



**EUCERD JOINT ACTION
WORKSHOP**

**RARE DISEASE
EUROPEAN REFERENCE NETWORKS
& STRUCTURAL FUNDS**

Rome, 28-29 October 2014



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INTRODUCTION

57 participants from 18 different EU Member States (MS) as well as Iceland and Norway attended a workshop in Rome 28-29th October 2014 on the topic of Rare Disease European Reference Networks (RD ERNs) and the use of structural funds to support activities for RD. The workshop involved a diverse range of stakeholders, with representatives from the European Commission Expert Group on RD (MS representatives), the European Commission, Competent National Authorities, National Patient Alliances, the EUCERD Joint Action, and experts from the field of structural funds for health purposes.

The workshop was prepared and organized under the guidance of the EUCERD Joint Action N° 2011 22 01, specifically the co-ordination group in Newcastle and the teams at Istituto Superiore di Sanità (ISS), EURORDIS (Rare Diseases Europe) and CIBER (the Spanish Biomedical Research Network for Rare Diseases). The workshop agenda and participant list are provided as Annexes).

MEETING REPORT

Session 1 – RD ERNs: Context and national experiences

The current situation with respect to progress towards the institution of ERNs and the status of the EUCERD Recommendations was reviewed by Enrique Terol and Kate Bushby. The results of a questionnaire to MS on their state of readiness for designation and other steps in the ERN process were presented by Enrique Terol and Domenica Taruscio. 26 countries responded to this questionnaire, and the overall picture is- as in 2011- variable. 12 MS now have a system for formally designating Centres of Expertise (CEs) and 7 already have a formal network of CEs in a related field. The data suggests, however, that the majority of MS face uncertainties in preparing for ERNs, with 18 having not yet envisaged how to endorse healthcare providers wishing to apply for the call of ERNs.

An overview of the work of the EJA WP7 on CEs was presented by Richard Wooley. CEs recognize clear benefits to networking, in terms of research (clinical, basic and translational), developing/sharing clinical guidelines, and enabling multidisciplinary (especially social) support; however, there are challenges to managing and coordinating multiple networking relationships. CE managers seem to favour a 'balanced' and flexible approach to designation criteria for CEs: sufficiently robust to avoid 'self-certification' whilst not so stringent as to preclude development for those which do not meet every point.

Finally, Enrique Terol presented the current status of the ERN development process. At present the EC is in a communication and media phase, engaging academics via journals etc. Individuals nominated for the Board of Member States will meet for the first time on Dec 5th 2014. The current timeline envisages the awarding of tenders, firstly for the Assessment Manual and toolkit (applications currently under evaluation), followed by the Tender for Framework of Assessment Bodies. In addition, a services study will determine the services to be provided by an ERN. The results of these activities will be shared at the next preparatory conference in September or November 2015 - workshops will be held simultaneously, to support specific groups in preparing for the official ERN call in December 2015. Assessment and approval of ERN applications will take place in 2016. In term of funding, the Public Health Programme (2014-2020) will support activities required for the formal establishment of ERNs along with the annual conferences/workshops and an IT platform (above what CEs use already). There is a possibility of project grants for select ERNs (2016-2020). Additional funding may be available via the following routes: HCO3 call within H2020; Connecting Europe Facility (CEF) in 2016, e-health; Structural Funds; European Social Funds; the Digital Plan of the new Commission (from the e-health perspective); Industry collaborations.

Specific budgets for co-ordination are *not* foreseen directly from the Commission, and funding for cross-border patient care will be via existing provisions within the Social Security Regulation and as set-out in the Cross-Border Healthcare Directive itself.

