# **Data Sharing Agreement**

**BETWEEN:**

**ASSISTANCE PUBLIQUE HOPITAUX DE PARIS (AP-HP),** established in 55 Boulevard Diderot, 75012 PARIS 12, France, VAT number: FR95267500452, represented for the purposes of signing the Agreement by the [title], [Name], **the “Coordinator”**

**UNIVERSITY MEDICAL CENTRE FREIBURG (UKLFR), on behalf of University of Freiburg, Faculty of Medicine, Excecuting Department: Department of Neuropediatrics and Muscle Disorders,** established in MATHILDENSTRASSE 1, FREIBURG 79106, Germany, represented for the purposes of signing the Agreement by the [title], [Name], **the “Registry Host”**

**STICHTING RADBOUD UNIVERSITAIR MEDISCH CENTRUM (Radboudumc),**

established in GEERTGROOTEPLEIN ZUID 10 9, NIJMEGEN 6525 GA, Netherlands, VAT number: NL861608884B01, represented for the purposes of signing the Agreement by the [title], [Name]

**STICHTING UNITED PARENT PROJECTS MUSCULAR DYSTROPHY (UPPMD),**

established in KONINGINNELAAN 69, VEENENDAAL 3905 GG, Netherlands, represented for the purposes of signing the Agreement by the [title], [Name]

**STICHTING DUCHENNE DATA FOUNDATION (DDF),**

established in WARMOESDREEF 10, BERGEN OP ZOOM 4614 HC, Netherlands, represented for the purposes of signing the Agreement by the [title], [Name]

**ASSOCIATION INSTITUT DE MYOLOGIE (AIM),**

A French non-profit organisation, established in GH Pitié Salpêtrière, Bâtiment Babinski, 47-83 BOULEVARD DE L’HOPITAL, 75651 PARIS, France, VAT number: FR75483754347, represented for the purposes of signing the Agreement by the [title], [Name]

**ASSOCIATION FRANCAISE CONTRE LES MYOPATHIES (AFM),**

established in RUE DE L'INTERNATIONALE 1, 91002 EVRY France, VAT number: FR00775609571, represented for the purposes of signing the Agreement by the [title], [Name]

Hereinafter jointly referred to as the “**Members of the Consortium**”

**AND,**

**ASSISTANCE PUBLIQUE HOPITAUX DE PARIS (AP-HP),**

Established in 55 Boulevard Diderot, 75012 PARIS 12, France, VAT number: FR95267500452,

represented for the purposes of signing the Agreement by the [title], [Name],

**The “Health Care Provider” or “HCP“**

**AND,**

**UNIVERSITY MEDICAL CENTRE FREIBURG (UKLFR), on behalf of University of Freiburg, Faculty of Medicine, Excecuting Department: Department of Neuropediatrics and Muscle Disorders,** established in MATHILDENSTRASSE 1, FREIBURG 79106, Germany, represented for the purposes of signing the Agreement by the [title], [Name],

**The “Health Care Provider” or “HCP“**

**AND,**

**STICHTING RADBOUD UNIVERSITAIR MEDISCH CENTRUM (Radboudumc)**

Established in GEERTGROOTEPLEIN ZUID 10 9, NIJMEGEN 6525 GA, Netherlands, VAT number: NL861608884B01, represented for the purposes of signing the Agreement by [title], [Name],

