



## **BOARD OF MEMBER STATES ON ERNS**

**25 JUNE 2019, 10:00-17:00**

**VENUE: CENTRE ALBERT BORSCHETTE, 5B**

Rue Froissart 36, 1040, Etterbeek, Brussels

### **APPROVED MINUTES**

**CHAIRS: ANDRZEJ RYS (CHAIR) & LENNART CHRISTIANSSON (CO-CHAIR)**

#### **1. Welcome, approval of the agenda and minutes of past**

The Chair, DG SANTE B Director welcomed all participants and opened the meeting. All EU Member States and Norway were represented.

Board members were asked if they had any comments to the minutes of the last meeting. One member presented comments related to Affiliated Partners (page 2 and 4) and related to the Statement on relations with Industry. The minutes were then approved and have been made publically available on SANTE's website<sup>1</sup>.

The Board considered the agenda prepared by the Secretariat and approved it as proposed.

#### **2. Feedback on the activities of the ERN Coordinators Group (ERN-CG)**

The Chair announced that Professor Irene Mathijssen, Coordinator of ERN CRANIO, became the new Chair of the Coordinators Group. The Chair thanked Professor Franz Schaefer, Coordinator of ERN ERKNet for its work during the past year and invited the past-Chair to summarise the developments of the past year and the new Chair to present the ideas and priorities for the year ahead of us.

The joint presentation focused on the following areas:

- ERN governance issues;
- Affiliated Partners;
- Monitoring;
- New diseases;
- Registries.

Members of the ERN-CG elected the day before, Professor Nicoline Hoogerbrugge, Coordinator of ERN Genturis, as the new vice-chair of the ERN-CG. The ERN-CG agreed to change the number of meetings from 3 or 4 meetings of 1 day per year to 2 meetings of 1,5 day per year. By having only 2 meetings per year would leave more time

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<sup>1</sup> [https://ec.europa.eu/health/sites/health/files/ern/docs/ev\\_20190326\\_mi\\_en\\_0.pdf](https://ec.europa.eu/health/sites/health/files/ern/docs/ev_20190326_mi_en_0.pdf)

to put in practice the decisions taken during each meeting. The ERN-CG also decided against expanding the mandate of the Chair, co-Chair and past Chair from 1 to 2 years. The Coordinators expressed their opinion that the process of rotation in place is enough to give the expertise necessary to the Chair of the ERN-CG.

The Coordinators expressed their opinion that the setting up of a Business Continuity Working Group was not necessary. Items such as procedures for termination of memberships or changes in coordinatorship can be dealt with by direct BoMS – ERN-CG Chairs collaborations.

On Affiliated Partners the ERN-CG Chair stressed the importance of expansion pointed however to some items that need some attention. In this context, underlined the amount of work created by the designations, of which some healthcare provider will also apply for full membership. Reiterated that some funding would be essential from Member States for Affiliated Partners. Finally, noted that some countries are still underrepresented, therefore the ERN-CG was looking forward to receive further designations of Affiliated Partners or full member applications.

On Monitoring it was highlighted that the results of the first monitoring exercise (2017/2018) were inconsistent. No valid conclusions are possible. The Working Group on Monitoring will improve definitions of indicators.

Regarding new diseases, three ERNs expressed the wish to expand their coverage of diseases. They have already developed the criteria for these diagnoses, therefore it could be included in the upcoming call. An inventory of uncovered diseases is scheduled.

ERN-wide registries are high priority for all ERNs. Integrated patient registration and follow-up will demonstrate added value of Networks. There are 5 ERN-wide registries currently funded by Chafea and Coordinators are very busy to prepare the applications to the call currently out to fund up to 19 additional ERN registries. All objectives of ERN registries (collection of epidemiological data on rare diseases, identification of current rare disease cohorts for clinical research, monitoring of natural disease history, monitoring of adherence to best-practice treatment protocols, outcome monitoring of therapeutic interventions) will not be achieved by all ERNs, but many will try so.