Discussion Session

All participants took part in a round table discussion. A clear wish to keep the process of discussion around ERNs as simple as possible was expressed, as over-complication of the issues was seen as a risk to the process. Other possible challenges to successful development of RD ERNs were identified. For example, the level of readiness of MS to designate RD CEs and ERNs, along with the heterogeneity of RD CEs, might be one factor causing delay, or even leading to MS deciding not to participate in the process at all. The tight timeline which has been agreed for the call for the first ERNs (December 2015) and the associated MS deadlines for nominations (e.g. for the Board of Member States, deadline 31st October 2014) and other factors were also recognized as challenges. Concerns were raised about the way that new committees and boards are now being set up again, thereby breaking continuity and risking loss of the “collective memory” which has developed in the groups existing up to now. It was noted that the National Contact Points lack knowledge in the field of RD, and engaging with these people was deemed essential. The lack of a systematic process specifically for RD ERNs was also identified as a challenge, with the concern that perhaps MS may not agree on the priority areas for the first ERN applications. The financial implications of ERN establishment were also highlighted as a key issue - ERNs will not come with designated funding *per se*, but rather a patchwork of funding opportunities. There was therefore a perception that centres and MS participating might put themselves at financial risk due to a) the costs of seeing more patients, for example from other countries, and/or b) the costs associated with networking itself (co-ordination, shared tools, need for meetings etc.). An additional challenge identified concerns the possibility that an organic, non-structured approach would allow several applications in overlapping areas, thereby increasing fragmentation rather than reducing it, and conversely aggravate isolation of the most vulnerable populations with a proportion of patients with RD not covered.

In order to ensure that the RD field benefits as it needs to from the potential to develop ERNs, there was some discussion about how these various challenges/risks might be mitigated. The existing EUCERD Recommendations on Centres of Expertise and on RD ERNs already cover many of the areas where some clarification is required. So for example, the ERN Recommendations recognize that there is huge heterogeneity in the way in which RD CEs are identified at national level and indeed in their composition, and to some extent this is reflected in the Acts where it is stated that, provided there is MS agreement, any healthcare provider (i.e. not only CEs) can be nominated to participate in an ERN.¹ This, to a certain extent, de-risks the concerns around the issue of designation of centres, although MS will of course be the gatekeepers for approval of these providers to apply to belong to a network. A stepwise approach to the development of RD ERNs, where more mature networks are designated first, is also in the Recommendations (though it was agreed this point could be extended to define “maturity” more specifically). The rest of the workshop was designed to look at strategies to address in greater detail the other identified challenges and determine how amendment or clarification of the Recommendations might help to consolidate these issues.

¹ EC Delegated Decision, preface (14) and Article 5

Session Two - Models and Organisation of RD ERNs

Session Two of the workshop began with a comparison of the EUCERD Recommendations and the European Commission Delegated and Implementing Acts, which was a collaborative effort between the UNEW and EURORDIS teams. Overall there was a high level of concordance; however, certain areas were identified which might need some revisiting. The position of the RD patient as central to the debate, and as part of the governance structures of the ERNs, was presented by Yann le Cam who emphasized the need for a clear structured approach to deliver the best for people living with RD and enhance readiness of the field, as we are only one year from the first call. This therefore implies that prompt action is needed to inform the development of specific criteria and conditions for the groups who will be involved in the development of the Manual for applications, assessment and evaluation. This includes for example specificities around designation, governance and a structured strategic approach which would maximize inclusion of all RD systematically. One major issue where EURORDIS has developed some specific work is around the role of networks for undiagnosed patients; therefore, one proposal might be to develop an ERN for undiagnosed patients to which all other networks would be affiliated.

Existing networks (examined in the presentation by Domenica Taruscio based upon the ISS preparatory document for this workshop) show a high level of heterogeneity and have been set-up through a variety of funding streams, sometimes on a voluntary basis and often with scientific aims as opposed to public health. Out of the 27 networks inventoried at European level, data collected was validated by the scientific coordinator for 15 networks. Problems with sustainability are a common theme with 7 of validated data of 15 networks having come to an end at the close of their funding period. Sustainability issues relate not only to financial resources but also to the sustainability of other resources such as personnel and technology.

