EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

MINUTES OF MEETING - DRAFT
BOARD OF MEMBER STATES ON ERNS
24TH OCTOBER 2023, 9:00-15:00
LUXEMBOURG AND WEBEX

Participants:

Commission: SANTE B3, SANTE D3

Member States present on-site: AT, CZ, FR, HU, MT, NO, RO.

Member States present online: BE, BG, CY, DE, DK, EE, FI, HR, IT, IE, LV, LT, LU, NL, PL, PT, SK, SI, SE.

ERNs: ERN Coordinators' Group Co-Chair

Invited: Contractor (infeurope & Mercury-97) to take minutes, Independent Evaluation Body (HRPA and IDOM) to hold presentations on the respective area of work covered by their contract

Agenda:

9:00 - 9:30 Arrivals and Dial-in		
1	**9:30 - 9:40**	**Opening** of the meeting
2	**09:40 - 10:00**	**Update from BoMS Chair (20') for information and discussion**
3	**10:00 - 10:20**	**Update from the ERN Coordinators Group (15') for information and discussion**
4	**10:20 – 10:50**	**Joint Action on integration of ERNs into the national healthcare systems (JARDIN) (30')**
10:50 - 11:05 Coffee Break		
5	**11:05 – 12:00**	**Commission Updates – RoP, ERN Network updates, Ombudsman recommendation & UA activities (55')**
6	**12:00 - 12:15**	**Any Other Business (AOB) (15')**
12:15 – 13:15 Lunch		

7	**13:15 – 14:20**	**Evaluation state of play for information and discussion (65')**
8	**14:20 – 15:15**	**Evaluation working methods: for information and discussion (55')**
9	**15:15 - 18:00**	**Evaluation results: for discussion and decision making (165')**

1 | 9:00 - 9:20 | Opening of the meeting

DG SANTE welcomed participants to the 27th meeting of the ERN Board of Member States and passed the floor to the Acting Director of 'Public Health, Cancer, and Health Security' Directorate, who provided a welcome speech to the group. He praised the efforts that the ERN Coordinators' Group (CG) and the BoMS dedicate to the development of the networks and continued by highlighting some of the most important recent developments for the ERNs.

There has been a visible increase in momentum in the area of rare diseases, as was demonstrated at the rare disease conference in Bilbao (Spain) that was rich in contributions by the EC, ERN coordinators, the EESC and other stakeholders.

He highlighted the letter sent by ERNs to the European Parliament, the European Commission, and the Council asking for their continued support of the ERNs. This letter included concrete numbers indicating the impact of the ERNs for patients with rare diseases in Europe. Sharing the impact of the ERNs and their concrete data can help them to obtain support at higher political levels. This was also a message shared with the ERN CG the day before: to use the new four-year grant to give more visibility to ERNs' activity, increase their impact on patients living with rare diseases and their families, and the important data they are gathering on the treatment of rare diseases. This topic is also linked to the ongoing discussions on the ERN registries landscape. Data in these registries will grow exponentially in the coming years, so information about national rules on data protection applicable to the registries will be of great help for the EC.

Regarding the new grant period 2023-2027, appreciation was expressed regarding the unified structure of work packages, which will be a great opportunity to boost the ERN community through peer learning, and better integration into the national health-care systems. JARDIN (Joint Action on ERN integration into national healthcare systems) also receives strong support from the EC and will play a key role in that process. Such extensive Joint Actions (JA) as JARDIN can succeed only if every partner fully engages in the process. That is why the BoMS members are called to act as ambassadors of JARDIN in their competent authorities, in their countries and share information with stakeholders as much as possible.

2 | 9:40 - 10:00 | Updates from the BoMS Chair: for information and discussion (20')

The ERN BoMS Co-Chair provided an update on the BoMS activities, which during the last year were mainly focused on the 5-year evaluation process and the development of JARDIN.

The evaluation is considered successful as all 24 ERNs were evaluated as satisfactory. 733 HCPs out of 836 HCPs achieved a satisfactory result. 81 HCPs were given an opportunity to submit improvement plans, out of which 71 HCPs submitted one, ten did not submit, and six decided to leave their network. Only 16 HCPs never started their self-assessment. It should also be noted that there are the big differences in the quality of the data provided by HCPs, which means there is room for improvement in the evaluation process and indicates the need to raise the motivation of specialists from HCPs who struggle to find enough time and resources to deal with the additional workload linked to the evaluation. The ERN BoMS Co-Chair suggested that these issues can be addressed by establishing a Joint Working Group (WG) on Evaluation Improvement, which should consider the general landscape of ERNs in Europe – in terms of capacities, demands, and the general goals of the networks as a viable system. There are still gaps in the geographical coverage of the networks, and more effort is needed to secure access to ERNs in every EU MS. It is important to have a clear picture of the capacity of ERNs to integrate new members and compare it to the general expectations of the representatives of the Member States. Such an analysis can be the basis for a strategy of the development of ERNs in the future. It is also crucial to re-evaluate the current scope of the networks in terms of disease coverage and initiate a new call for expansion if needed.

JARDIN presents an important opportunity for reinforcing the networks, but it is also important to note the involvement of many other projects, such as EJPRD, ERDERA, Horizon Europe, and the EU mission on cancer. They are key for ERNs contribution to research and innovation. Emphasis was put on the need for expanding the reach of ERNs' educational activities to different communities involved in the care process – from specialists to students, families, and primary care.

Regarding the responsibilities of the BoMS, the Co-Chair emphasised the complexity of the decision-making process that requires significant time for preparation and discussion. *Ad hoc* meetings of the BoMS are extremely important as well as all opportunities for triliteral collaboration and communication with the EC and the ERN CG. All kinds of formal and informal collaboration and exchange are strongly encouraged.

Discussion:

AT shared the opinion that access to ERNs is a big concern in the ERN coverage and stressed that more effort is needed to encourage a fairer geographical distribution of the ERN expertise, for instance via affiliated entities. Regarding the evaluation, AT expressed the concern that affiliated partners were not part of it and expressed the opinion that their resources should also be quantified and presented in a standardized way in the future.

CZ expressed their scepticism regarding the possibility of achieving geographical coverage of highly specialised care as centres cannot be moved and some peripheral areas will always be further away.

AT noted that statistics show big differences in the HCP distribution among the Member States, and this is something that could be addressed.

3 | 10:00 - 10:20 | Update from the ERN Coordinators Group for information and discussion (20')

The ERN CG Co-Chair provided an update from the ERNs Coordinators Group. He started by highlighting the success of the conference on rare diseases that took place on 11 October 2023 in Bilbao, Spain, and attracted participation of high-level decision-makers. Five ERN coordinators were able to present at the conference, making a good case for the achievements and the plans of the networks.

More efforts are needed to achieve broad understanding and more political support for the ERNs. A joint letter was therefore sent by ERNs and EURORDIS to the EU institutions requesting more support for ERNs. The Co-Chair also praised DG SANTE's continuous commitment to the ERNs and the regular communication with the BoMS. However, it is recommended to work on key actions, some of which started but were put on hold. These actions are the management training program for ERN coordinators, the expansion of disease groups for ERN/HCPs, and the ERN Academy. These actions could be implemented under the new grants.

