

Appendix 6: Data Access Policy

Public reference copy of Appendix 6 to the EURO-NMD Registry Data Sharing Agreement as amended by Amendment No. 2. The executed Agreement remains authoritative.

This Data Access Policy governs access to Registry Data within the EURO-NMD Registry. It complements Article 21 (Data Access), Article 20 (Results), and Appendix 4 (Data Security Policy) of the Data Sharing Agreement (the “DSA”).

The objective of this Policy is to ensure that access to Registry Data is granted, managed, and monitored in a secure, transparent, ethical, and lawful manner, consistent with the purpose of the Registry and the rights of Patients.

The Policy establishes:

- the categories of Registry Data that may be accessed;
- the access rights and responsibilities of Users and Recipients;
- the role and responsibilities of the Data Access Committee (DAC);
- the procedures governing requests for access to Registry Data; and
- the conditions applicable to the use, disclosure, and protection of Registry Data.

1. Principles

Access to Registry Data shall be governed by the following principles:

- Role-based permissions, ensuring that Users may access only the data and functions necessary for their authorised duties;
- The principle of least privilege, whereby access is limited to the minimum level necessary to perform authorised activities;
- Approval by the Data Access Committee (DAC), where required under this Policy;
- Compliance with this Policy, the DSA, and applicable Data Protection Legislation;
- Accountability and traceability, whereby all access to Registry Data is logged and auditable; and
- Respect for data ownership and control, whereby access to Registry Data does not confer any ownership rights. Ownership and control of Registry Data remain governed by Article 19 of the DSA.

2. Categories of Registry Data Accessible

Registry Data may be available in the following forms:

- Pseudonymised Data: Patient-level records from which direct identifiers have been removed and replaced with a unique Registry identifier.
- Aggregated Data: Statistics, analyses, or derived outputs that are no longer attributable to an individual Patient. Examples include counts, descriptive and comparative statistics, graphs, dashboards, and summary tables.

The Registry does not collect or store directly identifiable personal data. Each Patient is represented within the Registry by a unique pseudonym, while the corresponding re-identification key remains exclusively under the control of the contributing HCP.

3. Roles and Access Levels

3.1 Users

Users are authorised healthcare professionals or staff members of a participating HCP who have been granted access to the Registry in accordance with the DSA.

3.1.1 User Access Levels

The following User Access Levels may be assigned within the Registry:

- Data Viewer: May view records within their authorised scope. Cannot create, edit, rename, delete, import, or export data.
- Data Viewer and Export: May view records and export data through the Registry reporting and export functions. Cannot create, edit, rename, delete, or import data.
- Data Entry: May create, edit, rename, and delete records. Cannot import or export data.
- Data Entry and Import: May create, edit, rename, and delete records and perform data imports using the Data Import Tool. Cannot export data.
- Data Entry and Export: May create, edit, rename, and delete records and export data through the Registry reporting and export functions. Cannot import data.
- Data Entry, Import and Export: May create, edit, rename, and delete records, perform data imports using the Data Import Tool, and export data through the Registry reporting and export functions.

3.1.2 Data Access Groups (DAGs)

- Each User shall be assigned to one or more Data Access Groups (DAGs), corresponding to the organisational entity (e.g., department, unit, or service) with which they are affiliated.
- Users assigned to a specific DAG may only access Patient Data belonging to that DAG.
- An HCP may establish more than one DAG to segregate access between different departments, units, services, or research groups.

3.1.3 Responsibilities of HCP

The Hospital Coordinator (or Principal Investigator) of each HCP is responsible for:

- Approving and authorising User accounts for their HCP within the Registry;
- Determining the appropriate access level for each User;
- Determining and approving DAG assignments;
- Ensuring that access rights are reviewed and updated when a User's role changes;
- Requesting the suspension or removal of access without undue delay when a User leaves the HCP or no longer requires access;

Each HCP remains responsible for the activities carried out by its Users and shall promptly notify the Coordinator of any change affecting a User's authorisation or access rights.

3.2. Recipients

The following categories of stakeholders may request access to Registry Data:

- Contributing researchers;
- Non-contributing researchers;
- Health authorities and regulators;

- Policy and supervisory agencies;
- Patient organisations;
- Non-governmental organisations (NGOs);
- Payers and insurers; and
- Pharmaceutical companies, subject to any additional requirements relating to commercial use and patient consent.

