

# EURO-NMD Registry Data Sharing Agreement

## Amendment No. 2 | Public redacted copy

### PUBLIC REFERENCE COPY

Personal representative names, individual DPO contact details listed in Appendix 1, and signature information have been omitted. Detailed technical and organisational security measures have also been withheld from this public copy.

Institutional names, registered addresses and the remaining substantive provisions of the agreement have been retained.

This copy is provided for transparency and information only. The complete executed agreement held by the parties remains the authoritative version.

### EXECUTION

The complete, unredacted Agreement is supplied to prospective participating institutions. Return completed, unsigned Appendices 1 and 8 to the Registry Coordination Team with the legal signatory's full name, position and professional email address.

AP-HP initiates DocuSign: AP-HP signs first, then the HCP, within the same envelope. Alternative electronic or handwritten signing must be coordinated with AP-HP. Both signatures are required; accession takes effect on the date specified in Appendix 8.

The common DSA terms are not open to institution-specific negotiation. Completion of Appendix 1 and local adaptation of the consent form under Article 6 are permitted.

Registry access and patient data entry begin only after accession is executed and effective, applicable regulatory requirements are completed, and technical onboarding is completed.



## Amendment 2 of the Data Sharing Agreement

### BETWEEN:

1. **ASSISTANCE PUBLIQUE HOPITAUX DE PARIS (AP-HP)**, established at 55 Boulevard Diderot, 75012 Paris, France, VAT number FR95267500452, represented for the purposes of this Amendment No.2 of the Agreement by the Head of the Clinical Research and Innovation Department, [redacted], in its capacity as *Coordinator of the Registry* and as a *Consortium Member*;
2. **UNIVERSITY MEDICAL CENTRE FREIBURG (UKLFR)**, on behalf of the University of Freiburg. Faculty of Medicine, Department of Neuropediatrics and Muscle Disorders, established at Breisacher Str. 62, 79106 Freiburg, Germany, represented for the purposes of this Amendment No.2 of the Agreement by [redacted], EU-Liaison Officer, and [redacted], Medical Director of the Department of Neuropediatrics and Muscle Disorders, in its capacity as *Registry Host* and as a *Consortium Member*;
3. **STICHTING RADBOUD UNIVERSITAIR MEDISCH CENTRUM (Radboudumc)**, established at Geert Grooteplein Zuid 10, 6525 GA Nijmegen, Netherlands, VAT number NL861608884B01, represented for the purposes of this Amendment No.2 of the Agreement by [redacted], Head of the Department of Neurology, and [redacted], Head of Valorisation, as a *Consortium Member*;
4. **WORLD DUCHENNE ORGANIZATION (WDO)**, established at Koninginnelaan 69, 3905 GG Veenendaal, Netherlands, represented for the purposes of this Amendment No.2 of the Agreement by its Founder and President, [redacted], as a *Consortium Member*;
5. **STICHTING DUCHENNE DATA FOUNDATION (DDF)**, established at Turfsteeek 135, 3766 HT Soest, Netherlands, represented for the purposes of this Amendment No.2 of the Agreement by its Chair, [redacted], as a *Consortium Member*;
6. **ASSOCIATION INSTITUT DE MYOLOGIE (AIM)**, a French not-for-profit organisation organised under the French Law of 1 July 1901, established at 47-83 Boulevard de l'Hopital, 75651 Paris, France, VAT number FR75483754347, represented for the

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purposes of this Amendment No.2 of the Agreement by its Deputy Secretary General,  
[redacted], as a *Consortium Member*;

7. **ASSOCIATION FRANCAISE CONTRE LES MYOPATHIES – AFM-Téléthon (AFM)**, a French not-for-profit organization organised under the French Law of 1 July 1901, with headquarters at 47-83 Boulevard de l'Hopital, 75651 Paris Cedex 13, France, and principal offices at 1 Rue de l'Internationale, 91000 Evry Courcouronnes, France, VAT number FR00775609571, represented for the purposes of this Amendment No.2 of the Agreement by its President, [redacted], as a *Consortium Member*;

(collectively referred to as the “**Consortium Members**”)

**AND,**

8. **Healthcare Providers (HCPs):**

- ASSISTANCE PUBLIQUE HOPITAUX DE PARIS (AP-HP), acting in its capacity as a healthcare provider;
- UNIVERSITY MEDICAL CENTRE FREIBURG (UKLFR), acting in its capacity as a healthcare provider;
- STICHTING RADBOUD UNIVERSITAIR MEDISCH CENTRUM (Radboudumc), acting in its capacity as a healthcare provider;

(collectively, the “**HCPs**”).

The Consortium Members and the HCPs may be referred to individually as a “**Party**” and collectively as the “**Parties**”.

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**WHEREAS,**

Whereas the Parties have concluded a data sharing agreement EURO-NMD Registry (Reference No APHP 2021-578 /01) (hereinafter the “Agreement”) on 10/01/2024.

Whereas the Parties have signed an amendment No.1 to replace the former legal name of STICHTING UNITED PARENT PROJECTS MUSCULAR DYSTROPHY (UPPMD)” by “WORLD DUCHENNE ORGANIZATION (WDO)”.

Whereas the Agreement was initially intended to govern participation of Healthcare Providers affiliated with the ERN EURO-NMD.

Whereas the Parties now wish to extend participation to additional Healthcare Providers, including those not affiliated with the ERN EURO-NMD.

**ARTICLE 1 – OBJECT OF THIS AMENDMENT NO.2**

By this amendment No.2 (hereinafter the “Amendment No.2”), the Parties decide to replace entirely the provisions of the Agreement notably in order to adapt their wording to the participation of the Healthcare Providers not affiliated with the ERN EURO-NMD.

**ARTICLE 2: MODIFICATION OF THE AGREEMENT:**

The provisions of the Agreement are replaced in their entirety by the following:

**Whereas**

- (a) European Reference Networks (ERNs) are virtual networks of healthcare providers across Europe that aim to tackle rare and complex diseases requiring highly specialised treatment, concentrated knowledge and resources. Twenty-four ERNs have been established by the European Commission under Directive 2011/24/EU on Patients’ Rights in Cross-Border Healthcare, including the European Reference Network for Rare Neuromuscular Diseases (“ERN EURO-NMD”), which focuses on rare neuromuscular disorders. Neuromuscular diseases comprise a broad group of related disorders representing a major cause of mortality and lifelong disability in both children and adults.
- (b) On 1 May 2020, the European Commission, as funding authority, and Assistance Publique – Hôpitaux de Paris (“AP-HP”), as Coordinator of the ERN EURO-NMD, entered into Grant Agreement No. 947598 under the European Union’s Third Health Programme for the implementation of the action entitled “Patient Centred and

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Interoperable Registry Hub for Rare Neuromuscular Diseases – EURO-NMD Registry” (the “Action”). The Action was implemented by AP-HP together with University Medical Centre Freiburg (“UKLFR”), Radboud University Medical Center (“Radboudumc”), Stichting United Parent Projects Muscular Dystrophy (“UPPMD”), now the World Duchenne Organization (“WDO”), Duchenne Data Foundation (“DDF”), Association Institut de Myologie (“AIM”), and Association Française contre les Myopathies – AFM-Téléthon (“AFM-Téléthon”), as beneficiaries of the Grant Agreement, and resulted in the establishment of the EURO-NMD Registry.

- (c) AP-HP, UKLFR, Radboudumc, WDO, DDF, AIM, and AFM-Téléthon (collectively, the “Consortium Members”) entered into a Consortium Agreement on 1 May 2020 governing their collaboration in the establishment, development, maintenance, and governance of the EURO-NMD Registry.
- (d) The EURO-NMD Registry is a centralised patient registry that collects pseudonymised clinical data from paediatric and adult patients with rare neuromuscular diseases across Europe (the “Registry”). The Registry enables healthcare professionals to collaborate in improving the healthcare of patients with rare and complex neuromuscular conditions, advancing knowledge of these diseases, and strengthening clinical research to improve diagnosis, risk prediction, and the development of innovative therapies (the “Purpose”).
- (e) The Healthcare Providers (HCPs) are institutions that provide care to patients with rare neuromuscular diseases and wish to contribute to the ERN EURO-NMD Registry by sharing, with the consent of their Patients, Personal Data relating to such Patients in accordance with this Agreement.
- (f) Certain HCPs, namely AP-HP, UKLFR, and Radboudumc (collectively, the “Founding HCPs”), are also Consortium Members and members of the ERN EURO-NMD. They participate in the Registry in their dual capacity as Consortium Members and HCPs, and their obligations under this Agreement apply in both capacities.
- (g) Additional HCPs (the “Acceding HCPs”), whether or not affiliated with the ERN EURO-NMD, may participate in the Registry by executing an Accession Form (Appendix 8), with accession taking effect on the date specified therein.
- (h) The Parties therefore wish to enter into this Data Sharing Agreement (the “Agreement”) to establish the terms and conditions governing the contribution, Processing, sharing, access and use of data within the Registry.

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## I. Definitions

### I.1. Definitions:

Words beginning with a capital letter shall have the meaning defined in this Agreement or, where applicable, in Article 4 of the GDPR.

### I.2. Additional definitions:

|                                         |                                                                                                                                                                                                                                              |
|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>“Accession Form”</b>                 | means the document attached as Appendix 8 through which an Acceding HCP formally agrees to become a Party to this Agreement and to comply with all its terms and obligations;                                                                |
| <b>“Agreement”</b>                      | means this Data Sharing Agreement, including its preamble, recitals, annexes and any amendments thereto, which collectively govern the contribution, processing and sharing of data within the EURO-NMD Registry;                            |
| <b>“Aggregate Data”</b>                 | means all data derived from the Registry Data, no longer attributable to any individual Patient. This can include descriptive statistics, comparative statistics, graphs, presentations, counts or any other derived or aggregated data set; |
| <b>“Appendices”</b>                     | means the documents attached to this Agreement and forming an integral part thereof, as may be amended or updated in accordance with the procedures set out in this Agreement;                                                               |
| <b>“Consortium Members”</b>             | means the legal entities listed in the preamble that jointly developed and maintain the EURO-NMD Registry and that are Parties to this Agreement in their capacity as members of the EURO-NMD Registry Consortium;                           |
| <b>“Coordinator”</b>                    | means Assistance Publique – Hôpitaux de Paris (AP-HP), acting in its capacity as coordinating institution of the ERN EURO-NMD and the EURO-NMD Registry;                                                                                     |
| <b>“Data Access Committee” or “DAC”</b> | means the independent committee appointed to approve access to Registry Data in accordance with the Data Access Policy set out in Appendix 6;                                                                                                |
| <b>“Data Access Policy”</b>             | means the policy adopted by the Steering Committee defining the principles, procedures, and criteria governing access to data collected in the EURO-NMD Registry;                                                                            |

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| <b>“Data Breach”</b>                          | means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data transmitted, stored or otherwise processed;                                                                                                                                                                                                                                                                                                                                         |
| <b>"Data Protection Legislation"</b>          | means (a) any law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding restriction (as amended, consolidated or re-enacted from time to time) which relates to the protection of individuals with regards to the processing of Personal Data to which a Party is subject and the GDPR or all legislation enacted in each Country in respect of the protection of Personal Data; and (b) any code of practice or guidance published by a Regulatory Body from time to time ; |
| <b>“Data Protection Officer”<br/>or “DPO”</b> | means the data protection officer appointed by a Party to oversee compliance with European Data Protection Legislation in relation to the processing operations carried out by that Party;                                                                                                                                                                                                                                                                                                                                                  |
| <b>“Data Subject”</b>                         | Means Patients and Users;                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>“Effective Date”</b>                       | means the date on which this Agreement enters into force, as specified on the signature page or, for acceding HCPs, the date of effect indicated in their duly signed Accession Form;                                                                                                                                                                                                                                                                                                                                                       |
| <b>"GDPR"</b>                                 | means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data and repealing Directive 95/46/EC (General Data Protection Regulation), OJ L 119, 4.5.2016, p. 1;                                                                                                                                                                                                                                                          |
| <b>“Healthcare Provider”<br/>or “HCP”</b>     | means hospitals, clinical centres, or other healthcare organisations providing specialised diagnosis, care and treatment services for patients with rare neuromuscular diseases, whether or not formally affiliated with the ERN EURO-NMD, and includes both Founding HCPs and Acceding HCPs participating under this Agreement;                                                                                                                                                                                                            |
| <b>"HCP Data"</b>                             | means all Personal Data entered by the HCP in the Registry, including Users’ Data and the Patients’ Data;                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| <b>“Joint Controllers”</b>                    | means two or more Controllers that jointly determine the purposes and means of Processing in accordance with Article 26 of the GDPR. For the purposes of this Agreement, the Parties act as Joint Controllers with respect to the Processing of Personal Data carried                                                                                                                                                                                                                                                                       |

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|                                   | out within the Registry, in accordance with the respective roles and responsibilities allocated in Appendix I;                                                                                                                                                                                                                                                                                            |
| <b>“Patient”</b>                  | means the natural person selected by the HCP, receiving treatment at the HCP and having consented to the processing of their Personal Data through the Registry;                                                                                                                                                                                                                                          |
| <b>“Patient Data”</b>             | means the Personal Data relating to Patients of an HCP that are entered into the Registry by the HCP using one of the available questionnaire forms, as further described in the Registry Data Dictionary;                                                                                                                                                                                                |
| <b>“Pseudonymisation”</b>         | means the processing of Personal Data in such a manner that the Personal Data can no longer be attributed to a specific Data Subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and organisational measures to ensure that the Personal Data are not attributed to an identified or identifiable natural person; |
| <b>“Recipients”</b>               | means any natural or legal person, public authority, other HCP, agency or other body authorized by the Data Access Committee to receive Pseudonymised and/or Aggregated Registry Data for approved Research Projects in accordance with the Data Access Policy (Appendix 6);                                                                                                                              |
| <b>“Registry Data”</b>            | means the collection of Patients’ Data submitted by HCPs and maintained in the Registry Database;                                                                                                                                                                                                                                                                                                         |
| <b>“Registry Data Dictionary”</b> | means the document describing the data elements or data items of the Registry Database, together with the corresponding specifications, definitions, formats, and coding applicable to each variable collected within the Registry;                                                                                                                                                                       |
| <b>“Regulatory Body”</b>          | means any competent governmental, statutory, regulatory, supervisory, or enforcement authority or regulator having jurisdiction over the activities carried out by any Party pursuant to this Agreement;                                                                                                                                                                                                  |
| <b>“Registry Database”</b>        | means the structured data system of the Registry designed to collect, organise, store, manage, and display Registry Data in a systematic manner, accessible by electronic means and/or via internet, and including all systems, infrastructure, and processes necessary for its operation and access;                                                                                                     |
| <b>“Registry Host”</b>            | means University Medical Center Freiburg, which hosts and maintains the Registry Database;                                                                                                                                                                                                                                                                                                                |

