Online Workshop
Ethics and regulatory considerations for ERN Data Access Committee members
30 June 2022
10:00 am-12:30 pm (CET) - Online
Upon invitation

This workshop is the fourth of the ERN data strategy workshop series. It primarily aims to train the members of the ERNs Data Access Committee members on the legal and ethical aspects to consider when examining an incoming data access request.
In this workshop, organised jointly by ERICA WP2 and EJP RD WP18, the type of data sharing that the ERNs envision with the different stakeholders will be presented. The role of the data access policy in regulating the access to the data will be explained and the structure of the data access request and of the data access request feedback form will be then presented, together with some practical aspects of the DAC work. Afterward, the ethics and regulatory considerations to consider for any incoming data access request will be presented. A distinction will be made between data access requests for-profit versus not-for-profit projects as well as data access requests for pseudonymised or anonymised data. Subsequently, the importance of keeping an open mind upon the examination of a data request and how an overly careful approach with respect to data sharing can undermine research progress for rare disease patients will be discussed. The use of the Common Conditions of use Elements (CCE) as a tool to build use conditions policy covering the general use conditions for a resource will then be presented. Finally, current DAC members (ERN coordinators, ERN researchers, patient representative) will be invited to present their perspective and their experience of dealing with incoming data access requests. Following these presentations, any further open questions will be addressed in an open discussion and a Q&A session.

Agenda

Moderator: Franz Schaefer, Heidelberg University Hospital, ERN ERKNet coordinator, ERICA WP2 co-lead

1. **Welcome & Introduction** *(5 minutes)*
   Speaker: Roseline Favresse, EURORDIS

2. **What is the data access policy and how does it regulate the access to the data?** Structure of a data access request and data access request feedback form. Presentation of the template documents developed by ERICA WP2. Practical aspects of the DAC work. *(15 minutes)*
   Speakers: Clémence Le Cornec, Heidelberg University Hospital, ERICA WP2 project manager & Prof Franz Schaefer, Heidelberg University Hospital, ERN ERKNet coordinator, ERICA WP2 co-lead

3. **Feedback and experience from current DAC members**. The experience from ERN coordinators, ERN researchers and patient representatives. *(2-3 slides, 3-5 minutes per speaker)*
Speakers: DAC members

4. **What type of data sharing do the ERNs envision with each stakeholder (internal researcher, industry, patient organisation, etc.)?** Presentation of the data sharing matrix. *(10 minutes)*
Speaker: Prof Franz Schaefer, Heidelberg University Hospital, ERN ERKNet coordinator, ERICA WP2 co-lead

5. **Ethics considerations for an incoming data access request.** A distinction will be made between data access request for profit and not for profit projects, as well as between data access request for anonymised and pseudonymised data. *(10-15minutes)*
Speaker: Annalisa Landi, Researcher, Gianni Benzi Foundation

6. **Regulatory considerations for an incoming data access request.** A distinction will be made between data access request for profit and not for profit projects, as well as between data access request for anonymised and pseudonymised data. *(10-15 minutes)*
Speaker: Leonardo Cervera Navas, Director, European Data Protection Supervisor (EDPS)

7. Registry **data reuse from the patient perspective**: what are the main interest and concerns *(10 minutes)*
Speaker: Jelena Malinina, Patient Data Director, EURORDIS

8. Keeping an open mind and granting access to the data when a reasonable request comes in. How an overly careful approach with respect to data sharing can undermine research progress for rare disease patients. A **policy perspective**. *(10 minutes)*
Speaker: Guillaume Byk, Legislative Officer, European Commission

9. "**Common Conditions of Use" Elements** (CCE) as a tool to build use conditions policy covering the general use conditions for a resource *(5-10 minutes)*
Speaker: Prof Tony Brookes, University of Leicester

10. **Questions & answers** *(15-20 minutes)*
Speakers: all

11. **Conclusion and wrap-up** *(5 minutes)*
Speakers: Dr Birute Tumiene, Vilnius University Hospital & Prof Franz Schaeffer, Heidelberg University Hospital, ERN ERKNet coordinator, ERICA WP2 co-lead