3.2.1 Access Conditions

The specific conditions applicable to each category of Recipient, including eligible cohorts, available Data Elements, access levels, DAC review requirements, authentication measures, and applicable fees, are set out in Annex 1.

Recipients shall:

- receive access only to Pseudonymised Data or Aggregated Data, limited to the datasets and cohorts approved by the DAC or otherwise permitted under Annex I;
- use appropriate authentication measures, with all access activities being logged and auditable;
- pay any applicable fees specified in Annex I; and
- comply with Section 5 (Data Access Process), including the execution of any required Data Transfer Agreement, Data Access Agreement, or equivalent legal arrangement, and adherence to the approved scope of access.

3.3. Registry Host and Coordinator

The Registry Host (UKLFR) and the Coordinator (AP-HP) may access Registry Data only to the extent strictly necessary to:

- operate, maintain, secure, and back up the Registry;
- manage User accounts and provide technical or operational support; or
- comply with applicable legal, regulatory, or contractual obligations.
- All such access shall be logged and auditable.

4. Data Access Committee (DAC)

4.1 Mandate

The Data Access Committee (DAC) is responsible for reviewing, evaluating, and deciding upon requests for access to Registry Data submitted by Recipients.

The DAC shall ensure that requests are assessed in accordance with:

- the objectives of the Registry;
- the informed consent provided by Patients;
- this Policy;
- the Data Sharing Agreement (DSA); and
- applicable legal, ethical, and regulatory requirements, including the GDPR.

4.2 Composition

The DAC shall be composed of:

- Two Co-Chairs appointed by the Registry Steering Committee.

- One HCP representative nominated by the EURO-NMD Board.
- One Patient representative nominated by the EURO-NMD Patient Advisory Board.
- One disease expert nominated by the relevant EURO-NMD Thematic Disease Group.
- Ad hoc experts as required (e.g. ethics, privacy, scientific merit).
- Secretariat provided by the EURO-NMD Coordination Office.

Members shall serve under a rotation system designed to ensure broad representation across participating stakeholders and disease areas.

4.3 Responsibilities

The DAC shall:

- evaluate requests from scientific, ethical, legal, and operational perspectives;
- ensure consistency with patient consent, applicable Data Protection Legislation, and the objectives of the Registry;
- verify the qualifications, affiliations, and authorisations of requestors where appropriate;
- assess the feasibility and proportionality of the requested access;
- prevent unnecessary duplication of research activities and encourage collaboration where appropriate;
- identify, declare, and manage actual or potential conflicts of interest;
- determine any conditions, restrictions, or safeguards applicable to approved requests; and
- communicate its decisions and any applicable conditions in writing to the requestor.

5 Data Access Process

5.1 Submission of Requests

- Recipients seeking access to Registry Data shall submit a Data Access Request Form for each proposed project or purpose.
- Requests shall include sufficient information to enable the DAC to assess the scientific, ethical, legal, and operational aspects of the proposed use of Registry Data.
- Upon receipt, the DAC Secretariat shall review the request for completeness and eligibility and may request additional information where necessary.

5.2 Review and Evaluation

- Complete requests shall be submitted to the DAC for review in accordance with its Standard Operating Procedures.
- The DAC may request clarifications, revisions, additional documentation, or evidence of approvals before reaching a decision.
- Certain categories of requests identified in Annex A may not require full DAC review. Such requests shall nevertheless be submitted in writing and verified by the DAC Secretariat for compliance with this Policy and the applicable eligibility criteria.
- The DAC's decision, including any conditions, restrictions, or recommendations, shall be communicated to the requestor in writing.

5.3 Conditions for Access

Access to Registry Data may be granted only where all applicable conditions have been satisfied.

5.3.1 Regulatory and Ethical Requirements:

- Where required, appropriate ethics committee, institutional review board (IRB), or other regulatory approvals shall be obtained before access is granted.
- The requested use must be consistent with the informed consent provided by the Patients whose data are included in the requested dataset.
- For requests involving commercial entities, access shall be limited to data relating to Patients who have consented to commercial use, where applicable.

