EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

MINUTES OF MEETING:
BOARD OF MEMBER STATES ON ERNS
27TH OF JUNE 2023, 9:00-15:00
VIDEO-CONFERENCING VIA WEBEX

Participants:

Commission: SANTE.B3

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

ERNs: ERN CG Co-Chair, ERN LES WG Co-Chair

Invited: Contractor (infeurope & Mercury-97), contractor FNLC

Agenda:

8:45 – 9:00 Dial-in		
1	**9:00 – 9:20**	Error! Reference source not found.
2	**9:20 – 10:00**	**Appointment of the new BoMS chair (40')**
3	**10:00 – 10:15**	**Update from the ERN Coordinators Group (15') for information and discussion**
4	**10:15 – 10:45**	**Evaluation Process (30') for decision making**
10:45 – 11:00 Coffee Break		
5	**11:00 – 11:35**	**Joint Action on integration of ERNs into the national healthcare systems (JARDIN) (35') for discussion**
6	**11:35 – 11:55**	**Study on Financing Not Linked to Costs – (20') for discussion**
7	**11:55 – 12:20**	**Working Group on Legal and Ethical issues (25') for discussion**
8	**12:20 – 12:45**	**Support to Ukraine under the new grants (25')**
9	**12:45 – 13:00**	**Any Other Business (AOB) (15')**

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

The DG SANTE Co-Chair opened the meeting with an introductory speech regarding the importance of ERNs in providing healthcare services in Europe for Rare Diseases (RD) and DG SANTE's current most important ongoing initiatives in public health. The European Health Data Space (EHDS) legislation seeks to address the challenges stemming from the different legal basis for health data processing across the EU by harmonizing the landscape for pseudo-anonymized data. The proposed EHDS will facilitate the use of digital health data for secondary uses, it will allow researchers to access large quantities of high-quality data more easily while respecting patients' privacy, as well as facilitate research on new medicinal products and the development of AI.

The Communication on Mental Health published on 7 June 2023, the European Commission seeks to draw the attention of the Member States (MS) to the current situation of deterioration for mental health in Europe. This Communication urges the MS to take actions to strengthen prevention, early intervention, and to develop a new strategic approach for mental health. It also provides an overview of the EC actions for various groups at risk and indicates the financial support available under EU4Health work programme. In April 2023, the Commission proposed revisions to the pharmaceutical legislation. The reform includes two main proposals: a new Directive and a new Regulation, which will constitute the overall EU regulatory framework in this area. The legislation aims to boost innovation, facilitate patients' access to medicines in the EU, improve conditions for approval of new medicines, and reduce administrative burdens. As part of the reform of the pharmaceutical legislation the EC also adopted a Recommendation on measures addressing antimicrobial resistance.

With regard to the EC actions on Rare Diseases (RD), the 24 ERNs are a flagship initiative. This year, DG SANTE launched a 77.4 million EUR call for direct grants for the ERN continuity of work over the next four years, with higher funding than previously allocated. This funding will enable the ERNs to continue their work in core areas using an agreed set of indicators to measure progress. The ERNs will continue bringing together experts to diagnose and discuss patients from different parts of Europe, expand the use of registries as a source of data for relevant research, and develop new clinical guidelines on the respective RD.

The upcoming Joint Action JARDIN is also an important milestone for ERNs in tackling RD. Following its launch in autumn, the JA will help to better integrate ERNs in national health systems of Member States, improve national healthcare services for RD, and ensure the sustainability of ERNs. The success of JARDIN will depend largely on the involvement of the BoMS, as they work at the highest level in their respective Member States with access to national ministries of health and therefore will greatly contribute in concretising the presence of ERNs in Member States.

The five-year evaluation of ERNs, based on the AMEQUIS project, also marks an important milestone for the networks, and the DG SANTE Co-Chair thanked Member States for their involvement in the process.

Alongside DG SANTE, other EC services are also working on RD – such as DG RTD – which is preparing a new Partnership on Rare Diseases under the Horizon Europe Programme to support research activities in the area of rare diseases. The Joint Research Centre is further developing the European Platform on Rare Disease Registration (EU RD Platform), making data on rare diseases findable and searchable and thus countering fragmentation of rare disease patients' data contained in hundreds of registries across Europe.