The European Rare Kidney Disease Registry, ERKReg was presented in details. The importance of registries in improving patient management and research was underlined. With registries the practical and direct monitoring of treatment adequacy is possible. There is a substantial running cost for data entry and analysis. However Chafea grants will only cover 3 years and the Networks will need to sustain these unique registries. Therefore, there is a key concern of long-term sustainability. The question is who will pay for it. There are potential sources of continued funding: the Commission, the National healthcare systems, the Healthcare providers (for local efforts), Charity foundations or the Industry (under strictly regulated conditions). We need to think under which conditions we could allow industry funding, unless the Commission or national health systems are stepping in.

Related to Research activities it was noted that the funding of rare disease research has increased significantly with the EJP. In the WP6 on Joint Transnational Calls, the focus is on disease-specific registries. So far 217 applications were received; vast majority of them is affiliated with ERNs. In the WP 17 on ERN Research Teaching and Training Programme the focus is on training seminars/workshops for ERN researchers and on short-term exchange visit programme for ERN researchers.

The presentation was followed by an extensive discussion mainly focusing on the sustainability of the registries, the designation of Affiliated Partners, the type of coding used in the registries. Compatibility with existing registries, reinforcement of orphacodes, the JRC minimum common dataset and evolution of coding were also mentioned as factors to be taken into account by the members of the Board. On Affiliated Partners the Coordinators underlined that the approval process for the new full members will last more than a year, during which time they are more than happy to work with the new Partners.

### **3. ECA report on Cross-border healthcare**

The Commission made a brief presentation on the European Court of Auditors (ECA) Report<sup>2</sup> on cross-border healthcare in the EU. The auditors have examined the European Commission's monitoring and support for putting the EU legislation on cross-border healthcare access into effect, the results achieved to date for patients, and the effectiveness of the EU funding framework and of the actions funded.

The auditors examined whether the European Commission has monitored the implementation of the EU cross-border healthcare directive and supported Member States in informing patients of their rights. They assessed the results achieved on exchanges of health data across borders and checked key actions on rare diseases. They also examined key recent EU actions in the field of rare diseases focusing on the creation of the European Reference Networks.

Based on their conclusions, the auditors made recommendations. A follow-up is expected which may have an impact on future financing.

At present the Commission is working on a plan to address the recommendations. It is important to underline that the recommendation on Integration of ERNs into the national health system of the Member States, falls mainly under the competence of Member States.

A follow-up audit is expected in 2023/2024. Question if it will be carried out in a package with eHealth or earlier if ECA only concentrates on ERNs.

### **4. Working Group on Integration, adoption of Board Statement**

The Chair recalled that the Working Group on Integration was mandated by the BoMS at its last meeting to prepare and present for adoption a draft Statement on Integration. By means of teleconferences, the Working Group worked intensively during the last months and prepared a draft Statement that is now tabled for adoption to the BoMS. The Statement fully respects the very delicate balance between two principles: protecting Member States exclusive competence in organising and delivering health services from one side and protecting the ERN system and encourage Member States to facilitate the development of the initiative on the other side. The overall objective of the Statement is to support the Member States in the integration process of ERNs into the national healthcare systems.

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<sup>2</sup> <https://www.eca.europa.eu/en/Pages/DocItem.aspx?did=49945>

The Chair of the Working Group on Integration presented the background, the timeline, the methodology and the legal environment.

Ensuring a proper and sustainable functioning of the Networks and to reap all benefits for patients suffering from rare and low prevalence complex diseases across the EU was recalled being the overall objective of integrating ERNs into the national health systems of the Member States.

The link to the Expert Panel on Effective Ways of Investing in Health Opinion on the application of the ERN model in European cross-border healthcare cooperation outside the rare diseases area and to the European Court of Auditors Special Report on EU actions for cross-border healthcare was made.

The key areas of intervention and the respective recommendations were presented in details:

1. National rare disease plans/ strategies and legal framework for ERN integration.
2. Patient care pathways.
3. Referral systems to the ERNs.
4. Support by Member States to ERN Coordinators, Full Members and Affiliated Partners.
5. Information on ERNs provided at MS level.

