

**MEETING MINUTES: ERN BOARD OF MEMBER STATES MEETING****MORNING SESSION****PARTICIPANTS:**

Commission: DG SANTE.B3

ERNs present onsite or online: ERKNet, ENDO-ERN, ERN BOND, ERN CRANIO, ERN EpiCARE, ERN eUROGEN, ERN EURO-NMD, ERN EYE, ERN GENTURIS, ERN GUARD-HEART, ERNICA, ERN ITHACA, ERN LUNG, ERN PaedCAN, ERN RARE LIVER, ERN ReCONNET, ERN RITA, ERN-RND, ERN SKIN, ERN TransplantChild, MetabERN, VASCERN.

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

Member States absent: DE, EL, HU

Invited: Contractor (infeurope & Mercury-97)

- *Chair: Donata Meroni, Head of Unit, Health monitoring and cooperation, Health networks & Birute Tumiene, Co-Chair of the Board of Member States*

**1. Opening of the meeting**

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DG SANTE welcomed participants to the 20<sup>th</sup> meeting of the ERNs Board of Member States, joined in the morning session by the ERN Coordinators, and passed the floor to the first speaker of the day. The Chair presented the agenda and reminded that the meeting will be recorded for the purpose of minute taking.

**2. Joint Action JARDIN**

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Updates on the Joint Action on integration of ERNs into national healthcare systems (JARDIN) were presented by the JA Coordinator.

A kick-off meeting took place in Brussels on 6<sup>th</sup> and 7<sup>th</sup> March 2024, followed by a conference co-organised by the Commission and the European Economic Social Committee. The minutes of the meeting were being drafted. The drafts of the Communication and Dissemination Plan (WP2) and the Evaluation Plan (WP3) are currently under review and should be ready to be published by 31<sup>st</sup> July and 31<sup>st</sup> May 2024 respectively. Under WP6 – Care Pathways, a letter for information regarding existing pathways and expression of interest was recently sent to ERN Coordinators. Four separate surveys for stakeholders have been developed to provide the robust state of the art analysis needed as the first steps for WPs 4,5,7,8,9:

- Survey on contact details already running
- Survey on national reference networks and undiagnosed disease programmes (WP7) to be released on 3<sup>rd</sup> June
- Survey on healthcare policy and governance (WP4,5) to be released on 23<sup>rd</sup> May 2024
- Survey on data management (WP8,9) with release date in mid-June

ERN Coordinators and Member States Representatives are highly encouraged to contribute to these surveys. In relation to this, JARDIN Coordination also proposes setting up a regular communication line with the BoMS by adding ad-hoc meetings or publishing a regular detailed newsletter. During the discussion it was agreed that communication from JARDIN should be sent to both ERN Coordinators and the ERN Project Managers. Some Member States noted that WP1 Coordination should be enhanced to provide clear and timely information thus contributing to an efficient implementation of the JA.

**Next steps:**

- JARDIN coordination to send any communication that requires follow-up to both the ERN Coordinators and the ERN Project Managers
- Coordination and communication of the Joint Action to be improved

**3. ERN disease list review and disease expansion + OD4RD – coding of rare diseases in ERNs**

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The Chair of the ERN Coordinators Group (ERN CG) gave a short presentation on the issues linked to the current disease coverage of the ERNs. Current codification of diseases allows the use of both ICD10 and ORPHAcodes for disease annotation. There is no clear and binding guidance at which level the codification should take place and no requirement to use codification for procedures, interventions, and tests. This raises the need to perform a gap analysis of the diseases covered by ERNs and introduce unified codification of rare diseases.

Then ORPHANET presented an analysis of the rare disease coverage by ERNs carried out under the ORPHANET Data for Rare Diseases 2 (OD4RD2). The analysis is based on the information about the thematic and sub-thematic groups of disorders mapped through ORPHAcodes, the information on ERNs' websites and the expert centers' database. Results show that 11 out of 24 ERNs provide full or almost full coverage of the ORPHANET classification, but this is still only around 10% of all rare diseases at the disorder level. In terms of complementarities, there are two kinds of overlaps: complete group overlaps and multi-classified rare diseases. In order to go further with the qualitative analysis, ORPHANET requests feedback from the ERN CG.

