



Brussels, 15/11/19 – V1

DRAFT MINUTES OF THE 9TH INTERNAL MEETING OF THE EUROPEAN REFERENCE NETWORKS COORDINATORS GROUP (ERN CG)

Chair: I. Mathijssen, Chair of the ERN CG

1. Meeting schedule

This year, the internal meeting of the ERN CG is held after the meeting of the ERN-CG with the European Commission (EC). The ERN CG does not find the situation ideal but there was no other option for multiple reasons:

- The Research Working Group (RWG) held a workshop on Wednesday 13 November for all ERNs so the internal ERN CG meeting could not happen that day
- The ERN coordinators and project managers cannot access the EC buildings during the evenings so the meeting could not be held on Wednesday evening either.
- The internal meeting could not happen another week because the ERN CG chair needs to attend the BoMS meeting, just like the chair of the BoMs needs to attend the internal meeting of the ERN CG. Both meetings thus must happen on the same week.

Maurizio Scarpa offered to ask the MetabERN HCPs in Brussels if they could potentially use one of their rooms to have the internal meeting of the ERN CG for future meetings. This would allow the internal ERN CG meeting to take place on Wednesday afternoon/evening, before the meeting with the EC on Thursday and the meeting with the BoMS on Friday. Alain Verloes will also ask the ITHACA HCPs in Brussels for the same possibility.

2 Applications of AP and FM

The applications of Affiliated Partners (APs) and Full Members (FMs) are coming in. The ERN CG produced a list of the remaining items that need to be addressed and answered. The list was sent to Anna Mirandola at the EC. She will respond to all queries and publish the answers on the ERN website.

Some countries are still missing or almost completely missing from the ERNs. In Austria, no applicants for full membership received a letter of endorsement from the MS. Ruth Ladenstein created a letter that the ERNs could all sign to ask the government to revise

their position on endorsement. The letter would confirm that there is research excellency and experts in Austria's Healthcare Providers (HCPs) deserving of becoming members. Irene Mathijssen offered to bring the point in a general manner in front of the BoMS since other countries, like Greece, are also affected by a similar situation.

The ERN coordinators raised the issue of APs who are not able to participate to ERN meetings due to lack of funding. A quick survey during the ERN CG internal meeting demonstrated that the ERNs had 2 approaches used equally across the networks: They either covered their APs' costs like they do for full members or they do not cover them at all. Some ERNs would like to cover their costs but lack the funding. It was noted that it would be important to have a common procedure among the ERNs otherwise problems might arise in the future.

3. ERN interaction

There are 2 important procedures coming up for the ERNs:

- Procedure to allow members to extend their diseases coverage
- Procedure to assess the new full member applicants

The ERNs feel it would be valuable to have a common approach to those procedures even if each ERN would still be free to follow different guidelines, as long as these are in accordance to the ERN-related legislation. Sharing the procedures that have already been created and developing a common approach would help save time for all ERNs.

Renée De Ruitter presented the results of a survey that was sent to all Project Managers (PMs) to gather input on the existing governance documents and evaluate those that are missing. Renée received answers from 20 out of 24 ERNs. The results of the survey show that a lot of governance documents have already been created in the ERNs, yet some documents mentioned were new to her. All ERN members would benefit from sharing what has already been produced. A common repository could be created to gather all documents in one place. The survey also identified a lot of missing documents: documents related to registries, data access policies, data sharing agreement and GDPR related forms among others.

The survey also asked information about the individual organisational structures of each ERNs. There are a lot of overlaps between the ERNs, but she was curious to compare the working mechanisms.

Certain elements became evident such as the fact that the ERNs would benefit from having a common procedure to assess new members and from sharing good practices among themselves.

This sharing of information between ERNs would open the dialogue among the networks regarding recurrent issues, would reduce the workload of members and save time. The survey highlighted a few possible options to raise the collaboration between ERNs: The

members might use time during the ERN CG meeting to share good practice examples and PMs could organise more meetings during the years to discuss important issues. It was reminded to the members that a common space dedicated to PMs exist on the European Collaborative Platform (ECP) for their usage.