Following the presentation, several members of the BoMS expressed full support to the draft Statement. It was termed to be an ambitious Statement which leaves enough room for manoeuvre for the Member States in implementing it. Sharing knowledge, good practices and the importance of national rare disease plans / strategies were mentioned as most important elements in the way forward.

Annexed to the Statement a list of prioritised potential actions that were considered by the Members of the Working Group to be relevant for the planning and implementation of sustainable integration processes were also presented.

In conclusion, the BoMS proceeded with the adoption of the Statement with unanimous support. The Statement<sup>3</sup> and its annex<sup>4</sup> were then made publically available on SANTE's website.

## **5. Country presentation – national approach to integration**

In the context of exchanging good practices on how to link, integrate ERNs into the national health system, the Polish representative of the Board made a presentation on the Polish approach.

The Polish national plan for rare diseases is now ready. It aims to overcome the currently much dispersed care and funding. The most important challenges and needs of the current system are: the shortage of epidemiology data (no dedicated coding and reporting required by the system, few central registries) and limited economic data; no reference system for in- and out-patient care; no clear patients' pathways; shortage of widely accepted clinical SOPs; low budget for reimbursed rare diseases therapies; no dedicated system of decision-making processes of the reimbursement of orphan drugs (central,

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<sup>3</sup> [https://ec.europa.eu/health/sites/health/files/ern/docs/integration\\_healthcaresystems\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ern/docs/integration_healthcaresystems_en.pdf)

<sup>4</sup> [https://ec.europa.eu/health/sites/health/files/ern/docs/integration\\_healthcaresystems\\_annex\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ern/docs/integration_healthcaresystems_annex_en.pdf)

governmental procedure equal for all the applicants); no coordinated care models; limited inclusion of patients/parental organizations and advocacy groups in decision-making processes; limited social awareness and understanding of rare diseases needs; underestimated costs of highly specialized medicine (including diagnosis, like genetic tests, and medical therapies).

In 2018 the Ministry of Health established a new committee for rare diseases with the mandate to work on the National rare disease Plan. Poland decided to base the Plan on 4 pillars: diagnosis and treatment, acceptance and support; rehabilitation and education, research, social awareness and information. The aim and topics to be covered by each pillar was presented.

The Plan is scheduled to last 5 years; the follow-up plan will come thereafter. The first outcome measures will come in 2 years, annual assessment by external committee at Ministry of Health. The first 2 years will focus on preparation and implementation of legal environment for Plan's activities. Most budget-associated activities will start as of the third year. Around 5-10% of the total healthcare budget will be dedicated to rare diseases. This will also cover reimbursement of orphan drugs.

At present Poland is underrepresented in the ERN system, the aim is to improve this situation.

The model future care, coordinated care, for rare diseases in Poland was also presented and explained in details. And the Rare Disease Passport concept was mentioned.

Finally the timeline for adoption of the Plan was presented. After its adoption by the Ministry of Health in March 2019 it is currently proceeded by the Government. It seems to have a strong political support. It is planned to be passed as a Parliament bill in 2019, to be followed by individual ministries decisions in 2020.

The presentation was followed by a discussion. Members of the BoMS valued the fact that the Polish Plan is planned with a budget. The pros and cons of the rare disease passport concept were brought up. The importance of a proper system for genetic testing (laboratories and funding) was mentioned.

## **6. Board Statement on relations with Industry**

The Chair of the Working Group on Legal, Ethical issues and relations with Stakeholders updated the BoMS on the revised update of the 2016 Board Statement on relations with Industry. Before presenting the draft in details the background and the short history were also explained.

The present version of the Statement is the third version that the Working Group has elaborated. It tries to accommodate all comments received. This version has been drafted since the last BoMS meeting and was sent a month prior to this meeting to all BoMS members.

The overall twin aim is to reflect on the elements that have changed since 2016 and clarify which activities are allowed (or not) for industry (or other private) to support. Further it aims to possibly allowing the exploration of "joint" funding mechanisms where several private partners could jointly support one (or even several) ERN(s).

Preparing an "Addendum" has been started to better clarify / explain issues when required (other stakeholders, registries, outcome measures etc.).