During the discussion, ERNs reminded the BoMS that there was on-going work on expanding the disease area for ERNs which would be important to finalize. This expansion is, however, still pending approval by the BoMs. The BoMS noted this and emphasised the importance of the link with JARDIN WP8.

**Next steps:**

- DG SANTE to review proposal for disease expansion of ERNs sent previously and review past discussions in the Board of Member States. To be followed up with potential new proposal to the Board of Member States.
- ERNs & ORPHANET to work on follow up analysis on disease coverage in ERNs with outcome presented in next plenary
- WG on evaluation should take into consideration the minimum/specific criteria for new disease groups.

#### **4. Updates from the Commission: Pharmaceutical legislation & European Health Data Space**

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The EU pharmaceutical reform for rare disease medicines was presented by DG SANTE. The reform is part of a new legislative proposal under negotiation since September 2023. Its main objectives are to foster innovation for rare diseases, promote availability while rewarding innovation, ensure access to orphan medicines, and reduce the regulatory burden. The reform proposes high-level indication and effect criteria to define unmet medical needs. The regulation also aims at improving the accessibility of orphan medicines in all MS through market launch incentives and changes in the market exclusivity conditions.

DG SANTE then presented the European Health Data Space (EHDS). EHDS has three main parts: primary use of data for healthcare, secondary use of data, and the electronic health record systems (EHR). Regarding the primary use of data, the EHDS will introduce new access rights for patients and facilitate access to electronic health data for healthcare professionals. This is already piloted through the existing MyHealth@EU infrastructure. In terms of secondary use, the EHDS introduces common EU rules on which data have to be made available and imposes data permits and common safeguards for the use of health data. For these purposes, the EHDS is establishing Health Data Access Bodies (HDABs) and is introducing a set of obligations for data holders and data users.

The new Regulation will enter into force in 2026, but the introduction of obligations will start from 2028 onwards. In the discussion, Member States emphasised that close connection should be established between the EHDS and JARDIN WP8 on data management. Coordinators also suggested to run a pilot of the EHDS with ERNs.

##### **Next steps:**

- DG SANTE C1 to be invited to present at the next WP8 meeting of JARDIN

#### **5. Presentation of the activity of one ERN: MetabERN**

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The coordination of the European Reference Network for Rare Inherited Metabolic Disorders (MetabERN) gave a detailed presentation of its activities. The network includes 94 HCPs and 44 patient organisations across 27 countries. It has published 227 peer reviewed papers and 15 international guidelines. MetabERN runs a registry with data of more than 5,000 patients. Among the main achievements of the ERN is its full educational programme for healthcare professionals. MetabERN is currently piloting an AI innovation programme with the aim to develop algorithms for identifying patients at risk of metabolic disorders.

#### **6. Presentation of the activity of one ERN: ERN RND**

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The European Reference Network for Rare Neurological Diseases (ERN-RND) gave a detailed presentation of its ERN activities. It covers 68 HCPs in 24 Member States providing services to over 35,000 patients per year. The network has several priority activities: (1) cross border healthcare (CPMS); (2) training and education; (3) patient journeys development; (4) data registries; and (5) guidelines development. It also focuses on providing highly specialised healthcare services. ERN-RND has introduced an automatic indicator collecting system to

measure and encourage the contribution of HCPs. Some other ERNs have also introduced a unified measurement system across all networks.

During the discussion, CZ remarked that thinking about the CPMS as about cross-border healthcare opens the door to rethinking the funding sources and the reimbursement rules for activities in the platform, which is also a task of WP9 of JARDIN.

**Next steps:**

- A survey to collect data regarding the HCPs' use of the CPMS and the reimbursement for these activities across Member States will be disseminated under WP9 of JARDIN.
- Member States are kindly asked to respond to the survey under JARDIN WP9 when available.

