EURO-NMD Registry Hub
European Reference Network for neuromuscular diseases

Operating Procedures

EURO-NMD Registry Steering Committee (SC)

1. Introduction

The Steering Committee (SC) of the EURO-NMD Registry is the Registry's main governing and decision-making body.

The SC is established to provide oversight, guidance, and strategic direction for the operation and management of the Registry.

This document serves as the operating procedures for the SC and supplements or replaces the relevant provisions of the previous Consortium Agreement governing the functioning of the SC.

2. Composition of the SC

- The SC comprises representatives from partner organizations of the EURO-NMD Registry Consortium, including healthcare providers and patient organizations, as well as one representative from each of the EURO-NMD thematic working groups and one representative from the Patients Advisory Board (PAB).
- Additionally, members of the registry management team are included in the SC.
- The Coordinator of the European Reference Network (ERN) EURO-NMD serves as the lead of the Registry on behalf of the Network and acts as the SC Chair.
- The Chair plays a central role in guiding the activities of the SC, facilitating discussions, and ensuring alignment with the goals and objectives of the EURO-NMD Registry.
- Equal Representation is ensured, with the same percentage of Patient Representatives and clinicians within the SC.
- The composition of the SC is periodically reviewed at least every 3 years or whenever changes are required.

The current composition of the SC is as follows:

SC Chair: Teresinha EVANGELISTA, EURO-NMD Coordinator

Representatives from the EURO-NMD Registry Consortium
François LAMY, French Muscular Dystrophy Association (AFM-Téléthon)
Hadrien DELATTRE, French Muscular Dystrophy Association (AFM-Téléthon)

Maxime JACOUPY, Institute of Myology (AIM)
Guillaume BASSEZ, Assistance Publique–Hôpitaux de Paris (AP-HP)
George PALIOURAS, Duchenne Data Foundation (DDF)
Elvina SAKELLARIOU, Duchenne Data Foundation (DDF)
Peter-Bram 't HOEN, Radboud university medical center (Radboudumc)
Jan KIRSCHNER, University Medical Centre Freiburg (UKLFR)
Dimitrios ATHANASIOU, World Duchenne Organization (WDO)
Elizabeth VROOM, World Duchenne Organization (WDO)
Representatives from the EURO-NMD Network
Kristl CLAEYS, Thematic Grouping: Muscle diseases
Davide PAREYSON, Thematic Grouping: Peripheral Nerve diseases
Hanns LOCHMULLER, Thematic Grouping: Neuromuscular junction defects
Michelangelo MANCUSO, Thematic Grouping: Mitochondrial diseases
Gaelle BRUNETEAU , Thematic Grouping: Motor Neuron diseases
Michela ONALI, Patient Advisory Board

Management team:

Carla D'ANGELO (Project Manager)

Antonio ATALAIA (Clinical Advisor)

Adrian TASSONI (IT Team Manager)

Dagmar WANDREI (IT Specialist)

Nawel LALOUT (FAIR data expert)

3. Responsibilities of the SC

- Provide strategic direction and guidance for both the EURO-NMD Registry (the centralized database where data are stored) and the Registry Hub (the federated infrastructure that connects various registries allowing predefined queries to be answered) in alignment with its objectives and mission.
- Oversee the development, implementation, and evaluation of registry policies, procedures, and initiatives.
- Approve the EURO-NMD Registry Data Access Policy, including criteria and processes for data access requests, to ensure fair and ethical use of data.

- Review and approve proposals for major changes or enhancements to the registry platform, infrastructure, or data collection protocols to improve functionality, accessibility, and utility.
- Monitor and evaluate the performance of the EURO-NMD Registry and the Registry Hub to identify areas for improvement. Take corrective actions as necessary to ensure their effectiveness.
- Provide guidance on data governance, privacy, and security measures to safeguard the integrity and confidentiality of data. Ensure compliance with data protection regulations and ethical standards in all aspects of registry operations.
- Foster collaboration and communication among EURO-NMD member institutions, stakeholders, and external partners involved in registry activities to maximise impact and efficiency.
- Determine the appropriate course of action regarding the handling of data, including in the event of discontinuation of the Registry.
- Address any conflicts, disputes, or issues arising within the SC or related to registry operations in a timely and constructive manner.

4. **Responsibilities and composition of the Management Team**

- Under the guidance of the SC, the Management Team is responsible for the daily management and operations of the Registry.
- The Management Team comprises:
  - Coordination Team (Paris): based in the APHP EURO-NMD Coordination Office, the team is responsible for coordinating activities, ensuring effective communication with stakeholders, and managing administrative and contractual matters within the Registry.
  - IT Aspects and Data Operations Team (Freiburg): based in the University Medical Centre Freiburg, where the registry is hosted, the team is responsible for managing IT aspects and data operations related to the registry.
  - Interoperability Team (Nijmegen): based in the Radboud university medical center, the team is responsible for the federated infrastructure and provides support and assistance to external registries in the process of connecting with the Registry hub.

5. **Meetings and Decision-Making**

- The SC will convene regular meetings at least once every 3 months to discuss registry-related matters, review progress, and make decisions.

- Members are expected to attend meetings or appoint a substitute or proxy to attend on their behalf.
- The Registry Coordinator shall chair all meetings of the SC, unless decided otherwise by the SC.
- Meeting agendas and relevant documents will be circulated to SC members in advance to facilitate informed discussions and decision-making.
- Any agenda item requiring a decision by the Members will be clearly identified as such on the agenda.
- Decisions of the SC will be made by consensus whenever possible. In cases where consensus cannot be reached, decisions will be made by a vote of SC members.
- Each Member present or represented in the meeting, including the Chairman of the SC, is entitled to one vote. A majority of two-thirds (2/3) of the votes cast is required to make a decision. Additionally, 2/3 of the total eligible voters must vote for the voting process to be considered valid in order to ensure that a significant majority is present for decision-making processes.
- The management teams do not participate in the voting process.
- If a decision needs to be made but a formal meeting cannot be convened or a quorum cannot be reached, alternative methods of decision-making or consultation may be considered, such as electronic voting after asynchronous discussions.
- The registry coordinator has authority to make routine or administrative decisions related to the daily management and operations of the registry but strategic decisions are made collectively by the SC.
- Minutes of SC meetings, including decisions made and action items, will be recorded and distributed to SC members for review and approval.

6. **Confidentiality and Conflict of Interest**
   - SC members are required to maintain the confidentiality of discussions and decisions made during SC meetings.
   - Any conflicts of interest among SC members must be disclosed and dealt with appropriately. This may involve recusal from specific discussions or decisions related to the conflict, abstaining from voting on relevant matters, or other measures to mitigate the impact of the conflict.
7. **Review and Revision**
   - These operating procedures will be reviewed periodically by the SC to ensure their effectiveness and relevance.

- Revisions to the operating procedures will be made as necessary and approved by the SC.

8. **Approval**

   - These operating procedures are approved by the EURO-NMD Steering Committee and effective as of 13 May 2024.

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History of changes

Version	Date	Description
V 0.1	20/03/2024	Draft
V 0.2	03/04/2024	Review 1
V 0.3	26/04/2024	Review 2
V 0.4	30/04/2024	Review 3
V 1.0	13/05/2024	Final version