At the previous occasion of the BoMS meeting it was also proposed to implement two pilots, possibly on clinical trials and registries, to test solutions and mechanisms for the cooperation with industry. The pilots will be developed in two steps: 1) collect examples of projects, initiatives (EU funded, national etc.) and develop the concept for pilots applicable to ERNs (not only to ERN members but for Networks) and 2) once the Board will have agreed on the concept developed, implement the selected pilots and draw some lessons from them. Depending on results of the pilots, the Statement could further evolve in the future.

Further to the Addendum and the pilots, there are 3 other documents under preparation by the Working Group. The policy document "Managing conflicts of Interest", the "Disclosure form" for conflicts of interests and the "Code of Conduct".

The present version of the Statement in addition to improving the formulation and setting the context, clarifies the "red lines" for which no direct funding of the industry will be allowed ("*management and running of the Network nor for any type of activity relating to the development of diagnostic and clinical practice guidelines or any other clinical decision-supporting tools, development of outcome measures as well as establishing and maintaining patient registries*") and also stating that "*for other activities*", ERNs should preferably seek public funding but, once exhausted, they could also look for solutions enabling shared funding from more than one industry partner. "*In case of financial support coming from multiple Industry partners or when activities in several ERNs are jointly funded, an independent external body could preferably be responsible for governance and reporting.*"

The presentation was followed by intense discussion. The issue of registries and their financing was at the heart of the discussion. Difficulties arose from the fact that the addendum meant to accompany the Statement still needs to be developed providing examples, clarifications of the concepts used in the Statement (direct-indirect, multiple funding mechanism – single funding, independent assessment body) and putting it in into the ERN context. Importance of proceeding with the proposed "pilots" was also emphasised.

Overall, after the lengthy discussion, several members were in favour of adoption while some countries had reservations. Many members were very constructive in the debate and finally with some changes in the text, the Statement was adopted by the Board. It was made publically available on SANTE's website<sup>5</sup>.

Importance of defining concepts of the Statement in the addendum and importance of proceeding with the work on the pilots was emphasized by the BoMS when adopting the Statement.

## **7. Amendment of the Implementing decision**

The Commission updated the Board on the amended Implementing Decision. The amendment aims to clarify the role of Board of Member States in steering the ERNs, modify the procedure concerning the application for membership of existing ERNs and add provisions concerning the establishment of the Clinical Patient Management System and rules on co-controllership of personal data in compliance with the General Data Protection Regulation.

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<sup>5</sup> [https://ec.europa.eu/health/sites/health/files/ern/docs/statement\\_industry\\_conflictinterest\\_en.pdf](https://ec.europa.eu/health/sites/health/files/ern/docs/statement_industry_conflictinterest_en.pdf)

Following several discussions at the Cross-border Healthcare Committee (CBHC), the Commission launched a written procedure for vote in the CBHC. The vote was finalised on 11 June 2019 with a positive opinion of 27 Member States for and 1 against.

The Commission expects the College of Commissioners to finalise the adoption by mid-July. After adoption, the Commission intends to launch the call for application for membership to existing ERNs.

The Commission presented the whole procedure concerning the application for membership. The call should be easier with the help of an online tool, on which the Commission is currently working. It will be available at the moment of the opening of the call for the Healthcare providers wishing to join existing Networks.

The application process for the new members will be done online. The Applicants will fill out the application and self-assessment, and upload the endorsement letter which shall be signed by the responsible Ministry.

The BoMS and an Independent Assessment Body will have access to the eligible applications for their opinions, the process will take place online, within the tool.

The process of application will be described in the manual of the application process, which will be provided together with the documents related to the call, at the moment of the launching of the call.

## **8. Enlargement process of the Networks (designation of Affiliated Partners, new call)**

The Commission updated the BoMS about the state of play for Affiliated Partners (APs). In the context of enlargement of the Networks, the current state of play regarding the designation of Affiliated Partners, recent developments, next steps and the timeline were addressed.

