EURO-NMD Registry Hub
European Reference Network for neuromuscular diseases

Operating Procedures

EURO-NMD Registry Data Access Committee (DAC)

1. Introduction

The Data Access Committee (DAC) is established to review and assess third party requests for data access to the EURO-NMD Registry. The DAC ensures that access to registry data is granted in accordance with established policies, procedures, and ethical guidelines. In this regard, the different levels of data access authorisation based on the type of data requested, the nature of the requestor and the purpose of the request, as well as the process for requesting access to Registry data are detailed in the Data Access Policy (DAP) of the EURO-NMD Registry.

This document outlines the operating procedures of the DAC to ensure transparency, fairness, and compliance with data protection regulations.

2. Composition of the DAC

- DAC Co-Chairs: The co-chairs of the DAC are appointed by the EURO-NMD Registry steering committee (SC). The two co-chairs include a patient representative and a healthcare professional that are nominated amongst the SC members. The Co-chairs oversee the activities of the DAC to ensure that data access decisions align with the strategic priorities and goals of the Registry.

  The current Co-chairs of the DAC are:

  - Peter-Bram ’t Hoen, Radboud university medical center Nijmegen
  - Dimitrios Athanasiou, World Duchenne Organization

- DAC Members:

  - A representative from the EURO-NMD healthcare providers (HCPs), contributing insights and aligning decisions on data access with the mission of the EURO-NMD Network.
  - A patient representative nominated by the EURO-NMD Patient Advisory Board (PAB), based on the specific disease under consideration, ensuring that the interests and rights of patients are prioritised.
  - A disease expert nominated by the EURO-NMD Thematic Disease Groups, based on the specific disease under consideration, providing specialized

insights into the relevance of the data access request in the context of the disease area.

- DAC Secretariat: The DAC is supported by a secretariat, responsible for coordinating DAC activities. Carla D'Angelo, Project Manager at APHP EURO-NMD Coordination Office, serves as the DAC Secretariat.
- Rotation system:
  - HCP Representatives: Rotated every three years, considering availability and geographical representation.
  - Patient Representatives and Disease Experts: Rotated based on specific neuromuscular diseases relevant to data access requests.
- Periodic Review: The structure of the DAC and DAC co-chairs will be reviewed at least every three years or whenever changes and updates are necessary.
- Ad Hoc Expertise: The DAC may seek additional perspectives and expertise on an ad hoc basis to ensure comprehensive evaluation of data access requests. This may include input from experts in relevant scientific disciplines, disease-specific domains, ethics, data privacy, or any other area deemed necessary.

3. Responsibilities of the DAC

- Review and evaluate data access requests submitted to the EURO-NMD Registry.
- Review and validate the queries that will be used within the Registry Hub (the federated infrastructure that connects various registries allowing pre-defined queries to be answered through data visiting) to secure and control the answers generated by the queries and the data shared with third parties.
- Ensure requests align with the objectives of the registry and comply with the EURO-NMD Registry DAP and relevant data protection regulations, such as GDPR.
- Ensure that the third-party requesting data is appropriately qualified and authorised to access the specific type of data requested (e.g., pseudonymized data vs. aggregate data, full dataset vs. limited dataset) based on its nature and intended use, as specified in the DAP.
- Confirm that the requesting party has obtained any necessary approvals or authorizations required for accessing and using the data, such as institutional review board (IRB) approval or ethics committee approval.

- Provide advice on improving proposed projects and identify any potential overlaps with ongoing projects to optimize research efforts, foster collaboration and minimize duplication of efforts.
- Provide regular updates to the EURO-NMD Steering Committee on data access activities and decisions, and any relevant issues or challenges. The DAC Co-chairs serve as liaisons between the DAC and the SC.
- Respond to all data requests within a specified timeframe and communicate decisions to requestors with appropriate feedback.

4. **Data Access Request Process**

- Data requestors complete the online Data Access Request Form for every proposed research question/project.
- The DAC Secretariat receives requests from data requestors and conducts an initial review within 3 weeks of submission to ensure that the application is satisfactorily completed; if any clarification or additional information is required, the Secretariat communicates with the data requestor to address these concerns.
- Once the request is deemed complete and eligible for DAC review, the Secretariat submits the request to the DAC using the dedicated request forms.
- The DAC convenes to review the submitted data access request(s); the committee may request additional information or clarification from the applicant as needed.
- Following the review, the DAC provides feedback on the request using the dedicated Feedback Form, including any recommendations or conditions for approval.
- After approval of a request and prior to the transfer of any information, data requestors are asked to sign the Data Transfer Agreement (DTA), outlining the terms and conditions of data use, including permitted uses and any restrictions on data use, sharing and dissemination, and obligations regarding data confidentiality and security.

5. **Meetings and decision-making processes**

- The DAC will convene regular meetings at appropriate intervals to address data access requests in a timely manner, taking into account factors such as the volume of requests and the urgency of decisions.
- Prior to each meeting, the DAC Secretariat will distribute data access requests to DAC members for review.
- The DAC Co-chairs will serve as the primary facilitators and presiders of all meetings of the DAC. The Co-chairs shall lead discussions, manage debate, and guide the committee towards consensus on decisions regarding data access requests.

- The Co-chairs may delegate specific tasks or responsibilities related to meeting management to other members of the DAC as needed, but overall accountability for the conduct and outcomes of DAC meetings rests with the Co-chairs
- In the absence of one Co-chair, the other Co-chair shall assume full responsibility for chairing the meeting
- DAC members will strive to reach consensus on whether to approve, modify, or reject each request based on established criteria and policies.
- Each DAC member, including Co-chairs, typically has one vote and decisions will be made based on simple majority or predefined criteria established by the DAC.
- The DAC secretary will document decisions made by the DAC (and all disclosed conflicts of interest) and provide feedback to data requestors regarding the outcome of their requests and any conditions or requirements associated with approved access.

6. Conflicts of Interest

- Members of the DAC should disclose any potential conflicts of interest they may have regarding specific data requests.
- The remaining DAC members will evaluate the disclosed conflict of interest and determine whether the member should recuse himself or herself from further involvement in the specific data access request under consideration.
- Recusal decisions shall be made by a majority vote of the non-conflicted DAC members present.
- Recused members shall not have access to privileged information or participate in any discussions or decisions related to the conflicted data access request.

7. Confidentiality and Data Security

- Members of the DAC are required to maintain the confidentiality of data access requests and deliberations.
- Data access requests and related documents will be stored and managed in a secure manner to prevent unauthorized access or disclosure.
- Access to registry data will be restricted to authorized personnel in accordance with established procedures for data transfer and access.

8. Review and Revision

- These operating procedures will be reviewed periodically by the DAC to ensure their effectiveness and relevance.

- Revisions to the operating procedures will be made as necessary and approved by the EURO-NMD Steering Committee.

9. **Contact Information**

   - For inquiries regarding data access requests or the operations of the DAC, please contact the DAC Secretariat [Insert Contact Information].

10. **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