The DG SANTE Co-Chair wished everyone a successful meeting and fruitful discussions, and thanked the BoMS for the continued support of ERNs through the involvement and full commitment of national authorities.

2 | 9:20 – 10:00 | Appointment of the new BoMS chair

EC reiterated the Rules of Procedures for the appointment of the new BoMS chair. Member States representatives of the Board are to vote for the appointment of one of the three candidates, who will have as the new BoMS Co-Chair a mandate of 2 years. It was clarified that the BoMS Co-Chair and EC do not have voting rights and therefore should not cast a vote. In terms of voting for the first round, a quorum of two-thirds of the BoMS is required for the successful appointment of a new BoMS Co-Chair. If the two-thirds quorum is not reached, a second round will be held which will determine the selected candidate by simple majority. Each Member State has one vote, regardless of the number of representatives attending the meeting. For the purpose of the vote, a poll platform was used.

The appointment process proceeded with the introductions of the candidates. They were:

- AT – Till Voigtländer
- IT – Giampaollo Latella
- LT – Birute Tumiene

AT, IT, and LT candidates provided a short introduction regarding their application to their role.

The presence of each Member State was thereafter confirmed, with twenty-two designated representatives of respective Member States who confirmed their presence and having voting rights. BG, DE, HR, and EE were absent.

The designated representatives of Member States submitted their vote, with the initial round providing 46% of the votes for LT, 29% of votes for AT, and 25% of the votes for IT.

Since no candidate reached a majority of 2/3 (66.7%) of the votes, a second round of voting was held, with Member States having the option to vote for AT or LT.

The second round provided 65% of the votes for LT and 35% of the votes for AT.

Birute Tumiene - LT was appointed as the new Chair of the BoMS. Proposed priorities of the new co-chair for the next two years included further invigoration of ERN BoMS activities, as a 1) body to steer ERN activities and a European forum for exchanging information and

expertise on relevant issues; 2) body to promote discussions with other relevant EU fora and 3) body for liaison with national health systems. To achieve this aim, several steps are required: 1) carefully prepared decision-making process (that mostly takes part in the formal ERN BoMS meetings) through preparatory discussions in the ad hoc ERN BoMS calls, ERN Working groups, JA JARDIN meetings, consultations with ERN CGs and other stakeholders; 2) timely and efficient information exchange (possible extension of Plaza functions), 3) communication and sharing of best practices among MS (e.g., regionally, bilaterally), 4) deep analysis of collected data (e.g., 5-year evaluation of ERNs) and extended, thorough discussions (e.g., JA JARDIN and Hospital Managers meetings) for the development of long-term strategies. Certain responsibilities of the ERN BoMS towards MS and ERNs that may require additional attention in 2023-2026: 1) smooth day-to-day functioning of ERNs, including further reduction of administrative burdens, financial sustainability (esp. beyond 2027), regional/national/ERN data interaction, timely support and guidance to ERNs/ HCPs on relevant issues (legal and organizational), support to the whole range of ERN activities; 2) integration of ERNs into national systems to reap their benefits for every MS and to ensure ERNs‘ sustainability (main focus on JA JARDIN and its interaction with ERN BoMS); 3) continuous cycle of quality assurance incl. deep analysis and improvement of ERN evaluation process, alignment of assessment/ monitoring/ evaluation procedures and their interaction with national quality assurance systems.

3 | 10:00 – 10:15 | Update from the ERN Coordinators Group for information and discussion

3.1 Presentation (Co-chair of ERN CG) (5’)

The ERN CG Co-Chair provided an update from the ERNs Coordinators Group. The ERNs were put into a broader perspective by explaining that they encompass more than just 24 coordinators. In total, they represent 500 hospitals, 2000 medical teams, and a minimum 20.000 medical doctors. There are more than 30 million patients with rare or complex diseases speaking 27 different languages across Europe. An important aspect to consider is that while significant funding has been provided for the ERNs management, it may not be sufficient for other areas addressed by the ERNs. Another challenge is the concept of virtuality – the ERNs are networks of medical teams but as networks, they do not clinically examine patients. Consequently, the quality of their input into diagnosis, care, and sharing of knowledge depends upon the competencies and the diagnostic tools of referring healthcare professionals, on the quality of health data their HCP members receive and the HCP links to other actors at the national level.