Furthermore, the ERN CG Co-Chair underlined that the integration of the ERNs within national healthcare systems is the major challenge and task for the next years. While the main tasks on the adaptation of national systems will be performed under JARDIN, effort is also needed from individual ERNs that will have to improve their integration readiness by suitable implementation and delivery of their core activities.

On the communication side, the ERN CG Co-Chair highlighted the need for better promotion of the ERN resources. The ERN CG called for the creation of a single access repository system with training resources, patient journeys, registries, clinical guidelines, as well as for the completion of a bespoke metadata catalogue of ERN registries.

The ERN CG Co-Chair presented a proposal for four concrete action points:

- Establish an ERN resource access platform (ideally hosted by DG SANTE).
- Develop and implement ERN coordinators training platform.
- Update and enrich DG SANTE ERN website.
- Form a joint CG/BoMS/DG SANTE working group on evaluation improvement.

Discussion:

CZ and AT expressed the concern that BoMS were not informed about the letter sent to EU institutions regarding the call for ERN support and stated that their corresponding ministries have not received this communication. It is desirable that ERNs inform BoMS in advance about such actions as the letter in question.

It was agreed that a link to the letter will be sent to participants after the meeting, who are in return asked to bring it to the attention of the respective national authorities[1].

4 | 10:20 - 10:50 | Joint Action on integration of ERNs into the national healthcare systems (JARDIN) (30')

The coordinator of the Joint Action JARDIN (Joint Action on integration of ERNs into national healthcare systems) provided an update to the group. JARDIN falls under the exceptional utility rule with 80% funding of the EC and 20% by Member States, with a total budget of EUR 18.750 million (More than EUR 15 million funding from the EC). Its main goal is to improve the sustainability of ERNs and better integrate them into national healthcare systems. The final grant agreement is currently under preparation, and the deadline for signing the grant is set for 14th December. The project should be launched on 1st February 2024 and run for three years until 31st January 2027. JARDIN has a total of 9 Working Packages:

- **WP1 – Coordination and Management**
- **WP2 – Evaluation**
- **WP3 – JA dissemination and ERN dissemination.** This work package includes the development of full-scale professional information campaigns for two main target groups – 1/Patients and 2/ Medical doctors and staff on a more primary care level. Pilots have started in IT, RO and IE. Results will be analysed and used to provide materials for all Member States.
- **WP4 – Sustainability and National Plan Capacity**. This package is dedicated to actions for securing the sustainability of the actions started under JARDIN after the end of the 3-year project. JARDIN's mission is to develop toolboxes, documents, blueprints and pilots that are picked by Member States and motivate national governments to take more responsibility and provide support to ERNs even without EU funding.
- **WP5 - National governance and quality assurance**, including developing national governance models for ERNs/HCPs, introducing indicators for national monitoring of rare diseases and indicators for national ERN integration.
- **WP6 - Development of national care pathways for rare diseases and ERN referral systems**
- **WP7 – Development of undiagnosed rare disease programs**
- **WP8 - Data management.** This work package is the biggest one in terms of budget. Funding is secured for pilots for better interoperability and better secondary use of data, data sharing and electronic health records.
- **WP9 - National support options for ERN-HCP**. The aim of this WP is to develop recommendations for national and hospital-level support of ERN/HCP as well as recommendations for reimbursement model of CPMS activities.

The Joint Action will rely on a multistakeholder advisory group, composed by four subgroups:

1. National Policy Contact Point Group
2. Hospital Managers Advisory Group
3. Patient Advisory Group

[1] https://paedcan.ern-net.eu/wp-content/uploads/sites/2/2023/10/open-letter-erns-180923.pdf

4. Data Management Advisory Group.

The National policy Contact Point Group will include one contact point for each Member State. The aim for these contact points is to be high-level official representatives of the Ministry of Health of each Member State with a certain level of policy mandate and close links to all related topics of the Work packages targeted by the project.

The Hospital Managers Group should include all hospital managers from the ERN coordination centres in six (6) countries plus one hospital manager per country for the remaining twenty-one (21) countries. Any support by the BoMS on selecting and contacting managers will be highly appreciated. Through the Data Management Advisory Group the contact with the ERNs will be ensured.

As a conclusion, the JARDIN Coordinator remarked that the success of the JA will depend considerably on the active involvement of key stakeholders in the Member States – health authorities, hospital managers, and decision makers. That is why the support of the BoMS in that direction is essential.

Discussion:

The BoMS Co-Chair suggested that a discussion in JARDIN should take place on creating and sending to Ministries of Health clear guidance on the criteria for the appointment of national contact points and members of the Hospital Managers Advisory Group. JARDIN Coordinator invited all members to share insights or comments on how general guidelines can be adapted for their national context.

IT and FR stressed that work on data under WP8 should be developed in connection to the European Health Data Space (EHDS). It is recommended to have a contact point for the EHDS for each country involved in JARDIN. The involvement of hospital IT managers was also mentioned as an important component of the Work Package.
DG SANTE explained that the EHDS implementation is within the DG SANTE remit, thus synergies could be easily created, and suggested that representatives of the dedicated Unit (C1) could be invited to the next BoMS meeting.

ES informed that it has developed a platform that can be used by healthcare providers to present clinical cases to reference centres in hospitals. Reference centres then can analyse the cases and decide on their referral to the ERNs. The pilot of the platform is planned for the first trimester of 2024.

CZ raised concerns about the way national policy contact group and hospital managers representatives should be appointed. The situation varies significantly between Member States. In many countries, the competent authorities are the ministries, but for a certain proportion of Member States these are university hospitals appointed by the ministries. It was proposed that a letter with the requirements about the competences of the national contact points should be

sent to ministries of health by DG SANTE to maintain the communication at the highest level possible. Regarding the hospital managers group, CZ suggested to consider the type of hospital (in the national healthcare system and university hospital), their type of governance, and to set a threshold of a minimum number of ERN centres within the hospital (e.g. 6).

HU remarked that communication activities under JARDIN should send the message that rare disease patients are as important than other patients. Communication activities should also try to show the tangible results that ERNs have on the wellbeing of patients.

4 | 11:05 - 12:00 | Commission Updates – RoP, ERN Network updates, Ombudsman recommendation & UA activities: for information (15')

Presentation RoP

DG SANTE presented a quick overview of the proposed changes on the Rules of Procedures of the ERN BoMS. The goal of the proposed update is to unify the deadlines with the ERN CG Rules of Procedure for the EC to streamline communications with these two groups. A group in Microsoft Teams will be created, where participants can provide feedback or propose additional changes. All proposed changes are considered minor. The most significant ones include:

- Article 1.3 Members of the Board – It is proposed to include that it is highly advisable that at least one of the representatives comes from the Ministry of Health.
- The addition of a new Article 1.6 on *ad hoc* alternates of the representatives – If neither of the two official representatives can attend a meeting, an ad-hoc alternate can be designated by one of the official representatives with signed authorization.
- Article 3.1 Convening a meeting – Meetings of the Board are convened at least once per year, but preferably twice as a standard procedure. The EC has the right to request an ad-hoc meeting. In such cases the delivery of the agenda and the supporting documents can be delivered less than 15 days before the meeting.
- Article 9 Admission of third parties–Co-Chairs are no longer the only ones who can invite third parties to the ERN BoMs meetings. The EC also receives the right to do it.