**The “Health Care Provider” or “HCP“**

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

**WHEREAS,**

1. European Reference Networks (ERNs) are virtual networks involving healthcare providers across Europe and supported by the European Commission. They aim at facilitating discussion on complex or rare diseases and conditions that require highly specialized treatment, and concentrated knowledge and resources. Twenty-four ERNs are working on a range of thematic issues and one of these ERNs is specialized with rare neuromuscular diseases (the “**ERN EURO-NMD**”). Neuromuscular diseases is a broad group of related disorders that represent a major cause of mortality and lifelong disability in children and adults.
2. In order to support the development of research capabilities within ERNs, the European Commission decided to launch a call to support the development of rare disease (RD) registries for the ERNs, and on the 1st of May 2020, the European Commission, as funding agency, and the Assistance Public Hôpitaux de Paris, as Coordinator of the ERN EURO-NMD, signed the Grant agreement in the 3rd European Union’s Health Program (3HP-2019), for the execution of the action entitled *Patient centered and interoperable registry hub for Rare Neuromuscular Diseases – EURO-NMD Registry* (the “**Action**”). The general objective of the Action was to build a registry hub for all neuromuscular diseases, including undiagnosed patients, and connect with the existing ones. UKLFR, Radboudumc, UPPMD, DDF, AIM and AFM signed Accession Forms for Beneficiaries to become beneficiaries in the same Grant agreement and share their considerable experience in fields in connection with the Action.
3. The Coordinator, UKLFR, Radboudumc, UPPMD, DDF, AIM and AFM entered into a Consortium Agreement on the 1st of May 2020, in order to settle the building, structuration and development of the EURO-NMD registry.
4. The EURO-NMD registry (<https://registry.ern-euro-nmd.eu/>) is a centralized rare disease patient registry collecting clinical data from pediatric and adult patients with rare neuromuscular diseases across Europe (the “**Registry**”). The Registry allows healthcare professionals of the ERN EURO-NMD to strengthen collaboration to improve the healthcare of patients with rare and complex neuromuscular conditions, which requires highly specialized care. The Registry also helps to improve the knowledge about rare neuromuscular diseases and reinforce clinical research for improved diagnosis, risks prediction and the development of innovative therapies (the “**Purpose**”).
5. The Health Care Provider is an approved ERN EURO-NMD member by decision of the Board of Member States, on the basis of the criteria and conditions set in point 2 of Annex II to Delegated Decision 2014/286/EU.[[1]](#footnote-1) Having among its Patients, Patients with rare neuromuscular diseases, the Health Care Provider wishes to contribute to the ERN EURO-NMD Registry by sharing with their consent, the Personal Data of their Patients (as defined below).
6. Therefore, the Parties have agreed to enter into the present agreement (the “**Agreement**”) in order to set the terms and condition of data sharing within the Registry.

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1. **Section: Definitions**
   1. **Definitions**

Words beginning with a capital letter shall have the meaning defined either herein or in the Grant Agreement including its Annexes or in article 4 of the GDPR.

* 1. **Additional definitions**

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| **“Aggregate Data”** | 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; |
| **“Data Access Committee“** | means the independent committee appointed to approve access to the Registry Data in accordance with the Data Access Policy (Appendix 6). |
| **“Data Breach”** | 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 ; |
| "**Data Protection Legislation**" | 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 ; |
| “**Data Protection Officer**”  “**DPO**” | means the person responsible for implementing compliance with the European Data Protection Legislation within the organization that has appointed him/her for all processing operations carried out by that Organization;  All the Parties shall have appointed a DPO. |
| **“Data Subject”** | Means Patients and Users |
| **"GDPR"** | 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 119/1, 4.5.2016 ; |
| **“HCP”** | means a healthcare organisation with highly specialised services and professionals that belong to the ERN EURO-NMD; |
| **"HCP Data"** | means all Personal Data entered by the HCP in the Registry;  In the context of the Registry, HCP Data are the Users’ Data and the Patients’ Data. |
| **“Joint controllers“** | means two or more Controllers jointly determining the purposes and means of Processing; Each of the healthcare providers processing personal data in the Registry shall be joint controllers of the processing of these data in the Registry; |
| **“Patient”** | 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 ; |
| **“Patient Data”** | means the Personal Data of the Patients of the HCP entered into the Registry by the HCP using one of the available questionnaire forms;  A list of the data collected by the Registry is set out in the Registry Data Dictionary; |
| **“Pseudonymisation”** | 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 organizational measures to ensure that the personal data are not attributed to an identified or identifiable natural person ;  All Patients’ Data entered into the Registry is pseudonymised. |
| **“Recipient”** | means all natural or legal person, public authority, other HCP, agency or other body authorized to access the Registry Data, according to the conditions specified in the Data Access Policy (Appendix 6); |
| **“Registry Data”** | means the collection of Patients’ Data submitted by all HCPs and maintained in the Registry Database; |
| **“Registry Data Dictionary“** | means a file that describes the data elements or data items of the Database along with detailed specifications and codes for each variable. A list of core data elements to be collected in all Patients is proposed, including a set of 16 common data elements (CDEs); |
| **"Regulatory Body"** | means any competent governmental, statutory, regulatory or enforcement authority or regulator concerned with the activities carried on by any Party or any part, division or element thereof, in respect of the activities carried out pursuant to this Agreement ; |
| **“Registry Database”** | means the structured data system of the Registry that allows to collect, organize and display the Registry Data in a systematic or methodological manner, and which is accessible by electronic means and/or via internet. The Database contains all the necessary systems and processes for its functioning and its access; |
| **“Registry Host”** | means University Medical Center Freiburg who hosts and maintains the Registry Database; |
| **“Research Project”** | means any research project accepted by the Data Access Committee and using the Registry Data; |
| **“Results”** | means all results, in whatever form, any creation, invention, specification, information, knowledge or process developed during the course of a Research Project, whether or not they are likely to be protected by an intellectual property right, as well as any product, prototype or process resulting from a Research Project; |
| **“Research project leader”** | means the legal entity, which takes the responsibility, initiates and oversees a Research Project; |
| **“Supervisory Authority”** | means an independent public authority, which is established by a member State of the European Union. The Supervisory Authority is responsible for monitoring the application of the GDPR, in order to protect the fundamental rights and freedoms of natural persons in relation to processing. The Supervisory Authority have investigative and corrective powers; |
| **“Users”** | means the healthcare professionals (or qualified staff) working at the HCP and designated as authorized to collect, enter and/or access the HCP Data via the Registry Database; |
| **“Users’ Data”** | means the Personal Data collected about each of the Users and their institution when they request to have an account created in the Registry. This includes the user’s name, email address, institution name, and any relevant institution details. |

