R-LIVER Data Access Policy

Background

This Data Access Policy (DAP) document applies to the European Reference Network ERN RARE-LIVER, R-LIVER 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 R-LIVER registry.

R-LIVER is the prospective registry of ERN RARE-LIVER. It currently focuses on autoimmune diseases AIH, PBC and PSC, vascular liver diseases and biliary atresia. More information is available under (rare-liver.eu) and more diseases will be added in the future.

The main objective of the registry is to monitor differences and outcome of care, to contribute to the advancement of scientific knowledge and to facilitate research in the field of rare liver diseases.

Tasks of the Data Access Committee

The overall aim of the Data Access Committee (DAC) is to provide a coordinated access to R-LIVER data that complies with the aims of ERN RARE-LIVER, and to promote the research use of the data that are being collected in the R-LIVER registry through a transparent and simple approach ensuring the long-term sustainability of the project. The DAC should not act as another 'research ethics committee', which is a responsibility that rests at the level of the data requester. The DAC should:

- Check that the proposed work complies with the terms and conditions of the ethics approval provided to the R-LIVER registry and the statutes of ERN RARE-LIVER.
- Assess 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 elsewhere.
- Advise that all participating centres must give consent to the use of their data and 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 as of March 2024

The Data Access Committee comprises the following members:

- the Registry Coordinator, Prof. Dr. Christoph Schramm,
- two members from each expert disease working group represented in the registry (AIH, PBC, PSC, BA, VLD). The members should represent ERN member centres that actively contribute to the registry. The aim is to include one adult and one paediatric hepatologists,
- two patient representatives,
- one data manager,
- R-LIVER project manager

In addition to the standing DAC members, 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 by the coordinator of ERN RARE-LIVER together with the management board members and confirmed by the ERN RARE-LIVER members.

The committee will meet every 3 months to discuss requests or when necessary. The R-LIVER project management team will invite to the meetings at least two weeks ahead of time.
The decision of requests will be upon majority of votes.
Attendance of at least 50% of DAC members is required to be able to take decisions.
The term of the DAC members is 2 years. Re-election is possible.

Health Care Providers (HCPs) participating in R-LIVER will be notified by the ERN office and/or the data manager of any data transfer requests. A HCP's data will be included in the data transfer only after they have provided consent for the transfer of their own data. The HCPs should confirm in a written email that patients have consented to have their data shared within or outside the EU, as appropriate.

Stakeholders entitled to Request Registry Data

The following stakeholders are entitled to request data from the R-LIVER registry:

- Researchers contributing to the R-LIVER registry
- External researchers from EU countries
- Researchers from non-EU countries
- Other third parties

Categories of requestable data

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

Pseudonymized patient-level data	All the directly identifying data that relate to the patient has been removed by the data providing HCP and replaced by a pseudonym. Only the HCP that has provided that specific data to the Registry 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.

Responsibility for the data

In the R-LIVER registry, the patient participant (who is the 'data subject') is the primary owner of the data and has given consent to use such data for research and other purposes.

The responsibility for the R-LIVER-Registry (the platform and the technical infrastructure) lies with the UKE, 1st Department of Medicine, on behalf of ERN RARE-LIVER.

The HCP that has entered the data into the registry has control over the data of that particular data subject and has to consent to any provision of the data to a requestor/any applicant.

For all data submitted to the central registry database, the 1st Department of Medicine, UKE and its representing principal investigator Prof. Dr. Christoph Schramm 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 Data Sharing Agreement (DSA) whilst using the data supplied for the purpose stated in the Data Request Form (DRF).

Ethics approval and general rules of data handling

The R-LIVER registry has been approved by the Ethics Committee of the Hamburg Medical Association. For further information visit (rare-liver.eu).

The aforementioned stakeholders 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 project is likely to add something useful to existing knowledge, to help disseminate knowledge and raising awareness about rare liver diseases, to help improving quality of care for patients.
- 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 double pseudonymised prior to release to external third-parties.
- The stakeholders 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 sharing agreement must be in place with all the stakeholders requesting access to the data to ensure processing of the data in accordance with the terms of the ethics approval, data protection issues and any other conditions required by ERN RARE-LIVER.
- For research projects, the research protocol, has been subject to scientific review by the DAC, and is appropriately designed in relation to its objectives.

Process for seeking access to the data

- The requesting investigator shall need to complete the Data Request Form, which includes information on the scope of the project, the data requested, the centres involved, ethics approval and statistical analysis plan.
- The completed forms shall be submitted to the R-LIVER Project Management Team who will check their completeness and forward to the DAC.
- The DAC shall provide their feedback using the Feedback Form within 3 weeks from initial application.
- Once a study has been approved by the DAC, the R-LIVER Project Management Team in coordination with the data managers will inform the relevant HCP by email requesting to express its willingness to share data for the approved study. If an HCP does not wish to share its data for the approved study, it can opt out from the study. The HCP should inform the R-LIVER Project Management Team within 2 weeks.
- In case the contents of a new application overlap with an existing active application, the investigators of the two applications will be jointly advised to discuss the overlap.
- The requesting investigator shall then need to complete and comply with the Data Sharing Agreement.

All documents are accessible on the ERN RARE-LIVER website (rare-liver.eu). And through contacting the ERN RARE-LIVER project management team at: ern.rareliver@uke.de.

Governance review

This document will be reviewed regularly and may be subject to change.