ERKReg
The European Rare Kidney Disease Registry

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Data Access Policy

Role-based access rules

Access of authorized users to the registry is controlled by assignment of a secure, individualized password. A hierarchical access authorization system is implemented.

Project Management Team ('super-administrator')	This group will have access to the global database.
Sub-Registry Leads ('sub-administrator')	This group will have access to all patient level anonymized data in the associated sub-registry.
Center users	This group will have access to their own center´s data.
Investigators	This group may propose analyses of registry data by submitting an Analysis Request Form for review and approval by the Data access committee.

Eligibility criteria for data access requestors

Investigators of active contributing units (having enrolled at least 50 patients in total and 3% of the enrolled population of interest+ clear scientific interest and expertise) or external investigators with an active ERKReg collaborator (fulfilling the same rules) are entitled to request data analyses.

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Data Access Procedure

- The requestor shall need to complete the survey "Data Access Form/Registry Analysis Concept Sheet"

- The completed form shall be submitted to the ERKReg Project Management Team which will check the compliance with the formal requirements and forward the request to the Data Access Committee (link to website).

- The Data Access Committee shall provide their feedback using the Feedback Form within 6 weeks from initial application.

- Data access is granted when 75% agreement has been reached.

- In case of competing applications, the investigators will be informed and encouraged to join their applications.

- Prior to the sharing of any data, a Data Transfer Agreement (DTA) including a confidentiality statement must be executed to ensure the protection and proper handling of all shared information

- The principles of data sharing for different stakeholders are described in the table below

Stakeholder	Data to be shared	Highest data level	Access Modality
ERKReg researcher	all available data	Pseudonymized data	Free of charge
academic researcher with ERKNet affiliation	CDE+ selected data	Anonymized data	Free of charge In collaboration with ERKReg collaborator
academic researcher without ERKNet affiliation	CDE+ selected data	Anonymized data	Fees may apply In collaboration with ERKReg collaborator
Industry researcher	CDE + selected data	Anonymized or aggregated data	Fees apply
National health authority	CDE only	Aggregated data	Free of charge
Regulatory authority (EMA)	CDE only	Aggregated data	Free of charge
Patient organisation, NGO	CDE only	Aggregated data	Fees apply
HTA / Insurance companies …§	CDE only	Aggregated data	Fees apply

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Explanations:

What does CDE mean?

The Joint Research Centre (JRC) of the European Commission has developed Common Data Elements (CDEs) aiming to increase interoperability of rare disease registries.

Please find the set of CDE at:

https://eu-rd-platform.jrc.ec.europa.eu/system/files/public/CDS/EU_RD_Platform_CDS_Final.pdf

What does "anonymized data" mean?

Definition: Data from which all personally identifiable information has been removed or altered in such a way that individuals cannot be identified by any means, either directly or indirectly. Anonymization involves deleting details such as dates, centre and countries information, patient identifier, ERKReg identifier.

Re-identification: Anonymization is intended to be irreversible, meaning there should be no way to re-identify the individuals from the anonymized data.

What does "pseudonymized data" mean?

Definition: Data where personally identifiable information has been replaced with pseudonyms or codes. However, the original information is kept separately and securely, allowing for potential re-identification if necessary.

Re-identification: Pseudonymization is reversible, meaning that it is possible to re-identify individuals if you have access to the key or information that links the pseudonyms to the original data.

What does "aggregated data" mean?

Definition: Aggregated data includes statistics like averages, counts, percentages, and rates, and excludes personally identifiable information to ensure confidentiality.

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