Teresinha Evangelista and Victoria Hedley presented the document on the Grouping of Rare Diseases. There is a strong argument for grouping RD for ERN designation and this is captured in the EUCERD Recommendations. Various models can be identified from current MS practice, ICD10 coding and from the literature. Considerations leading to the development of these models include political and practical issues within the different countries as well as an overall strategic vision. Despite variation in the details of some of the models, a group of approximately 25 clinical disease areas form the core of the different systems and could be a starting point for a cohesive European approach (Table 1). At EU level, a structured concept for the strategic development of ERNs could ultimately also assist MS in developing strategic groupings. Ensuring that a group exists for all RD patients would have the added value of being inclusive and avoiding the need for prioritization.

Discussion Session

General agreement was reached on the concept of one RD ERN per thematic group. Such a thematic model can cope with the diversity of CEs and allow flexibility of the model and membership and flexible evolution of members and disease coverage. There seemed to be preference for disease groupings across the RD field, as opposed to establishing ERNs for specific procedures/techniques or more transversal concepts such as genomics, though it was recognized that ERNs for specific procedures could be important and accessed by patients with RD as well as those with more common conditions (e.g. ERNs around transplantation techniques: here referral across ERNs might be necessary in specific settings for specific indications without challenging the concept of the original “home” ERN). Although experience of MS in how national CEs and networks for RD varied considerably, based in part on the size of country, size of population and approach to disease management, the consensus of the MS at the meeting was that they were not opposed to the concept of an EU system for RD ERNs within which all patients could find a home: despite the diversity of their own systems, they would be comfortable with nominating centres with the appropriate experience to join ERNs even where the ERN is not directly aligned to a matching local centre and/ or network. Richness, diversity and granularity at the national level would complement a more overarching system at EU level.

Commission representation confirmed that the Expert Group would be happy to receive this clarification on grouping. However, a more global agreement from MS authorities beyond the RD representatives present here and from the players (clinicians etc.) would be necessary as well. Such a structuring of the response of the RD field to the call for ERNs has not been specified in a legal sense, and additional concrete points like this would not be able to be added. Agreement at Expert Group, MS and provider level is more important but would be on a voluntary basis. There remains therefore the risk that this could be problematic in terms of ensuring compliance.

An additional key factor from the patient perspective is the involvement of patient organisations as integral members of network boards. Patient empowerment and involvement is integral to the Implementing and Delegated Acts, and membership of the governing boards or evaluation procedures is definitely not excluded. Further emphasis of this point at EG level could be useful for the developers of the assessment and evaluation Manual from the perspective of RD ERN applications.

A lively discussion on funding demonstrated that MS were not enthusiastic about taking on the costs associated with co-ordination of an ERN over and above the funding already given to centres or national network co-ordination roles where these exist. It was suggested that it would be helpful to MS if network applications were required to include clear business case planning (including possible industry co-funding models arising from the presence of an ERN) and clear plans to demonstrate and prove the added value of the existence of a network (as well as disease specific outcomes).

Session 3 - Opportunities to support RD ERNs and RD activities using European Structural Investment Funds

Gerhard Steffes (European Commission) presented Wolfgang Buecherl's presentation, which outlined the European Structural Investment Funds (ESIF). The European Regional Development Funds and European Structural Funds are most relevant for health. Several Thematic Objectives could be relevant for RD, although RD possibilities/needs are not explicit in the current regulatory framework, meaning interested Ministries of Health would need to lobby strongly at National level. Timing is a concern, as Partnership Agreements are adopted and most draft Operational Programmes are now submitted.

Romana Smetankova from Ernst & Young (Czech Republic) shared insights from the current Contract supporting MS in using ESIF for health. A key priority is cementing partnerships between Ministry of Health (MoH) teams and the Managing Authorities (MA) of the Operational Programmes (no MoH acts as Managing Authority, in any MS, although there may well be departments within MoHs dealing with ESIF). Romana's presentation specified each step required to access ESIF for health, stressing at the beginning of the process the need to align what one wishes to do with the national healthcare strategy (ex ante conditionality). Projects must be comprehensive: in an e-health project for example, there should be a stage for developing the infrastructure (i.e. IT tools), followed by HR development (training people to use the new tool) and finally a public relations campaign to promote it.