Participants were also updated on the appointment of the ERN new CG Co-Chair, Luca Sangiorgi (2024-2025), who will be joining Alexis Arzimanoglou and Holm Graessner. The following main conclusions were thereafter made:

The Co-Chair of the CG made it clear that the ERN Coordinators had been very busy in the past years. Regarding the ERN-CG bridging grant period, the opening of the direct Grants call (support for coordination) for ERNs began on 27 January 2022 and ended on 1 March 2022. The ERNcare4UA and medical support to Spanish Hub were launched in March 2022. Since the beginning of 2023 there has been a new call for direct grants open with the ERN coordinators drafting the applications and this was preceded by the discussion on new

indicators. All other ERN activities, such as sharing expertise, developing clinical research, and supporting national networks were reduced for 6 months with the Co-Chair making a point that the ERNs have been involved in large amounts of administrative work. They consequently call for a reduction of administrative work and improved alignment of the work between the different Commission services and Agencies dealing with ERNs.

Opening the ERNs to new members over the next four years is not supported since it would multiply the work of the coordinating centers. Therefore, it is suggested that such new members are only "affiliated" while waiting for the conclusions of the JARDIN project and how it links to the ERNs. Additionally, there has to be proof of active contribution, revision of the rule that if an affiliated member becomes a full member, other affiliated entities in this MS lose their status and revised definition of the rules for exclusion.

The financial sustainability should be reviewed, as the budget provided for the management of ERNs should not be confounded with the support to HCP members.

Support by the national authorities and hospital administrations for ERN activities and the medical teams should be increased.

As healthcare pathways for RD are not comparable within Europe, providing evidence-based suggestions to national authorities should be considered as a priority of the ERN deliverables in the coming years, as it is also a key expectation within JARDIN

It is of utmost importance to solidify coordination between the JA, the ERN CG, and the ERN BoMS and strengthen the collaboration of the ERNs with national networks for the integration of ERNs into national healthcare systems in EU Member States.

The ERN CG also requested ERNs to be exempted from unit costs as implementing unit costs with a 4-year provision is extremely time-consuming for ERNs and a large number of their individual members.

The ERNs have positive global feedback on Independent Evaluation Body's (IEB) work, however, the CG noted that the AMEQUIS tool needed to be revised for better adaptation to the specifics of ERNs. Namely, there is permanent confusion between the evaluation of ERNs as networks, the evaluation of HCP members as to their contribution to the network activities, and the evaluation of the quality of care provided by HCPs which is not under the authority of the ERNs, but rather under the authority of the respective Ministries of Health. CG further noted that the ERN event network meetings should be included as indicators and taken into consideration in the evaluation process as they are important for advancing the network's work.

The ERN CG Co-Chair suggested having regular calls of 45 minutes every second month between the ERN Coordinator Chairs, the Board of Member States (BoMS) Chair and the European Commission, and short calls with DG SANTE and HaDEA as needed.

Important outstanding issues are the centralisation of data on RD as data sharing remains a challenge, and to urgently clarify the issues related to relations with the pharmaceutical industry.

The new ERN CG Co-Chair stated that the main challenge of the ERN ecosystem is the heterogeneity of the core activities of different ERNs. The grant applications recently submitted led to the conclusions that there is a lack of appropriate health outcomes of RD patients that can be used to measure the effect of the ERN activities, the integration of ERN into national healthcare systems and the lack of support of ERN activities by the national authorities, as well as for their financial sustainability. In the next 4 years, ERN Coordinators believe they need to deliver on these core activities and focus on providing highly specialised healthcare services to rare disease patients, with JA JARDIN strengthening the understanding in the Member States of the healthcare benefits ERNs provide to their citizens. Indeed, it is important to highlight that the ERNs function as an intervention to change the healthcare systems at the Member States level.