Presentation Coordinator changes & voluntary withdrawals

DG SANTE informed that it has identified procedures to be followed in three different situations that have materialized so far in the ERNs regarding a voluntary withdrawal on an HCP and a change in an ERN coordination. The cases are as follows:

1. An HCP wants to voluntarily withdraw from an ERN.
2. An ERN is affected by a change in its coordinating person.
3. An ERN is affected by a change in its coordinating clinical centre.

The procedures will be formalized and distributed to the ERN CG and the BoMs. Cases that have not materialized so far, such as the case in which an ERN might decide to select a new coordinating centre from another ERN, have not been discussed.

Presentation Ombudsman recommendation

DG SANTE presented the European Ombudsman decision of 18th September 2023 on how the European Commission handled concerns about guidelines developed by ERN CRANIO for the medical condition Pierre Robin sequence (Case number 1900/2021/FA). The complaint concerned the choice of healthcare providers involved in the development of the guidelines; the absence of patients' representatives; and the non-compliance with the "Methodological Handbook & Toolkit for Clinical Practice Guidelines and Clinical Decision Support Tools for Rare Disease" in the process of guidelines elaboration. As regards the latter, the Ombudsman noted that the methodological handbook is a non-binding document available to ERNs. As regards the other claims, the Ombudsman noted that there is no means for parties to lodge a complaint if no solution is found at the level of the individual ERN. It was also noted that ERNs undergo an external evaluation every five years, but this evaluation is general in nature; and the BoMS cannot trigger an evaluation of ERNs outside the periodical evaluation exercise regardless of the concern raised. Therefore, unless a periodical review is imminent, all complaints would be deferred until the following evaluation cycle. In order to address the lack of mechanisms for second level complaints, the Ombudsman issued the following suggestion:

'The Commission should put in place, in agreement with Member States, a complaint mechanism to address concerns raised by third parties on the activities and functioning of ERNs in a timely way. In this context, it should ensure that the remaining concerns raised by the complainant on how the clinical practice guidelines for Pierre Robin sequence were developed are addressed.'

BoMs were invited to share their opinion on the possibilities for follow-up actions for second level of appeal against ERNs. There was no discussion on this point.

Presentation UA activities

DG SANTE gave un update on the Ukraine-related activities. The pilot UA activities started as an emergency response, but since January 2023, the Ukrainian Rare Disease Hub has been transferred to Kiev at the Okhmatdyt National Specialised Children's Hospital. With the Hub receiving about 100 requests for further processing, the focus has also changed to be more akin to those provided by ERN HCPs in Europe, such as diagnosis and treatment of rare diseases, access to pharmaceutical products, legal advice, second opinions, clinical trials, and emergency evacuation abroad. Currently the hub is funded by EURORDIS. Future funding for the activities will come under JARDIN, to which UA is an associated partner, and under the ERN grant, where two WPs are dedicated to UA.

There is a strong political will to help UA in rare diseases, which is also reflected by the activities provided by the new grants. The scope of the cooperation activities that can be funded under the grant is capacity building and best practice sharing. The range of activities is wide and encompasses:

- translation and dissemination of information materials
- awareness raising campaigns on rare diseases by the Ukrainian authorities and healthcare units
- twinning and exchange programs
- development of educational materials for the Ukrainian authorities and healthcare units
- provision of virtual or physical training to the Ukrainian authorities and healthcare units
- provisions of guidelines for patient care and treatment.

Some activities with UA require certain safeguard measures to secure data protection. An update of the legal framework should be in place before the end of 2023, as it affects activities in WP9 of the grants. A dedicated consultation session with ERNs should take place in November to further explain the framework. In addition, an information session for medical professionals on the data transfer to third countries through CPMS will be planned and organised in the future, if deemed necessary.

Discussion on other subjects:

CZ remarked that regarding the RoP, it should be considered how to improve the connection between the ERN CG and the ERN BoMs.

The possibility to invite CG members as observers of BoMS meeting was questioned by DG SANTE because, according to the current legal framework, BoMS meeting should be closed. However, BoMS can be invited to the CG meetings. It was suggested that this can be clarified in the Rules of Procedure.

CZ also raised concerns that the ERNs still lack a clear list of diseases they cover. The quality and granularity of the list differs significantly between ERNs. Such a list is a basic prerequisite for all further discussions on reimbursement of clinical care. It is also necessary to provide clear definitions of the disease scope for ERNs, which could be made in collaboration with Orphanet.

The ERN CG Co-Chair agreed that the use of orphacodes for the purpose of the optimization of the list of disease covered is a necessity. He remarked that orphacoding can use different levels and it is recommended to use the disease entity level.

BoMS Co-Chair remarked that using orphacodes is not suitable for all ERNs such as EURACAN or PaedCan that have developed separate coding systems. One ERN, TransplantChild, does not use orphacodes at all. Orphacoding is not an easy exercise.

In response to CZ's concern that the categorisation of collaborative centres is not following unified rules which leads to inconsistencies in the listing among ERNs, the ERN CG Co-Chair explained that the only legitimate mechanism in place is 'supporting partners', which does not replace membership or associated membership.

6 | 12:00 - 12:15 | Any Other Business (AOB) (15')

Under AOB a representative of DG SANTE D.3 briefly presented the challenges that the new tightened requirements for certification and safety of medical devices pose for the treatment of rare diseases, as it may provoke shortage of important equipment. The Task Force (TF) is reaching out to ERN registries to enquire whether those registries could be a potential source of clinical data regarding medical device safety and/or performance, which could be used for manufacturers of orphan devices to contribute to the clinical evidence supporting the certification of devices. The TF initiated a collaboration with the ERN CG to identify relevant registries and retrieve the necessary data.

7 | 13:15 – 14:20 | Evaluation state of play for information and discussion (65')

DG SANTE gave a brief presentation on the legal framework of the evaluation and the role of the BoMS in the process. This was the first periodic evaluation of the ERNs and their members. DG SANTE expressed the view that the evaluation results are overall positive and took all identified problems as an opportunity to learn and improve the existing system. The preparatory process for the evaluation was performed through AMEQUIS. The evaluation was conducted by an Independent Evaluation Body (IEB). Its main objective was to assess the fulfilment of the criteria and conditions as set in the Delegated Decision 2014/286/EU as well as to identify the main areas of improvement for the care for patients with rare diseases. The criteria of the evaluation are set by an EC Implementing Decision 2014/287/EU. The Decision also sets the criteria for the loss of membership (Article 12) and procedures to be followed in case of a negative evaluation (Article 14).

According to **Article 12 - Loss of Membership** can happen in case of:

- Voluntary withdrawal
- Negative evaluation report of the member
- If the member refuses to be evaluated
- By decision of the Board of the Network.

The loss of membership shall lead to an automatic loss of all rights and responsibilities associated with the network, including the right to use the logo.