Regarding the common approach towards the various procedures such as the assessment of new members, the ERNs could discuss the step by step approach that would then be acted on by the PM. The procedures would first have to be approved by the Board of Member States (BoMS). Michelle Battye suggested that for the next meeting of the ERN CG, the PM come a bit earlier to have a private meeting before the common meeting.

The ERN CG members raised the issue of the procedure to follow when an ERN centre loses its expertise. The ERNs need to agree on what should be the procedure when an expert retires or changes centre. The ideal solution would be to perform assessments on the concerned centres and withdraw the expertise when needed.

Most countries do not have a regular reassessment procedure for acknowledgement of expertise, while this should be part of the national plan for RD.

The coordinators discussed the strategy to handle the massive number of applicants for the second call for full membership. eUROGEN, MetabERN and PaedCAN shared their experience of having created smaller comities to handle the applications assessments. They considered it a waste of time to ask all the members of the Board of the Network (BoN) to take care of it. A smaller comity will make the task easier and quicker and the BoN could be consulted for problematic cases. Michelle Battye informed the members that, in order to create the smaller comities, all the BoN members need to be asked for their consent and everything needs to be recorded carefully as those procedure are susceptible to audit.

Maurizio Scarpa informed the ERN CG members that he asked Andrzej Rys, director of DG SANTE, to send a letter to the ERN hospitals general directors to inform them that the call for membership will put additional work on the shoulders of the ERN coordinators for the next 3 months.

The ERNs addressed the problem of funding of the networks. With the increase of members, 200.000 euros per year per ERN will not be enough to cover all the costs. Irene Mathijssen will bring this to the attention of the BoMS.

The ERN CG members addressed the issue of the assessment of new members. Discussions made it clear that each ERN has a different view on how those members should be assessed, what they should bring to the ERNs and the valid criteria to refuse an applicant. Common guidelines need to be created and approved by the BoMS. The common guidelines would be legally binding and would avoid future issues.

The coordinators agreed to start working on the following documents together:

- Guidelines to increase the disease coverage of an HCP
- Guidelines for the assessment of new members
- Guidelines to handle non-responsive HCPs
- Integration document
- Sharing of best practice

Michelle Battye will share the documents that are under development with Renee de Ruiter and once they are more advanced will be shared with the coordinators for comments.

4. Involvement ERN coordinators

The ERN coordinators commented on the fact that very little or no input at all was asked of the ERNs for the tender of the Taxonomy project. The same applies to other tenders created by the EC for the ERNs. The coordinators would like to be more involved in those processes if this is legally possible. Irene Mathijssen will inform Enrique Terol that the ERN coordinators are willing to be consulted when they are tenders related to the ERNs.

The coordinators shared their view on the tender for the Education and Training of Clinicians. They did not know the tender was going to be created and they feel like this is a potential loss of money since there is a similar programme in EJP RD. Franz Schaefer and Alberto Pereira have already defined how the weeks could be divided between the researchers for the EJP RD programme, they offered to use the same governance documents to handle the division of weeks for the clinicians inside the ERNs. Maurizio Scarpa, member of the Knowledge Generation WG, informed the coordinators that the tender would not concern this aspect of the process. The tender will be published to hire a contractor who would only handle the practical details of the exchange like the traveling and other practical details. The ERNs would all receive a quota of weeks depending on the size of their networks. They would then oversee themselves who will travel and to which location. There would be no competition between the ERNs to “win” weeks, the weeks would be given in advance. The tender has not been published yet, so the precise terms of reference are not available yet.

5. Legal status of ERN-based guidelines, consensus statements and standards of care?

There are still many questions as to what defines a guideline, a standard of care and other documents of the kind. The ERNs are not certain what would be the legal status of an ERN guidelines. Until the contract with the contractor is signed, the EC will not be able to provide clearer details on the tender. The contract will be signed in January 2020 and the project kick-off will take place in February.

The tender is aimed at companies that could help the ERNs produce various guidelines. Every ERN will receive a specific amount of money to create a certain number of documents. The money will need to be used to work with the contractor hired by the EC.

Outside of this money and the target number of documents, the ERNs can work with whomever they want to produce other kinds of documents.

The ERNs are not certain whether it will be mandatory to implement those guidelines at national level. It would be important to determine if the guidelines have any implication on the national plan if one is in place. Irene Mathijssen will ask the question during the meeting with the BoMS but she thinks it is specific to each MS.