4 | 10:15 – 10:45 | Evaluation Process for decision making

DG SANTE updated participants on the next steps of the evaluation process after the presentation of the preliminary results at the 18th ERN CG meeting.

The evaluation process is approaching its final stage. All 24 ERNs completed the self-assessments as well as other stages of the evaluation process and received a satisfactory result. In terms of the HCPs, 840 HCP (nearly 95%) completed the self-assessments and went through the technical evaluation. The draft evaluation reports have been sent to all ERNs and HCPs. Of these, 266 have been evaluated as "the need for improvement". The HCPs may send comments to the IEB within 2 months of receiving the draft evaluation report. In case of receiving a "needs improvement" result, an HCP has an opportunity to prepare an improvement plan within 2 months of receiving the draft evaluation report, which will then be reviewed by the IEB. The possibility of extending the deadline for submitting the improvement plan by 1 month (30 September 2023) was discussed with the contractor. However, the ERNs and HPCs were encouraged to send their comments on the draft evaluation reports as soon as possible. The assessment of the improvement plan will be attached to the final evaluation report which will be sent by the contractor to the HCP in question and to EC.

DG SANTE will send the final evaluation reports to BoMS. According to the Rules of Procedure, Article 7 '*Voting rules and decisions making process of the Board'*, the BoMS shall decide by consensus as far as possible, and a vote shall be taken if any Board Member so requests about the termination of HCP and/or about the implementation of the improvement plan. If the decision of BoMS differs from the IEB, the Member States should give a reason for it.

With regards to the conditions of the termination of the ERNs and the HCP members, apart from termination, a voluntary withdrawal is also possible. The HCPs who have not started the self-evaluation will be automatically terminated with the approval of the BoMS. The Cross Border Healthcare Directive of 2011 sets out the conditions related to reasons for the loss of membership, as described in Article 12, paragraph: voluntary withdrawal, according to the rules and procedures agreed by the Board of the Network; by decision of the Board of the Network, according to the rules and procedures agreed by the Board; if a Member State of establishment notifies to the Member of the Network that its participation in the Network no longer complies with national legislation; if the Member refuses to be evaluated pursuant to Article 14; if a

negative evaluation report on the Member has been drawn up pursuant to Article 14; and if the Network where the Member participates is terminated.

DISCUSSION:

LT noted that there have been misunderstandings in previous assessments and therefore, the process requires high transparency. The consequences for Member States following member termination should also be considered.

ES commented on the importance of healthcare centres' feedback on the evaluation process.

CZ stated that information should be collected from HCPs regarding the evaluation, and emphasised that the evaluation does not reflect the quality of specialised care for RD and complex patients and this is therefore critical to be discussed with the Commission.

AT commented on the need to have a dedicated meeting to discuss the individual decisions to be taken on the centres with unsuccessful self-evaluations, and enquired about the strategy to communicate with national health administrations. Regarding the evaluation process, AT stated that the focus should be on highly specific expertise participation in cross-border healthcare and the improvement plans should entirely depend on the HCPs and not on their administration units.

DG SANTE responded that the evaluation should also be viewed as an opportunity to improve ERNs efficiency and for the EC to receive feedback on the methodology of the evaluation. ERNs and BoMS are welcome to send their feedback to the contractor which will be taken into consideration in the final report. Discussions on the improvement of the evaluation will continue in the future. Regarding the HCPs that do not meet the criteria, the final decision is in the authority of the BoMS. The final reports with the improvement plan attached will be sent in advance to allow BoMS to prepare for a dedicated discussion and a formal decision.

CZ asked for the access to the self-assessment reports and remarked that national authorities should receive all of the information of HCPs submitted to IEB.

LT noted that the ERNs should have the possibility to exclude members that have joined without proper consideration of the workload. The new Chair explained that under these circumstances the improvement plans are fair and MS should take responsibility in this regard as every member has to contribute to the common goals of ERNs, even though it may involve difficult decisions. DG SANTE added that it is necessary to jointly agree on the conditions under which withdrawal or termination can be conducted.