According to **Article 14**, any decision on the loss of membership on account of a negative evaluation should be approved by the BoMS. The BoMS may offer one year to the negatively evaluated centre to improve its performance only in case that the member presents an improvement plan and this plan is approved by the BoMS. Voting on the improvement plans requires a quorum of two thirds of the BoMS. Decisions on the loss of membership should be taken by consensus. If consensus is not possible, the outcome is decided by a two thirds majority of the present representatives. Each MS shall have one vote.

The IEB then proceeded to give a presentation on the main findings of the evaluation.

The evaluation exercise was completed in 10 months and encompassed self-evaluation, documentation review, and on-site visits in the HCPs. All 24 ERNs and a total 836 HCPs were evaluated.
All ERNs are evaluated as completely developed and only 84 of the evaluated HCPs achieved a non-satisfactory result. The centres with non-satisfactory results, which followed the evaluation process, were offered the opportunity to present an improvement plan and undergo a re-evaluation in one year's time. 71 of the HCPs in question submitted an improvement plan. According to the nature of issues identified and the consistency of the improvement actions proposed, the plans were categorised into three groups: (1) 'very good' – 29 HCPs; (2) 'acceptable' – 39 HCPs, and (3) 'risky' - 3 HCPs.
This classification will also affect the level of the re-evaluation after the one-year extension. If centres achieved a 'very good' result on their improvement plan, they will undergo a light evaluation – if they achieved an 'acceptable' result, a partial re-evaluation will take place – and if they achieved a 'risky' outcome, they would require to complete another full-scale evaluation. The IEB believes that all 71 centres showed strong interest and commitment to continue their work within the networks and therefore recommended the BoMS to approve the possibility of implementing their improvement plans.
A total of 13 centres with non-satisfactory result did not present an improvement plan despite the continuous effort for communication and the numerous reminders sent. Three of them opted for a voluntary withdrawal from the network. The IEB proposes to terminate the remaining ten.

The IEB also highlighted some of the main strengths and weaknesses of the ERNs as shown by the evaluation. Strengths include the clear governance framework, the development of educational and training activities, the proper identification of target groups, and the possibilities for data gathering and sharing that make important contributions to research. Weaknesses concern the lack of measurement of the clinical guidelines' implementation, the need for optimisation of the CPMS use, the lack of measurements of the patients' and families' experiences, as well as the need for standardisation of the verification and the analysis of the monitoring and clinical indicators. Once the final report is available, the findings should be discussed.

The IEB suggests concrete areas for the improvement of the evaluation methodology. These include a review of the schedule of the evaluation stages and leaving more time for experts to focus on the process. There is a need for the review of the criteria for the evaluation of HCPs, which should focus on their contribution to ERNs through clinical activities, and a review of the operational criteria for both ERNs and HCPs. It was also remarked that specific national data protection regulations and the approvals of ethical committees have been an obstacle regarding the access to documents and the interviews with patients. A complete report with the main strengths and weaknesses including the main recommendations will be finalised and distributed to the BoMs.

The ERN CG Co-Chair provided an overview of the evaluation process from the lens of the ERN CG. It was underlined that the evaluation is an important milestone that proved the ERNs' capacity to deliver results in accordance with the legal framework. Still, its implementation leaves room for improvement.

A detailed survey has been conducted by the ERN chair among ERNs to detect the main issues encountered by them during the evaluation process. ERNs' main concerns are the significant number of working hours dedicated to the evaluation. It was calculated that ERN coordination offices spent around 2-person month on average to finalise the evaluation. For HCPs that received an on-site visit, the process cost six (6) person days per audit. This is valuable time for the clinicians and rare disease experts that can otherwise be dedicated to patients.

In the list of identified problems identified by the ERNs it is also stressed that:

- The main focus was on hospitals and not on expertise centres contributing to ERNs.
- There was no coordination with national audit activities – this needs alignment to avoid double work.
- There was not enough support from HCP administrations and management, which means that the additional workload was shouldered by experts.
- The translations of the main evaluation documents and interpretation during on-site visits were paid by hospitals.
- Some of the definitions of measurable elements were ambiguous.
- The evaluation process cost too much time and its relevance is arguable.

A list of concrete proposals for improvement were also presented. It included:

- Focus on structures and processes that ERN units can change/improve.
- Ensure homogeneity on evaluation across evaluations.
- Align evaluation with ERN monitoring and build an integrated system.
- The IEB should evaluate only ERNs and leave the evaluation of HCPs to Member States to avoid overlap.
- Form a joint DG SANTE/BoMS/CG working group on evaluation improvement.

The ERN CG Co-chair concluded that the ERN evaluation suffered from the shortcomings of AMEQUIS since AMEQUIS was taken as the basis for the process. It was claimed that this is a consequence of the fact that ERNs comments on AMEQUIS were taken into consideration only to a limited extent due to the necessity to follow the legal requirements in force. A logical question to be considered is if the legal system currently in place should be changed to achieve optimal evaluation.

Discussion:

The Chair informed that the dedicated session on the improvements of the evaluation methodology would take place the next day at the BoMS meeting on 25th October.

CZ asked for more details on the exact rules of the three levels of the evaluation of the centres that presented an improvement plan as the level of acceptance of their improvement plans is not included in the reports available. In response, the IEB explained that the evaluation manual does not explain how improvement plans should be evaluated. The proposed categories are provisional, and the re-evaluation will be subject to further discussions with the EC. Information on the categorisation is included in the 'country overview' part of the report.

DG SANTE explained that not all suggestions of the CG and BoMS could be taken into consideration because of the criteria needed to meet the legal requirements. These legal requirements can be revised for the evaluation scheduled in 2027 if duly justified after analysis.

The re-evaluation of the HCPs with non-satisfactory result is required to follow the current framework. It was also remarked that a revision of methods and criteria should not lower the ERN and HCP standards as patients deserve the best care. Regarding the categorisation of HCPs within implementation plans, DG SANTE explained that the three categories have been created for the purpose of transparency and to give a clear picture of the workload linked to the improvements that HCPs should expect.

According to FI, the evaluation had too little to do with the actual expertise of centres and was too concentrated on the hospital governance.

In response to a question by ES, the IEB explained that the evaluation did not measure the individual contributions of each HCP to the general activity of the ERN, since there is no methodology available to perform such a measurement.

8 | 14:20 – 15:15 | Evaluation working methods: for information and discussion (55')

The BoMS Co-Chair provided information on the decision-making process regarding the following items:

1. Group 1: 24 ERNs received satisfactory results.
2. Group 2: 6 HCPs declared voluntary withdrawal.
3. Group 3: 733 HCPs achieved satisfactory results.
4. Group 4: 81 HCPs needed improvement plans of which:
    a. 71 HCPs submitted improvement plans.
    b. 10 HCPs did not submit improvement plans.
5. Group 5: 16 HCPs never started the self-assessment and did not follow the evaluation process.

The BoMS Co-Chair reminded that

- the decisions are taken in accordance with Article 12 and Article 14 of the EC Decision 2014/287/EU, presented in detail under point 7.
- Decisions are to be taken by consensus. If objections are raised, the voting procedure would be implemented. Voting would be open and made country by country with one vote from each present Member State representative.

