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RD-ACTION Workshop

‘Exchanging data for virtual care within the ERN Framework’

28th-29th September 2016 Brussels

Thon Hotel EU, Rue de la Loi 75, B-1040 Brussels

Aim of the Workshop:

The overall aim of the workshop is **to generate and agree guidance and good practices for ERNs to collect and share data for care within the framework of ERNs**

Context and Overall Objectives:

Ethos of RD-ACTION workshops: A key objective of the RD-ACTION Policy WP workplan is to continue to provide support to the rare disease community in conceptualising, implementing and evolving robust ERNs capable of meeting the needs and expectations of people living and working with conditions requiring a specific concentration of expertise. As the 1st ERNs are established and evolve, shared consensus guidance is important to support the Networks but also to ensure a baseline compatibility and interoperability (at various levels) between the ERNs.

ERNs are first and foremost dedicated to care. Once established, and connected by a dedicated IT platform, the Networks will support the exchange of knowledge and expertise between healthcare providers operating at the top of their game. It is important to emphasise that wherever possible (and appropriate), expertise will travel rather than the patients themselves. In practice, this will entail a significant degree of virtual healthcare provision. 24 proposals were submitted to DG SANTE in 2016 and of these, only a few conduct significant, formal eHealth-enabled consultations at present. Nonetheless, other applicants will have experiences and knowledge to share on this point, and it is vital that collectively the ERNs appreciate the state of the art in terms of interoperability in data collection, standardisation, sharing, storage and reuse (including the standards recommended by the EUCERD and Commission Expert Group on RD as well as the latest progress in initiatives such as IRDiRC, RD-Connect, HIPBI, Global Alliance for Genomics and Health etc.).

This workshop will allow the Applicant Network Coordinators and other key stakeholders to pool experiences and good practices and identify ways to approach data-sharing in ERNs, to add value to the planned approaches.

Specific Objectives:

- ***To define more clearly the different types of cross-border care encounter ERNs may involve and how to set-up and execute virtual encounters***
- ***To share the state of the art of coding rare diseases and harmonising phenotypes and explore how this can be used to add value to care provision within ERNs***
- ***To identify and agree good practices in order to optimise the collection and sharing of data for care within the ERN framework via a 'Tool-Kit' of resources***

Expected Outputs of the Workshop:

- **Workshop report, complete with PwPs of all presentations –(output of sessions 1-3)**
- **'Tool Kit' resources:**
    - **Practical suggestions regarding the organisation of virtual consultations (output of session 2)**
    - **A collection of example case report forms and consent forms for rare diseases, for possible use within the ERNs (output of session 2)**
    - **Guiding Principles for standardising data for care in the RD framework (output of session 3)**

Suggested Reading for Participants:

(Documents will be uploaded to a shared folder, before 26th at the latest) https://www.dropbox.com/sh/a7mo0c3ntdlqs27/AAB5QtnUMQCQF1o6Z_Lovfsva?dl=0 :

- What do coordinators require from an ERN ICT platform?
- Descriptive Document for ERN ICT platform (SaaS for a patient clinical management system) as published June 2016 (**pages 10-12** which list the Requirements for the SaaS)[1]
- 'Implementation report Health and Consumers on the Commission Communication on Rare Diseases: Europe's challenges and Council Recommendation of 8 June 2009 on an action in the field of rare diseases' (2014)

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[1] Please note that the workshop will not be able to discuss the specifics of the Tender for the ERN IT platform as the applicants will now be in the midst of their competitive dialogue and this process is confidential; nonetheless, the two documents touching upon the ICT platform (one official, the other an internal RD-ACTION document) have been provided insofar as they illuminate certain issues relating to the collection and sharing of data for virtual care and should support discussions on the feasibility of certain approaches relating to data sharing.

AGENDA

DAY 1: WEDNESDAY 28TH SEPTEMBER Begins at 11.30

Session 1: Aims of the workshop and the rare disease policy context

11:30- 11:45: Welcome to the Workshop and Participant Introductions

11:45-11:55: Summary of the ERN Status Quo (Enrique Terol)

11:55-12:10: Overview of this morning's discussions (Chairs from pre-workshop meeting)

12:10-12:20: Aims of this workshop and anticipated outputs (Victoria Hedley)

12:20-12:40: The EU Rare Disease framework: the context for ERNs (Jaroslaw Waligora)

12:40-13:10: What do we mean by virtual care? Summary of the state of the art across the RD field and beyond (Victoria Hedley) (Followed by Questions and Discussions)

13:10-14:00 Lunch (provided for participants in the hotel restaurant)

14:00-14:40: Special Address and Exchange with Mr Andrzej Rys (Health Systems and Medical products and Innovation Directorate DG SANTE)

Session 2: Virtual cross-border healthcare in action

14:40-15:00: Consent for sharing data cross-border for healthcare (and re-use): impact of the revisions to the Data Protection Regulation (Petra Wilson)

15:00-15:15: The Patient Perspective on sharing data cross-border for care (Matt Johnson and Valentina Bottarelli)

15:15-16:00: Discussion Session: what should be included in a model/shared consent form for all ERNs?

16:00 Coffee Break

16:30-17:15: Examples of rare disease virtual care in action, with a focus on good practices, challenges encountered and lessons learned

- example from paediatric oncology (Ruth Ladenstein)
- example from rare and complex epilepsies (Helen Cross)
- example from rare bone (Luca Sangiorgi)

17:15-18:15: Q&A and Discussion: good practices for virtual consultations (*Chairs: T. Voigtländer, M. Johnson and V.Hedley)*

Day 1 ends 18:15

DAY 2: THURSDAY 29TH SEPTEMBER

9:00 Overview of Day 1 (V Hedley)

09:10-09:45 Discussion on the circumstances under which patients are referred for shared care in the ERN – how do the Networks plan to approach this? (*Chairs: Matt Johnson and Till Voigtländer)*

Session 3: Adding value to rare disease data

9:45- 10:30 State of the Art in coding rare diseases (Ana Rath and Remy Choquet) (followed by Q&A)

10:30-11:00 The benefits of harmonising practices in capturing clinical (phenotypic) data for care and research in rare diseases (Ana Rath) (followed by Q&A)

11:00 (Coffee Break)

11:30-12:00 Global efforts to agree a Patient Unique Identifier for the rare disease field: current progress and what ERNs need to do to synergise: (Rachel Thompson)

12:00-12:20: Case Study: Practical Advice on agreeing harmonised phenotypic datasets for care and research: example and discussion of the steps needed to agree this (Holm Graessner)

12:20-13:00: Discussion: guiding principles and good practices for standardising RD data (*Chairs A. Rath and V. Hedley*)

13:00 -14:00 Lunch (provided for participants in the hotel restaurant)

14:00-14:50 Summary of the 'Tool-Kit' resources to be finalised post-workshop and next steps: (A. Rath and V. Hedley)

POST-WORKSHOP MEETING: From virtual care to research and future workshops

14:50 Presentation from DG Research & Innovation '***ERNs and the future of research in the area of rare diseases***' (Iiro Eerola) – followed by discussion on research priorities

15:20 Collective brainstorm on the content of future RD-ACTION ERN-related workshops and additional necessary meetings

16:00 Workshop ends