1. **Purpose**

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

1. **Purpose of the Processing & compliance with data privacy laws** 
   1. The Parties declare to each other that they shall Process the 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.
   2. The Parties and each Consortium Member as a standalone commit to processing the Registry Data exclusively for the Purpose for which the Registry Data is collected, within the limits of the informed consent of the Patients.
   3. The Parties shall not collect more Personal Data than strictly necessary for the Purpose.
   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.
2. **Lawfulness of Processing of Registry Data**

In order to ensure the lawfulness of the Processing of the Registry Data, according to article 6 of GDPR, the Parties may process the Registry Data only if and to the extent that at least one of the criteria set out in article 6 of 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 administrating the Registry, for the Processing of User’s Data, as set out in article 6.1f) of the GDPR.

1. **Processing of special categories of Personal Data**

Special categories of Personal Data are defined by Article 9 of 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 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.

1. **Data Subject rights**
   1. The HCP shall ensure that the Patients are informed in accordance with articles 12, 13 and/or article 14 of GDPR as applicable and according to its national and local laws.

The HCP is responsible for informing the Patients, and obtaining and recording the consent of Patients before enrolling them in the Registry and before entering any Patient Data in the Registry. To that regard, the HCP shall use the Patient information and informed consent form provided in the Appendix 3 as a basis and where necessary adjust the form in accordance with the local and institutional requirements. The consent form is age-appropriate.

The consent of Patients shall cover inter alia:

* The Processing of Patient Data by the Users of the Registry
* The Processing of the Patient Data by the Recipients within Research Projects approved by the Data Access Committee of the Registry.
* The Processing of Pseudonymized Patient Data to support research and development projects by for-profit Recipient to improve healthcare.
* The possible transfer of Pseudonymized Patient Data to non-EU countries, in compliance with GDPR, to support projects aimed to improve healthcare.
* The possible linkage of Pseudonymized Patient Data to existing databases/registries to improve healthcare.
* The possibility for Patients to be contacted by their medical doctor about Research Project related to their condition.
* The possibility for Patients to be contacted via the email address provided on the consent form for completing questionnaires about their health and to be informed of changes or updates to the Registry.
  1. The HCP shall be responsible for reviewing, at least every ten (10) years, the necessity of processing specific Patients' Data through the Registry, by asking the Patients to renew their consent.
  2. The medical doctors of the HCP will centralize the requests made by their own Patients and the HCP’s Data Protection Officers will centralize the requests made by the Users or Patients under the articles 15 to 18 and 20, 21 of the GDPR to access, modify, transfer, block, and/or delete (if and when applicable) their Personal Data, and manage and resolve them with the help of the Data Protection Officers of the Coordinator and/or the Registry Host.