The DG SANTE Co-Chair emphasised that the decision of unit termination is based on technical criteria only as there were some coordinators who expressed concern about external political influence. As the lack of collaboration by some of the units is problematic for ERNs, the evaluation results could be considered as a means to reconsider membership. DG SANTE stated that the Rules of Procedure of each respective networks should be checked for their withdrawal procedure of clinical units, which may also include conditions for obligatory contribution, non-conformance foreseen in ERN Consortium or Network agreements.

Conclusions:

DG SANTE will send an email to BoMS, summarising the next steps and asking for their preferences in the decision-making process. (A back-to-back meeting dedicated to the evaluation could be organised on 25 October.)

5 | 11:00 – 11:35 | Joint Action on integration of ERNs into the national healthcare systems (JARDIN) for discussion

AT – the Coordinator of the Joint Action JARDIN (Joint Action on Rare Diseases and ERN INtegration into national healthcare systems) provided an update. The Joint Action has 61 partner institutions and a total of 18.750 million EUR in funding (15.000 million EUR from EU and 3.750 million from MS). In the proposal, 30 Member States are participating, with a total of 28 Competent Authorities, 31 Affiliated Entities, and 2 Associated Partners (Switzerland and Ukraine). The structure of JARDIN is composed of the management level (Management Board, Steering Committee, and an extension to the Integration WG), horizontal WG packages – which include WP 1 to WP4, the vertical work packages – which are WP 5 to 9, and a multi-stakeholder Advisory Board composed of four subgroups (National policy Contact Point Group, Hospital manager Advisory Group, Data management Advisory Group, and Patient Advisory Group).

The work packages of JARDIN are:

- WP1 Coordination and Management
- WP2 JA dissemination & ERN dissemination
- WP3 Evaluation
- WP4 Sustainability and national plan capacity
- WP5 National governance and quality assurance
- WP6 National care pathways and ERN referral systems
- WP7 National reference networks & Undiagnosed disease programmes
- WP8 Data management
- WP9 National support options for ERN-HCP

WP1 and WP3 focus on the usual coordination, management, and evaluation procedures common in Joint Actions.

WP2 not only focuses on informing the public about JARDIN, but also includes additional tasks on the development of recipient-tailored information about ERNs and the creation of a large-sized blueprint of an information campaign regarding the pilot implementations, so as to provide better visualizations of patient pathways/expert resources. The WP lead is ERN TransplantChild.

WP4 is interested in establishing activities and measures to convince MS that the initiatives of JARDIN are important to maintain after the mandate of the Joint Action is completed. For ERNs, this means the integration of selected activities into new national plans of action or

extended RD strategies at MS level. The WP lead is LT, and there is a specific focus on Competent and Health Authorities.

WP5 wants to develop recommendations for national governance models of ERN HCPs which is adjusted to centralized, federal, or regionally organized national healthcare systems (NHS). There is a recommendation to include the establishment of a "national hub" to help steer the national healthcare systems and link to ERNs at the national level. The WP also focuses on the development of complementary national ERN integration (monitored at the national level). It is intended to decrease the burden of monitoring on ERNs. The WP is led by ERN BOND, ERN ReCONNET, AT.

WP6 is linked to both WP 8 and WP2. The content goal is the development of recommendations and guidelines for the establishment of well-defined patient pathways including the ERN referral. Supportive IT tools will be developed with pilot implementation pathways in selected MS. The WP co-leads are LT, IE, and AT.

WP7 has the content task of providing (1) recommendations for the development of National Reference Networks for ERNs, and (2) recommendations for the development of national, as well as an ERN-level, Undiagnosed Diseases Programmes. Both will require the start of pilot implementations. The WP is led by ERN-RND and AT.

WP8 focuses on easing the transfer of data and has several tasks, including: conducting a barrier and solution analysis regarding data sharing; improving semantic accuracy and interoperability of data; implementing pilots for the data transfer of HER to CPMS / HCP to registries; and developing a "European SE-Atlas" (visualization tool for patients to find experts in their country) including a "sign posting tool" for WP6. The WP is led by FR and NL, with the prominent involvement of EpiCARE, ERK-Net, Euro-NMD, ERN ITHACA, and ERN-RND.