5.3.2 Legal Requirements:

- Prior to receiving Registry Data, the Recipient shall execute any legal agreement required by the Coordinator or the DAC, including, where applicable, a Data Transfer Agreement (DTA), Data Access Agreement (DAA), or equivalent contractual arrangement.
- Such agreement shall require the Recipient to:
 - (i) use Registry Data solely for the approved purpose;
 - (ii) comply with applicable legal, ethical, and regulatory requirements;
 - (iii) refrain from attempting to re-identify Patients;
 - (iv) refrain from directly contacting Patients;
 - (v) implement appropriate technical and organisational measures to protect Registry Data; and
 - (vi) refrain from any onward disclosure, sharing, or secondary use of Registry Data unless expressly authorised by the DAC.

5.3.3 Scientific and Operational Requirements:

- Prior to submitting a request, applicants should review the Registry Data Dictionary and available Data Elements to assess the feasibility of their proposed project.
- Applicants should also review the list of approved Research Projects published by the Registry to avoid unnecessary duplication and to encourage collaboration where appropriate.
- Any proposed secondary use of Registry Data shall be notified to the DAC. The DAC shall determine whether the proposed use falls within the scope of the original approval or requires submission of a new Data Access Request.
- Fees may apply to certain categories of Recipients, including commercial entities, in accordance with Annex A and any applicable fee schedule adopted by the Registry.

5.4 Prohibited uses

Recipients shall not:

- attempt to re-identify Patients;
- use Registry Data beyond the scope, duration, or purpose approved by the DAC;
- disclose Registry Data to any third party without prior authorisation from the DAC and any other approvals required under the applicable legal agreement;
- use Registry Data for any unlawful, unethical, or unauthorised purpose.

6. Governance and Compliance

- Access to and use of Registry Data shall comply with this Policy, the DSA, applicable Data Protection Legislation, and any other applicable legal, ethical, or regulatory requirements.

- Each HCP remains responsible for obtaining and managing informed consent, facilitating the exercise of Data Subject rights, and complying with its obligations as Controller of the HCP Data in accordance with the DSA.
- Security requirements applicable to Registry Data are set out in Article 7 and Appendix 4 (Data Security Policy) of the DSA.
- Transfers of Registry Data to third countries or international organisations shall comply with Article 9 of the DSA and Chapter V of the GDPR.
- Personal Data Breaches shall be managed in accordance with Article 11 of the DSA, and each Party shall remain responsible for fulfilling its respective notification obligations.
- The appointment and management of Processors shall be governed by Article 8 of the DSA.
- DAC decisions, approvals, and conditions of access shall be documented and auditable.
- This Policy shall be reviewed periodically and may be updated where required to reflect legal, regulatory, operational, or technical developments.

Annex 1 to Appendix 6 – Stakeholders entitled to request data & data access authorisation levels.

Stakeholder	DAC permission required	Cohorts	Data elements	Data access level	Authentication	Fees
Contributing researcher	No	Own patients	All	Individual-level	Yes	No
	No	All patients	All	Aggregated	Yes	No
	Yes	All patients	All	Individual-level	Yes	No
Contributing patient	No	Own data	All	Individual-level	Yes	No
	No	All patients	All	Aggregated	Yes	No
	Yes	All patients	All	Individual-level	Yes	No
Non-contributing researcher	No	All patients	All	Aggregated	Yes	No
	Yes	All patients	All	Individual-level	Yes	No
Industry	No	All patients consenting to commercial use	CDE	Aggregated	Yes	Yes
	Yes	All patients consenting to commercial use	CDE + selected disease history/ intervention/ outcome data	Individual-level	Yes	Yes
Health Authorities	No	All patients	CDE	Aggregated	Yes	No
	Yes	All patients	CDE + selected disease history / intervention/ outcome data	Aggregated	Yes	No
Policy, supervisory or regulatory agencies	No	All patients	CDE	Aggregated	Yes	No
	Yes	All patients	CDE + selected disease history / intervention/ outcome data	Individual-level	Yes	No
Payers/insurers	Yes	All patients	CDE	Aggregated	Yes	Yes
Non-Governmental Organisations	Yes	All patients	CDE	Aggregated	Yes	Yes
Patient Organisations	No	All patients	All	Aggregated	Yes	No
	Yes	All patients	All	Individual-level	Yes	No