The contact details of the HCP Data Protection Officer must be provided in the Appendix 1.

The Parties acknowledge that Patients may withdraw or change their initial informed consent or object to processing of their Personal Data by exercising their rights under article 21 of GDPR. The HCP shall promptly notify the Coordinator / Registry Host of any such, withdrawal, change or objection of a Patient, which may affect the use of such Patients Data.

* 1. The Parties shall assist each other by appropriate technical and organizational measures, for the fulfilment of their obligation to respond to requests for exercising the Data Subjects’ rights under chapter II of GDPR.

1. **Security measures**
   1. Each Party shall take appropriate technical and organizational measures to protect and safeguard Registry Data, such action meeting the requirements of GDPR (including notably by taking all security measures required by articles 25 and 32 of GDPR).
   2. The Parties agree to implement the technical and organizational security measures as described in Appendix 4.
   3. The Registry Host shall ensure that appropriate technical and operational measures are in place to safeguard against any unauthorized or unlawful Processing of the Registry Data and against accidental loss or destruction of the Registry Data.
   4. The Coordinator will set up the Registry help desk to support the HCP, which can be contacted at [registry@ern-euro-nmd.eu](mailto:registry@ern-euro-nmd.eu).
2. **Contracting with Processors**
   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 GDPR.
   2. The HCP hereby provides written authorization 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 these subcontractor(s) operate according to Good Industry Practice and Security Requirements with 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 involved by such Party in processing of the Registry Data during the preceding calendar year, giving the HCP the opportunity to object to such changes.
   3. Moreover, the Coordinator and the Registry Host shall ensure that the chosen Processor processes the 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 an appropriate data processing agreement within the meaning of article 28 of the GDPR.
   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.
   5. The Coordinator has the right to inspect the data processing agreement(s) referred to in article 8.1 at all times.
3. **Transfer of Registry Data to third countries or international organizations**
   1. The Members of the Consortium agree and warrant each other that the Registry Database and Registry Data are hosted in the European Union.

The Registry is hosted at: Clinical Trials Unit, Faculty of Medicine and Medical Center, University of Freiburg, Freiburg, Germany

* 1. The Data Access Committee may authorize Patients Data transfer to third countries or international organization for Research Projects, if the Patient consented to such transfer and if the Research project leader applies the provisions laid down in chapter V of GDPR “*Transfers of personal data to third countries or international organisations*”, such as the standard contractual clauses of the European Commission, in order to ensure that the level of protection of Patients guaranteed by the GDPR is not undermined.
  2. The Users’ Data will not be transferred to any third country or international organization.

1. **Privacy impact assessment**
   1. On behalf of the Members of the Consortium, the Coordinator shall carry out a privacy impact assessment on the envisaged Processing of the Registry Data in accordance with the principles set forth in article 35 of GDPR.
   2. Each HCP shall carry out a privacy impact assessment of their part of the envisaged Processing on the protection of the HCP Data in accordance with the principles set forth in article 35 of GDPR, and taking into account the nature, scope, context and purposes of its part of processing that the HCP performs as a Joint-controller.
   3. The Parties shall consult the competent Supervisory Authority, in accordance with the principles set forth in article 36 of GDPR, where the privacy impact assessment indicates that Processing would result in a high risk in the absence of measures taken to mitigate the risk.
   4. The Parties shall assist each other, where necessary, in the performance of their respective privacy impact assessments.