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|                                  |                                                                                                                                                                                                                                                                                                                                                        |
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| <b>“Research Project”</b>        | means any research project approved by the Data Access Committee and using Registry Data;                                                                                                                                                                                                                                                              |
| <b>“Results”</b>                 | means any results, in whatever form, including any creation, invention, specification, information, knowledge, data, know-how, or process developed in the course of a Research Project, whether or not capable of protection by intellectual property rights, as well as any product, prototype or process resulting from such Research Project;      |
| <b>“Research Project Leader”</b> | means the legal entity that initiates, coordinates, and oversees a Research Project and assumes responsibility for its conduct;                                                                                                                                                                                                                        |
| <b>“Steering Committee”</b>      | means the primary governing and decision-making body of the EURO-NMD Registry;                                                                                                                                                                                                                                                                         |
| <b>“Supervisory Authority”</b>   | means an independent public authority established by a member State of the European Union pursuant to the GDPR, responsible for monitoring the application of the GDPR in order to protect the fundamental rights and freedoms of natural persons in relation to the Processing of Personal Data, and vested with investigative and corrective powers; |
| <b>“Users”</b>                   | means healthcare professionals or other qualified staff working at an HCP and authorised to collect, enter, and/or access HCP Data through the Registry Database;                                                                                                                                                                                      |
| <b>“Users’ Data”</b>             | means the Personal Data collected about each User and the User’s institution in connection with the creation and management of a Registry account, including the User’s name, email address, institution name, and other relevant institutional details.                                                                                               |

## 2. Purpose

The purpose of this Agreement is to set out with respect to the European Reference Network Registry for Rare Neuromuscular Diseases (EURO-NMD Registry), the relations between the Consortium Members, notably the Coordinator and the Registry Host, and the HCP that participates in the EURO-NMD Registry, in particular concerning their respective responsibilities as Joint Controllers, the terms and conditions of participation in the Registry, and related rights and obligations.

## 3. Purpose of the Processing & compliance with data privacy laws

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- 3.1. The Parties declare to each other that they shall Process Registry Data in a proper, careful, and transparent manner, in accordance with applicable Data Protection Legislation on the Processing of Personal Data, particularly (but not exclusively) with regard to the GDPR.
- 3.2. The Parties and each Consortium Member individually, undertake to process Registry Data exclusively for the Purpose for which Registry Data is collected, within the limits of the informed consent of Patients.
- 3.3. The Parties shall not collect more Personal Data than strictly necessary for the Purpose.
- 3.4. The Parties agree on the specification of the Processing and on their respective responsibilities, as described in Appendix 1, and the data entry and export process used in the Registry, as depicted in the Data Flow Diagram in Appendix 2.

#### **4. Lawfulness of Processing of Registry Data**

In order to ensure the lawfulness of the Processing of Registry Data, according to Article 6 of the GDPR, the Parties may process Registry Data only if and to the extent that at least one of the criteria set out in Article 6 of the GDPR applies.

Each of the Parties shall assess and confirm the validity of the criteria they have defined for the lawfulness of their Processing of Registry Data before starting the collection or Processing of Registry Data.

The Parties have defined the consent for the Processing of Patient's Data, as set out in Article 6.1a) of the GDPR.

The Parties have defined the legitimate interest of the Coordinator and the Registry Host in administering the Registry, for the Processing of User's Data, as set out in Article 6.1f) of the GDPR.

#### **5. Processing of special categories of Personal Data**

Special categories of Personal Data are defined by Article 9 of the GDPR as "personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, and the Processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation".

Should Registry Data fall into a special category of Personal Data, and in particular genetic data, data concerning health, or data revealing racial or ethnic origin, the Parties shall not process this Data unless one of the legal bases listed in Article 9-2 a), i) or j) of the GDPR applies.

Each of the Parties shall assess and confirm the validity of the legal basis under which they are Processing any Registry Data falling into a special category of Personal Data, before starting the Processing of such Registry Data.

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## 6. Data Subject rights

6.1. The HCP is solely responsible for:

- informing Patients in accordance with Articles 12, 13, and 14 of the GDPR, as applicable;
- ensuring compliance with national and local Data Protection Legislation;
- obtaining, documenting, and retaining valid informed consent from Patients prior to enrolling them in the Registry and entering any Patient Data into the Registry.

6.2. To fulfil these obligations, the HCP shall ensure that an appropriate informed consent process is in place.

The HCP may:

- use the template informed consent form provided in Appendix 3 as a basis, translating and adapting it as necessary to comply with applicable national, institutional, and ethical requirements; or
- use an existing consent form already in use at the HCP, provided it is properly adapted to explicitly cover participation in the EURO-NMD Registry and complies with all applicable Data Protection Legislation.

6.3. In all cases, the final version of the patient consent form used by the HCP must:

- be age-appropriate, and
- incorporate the core information listed in Appendix 3.

For the avoidance of doubt, the preparation, translation, legal validation, and adaptation of the patient consent form shall remain the sole responsibility of the HCP, which shall ensure its compliance with all applicable national, institutional, ethical, and regulatory requirements.

6.4. The HCP shall review, at least every ten (10) years, the necessity of continuing the Processing of Patients' Data within the Registry and, where necessary, obtain renewed consent from Patients.

6.5. The HCP shall ensure that requests made Users or Patients under Articles 15 to 18, 20, and 21 of the GDPR relating to the exercise of their rights of access, rectification, portability, restriction of Processing, objection, and erasure (where applicable) concerning their Personal Data are appropriately managed and centralised.

Requests relating to Patients' Data shall be handled through the treating medical doctors of the HCP, who maintain the local re-identification key, while the HCP's Data Protection Officer shall coordinate the management and resolution of such requests with the assistance of the Data Protection Officers of the Coordinator and/or the Registry Host, as appropriate.

The contact details of the HCP's Data Protection Officer shall be provided in the Appendix I.

The Parties acknowledge that Patients may withdraw or change their initial informed consent, or object to the Processing of their Personal Data by exercising their rights under Article 21 of

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GDPR. The HCP shall promptly notify the Coordinator and the Registry Host of any such withdrawal, change or objection that may affect the use of such Patient's Data within the Registry.

- 6.6. The Parties shall assist each other, through appropriate technical and organisational measures, in fulfilling their respective obligations to respond to Data Subjects' rights requests under Chapter III of the GDPR.

## 7. Security measures

- 7.1. Each Party shall implement appropriate technical and organisational measures to protect and safeguard Registry Data, in accordance with the requirements of the GDPR, including, in particular, the security measures required under Articles 25 and 32 of the GDPR.
- 7.2. The Parties agree to implement the technical and organisational security measures described in the Data Security Policy set out in Appendix 4, which forms an integral part of this Agreement.
- 7.3. The Registry Host shall ensure that appropriate technical and organisational measures are implemented to safeguard Registry Data against any unauthorised or unlawful Processing and against accidental loss, alteration, destruction, or disclosure.
- 7.4. Each HCP shall ensure that all Patient Data entered into the Registry is Pseudonymised with re-identification keys retained securely at the HCP and never transmitted to the Registry.
- 7.5. The Coordinator shall operate a Registry helpdesk to provide technical and operational support to the HCPs in relation to the use of the Registry.

## 8. Contracting with Processors

- 8.1. Each Party hereby warrants that any Processing performed by a third party on its behalf is governed by a contract in accordance with Article 28 of the GDPR.
- 8.2. The HCP hereby provides written authorisation to the Coordinator and the Registry Host to appoint subcontractor(s) as Data Processors regarding the Registry. The Coordinator and the Registry Host shall ensure that industrial subcontractor(s) operate according to Good Industry Practice and Security Requirements without prejudice to Article 22 herein. The Coordinator and the Registry Host shall provide the other Parties, within sixty (60) days of the end of each calendar year, a list of Processors engaged in Processing Registry Data during the preceding calendar year, giving the HCP the opportunity to raise reasonable, data protection-related objections.
- 8.3. Moreover, the Coordinator and the Registry Host shall ensure that the chosen Processor processes Personal Data in a proper and careful manner that complies with applicable Data Protection Legislation. Agreements regarding the Processing of Personal Data by a Processor shall be laid down in a written Data Processing Agreement within the meaning of Article 28 of the GDPR.

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- 8.4. The obligations arising from this Agreement shall also apply to those who process Personal Data under the Parties' authority, such as the Parties' Processors they have contracted.
- 8.5. The Coordinator has the right to inspect the Data Processing Agreement(s) referred to in Article 8.1 at all times.

## **9. Transfer of Registry Data to third countries or international organizations**

- 9.1. The Consortium Members agree and warrant each other that the Registry Database and Registry Data are hosted in the European Union.
- 9.2. The Registry is hosted by the Clinical Trials Unit, Faculty of Medicine and Medical Center, University of Freiburg, Freiburg, Germany.
- 9.3. The Data Access Committee may authorise the transfer of Patient Data to third countries or international organisations for Research Projects, provided that the Patient's informed consent (or that of their legal representative) covers such transfer.

In such cases, the Research Project Leader shall ensure compliance with chapter V of the GDPR relating to transfers of personal data to third countries or international organisations, including, where applicable, the implementation of appropriate safeguards such as the Standard Contractual Clauses adopted by the European Commission, in order to ensure that the level of protection guaranteed under the GDPR is not undermined.

- 9.4. Users' Data shall not be transferred to any third country outside the European Union or to any international organisation.

## **10. Privacy impact assessment**

- 10.1 On behalf of the Consortium Members, the Coordinator shall ensure that a Privacy Protection Impact Assessment ("DPIA") is carried out in relation to the envisaged Processing of Registry Data, in accordance with Article 35 of the GDPR.
- 10.2 Each HCP shall consult with its Data Protection Officer (or other relevant institutional body) and/or the relevant Supervisory Authority, as appropriate, to determine whether a DPIA is required in relation to its own Processing activities involving HCP Data, taking into account the nature, scope, context, and purposes of such Processing. Where such an assessment is required, the HCP shall ensure that it is carried out in accordance with Article 35 of the GDPR.
- 10.3 The Parties shall consult the competent Supervisory Authority, in accordance with Article 36 of the GDPR where a DPIA indicates that the envisaged Processing would result in a high risk in the absence of measures taken to mitigate such risk.
- 10.4 The Parties shall assist each other, where necessary, in the performance of their respective Privacy Impact Assessments.

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## 11. Data Breach

- 11.1 The Party under whose responsibility a Personal Data Breach occurs shall inform the other Parties without undue delay and, where feasible, no later than twenty-four (24) hours after becoming aware of the breach and shall proceed with any notification required to the competent Supervisory Authority in accordance with Article 33 of the GDPR.
- 11.2 The noticing Party shall provide the other Parties, without undue delay, with the following information, to the extent available:
- a description of the security breach, the nature and circumstances of the Data Breach;
  - the categories of Personal Data that was subject to the Data Breach and the approximate number of individuals and Personal Data affected;
  - the name and contact information of the Parties' Data Protection Officer and/or any other point of contact from whom additional information may be obtained;
  - a description of the likely consequences of the security breach;
  - a description of the measures to remedy the security breach, including, if applicable, measures to mitigate any adverse effects;
  - any other information that the other Parties may reasonably request regarding the security breach.
- 11.3 Upon becoming aware of a Personal Data Breach, the Parties shall consult each other without undue delay regarding actual and potential consequences for all Parties.
- 11.4 The Parties shall keep each other informed of the latest developments relating to the Personal Data Breach.
- 11.5 Notifications under this Article shall be made as follows:
- For each HCP, to the contact details specified in Appendix I
  - for the Coordinator, to the following address: [protection.donnees.dsi@aphp.fr](mailto:protection.donnees.dsi@aphp.fr)
- 11.6 The HCP shall fulfil its obligations under Article 34 of the GDPR to inform Patients of a Personal Data Breach where such breach is likely to result in a high risk to their rights and freedoms.
- 11.7 The Coordinator shall fulfil its obligations under Article 34 of the GDPR to inform Users in the event of a Personal Data Breach where such breach is likely to result in a high risk to their rights and freedoms.
- 11.8 Each Party shall remain independently responsible for notifying the competent Supervisory Authority of any Personal Data Breach occurring under its responsibility, in accordance with applicable Data Protection Legislation.

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- 11.9 Any costs incurred in resolving a Personal Data Breach and implementing corrective measures to prevent recurrence shall be borne by the Party under whose responsibility the breach occurred. The Parties may nevertheless agree to share such costs where the corrective measures implemented provide a common benefit to multiple Parties.
- 11.10 The Parties shall assist each other, by appropriate technical and organisational measures, in fulfilling their respective obligations under Article 33 and 34 of the GDPR.
- 11.11 Each Party shall remain independently responsible for documenting Personal Data Breaches as required under the GDPR.

## **12. Complaints**

- 12.1 Each Party shall be responsible for handling any complaints from Data Subjects concerning infringement of the GDPR or other applicable Data Protection Legislation for which that Party is responsible, in accordance with Article 15 (Liability).
- 12.2 If a Party receives a complaint which, in whole or in part, falls within the responsibility of another Party, it shall, without undue delay and in documented form, forward the relevant part of the complaint to the responsible Party for reply.
- 12.3 The Parties shall, on a confidential basis, keep each other informed of complaints received and their handling, insofar as relevant to this Agreement.

## **13. Records of Processing activities**

- 13.1 Each Party shall maintain in writing, including in electronic format, the records of its Processing related to Registry Data, in accordance with Article 30 of the GDPR.
- 13.2 Each Party shall provide the other Parties, where necessary, with the information required to maintain their respective records of Processing activities in accordance with Article 30 of the GDPR.

## **14. Duration of Processing, Data storage and Data disposal**

### **14.1 Duration of the Processing:**

The Processing of HCP Data by the HCP is deemed to start at the earliest of either the date on which the HCP first collects such HCP Data or the date on which the HCP is granted access to the Registry under this Agreement.

The Processing of such HCP Data shall be deemed to end for each Party upon termination of this Agreement in accordance with Article 24 or upon discontinuation of the Registry, as applicable.

