EURO-NMD Registry : Plenary session

EURO-NMD Annual Meeting, 22 Feb 2024

Carla D'Angelo
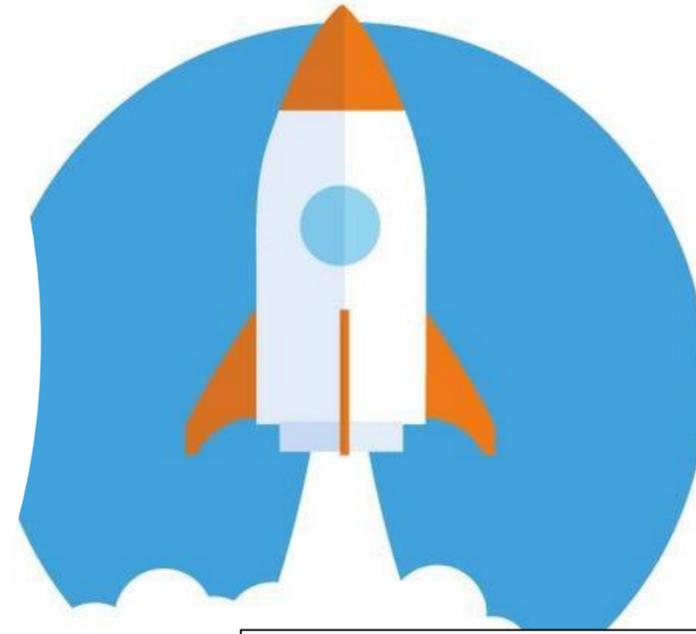(

LAUNCH OF THE FIRST EUROPEAN REGISTRY FOR ALL NEUROMUSCULAR DISEASES

EURO-NMD Registry Consortium :

- Assistance Publique–Hôpitaux de Paris (AP-HP)
- University Medical Centre Freiburg (UKLFR)
- Radboud University Medical Center (Radboudumc)
- World Duchenne Organization (WDO)
- Duchenne Data Foundation (DDF)
- Institute of Myology (AIM)
- French Muscular Dystrophy Association (AFM-Téléthon)

EURO-NMD registry: federated FAIR infrastructure, innovative technologies and concepts of a patient-centred registry for rare neuromuscular disorders

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HOW TO GET STARTED ?

01
SIGN
THE DATA SHARING AGREEMENT (ACCESSION FORM ATTACHED AS APPENDIX 8 TO THE DSA)

02
TRANSLATE
THE ENGLISH VERSION OF THE PATIENT INFORMATION AND CONSENT FORM (APPENDIX 3 TO THE DSA)

03
ASSESS
IF ETHICAL/ GOVERNANCE APPROVAL IS REQUIRED

OBTAIN
NECESSARY APPROVALS

04
RETURN
SIGNED DSA AND TRANSLATED ICF TO COORDINATION TO INITIATE CENTRE'S ENROLLMENT

HCP ENROLLMENT

▶ **Sign-up process:**

  ▶ activated by the HCP Rep (ERN Board representative)

  ▶ HCP rep will nominate the registry users & access rights and roles

  ▶ HCP rep will indicate the need (or not) to create different "DATA ACCESS GROUPS" for units or sites

▶ **Definitions:**

  ➤ HCPs = legal entities that have applied to become members of the ERN (individual hospitals or hospital consortia) -> Goal: onboard 82 ERN HCPs

  ➤ An HCP may consist of several <u>UNITS</u> = services/departements belonging to the same hospital (e.g. paediatric and adult)

  ➤ An HCP may act as a Consortium reporting on several <u>SITES</u> = different hospitals (legal entities) -> to access the registry, sites need to sign the DSA

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REGISTRY ROLL OUT

▶ **Onboarding**

- ➢ Enrolling an HCP into the registry happens on a rolling basis

- ➢ Pilot roll out : one-to-one meetings with HCP teams to assist with the onboarding based on needs, capabilities and data management practices (EURO-NMD Registry helpdesk: registryhelpdesk.euronmd@outlook.com)

▶ **Where we stand?**

- ✓ 1st meeting with Radboudumc (8 Feb)

- ✓ Collab w/ Belgium NMD Registry (BNMDR) & French National Registry for RDs (in progress)

- ✓ Meeting with APHP planned (1 Mar)

- ✓ Meeting with Norwegian registry for hereditary neuromuscular diseases (NORNMD) – (6 Mar)

- ✓ EOI from HCPs in Pisa (AOU Pisana) & Dublin (Beaumont Hospital)

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DATA ENTRY INCENTIVE PILOT

► **Financial compensation** 1 500 € per ERN HCP for the first 100 patients enrolled

    EURO-NMD 23-27 GA ≠101156434 (EUR 123 000)

► **EURO-NMD Registry Reimbursement Protocol**

   ➢ ERN HCPs will need to sign a collaboration agreement with the HCP Network Coordinator (APHP)