Jonathan Watson –who led the 2009-2011 project on ESIF for Health- revealed it was difficult to identify good practices of using ESIF for health. A key message is that ESIF should be used for things a MS would not routinely provide via national programmes, but which demonstrate sustainability planning. Proposals should not be a means to fund short-term projects. Jonathan presented the Psychargos project from Greece, relating to mental care reform. Valentina Bottarelli stepped in to deliver a presentation -drafted by CHAFEA- specifically on the use of structural funds for the RD field, illustrating the practical opportunities. Many of the national RD conferences have raised the possibility of using SF to support actions delineated in RD national plans/strategies (NP/NS). There are logical ways to integrate RD into several of the structural fund Thematic Objectives, with the acknowledgment that increasing cohesion and reducing inequalities sit at the heart of RD. The ex ante requirement can be fulfilled by NP/NS themselves, which is perhaps a good incentive to allocate funding to these programmes. Step-by-step examples were provided to show how structural funds could be used to strengthen CE operations and compliance with quality criteria e.g. to join ERNs, or support, for example, the use of Orphacode.

Discussion Session

The timelines and possibilities for using structural funds immediately were discussed at length, with the ultimate conclusion that it is probably too late to influence the current cycle of ESIF and that the field should begin the preparatory work for next time very soon, with a view to readying MS to use ESIF (including the European Social Fund) to support future national activities which are strategically -and sustainably- linked to a NP/NS for RD. This

requires a national lobbying effort. For cross-border activities such as ERNs, it is probably easier to aim for the Connecting Europe Facility (CEF) programmes although opportunities offered by the ESIF allocation for ETC (European Territorial Cooperation) should be further explored. The European Commission advised that the first step is to determine if there is a common message for the RD field. The second step is to make the connections the speakers advised, and identify key people in-country. The third step is to look at the replies coming from the EC regarding the current draft Operational Programmes, as there is a service consultation potentially available for 2016 (around telecommunications for ERNs). It was emphasised that the RD field must learn the 'language' of ESIF, in time for the mid-term review and final review of this cycle (2019). The difficulties facing different MS in accessing ESIF were also discussed.

CONCLUSIONS OF THE WORKSHOP AND NEXT STEPS

Review of the existing EUCERD Recommendations on Centres of Expertise and RD ERNs indicates that they remain highly relevant to the ongoing process of ERN application and designation and that provision already exists in them to mitigate many of the identified challenges to RD ERN designation. However, in order to provide further guidance on specific areas and move the debate forward, the workshop would like to propose to the EC Expert Group on Rare Diseases clarification of certain points from the EUCERD Recommendations of January 2013. The target audiences for these clarifications include the EC, MS involved in designating centres to participate in ERNs, the patient community, scientific societies, the groups involved in the delineation of the Manual, assessment procedure and evaluation of ERNs. The key factors relate to the grouping of RD and the stepwise approach to their designation so that all patients are covered by an RD ERN within a realistic timeframe.

These relate to the following Recommendations:

Recommendation 1: Coverage in a stepwise approach all RD patients including those in the process of seeking a diagnosis or in whom a final diagnosis is not yet confirmed (Table 1: suggested consensus disease groupings for Expert Group adoption).

Suggested action: UPDATE/ ADDENDUM TO RECS

Recommendation 6: Models to provide a mechanism for patients with an unclear diagnosis should be further explored: collaboration with research activities clearly required here.

Suggested action: to be addressed further via EJA WP8 and EURORDIS especially via the EJA genetics tasks and other integration activities

Recommendation 8: Patient organisations should play a role especially in the evaluation of RD ERNs where patient organisations exist.

Suggested action: EURORDIS to provide capacity building and background rationale with subsequent UPDATE/ ADDENDUM.

