Form are available in the ECP (Board of Member States network space). The current issues at stake are the latest developments due to Article 26 of the GDPR, on joint controllership, the delegation of administration rights and the first analysis for a “panel manager” role. The results of the surveys have been presented and discussed first at the IT Advisory Group meeting, on 5 June 2018.

The representative of DG SANTE IT Unit debriefed the Board on the CPMS activity and the outcome of the CPMS survey, and reported on the use of ECP by ERNs. By the end of June, 164 panels have been created; 48 of them have been closed or archived in the CPMS. There are 949 users registered and 67 healthcare providers have already enrolled a patient. In summary the survey showed that the training documents, videos and webinars were considered useful by ~90% of respondents. 69% agreed that further training is required. Some training materials were considered too long. Users are satisfied in general, but find difficulties in logging in. Some users considered the workflow too complex. Many do not have the time to learn about the system without extra support staff. As for the ECP, it has 1225 users with already 3485 documents uploaded. A new network space in the ECP, the “Plaza”, was launched mid-May with the main purpose of communicating among the different ERNs and BoMS representatives and thus create an ERN community. ECP users have to connect once to their network to be automatically added to the Plaza and receive the weekly newsletter.

8. Preparedness actions to UK withdrawal (*Chair TV*)

DG SANTE B Director provided information on preparedness actions for the withdrawal of the United Kingdom from the European Union. The withdrawal is announced for the 29th of March 2019. It will essentially mean that the 114 British hospitals which are currently ERN members will stop being members of their Networks. It may occur that a Withdrawal Agreement will define a transition period ending possibly in December 2020. According to the competent Commission services, during the transition period, the 114 British hospitals will continue being members of the ERNs. However, as the UK is already to be considered as a third country, UK representatives will be excluded from any governance of the ERN initiative and, in particular, cannot sit in the Board. At the same time, it is unknown if there will be a Withdrawal Agreement and a transition period. Therefore, to ensure that ERNs continue being operational in a EU-27 environment, there is a need to take measures to prepare for the worst scenario, a "hard Brexit", a split without a withdrawal agreement and without a transition period, which will mean that the 114 UK hospitals are not anymore ERN members on 29 March 2019.

This is particularly delicate for the 6 ERNs that have British Coordinators (EpiCARE, eUROGEN, ITHACA, NMD, RARE-LIVER, RITA). The Commission has therefore encouraged the 6 British Coordinators to launch an internal reflection in their Networks to identify the hospital that could replace them as Coordinating Member and, once the successor is known, to start preparing the transition. As for the right time at which to prepare for the replacement, it should be done now. The Commission will provide in time the information on the right time for the nomination.

The Board found reasonable the preparedness measures for the UK withdrawal as described.

Communication activities (*Chair TV*)

The member of DG SANTE ERN team in charge of Communication provided a comprehensive state of play related to communication activities.

The Commission ERN Communication plan which concerns external communication activities and covers the period of May 2018-May 2019 was adopted. It has several objectives, including to raise healthcare professionals' awareness on the existence of the ERNs and encourage them to inform their patients of the possibilities offered by the ERNs; to ensure that patients are getting the necessary information about the existence of the ERNs and to strengthen collaboration with the hospital managers. The spectrum of actions varies according to the specific targets.

Information was given on the particular aspects related to personal data protection in light of the GDPR to allow communication products to share testimonies of patients.

This information was accompanied by a call to set up an informal advisory group on communication activities which will gather volunteers from the BoMS, the ERN-CG and ePAGs, to support the Commission in the implementation of the ERN Communication

plan and help Member States and ERNs in their national dissemination endeavours. The representatives of Lithuania, Belgium, Austria and Greece volunteered.

Lastly, information was given related to the European Collaborative Platform where a specific space is dedicated to the members of the Board to facilitate internal communication activities (sharing documents, presentations etc.) and the Plaza which is a common space for the whole ERN community.

Any Other Business (*Chair TV*)

- The 2018 ERN Conference will take place on 21-22 November in Brussels.
 - 20 November Networking dinner;
 - 21-22 November Conference with 5 round tables and 8 parallel sessions.
- The list of SANTE B3 ERN team members was distributed.
- The Chair announced that Dr Teresinha Evangelista has become the new Coordinator of ERN EURO-NMD following retirement of Prof Kate Bushby.
- In response to a question the planned timing of the upcoming enlargement process was summarised by SANTE Director B:
 - end of September 2018 the Network specific criteria will be made publically available;
 - end of September and possibly at the latest by December 2018 Member States will designate Affiliated Partners;
 - end of 2018 – beginning of 2019 start with the modified procedure for healthcare providers to join existing ERNs as full members.
- The chair informed the members that the next Board meeting date is 20 November 2018 (Brussels).

END OF THE MEETING