6. Sustainability ERNs, financial and governance

The end of the first grant of the ERNs is set for March 2022. The coordinators asked if there were any definite answer on the renewal of the budget. The EC implied that this would fall under the EU budget that will be discussed and probably finalised during summer 2020. The ERNs stressed the importance to make sure there will be no gaps in funding. The subject should be put on the agenda of every meeting with the EC until it is settled to avoid future funding issues.

The ERN coordinators asked whether the EC was thinking of creating a new call for membership in 2022. They also enquired about a new call for Affiliated Partners (APs). The members stressed the importance to have the perspective of future calls as an opportunity to streamline members based on real input and activities and add new expertise. This would be an opportunity for a constant renewal process.

The ERN CG members mentioned that it would be easier to switch to a system of direct grants for a better management of the ERNs. Michelle Battye informed the ERN coordinators that the EC is already thinking of switching all ERNs to direct grants, like eUROGEN is, as it would supposedly be easier and faster to manage. Michelle could not yet confirm the two criteria as their first phase of reporting is not yet complete. The ERN CG members stressed the need to mind the timeline to ensure a continuity in funding.

Michelle Battye informed the ERN CG members that eUROGEN is getting in touch with the National Coordination Hubs (NCHs) to train them and give them access to relevant ERN information. They are traveling to visit an NCH in Malta on 28 November to present the ERNs in detail and train them on the CPMS. She invited other PMs to join her on this mission. Michelle Battye asked Irene Mathijssen to stress to the EC the importance of giving NCHs access to the CPMS. The EC told the ERNs they could not give NCHs access to the CPMS until their service directory is ready, which is difficult to understand for the ERNs. There is an Integration process in progress and the access to the CPMS is crucial in this approach.

It was confirmed by the EC that the contract for the CPMS should be renewed for 2 years. The ERN members want to open the discussion with the contractor to all ERNs. This process would allow all ERNs to give a feedback that would reflect better the realities of its usage by the networks. Ruth Ladenstein offered to create a questionnaire to send to all ERN members to gather their opinion and suggestions on the tool. Luca Sangiorgi

stressed the importance for the CPMS to change and adapt to the real needs of the ERNs. Otherwise the tool will not permit to gather the data corresponding to the 18 ERN indicators correctly and ERNs will have problems when they will be evaluated at the end of the 5 years period. He also stressed the need to open the access to the CPMS to a broader public. The ERNs are required to be embedded in the national context, but they do not have the permission to imbed the CPMS in the national context. The process lack logic considering the CPMS would be most useful for people who are not part of the ERNs and do not have access to the expertise. The CPMs would also be a valuable tool for the inclusion of cases in clinical trials.

7. How to coordinate and prioritize actions on overlapping diseases between ERNs?

Irene Mathijssen will ask Ana Rath from Orphanet to send the results of her analysis of the overlaps between ERNs. The ERNs will then need to review them to check if it is complete and identify the overlaps. The number of overlaps is bound to be important so the ERNs will need to prioritise diseases. The following task will be to identify what already exists and what is needed in terms of documentation and guidelines. It was suggested to work together to create a multi-ERN overview of diseases so patients could see the ERNs are collaborating to find a better treatment. The patient would then have the opportunity to choose the ERN that suits them best. Luca Sangiorgi stressed the importance to work on common guidelines together, so patients are not faced with different guidelines for the same disease. The ideal approach would be to look at what has already been created and see how to go from there. Existing guidelines covering the same diseases could be integrated into one. The ERNs could also keep a list on the ECP to inform other members of the guidelines they are currently working on. It would allow other members to join effort with them for overlapping diseases.

The second point of action regarding Orphanet's results is to determine which diseases are not covered. Orthopaedics and psychiatry are 2 areas not covered in any ERNs. It would be interesting to find the other potentially missing area and decide what should be done about them.

Wout Feitz from eUROGEN pointed out that it would be necessary to extend the Orphanet code to other codes to make it more complete.