It was remarked that for 'Group 2: Voluntary withdrawals' there was no need for approval from BoMS, as the centres have the right to voluntary withdraw. As such, the BoMS only take note of their decision.

There were no objections to the methodology presented.

9 | 15:15 – 18:00 | Evaluation results: for discussion and decision making (165')

The following section presents decisions of the BoMS's on the Independent Evaluation Body (IEB) proposals for actions regarding the evaluation results. Decisions were taken for five different groups as follows:

1) Decision on Group 1: 24 ERNs received satisfactory results:

No objections were presented. The positive evaluation of the 24 ERNs by the IEB was confirmed by consensus by the BoMS.

2) Decision on Group 2: 6 HCPs declared voluntary withdrawal.

Country	HCP	ERN
Belgium	University Hospital Liège	eUrogen
France	Assistance Publique-Hôpitaux de Paris, Hôpital Henri-Mondor	GENTURIS
Germany	Universitätsklinikum Münster	Endo-ERN
Germany	Universitätsklinikum Köln	ReCONNET
Italy	ASST-Fatebenefratelli-Sacco - Milan	VASCERN
Poland	University Swiecicki Hospital in Poznan	ERN-SKIN

According to the current regulation, voluntary withdrawals do not require approvement by the ERN BoMS. Note on the declared withdrawals was taken for information of the BoMS.

3) Decision on Group 3: 733 HCPs achieved satisfactory results

No objections were presented. The positive evaluation by the IEB of the 733 HCPs was confirmed by consensus by the ERN BoMS.

4) Decision on Group 4: 81 HCPs needed improvement plans of which:

a. 71 HCPs submitted improvement plans

The IEB proposal to allow 71 HCPS to implement their improvement plans, after positive assessment of their improvement plans, was approved by consensus by the BoMS. HCPs will be given one year to implement their improvement plans and undergo a re-evaluation after the end of this period.

b. 10 HCPs did not submit improvement plans (including 3 HCPs which withdrew)

Country	HCP	ERN
Estonia	Tartu University Hospital	BOND
France	Assistance Publique-Hôpitaux de Paris, Hôpital Bicêtre	EURO-NMD
France	Assistance Publique-Hôpitaux de Paris, Hôpital Cochin	BOND
France	Assistance Publique-Hôpitaux de Paris, Hôpital Necker-Enfants Malades	ERNICA
Germany	Universitätsklinikum Schleswig-Holstein	ERN-SKIN
Italy	AOU Siena	EURO-NMD
Italy	AULSS 2 Marca trevigiana	EURACAN
Italy	Candiolo Institute - IRCCS	EURACAN
Portugal	Centro Hospitalar e Universitário de Coimbra, EPE	EURACAN
Finland	Tampere University Hospital, Finland	EURO-NMD

The chair recalled that an Excel sheet with information on all categories, including categorization of the improvement plans as "very good'; 'acceptable' or 'risky', was disseminated prior to the ERN BoMS evaluation preparatory meeting on 9th October. The BoMS representatives were required to prepare and present arguments in support of the centres that have not submitted an improvement plan by the set timeline but expressed the intention to stay involved with their ERN and finalise the process submitting the improvement plan after the deadline.

There was disagreement within the BoMS on the approach that should be taken with the 10 centres in question which did not provide the improvement plan.

IT, FI, PL, HU and EE remarked that following a strict administrative procedure is less important than securing the continuation of centres that bring a significant contribution.

CZ and AT supported an individual approach to the decision-making but recommended to take decisions based on actual documentation and data provided by the Member States in support of the centres.

NL expressed the opinion that rules should be the same for everyone and that it is important to show that not meeting deadlines has consequences.

Due to the lack of consensus on whether the BoMS should vote by group on the termination of these 10 HCPs or on each individual centre separately, the BoMS Co-Chair implemented a voting procedure.

The quorum is set as 2/3 of the 28 members of the Board of Member States, i.e. 18 members, and it was achieved as twenty-two (22) MS were present. The Co-Chair reiterated that each Member State has one vote.

Voting results:

The BoMS decided to proceed to voting for the individual termination of each HCPs. Consequently, the following decisions were taken by the BoMS for each individual HCP respectively:

1. DE42 – Universitätsklinikum Schleswig-Holstein (ERN-SKIN)
    a. *The ERN BoMS agreed to terminate the centre's participation as an ERN HCP.*

2. EE02 - Tartu University Hospital
    a. *The ERN BoMS agreed to terminate the centre's participation as an ERN HCP.*

3. FI03 - Tampere University Hospital:
    a. The BoMs did not agree to terminate the centre's participation as an ERN HCP. FI explained that the Tampere University Hospital is one of the most valuable members of EURO-NMD in Finland. The centre had expressed its willingness to finalise the evaluation process and received strong support from the EURO-NMD coordinator. The Co-Chair requested to proceed to voting procedure. Quorum was achieved.
        i. **Voting results:** The ERN BoMS decided not to proceed with the centre's termination.

The HCP would consequently be given the chance to present an improvement plan until 13th November at the latest. If submitted, the proposal would be reviewed by the IEB prior to submitting the updated final report to the Commission on the 27th of November. An additional BoMS meeting would be organised to take a final decision by mid-December.

4. FR03 - Assistance Publique-Hôpitaux de Paris, Hôpital Cochin (ERN BOND)
    a. *The ERN BoMS agreed to terminate the centre's participation as an ERN HCP.*

5. FR02 - Assistance Publique-Hôpitaux de Paris, Hôpital Bicêtre (EURO-NMD)
    a. *The ERN BoMS agreed to terminate the centre's participation as an ERN HCP.*

6. FR09 - Assistance Publique-Hôpitaux de Paris, Hôpital Necker-Enfants Malades (ERNICA)

The termination of the centre was objected to. FR informed that the centre received very strong support by ERNICA coordinator as it is actively represented in the network. The BoMs Co-Chair proceeded to open the voting procedure.

i. Voting results: The ERN BoMS decided to proceed with the centre's termination.

7. IT18 - AOU Siena (EURO-NMD)
    a. *The ERN BoMS agreed to terminate the centre's participation as an ERN HCP.*

8. IT26 - AULSS 2 Marca trevigiana (EURACAN)
    a. *The ERN BoMS agreed to terminate the centre's participation as an ERN HCP.*

9. IT28 - Candiolo Institute – IRCCS (EURACAN)
    a. *The ERN BoMS agreed to terminate the centre's participation as an ERN HCP.*

10. PT03 - Centro Hospitalar e Universitário de Coimbra, EPE (EURACAN)

The termination of the centre was objected to. PT considers this HCP as a very important centre for the country. It was also informed that the coordinators of the centre have recently changed, which may be the reason for the non-delivery of an improvement plan on time. HU reminded that this centre met significant difficulties to enter the ERN and put a lot of hard work to meet the requirements for membership. The BoMS Co-Chair proceeded to voting procedure.

i. **Voting results:** The ERN BoMS decided to proceed with the centre's termination.

5) Decision on Group 5: 16 HCPs never started the self-assessment.

