**Data Request Form**

With this form you can request for ERN-RND registry data. For detailed information on requestable data see below. There are two options:

***1. Request for aggregated data***

Aggregated data can be provided directly from the registry if approved by the Data Access Committee.

***2. Request that requires personal data***

After approval by the Data Access Committee requests for personal data are forwarded to all centers that have uploaded patients with corresponding data to our registry. Each center is free to decide how to deal with your request.

**Please complete the data request form when submitting a request for ERN-RND registry data and indicate in the last field which data you require.** Here you see which data is collected: <https://eu-rd-platform.jrc.ec.europa.eu/mdr/detail/ERN-RND>

Please send the completed form to: ern-rnd-registry@med.uni-tuebingen.de

1. Contact information

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| --- |
| **Name of the Principal Investigator:** |
| **Affiliation:** |
| **Contact details:** |
| **Coinvestigators:** |
| **Date:** |
| **Name of study:** |
| **Summary of the proposed work to be performed with the registry data: (maximum 500 words)** |
| **<Optional> Lay summary for the public (for websites and other publicity materials): (maximum 50 words)** |

1. Analysis plan

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| **Background of the study** |
| **Research question/hypothesis** |
| **Primary aim** |
| **Need for further ethical approval:** *Any research project that requires additional procedures that are not part of routine clinical care, is not covered by generic approval for the Registry. These additional research procedures would require further ethical review, either as an amendment to the current terms of approval of the Registry, or a separate application for ethical review of a specific project. Please state whether the investigators aim to perform any procedures or measurements that are not undertaken as part of routine clinical practice.*  a) Do you already have a scientific committee and/or ethics committee approval for the project in your center (or project related to the data you are asking for)?  yes  no  b) Please specify: |
| **Expected outputs (include plans for dissemination):** |
| **Publication Plan for authorship in outputs:** |
| **Timeline from start of study to expected outputs:** |
| **<Optional> Overall data management and** **statistical plan:** |
| **<Optional> Will the study require contacting collaborating centres to collect additional routinely collected data?**  **Yes/No** |
| **<Optional> Source of funding:** |
| **<Optional> If no current funding, are you applying for funding?** |
| **<Optional> Deadline for funding application:** |
| **Storage of the data requested during the research:** |
| **What data would you like us to provide you? (Please specify the variables that you need for answering your research question).** The variables collected in the registry can be seen here: <https://eu-rd-platform.jrc.ec.europa.eu/mdr/detail/ERN-RND> |

**Categories of requestable data** (as specified in the Data Access Policy)

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

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| 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. |