Recommendation 12: The RD community has concerns about the lack of defined sustainable funding. Suggested action: A business model to incentivize MS to take on the leadership of ERN could be proposed.

Suggested action: ongoing work with ERN development group

Recommendations 16, 18, 19: Stepwise strategy for RD ERN designation: suggested grouping (Table 1) plus dynamic characteristic- increasing disease and geographical function. Should include maturity criteria: add elements of multidisciplinary, previous public funding support (Table 2)

Suggested action: UPDATE/ ADDENDUM TO RECS

Further discussion with different stakeholders is also planned with the support of the EJA for feedback to the EC Expert Group on Rare Diseases and other target groups

1. Engagement with existing and previous networks to prepare the field for applications and inform issues around co-ordination costs and requirements, governance, operational guidance and industry engagement: modeling ERNs (EJA WP8 workshop)
2. Further consolidation of outreach on EUCERD Recommendations on CEs and ERNs. Education of national contact points (WP4, national planning contacts and National Alliance members and WP7 workshop)
3. Ongoing discussion with ERN development group including on the development and funding of ERN tools etc. (WP8 integration role)
4. SF conclusion: to prepare for the next cycle of ESIF, supportive role of ISS/ EURORDIS to look for a common message on RD/ ERNs to lobby, influence national authorities, identify the key people at MS level. Role for EURORDIS/ISS to further explore, as a matter of priority, potential to support cross-border activities (ERN-related) using ETC (European Territorial Cooperation) programme or CEF.

Table 1: Possible Grouping of RD for Future ERNs (based on areas of overlap in systems outlined in preparatory document)

1. Rare cardiac diseases (with rare cardiac malformations ERN included or separate)
2. Connective tissue RD, and musculoskeletal (Rare rheumatological diseases)
3. Rare hereditary metabolic disorders
4. Rare haematological diseases
5. Rare diseases of brain development and rare intellectual disabilities
6. Rare auto-immune and auto inflammatory diseases
7. Rare cancers
8. Rare hepatic diseases
9. Rare gastrointestinal diseases
10. Rare neurological diseases
11. Rare neuromuscular diseases
12. Rare skin disorders
13. Rare pulmonary diseases (with Cystic Fibrosis ERN included or as additional ERN)
14. Rare malformations and developmental anomalies
15. Rare endocrine diseases
16. Rare urogenital diseases
17. Rare renal diseases
18. Rare multi-systemic vascular diseases
19. Rare head and neck diseases
20. Rare gynaecological and obstetric diseases
21. Rare eye diseases
22. Rare orthopaedic diseases
23. (Rare surgical thoracic diseases)
24. (Rare surgical abdominal diseases)
25. (Undiagnosed group)

Table 2: Matching of Networks/Projects supported by the EU with Groups of diseases for ERNs (synthesis of information for information only)

Groups of diseases	Networks/Projects
Rare cardiac diseases (with or plus rare cardiac malformations ERN)	CHD - Congenital Heart Defects
Connective tissue RD, and musculoskeletal (Rare rheumatological diseases)	PRINTO - paediatric rheumatology international trials organisation ESDN : European Skeletal Dysplasia Network
Hereditary Metabolic disorders	E-IMD - European registry and network for Intoxication type Metabolic Diseases EUROGLYCANET CDG : Congenital Disorders of Glycosylation
Rare haematological diseases	EPNET – European Porphyria Network EN-RBD - Rare Bleeding Disorders Paediatric Hodgkin's lymphoma Network ENERCA - European Network for Rare and Congenital Anaemias EUHANET - Haemophilia and the rare congenital deficiencies of other coagulation factors
Rare diseases of brain development and rare intellectual disabilities	
Rare auto-immune and auto inflammatory diseases	EURO-HISTIO-NET - A reference network for Langerhans cell histiocytosis and associated syndrome
Rare cancers	ExPO-r-NeT - European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment RARECARENet - Information network on rare cancers
Rare hepatic diseases	EUROWILSON : European network on Wilson disease
Rare gastrointestinal diseases	
Rare neurological diseases	NEUROPED - European Network of Reference for Rare Paediatric Neurological Diseases LEUKOTREAT : Leukodystrophies EUROSCA : European integrated project on spinocerebellar ataxias E-Pilepsy - Refractory Epilepsy
Rare Neuromuscular diseases	Care-NMD - Improving care for Duchenne muscular dystrophy TREAT-NMD – Neuromuscular network
Rare skin disorders	TAG - Together Against Genodermatoses GENESKIN : European network on rare genetic skin