Luca Sangiorgi remarked that it would be valuable to inform the BoMS that if they want to set up the various patients' journey documents, they have the expertise available inside the collaboration of the ERNs. The ERNs can indicate where the patient should go and where they MS could find the relevant information if they don't have it nationally. In addition, the patients' journey would be a valuable source of information for affiliated countries who don't have the expertise. Patients might also benefit from having an overview of what their journey might be. The possibility could be presented to Patients' organisations (POs) to see what their opinion is.

8. Which activities are allowed to accept funding for from industry? And more general: how is funding of ERNs going to be adapted given the tremendous expansion with new members and affiliated partners?

The European Commission wants to start a programme of 2 pilots to illustrate how the collaboration between the ERNs and the industries could work. The pilot would illustrate a project you have in place that could benefit from a support form the industry. It would serve to show that the project would not be corrupted by the joint effort with industries. Michelle Battye mentioned an example provided by eUROGEN of a potential study on penile cancer where the laboratory material required is very expensive and the support of the industries would be valuable. Any ERN that has a potential pilot case can send it to H  l  ne Le Borgne.

Maurizio Scarpa mentioned that before starting a practical project, the ERNs should decide how they want to collaborate with industries. He and Victoria Hedley participated to a meeting with industries held in Barcelona. They will produce a report that will distributed among the ERNs. He stressed the importance to speed up the process because the industries are becoming impatient with the ERNs due to the slowness of the procedure. They also find the ERNs too bureaucratic and too complicated compared to their way of working with the public sector. The fact that the ERNs have no legal status is a problem because they would need to have contracts with each individual HCP participating in the clinical trial instead of having just one contract with the ERN. As it is, they are currently bypassing the ERNs and working directly with the HCPs.

Ruth Ladenstein mentioned that the C4C project has a clear documentation on their interaction with industries for funding. She asked whether those procedures could be used in collaboration with EJP RD to render the funding of the ERNs by industries possible in a clear and transparent way.

Guillaume Jondeau showed a presentation created by a patient from VASCERN who also happens to be a lawyer. He participated to all calls of the WG on Legal & Ethical Issues and relations with Stakeholders (LES WG). He produced a lot of questions that would need to be answered by the ERNs before going forward with their project.

- Who stores and checks Conflict of Interest (COI) forms?
- What are the potential consequences of COI?
- How and when should the forms be updated?

He proposed the creation of an ERN lawyers' group that would be made of lawyers from the EC, ERNs hospitals, POs and independent lawyers selected via a tender. All those lawyers could be paid via a fix rate determined in advance.

The coordinators reacted by mentioning that many of those questions should be handled by the EC, not by the ERNs directly. The ERNs have to take care of the patients and should be careful not to become too bureaucratic. The EC will have to help them, including by helping store the COI forms that will not be stored at HCP level.

9. Joint CSA application with the chairs of the research WG

Franz Schaefer and Alberto Pereira updated the ERN CG members during the ERN CG meeting with the EC on the joint CSA application they are working on.

They will circulate a survey to collect the views of the ERNs on the main needs in clinical research in order to define the focus of the application. It was asked that the ERN members reply to the survey as quickly as possible so the application could be drafted and circulated for comments before being submitted in April 2020.

10. Special Issues of the Eur J of Medical Genetics dedicated to ERN publications

Alain Verloes, coordinator of ITHACA, presented the European Journal of Medical Genetics (EJMG) for which he is editor in chief. He offers the possibility to create special issues of the journal with publications from the ERNs. The journal could publish up to 3 special issues per year. The subject of the publications would have to be about genetics or genetic disorders. Since the journal is peer-reviewed, there should be at least 2 guest editors from the ERN per special issue who cannot be the writers of the same paper. The publications are free. It would be a nice opportunity to show the ERN work about genetics and examples of inter-ERN projects. The ERNs who are interested to participate in the project should contact Alain Verloes directly.

The coordinators also mentioned the possibility to published articles with other journals such as the Orphanet journal. The only issue with the Orphanet journal is that their reviewing process is extremely long.

11. How to deal with applications from centres with an acknowledged expertise for which no matching ERN exists (eg psychosis related to pregnancy)?