Pursuant to the Governance rules (Appendix 5), the Steering Committee shall determine, in accordance with applicable Data Protection Legislation, whether Registry Data shall be

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destroyed, returned to the originating HCP, or retained for lawful scientific and research purposes under appropriate safeguards in the event that the Registry or the EURO-NMD Network is discontinued for any reason, regarding the data collected prior to discontinuation.

#### **14.2 Data storage:**

Patient Data shall be stored in the Registry Database for a period of ten (10) years from the date of collection. If necessary, after this period of time, Patients shall be requested to renew their consent.

Users' Data shall be stored only for as long as the relevant User maintains an active role in the Registry as an employee of the respective HCP, unless further retention is required under applicable law or for security, audit, or accountability purposes.

Registry Data disclosed for Research Projects shall be retained by the relevant Research Project Leader in accordance with applicable Data Protection Legislation and the terms of the approved Research Project.

#### **14.3 Data disposal:**

Where a Patient withdraws consent, the relevant Patient Data shall not be used in new Research Projects but may continue to be Processed for Research Projects already approved and lawfully commenced prior to withdrawal, where necessary to safeguard scientific validity.

Where a User leaves the HCP, the relevant Users' Data shall be deleted or anonymised, unless further retention is required under applicable law or for legitimate security, audit, or accountability purposes.

Deleted Patient Data or User' Data may remain temporarily stored in encrypted backup systems for a maximum period of three (3) months before being permanently deleted.

Upon expiration or termination of this Agreement, the Coordinator shall destroy all HCP Data received from the HCP. Upon request from the HCP, the Coordinator shall confirm in writing the complete deletion of such HCP Data.

Notwithstanding the foregoing, the Registry Host may retain a single copy of the HCP Data strictly for the purpose of fulfilling lawful Registry Data transfer requests by Research Project Leaders for replication or validation of Research Projects conducted prior to termination of this Agreement.

### **15. Liability**

15.1 Each HCP shall maintain, at its own cost, appropriate insurance coverage or self-insurance arrangements with reputable insurers, in amounts reasonably sufficient to cover liabilities arising under this Agreement.

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- 15.2 Each Party shall remain solely responsible for risks of damage to its personnel, systems, and property arising from or in connection with the performance of its obligations under this Agreement.
- 15.3 Each Party shall be solely liable for any material and non-material damage, losses, costs, or third-party claims resulting from its own negligence, fault or omission in the performance of this Agreement, or any infringement of the GDPR or other applicable Data Protection Legislation for which it is responsible.
- 15.4 The compensation of Data Subjects for damage resulting from an infringement of the GDPR shall be governed by Article 82 of the GDPR. Any reference to Article 82 of the GDPR in this Agreement shall be interpreted in accordance with the version of the GDPR applicable at the relevant time.

## 16. Audit

- 16.1 If a Regulatory Body, including a Supervisory Authority, notifies a Party of an audit or other investigation relating to the Registry, the Party first notified shall promptly inform the other Parties of such notification, including by providing copies of any relevant correspondence received from such Regulatory Body or Supervisory Authority in connection with the audit or investigation, as well as any responses or other communications exchanged with such authority.

In such event, the Parties undertake to facilitate access to the relevant operational environments for such Regulatory Bodies or Supervisory Authorities and to cooperate fully with each other.

The audited Party shall, where legally permissible, consult the other Parties prior to providing substantive information relating to the Registry or shared Processing activities to the relevant authorities, in order to ensure consistency and coordination of responses. Nothing in this Agreement shall prevent a Party from complying with mandatory legal or regulatory obligations or from cooperating directly with a competent authority where required by applicable law.

For the purposes of such audit or investigation, the audited Party undertakes to communicate without undue delay to the other Parties any information or documentation requested by the relevant authorities, in the format required by such authorities.

- 16.2 Subject to ten (10) working days' prior notice, the Coordinator reserves the right to carry out any verification that it deems necessary to ascertain the HCP's compliance with its obligations under this Agreement, including through audit or inspection procedures.

The HCP shall cooperate in good faith with such audits carried out by the Coordinator itself or by a trusted third party auditor appointed by the Coordinator.

The HCP shall provide access to relevant documentation, records, systems, and personnel reasonably necessary to demonstrate compliance with this Agreement.

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Where an audit identifies non-compliance with this Agreement: (i) corrective measures will be studied by the Parties, which will decide on the appropriate follow-up and any corrective measures to be implemented, at no additional cost, (ii) the audit costs will be borne by the breaching HCP.

The Coordinator shall not have the right to conduct more than one such audit within any twelve (12)-month period, unless otherwise required by applicable law, regulation, or a competent Supervisory Authority.

## **17. Specific obligations of the Coordinator**

The Coordinator shall ensure transparency and accountability by making the following information available to participating HCPs and, where applicable, through the public website of the Registry:

- an up-to-date list of all HCPs contributing data to the Registry;
- a list of all Research Projects approved by the Data Access Committee;
- a list of all publications, presentations, and publicly available Results arising from the use of Registry Data;
- annual activity reports relating to the Registry.

## **18. Specific obligations of the HCP**

18.1 The HCP shall, where required, obtain and keep on file any license, approval or equivalent authorisation necessary for participation in the Registry.

18.2 Each HCP, in its capacity as Controller of the HCP Data and the local Processing activities carried out at the HCP, shall fully comply with all national, federal, state, and local laws and regulations pertaining to the activities contemplated herein including, without limitation, applicable Data Protection Legislation, Regulation EU No 536/2014 on clinical trials on medicinal products for human use (“Clinical Trials Regulation”); Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 (General Data Protection Regulation – GDPR); the principles of the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) E6 and E11; generally accepted professional standards relating to clinical care and research; and any applicable institutional, ethical, or professional guidelines governing the conduct of research at the hospital or other site where the data is collected.

18.3 In particular, each HCP shall remain independently responsible for:

- the collection of Patient Data;
- the management and secure retention of the local patient re-identification key;
- the informed consent process; and

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- compliance with applicable Data Protection Legislation in relation to the HCP Data and local Processing activities carried out at the HCP.
- 18.4 The HCP shall ensure, with good faith and care, the completion of the Registry Database with the set of Common Data Elements released by the European Platform on Rare Disease Registration (EU RD Platform) which are mandatory for all Patients enrolled in the Registry. Collection of extended datasets as described in the Registry Data Dictionary, is optional but encouraged where feasible. The Parties acknowledge that the Steering Committee may, by formal decision, designate additional datasets as mandatory in the future.
- 18.5 The HCP shall use reasonable efforts to ensure longitudinal follow-up of enrolled Patients at least once a year and to provide annual status updates on the Patients enrolled in the Registry using the appropriate questionnaire forms provided in the system.
- 18.6 In addition to its other obligations under this Agreement, each HCP shall respond in good faith to reasonable information requests from the Coordinator that are necessary for fulfilling the Coordinator's obligations under Article 17.

## 19. Data ownership

- 19.1 Patients remain Data Subjects under the GDPR and provide explicit informed consent prior to the inclusion of their Patient Data in the Registry for the agreed Purpose. Patients shall retain all rights relating to their Personal Data in accordance with applicable Data Protection Legislation.
- Users acknowledge that their Users' Data must be provided to the Coordinator and/or the Registry Host in order to create and manage access to the Registry for purposes that are legitimate, necessary for the operation and governance of the Registry, and consistent with the legitimate interests of the Coordinator as described in Article 4 of this Agreement. Users shall retain all rights relating to their own Personal Data in accordance with applicable Data Protection Legislation.
- 19.2 Each HCP shall remain responsible, in its capacity as Controller of the HCP Data and local Processing activities carried out at the HCP, for the collection and Processing of Patient Data contributed to the Registry.
- 19.3 The Registry Host and/or the Coordinator shall remain responsible for the collection and Processing of Users' Data in accordance with their respective roles and responsibilities under this Agreement.
- 19.4 Except for the rights expressly granted under this Agreement, nothing herein shall be construed as conferring upon the Coordinator, the Registry Host, or any other Party any ownership right, title, licence, exploitation right, or other proprietary interest in the HCP Data contributed by an HCP.

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- 19.5 Registry Data may be used by the contributing HCP, authorised Research Project Leaders, and authorised Recipients strictly within:
- the limits of the Patients’ informed consent;
  - the scope approved by the Data Access Committee (DAC); and
  - the requirements of applicable Data Protection Legislation.
- 19.6 Without requiring prior authorisation from the DAC, each HCP retains the right to use its own HCP Data for its internal healthcare, scientific, academic, educational, audit, regulatory, or research purposes, provided that such use complies with applicable Data Protection Legislation, ethical requirements, professional standards, and any other applicable legal or institutional obligations.
- 19.7 The Consortium Members jointly own the intellectual property rights and database rights relating to the Registry Database as such, namely its structure, organisation, arrangement, software, environment, and compilation of Registry Data. For the avoidance of doubt, these database rights do not affect the rights of Patients as Data Subjects under GDPR, nor the responsibilities of HCPs as Controllers of the Patient Data they contribute to the Registry.
- 19.8 No Party shall file, directly or indirectly, in its own name or in the name of any third party, any patent, copyright, database right, trademark, or other intellectual property claim asserting ownership over the Registry Database or Registry Data.

## 20. Results

### 20.1 Ownership of Results

The HCP retains all rights and interests in its own HCP Data.

The Parties agree that Results arising from a Research Project shall belong to the relevant Research Project Leader.

Where a Research Project is conducted jointly by a Research Project Leader together with one or more Parties to this Agreement, including Consortium Members or HCPs contributing data to the Registry, the ownership of Results shall belong:

- to the Party that solely generated or developed such Results; or
- jointly to the Parties that jointly generated the Results,

unless otherwise agreed in writing between the relevant Parties.

Each Party undertakes not to file, in its own name or in the name of a third party, in any country whatsoever, an application for patents or intellectual property rights relating to the property rights of the other Parties. Any filing of an industrial property title on co-owned rights shall be made jointly by the Parties.

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## 20.2 **Use of the Results**

Each Party may freely use the Results and intellectual property rights it holds alone in accordance with Article 20.1.

For the avoidance of doubt, Results do not include Patients' Data or other Personal Data contained in the Registry.

## 21. **Data Access**

21.1 The Registry Host provides secure access to the system to authorised Users of the Registry and to Recipients. The Registry Host ensures that Registry Data are stored and processed on secure servers with an appropriate level of encryption and audit logging as defined in the Data Security Policy (Appendix 4).

21.2 Recipients and Users of the Registry shall access Registry Data strictly in accordance with the Data Access Policy set out in Appendix 6 (the "Data Access Policy").

21.3 The Parties shall limit access to Registry Data to the minimum necessary in accordance with the principle of least privilege, ensuring that Users' access follows their role-based permissions under the Data Access Policy and that Recipients' access is limited to the specific dataset, purpose and duration approved by the Data Access Committee (DAC).

Users of the Registry may access only the Patients' Data contributed by their own HCP and their own Users' Data through the Database within the scope of their role-based authorisation, as defined in the Data Access Policy.

21.4 The HCP acknowledges and agrees that HCP Data may be disclosed to authorised Recipients in Aggregated or Pseudonymised form in accordance with the Data Access Policy and subject to approval by the DAC.

21.4.1 The HCP shall be responsible for all access to the Registry and Registry Data by its Users through accounts issued under its authority. The HCP shall promptly notify the Coordinator whenever a User changes role, leaves the HCP, or otherwise no longer requires access to the Registry, so that the corresponding access rights may be modified, suspended, or revoked without undue delay.

## 22. **Confidentiality**

### 22.1 **General disposition**

22.1.1 All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Receiving Party") in connection with Research Projects or in relation with business, affairs, customers, clients or suppliers of the other Party, is "Confidential Information".

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22.1.2 The Receiving Party hereby undertakes for a period of five (5) years after the end of the Research Project:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent by the Disclosing Party;
- ensure that internal distribution of Confidential Information by the Receiving Party shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information disclosed to the Receiving Party, including all copies thereof, and to delete all information stored in a machine-readable form to the extent practically possible. The Receiving Party may keep a copy where required to comply with applicable laws or regulations or to prove ongoing obligations, provided that the confidentiality obligations herein shall continue to apply as long as such copy is retained.

22.1.3 The Receiving Party shall be responsible for the fulfilment of the above obligations on the part of its employees or third parties involved in the Research Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Research Project and/or after the termination of the contractual relationship with the employee or third party.

22.1.4 The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Receiving Party can show by written evidence that:

- the Confidential Information has become or becomes publicly available by means other than a breach of the Receiving Party's confidentiality obligations;
- the Disclosing Party subsequently informs the Receiving Party that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Receiving Party without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the Confidential Information, at any time, was developed by the Receiving Party completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Receiving Party prior to disclosure, or
- the Receiving Party is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 22.1.7 hereunder.

22.1.5 The Receiving Party shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of a Research Project as with its own confidential and/or proprietary information, but in no case less than reasonable care.

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22.1.6 Each Party shall promptly advise the other Party in writing of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

22.1.7 If any Party becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure:

- notify the Disclosing Party, and
- comply with the Disclosing Party's reasonable instructions to protect the Confidential Information.

## **22.2 Confidentiality of Personal Data**

22.2.1 All Personal Data, including pseudonymised Patient Data processed within the Registry, are considered Confidential Information and must therefore be treated as such. The Parties shall impose this duty of confidentiality on all natural persons and legal entities they engage to process Personal Data, including but not limited to employees, Processors and other authorised Recipients of Personal Data.

22.2.2 The Parties shall keep all Personal Data confidential and shall not disclose them to internal or external parties in any way whatsoever, except in cases where:

- Disclosure and/or transmission of the Personal Data is necessary for the Purpose of the Registry;
- The Parties are required to disclose, transmit and/or transfer the Personal Data due to mandatory legal provisions, a court order issued by a competent court, or on the instruction of some other government agency having authority over the Parties, provided that the Parties shall notify the other Parties in advance of this requirement to the extent legally permissible.

## **23. Publication**

23.1 Any report, presentation, abstract, poster, manuscript, or other publication arising from the use of Registry Data shall comply with the Publication and Authorship Policy set out in Appendix 7.

23.2 Without limitation to the foregoing, publications arising from the use of Registry Data shall appropriately acknowledge the EURO-NMD Registry and the contribution of participating HCPs in accordance with Appendix 7.

23.3 Authorship of scientific publications arising from the use of Registry Data shall be determined in accordance with Appendix 7.

## **24. Entry into force, duration and termination**

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### 24.1. Entry into force and Accession

This Agreement shall enter into force on the date of the last signature by the Parties (the “Effective Date”).