   ➢ Each HCP receives a flat amount of 1 500 € upon receipt of invoice **only if** they have completed the minimum mandatory data set (next slide →)

   ➢ Where a single HCP represents a consortium of different clinical sites, **only** the ERN HCP who submitted the Network Application (ERN Member) is eligible

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Set of CDEs for RD Registration
(EU RD Platform)

1– Pseudonym

2– Date of birth

3– Sex

4– Patient's status

5– Date of death

6– Date of first contact with specialised centre

7– Age at onset

8– Age at diagnosis

9– Clinical diagnosis

10– Genetic diagnosis

11– undiagnosed case in HPO / HGVS terms

12– Agreement to be contacted for research purposes

13– Consent to the reuse of data

14– Biological sample available for research

15– Link to a biobank

16– Disability profile score according to WHODAS2.0

DATA SHARING AGREEMENT

WHAT ?

► Relations between <u>Parties</u> : responsibilities (under GDPR), terms and conditions of participation, rights & obligation

► Each of the Parties are Joint Controllers: share responsibility for compliance with GDPR & are jointly liablility!!

WHO (Parties to the DSA) ?

► EURO-NMD Registry <u>Consortium</u>

► Registry <u>coordinator</u>: APHP is the coordinator of the EURO-NMD Registry as well as a <u>data provider</u>

► Registry <u>host</u>: registry is hosted by the University Medical Centre Freiburg (UKLFR), which is also a <u>data provider</u>

► HCPs participating in the Registry (<u>data providers</u>)

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DATA SHARING AGREEMENT

Specific responsibilities of HCPs as joint controllers (Appendix I)

1. Implementation of security measures (pseudonymisation, users access)

2. Dissemination of the information to the Patients

3. Collection of the consent for Patients

4. Recording of consent of Patients

5. Receiving and answering requests of Patients

6. Informing the other joint controllers of a Data Breach

WHAT ?

► Third parties entitled to request data, data access authorization levels & procedures

  ➢ HCP agrees that HCP Data may be shared with third parties according to the conditions defined in the DAP

  ➢ Only aggregated (anonymised) or individual-level (pseudonymised) data will be shared by the Registry

  ➢ DAC approval is always required for access to individual-level (pseudonymised) data
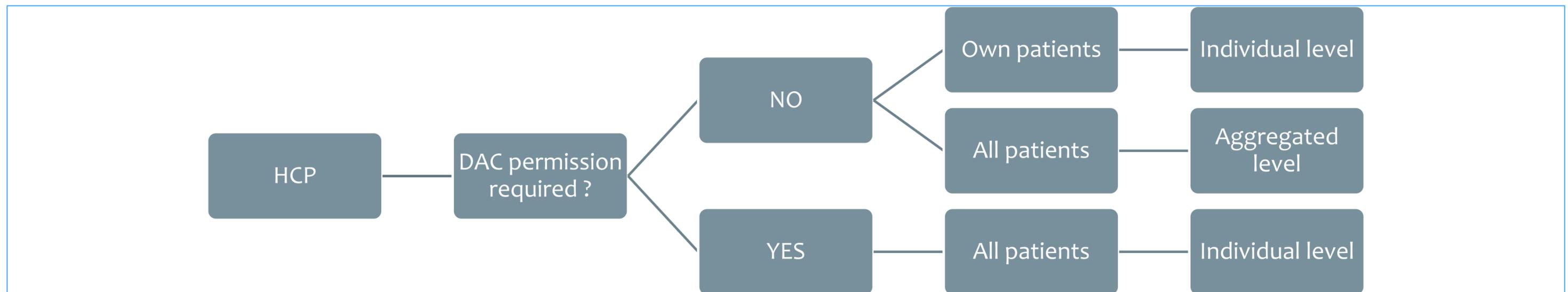
AUTHORSHIP POLICY
(Appendix 7 to DSA)

WHEN ?

▶ Any form of publication produced using data from the Registry

▶ EXCEPTION: contributing hospitals are free to publish their own data (with acknowledgement of the Registry)

Authorship criteria:

▶ Will be granted to <u>at least one</u> representative from HCPs that have contributed with data for the study

▶ Number of co-authors will depend on the size of the study and number of HCPs:

  ▶ the criteria for defining the number of co-authors per HCP will be the number of included patients

  ▶ In special cases, only centres that contributed data for substantial numbers of patients meeting the eligibility criteria for a study will be invited to become co-author

PARTICIPATION REQUIREMENTS

To ensure the success of the Registry, HCPs must:

► ensure adequate resources and accurate information, including:

➢ named staff who will have access to the EURO-NMD Registry

➢ contact person who will be responsible for all registry-related communications

► inform patients about the Registry and obtain patient informed consent

► For a dataset to be considered complete:

➢ collect the mandatory set of data known as the Common Data Elements (CDEs)

► complete follow-up questionnaires annually after the baseline visit

► assist with data quality assurance processes

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