WP9 includes the analysis and development of recommendations for national support options for ERNs and HCP and also focuses on recommendations for CPMS reimbursement strategies. It is led by CZ.

The Joint Action also includes Ukraine with capacity building to establish and operate a rare disease hub as well as capturing lessons learnt and recommendations from a healthcare system in a state of emergency for early emergency response.

JA coordinator also provided an update on the proposal's evaluation results. The evaluation is performed applying 4 different criteria: 1) relevance, 2) quality of project design and implementation, 3) quality of project team and cooperation, and 4) impact. The JA received excellent result on criterion 1, satisfactory on criterion 3, and borderline on criteria 2 and 4, which must be addressed through responding to the evaluators' requests by introducing new information into the proposal.

Regarding criterion 2 (project design and implementation), the evaluators' feedback states that it is not clear how the specific objectives of the project design and implementation fulfil the criteria to be specific, measurable, achievable, and time-bound and that the management lacks

a robust structure. Points for revision were also suggested at the evaluation, risk management, and budget levels. Regarding evaluation, the impact indicators were assessed as not entirely suitable to truly measure impact. In terms of risk management, the risk of possibility of participating countries not willing to implement the pilots or adopt the ERNs was overlooked while the travel and subsistence budget for UMW as well as budget distribution for some of the partners were considered rather high. On criterion 3 (project team and cooperation), points of criticism were raised in terms of unclear decision-making processes and management structure as well as overlooking the potential link between the Steering and Scientific Committees. The feedback on Criterion 4 (impact) reported an overly ambitious timeframe for the project and a lack of sufficient details on the dissemination plan and strategy. Moreover, the proposal lacks evidence and indicators to monitor the effectiveness of all interventions in each work package. In terms of sustainability, the proposed actions in WP4 were assessed as not convincing to directly ensure sustainability of the project beyond EU funding and that the sustainability models are not demonstrated sufficiently.

In the next 3 months, the JA will focus on replying to the requests of the evaluators and prepare the grant data and annexes, complete the first analysis of the requests and the main writing work, as well as hold respective virtual meetings with the consortium and selected groups/partners in order to receive targeted support. Within 6 weeks, the signature of Declaration of Honour (DoH) by each Beneficiary and each Affiliated Entity is necessary. Of importance to note, only beneficiaries have direct access to the project in the portal and should therefore download the DoH from the portal for their national affiliated entities (AEs) and upload the signed DoH on their behalf. Further steps are to prepare the grant agreement (MUW legal department), draft the consortium agreement, and revitalise the virtual meetings to prepare for the start of the project.

DISCUSSION:

HaDEA stated that two out of the three HU partners cannot be signatory or paid beneficiaries of the Grant Agreement because they are mentioned within the Implementing Decision (EU) 2022/2506 on measures for the protection of the Union budget against breaches of the principles of the rule of law in Hungary that took effect on 16 December 2022. Therefore they cannot be listed as a Contracting Authority, as an Affiliated Entity or as a Subcontractor. This is in line with the Council Implementing Decision.

HU asked if it would be possible for them to work on the project given that the HU government provides the financing, and stated that another possibility may be if the contracting authority is the Ministry of Health instead of the University. It was agreed to have a separate meeting to discuss this issue.

DG SANTE highlighted all Member States should be involved at the highest level possible in order to ensure the aim of the Joint Action is reached, thereby ensuring the financial sustainability of the ERNs.

6 | 10:15 – 10:45 | Working Group on Legal and Ethical issues for discussion

The Legal and Ethical Working Group deals with the challenges related to conflicts of interest, funding, and registries. They have proposed a legal solution with the creation of a legal entity. The proposed legal form is the AISBL. According to HaDEA, costs for creation and maintenance of an AISBL are not eligible for under the call for direct grants. Therefore, additional specific funding should be identified to cover costs for the creation and maintenance of AISBL serving the ERNs. The ERN CG have clarified that they are not in a position to commit themselves to the establishment of an AISBL and have raised concerns about the reaction of their hospital management teams regarding an AISBL establishment. They highlighted that they have no legal mandate to take positions on this issue on behalf of the hospitals management teams that they represent. As the CG members are not legally entitled to take position on the establishment of an AISBL for the ERNs, it was proposed to proceed with a hospital managers meeting covering every Member State.