The IEB proposed to terminate the membership of 16 HCPs that did not start the self-assessment. No objections were presented. The evaluation outcome to terminate the 16 HCPs was confirmed by consensus by the ERN BoMS.

Country	HCP	ERN
Czech Republic	University Hospital Královské Vinohrady	Endo-ERN
France	Assistance Publique-Hôpitaux de Paris, Hôpital Cochin	RITA
France	Assistance Publique-Hôpitaux de Paris, Hôpital Trousseau	EuroBloodNet
France	Hospices Civils de Lyon	MetabERN
France	CHU de Rennes	EuroBloodNet
Germany	Klinikum der Universität München	BOND
Germany	Klinikum der Universität München	PaedCAN
Germany	Universitätsklinikum Köln	EuroBloodNet
Germany	Universitätsklinikum Gießen und Marburg	Endo-ERN
Italy	Oncological Referral Center - Aviano	EURACAN
Italy	AULLS 12 – Mestre hospital – rare eye diseases	ERN-EYE
Italy	E.O. Ospedali Galliera, Genoa	EuroBloodNet
Netherlands	Amsterdam University Medical Centers Location AMC	RARE-LIVER
Netherlands	University Medical Centre Groningen	EuroBloodNet
Portugal	Centro Hospitalar e Universitário de Coimbra, EPE	PaedCAN
Portugal	Instituto Português de Oncologia do Porto	EuroBloodNet

The meeting was thereafter adjourned.

The next meetings of the ERN BoMs are scheduled for 22 May and 22 October 2024

EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Minutes of Meeting - Draft
Board of Member States on ERNs
25th of OCTOBER 2023, 9:00-15:30
Hybrid – Luxembourg and Webex

Participants:

Commission: SANTE.B3

Member States present: AT, BE, BG, CY, CZ, DK, EE, FR, FI, HR, HU, IE, IT, LT, LU, LV, MT, NL, NO, PL, PT, RO, SE, SI, SK.

Invited: Contractor (infeurope & Mercury-97) to take minutes, and Independent Evaluation Body (IEB) to provide information about the evaluation exercise

Agenda:

8:30 - 9:00 Arrival and Dial-in		
1	**9:00 - 9:10**	Resuming of the Meeting
2	**9:10 - 10:30**	Evaluation: for information and discussion
	10:30 - 10:45 Coffee Break	
2	**10:45 - 12:20**	Evaluation: for information and discussion
	12:20 - 13:20 Lunch Break	
2	**13:20 – 15:00**	Evaluation: for information and discussion
3	**15:00 – 15:30**	Evaluation Next Steps: for information and discussion

1 | 9:00 - 9:10 | Resuming of the Meeting

The meeting was resumed. The Independent Evaluation Body (IEB) prepared a draft evaluation report to support the BoMS in deciding ERN HCPs' membership termination and assessing the ERN improvement plans.

2 | 9:10 - 10:30 | Evaluation: for information and discussion

The BoMS MS Co-Chair provided an update on the evaluation manual. Subject to improvement within the evaluation manual are:

a) criteria along with measurable elements

b) procedures with respect to data submitters, process (sampling methodology), and assurance of evaluation quality

c) further areas for evaluation improvement are the ERN-defined specific criteria on which the reduction/expansion of disease expertise depends, the timeline for evaluation improvement, as well as the composition of a WG for the improvement of the evaluation including both BoMS and ERN coordinators members.

The BoMS MS Co-Chair provided an overview of topics subject to discussion:

1. **Evaluation manual:**
    a. It includes a set of core and additional criteria, as well as measurable elements
    b. The evaluation procedures such as the submission of data from ERN coordinators, HCP experts, hospital managers, and national authorities. The process of the evaluation and its assurance in the quality evaluation should also be reviewed (i.e. documentation review plus on site visits, measures to ensure homogeneity, criteria for selection of evaluators, trainings, etc.)
2. **ERN-defined specific criteria**
3. **Timeline for evaluation improvement:**
    a. The next evaluation is to take place in 2027 for 626 HCP that joined in 2022 Deadline for evaluation improvement: end of 2025.
4. **Composition of the Working Group on evaluation**

The co-chair reminded that the legal Basis, is Commission Delegated Decision 2014/286/EU[2],providing the *general criteria and conditions for all applicant HCP with regard to:*

i. Patient empowerment and patient centered- care
ii. Organization, management and business continuity
iii. Exchange of expertise, information systems and e-health tools
iv. Research and training capacity
v. Expertise, good practices, quality, patient safety and evaluation
vi. Competence, experience and outcomes of care
vii. Specific human, structural and equipment resources and the organization of care.

[2] Commission Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil Text with EEA relevance, Article

The evaluation manual must be used for the evaluation and an Independent Evaluation Body (IEB) appointed by the Commission is to periodically evaluate networks and their members. The assessment and evaluation manuals should be based on internationally recognized practices and contain the core principles and methodologies for carrying out assessments and evaluations. Personal data security related to establishing and evaluating the networks should be processed in compliance with Regulation (EU) 2018/1725[3].

The BoMS MS Co-Chair noted that HCPs have expressed concern about providing medical data in national languages subject to national regulations. They expressed the opinion that this sensitive data could be subject to national evaluation.

Discussion:

The BoMS MS Co-Chair opened the discussion to collect BoMS's preliminary views by stating this was the first evaluation based on the legislation, with a certain methodology being used for the first time, and IEB conducting the process for the first time. In the future there is an opportunity to make improvements drawing on lessons learnt. A proposal was made to compose a joint WG on evaluation with the aim of alleviating administrative burdens, identifying shortcomings, and ensuring continued improvement.

FR commented on the evaluation being a good opportunity to reinforce coordination in the national country between the hospital directors and centres of expertise, as well as the link between the national and European levels. Furthermore, it is an opportunity to look at the legal responsibility of HCPs.

CZ indicated several points that demand discussion. The activity of the planned Working Group on Evaluation Improvements should be carried out in close collaboration with JARDIN WP5 to avoid duplication of work. Furthermore, the JARDIN Hospital Managers' Advisory Group should act as an advisory group of the new WG. JARDIN could be the advisory consultancy group for the quality of care at the national level given the BoMS are creating a group of contact points for JARDIN. The main subgroups of the WG should also be defined. Regarding the evaluation improvements, CZ suggested aligning legal requirements with individual operational criteria.

IE endorsed the idea of involving experts in the European law in the WG as equity issues should be enshrined in the composition of the WG.

AT highlighted that given that the ultimate goal of the ERN activities is to improve the overall quality of life of people with rare diseases (RD), medicine and health administrations can benefit from a human rights and medical ethics perspective and can utilize existing pathways to ensure that families of children with RD have the necessary support. On another note, AT made a remark on the communication with health administrations, stating that it would be

[3] Regulation (EU) 2018/1725 of the European Parliament and of the Council. of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

useful to align these activities in Member States (MS) with the evaluation at EU level. Concerning the evaluation results, it would be useful to include sufficient quantitative indicators (such as the number of patients treated in a given HCP) in subsequent evaluations in order to justify the resources invested.

