ERN RITA Registry

Reimbursement protocol

Version 14.03.2024

In case of questions, please contact the RITA Registry team:
rita-registry@umcutrecht.nl

RITA Registry – Reimbursement

Version 2024.03

1. Aim

The RITA Registry aims to identify patients (both adults and children) with rare immunological diseases in Europe. For this goal, the RITA Registry will only collect and report Common Data Elements (CDEs) as defined by the European Commission: EU_RD_Platform_CDS_Final.pdf (europa.eu). These CDEs include diagnosis, sex, age, and age at diagnosis. An additional focus of the RITA Registry is cataloguing the treating centres of patients with specific rare diagnoses, thus simplifying engagement with participants for future scientific research.

Several steps need to be taken to participate in the RITA Registry and qualify for reimbursement

- Assigning a contact person
- Prepare documents & Apply for ethical approval
- Sign documents (after ethical approval in HCP)
- Account for data entry
- Recruitment and data entry
- Bulk upload
- Data quality

For detailed information, please read the annex.

2. Qualifying criteria

- Reimbursement for participation will be based upon data upload (bulk or manually)
- Data can only be uploaded after:
    - Obtaining ethical approval
    - Setup of a data entry system
- Uploaded data will be checked for quality by the RITA Registry team.
- After confirmation by the registry team, HCPs can then send an invoice.
- We strongly encourage to request reimbursement before sept 2025. September 2025 we have to draft the grant mid-term report, which also includes progress of the RITA registry.
- HCPs that cannot, or are not able to start data sharing before the end of September 2025 should contact the registry team for further guidance (rita-registry@umcutrecht.nl).

3. Reimbursement

Specifications

- A reimbursement fee of 1880 euro is available for each participating HCP.
- Payments are made to HCPs, not to individual experts.
- Invoices should state the following: UMC Utrecht, Reimbursement fee HCP bulk upload RITA Registry, Cost centre: V.0002074, Costs: 1880 euro.

Annex – RITA Registry participation

Participating in RITA Registry takes several steps before an HCP can enter patient data:

- **Assigning a contact person**
  An HCP will need to have a designated person responsible for data entry and contact with the registry coordinator. This person will need to contact the registry coordinator for exchange of protocols, patient information letters and setup of accounts. This person should have right of access to the local patient data.
- **Prepare documents & Ethical approval**
  Each HCP should contact their own local ethical research board and ensure ethical approval is in place before participation with RITA registry can start. Rules and regulations differ between countries and hospitals, the RITA coordination team can therefore only advice HCP on which steps should be taken. The coordination team will help HCP with the protocol and with templates for the patient information letter and informed consent form. Some templates are available in each European language but will need to be adjusted according to local rules and regulations. The registration team can also share the ethical approval obtained in Utrecht, where informed consent for the RITA registry can be obtained orally.
- **Sign documents**
  Data sharing agreement between the participating HCP and the ERN RITA coordination team has to be signed before starting data entry.
- **Account for data entry**
  Together with the coordinating team, the local designated person will setup accounts for data entry. Data is collected in Castor EDC, the accounts will be made by the RITA Registry coordinator. The designated person will need to employ two-factor authentication for the local Castor account.
- **Recruitment and data entry**
  Once ethical approval and accounts are in place, HCP can start patient recruitment and data entry. Data can be entered per individual patient, or per bulk upload. The RITA registry coordinating team recommends the setup of bulk upload; once extraction of data from a source (electronic medical file) into a file suitable for upload is in place, future data sharing will be easy and durable. Data extraction and upload can then be performed e.g. every six months.
- **Bulk upload**
  To setup data extraction, data processing and creation of a file suitable for bulk upload into the Castor system, we recommend to contact a local IT department or data management team. It would be useful if the local designated person has some experience with data management.
- **Quality check**
  The RITA Registry team will regularly check uploaded data and assess data quality and missing data. In case of missing or unclear data, the RITA Registry team will query to update the data.