It was recalled that the process of designating APs was initially triggered to cover the issue of geographical coverage. There are still 3 countries without any representation in the ERNs: Greece, Slovakia and Malta. Since the last meeting of the Board, 5 Member States designated new APs. The designations are very different in term of numbers and types. At present there is a total of 160 designations made by 9 countries. So far, 2 countries opted for the designation of a National Coordination Hub. More new designations are expected based on bilateral contacts.

Following the designations, the Coordinators will have to establish bilateral cooperation agreements (one with each APs) and develop clear strategies (one by Network) on the integration and participation of APs in the Networks. For both documents a template has been worked out.

A new Q&A document was also compiled to answer the questions of the Coordinators and Member States.

A restricted section dedicated to APs was created on the ERN Collaborative Platform<sup>6</sup>. This section is meant to serve as a repository for all documentation related to APs. All

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<sup>6</sup> <https://webgate.ec.europa.eu/ern/>

designations (by Network and by country) and all established cooperation agreements are being saved here. Coordinators, ERN project managers and BoMS members have access to this section. All members are invited to report any discrepancies to the Commission.

The Coordinators are now expected to process the designations received: the ERN establishes contact with the potential AP, prepares the bilateral cooperation agreements and the Integration Strategies and sends them to DG SANTE (SANTE-ERN-AFFILIATED-PARTNERS@ec.europa.eu). The Integration Strategies will have to be presented to and approved by the BoMS. The deadline for presenting Integration Strategies was initially February 2019 but it must now be adapted. The designation of APs is open until the launch of the next call for new Members.

Following the presentation some Member States argued in favour of keeping the affiliation process open even during the call for new full members. Finally it was agreed that once the outcomes and consequences of the exercises on affiliation and membership have been finalized and analysed, and in agreement among all Member States in the Board, in coordination with the Coordinators and in accordance with the relevant Board Statement, the process could be restarted.

## **9. Debriefing from the Hospital Managers' meeting**

The Commission updated the BoMS on the third meeting of the ERN Hospital Managers which took place in Hôpital Saint Louis (Assistance Publique – Hôpitaux de Paris) in Paris on 16th and 17th May 2019. Overall 54 Hospital managers attended the meeting.

Several topics of interest of the ERNs system were extensively discussed during plenary sessions and workshops including: a) the tertiary care hospital of the future b) adjusting hospital financing to new roles and low prevalence conditions and c) sharing best practices to support the ERNs on communication, e-training and e-learning actions; data management; human potential and transversal support services.

ERN hospital managers committed to strengthen collaboration to support the implementation of the ERNs. For the next year, the ERN Hospital managers will continue to cooperate, coordinate their actions and exchange best practices in four main areas: communication, e-training and e-learning actions; data management; human potential and transversal support services.

A plenary session was devoted to have an intensive dialogue with the main stakeholders of the ERNs system (ERN Coordinators, Member States' representatives, patients' representatives and rare diseases experts).

Another plenary session debated the ERN environment and actors. The elements debated were the support of the Hospital Managers to the daily work of the health professionals in the ERNs (allocated working time and/or substitution by other staff to dedicate time to the ERNs, additional funds or administrative support); how to manage the increasing size of the ERNs; contribution of Hospital Managers to the integration of ERNs in the national health systems and elaborate patients' pathways and the support to networking at national level and avoid competition across hospitals.

The Hospital managers stated that ERNs are an opportunity to leverage innovation, not only in the field of rare diseases, but also in the way hospitals are managed and interconnected across Europe through networking.



A structured cooperation with Hospital Managers is being put in place. In this context, a dedicated section in the ERN Collaborative Platform for Hospital Managers was made. Once a year a face to face meeting is being organized and 4 working groups were established on: data sharing, communication, transversal support and human resources support.

The 4<sup>th</sup> meeting will take place in May or June 2020, possibly in Poland.

Two countries called to better exploit synergies between the different ERN entities, especially when it comes to integration of ERNs.

## **10. Expansion of the ERNs diseases coverage**

The Commission recalled that the initial 24 Network proposals were quite exhaustive in terms of the diseases coverage. Nevertheless, two years after the launch of the ERN, it has been considered appropriate to reflect on the possible gaps to be addressed in order to complete the diseases coverage of the Networks.