An HCP may accede to this Agreement by executing an Accession Form in the form set out in Appendix 8. The Accession Form shall be signed by the Acceding HCP and the Coordinator. The accession shall take effect on the date specified in the Accession Form, from which date the Acceding HCP shall become a Party to this Agreement.

### 24.2. Duration and termination

24.2.1 This Agreement shall continue in full force and effect during ten (10) years from the Effective Date.

The duration of this Agreement may be extended by agreement of the Parties.

24.2.2 However, this Agreement may be terminated in accordance with the terms of this Agreement.

24.2.2.1 In the event of total or partial non-performance by one of the Parties of any of its obligations, the Party noting such non-performance shall send the defaulting Party notification by registered letter with acknowledgement of receipt setting out the breach of the obligations of the Agreement. If the breach is not remedied within sixty (60) calendar days following receipt of such notice, the non-defaulting Party may terminate this Agreement by written notice. The exercise of this right of termination shall not exempt the defaulting Party from fulfilling the obligations entered into up to the date on which the early termination of the Agreement takes effect.

24.2.2.2 The Agreement may be terminated by written agreement of the Parties.

24.2.2.3 In the event of refusal of authorisation, suspension or withdrawal of authorisations necessary for the Registry, the Parties shall have two (2) months from the date of receipt by the Party concerned of the notification from the administrative authority of the refusal of authorisation, suspension or withdrawal of authorisation, to reach an agreement on the continuation of the Agreement. After this period, the more diligent Party may give notice of termination in whole or in part, depending on the scope of the decision of the said authority, as of right. Termination shall take effect from the date of presentation of the above-mentioned letter, sent by registered mail with acknowledgement of receipt by the more diligent Party.

24.2.2.4 In all cases of termination referred to herein, the Parties undertake to meet beforehand to discuss the terms and conditions of such termination of the Agreement.

24.2.2.5 Upon expiration or termination of this Agreement, the HCP's right to access and use Registry Data through the Registry shall automatically cease, without prejudice to any rights or obligations that expressly survive termination under this Agreement.

### 24.3 Survival of rights and obligations

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The provisions relating to Confidentiality, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Agreement.

## **25. Miscellaneous**

### **25.1 Attachments, inconsistencies and severability**

This Agreement consists of this core text and Appendices.

In case of conflicts between the Appendices and the core text of this Agreement, the latter shall prevail.

Should any provision of this Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated that fulfils the purpose of the original provision.

### **25.2 No representation, partnership or agency**

No Party shall be entitled to act or to make legally binding declarations on behalf of any other Party. Nothing in this Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

### **25.3 Force Majeure**

“Force Majeure” means an event or circumstance that was not reasonably anticipated as of the Effective Date: (a) that was not within the control of the Party claiming its occurrence; (b) that could not have been prevented or avoided by such Party through the exercise of reasonable diligence; and (c) that directly prohibits or prevents such Party from performing its obligations under this Agreement.

If a Party is unable to fulfill its contractual obligations in the event of Force Majeure, performance of the Agreement shall be suspended for the time that this Party is unable to perform the obligations concerned. The Party so prevented undertakes to inform the other Party as soon as possible of the event of which it is the victim and the causes thereof. The obligations of the Agreement shall resume as soon as the impediment due to Force Majeure ceases, for the duration remaining at the date of occurrence of said Force Majeure. If the case of force majeure invoked by one of the Parties lasts for more than three (3) consecutive months, the Parties agree to meet in order to define the conditions under which they will terminate the Agreement, unless the Parties agree, after consulting each other, to modify it in order to adapt it to the circumstances arising from the Force Majeure. This solution must be expressly accepted by the Parties.

### **25.4 Notices and other communication**

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Any notice to be given under this Agreement shall be in writing to the addresses and recipients as listed in the most current address list kept by the Coordinator.

Formal notices:

If it is required in this Agreement that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery or fax with receipt acknowledgement.

Other communication:

Other communication between the Parties may also be made by other means such as e-mail with acknowledgement of receipt, which fulfils the conditions of written form.

Any change of persons or contact details shall be notified immediately by the respective HCP to the Coordinator.

## **25.5 Assignment and amendments**

No rights or obligations of the Parties arising from this Agreement may be assigned or transferred, in whole or in part, to any third party without the other Party's prior formal approval. Amendments and modifications to the text of this Agreement require a separate written agreement to be signed between all Parties.

## **25.6 Mandatory national law**

Nothing in this Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

## **25.7 Language**

The language of this Agreement is English.

## **25.8 Applicable law**

Regardless of the European legislation when it applies, this Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

## **25.9 Settlement of disputes**

The Parties shall endeavor to settle their disputes amicably.

If a solution cannot be found, the Parties undertake to first submit their difference to conciliators appointed by each of them, unless they agree on the appointment of a single conciliator. The conciliator(s) shall be appointed within a maximum period of thirty (30) days as from service of notice of the dispute by one of the Parties to the other Party. The conciliator(s) will strive to settle the difficulties and to have the Party agree to an amicable solution within a period of sixty (60) days as from the date of appointment of the conciliator(s).

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If, and to the extent that, any such dispute, controversy or claim has not been settled pursuant to the conciliation within sixty (60) calendar days of the commencement of the conciliation, the relevant courts of Brussels, Belgium shall have exclusive jurisdiction.

Nothing in this Agreement shall limit the Parties' right to seek injunctive relief in any applicable competent court.

## 25.10 Appendices

The Agreement includes the following Appendices, which are an integral part of the Agreement:

- Appendix 1: Details of the Processing and Allocation of Responsibilities under the Joint Controllershship Arrangement
- Appendix 2: General Data Workflow
- Appendix 3: Informed Consent Form Template
- Appendix 4: Data Security Policy
- Appendix 5: Governance Rules
- Appendix 6: Data Access Policy
- Appendix 7: Publication and Authorship Policy
- Appendix 8: Accession Form

## 25.11 Signature

The Parties agree and accept to sign this Agreement by means of an electronic signature system, such as DocuSign, which is legally valid in accordance with eIDAS regulations.

## ARTICLE 3 – MODIFICATION OF THE APPENDICES OF THE AGREEMENT

For better understanding of the Parties, any reference in the Agreement to an Appendix shall be construed as a reference to the corresponding Appendix as replaced by this Amendment No. 2.

The provisions of the **Appendix 1: Details of the Processing and Allocation of Responsibilities under the Joint Controllershship Arrangement** to the Agreement are replaced in their entirety by the Appendix 1 attached to this Amendment No.2.

The provisions of the **Appendix 2: General Data Workflow** to the Agreement are replaced in their entirety by the Appendix 1 attached to this Amendment No.2.

The provisions of the **Appendix 3: Informed Consent Form Template** to the Agreement are replaced in their entirety by the Appendix 1 attached to this Amendment No.2.

EURO-NMD Registry Data Sharing Agreement|Amendment No. 2 – Agreement Ref: APHP 2021-578 /01 dated 10 January 2024 and amended by Amendment No. 1 dated 16 March 2024.

*The EURO-NMD Registry was established within the framework of the European Reference Network for Rare Neuromuscular Diseases (EURO-NMD) with support from European Union funding programmes.*

Ref APHP 2021-578 /02



The provisions of the **Appendix 4: Data Security Policy** to the Agreement are replaced in their entirety by the Appendix I attached to this Amendment No.2.

The provisions of the **Appendix 5: Governance Rules** to the Agreement are replaced in their entirety by the Appendix I attached to this Amendment No.2.

The provisions of the **Appendix 6: Data Access Policy** to the Agreement are replaced in their entirety by the Appendix I attached to this Amendment No.2.

The provisions of the **Appendix 7: Publication and Authorship Policy** to the Agreement are replaced in their entirety by the Appendix I attached to this Amendment No.2.

The provisions of the **Appendix 8: Accession Form** to the Agreement are replaced in their entirety by the Appendix I attached to this Amendment No.2.

## ARTICLE 4 – EFFECTIVE DATE

This Amendment No.2 takes effect from its last date of signature by the Parties and shall remain in effect for the same duration as the Agreement.

## Signatures

### AS WITNESS:

The Parties have caused this Amendment to be duly signed by the undersigned authorised representatives in separate signature pages the day and year first above written.

[Signatures on the following pages]

EURO-NMD Registry Data Sharing Agreement|Amendment No. 2 – Agreement Ref: APHP 2021-578 /01 dated 10 January 2024 and amended by Amendment No. 1 dated 16 March 2024.

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# Appendix I: Details of the Processing and Allocation of Responsibilities under the Joint Controllership Arrangement

This Appendix forms an integral part of the Agreement and sets out the details of the Processing carried out within the EURO-NMD Registry and the allocation of responsibilities between the Joint Controllers pursuant to Article 26 of Regulation (EU) 2016/679 (GDPR).

Each HCP acceding to the Agreement shall complete the sections of this Appendix identified as requiring HCP-specific information, including the identity and contact details of the HCP, its Data Protection Officer, and its competent Supervisory Authority. The completed Appendix shall be submitted together with the Accession Form and shall form part of the Agreement upon accession.

## A. IDENTITY OF THE JOINT CONTROLLERS

|                                   |                                                                                                                                                                                                                                                                                                                                      |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>The HCP:</b>                   | <b>Name:</b> ...<br><b>Address:</b> ...<br><b>DPO's name and contact details:</b> ...                                                                                                                                                                                                                                                |
| <b>AP-HP / the Coordinator:</b>   | <b>Name:</b> Assistance Publique - Hôpitaux de Paris<br><b>Address:</b> Delegation of Clinical Research and Innovation, Carré Historique de l'Hôpital Saint-Louis, 1 avenue Claude Vellefaux, 75010 Paris, FRANCE<br><b>DPO contact details :</b> <a href="mailto:protection.donnees.dsi@aphp.fr">protection.donnees.dsi@aphp.fr</a> |
| <b>UKLFR / the Registry Host:</b> | <b>Name:</b> Universitaetsklinikum Freiburg<br><b>Address:</b> Data Protection Officer / Datenschutzbeauftragter, Breisacher Straße 153, 79110 Freiburg, Germany<br><b>DPO contact details:</b> <a href="mailto:datenschutz@uniklinik-freiburg.de">datenschutz@uniklinik-freiburg.de</a>                                             |
| <b>RADBOUDUMC</b>                 | <b>Name:</b> Stichting Radboud Universitair Medisch Centrum<br><b>Address:</b> Geertgrooteplein Zuid 10 9, Nijmegen 6525 GA, NETHERLANDS<br><b>DPO contact details:</b> [redacted]<br>[redacted]                                                                                                                                     |
| <b>WDO</b>                        | <b>Name:</b> World Duchenne Organization<br><b>Address:</b> Koninginnelaan 69, Veenendaal 3905 GG, NETHERLANDS<br><b>DPO contact details:</b> [redacted]<br>[redacted]                                                                                                                                                               |

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|            |                                                                                                                                                                                                                                                                     |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>DDF</b> | <b>Name:</b> Stichting Duchenne Data Foundation<br><b>Address:</b> Turfstreek 135, 3766HT Soest, NETHERLANDS<br><b>DPO contact details:</b> [redacted]<br>[redacted]                                                                                                |
| <b>AIM</b> | <b>Name:</b> Association Institut de Myologie<br><b>Address:</b> GH Pitié Salpêtrière, Bâtiment Babinski, 47-83 boulevard de l'hôpital, 75651 Paris, FRANCE<br><b>DPO contact details:</b> <a href="mailto:dpo@institut-myologie.org">dpo@institut-myologie.org</a> |
| <b>AFM</b> | <b>Name:</b> Association Française contre les Myopathies<br><b>Address:</b> 1 Rue de l'internationale, 91002 Evry, FRANCE<br><b>DPO's contact details:</b> <a href="mailto:dpo@afm-telethon.fr">dpo@afm-telethon.fr</a>                                             |

## B. DESCRIPTION OF PROCESSING

|                                                                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|---------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <i>Categories of data subjects whose personal data is processed</i>                                           | <ul style="list-style-type: none"> <li>• Patients enrolled in the Registry;</li> <li>• Users of the Registry (healthcare professionals and authorised staff members of participating HCPs).</li> </ul>                                                                                                                                                                                                                                    |
| <i>Categories of personal data processed</i>                                                                  | <u>For Patients:</u> <ul style="list-style-type: none"> <li>• Common Personal Data;</li> <li>• Special Categories of Personal Data;</li> </ul> as further described in the Registry Data Dictionary.<br><br><u>For Users:</u><br>Name, institutional email address, institution name, role and other relevant institutional details required for account administration and access management.                                            |
| <i>The frequency of the Processing (e.g., whether the data is processed on a one-off or continuous basis)</i> | Continuous                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <i>Nature of the Processing</i>                                                                               | <u>For the HCPs:</u> <ul style="list-style-type: none"> <li>• Collection of Patient Data;</li> <li>• Recording and entry of Patient Data into the Registry;</li> <li>• Consultation, updating and correction of Patient Data;</li> <li>• Retrieval and extraction of Patient Data relating to their own Patients;</li> <li>• Deletion, restriction or modification of Patient Data where required.</li> </ul> <u>For the Coordinator:</u> |

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|                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                         | <ul style="list-style-type: none"> <li>• Consultation and use of Registry Data for Registry management and oversight purposes;</li> <li>• Management of Users' Data;</li> <li>• Retrieval and extraction of Registry Data in accordance with the Agreement and applicable policies;</li> <li>• Disclosure of authorised Registry Data to approved Recipients.</li> </ul> <p><u>For the Registry Host:</u></p> <ul style="list-style-type: none"> <li>• Hosting and storage of Registry Data;</li> <li>• Organisation and structuring of Registry Data within the Registry Database;</li> <li>• Retrieval and extraction of Registry Data;</li> <li>• Provision of authorised access to Registry Data;</li> <li>• Backup, restoration and deletion of Registry Data.</li> </ul> <p><u>For the Consortium Members:</u></p> <ul style="list-style-type: none"> <li>• Consultation and use of Registry Data for governance, scientific oversight and Registry development purposes;</li> <li>• Retrieval and analysis of Aggregated Registry Data where authorised.</li> </ul> |
| <i>Purpose(s) of the data process and further Processing</i>                                                                            | The EURO-NMD Registry is a prospective observational multicentre registry established to improve the quality of care and outcomes for patients with rare neuromuscular diseases; facilitate clinical, epidemiological, and translational research; support clinical trial feasibility and recruitment; and inform healthcare, policy, and regulatory decision-making.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <i>The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period</i> | <p><u>For Patients Data:</u><br/>Ten (10) years from the date of collection. Where continued storage beyond this period is necessary, renewed consent shall be obtained where required by applicable law.</p> <p><u>For Users Data:</u><br/>As long as the User is contributing to the Registry as an employee of the HCP.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| <i>The types of Recipients who will have access to the Personal Data;</i>                                                               | <p><u>Patients Data:</u><br/>The contributing HCP in relation to its own Patients.</p> <p><u>Users Data:</u><br/>The Coordinator and the Registry Host for the purposes of user management, access control, security and operation of the Registry.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

EURO-NMD Registry Data Sharing Agreement|Amendment No. 2 – Agreement Ref: APHP 2021-578 /01 dated 10 January 2024 and amended by Amendment No. 1 dated 16 March 2024.

