

ERN Data Management Strategy Multistakeholder Workshop

Organisers: ERICA WP2 (Franz Schaefer, Clémence Le Cornec)

Scientific programme committee: Franz Schaefer, Clémence Le Cornec, Inés Hernando, Vittoria Carraro, Kristina Larsson and Leo Schultze Kool

Date and time: Heidelberg, 17th – 18th of October 2022 (online if the corona restrictions do not allow the meeting to take place face to face)

Description:

This conference is the final of the series of workshops on the ERN data management strategy. This workshop will provide an **opportunity for all stakeholders** – patients, researchers, industry, and regulatory authorities - to make their needs and expectations heard and ensure their consideration in the principles and implementation of a coherent data management strategy by the ERNs.

It is planned to develop a **white paper on a data management strategy for the ERNs** based on the conclusions from the preliminary workshops and seminars and on the discussions held during this final 2-day workshop in Heidelberg.

Preliminary Agenda

17th October (9h00 – 18h00)

9h00 - 9h05	Welcome, aims & objectives of the meeting <i>Franz Schaefer</i>
9h05 – 9h25	<i>Keynote lecture:</i> Innovative use of healthcare data <i>CPATH – Speaker to be confirmed</i>
Session 1: Data use by the ERNs: Status update	
9h25 – 9h50	Scope of clinical data use for research by the ERNs (including but not limited to ERN registries) <i>Leo Schultze Kool</i>
9h50 – 10h15	Current status of ERN registry data: ERNs data dictionary, data collection process, data quality framework <i>EJP RD FAIRification Steward - Speaker to be confirmed</i>
Session 2: Stakeholder expectations regarding ERN Registry data	
10h15 – 10h35	ERN researchers' expectations for the use of registry data & vision to share data <i>ERN coordinators (ERKNet, VASCERN, eUrogen or Genturis)</i>
<i>10h35 – 11h00</i>	<i>Coffee break</i>
11h00 – 11h15	Needs and expectations of industry <i>Speaker to be confirmed</i>
11h15 – 11h30	Needs and expectations of HTA agencies <i>Speaker to be confirmed</i>

11h30 – 11h45	Needs and expectations of European regulatory authorities <i>EMA, name of the speaker to be confirmed</i>
11h45 – 12h00	Needs and expectations of patient community <i>Elizabeth Vroom (Duchenne Parent Project)</i>
12h00 – 12h15	Needs and expectations of national and European health authorities <i>Anne-Sophie Lapointe</i>
12h15 – 13h00	Plenary discussion: What is needed to align the expectations and collaborate (governance, data sharing aspects ...) <i>All</i>
<i>13h00 – 14h00 Lunch break</i>	
Session 3: Structural and functional requirements to meet stakeholders' expectations	
14h00 – 14h15	What is needed from the registries to allow for data analysis and modelling? Quality, quantity, granularity of data. <i>Speaker to be confirmed</i>
14h15 – 14h30	Structural models of the ERN registries (federated, centralised, semi-centralised approaches): Implications of model choice. <i>Speaker to be confirmed</i>
14h30 – 15h00	EJP RD Virtual Platform: existing and future infrastructure, requirements for data holders and data users. Authentication and authorization management. How will the VP integrate into the CRN of the Rare Disease Partnership? <i>Ana Rath</i>
15h00 – 16h00	Plenary discussion: What are the key requirements to collect fit-for-purpose data for the different stakeholders' identified needs? How to address these requirements? How to make the data findable, accessible, interoperable, and reusable? How to enhance collaboration? <i>All</i>
<i>16h30 – 17h00 Coffee break</i>	
Session 4: Operational aspects to implement an ERN wide data management strategy	
17h00 – 17h45	Implementation of an efficient system of data collection (summary and discussion of Essentials from previous ERICA Workshop). <ul style="list-style-type: none"> - Patient enrolment routines - Choice of data to be collected - Data capture routines - Patient involvement in data collection (patient access to eCRF, role of wearables in rare diseases...) <i>Clémence Le Cornec</i>

18th October (8h30 – 14h15)

8h30 – 9h15	Implementation of a data quality strategy (summary and discussion of Essentials from previous ERICA workshop). <i>Clémence Le Cornec</i>
9h15 – 10h00	Implementation of a data access policy (summary and discussion of Essentials from previous ERICA workshop). - Principles - Governance - Workflow - Future embedding in EJP RD, EHDS <i>Franz Schaefer</i>
<i>10h00 – 10h30</i>	<i>Coffee break</i>
10h30 – 11h00	Use of pseudonymised and anonymised data (summary and discussion of Essentials from previous ERICA workshop). <i>Clémence Le Cornec</i>
11h00 – 12h15	Funding models for the ERN registries: ensuring the short-, medium- and long-term viability of the ERN registries and the reuse of the data collected. The c4c initiative will be presented, followed by an hour discussion on the ERN registries funding models. <i>Speaker to be confirmed</i>
12h15 – 13h00	Outline of the white paper and distribution of writing tasks <i>All</i>
13h00 – 13h15	Conclusion from the workshop <i>Franz Schaefer</i>
<i>13h15 – 14h15</i>	<i>Lunch and end of the workshop</i>