Several Networks have been raising this issue in the last months and in order to better understand the apparent needs and proposals of the 24 ERNs. A survey was conducted in May 2019 by the Commission on the potential disease expansion of the current 24 ERNs.

The outcome of the survey was presented in details. 16 ERNs filled the survey out of which 9 ERNs are proposing an expansion. 3 of 9 would need new member profile, 6 of 9 would need definition of new specific criteria/thresholds and 8 of 9 would like to include the new diseases in the forthcoming call.

Based on the outcome of the survey and taking into account the urgency of the situation, a proposal to further proceed in order to decide whether an expansion of complementary diseases (to the current scope of the 24 ERNs) would be feasible and appropriate was made.

In the proposal several issues must be addressed ranging from how to assess the gaps of disease coverage to the handling of overlaps across the ERNs and how to ensure there will be no competition between different Networks.

The cornerstone are the following: any possible expansion must be approved by the ERN BoMS; only new diseases (not covered by any ERNs) fall under the scope; in case of diseases already covered by one of the ERNs, an analysis of the complementarity of other possible ERNs should be carried out; proposals that imply new member profiles would need a definition of new criteria following a structured and transparent process; proposals not implying new profiles (with or without new criteria) could be included in the upcoming call. The competence of the current members could be assessed through a peer review process.

Some members argued in favour of developing a "light" procedure, but the need of a clear documentation with the justification of the Networks was stated. Avoiding fragmentation and duplication was also underlined.

It was agreed that COM will prepare a "package" with justification of the Networks and include a proposal for decision to the Board. This will be done in a written procedure with the aim to include the additional diseases in the next call for new members.

## **11. Communication**

The Commission updated the Board on the most recent developments concerning Communication activities on ERNs.

A new communication tool, an ERN newsletter will soon be released after the Board meeting. It will address both the ERN community (ERN Coordinators and members, Hospital managers, Member States, patients' representatives) and external stakeholders. It aims at giving an overview on the last developments of the ERNs system, and to allow an exchange of information and good practices which are likely to be interesting for the whole ERN community beyond a sectorial disease approach. All members of the ERNs community are welcome to provide contributions. The newsletter is expected to be released three times a year.

Further information was provided on projects currently under development. The production of two new reportages and the creation of an interactive map on ERNs to be hosted by EUROPA's webpage. Both expected to be delivered by end of 2019.

Member States were also informed of the possibility to use the eTranslation tool. This tool has initially been designed for the translators of the Commission, so it addressed primarily aspects related to the *acquis communautaire*, but its access has then been opened to all public administrations in Europe. It allows a very quick translation of documents, through an automatic engine, keeping the initial format of the document.

## **12. Monitoring – state of play of data collection**

The Commission update the Board on the outcome of the very first data collection exercise and present the corrective measures which aim the improvement of the quality and validity of the system.

The monitoring exercise is necessary to prove the value of the ERN system. Monitoring in time will ensure the availability of financial resources. Evaluation of the Networks is also a legal requirement.

A core set of 18 ERN indicators was agreed by the ERN-CG and approved by the ERN Board in September 2018. The set of 18 indicators was build following an extensive consultation process and systematic approach that started in June 2017 and is covering the main goals and areas of work of the ERNs (structure, process and outcomes). Based on the technical specifications, the IT unit of DG SANTE developed a web-based data collection system that went live in January 2019.

The first data collection exercise was launched for the period 2017–2018 between January to April 2019. The system has been filled by the data already included in the ERN information system at DG SANTE (CPMS, Directory of Centres etc.) and by the data collected by the ERNs (7 indicators).

The main aim of this first data collection exercise was to test the functionality of the online data collection system, the information systems and the capacity at network level to collect the data and the quality and consistency of the data collected.

The first conclusion of the exercise is that the indicators were not interpreted homogeneously by the ERNs. Moreover, there were gaps and missing data and two ERNs did not submit any data. Consequently, the number of outliers and inconsistencies

among the data reported make the outcomes of this first monitoring exercise unreliable and not usable. No conclusion on the performance of the ERNs can be drawn.