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|  |                                                                                                                                                                                                                                                                                                                                                 |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p><u>Pseudonymised Registry Data:</u><br/>Recipients authorised in accordance with the Data Access Policy, including Research Project Leaders, participating HCPs and other authorised entities approved by the Data Access Committee.</p> <p><u>Aggregated Data:</u><br/>Recipients authorised in accordance with the Data Access Policy.</p> |
|--|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

C. COMPETENT SUPERVISORY AUTHORITIES

The HCP shall complete the details of its competent Supervisory Authority upon accession to the Agreement.

|                                |                                                                                                                                                                                                                                                                                           |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| For the HCP:                   | <p>Name:</p> <p>Address:</p> <p>Website:</p>                                                                                                                                                                                                                                              |
| For the Coordinator (AP-HP):   | <p>Name: Commission Nationale de l'Informatique et des Libertés (CNIL)</p> <p>Address: 3 Place de Fontenoy, TSA 80715, 75334 PARIS CEDEX 07, FRANCE</p> <p>Website: <a href="https://www.cnil.fr/">https://www.cnil.fr/</a></p>                                                           |
| For the Registry Host (UKLFR): | <p>Name: Landesbeauftragte für den Datenschutz und die Informationsfreiheit Baden-Württemberg</p> <p>Address: Postfach 10 29 32, 70025 Stuttgart, Germany</p> <p>Website: <a href="https://www.baden-wuerttemberg.datenschutz.de/">https://www.baden-wuerttemberg.datenschutz.de/</a></p> |
| For RADBOUDUMC:                | <p>Name: Autoriteit Persoonsgegevens</p> <p>Address: Hoge Nieuwstraat 8 P.O. Box 93374 2509 AJ Den Haag/The Hague NETHERLANDS</p> <p>Website: <a href="https://autoriteitpersoonsgegevens.nl/">https://autoriteitpersoonsgegevens.nl/</a></p>                                             |

D. LIST OF PROCESSORS

For the HCP: No data processor.

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**For the Coordinator:** No data processor.

**For the Registry Host:** No data processor.

## **E. ALLOCATION OF RESPONSIBILITIES UNDER THE JOINT CONTROLLERSHIP ARRANGEMENT**

| <b>Responsibility</b>                                                                                      | <b>Coordinator</b> | <b>Registry Host</b> | <b>Other Consortium Members</b> | <b>HCPs</b> |
|------------------------------------------------------------------------------------------------------------|--------------------|----------------------|---------------------------------|-------------|
| <b>Definition of the characteristics of the Processing</b>                                                 |                    |                      |                                 |             |
| Definition of the purposes of the Processing                                                               | X                  | X                    | X                               | X           |
| Designation of the Data Subjects or categories of Data Subjects                                            | X                  | X                    | X                               |             |
| Definition of the legal basis for each purpose of the Processing                                           | X                  | X                    | X                               |             |
| Definition of the technical and material means of Processing                                               | X                  | X                    | X                               |             |
| Definition of the human and organizational means of the Processing                                         | X                  | X                    | X                               | X           |
| Control of the principle of lawfulness - fairness and transparency of the Processing                       | X                  | X                    | X                               | X           |
| Control of the principle of limiting the purposes of the Processing (determined - explicit and legitimate) | X                  | X                    | X                               | X           |
| Control of the principle of minimization of the processed data (adequate - relevant and limited)           | X                  | X                    | X                               | X           |
| Definition of the duration of data storage                                                                 | X                  | X                    | X                               |             |
| Deletion of data after the end of the data retention period                                                |                    | X                    |                                 |             |
| Archiving of data after the end of the data retention period                                               |                    | X                    |                                 |             |

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|                                                                                                                                                                                                                                                                              |   |   |   |   |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|---|---|---|
| Maintaining documentation of the Processing                                                                                                                                                                                                                                  | X | X |   | X |
| Performing data extraction from database                                                                                                                                                                                                                                     | X | X |   | X |
| <b>Generic obligations</b>                                                                                                                                                                                                                                                   |   |   |   |   |
| Designation of a Contact Point for the Data Subject                                                                                                                                                                                                                          | X | X |   | X |
| Supervision of subcontracting                                                                                                                                                                                                                                                | X | X | X | X |
| Keeping a register of processing activities                                                                                                                                                                                                                                  | X | X | X | X |
| Cooperate with the Protection Authority and respond to any request for information from the Protection Authority or any other competent data protection authority                                                                                                            | X | X | X | X |
| Alerting each other in case of doubt as to whether an instruction complies with the Regulation or any Community or national regulation applicable to the Processing                                                                                                          | X | X | X | X |
| To organize the possible implementation of a data transfer to a third country or an international organization                                                                                                                                                               | X | X | X | X |
| Take - and document - the precautions, measures and technical guarantees necessary to preserve the confidentiality and security of the data and in particular to prevent them from being distorted, damaged or communicated to unauthorized third parties and more generally | X | X | X | X |
| <b>Aspects relating to the Registry</b>                                                                                                                                                                                                                                      |   |   |   |   |
| Verification of compliance with privacy by design / privacy by default                                                                                                                                                                                                       | X | X | X |   |
| Maintenance in operational conditions of the Registry                                                                                                                                                                                                                        |   | X |   |   |
| Corrective maintenance of the Database                                                                                                                                                                                                                                       |   | X |   |   |

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|                                                                                                   |          |   |   |   |
|---------------------------------------------------------------------------------------------------|----------|---|---|---|
| Implementation of security measures related to the Registry                                       |          | X |   | X |
| Establishment and validation of a quality and security assurance plan for the Registry            |          | X |   | X |
| Assigning, managing and deleting User access rights to the Database                               | <b>X</b> | X |   |   |
| <b>Information and consent of the Persons concerned</b>                                           |          |   |   |   |
| Drafting of the information relating to the Processing                                            | X        | X | X |   |
| Dissemination of the information to the Users                                                     | X        | X | X | X |
| Dissemination of the information to the Patients                                                  |          |   |   | X |
| Collection of the consent for Patients                                                            |          |   |   | X |
| Recording of consent of Patients                                                                  |          |   |   | X |
| Control of the majority of the Patients / collection of the agreement of the legal representative |          |   |   | X |
| <b>Management of the requests of the Data Subjects</b>                                            |          |   |   |   |
| Receipt of the requests of the Patients                                                           |          |   |   | X |
| Receipt of the requests of the Users                                                              | X        | X |   |   |
| Instruction of the requests of the Patients                                                       |          |   |   | X |
| Instruction of the requests of the Users                                                          |          | X |   |   |
| Answer to the requests of the Patients                                                            |          |   |   | X |
| Answer to the requests of the Users                                                               | X        | X |   | X |
| Notification of the rectification or deletion of Personal Data or the limitation of the           | X        | X |   | X |

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|                                                                                      |   |   |   |   |
|--------------------------------------------------------------------------------------|---|---|---|---|
| Processing to the Joint Controllers, Processors and Recipients                       |   |   |   |   |
| <b>Privacy Impact Assessment</b>                                                     |   |   |   |   |
| Carrying out a data protection impact analysis                                       | X | X | X | X |
| Preparation of the consultation file for the Data Protection Authority, if necessary | X | X |   | X |
| Interaction with the Data Protection Authority, when it is consulted for an opinion  | X |   |   | X |
| <b>Data breaches</b>                                                                 |   |   |   |   |
| Informing the other joint controllers of a Data Breach                               | X | X | X | X |
| Managing the investigation of Data Breaches                                          | X | X | X | X |
| Compliance and compliance monitoring                                                 | X | X | X | X |
| Centralized documentation of the Data Breach                                         | X | X | X | X |
| Notification of data breaches to the Data Protection Authority                       | X | X |   | X |
| Communication to Patients of a Data Breach                                           | X |   |   | X |
| Communication to Users of a Data Breach                                              | X | X |   |   |
| Appointment of a Data Protection Officer                                             | X | X | X | X |

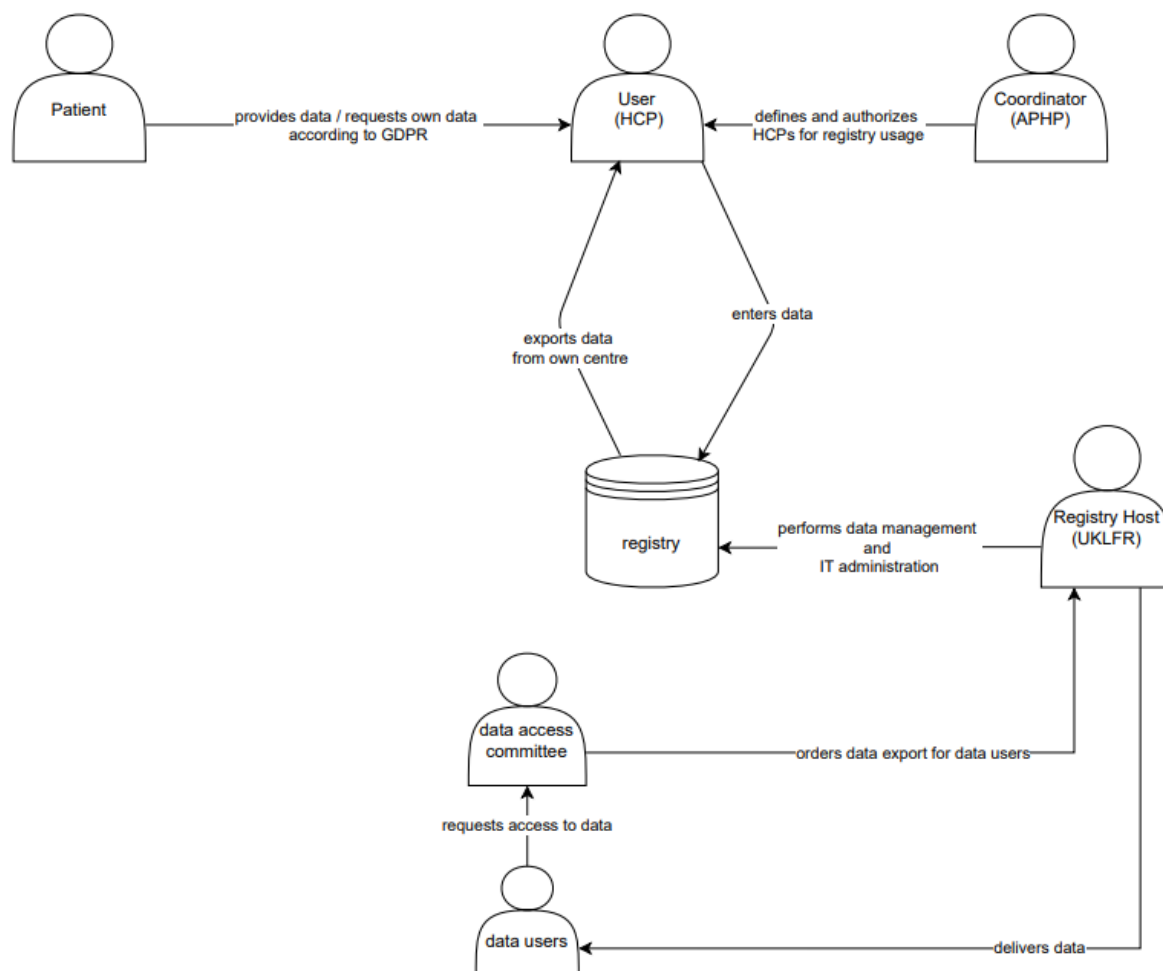
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## Appendix 2: General Data Workflow



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## Appendix 3: Informed Consent Form Template

### INFORMED CONSENT FORM

Dear Patient [parent(s)/legal representative],

We invite you to take part in a patient registry for Rare Neuromuscular Diseases under the European Reference Network EURO-NMD: the [EURO-NMD Registry](https://registry.ern-euro-nmd.eu). Participation is voluntary and requires your written consent as a legal basis to use your data [the data of your child/the patient]. Please read this information carefully and ask your medical doctor for an explanation if you have any questions.

### EUROPEAN REFERENCE NETWORK REGISTRIES

- European Reference Networks (ERNs) are networks of healthcare professionals for rare diseases across Europe working together to support patients with rare and complex diseases.
- EURO-NMD is the European Reference Network covering neuromuscular diseases, the large majority of which are simultaneously genetic conditions and Rare Diseases. The EURO-NMD Registry (<https://registry.ern-euro-nmd.eu>) is the platform that has been built to support the monitoring of the quality of care of patients treated within the participating health care providers of the ERN EURO-NMD, while providing precious input for a better understanding of these diseases, their diagnosis, management and treatment. Neuromuscular Diseases frequently cause chronic health problems, and many are life-threatening or present particular challenges for the quality of life of affected patients. They are infrequent and often require numerous resources and multidisciplinary teams to reach a correct diagnosis, management and treatment. The challenge to bring together sufficient data regarding these patients to launch research and clinical trials is fundamental for improving the condition of neuromuscular patients and can be achieved only by extensive data collection such as the one registries allow.
- To understand the course of a disease and investigate new diagnostic procedures and treatments in order to improve patient care, ERNs need databases (also known as “registries”) for research and knowledge development.
- To build such registries, data from many patients must be combined. We ask for your consent to include your data [the data of your child/ the patient] in the EURO-NMD Registry to perform monitoring of care quality and research, as described below, in accordance with national and European data protection laws and ethics guidelines<sup>1</sup>.