The joint meeting of the ERN CG and BoMS was thereafter closed, the afternoon session of the plenary meeting was only open to BoMs representatives.

**MEETING MINUTES: ERN BOARD OF MEMBER STATES MEETING****AFTERNOON SESSION****PARTICIPANTS:**

Commission: DG SANTE.B3

Member States present onsite or online: AT, BE, CY, CZ, DK, EE, ES, FR, FI, HR, IT, IE, LV, LT, LU, MT, NL, PL, PT, RO, SK, SI, SE & NO

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**1. Updates from the CG Chair**

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The closed meeting of the BoMS started with a short presentation on the updates from the ERN CG. All 24 ERN grant agreements have been signed. The CG Chair indicated that the last signature came 6 months after the beginning of the grants. Such delays create problems with cashflow management and employment contracts and should possibly be avoided in the future.

A change of the coordinators is taking place in ERN-RITA and eUROGEN, which also requires a change of the ERN Monitoring WG Chair. The transition creates the need to provide training for the new generation of coordinators.

A survey regarding the expansion of the networks was conducted among all ERNs. The main conclusion is that ERNs are in favour of facilitating a better geographical coverage and the most voted option for this was a call for Affiliated Partners in countries with no ERN coverage.

In relation to the HCP termination policy, the ERN CG suggests establishing a unified ERN CG, BoMs, and SANTE procedure for ERN members' termination that reflects the interest of all stakeholders. Some BoMS noted that several different termination procedures have been established in different ERNs.

**Next steps:**

- ERNs Managers group to share existing protocols for termination across other ERNs
- ERN Mangers Group to consider amending existing protocols to include a role for BoM support in the process
- BoMs to review the protocol and agree and help support the process of the protocols for termination

**2. Different types of ERN memberships & Results of survey**

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DG SANTE presented the different types of ERN memberships and the options for geographical coverage of the networks. DG SANTE presented specificities of the different types of membership regarding their obligations, evaluation, the use of the CPMS, the use of the ERN logo, as well as the criteria and conditions for membership applicants. The results of the survey on a possible call for the new members of the ERNs were also presented. In the survey, the BoMS representatives were asked to express their opinions on three options:

- Call for Affiliated Partners
- Targeted call for Full Members (in MS with no ERN coverage)
- Call for Full Members in all MS

As a result, 27 out of 28 eligible MS responded. Launching a call for Affiliated Partners was the option that received highest support, with 20 BoMS in favour. DG SANTE proposed to develop further expansion scenarios covering the timing, the procedures, and the budget implications of the different options.

During the discussion, BoMS discussed the “1HCP/10 million inhabitants” rule, which might leave behind smaller countries. Several Member States (IT, CZ, CY) see the call for Affiliated Partners as the most effective way to achieve more inclusivity and better geographical coverage. Important to notice is that part of the obligations of Affiliated Partners is defined on bilateral agreements with ERNs. This leads to significant differences in their engagement, role and responsibilities. One of the solutions would be to compare bilateral agreements between Affiliated Partners. It is important to keep in mind that BoMS and the Commission have no access to bilateral agreements, which are documents signed/agreed between the Affiliated Partner and the respective ERN. According to AT, before a new call for Affiliated Partners is issued, it would be important to revise the network-specific conditions for Affiliated Partners and set a clear baseline. CY underlined that the specific criteria for Affiliated Partners and Full Members may also need revision, especially concerning the administrative burden, which is discouraging for HCPs. AT, PT and CY also consider that to motivate HCPs there should be a clear procedure with quality and quantity indicators for the transition of Affiliated Partners to full members and vice versa.

