

Appendix 5: Governance

Public reference copy of Appendix 5 to the EURO-NMD Registry Data Sharing Agreement as amended by Amendment No. 2. The executed Agreement remains authoritative.

The EURO-NMD Registry is a pan-European patient registry for rare paediatric and adult neuromuscular diseases established within the framework of the European Reference Network for Rare Neuromuscular Diseases (ERN EURO-NMD).

The purpose of the Registry is to improve the quality of care and outcomes for patients with rare neuromuscular diseases, support research and clinical trials, and inform healthcare, policy, and regulatory decision-making.

The Registry is governed by the bodies described below. These bodies operate in accordance with the Agreement, applicable Registry policies, and their respective Standard Operating Procedures (SOPs).

1. Governance Structure

The governance of the EURO-NMD Registry is composed of the following bodies:

(a) Steering Committee (SC)

- The Steering Committee (“SC”) is the principal governing and decision-making body of the Registry.
- The SC is composed of:
 - representatives of the Registry Consortium Members;
 - one representative from each EURO-NMD Specialist Disease Group; and
 - one representative from the EURO-NMD Patient Advisory Board (PAB).
- The SC is chaired by the EURO-NMD Coordinator.
- The SC operates in accordance with the EURO-NMD Registry Steering Committee Standard Operating Procedures.
- Decisions shall be taken by consensus whenever possible. Where consensus cannot be reached, decisions shall be adopted by a two-thirds majority of the members present or represented.
- The composition of the SC shall be reviewed every three (3) years, and members may be renewed, replaced, or reconfirmed as appropriate.
- The SC shall:
 - provide strategic direction for the Registry;
 - oversee the implementation and evolution of the Registry;
 - approve Registry policies and governance documents;
 - monitor compliance with the Agreement and applicable legal requirements;
 - oversee the sustainability and long-term development of the Registry;
 - supervise the activities of the Data Access Committee and Management Team; and
 - determine the continuation, transfer, retention, or disposal of Registry Data in the event of the termination or discontinuation of the Registry or the Network.

(b) Management Team

- The Management Team supports the SC and is responsible for the day-to-day management and operation of the Registry.
- The Management Team is composed of:
 - (i) the EURO-NMD Coordination (AP-HP, Paris), responsible for administrative, contractual, financial, and operational management;
 - (ii) the Data Operations and IT Team (UKLFR, Freiburg), responsible for system hosting, platform maintenance, data operations, technical support, and information security; and
 - (iii) the Interoperability Team (Radboudumc, Nijmegen), responsible for the development and maintenance of interoperability services, federated infrastructure, and integration with external registries and data sources.
- The Management Team shall report regularly to the SC on operational activities, performance indicators, risks, and ongoing developments.

(c) Data Access Committee (DAC)

- The Data Access Committee ("DAC") is responsible for reviewing, evaluating, and deciding upon requests for access to Registry Data submitted by Recipients.
- The composition of the DAC is defined in Appendix 6 (Data Access Policy).
- The DAC operates in accordance with the EURO-NMD Registry Data Access Committee Standard Operating Procedures.
- Decisions shall be taken by consensus whenever possible. Where consensus cannot be reached, decisions shall be adopted by simple majority, provided that the required quorum is met.
- The DAC shall act independently when assessing access requests and shall document its decisions and their justification in accordance with its SOPs.
- The DAC shall ensure that all requests are assessed:
 - ethically;
 - scientifically;
 - in accordance with the objectives of the Registry;
 - in accordance with the consent provided by Patients;
 - in accordance with the Data Access Policy (Appendix 6); and
 - in compliance with applicable Data Protection Legislation, including the GDPR.
- The DAC may approve, reject, or request modifications to any access request and may impose conditions or safeguards as a prerequisite for access.

2. Review of Governance Rules

These Governance Rules may be reviewed and updated by the Steering Committee from time to time, provided that any amendment remains consistent with the Agreement and applicable law. Material amendments shall be communicated to all participating HCPs and other affected stakeholders.