<sup>1</sup> including the European General Data Protection Regulation (GDPR), Reg. (EU) 2016/679; the Declaration of Helsinki 2013; the International Ethical Guidelines for Biomedical Research Involving Human Subjects CIOMS-WHO (2016); the Oviedo Convention and its Additional Protocol on human rights and biomedicine, concerning



- Only the data required for such research will be recorded and may be shared with users as outlined below. Such data may include age, sex, the signs and symptoms of the disease, results of diagnostic procedures (e.g., laboratory test results, genetic information, imaging studies), as well as therapeutic interventions and their long-term outcomes.
- Your data [your child/ the patient data] privacy will be secured as described below in this form. Only your doctor will be able to link your data to you. Therefore, the risk of re-identification by unauthorized persons is minimal.

## VALUE & BENEFITS

### HOW WILL THE DATA BE USED?

The data collected in this registry is used to improve the delivery of healthcare, including the diagnosis, treatment and prognosis of patients with Rare Neuromuscular Diseases.

The data may be used later on in order to perform research (academic, clinical, or industrial). Research is often carried out in collaboration with other researchers. By sharing data, more questions can be answered. Research is often carried out in collaboration with other researchers. By sharing data, more questions can be answered.

Only users authorised by the Registry Data Access Committee can use the data. This Committee is composed of qualified health professionals, patients' representatives as well as members with legal and ethical expertise. It ensures that the request for data use aligns with the purposes of the registry and its policy.

The Registry Data Access Committee may provide data access to clinical researchers from within or outside the ERN EURO-NMD, patient organisations, and the pharmaceutical industry in order to develop projects, policies or studies aimed to improve the delivery of healthcare for rare diseases. Also, registry data may be shared with health authorities, policy makers and regulators to inform their decisions on rare disease health policy and approval of medicines.

### Data use for commercial purposes

Companies might request access to data stored in the registry to perform research aimed to develop new therapies for your condition. For example, the registry can inform companies how many patients live with a certain disease and help find patients in clinical trials of new therapies.

Typically, the results of this research will become property of the company that may also use them for further **commercial purposes** and to patent. You [your child/ the patient] will not acquire

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biomedical research (2005); the [“standard contractual clauses for the transfer of personal data to third countries” \(EU\) 2021/914](#) and .... **<please include any other applicable law>**

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any rights over these results, own them in any way, or be entitled to share any future financial benefit derived from this research.

You may choose if you want to allow the use of your data [your child/ the patient data] for commercial research.

### Data transfers outside the EU

Data without any personally identifiable information may also be forwarded to researchers working in countries outside the EU, where the General Data Protection Regulation (GDPR) does not apply. In this case, a written agreement will be set up to ensure that the data is processed in compliance with the GDPR.

You may choose if you want to allow the transfer of your data [your child/ the patient data] to non-EU countries to contribute to projects directly aligned with the aims of this registry within a framework compliant with GDPR.

### Future changes in data collection

To gain more insight on your condition [your child/ the patient condition] we may need additional data in the future. This information will be published on the registry website <https://registry.ern-euro-nmd.eu>.

Furthermore, we may request additional data from existing disease- or treatment-specific registries/databases, including other ERN registries. You may choose if you want to allow the linking of your data [your child/ the patient data] with additional data as described above.

### Re-contacting to participate in research projects

In the future, research projects on the diseases and conditions covered by this registry may be proposed. You may choose if you want to be re-contacted by your medical doctor [your child/ the patient medical doctor] to participate in such studies. If you agree to be contacted, you are free to refuse, without any prejudice, participation in the proposed studies after you have been fully informed. Your current care [the current care of your child/ the patient] will not change in any way if you choose not to give your consent.

## WHAT ARE THE BENEFITS?

While there is no direct benefit from participating in this registry, the knowledge about the disease will be improved. This may benefit you [your child/ the patient] and other patients suffering from the same disease by improving healthcare and quality of life.

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The participants may benefit by facilitated access to clinical studies aimed to prevent and treat the disease.

### Communication of research results

The results of the research will be communicated through the registry website (the information about projects given access to registry data is publicly available on the registry website), conferences or publications in scientific journals where personal data are not provided. The privacy of your data [your child/ the patient data] will always be protected as described below.

## PROTECTION

### WHAT ARE THE RIGHTS OF THE REGISTRY PARTICIPANT?

- The processing of your personal data [your child/ the patient personal data] is necessary for the conduct of the registry and is based on the consent
- You decide whether to participate in the registry [let your child/ the patient participate in the registry]. Please take as much time as you need to make this decision. You do not have to sign anything. You can decline participation without giving any reasons. You [your child/ the patient] will receive the same treatment irrespective of whether or not you agree to participate in this registry. Even if you agree to participate in the registry, you may at any time oppose the processing of your personal data [your child/the patient personal data] for the purpose of carrying out research. In this case, no additional information about you [your child/ the patient] will be collected.
- You have the right to give or withhold your consent at any time. If you consent today, you may modify or withdraw your consent later, without any prejudice. Your doctor will explain how your consent can be modified and how the data can be removed from the registry if you wish so. Please be informed that, to guarantee the validity of any research performed, data already processed cannot be deleted. However, this data will not be used in new research projects after withdrawal.
- You can also request the limitation of the processing of your personal data [your child/ the patient data] (i.e. ask the promoter to temporarily freeze the use of your personal data [your child/ the patient data]).
- You also have the right to portability of your data [your child/ the patient data] (the right to portability gives you the possibility to recover part of your data [your child/ the patient data] in a machine-readable format).
- You are entitled to receive further information about the purposes for which your data [your child/ the patient data] will be processed and who will have access to it. You can also request to access your data [your child/ the patient data] at any time.
- The hospital where you are treated [your child/ the patient is treated] is the local controller responsible for the local protection of confidential patient data. If you have any concerns about the way in which your data [your child/ the patient data] is processed, you would like more information or to exercise your rights, you may contact your medical doctor [your child/ the patient medical doctor]. In case of difficulty, you can contact the Data Protection Officer

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of your hospital [your child/ the patient hospital], or you may raise a complaint to the relevant data protection authority. You can find contact details of the local Data Protection Officers at the registry website (<https://registry.ern-euro-nmd.eu>). They have the duty to ensure the data is processed safely and to notify you if a breach of data security occurs. Any inquiries should be addressed by the Data Protection Officer within 30 days.

- For all data submitted to the central registry database, the Assistance Public Hôpitaux de Paris (AP-HP), Coordinator of the European Reference Network for Rare Neuromuscular Diseases (ERN EURO-NMD), and its principal investigator, Dr. Teresinha EVANGELISTA, Neurologist at AP-HP, is responsible for the storage and use of transferred data: The AP-HP Data Protection Officer may be contacted at : [protection.donnees.dsi@aphp.fr](mailto:protection.donnees.dsi@aphp.fr)

### HOW WILL DATA BE SECURED?

- Participation in the registry will be kept strictly confidential and all information will be handled through very secure electronic systems. As the registry involves collecting information from many centres, the system will be password protected and only persons specifically involved with the registry will have access.
- The registry users and administrators will not be able to contact you because your name, address and hospital number [your child/ the patient's name, address and hospital number] will not be recorded. All your data [your child/ the patient data] will be pseudonymised before being stored in the registry. This means that all identifiers that relate to you [your child/ the patient] will be removed and replaced by a pseudonym<sup>2</sup>. Only your medical doctor [your child/ the patient medical doctor] can link the pseudonym to you [your child/ the patient]. Therefore, the risk of re-identification by unauthorized persons is minimal.
- In all publications emerging from the registry, it will be ensured that it is not possible to identify an individual patient, e.g., by providing data in tables or presenting age categories rather than the real age.
- A pseudonymisation service will be used for this purpose. It allows to identify duplicate registration of patients, linkage between registries and other data resources, keep data protected and preserve the possibility of re-contacting by the medical doctor in charge.
- The registry data will be stored on a secure REDCap server physically located at the Clinical Trials Unit of the University Medical Center Freiburg that contain all necessary security facilities for 10 years. After this period, your doctor will review whether it is still necessary to keep your data in the registry. If it is, you may be asked to give your consent again.

### COULD PARTICIPATION IN THE REGISTRY CAUSE ANY HARMS?

- Participating in this observational registry will not cause any health risks.
- Even though the registry has processes in place to ensure your personal information is protected, there is a remote risk the data could be matched with information you have already authorized in publicly available databases such as ancestry websites or public rare

<sup>2</sup> A pseudonym is a sequence of letters and numbers that replaces all identifiers that relate to a patient; the data of the patient is then called "pseudonymised data". These identifiers can only be retrieved, from the pseudonym, by the authorised health care professionals enrolling the patient in the registry.

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disease registries with identifiable information. To minimize this risk, researchers asking for access to registry data will confirm in writing not to try to identify you by any means, applying their duty of professional secret.

## ADDITIONAL INFORMATION

### Costs

Participation in this registry will not entail any costs for you.

### Insurance

<please include information about insurance taken for the registry activities if applicable, as requested by some Ethics Committees – otherwise, please delete this paragraph>

### Ethics Committee Approval

This Informed Consent Form has been reviewed and approved under the number <Ethics Committee/ IRB number> by [name of the (local) Ethics Committee/IRB]

If you have any other question about the registry, please contact the central registry office at [registry@ern-euro-nmd.eu](mailto:registry@ern-euro-nmd.eu)

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## INFORMED CONSENT

Patient First and Last Name:.....

Date of Birth (dd/mm/yyyy):...../...../..... ID number:.....

I have read the information sheet about the EURO-NMD Registry.

I have been given the time and opportunity to ask questions about the objectives of the registry and the use of my data [my child/the patient data] and that I have solved all my doubts with the medical doctor.

I understand that my participation is voluntary and that I can withdraw the consent at any time without the need of justification and without affecting my future medical care [the future care of my child/the patient].

I approve that my data [my child/the patient data] will be stored in the EURO-NMD Registry, used for non-profit purposes and shared with approved users to improve the delivery of healthcare as described above.

I consent to the processing of my pseudonymized data [my child/the patient pseudonymized data] for the purposes described above.

**The following consent conditions are optional. Please indicate your preferences by writing your initials in the relevant box. If you leave the boxes EMPTY, we assume you DO NOT AGREE to the statements.**

**YES**

**NO**

☐
☐

**I CONSENT** that my pseudonymized data [my child/the patient pseudonymized data] may also be **used to support commercial projects** aimed to improve healthcare.

☐
☐

**I CONSENT** that my pseudonymized data [my child/the patient pseudonymized data] **may be transferred to non-EU countries, in compliance with GDPR**, to support projects aimed to improve healthcare.

☐
☐

**I CONSENT** that my pseudonymized data [my child/the patient pseudonymized data] may be **linked to existing databases/registries** to improve healthcare.

☐
☐

**I WOULD LIKE TO BE CONTACTED** by my medical doctor [my child/the patient medical doctor] about any **research project**

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|                                                                                        |                                                                                                                                                                                                                  |
|----------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>and/or clinical study related to my condition</b> [my child/the patient condition]. |                                                                                                                                                                                                                  |
| <div></div>                                                                            | <div><b>I CONSENT</b> to provide my email address and to be contacted for the purpose of completing questionnaires about my health [the health of my child/the patient], as part of the EURO-NMD Registry.</div> |
| Email address:.....                                                                    |                                                                                                                                                                                                                  |

| PATIENT [PARENT/LEGAL GUARDIAN] | MEDICAL DOCTOR / AUTHORISED WITNESS            |
|---------------------------------|------------------------------------------------|
| Date and Signature:             | Full name:<br>Position:<br>Date and Signature: |

**Please keep one copy of this Informed Consent Form in case records and hand one copy to the person who has signed this form.**



## Appendix 4: Data Security Policy

This Data Security Policy forms an integral part of the EURO-NMD Registry Data Sharing Agreement (the “Agreement”) and describes the technical and organisational measures implemented to protect the confidentiality, integrity, availability, and resilience of Registry Data.

This Policy complements Article 7 (Security Measures) and Article 21 (Data Access) of the Agreement and applies to all Parties participating in the EURO-NMD Registry, including the Coordinator, the Registry Host, Consortium Members, and participating Healthcare Providers (HCPs).

The objective of this Policy is to ensure that Registry Data are processed securely and in compliance with applicable Data Protection Legislation, including the General Data Protection Regulation (GDPR), and to establish a common framework for information security across the Registry.

All Parties shall implement and maintain appropriate technical and organisational measures to protect Registry Data against accidental or unlawful destruction, loss, alteration, unauthorised disclosure, unauthorised access, or any other form of unlawful Processing.

### I. System Hosting

- The Registry Database is hosted and maintained by the University Medical Centre Freiburg (UKLFR).
- The Registry is implemented using REDCap, a secure web-based electronic data capture platform developed by Vanderbilt University.
- The hosting environment includes appropriate technical and organisational safeguards, including access controls, system monitoring, backup procedures, and redundancy mechanisms designed to ensure the confidentiality, integrity, availability, and resilience of Registry Data.
- The Registry infrastructure is operated in accordance with applicable Data Protection Legislation and institutional information security requirements.

### 2. Pseudonymisation and Personal Data Protection

- All Patient Data entered into the Registry must be pseudonymised by the contributing HCP prior to submission to the Registry.
- Each Patient is assigned a unique Registry identifier within the Registry Database.
- The patient re-identification key linking the Registry identifier to the identity of the Patient shall remain exclusively under the control of the contributing HCP and shall never be transmitted to, or stored within, the Registry.
- The Registry does not collect directly identifying data such as patient names, personal email addresses, postal addresses, or national identification numbers.

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- Limited demographic and clinical information necessary for the purposes of the Registry may be processed, including date of birth, sex, and health-related data, as further described in the Registry Data Dictionary.
- Where Registry Data are disclosed to authorised Recipients, additional data minimisation and pseudonymisation measures shall be applied in accordance with the Data Access Policy.

### **3. Data Transmission and Storage**

- Registry Data transmitted to or from the Registry Database shall be protected using industry-standard encryption protocols, including SSL/TLS encryption.
- The Registry Host shall implement appropriate technical and organisational measures to protect Registry Data, including access controls, firewalls, malware protection, system monitoring, and vulnerability management.
- Backup copies of the Registry Database shall be performed regularly, retained for a minimum period of ninety (90) days, and stored separately from the production environment.
- The Registry infrastructure shall be operated in a manner designed to ensure the availability, integrity, and resilience of Registry Data and services.

