# Data Access Policy

## Background

This Data Access Policy (DAP) document applies to the European Reference Network ERN-RND registry. It covers the composition of the Data Access Committee (DAC) as well as the entire process to be followed for requesting access to the data captured in the ERN-RND registry.

The ERN-RND Registry is a demographic platform for collection of relevant core patient information. The single data base encompassing all rare neurological diseases in pediatric and adult patients (the ERN-RND Registry), according to the "Set of common data elements for Rare Diseases Registration". The overall goal of the ERN-RND is to improve access to high quality healthcare for patients with rare neurological diseases and complex conditions. ERN-RND Registry allows healthcare professional to work together to support patients with such rare and complex diseases, which require highly specialised care. ERN-RND Registry also improves knowledge about rare neurological diseases and support clinical research for improved diagnosis, risks prediction and the development of innovative therapies. More information is available under https://www.ern-rnd.eu/ern-rnd-registry/.

## Tasks of the Data Access Committee

The overall aim of the Data Access Committee (DAC) is to promote the research use of the data that are being collected in the ERN-RND registry through a transparent and simple approach ensuring the long-term sustainability of the project. The DAC should advise on the maintenance of the highest levels of custodianship of the data. Whilst it should have a good knowledge of ethics and data protection, it should not act as another 'research ethics committee' which is a responsibility that rests at the level of the data controllers. The DAC should:

- Check that the proposed work complies with the terms and conditions of the ethics approval provided to the ERN-RND registry.
- Look for evidence that the third-party requesting data is appropriately qualified for use of the data.
- Advise on improving the projects and any overlaps with ongoing projects.
- Ensure that the effort of all those involved is appropriately acknowledged.
- Aim to respond to all data requests promptly.
- Communicate to the requestor with appropriate feedback.
- Be aware of their own conflicts of interest.
- Treat all data requests confidentially.

## Composition of the Data Access Committee

The Data Access Committee comprises the following members:

- The Clinical Coordinator
- The ERN-RND registry manager
- One member from each disease group of the ERN. The members should represent ERN member centres that actively contribute to the registry.
- A patient representative

In addition to the standing DAC members, an expert in ethico-legal issues will join if necessary and lead investigators of disease-specific sub-registries will join the DAC on an ad hoc basis whenever data access requests concerning data collected in their sub-registry are received.

DAC members are proposed and confirmed by the members of the respective disease group/group of patient representatives.

The term of the DAC members is until the end of the current ERN-RND funding period, that is by 31 August 2027.

## Registry authorized users

Access of authorized users to the registry is controlled by assignment of a secure, individualized password. The following group will require access to the data in the ERN-RND registry:

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| Central Project Management Team | Has access to all data and provides role-based access. |

## Stakeholders entitled to request registry data

The following stakeholders (in the following called “the applicants”) are entitled to request data from ERN-RND registry:

- Clinicians and Researchers contributing to the ERN-RND registry
- External researchers from EU countries
- Researchers from non-EU countries
- Researchers from for-profit companies
- Regional, National and EU health authorities
- Regional, National and EU policy, supervision or regulatory agencies
- Patient organizations
- Non-Governmental Organisation

## Categories of requestable data

The applicants entitled to request registry data can request the following type of data:

| | |
|---|---|
| Pseudonymized patient-level data | All the personal data that relate to the patient is removed and replaced by a pseudonym. Only the HCP is able to link the pseudonym to the patient. Pseudonymized data can be used to distinguish individuals and combine their data from different records. Their processing is subject to data protection regulations. |
| Fully anonymized patient-level data | This can be achieved by removing all information that could be used to indirectly identify a patient. It may be necessary to obfuscate data by slightly changing the original data. Anonymized data are no longer considered as personal data and are not subject to data protection regulations. |
| Fully anonymized data (in tabular format) | All the personal data that relate to the patient is processed in a manner that makes it impossible for the controller or third parties to identify individuals from them. Anonymized data are no longer considered as personal data and are not subject to data protection regulations. |
| Aggregated Data | This is summarized data from some or all HCPs, like number of patients of a certain disease group, number of patients in a certain country etc. |
| Contact data of ERN-RND centers that have submitted data to ERN-RND registry and are of particular interest for a data requesting applicant | DAC will pass on contact data only after prior confirmation by HCP. |
| Personal data | Only ERN-RND HCPs can link the pseudonym to the patient and to the respective personal data. |

## Ownership of the data

In the ERN-RND registry, the patient participant (who is the 'data subject') is the primary owner of the data and will grant each of the users and will give consent to use such data for research and other purposes. In case the patient participant is under the age of majority, or subject physically or legally incapable of giving consent, parent(s) or legal guardian(s), is/are the primary owner(s) of the data and will grant each of the users and give the consent to use such data for research and other purposes.