As regards the next step, the Monitoring Working Group created a reduced drafting group to work on the definition of the indicators to make them clearer. The work is essential so as the monitoring exercise can give results that can be used to show the work done by the ERNs. From the current quarterly approach, we will move towards data collection every six months. The next deadline for the data collection for the first semester of 2019 is thus 31 October 2019.

The Board stressed the importance of having this exercise carried out properly for the credibility of the whole ERN initiative. Some countries wondered if any kind of monitoring activity on the policy development on Integration would be possible.

### **13. Update on research and registries for ERNs**

The Commission informed the BoMS on the most recent developments on registries for ERNs. At present there are ongoing registries projects for 5 ERNs. With adoption of the annual work programme 2019 of the EU Health Programme in March 2019 and the launch of a call for grants on registries the remaining 19 ERNs can start their registries projects. The ERN Research Working Group recently created a sub-group: the Registry Task Force (RTF), to focus on synergies across ERNs and on the preparation on the call for grants.

A call for the Task Force was organised on 14 May 2019 to allow the 5 ERNs with Registries to present their projects so the other 19 ERNs could learn from their experience. A second call was organised on 14 June to gather information from the 19 ERNs that are planning to apply for a grant. A survey was launched to better understand the needs in terms of Registries. Many ERNs would find it interesting to find synergies between the Networks.

A face-to-face meeting is planned on 18 July 2019 in Brussels to discuss the technical aspects linked to the call and potential synergies. The Commission also reminded about the standards developed by the Joint Research Centre in cooperation with DG SANTE and the necessity for all ERNs working on registries to take into account them. Further, an FAQ for the call is being developed. And a short extension of the deadline for the call is being envisaged.

The Research Working Group hopes that all those measures will help to ensure the future interoperability and sustainability of the Registries.

### **14. Support for digital transformation of care for ERNs in the next MFF**

DG CNECT presented the state of play on Data-driven Health Care Innovation and the Digital Single Market.

The 1 Million Genome is an initiative started by 13 Member States in April 2018 to provide access to 1 million genomes by 2022. By now 20 MS have signed the declaration. The project is coordinated by experts identified by the Member States. They are working on the underpinnings to access the genomes across the borders, on genomic practices, interoperability, quality of data, legal and ethical framework to access cross-border database. They have determined 3 priorities: Cancer, Prevention and Rare

Diseases. The work of the ERNs was conveyed to those experts so there could be a cross-competence work of all the entities working on rare diseases.

The Commission has issued a recommendation to encourage and support Member States to develop interoperable and citizen centric electronic health records systems. The recommendation is made of two parts. The first part is made of the principles ruling the access to and the cross-border exchange of electronic health records. The principles are patient centric to ensure trust with a strong security and data protection component. The second part details a baseline for a European electronic health record exchange format to ensure the semantic interoperability of the information.

Update on Horizon 2020 was also given. Several calls will be launched on 26 July 2019 with a first wave closing in November 2019 and a second wave closing in April 2020. The programme aims at giving access to the Member States to genomic material and opening the possibility for clinical experimentation or in other domains such as Artificial Intelligence (AI). Two factors will be cross-acting in the project. The first aspect is to support cross-border access to genomic material for personalised medicines. The second aspect is the development of a roadmap for interoperable solutions across Europe.

DG CNECT is working on the next funding opportunities for eHealth 2021-2027. Building on the innovation financed under Horizon Europe, the Commission has proposed to take the solutions and embed them into the healthcare settings through the Digital Europe Programme. It revolves around 5 major blocks: Digital transformation & Interoperability, High Performance Computing, Artificial Intelligence, Cybersecurity & Trust and Advanced Digital Skill. The total budget is 9.2 billion euros.

## **15. AOB**

The Chair informed the members that the next Board meeting is booked for 15 November 2019, to take place in Brussels.

As for the next year is concerned, the Commission proposed to change the number of meetings of the BoMS from 3 to 2 meetings of 1,5 day per year. By having only 2 meetings a year, would leave more time to implement the decisions taken during the meetings.

**END OF THE MEETING**