The LES WG posed the following questions to the group regarding whether ERNs would prefer to: (a) consider alternative solutions for the challenges stated, (b) leave the situation as it is, or (c) like to keep the discussions going.

DISCUSSION:

ES raised the concern on the role of the LES WG in establishing the proposal and highlighted the crucial role of Member States.

LT asked about the expected budget and what the envisioned interaction is between the national rules on the management of conflicts of interest and legal entities at the ERN level.

ERN CG Co-Chair stated that the discussion on this subject has been prolonged because the ERN Coordinators do not have any legal expertise.

ERN VASCERN, the patient's advocate, clarified that the goal of the LES working group is discussion rather than decision and responded to the comment made regarding the expected budget that there is an estimation of the funding budget at 100.000 EUR and 250.000-300.000 EUR budget annually. Regarding the interaction between conflicts of interest at the national and international level, a policy applicable at the EU level is necessary in order to be able to act on the international level.

It was agreed to contact hospital managers covering every Member State as suggested by LT and the Legal and Ethical Stakeholder Working Group will further prepare for this meeting by preparing a discussion on a distinct list of topics and summarise the outcomes in a document.

7 | 10:15– 10:45 | Support to Ukraine under the new grants

DG SANTE provided an update on the legal advice received regarding Ukrainian participation in the European Reference Network's Clinical Patient Management System (CPMS).

The implementing acts adopted on its basis of the Directive 2011/24/EU do not provide for a formal participation of Ukrainian healthcare providers in the ERNs or to use the CPMS, while the EU4Health Programme can only provide a basis for financing certain actions. Therefore, the exchange of information between Ukrainian healthcare providers and ERN healthcare professionals could take place on the basis of Article 427(2) of the EU-Ukraine Association Agreement and an Administrative Arrangement based thereon, which may provide the means to allow the use of the CPMS by Ukrainian healthcare professionals with "guest accounts" on the condition that personal data is processed in compliance with the EUDPR and participating healthcare providers are obliged to do so in compliance with GDPR. The Arrangement would allow Ukraine healthcare providers to seek advice on their own Ukrainian patients from members of ERNs. The elaboration of the Administrative Arrangement is under discussion.

DG SANTE updated the group that efforts are being made to support the Ukrainian hub in Kiev by providing them with an access to the CPMS tool[1]. The ultimate objective is to provide support to the newly established hub in Children Hospital in Kiev and to the RD community in Ukraine through the new wave of ERNs grants and through the Member States Joint Action JARDIN.

No discussion was held on this topic.

8 | 10:15 – 10:45 | AOB

In analogy to the procedure in the Subgroup on Cancer of the Public Health Expert Group, AT suggested that members exchange contact details in line with GDPR in order to facilitate exchanges outside of BoMS meetings. DG SANTE clarified that all board members can access an internal platform with a common shared space for this purpose and will provide access to AT and others who do not have the credentials.

The DG SANTE Co-Chair thanked everyone for their participation and support and summarised the follow-up actions.

DG SANTE is to (1) send a reminder for the dates of the next meeting are 23 and 24 October, held in person in Luxembourg, (2) send PowerPoints of the meeting to the Board, (3) send documents for the evaluation process for the BoMs' assessment and (4) arrange a meeting with hospital managers to discuss the WG LES proposal on a legal entity.

The BoMS chair is to communicate dates to DG SANTE for the BoMS assessment on the evaluation process. The BoMS is to provide feedback, in coordination with the ERN Coordinator Group on the evaluation process as well as identify contact details for hospital managers and to send this to DG SANTE.

WG LES is to draft a document summarizing the situation including a list of topics that needs to be addressed to inform upcoming meetings on this topic.

[1] Subject to legal screening by the European Commission and, if needed, possible further steps regarding the legal framework for cooperation between the European Commission and Ukrainian competent authorities.

The meeting was adjourned.

The next ERN CG and ERN BoMS meetings are being held in Luxembourg on October 23rd and 24th, 2023.