

EURO-NMD Registry participation instructions

For prospective participating healthcare providers

Participation requires legal accession, completion of applicable regulatory requirements, and technical onboarding. Submit the documents below to the Registry Coordination Team at registry@ern-euro-nmd.eu. Patient data entry begins after these requirements are completed and accession is effective.

1 Legal accession

The DSA is a single agreement applicable to all participating centres. Its common terms are not open to institution-specific negotiation. Completion of the institutional fields in Appendix 1 and local adaptation of the consent form under Article 6 are permitted.

- Complete Appendix 1 with the HCP's institutional details, DPO contact details and competent supervisory authority.
- Complete Appendix 8 with the HCP's official name and the same agreed accession date in both paragraphs. Return both completed documents unsigned, together with the authorised legal signatory's full name, position and professional email address.

AP-HP initiates the DocuSign process. The proposed order is AP-HP first, followed by the HCP's authorised legal representative, within the same envelope. Do not sign in advance unless an alternative arrangement has been coordinated with AP-HP. Both signatures are required; accession takes effect on the date specified in Appendix 8, in accordance with Article 24.1 of the DSA.

If this DocuSign process is not possible, coordinate an alternative with AP-HP before signing. The HCP may use a qualified electronic signature and must provide the original electronically signed PDF, the platform's signature summary/audit trail and information enabling signature validation. The file must permit any remaining signature without altering signed content or invalidating existing signatures. If an acceptable electronic route cannot be arranged, use handwritten signatures as coordinated with AP-HP.

2 Regulatory requirements

- Confirm compliance with applicable local regulatory requirements, including institutional and/or ethics approvals where required.
- Submit a copy of the local ethics approval, where applicable.
- Submit the final patient informed consent form that will be used at the institution. The Appendix 3 template may be translated and adapted, or an existing institutional form may be adapted to explicitly cover EURO-NMD Registry participation.

The final consent form must be age-appropriate and incorporate the core information in Appendix 3. Preparation, translation, local adaptation and validation remain the HCP's responsibility under Article 6. Submission to the Registry Team does not replace that responsibility.

3 Technical onboarding

Once legal and regulatory requirements have been completed, request institutional onboarding and REDCap user accounts using the account request form:

<https://forms.office.com/e/5CPXG7frQy>

The Registry Coordination Team will coordinate account creation and an onboarding session with the Registry Team at the University Medical Centre Freiburg. Technical onboarding includes configuration of user roles and Data Access Groups (DAGs), and an introduction to the Registry, its data model, data entry, quality assurance and REDCap.

4 Activation of participation

Access and patient data entry are activated once the Accession Form has been signed by both parties and accession is effective, applicable regulatory requirements are completed, and technical onboarding is completed. The HCP must obtain, document and retain valid informed consent before enrolling each patient and entering their pseudonymised data.

Contact

For assistance, contact the EURO-NMD Registry Manager through the Registry helpdesk: registry@ern-euro-nmd.eu.