13 June 2018
EMA/270801/2018
Stakeholders and Communication Division

Agenda – RD-ACTION, European Medicines Agency, and European Commission-DG SANTE workshop: how European Reference Networks can add value to clinical research

29 – 30 May 2018, Meeting room: 3F

DAY 1, 29 May – 'State of Play'

Day 1		Speaker
08:30	Registration	
Session 1: Setting the Scene – Aims and Context of the workshop[1] Session chairs: Isabelle Moulon (EMA) and Valentina Bottarelli (EURORDIS / RD-ACTION)		
09:00	Welcome and opening remarks	Noël Wathion, Deputy Executive Director – EMA
09:10	1.1 Introduction to the Workshop: aims and expected outputs	Victoria Hedley, RD-ACTION
09:25	1.2 European Reference Networks (ERNs) in 2018: where we are and where we hope to go	Maurizio Scarpa, Chair of ERN Coordinators Group (ECG) and Coordinator of MetabERN
09:55	1.3 (1.3.1, 1.3.2, 1.3.3) ERNs and Research: state of play from the European Commission perspective	Iiro Eerola, European Commission – DG RTD Hélène le Borgne, European Commission – DG SANTE Anneli Torronen, European Commission – DG SANTE
10:20	Q&A	
10:30	*Coffee break*	

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Day 1		Speaker
Session 2: How are ERNs planning to add-value to clinical research? Session chairs: Hélène le Borgne (DG SANTE) and Victoria Hedley (RD-ACTION)		
10:45	2.1 'Snapshot' of Transversal activities regarding ERNs and Clinical Research	Eduardo López Granados, Chair of the ERN Research Working Group and Coordinator of ERN TRANSPLANT-CHILD Eileen Treacy, Board of Member States Representative, Ireland Daria Julkowska, E-RARE / European Joint Programme Cofund on rare diseases
11:00	2.2 *Status Quo* of ERNs and clinical research: Results of the ERN-wide survey	Luca Sangiorgi, EMA Liaison Chair for ERNs and Coordinator of ERN BOND
11:20	Questions and open discussion	
11:30	2.3 ERN case studies • 2.3.1 MetabERN (ERN on hereditary metabolic disorders) • 2.3.2 ERN EURO-NMD (ERN on neuromuscular diseases) • 2.3.3 ERN BOND (ERN on bone disorders) • 2.3.4 ERN EURACAN (ERN on adult cancers (solid tumours))	Jean Michel Heard Teresinha Evangelista Luca Sangiorgi Stephane Lejeune
12:30	Questions and open discussion	
12:50	*Lunch break*	
13:40	2.4 Patient expectations for meaningful engagement in ERN-related clinical research	Russell Wheeler, European Patient Advocacy Group (ePAG) representative for ERN EYE Alain Cornet, ePAG representative for ERN ReCONNET
14:00	Questions and open discussion	
Session 3: Overview of EMA role and support tools in medicine development Session chairs: Isabelle Moulon (EMA) and Luca Sangiorgi (BOND ERN, alternate EMA CAT member)		
14:15	3.1 General presentation of EMA, engagement with stakeholders, and the role of academic experts	Ivana Silva, EMA

Day 1		Speaker
14:45	3.2 Early engagement and support for medicine development	Stiina Aarum, EMA
15:30	*Coffee break*	
15:45	3.3 Advanced Therapy Medicinal Products (ATMPs)	Patrick Celis, EMA
16:15	3.4.1 Clinical trials in the EU 3.4.2 EMA's registries initiative	Laura Pioppo, EMA Xavier Kurz, EMA
17:15	Questions and open discussion	
17:30	Wrap up of day 1	Isabelle Moulon (EMA) and Luca Sangiorgi (ERN BOND)
	End of day 1	

Day 2, 30 May – 'Where do we want to go, and how do we get there?'

Day 2		Speaker
09:00	Overview of Day 1 and introduction to day 2 discussions	Victoria Hedley (RD-ACTION) and Luca Sangiorgi (EMA Liaison Chair for ERNs)
Session 4: How can ERNs impact positively on future clinical research, with a particular emphasis on forging strategic EMA engagement?		
09:30	Discussion topic 1: what sorts of activities under the heading of 'clinical research' will ERNs engage in, and what are the advantages of the ERN structure? Discussion facilitators: Maurizio Scarpa (EMA Liaison Chair for ERNs and Coordinator of ERN BOND), Hélène le Borgne (European Commission – DG SANTE), Victoria Hedley (RD-ACTION)	
10:30	*Coffee break*	
10:45	Discussion topic 2: what opportunities exist under current EMA structures and resources presented on Day 1, and how might ERNs engage with these? Discussion facilitators: Enrica Alteri (EMA), Luca Sangiorgi (ERN BOND), Virginie Hivert (EURORDIS)	
11:30	Discussion topic 3: identifying concrete roles and recommended practices to involve patients in the various types of ERN-related Clinical Research Discussion facilitators: Isabelle Moulon (EMA), Dimitrios Athanasiou (PDCO), Andrea Gressani ePAG representative for ERN RITA	
12:15	*Lunch*	
12:45	Discussion topic 4: how can ERNs generate/link/exchange data to support the planning and	

Day 2		Speaker
	execution of clinical trials and studies? Discussion facilitators: Fergus Sweeney (EMA), Ana Rath (RD-ACTION)	
13:30	Concluding remarks and next steps	Victoria Hedley (RD-ACTION), Luca Sangiorgi (EMA Liaison Chair for ERNs), Isabelle Moulon (EMA)
14:00	*End of workshop*	