### **4. User Access and Authentication**

- Each User shall be assigned an individual, non-transferable, and non-shared user account approved by the Principal Investigator or authorised representative of the relevant HCP.
- Access to the Registry shall be restricted through authentication mechanisms and role-based access controls, in accordance with the principle of least privilege and the Data Access Policy (Appendix 6).
- Access rights shall be limited to those necessary for the performance of the User's authorised functions.
- Export, extraction, or download of Registry Data by Users shall be permitted only where authorised under the applicable role-based permissions defined in the Data Access Policy.
- The Registry shall maintain audit logs recording relevant user activities, including user authentication events, data exports, and modifications to Registry Data.
- User accounts shall be reviewed periodically and deactivated, suspended, or removed without undue delay where access is no longer required.
- The Registry Host shall implement session management, audit logging, and other technical safeguards proportionate to the risks associated with the Processing.

### **5. Confidentiality and Accountability**

- Personnel of the Registry Host and the Coordinator may access Registry Data only to the extent strictly necessary for system administration, maintenance, security, technical support, legal compliance, or other authorised purposes under the Agreement. Such access shall be logged where technically feasible.
- Each HCP and its authorised Users remain responsible for the accuracy, completeness, lawfulness, and quality of the HCP Data submitted to the Registry.

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- Personnel of the Registry Host and the Coordinator with access to Registry Data shall be bound by confidentiality obligations, whether through employment contracts, institutional policies, confidentiality undertakings, or equivalent legally binding arrangements.
- The Registry Host and the Coordinator shall maintain documented procedures for security incident management, including the detection, reporting, investigation, mitigation, and notification of Personal Data Breaches in accordance with the Agreement and applicable Data Protection Legislation.

## 6. Third-Party Access (Recipients)

- Recipients may receive access only to Aggregated Data or Pseudonymised Registry Data, subject to approval by the Data Access Committee (DAC) and in accordance with the Agreement and the Data Access Policy (Appendix 6).
- Any disclosure of Registry Data to a Recipient shall be subject to an appropriate legal agreement, including where applicable a Data Transfer Agreement, Data Access Agreement, or equivalent contractual arrangement specifying the permitted use, duration, security requirements, and other applicable safeguards.
- Any attempt to re-identify Patients or to use Registry Data for purposes outside the scope approved by the DAC is strictly prohibited.
- Where Registry Data are disclosed to commercial entities, only data relating to Patients who have consented to such use may be shared, in accordance with the informed consent provided and the Data Access Policy.
- Recipients shall not directly contact Patients or attempt to recruit Patients using Registry Data. Any approved patient contact or recruitment activity shall be conducted exclusively through the treating HCP and in accordance with the Agreement and the Data Access Policy.

## 7. Governance and Compliance

- Each HCP shall obtain and maintain all approvals, authorisations, ethics committee approvals, and other governance approvals required under applicable national, institutional, and regulatory requirements before contributing data to the Registry.
- The Processing of Patient Data within the Registry is based on the informed consent of the Patient or, where applicable, their legal representative. Each HCP is responsible for obtaining, documenting, and retaining valid informed consent prior to entering Patient Data into the Registry, in accordance with Article 6 of the Agreement.
- In accordance with Article 10 of the Agreement, the Coordinator has conducted a Data Protection Impact Assessment (DPIA) for the Registry processing activities. Each HCP shall assess, in consultation with its Data Protection Officer and in accordance with applicable national and institutional requirements, whether it is required to conduct an additional DPIA in relation to its own Processing activities.
- The Registry shall be operated in accordance with the Agreement, applicable Data Protection Legislation, the Governance Rules, the Data Access Policy, and other Registry policies adopted by the Steering Committee.

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- This Policy shall be reviewed periodically and may be updated to reflect changes in applicable legislation, security requirements, Registry operations, or recognised best practices. Any material updates shall be communicated to participating HCPs and other relevant stakeholders.

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# Detailed security measures

Annex 1 to Appendix 4 | Original pages 56-58 omitted

## Disclosure notice

The detailed technical and organisational security measures implemented by the Registry Host are withheld from this public copy.

The general Data Security Policy in Appendix 4 is retained. This omission affects disclosure only: the annex remains part of the authoritative signed agreement and the parties' obligations are unchanged.



## Appendix 5: Governance

The EURO-NMD Registry is a pan-European patient registry for rare paediatric and adult neuromuscular diseases established within the framework of the European Reference Network for Rare Neuromuscular Diseases (ERN EURO-NMD).

The purpose of the Registry is to improve the quality of care and outcomes for patients with rare neuromuscular diseases, support research and clinical trials, and inform healthcare, policy, and regulatory decision-making.

The Registry is governed by the bodies described below. These bodies operate in accordance with the Agreement, applicable Registry policies, and their respective Standard Operating Procedures (SOPs).

### I. Governance Structure

The governance of the EURO-NMD Registry is composed of the following bodies:

#### (a) Steering Committee (SC)

- The Steering Committee (“SC”) is the principal governing and decision-making body of the Registry.
- The SC is composed of:
  - representatives of the Registry Consortium Members;
  - one representative from each EURO-NMD Specialist Disease Group; and
  - one representative from the EURO-NMD Patient Advisory Board (PAB).
- The SC is chaired by the EURO-NMD Coordinator.
- The SC operates in accordance with the EURO-NMD Registry Steering Committee Standard Operating Procedures.
- Decisions shall be taken by consensus whenever possible. Where consensus cannot be reached, decisions shall be adopted by a two-thirds majority of the members present or represented.
- The composition of the SC shall be reviewed every three (3) years, and members may be renewed, replaced, or reconfirmed as appropriate.



- The SC shall:
  - provide strategic direction for the Registry;
  - oversee the implementation and evolution of the Registry;
  - approve Registry policies and governance documents;
  - monitor compliance with the Agreement and applicable legal requirements;
  - oversee the sustainability and long-term development of the Registry;
  - supervise the activities of the Data Access Committee and Management Team; and
  - determine the continuation, transfer, retention, or disposal of Registry Data in the event of the termination or discontinuation of the Registry or the Network.

#### (b) **Management Team**

- The Management Team supports the SC and is responsible for the day-to-day management and operation of the Registry.
- The Management Team is composed of:
  - (i) the EURO-NMD Coordination (AP-HP, Paris), responsible for administrative, contractual, financial, and operational management;
  - (ii) the Data Operations and IT Team (UKLFR, Freiburg), responsible for system hosting, platform maintenance, data operations, technical support, and information security; and
  - (iii) the Interoperability Team (Radboudumc, Nijmegen), responsible for the development and maintenance of interoperability services, federated infrastructure, and integration with external registries and data sources.
- The Management Team shall report regularly to the SC on operational activities, performance indicators, risks, and ongoing developments.

#### (c) **Data Access Committee (DAC)**

- The Data Access Committee ("DAC") is responsible for reviewing, evaluating, and deciding upon requests for access to Registry Data submitted by Recipients.
- The composition of the DAC is defined in Appendix 6 (Data Access Policy).
- The DAC operates in accordance with the EURO-NMD Registry Data Access Committee Standard Operating Procedures.
- Decisions shall be taken by consensus whenever possible. Where consensus cannot be reached, decisions shall be adopted by simple majority, provided that the required quorum is met.
- The DAC shall act independently when assessing access requests and shall document its decisions and their justification in accordance with its SOPs.
- The DAC shall ensure that all requests are assessed:

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- ethically;
  - scientifically;
  - in accordance with the objectives of the Registry;
  - in accordance with the consent provided by Patients;
  - in accordance with the Data Access Policy (Appendix 6); and
  - in compliance with applicable Data Protection Legislation, including the GDPR.
- The DAC may approve, reject, or request modifications to any access request and may impose conditions or safeguards as a prerequisite for access.

## 2. Review of Governance Rules

These Governance Rules may be reviewed and updated by the Steering Committee from time to time, provided that any amendment remains consistent with the Agreement and applicable law. Material amendments shall be communicated to all participating HCPs and other affected stakeholders.



## Appendix 6: Data Access Policy

This Data Access Policy governs access to Registry Data within the EURO-NMD Registry. It complements Article 21 (Data Access), Article 20 (Results), and Appendix 4 (Data Security Policy) of the Data Sharing Agreement (the “DSA”).

The objective of this Policy is to ensure that access to Registry Data is granted, managed, and monitored in a secure, transparent, ethical, and lawful manner, consistent with the purpose of the Registry and the rights of Patients.

The Policy establishes:

- the categories of Registry Data that may be accessed;
- the access rights and responsibilities of Users and Recipients;
- the role and responsibilities of the Data Access Committee (DAC);
- the procedures governing requests for access to Registry Data; and
- the conditions applicable to the use, disclosure, and protection of Registry Data.

### I. Principles

Access to Registry Data shall be governed by the following principles:

- Role-based permissions, ensuring that Users may access only the data and functions necessary for their authorised duties;
- The principle of least privilege, whereby access is limited to the minimum level necessary to perform authorised activities;
- Approval by the Data Access Committee (DAC), where required under this Policy;
- Compliance with this Policy, the DSA, and applicable Data Protection Legislation;
- Accountability and traceability, whereby all access to Registry Data is logged and auditable; and
- Respect for data ownership and control, whereby access to Registry Data does not confer any ownership rights. Ownership and control of Registry Data remain governed by Article 19 of the DSA.

### 2. Categories of Registry Data Accessible

Registry Data may be available in the following forms:



- **Pseudonymised Data:** Patient-level records from which direct identifiers have been removed and replaced with a unique Registry identifier.
- **Aggregated Data:** Statistics, analyses, or derived outputs that are no longer attributable to an individual Patient. Examples include counts, descriptive and comparative statistics, graphs, dashboards, and summary tables.

The Registry does not collect or store directly identifiable personal data. Each Patient is represented within the Registry by a unique pseudonym, while the corresponding re-identification key remains exclusively under the control of the contributing HCP.

### 3. Roles and Access Levels

#### 3.1 Users

Users are authorised healthcare professionals or staff members of a participating HCP who have been granted access to the Registry in accordance with the DSA.

##### 3.1.1 User Access Levels

The following User Access Levels may be assigned within the Registry:

- **Data Viewer:** May view records within their authorised scope. Cannot create, edit, rename, delete, import, or export data.
- **Data Viewer and Export:** May view records and export data through the Registry reporting and export functions. Cannot create, edit, rename, delete, or import data.
- **Data Entry:** May create, edit, rename, and delete records. Cannot import or export data.
- **Data Entry and Import:** May create, edit, rename, and delete records and perform data imports using the Data Import Tool. Cannot export data.
- **Data Entry and Export:** May create, edit, rename, and delete records and export data through the Registry reporting and export functions. Cannot import data.
- **Data Entry, Import and Export:** May create, edit, rename, and delete records, perform data imports using the Data Import Tool, and export data through the Registry reporting and export functions.

##### 3.1.2 Data Access Groups (DAGs)

- Each User shall be assigned to one or more Data Access Groups (DAGs), corresponding to the organisational entity (e.g., department, unit, or service) with which they are affiliated.
- Users assigned to a specific DAG may only access Patient Data belonging to that DAG.

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- An HCP may establish more than one DAG to segregate access between different departments, units, services, or research groups.

### 3.1.3 Responsibilities of HCP

The Hospital Coordinator (or Principal Investigator) of each HCP is responsible for:

- Approving and authorising User accounts for their HCP within the Registry;
- Determining the appropriate access level for each User;
- Determining and approving DAG assignments;
- Ensuring that access rights are reviewed and updated when a User's role changes;
- Requesting the suspension or removal of access without undue delay when a User leaves the HCP or no longer requires access;

Each HCP remains responsible for the activities carried out by its Users and shall promptly notify the Coordinator of any change affecting a User's authorisation or access rights.

## 3.2. Recipients

The following categories of stakeholders may request access to Registry Data:

- Contributing researchers;
- Non-contributing researchers;
- Health authorities and regulators;
- Policy and supervisory agencies;
- Patient organisations;
- Non-governmental organisations (NGOs);
- Payers and insurers; and
- Pharmaceutical companies, subject to any additional requirements relating to commercial use and patient consent.

### 3.2.1 Access Conditions

The specific conditions applicable to each category of Recipient, including eligible cohorts, available Data Elements, access levels, DAC review requirements, authentication measures, and applicable fees, are set out in Annex I.

Recipients shall:

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- receive access only to Pseudonymised Data or Aggregated Data, limited to the datasets and cohorts approved by the DAC or otherwise permitted under Annex I;
- use appropriate authentication measures, with all access activities being logged and auditable;
- pay any applicable fees specified in Annex I; and
- comply with Section 5 (Data Access Process), including the execution of any required Data Transfer Agreement, Data Access Agreement, or equivalent legal arrangement, and adherence to the approved scope of access.

### 3.3. Registry Host and Coordinator

The Registry Host (UKLFR) and the Coordinator (AP-HP) may access Registry Data only to the extent strictly necessary to:

- operate, maintain, secure, and back up the Registry;
- manage User accounts and provide technical or operational support; or
- comply with applicable legal, regulatory, or contractual obligations.
- All such access shall be logged and auditable.

## 4. Data Access Committee (DAC)

### 4.1 Mandate

The Data Access Committee (DAC) is responsible for reviewing, evaluating, and deciding upon requests for access to Registry Data submitted by Recipients.

The DAC shall ensure that requests are assessed in accordance with:

- the objectives of the Registry;
- the informed consent provided by Patients;
- this Policy;
- the Data Sharing Agreement (DSA); and
- applicable legal, ethical, and regulatory requirements, including the GDPR.

### 4.2 Composition

The DAC shall be composed of:

- Two Co-Chairs appointed by the Registry Steering Committee.
- One HCP representative nominated by the EURO-NMD Board.

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- One Patient representative nominated by the EURO-NMD Patient Advisory Board.
- One disease expert nominated by the relevant EURO-NMD Thematic Disease Group.
- Ad hoc experts as required (e.g. ethics, privacy, scientific merit).
- Secretariat provided by the EURO-NMD Coordination Office.

Members shall serve under a rotation system designed to ensure broad representation across participating stakeholders and disease areas.

### 4.3 Responsibilities

The DAC shall:

- evaluate requests from scientific, ethical, legal, and operational perspectives;
- ensure consistency with patient consent, applicable Data Protection Legislation, and the objectives of the Registry;
- verify the qualifications, affiliations, and authorisations of requestors where appropriate;
- assess the feasibility and proportionality of the requested access;
- prevent unnecessary duplication of research activities and encourage collaboration where appropriate;
- identify, declare, and manage actual or potential conflicts of interest;
- determine any conditions, restrictions, or safeguards applicable to approved requests; and
- communicate its decisions and any applicable conditions in writing to the requestor.