The BoMS MS Co-Chair mentioned that HCPs were reluctant to provide high quality data.

CZ included several additional points into the discussion. The terminology should be revised in future evaluation reports, where 'HCP' refers to the centre instead of the hospital. Furthermore, generic procedures within the hospital should be evaluated as part of the hospital administrations by the Member States not as parts of the expert centres. CZ also stressed the fact that the quality of laboratories should be incorporated in the evaluation and that the BoMS have not yet received the results of the ERNs evaluation.

PL agreed with CZ that evaluation for the hospital as a whole and the expert centre should be separated. They added that certain aspects of patient care, e.g. social aspects, are not dependent on the hospital nor the experts, but rather on the legal regulations within the country. Therefore, the focus should be on aspects that are in the remit of the expert centres and not the national systems, which should be evaluated in a separate process. Further, PL suggested that specific questions within the evaluation, which are difficult to answer at this stage of the ERN development, should be reviewed by the coordinators in advance.

NO supported CZ regarding distinguishing evaluation between HCPs and expert centres as well as forming a WG.

LT agreed with CZ and PL. Sometimes the required assessment is not available due to incorrectly formulated questions that are intended for the institution and not for the reference centre specialized in the RD. Criteria should be thus adjusted for the centres. In addition, eligibility criteria, training, and feedback are necessary for the evaluators. Specific criteria should also be adjusted for small country centres.

ES agreed on the importance of obtaining more quantitative data on patients in the evaluation. They emphasized that collecting data regarding specific contribution of each hospital or centre to the respective ERN is important to acquire a better idea on how each centre is participating in their ERN.

PT agreed with the suggestions made and emphasized the need for having a manual on definitions as well as the importance of defining the minimal dataset given that there are big differences between big and small countries.

NL agreed with CZ and PL that the assessment should be focused on the centre of expertise, while the quality of the hospitals is up to the responsibility of the Member States (MS). Many MS have national assessment procedures to select the centres of expertise in place, hence being assessed in this evaluation creates duplicated work. DK agreed.

The BoMS MS Co-Chair noted that the IEB should take into account the data of the national quality assurance systems as many countries have them.

CZ commented that the instructions for the monitoring process are unclear and that the centres commencing with the monitoring system do not have sufficient information.

In this relation, the BoMS MS Co-Chair stated that the WG on evaluation improvement should be aligned not only with JARDIN, but also with the WG on monitoring and consider designation procedures as well.

AT concluded that they agree on splitting the evaluation process in terms of competencies of the centres and MS in hospitals. Second, they suggested that the BoMS transmit the results of their national evaluations to the IEB consideration as well. As regards the 30 affiliated centres in AT, their contribution to the ERNs is not sufficiently represented in the evaluation because they have not been evaluated.

The BoMS MS Co-Chair stressed several points:

a) The scope of the evaluation covers the ERNs and their full members.
b) National assurance systems should be examined for overlaps or replacement to avoid duplication of evaluation. The evaluation aims at ensuring uniformity and having a minimum common denominator for all ERNs in place.
c) According to Article 168 of the Treaty, the organization and provision of healthcare system belongs to Member States and it is important to respect the competence of MSs.
d) Sustainability of the healthcare centres should be investigated.

Regarding monitoring, DG SANTE clarified that the centres report to the ERNs which monitor the data, which in turn report it to the EC. However, the monitoring will now become an exercise of the centres (HCPs) as well and they will directly report to the European Commission annually. Incorporating more data into the monitoring exercise is challenging as it is not feasible in terms of the workload to align it with the evaluation. It would also be useful to find a way to streamline the evaluations in one exercise for every period instead of having two subsets of centres being evaluated in two different timelines.

CZ noted that although the EC cannot evaluate individual Member States and hospital systems, up to 50% of the evaluation referred to the hospitals and therefore, it should be stated officially or not done whatsoever. The BoMS MS Co-Chair clarified that the aim is not to evaluate hospitals organization, but to determine whether the centre has sufficient capacity to deliver the activity of the HCP under the ERNs.

DK asked about the possible composition of the WG. The BoMS MS Co-Chair stated that according to the RoP, the Joint WG should be comprised of BoMS and ERN coordinators. Third parties can be invited depending on the requirements and the decision of the WG.

In terms of interoperability, CZ suggested that the newly established WG should join efforts with the registry WG to incorporate the data in the registry and enable the retrieval automatically. With no objections to the establishment of the WG, the BoMS MS Co-Chair invited members to participate in the WG on evaluation improvement.

Composition of WG: the following MS have expressed their interest: NO, CZ, RO, FR, AT, SE, LT, DK, PO, BE, NL, IE*.

*IE noted their interest but have yet to determine the participating representative.

2 | 10:45 - 11:45 | Evaluation: for information and discussion

The BoMS MS Co-Chair introduced the subject of the ERN-defined specific criteria. The latter were developed in 2016 in preparation for the launch of the ERNs. The BoMS MS Co-Chair opened the floor for discussion with the question whether the ERN Coordinators should revise the ERN-defined specific criteria.

Discussion:

AT commented that they base their national certification process and evaluation based on the different areas set out by the ERN-defined specific criteria, in which they notice a big difference in granularity and the use of ICT codes in parallel with orphacodes. Thus, they call for uniform granularity across all ERNs according to the latest version of orphacodes. AT supported agreeing on common granularity and uniform categorization.

With respect to orphacodes, the BoMS MS Co-Chair remarked that numerous diseases are described each year and can involve thousands of orphacodes. Patients with rare diseases might be initially diagnosed with different codes as well.

CZ added that disease nomenclatures are different from nomenclatures within the Orphanet, which does not have the capacity to be up to date with the classification systems of the disease groups. Working on updating the Orphanet will have to be aligned with what individual ERNs choose as their classification for orphacodes. In addition, diseases for specific criteria should be grouped in a certain level of granularity and not in the level of individual diseases because that would lead to thousands of codes. Moreover, the existing criteria differ significantly between the ERNs and should be more comparable.

In terms of having good quality registries on ultra-rare diseases, FR stressed the importance of the implementation and update of orphacodes, which is also one of the elements of WP5 of JARDIN. CZ added that one disease may be included in the portfolio of several ERNs and expressed their opinion that it should be one ERN confirming a diagnosis and entering the orphacode.

IE mentioned that in WP6, the preliminary data shows that many RD are covered by several ERNs. While it is not feasible to list thousands of diseases, they can be categorized in thematic areas as to where the ERNs best match would be. On another note, they agree on using orphacodes and noted the necessity for also matching with ICD 11, which is in consideration from FR.

FR suggested mapping the orphacode of all national reference centres and 24 ERNs to identify disease overlapping. NL proposed to ask the coordinators where the overlap is, and to examine the thematic areas of the ERNs as there is quite a difference in thematic and sub-thematic areas.

PL noted that the transition of care should be taken into account, e.g. adult and pediatric care are provided by separate hospitals in many countries, which can entail transferring patients. As the national history of RD is complex and may change over time, PL believes that members should not be rigid about the number of diseases that change their history with treatment.

