

EURO-NMD Registry: Data entry Pilot Reimbursement Protocol

Background

Following the HP-PJ-2019 call for proposals on rare disease registries for the European Reference Networks (ERNs), EURO-NMD launched the EU-funded project "Patient-Centered and Interoperable Registry Hub for Rare Neuromuscular Diseases - EURO-NMD Registry" on May 1, 2020 (Grant Agreement No. 101055286).

The EURO-NMD Registry is the first European registry covering all rare neuromuscular diseases. Affiliated with ERN EURO-NMD, it provides an interoperable, web-based platform for collecting standardized clinical data on patients treated or followed up by ERN EURO-NMD full members and affiliate partners. The registry aims to improve patient care and support research.

The Registry is built on REDCap, a secure online relational database system, and is hosted at the University Medical Centre of Freiburg, Germany. It operates as a centralized database, where each participating center has access only to its own data through the creation of Data Access Groups.

Testing with ERN HCPs began in January 2021, and technical implementation was completed in April 2023, making the registry fully operational for real data entry. The Registry became available online in January 2024 and is currently being rolled out to ERN centers.

Aim

As part of the European Commission (EC) support for the functioning of the ERN registries within the current EU financial framework, EURO-NMD has allocated part of its budget to launch a pilot scheme aimed at supporting HCPs in populating the EURO-NMD Registry with patient data. The total budget allocated for the EURO-NMD Pilot Reimbursement Scheme is €123,000.

The EURO-NMD Registry Data Entry Pilot Reimbursement Scheme is part of *Work Package 5 - Registries, data management and analysis*, specifically Task 5.4 (Data entry, management and support services), within the current ERN grant EURO-NMD 23-27 (Grant Agreement #1001156434), covering the period from 1 October 2023 to 30 September 2027. It is closely linked to Task 5.3, Onboarding of HCPs to the Registry, which focus on establishing processes required to facilitate the onboarding of HCPs to the Registry and enable them to begin contributing patient data.

This document outlines the process for reimbursing the ERN EURO-NMD HCP under this pilot scheme.

Eligibility

- Each full member or affiliated partner of ERN EURO-NMD is entitled to a financial compensation of €1,500 for enrolling the first 100 patients in the EURO-NMD Registry, and this is granted only:
 - **Once the first 100 patients have been enrolled in the registry.**
 - **And only if the HCP has completed the mandatory minimum dataset**, specifically the "Set of Common Data Elements for Rare Diseases Registration" developed by the EU RD Platform (https://eu-rd-platform.jrc.ec.europa.eu/set-of-common-data-elements_en).
- The eligibility for reimbursement, attributed to each HCP that meets the established eligibility criteria, will be verified by the EURO-NMD Coordination Team.
- In cases where a single HCP represents a consortium of different hospitals/clinical centers, only the HCP that submitted the Network Application on behalf of the consortium and is officially recognized as the Network Member is eligible for the pilot scheme. The full list of HCPs that are members of the ERN EURO-NMD can be found here: <https://ern-euro-nmd.eu/healthcare-providers/>

Payments

- Payments will be made in **EUR only**
- Reimbursements of the **flat amount of 1 500 €** will only be made **once the first 100 patients have been enrolled** in the registry.
- Payments are made to the ERN HCP (healthcare institution), not to individual clinicians or data entry staff.
- Reimbursements are subject to the **signing of a cooperation contract** with Assistance Publique – Hôpitaux de Paris (AP-HP), the HCP Network Coordinator.
- As specified in the contract, payments will only be processed **upon submission of invoices** issued by the ERN HCP within the required timeframe and will be made within 60 days from the invoice issuance date.
- All payments must be processed before 30 September 2027, which marks the end date of the EURO-NMD 23-27 grant in accordance with its funding requirements.
- **No invoices will be accepted beyond September 1, 2027** to ensure timely processing of payments and compliance with the EURO-NMD 23-27 grant requirements.