## 5 Data Access Process

### 5.1 Submission of Requests

- Recipients seeking access to Registry Data shall submit a Data Access Request Form for each proposed project or purpose.
- Requests shall include sufficient information to enable the DAC to assess the scientific, ethical, legal, and operational aspects of the proposed use of Registry Data.
- Upon receipt, the DAC Secretariat shall review the request for completeness and eligibility and may request additional information where necessary.

### 5.2 Review and Evaluation

- Complete requests shall be submitted to the DAC for review in accordance with its Standard Operating Procedures.



- The DAC may request clarifications, revisions, additional documentation, or evidence of approvals before reaching a decision.
- Certain categories of requests identified in Annex A may not require full DAC review. Such requests shall nevertheless be submitted in writing and verified by the DAC Secretariat for compliance with this Policy and the applicable eligibility criteria.
- The DAC's decision, including any conditions, restrictions, or recommendations, shall be communicated to the requestor in writing.

### 5.3 Conditions for Access

Access to Registry Data may be granted only where all applicable conditions have been satisfied.

#### 5.3.1 Regulatory and Ethical Requirements:

- Where required, appropriate ethics committee, institutional review board (IRB), or other regulatory approvals shall be obtained before access is granted.
- The requested use must be consistent with the informed consent provided by the Patients whose data are included in the requested dataset.
- For requests involving commercial entities, access shall be limited to data relating to Patients who have consented to commercial use, where applicable.

#### 5.3.2 Legal Requirements:

- Prior to receiving Registry Data, the Recipient shall execute any legal agreement required by the Coordinator or the DAC, including, where applicable, a Data Transfer Agreement (DTA), Data Access Agreement (DAA), or equivalent contractual arrangement.
- Such agreement shall require the Recipient to:
  - (i) use Registry Data solely for the approved purpose;
  - (ii) comply with applicable legal, ethical, and regulatory requirements;
  - (iii) refrain from attempting to re-identify Patients;
  - (iv) refrain from directly contacting Patients;
  - (v) implement appropriate technical and organisational measures to protect Registry Data; and
  - (vi) refrain from any onward disclosure, sharing, or secondary use of Registry Data unless expressly authorised by the DAC.

#### 5.3.3 Scientific and Operational Requirements:



- Prior to submitting a request, applicants should review the Registry Data Dictionary and available Data Elements to assess the feasibility of their proposed project.
- Applicants should also review the list of approved Research Projects published by the Registry to avoid unnecessary duplication and to encourage collaboration where appropriate.
- Any proposed secondary use of Registry Data shall be notified to the DAC. The DAC shall determine whether the proposed use falls within the scope of the original approval or requires submission of a new Data Access Request.
- Fees may apply to certain categories of Recipients, including commercial entities, in accordance with Annex A and any applicable fee schedule adopted by the Registry.

#### 5.4 Prohibited uses

Recipients shall not:

- attempt to re-identify Patients;
- use Registry Data beyond the scope, duration, or purpose approved by the DAC;
- disclose Registry Data to any third party without prior authorisation from the DAC and any other approvals required under the applicable legal agreement;
- use Registry Data for any unlawful, unethical, or unauthorised purpose.

### 6. Governance and Compliance

- Access to and use of Registry Data shall comply with this Policy, the DSA, applicable Data Protection Legislation, and any other applicable legal, ethical, or regulatory requirements.
- Each HCP remains responsible for obtaining and managing informed consent, facilitating the exercise of Data Subject rights, and complying with its obligations as Controller of the HCP Data in accordance with the DSA.
- Security requirements applicable to Registry Data are set out in Article 7 and Appendix 4 (Data Security Policy) of the DSA.
- Transfers of Registry Data to third countries or international organisations shall comply with Article 9 of the DSA and Chapter V of the GDPR.
- Personal Data Breaches shall be managed in accordance with Article 11 of the DSA, and each Party shall remain responsible for fulfilling its respective notification obligations.
- The appointment and management of Processors shall be governed by Article 8 of the DSA.
- DAC decisions, approvals, and conditions of access shall be documented and auditable.

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- This Policy shall be reviewed periodically and may be updated where required to reflect legal, regulatory, operational, or technical developments.

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## **Annex I to Appendix 6 – Stakeholders entitled to request data & data access authorisation levels.**

| <b>Stakeholder</b>                 | <b>DAC permission required</b> | <b>Cohorts</b>                                   | <b>Data elements</b> | <b>Data access level</b> | <b>Authentication</b> | <b>Fees</b> |
|------------------------------------|--------------------------------|--------------------------------------------------|----------------------|--------------------------|-----------------------|-------------|
| <b>Contributing researcher</b>     | <b>No</b>                      | <b>Own patients</b>                              | <b>All</b>           | <b>Individual-level</b>  | <b>Yes</b>            | <b>No</b>   |
|                                    | <b>No</b>                      | <b>All patients</b>                              | <b>All</b>           | <b>Aggregated</b>        | <b>Yes</b>            | <b>No</b>   |
|                                    | <b>Yes</b>                     | <b>All patients</b>                              | <b>All</b>           | <b>Individual-level</b>  | <b>Yes</b>            | <b>No</b>   |
| <b>Contributing patient</b>        | <b>No</b>                      | <b>Own data</b>                                  | <b>All</b>           | <b>Individual-level</b>  | <b>Yes</b>            | <b>No</b>   |
|                                    | <b>No</b>                      | <b>All patients</b>                              | <b>All</b>           | <b>Aggregated</b>        | <b>Yes</b>            | <b>No</b>   |
|                                    | <b>Yes</b>                     | <b>All patients</b>                              | <b>All</b>           | <b>Individual-level</b>  | <b>Yes</b>            | <b>No</b>   |
| <b>Non-contributing researcher</b> | <b>No</b>                      | <b>All patients</b>                              | <b>All</b>           | <b>Aggregated</b>        | <b>Yes</b>            | <b>No</b>   |
|                                    | <b>Yes</b>                     | <b>All patients</b>                              | <b>All</b>           | <b>Individual-level</b>  | <b>Yes</b>            | <b>No</b>   |
| <b>Industry</b>                    | <b>No</b>                      | <b>All patients consenting to commercial use</b> | <b>CDE</b>           | <b>Aggregated</b>        | <b>Yes</b>            | <b>Yes</b>  |

EURO-NMD Registry Data Sharing Agreement|Amendment No. 2 – Agreement Ref: APHP 2021-578 /01 dated 10 January 2024 and amended by Amendment No. 1 dated 16 March 2024.

*The EURO-NMD Registry was established within the framework of the European Reference Network for Rare Neuromuscular Diseases (EURO-NMD) with support from European Union funding programmes.*

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|                                                   |            |                                                  |                                                                    |                         |            |            |
|---------------------------------------------------|------------|--------------------------------------------------|--------------------------------------------------------------------|-------------------------|------------|------------|
|                                                   | <b>Yes</b> | <b>All patients consenting to commercial use</b> | <b>CDE + selected disease history/ intervention/ outcome data</b>  | <b>Individual-level</b> | <b>Yes</b> | <b>Yes</b> |
| <b>Health Authorities</b>                         | <b>No</b>  | <b>All patients</b>                              | <b>CDE</b>                                                         | <b>Aggregated</b>       | <b>Yes</b> | <b>No</b>  |
|                                                   | <b>Yes</b> | <b>All patients</b>                              | <b>CDE + selected disease history / intervention/ outcome data</b> | <b>Aggregated</b>       | <b>Yes</b> | <b>No</b>  |
| <b>Policy, supervisory or regulatory agencies</b> | <b>No</b>  | <b>All patients</b>                              | <b>CDE</b>                                                         | <b>Aggregated</b>       | <b>Yes</b> | <b>No</b>  |
|                                                   | <b>Yes</b> | <b>All patients</b>                              | <b>CDE + selected disease history / intervention/ outcome data</b> | <b>Individual-level</b> | <b>Yes</b> | <b>No</b>  |
| <b>Payers/insurers</b>                            | <b>Yes</b> | <b>All patients</b>                              | <b>CDE</b>                                                         | <b>Aggregated</b>       | <b>Yes</b> | <b>Yes</b> |
| <b>Non-Governmental Organisations</b>             | <b>Yes</b> | <b>All patients</b>                              | <b>CDE</b>                                                         | <b>Aggregated</b>       | <b>Yes</b> | <b>Yes</b> |
| <b>Patient Organisations</b>                      | <b>No</b>  | <b>All patients</b>                              | <b>All</b>                                                         | <b>Aggregated</b>       | <b>Yes</b> | <b>No</b>  |
|                                                   | <b>Yes</b> | <b>All patients</b>                              | <b>All</b>                                                         | <b>Individual-level</b> | <b>Yes</b> | <b>No</b>  |

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## Appendix 7: Publication & Authorship Policy

This Policy establishes the rules governing publications, presentations, abstracts, posters, manuscripts, and other dissemination activities arising from the use of Registry Data.

It applies to all individuals and organisations that access or use Registry Data and intend to publish, present, or otherwise disseminate Results derived from such data.

The objectives of this Policy are to:

- ensure appropriate acknowledgement of the EURO-NMD Registry and participating HCPs;
- promote transparency, fairness, and scientific integrity in the attribution of authorship;
- encourage collaboration among contributing investigators and institutions; and
- ensure that publications arising from Registry Data are conducted in accordance with internationally recognised standards of scientific authorship and good research practice

This Policy does not apply to data held exclusively by an individual HCP outside the Registry. Contributing HCPs remain free to analyse and publish their own local data, provided that any use of Registry Data is conducted in accordance with this Policy and that the EURO-NMD Registry is appropriately acknowledged where applicable.

### I. Acknowledgement of the Registry

The EURO-NMD Registry shall be acknowledged in any publication, presentation, abstract, poster, manuscript, or other dissemination activity arising from the use of Registry Data using the following acknowledgement statement:

*This study makes use of data provided through the EURO-NMD Registry, an initiative of the European Reference Network for Rare Neuromuscular Diseases (ERN EURO-NMD). The Registry was established with support from European Union funding programmes.*

In recognition of the contribution made by participating HCPs to the collection and maintenance of Registry Data, publications should, where appropriate, acknowledge the contributing institutions and investigators. Where contributors do not meet the criteria for authorship, they may be recognised as collaborators or acknowledged in accordance with the publication requirements and journal policies.

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## 2. Authorship criteria

Authorship of scientific publications arising from Registry Data shall be determined in accordance with the recommendations of the International Committee of Medical Journal Editors (ICMJE).

To qualify for authorship, an individual must satisfy all of the following criteria:

- (i) substantial contributions to the conception or design of the work, or to the acquisition, analysis, or interpretation of data;
- (ii) drafting the work or critically revising it for important intellectual content;
- (iii) final approval of the version to be published; and
- (iv) agreement to be accountable for all aspects of the work and to ensure that questions relating to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

## 3. Eligibility

- Authorship may be granted to at least one representative from centres that contributed data to the Registry within the period covered by a given study.
- Only active investigators (defined as having submitted at least 50 complete patient entries) are eligible to submit data access requests for projects intended for publication and to be considered for authorship on publications arising from Registry projects, provided they also meet ICMJE criteria.
- All investigators from contributing HCPs, whether ERN Members, Affiliated Partners, or non-ERN centres that have acceded to the Registry, shall be entitled to the same authorship opportunities, provided they meet the ICMJE criteria and the conditions set out in this Policy.

## 4. Writing Committee and Authorship Attribution

Unit leads from contributing centres will be invited to participate and/or to nominate a team member to join the Writing Committee.

To qualify for co-authorship, nominated individuals must contribute meaningfully in accordance with ICMJE criteria. Those who do not meet the criteria will be acknowledged as collaborators.

Typically, one or two potential authors may be selected per centre, depending on the size of the study and the number of centres involved. Where needed, the number of authors per centre will be weighted according to contribution; e.g. centres in the top five for patient numbers or contributing ≥10% or study cases.

In some cases, only centres that contributed data meeting the eligibility criteria for a study will be solicited to join the Writing Committee.

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Authorship order will reflect both intellectual contribution and, where relevant, the scale of data contributed. ICMJE criteria always take precedence.

When journals impose limits on the number of authors, group authorship under “EURO-NMD Registry Writing Committee” may be used, with individual names listed elsewhere in the manuscript or supplementary materials.

## **5. Studies Initiated by Contributing HCPs**

For studies initiated by investigators from participating HCPs, up to two authorships may be allocated to the lead centre, with the PI typically listed as the first author. Additional contributors from the same centre may be listed in the collaborator section or acknowledged, unless they have played a significant role in study design, analysis, or manuscript drafting, in which case they may be considered for additional authorship in line with ICMJE criteria.

## **6. Use of Published Registry Data and Publication of own data**

HCPs may publish comparisons of their local hospital data with published Registry data (including data published in the Registry’s annual report), provided the Registry is properly acknowledged.

Investigators who solely use data already published on the EURO-NMD website may do so without involving centre investigators as co-authors, provided proper citation is given.

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## Appendix 8: Accession Form

### ACCESSION OF A NEW PARTY TO THE EURO-NMD REGISTRY DATA SHARING AGREEMENT

Reference: EURO-NMD Registry Data Sharing Agreement, (Agreement Ref. APHP 2021-578/01), as amended by Amendment No. 2 (Ref. APHP 2021-578/02), dated [DATE]

**[OFFICIAL NAME OF THE NEW PARTY]** (the “Acceding HCP”) hereby accedes to the EURO-NMD Registry Data Sharing Agreement identified above and accepts all rights and obligations arising therefrom with effect from [date], in accordance with the provisions of the Agreement.

**ASSISTANCE PUBLIQUE – HÔPITAUX DE PARIS (“AP-HP”)**, acting in its capacity as Coordinator of the EURO-NMD Registry, hereby acknowledges and accepts the accession of **[OFFICIAL NAME OF THE NEW PARTY]** to the Agreement with effect from [date].

The Acceding HCP confirms that it has completed and submitted the HCP-specific information required under Appendix I of the Agreement.

This Accession Form may be executed by means of an electronic signature system, including DocuSign, which shall be deemed legally valid in accordance with the eIDAS Regulation. All executed versions, whether signed electronically or in hard copy, shall be deemed equally authentic, legally valid, and binding upon the Parties.

[Date and Place]

**[OFFICIAL NAME OF THE ACCEDING HCP]**

Signature(s)

Name(s)

Title(s)

[Date and Place]

**ASSISTANCE PUBLIQUE – HÔPITAUX DE PARIS**

Signature(s)

Name(s)

Title(s)

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