The University Hospital of Tübingen is the current owner of the ERN-RND registry platform.

The institution of the clinician participant who has entered the data is the owner of the data of that patient participant and acts as the 'data controller' at the local centre.

For all data submitted to the central registry database, the Clinical coordinator and the ERN-RND registry manager are responsible for the protection of the data, its storage, use and access.
When processed, the data become research data and are then the intellectual property

of the investigator who is the 'third party'. This third party has to abide by the agreement reached in the ERN-RND Data Sharing Agreement whilst using the data supplied for the purpose stated in the Data Request Form.

## Ethics approval

The ERN-RND registry has been positively evaluated by the local ethics committee of the University of Tuebingen.

The data governance standards in the ERN-RND registry comply with the General Data Protection Regulation (GDPR).

The aforementioned applicants can request data for research and/or non-research projects (hereafter the "project"). A project using data from the registry will be considered to have ethics approval subject to the following conditions:

- The project is within the fields of research described in the application. The application has to contain information on publication agreements such as authorship (all involved HCPs have to be named in a list of contributors).
- The project is likely to add something useful to existing knowledge, to help disseminate knowledge and raising awareness about rare neurological diseases or to help improving care quality for patients with rare neurological diseases
- The project must be conducted in circumstances such that data subjects are not identifiable to the external third-parties. Data must be effectively anonymised or pseudonymised prior to release to external third-parties.
- The applicants requesting access to the data will treat datasets in confidence and declare to refrain from any attempt to re-identify data subjects through including but not limited to linkage with other datasets, use of publicly available databases.
- A data transfer agreement must be in place with all the applicants requesting access to the data to ensure processing of the data in accordance with the terms of the ethics approval and any other conditions required by the Project Management Team.
- For research projects, the research protocol, has been subject to scientific critique by the DAC, is appropriately designed in relation to its objectives.

## Research and data analysis

The data in the ERN-RND registry shall undergo analysis at regular intervals by the Project Management Team for detailed data consistency evaluations. This analysis will focus on overall data accrual, content, quality, and headline descriptions of care. This analysis will not require approval from the DAC but shall be performed closely with oversight of the DAC to provide progress reports.

After finalisation of the annual data submission phase, aggregated data will be created and be published on the ERN-RND website.

Aggregated data will include total number of patients, patients per country, patients per

disease group in total and per country, patients for which biosamples are available, the number of patients without OMIM code (without molecularly confirmed diagnosis), number of different Genes and the age range and sex distribution of patients per disease group.

All other analysis will require completion of a Data Transfer Agreement and the Data Request Form.

## Process for seeking access to the data

1. The applicant shall need to complete the Data Request Form.
2. The completed form shall be submitted to the ERN-RND Project Management Team who will check their completeness and forward to the DAC.
3. The DAC shall meet online or communicate in written form to discuss the request and decides on approval.
4. The DAC shall provide its feedback using the Feedback Form within six weeks from initial application.
5. If the application is approved,
    a) in case of aggregated data the ERN-RND Project Management Team can provide data of the registry.
    b) in all other cases of data the respective HCPs are informed by the ERN-RND Project Management Team that an applicant is interested. If the HCPs are interested as well, they get in contact with the applicant directly and inform the ERN-RND Project Management Team on this decision.
6. In case the contents of a new application overlap with an existing active application, the applicants of the two applications will be jointly advised to discuss the overlap.
7. The requesting applicant shall then need to complete and comply with the Data Transfer Agreement.

All documents are accessible on the ERN-RND website https://www.ern-rnd.eu/ern-rnd-registry/ and through the ERN-RND registry project management team.

## Governance review

This document will be reviewed every two years and may be subject to change.