#### **Next steps:**

- DG SANTE to continue bilateral meetings with Member States to better understand the national needs
- Geographical coverage of the ERNs to be further discussed at the next BoMS plenary
- DG SANTE to develop further provisions for Affiliated Partners in collaboration with ERN Coordinators and BoMS

### **3. BoMS updates**

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Under this point AT presented some pending issues of transparency and accountability of the ERNs. Five main needs were highlighted:

1. The need to introduce harmonised standards for the information provided by ERNs on websites and other digital channels.
2. The need to better describe the basic disease coverage criteria for HCPs and make them available.
3. The need to create a document that addresses the uphold of principles or ethical standards for all ERNs.
4. The necessity to streamline the provision of information among MS.
5. The need to better define Affiliated Partners and introduce transparent bilateral agreements and baseline requirements across ERNs.

**Next steps:**

- ERNs are tasked to discuss and review uniformity of communication on websites of the ERNs and revert to the BoMs.

**4. ERN registries: state of play**

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DG SANTE provided a short presentation on the state of play of the ERN registries followed by a longer presentation by WP2 lead of ERICA. Extensive surveys have been conducted among all ERNs on the status of their registries. Currently, there are 29 registries covering around 62,000 patients. About 1/3 of the registries have comprehensive coverage with HCPs, actively contributing patient information. The main conclusion of the surveys is that some ERN registries are ready to scale-up and increase their contribution to patient care and innovative research. It was remarked that data upload is done manually in the majority of the ERNs, so the upscaling depends on increasing the support to HCPs and to the staff performing this activity.

**Next steps:**

- DG SANTE will soon propose concrete actions for ERN registries and consider the possibility of a pilot program under the European Health Data Space.

**5. ERDERA**

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The European Rare Disease Research Alliance (ERDERA) was presented by Daria Julkowska, Coordinator of the project. ERDERA aims at reinforcing the already existing elements of the research ecosystem in Europe and will bring new strategies to address the remaining needs of rare disease patients. It encompasses 178 organisations and represents 37 countries. The overall budget of the Partnership is approx. €385.5 million, from which approx. €150 million is direct EU funding. The Partnership is built around three main goals: acceleration of diagnosis for rare diseases, acceleration of treatment development, and better understanding of the impact of rare diseases on both patients and the wider society. ERDERA is divided into 25 WPs. It aims at developing a Clinical Research Network for faster diagnosis and enhanced clinical trial readiness for rare diseases. The project also aims at expanding data sharing in a federated manner in close linkage with national resources and infrastructures. Three WPs are dedicated to international capacity alignment, where the participation of MS will be extremely valuable. Special focus will be put on fostering the engagement of underrepresented countries. The Partnership should run for 7+3 years starting in September 2024.

**6. Commission Updates – CPMS; 2023 monitoring exercise; WG Evaluation; administrative points:**

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DG SANTE announced that CPMS 2.0 is ready to be deployed by the end of May 2024. Due to the longer time needed for data migration, ERN transition to the new software may experience some delays. Compared to its predecessor, CPMS 2.0 is more intuitive and flexible. It allows to organise discussions not linked to a concrete case and can be used for consulting cases with Ukraine.

Regarding the continuous monitoring exercise, DG SANTE informed that this year the HCPs were directly involved in the reporting by uploading data to the central portal in the first stage of the monitoring. The new approach makes it possible to provide information on the participation of HCPs by Member States. With respect to the results, there are big differences among ERNs in several areas, which can be seen as evidence that some indicators have been subject to different interpretations.

DG SANTE also provided an update on the Working Group on Improvement of the Evaluation. Its objective is to revise the current evaluation methodology and propose modifications in line with the ERN legal framework. The WG should be active until March 2025. Two meetings have taken place so far, with 4 more planned until the end of the year. A Technical Report on the Evaluation will be provided as an end-deliverable to be used by the Contractor for the redrafting of the evaluation manual and toolbox for the next evaluation planned for 2027.

**Next steps:**

- BOMs to raise more awareness of the importance of the monitoring among national HCPs

**7. Any other Business (AOB)**

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As HU was absent, the administrative points and priorities of the Hungarian Presidency of the Council regarding ERNs could not be shared with the participants.

**The next meetings of the ERN BoMs will be held virtually on 22<sup>nd</sup> October 2024**