On Wednesday 13 November, the Research Working Group organised a workshop with the ERNs and the Research Infrastructures. The cases discussed and solutions provided were mainly about drug-related researches. As a member of a surgical based ERN, Irene Mathijssen would be interested to have a similar workshop oriented towards the surgical-based ERNs. This workshop brought on to light the fact that they do not have a clear view on how surgeons are involved in some ERNs or how certain diseases are affected by surgical-related issues. She would offer to create a working group for ERN surgeons to discuss the matter further. It could also be a way to involve for example orthopaedic surgeons who are reluctant to get involved in the ERNs. Irene Mathijssen will reach out to all the ERNs to offer them to designate members to join the surgical group.

It was pointed out that a similar working group on surgical guidelines would be beneficial to the work of the ERNs.

12. Recap of the point to be addressed with the BoMS

- The ERNs coordinators and project managers will come up with proposals for the documents on integration, non-respondent HCPs, the assessment of new members, among others.
- The question of funding with the expansion of members. Funding should come either from HCP or the National Boards. Industries should be a valid option if those entities cannot provide funding.
- How to deal with experts moving, retiring. There should be a procedure to handle the centres who have lost their expertise.
- Ask the legal status for guidelines in each MS.
- Ask for a new call for full members and APs to keep the process as dynamic as possible.
- Ask for CPMS guest users for NCHs and mention eUROGEN's outreach towards them.
- Try to set up common training and education programme for the ERNs and how to include them in the national training and education programmes for clinicians. It would allow the ERNs to become more popular and more established in the national context.
- The ERNs now have an assessment monitoring and evaluation quality improvement system. It would be valuable to know if they have a similar system for the integration in the national systems in each MS. Each country should have a RD plan and it should be updated and monitored and it also includes the integration of the ERNs into the national healthcare system.

12. Any Other Business

Guillaume Jondeau from VASCERN mentioned the possibility that the ERNs could act as advisory boards for each other. They would be the best to advise on how to work and the sharing of experience could be beneficial to all. It was agreed that it would be valuable for the ERNs to invite members from other ERNs during their respective general meeting to get an idea of their internal working. They noted, however, that advisory boards were more complicated since they all depend on the topics of each ERN. The sharing of experience and collaboration could, however, be a good way to show those at the periphery of the ERNs that the members are working together to solve common issues.

The Working group on Knowledge Generation will soon start to work on a proposal for a CV for professionals on rare diseases.

ERN Skin mentioned that they organised training courses and asked to receive accreditations for them from the European Union of Medical Specialists (UEMS: <https://www.uems.eu/>). They encourage the other ERNs who organise courses to do the same.

It was reminded that HCPs who want to extend their area of expertise should not apply to the new call for membership. The ERN coordinators will work on a proposal to present

to the Board for the expansion of expertise. The proposal will cover such important topics as the review of criteria and the integration inside the ERN.

13. Report from the Board of Member States

Lennart Christiansson, Chair of the BoMs, reported on the points discussed during the morning meeting of the BoMS.

They discussed the possibility to change the format of their meeting. The idea proposed would be to reduce the number of meeting to twice a year. The meeting would be spread over 2 days, starting around lunchtime the first day and finishing early afternoon on the second day. The BoMS still needed to vote on it. If the proposal is accepted, there will be a discussion with the ERN team in the EC on how the meetings could be coordinated with the meetings of the ERN CG.

The Board had a long discussion on the ongoing call for membership. They stressed the importance to stick to the criteria already established to avoid many issues that appeared during the last call such as compliance issues and questions about whether the requirements were met.

The Board also discussed the issue of not waiting for the end of the first 5-year period of the ERNs to assess their members. They are open to terminate members when needed and the member states can reconsider their endorsement, but they need a clear procedure. Irene Mathijssen confirmed the ERNs were already planning to draft such a document with the input of all the ERNs. They would include an improvement planning as a last opportunity for the HCP to meet the criteria before termination.

The Board had along discussion about consortium, what defines it and if they should be accepted inside the ERNs. The Integration statement of the BoMS stipulates that ERN members need to be HCPs with one CEO or authority signing for it. The issue is that what makes a healthcare provider is a national competence, not all MS accept consortium or have the same criteria for them. The ERN team of the EC will work on determining the basic criteria necessary for a consortium to be accepted inside the ERNs. Guard-Heart remarked that there is already one example of a working consortium inside the ERNs: the consortium AP-HP Pitié Salpêtrière Hospital which includes the 6 universities of Paris. The consortium works well, the only issue is that they only appear as one HCP in the CPMS.