	diseases
Rare Pulmonary diseases (with or plus CF ERN)	<p>ECORN CF – Expert Advice on Cystic Fibrosis</p> <p>PAAIR - Patient Associations and Alpha1 International Registry</p> <p>ENCE CF-LAM-LTX - European networks of centres of expertise for CF (Cystic Fibrosis), LAM (Lymphangiomyomatosis), and LTX (Lung Transplantation)</p> <p>EUROCARE CF - Cystic Fibrosis</p>
Rare malformations and developmental anomalies	<p>DYSCERNE - Rare Dysmorphic Syndromes</p> <p>EUROCRAN - Craniofacial anomalies</p>
Rare endocrine diseases	
Rare Urogenital diseases	
Rare Kidney diseases	EuroCYST initiative - Polycystic Kidney Diseases
Rare multi-systemic vascular diseases	
Rare Head and neck diseases	
Rare Gynaecological and obstetric diseases	
Rare Eye diseases	
Rare orthopaedic diseases	
Rare surgical thoracic diseases	
Rare abdominal surgical diseases	



ANNEX 1: WORKSHOP AGENDA

EUCERD Joint Action WP4 & WP8

Workshop on Rare Disease European Reference Networks and Structural Funds

28-29th October 2014

Casa dell'Aviatore, Viale dell'Università, 20 - Rome (Italy)

Aim of the Workshop: To provide a forum for Member State (MS) Representatives (both Commission Expert Group members and Competent National Authorities) to discuss the implementation of rare disease (RD) ERNs and how the Expert Group can provide ongoing input and support during this phase and beyond. Key legislative and policy documents acknowledge RD as a focal area for ERNs, given the specificities, challenges, and the potential for high added-value through a collaborative European approach, specifically: the Council Recommendation 2009/C151/02 on an Action in the Field of Rare Diseases; Commission Communication - Rare Diseases, Europe's Challenge; Cross-Border Healthcare Directive (2011/24/EU) Articles 12 and 13; EUCERD Recommendations on RD ERNs and the Commission Delegated Acts (2014/286/EU). In the implementation of the Delegated Acts there has been a convergence on common transversal criteria and conditions for the assessment and establishment of ERNs.

The workshop will focus on the ways in which MS might address the specificities of RD in line with the requirements of this European legislation, in preparation for the first calls for ERNs to be announced in 2015. It will facilitate discussions on how to collaborate, organise and mobilise national resources and the RD community to ensure RD ERNs will address the needs of all RD patients across Europe.

An additional, related aim is to explore the potential of structural funds to support RD infrastructure, including RD ERNs themselves.

Specific questions to be addressed include:

1. What is the most suitable 'model' for RD ERNs? Sharing expertise and identifying the pertinent issues for MS endorsement of centres participating in RD ERNs, and how MS use this framework
2. How can RD be strategically grouped to ultimately enable RD ERNs to benefit MS healthcare systems by alleviating challenges such as scarcity of resources and meet the needs of all RD patients?
3. How might structural funds support RD ERNs (and additional activities delineated within the National Plans and Strategies for RD?)
4. What recommendations can be made from the Expert Group based on the existing EUCERD recommendations but in the context of the Delegated Acts?