NL stated that in general, all rare diseases could have an orphacode. It is ERNs and Orphanet's responsibility to improve the orphacode classification. In NL, only the centres based on orphacodes are endorsed (also for ERN TransplantChild), because they should have expertise on all aspects (also interventions) for a specific rare disease. Therefore, the interventions could be linked to the underlying diseases with orphacodes.

The BoMS MS Co-Chair concluded that a request will be made to the ERN coordinators to revise the ERN-defined specific criteria accompanied with the request to mind overlaps, involving the BoMS in the decision.

3 | Evaluation Next Steps: for information and discussion

The BoMS MS Co-Chair invited participants to express their views on the next steps of the evaluation follow-up, in terms of a potential call for affiliated partners and a call for expansion/reduction of disease coverage.

On the first point, the BoMS =stated that the BoMS, ERN coordinators, as well as patient representatives have expressed interest in a call for affiliated partners. Members were informed that certain ERNs have highlighted the capacity to be able to absorb more members within the Networks. DG SANTE also asked the views of the BoMs on the need for a call for a full membership.

Discussion:

RO supported the call for affiliated partners and explained that RO have full members in just 12 ERNs, leaving 12 ERNs uncovered. Yet there are huge demands from patients for the ERN expertise.

IE supported the call for affiliated partners adding that some HCPs do not have the capacity to do the heavy administration for full membership. However, they have interest in becoming affiliated members. Affiliated entities also bring opportunity to consider more informal collaboration as some HCPs may be disheartened when they are terminated.

PT supported the call for affiliated partners as well, since promoting the affiliated centres into ERNs improves quality and practice.

FR fully supported the proposal for affiliated partnership. It was noted that termination and inclusion of new members should be balanced, and that ensuring that the ERNs are a viable, living system is very beneficial.

IT and BG also expressed their support for the call for affiliated partners.

According to AT, the landscape of ERNs should be more dynamic and reflect the current situation in a given country (e.g. post-COVID personnel fluctuations and loss of expertise). They support a call for full membership because they only have 10 full members. A call for affiliated partnership should be used as an opportunity to define their role in the ERNs more adequately and have a better indication of what the scope of activity is for existing affiliated members.

CZ stressed that the formation of national reference networks is crucial for the care of patients with rare diseases, as FR has demonstrated being an extremely successful example. They suggested allowing the status of affiliated members for those members who are also full members in the national networks. Another option would be to recognise more officially the situation of the collaborating centres, who can be potential candidates for full membership.

The BoMS MS Co-Chair remarked that the more members a given network has, the more difficult it is to manage.

DG SANTE pointed to possible limitations in terms of network-affiliated partners collaboration. In terms of legislation, to comply with the Commission Delegated Decision of 2014/286/EU, and to collaborate closely with other centres of expertise and networks at national and international level: 'the network must collaborate with associated national centres and collaborative national centres chosen by MS ***with no member of a given network*** particularly if the objectives of the network are among those listed under Article 12.'. Affiliated partners are defined as 'associated national centres, collaborative centres, and national collaboration hubs. Additionally, any new groups (e.g. affiliated members) or categories the MS would like to create would have to be reflected in the legislation.

In order to collect the opinion from each MS, a survey will be disseminated to the BoMS regarding: 1) having a new call for affiliated partners; 2) a new call for membership; 3) the respective timeline; and 4) the definitions of the different partners.

AOB

Under any other business, participants were informed by DG SANTE that a short survey on the new CPMS system is currently being developed and will be sent to MS to evaluate their needs.

The new CPMS platform will have dashboards at national/hospital/ERN levels. At national level, the dashboard will include the participation of national hospitals in the CPMS discussions in two perspectives:

1. Number of participations in CPMS discussions in which the centre provides advice.
2. Number of participations in the CPMS discussion in which the centre requests advice.

Members were also updated on two proposals from the ERN CG concerning the structure of the BoMS and ERN CG meetings:

- To have a short presentation of an ERN in the BoMS meetings
- To have a short presentation on National Healthcare Systems/organization of services in a MS in the ERN CG

Following a request from AT, DG SANTE asked the BoMS for their permission to upload their contact details amongst the BoMS members. It was agreed that DG SANTE will follow up after receiving written confirmation from all BoMS.

The EC BoMS Co-Chair made a concluding remark on the Cross-Border Healthcare Directive. Following its evaluation, it was concluded that many patients are unaware of their rights as regards accessing cross-border healthcare. To address this, local workshops will be organised in cross-border regions and a call for interest is to follow. The target audience are general practitioner insurers, policymakers, patient organizations, and ERNs to present their activities as an example of cross-border healthcare. As a final comment, the EC BoMS Co-Chair reminded the participants of the meeting to distribute the Flash Report to their Ministries.

AT brought to the attention of the BoMS the ongoing Joint Action (JA) of the EU4Health program, which focuses on organizing expertise networks on rare cancer, 'JANE', launched in 2021. Another JA was launched in 2023 with a significant budget. They suggested to invite the coordinator of JANE to the next BoMS meeting to demonstrate how cooperation within these networks is planned.

CZ has been asked by their Ministry to raise the topic of new orphan medicines for RD. The entry of orphan medicines is difficult in small countries because the companies that develop these drugs do not see the market in smaller countries. This issue overlaps with the ERNs as these RDs are treated within ERN centres in small countries. CZ asked to include this topic and how EMA approves the drugs in the next discussions. The EC BoMS Co-Chair noted that following a wide consultation with institutions and RD organizations initiated by the EC, revisions in the legislations have been made on both orphan and paediatric drugs. The BoMS will be informed about the revisions. The EC BoMS Co-Chair also stated that there is a pharmaceutical legislation under revision at the Council/Parliament level which also concerns the question of orphan drugs for RD. The new legislative proposal should improve incentives for the industry. The unit tasked with this topic in DG SANTE may be invited to present on this work in the next meeting of the BoMs.

In response to ES regarding latest updates on the legal entity DG SANTE informed the members that there are differing positions of ERN Coordinators for this idea. The issue of legal entity is complex and has been put on hold for the moment. The topic can be discussed in more detail in the next meeting.

Thereafter, the meeting was adjourned.

The next meetings of ERN BoMS are scheduled for 22 May and 22 October, 2024.

Action points as follow-up of the meeting:

1. DG SANTE: to convene a meeting with the BoMS regarding final decision on Tampere HCP
2. DG SANTE to send information to the relevant stakeholders on the results of 5-year evaluation
3. DG SANTE to provide the BoMS with updated Rules of Procedures for their review and comments
4. DG SANTE to provide the BoMS with the state of play of the Working Groups
5. DG SANTE to take action leading to the creation of the Working Group on Evaluation Improvement
6. DG SANTE to send surveys to the Members of the Board of the Member States to gather their views on the possible expansion of the ERNs, with focus on Affiliated Partners
7. DG SANTE: to consult the BoMS on the appeal procedure against ERN actions as requested by the Ombudsman.
8. DG SANTE to discuss with the ERNs codification of rare diseases among the networks (disease groups and use of orphacodes)
9. JARDIN coordinator: to ensure coordination for the European Health Data Space (EHDS) for each country involved in JARDIN, DG SANTE will involve the relevant Unit dealing with EHDS