Commenté [MS1]: AP-HP is a ocnsortium in France but each hospital in the ERNs appears as a single hospital with their own single CEO, so this is not a consortium in the ERN.

The inclusion of a consortium in the ERNs raises several questions such as who in the consortium can use the official logo. The ERN members are encouraged to share their opinion on the subject with the EC.

The new applicants for membership ask as lot of questions about consortium. The EC is compiling a Q&A document based on all the questions received that will soon be disseminated.

The ERN coordinators confirmed they would be working on a common, consistent procedure for all ERNs to assess new members. It will be shared with the European Commission for legal checking and then with the BoMs for comments.

Regarding the CPMS guest users, the ERN have several messages they would like Lennart Christiansson to take back to the BoMs:

- The ERN members do not use the CPMS as often as expected but they expect an increase in use with arrival of new APs. Their expertise level is lower so they will benefit more from the tool.
- The ERNs have an issue with the reluctance of the EC to allow NCHs to use the CPMS. There is currently an outreach towards us to bring them towards the ERNs. It does not make sense to have a CPMS if NCHs cannot use it as they need it the most.
- The ERNs have an issue with the limitation of guest user access to 90 days. Some experts should be there for the long terms. They should not have to create a new account every 90 days to keep their access to the tool. Those experts could be identified by the ERNs themselves. The hospitals and HCPs in the community should also be able to have a long-term guest access user because this is where patients are coming from and where the expertise is needed.
- The access to CPMS needs to be extended outside the ERN community as the CPMS is also the only safe and GDPR compliant way to share cases. Otherwise the cases are shared via emails.
- The way the CPMS is financed (paying for the number of users) is in contradiction with the mission of the ERNs to share knowledge.

The final point raised by the ERNs for the BoMs is that there is a need for a sustainable financing system for the ERNs. They cannot wait until the end of the 5-year period to decide, the discussion must start now.

14. End of the meeting

The presentations will be sent after the meeting to the ERN coordinators and project managers.

The minutes will be producing by the ERN secretariat. The usual delay of 1 week will not be maintained due to the large number of ERN meetings happening during the week of the internal meeting of the ERN CG. The minutes will be sent by the secretariat to Irene Mathijssen within 2 weeks after the meeting.

Annex: Participants

	Network	Last Name	First Name
1	ERN BOND	SANGIORGI	Luca
2		CASARETO	Lorena
3	ERN CRANIO	MATHIJSEN	Irene
4		DE RUITER	Renée
5	ERN EURACAN	CASALI	Paolo Giovanni
6		BAYSSIERE	Magali
7	ERN EURO-NMD	EVANGELISTA	Teresinha
8		PASCAL	Heike
9	ERN EYE	DOLLFUS	Hélène
10	ERN EpiCARE	MATHEY	Laurène
11	ERN EuroBloodNet	VAN BEERS	Eduard
12	ERN GENTURIS	GEVERINK	Nicoline
13	ERN GUARD-HEART	HOFMAN	Nynke
14		WILDE	Arthur
15	ERN ITHACA	VERLOES	Alain
16		SELATNIA	Sarra
17	ERN PAEDCAN	DOBAI	Zoltán
18		LADENSTEIN	Ruth
19	ERN RARE-LIVER	FRANKE	Aileen
20	ERN RITA	UITTERHAEGEN	Bart
21	ERN RND	REINHARD	Carola
22	ERN ReCONNET	TALARICO	Rosaria
23		MARINELLO	Diana
24	ERN Skin	GUILLOU	Marie
25	ERN TransplantChild	TEJEDOR-BOTELLO	Marisa
26	ERN eUROGEN	BATTYE	Michelle
27		FEITZ	Wout
28	ERNICA	SPIVACK	Olivia
29	Endo-ERN	VAN BEUZEKOM	Charlotte
30	MetabERN	SCARPA	Maurizio
31	VASCERN	JONDEAU	Guillaume
32		HURARD	Marine

	Other Stakeholders	Last Name	First Name
33	ERN BoMS Chair	CHRISTIANSOON	Lennart
34	Tipik	VAN HECKE	Coline