Day 1: Tuesday 28th October 2014

09:00-09:10 Welcome to the Workshop. Where do we want the workshop to go? What are the expectations of the participants? (*Kate Bushby and Domenica Taruscio*)

SESSION 1- RD ERNs: Context and national experiences (relates to workshop Question 1)

09:10-09:40 The ERN Policy framework (*Kate Bushby and Enrique Terol*)

09:40-10:00 How are the EU MS preparing for RD ERNs? (*Enrique Terol and Domenica Taruscio*)

10:00-10:30 WP7 conclusions to date: Networking of CEs and current readiness of the field for ERNs (*Francesc Palau and Richard Woolley*)

10:30-10:50 Coffee Break

10:50-11:10 Implementation of European Reference Networks: Timeline and Calls (*Enrique Terol*)

11:10-13:00 Round Table - How are MS approaching the issue of ERNs for RD? To be followed by **Discussion and Q & A on Session 1** (*Moderators Kate Bushby and Francesc Palau*)

Output of Session 1: A discussion document/non-paper on national experiences and designation of centres to participate in ERNs, to serve as information to the Commission Expert Group on RD.

13:00-14:00 Lunch

SESSION 2: Models and Organisation of RD ERNs (relates to workshop Question2)

14:00-14:30 Presentation of Preparatory Discussion Document (*Kate Bushby*)

14:30-15:00 Patient's perspective on added value of strategically-conceived Rare Disease ERNs (*Yann Le Cam*)

15:00-15:20 State of the art of rare diseases networks in EU (*Domenica Taruscio*)

15:20-15:40 Disease grouping and models for RD ERNs (*Teresinha Evangelista and Victoria Hedley*)

15:40-16:00 Coffee Break

16:00-18:00 Discussion on Session 2 to include Q&A session (*Moderators Yann le Cam and Enrique Terol*)

Output of Session 2: Guidance for dissemination to Expert Group on Rare Diseases.

18:00 Day 1 Ends

Day 2: Wednesday 29th October 2014

SESSION 3: Opportunities to support RD ERNs and RD activities using European Structural Investment Funds (relates to workshop Question 3)

09:00-09:10 Introduction to Session 3 (*Kate Bushby, Domenica Taruscio and Yann Le Cam*)

09:10-09:30 European Structural and Investment Funds (ESIF) 2014-2020 (*Gerhard Steffes*)

09:30-10:00 Supporting EU MS for the effective use of ESIF for health investments in the programming period 2014 - 2020 (*Romana Smetankova*)

10:20-10:50 Coffee Break

10:50-11:10 Accessing and using Structural Funds - Greek experience with mental health reform and its implications for tackling rare diseases (*Jonathan Watson and Kyriakos S Hatzaras*)

11:10-11:30 From policy to implementation: how to leverage ESIF in support of a National Plan/Strategy for Rare Diseases (*Valentina Bottarelli*)

11:30-12:00 **Discussions and Q&A on Session 3** (*Moderators Domenica Taruscio and Gerhard Steffes*)

Output of Session 3: *Concept paper on Opportunities to support RD activities using European Structural Investment Funds.*

12:00-13:00 Lunch

SESSION 4: Consolidating Expert Recommendations in the context of the Delegated Acts (relates to workshop Question 4)

13:00-13:45 **Discussion Session on 'Preparatory Document to outline the 'Specific Criteria and Conditions' in the field of Rare Diseases''**. Building upon the previous day's sessions, to include the following topics: what is the group consensus regarding readiness for ERNs and main needs of the RD field? What are the participants' comments on the new document? How should it be used? What follow-up discussions/workshops will be needed and what should be the next steps of the Expert Group and the Joint Action? (*Moderators Kate Bushby and Yann Le Cam*)

Output of Session 4: *Revised 'Document to outline the 'Specific Criteria and Conditions' in the field of Rare Diseases'*

13:45-14:00 Summary of combined next steps and action points (*Domenica Taruscio, Kate Bushby, and Yann Le Cam*)

14:00 Workshop ends

ANNEX 2: PARTICIPANT LIST

AALVIK, Ingunn	<i>Ministry of Health and Care Services</i>	Norway
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