1. **Data Breach**

* 1. The Party under responsibility of a Data Breach occurs shall inform the other Parties of the Data Breach without undue delay, and in any event within 24 hours, and shall be responsible for making the decision whether to notify the Data Breach to the competent supervisory authority and proceed to the notification thereof to the competent supervisory authority in accordance with the principles set forth in article 33 of GDPR and to the other Parties, without undue delay and, where feasible, no later than 72 hours after having become aware of it.
  2. The noticing Party shall inform the other Party without delay of the following:
* 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.
  1. If the Parties are notified of a Data Breach, they shall consult each other on the consequences and potential consequences for all Parties.
  2. The Parties shall notify each other of the latest developments regarding the Data Breach.
  3. For the HCP the notification shall be made at the address indicated in Appendix 1

For the Coordinator the notification shall be made at the following address: [protection.donnees.dsi@aphp.fr](mailto:protection.donnees.dsi@aphp.fr).

* 1. The HCP shall meet the statutory obligations of Patients information in the event of a Data Breach that is likely to result in a high risk to the rights and freedoms of the Patients (article 34 of GDPR).
  2. The Coordinator shall meet the statutory obligations of User’s information in the event of a Data Breach that is likely to result in a high risk to the rights and freedoms of the Users (article 34 of GDPR).
  3. Each Party shall be separately responsible for reporting a Data Breach to the Supervisory Authority if a Data Breach occurred under its responsibility.
  4. If any costs are incurred in the attempt to resolve the Data Breach situation and ensure that it will not occur again in the future, said costs shall be borne by the Party on whose premises the Data Breach occurred, although the Parties may consider sharing the costs if the solution will benefit all participating Parties.
  5. The Parties shall assist each other by appropriate technical and organizational measures, for the fulfilment of their respective obligations under article 33 and 34 of GDPR.
  6. Each Party is separately responsible for recording Data Breaches in a register.

1. **Complaints**

* 1. Each Party is responsible for the handling of any complaints from Data Subjects if the complaints relate to the infringement of GDPR, for which the relevant party is responsible in accordance with article 15 below (Liability).
  2. If one of the Parties receives a complaint, part of which should rightfully be handled by the other Parties, such part is forwarded for reply by the relevant Party without undue delay.
  3. Generally, the Parties inform each other, on a confidential basis, about all complaints received.

1. **Records of processing activities**

* 1. Each Party shall maintain in writing, including in electronic format, the records of its processing related to the Registry Data in accordance with the principles set forth in article 30 of GDPR.
  2. Each Party agrees to communicate to the other Parties, for the purpose of recording, the information required in the records of their processing in accordance with the principles set forth in article 30 of GDPR.

1. **Duration of Processing, Data storage and Data disposal**
   1. **Duration of the Processing:**

The Processing of HCP Data for the HCP is deemed to start at the earliest of either the date it has obtained the HCP Data or the date it has been granted access to the Registry according to the Agreement.

The Processing thereof is deemed to end for each Party when the Registry will end or in case of termination of this Agreement in accordance with article X, at the date of termination of the Agreement.

As set out in the Governance rules (Appendix 5), in the event that the Registry or the Network are discontinued for any reason, the data will remain the responsibility of the EURO-NMD Registry Steering Committee. This Steering Committee has the responsibility to make sure that data collected through the EURO-NMD Registry will be stored securely and preserved for a period of 10 years.

* 1. **Data storage:**

The Patient Data will be stored for a maximum of ten (10) years. If necessary, after this period of time, the Patients will be asked to renew their consent.

The Users Data will be stored as long as the User is contributing to the Registry as an employee of the HCP.

All Registry Data used in a Research Project will be kept by the Research project leader in accordance with the applicable Data Protection Legislation.

* 1. **Data disposal:**

In the event it is required to destroy the Patient Data (e.g. Patient's withdrawal) or the Users Data (e.g. when a User leaves the HCP), the Patient Data or User Data will persist in backups for another 3 months and then be deleted permanently.

The Parties agree that to guarantee the validity of any Research Project performed, the Patient’s Data already processed and lawfully obtained under the Patient’s consent, cannot be deleted. However, the Patient’s Data will not be used in new Research Projects after withdrawal.

After expiration or termination of this Agreement, the Coordinator will 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.

However, the Registry Host may retain one copy of the HCP Data solely to comply with the Registry Data transfer requests that Research project leader may make for replication of Research Projects conducted before the termination of this Agreement.

1. **Liability**
   1. The HCP shall maintain in force at its sole cost and expense, with reputable insurance companies or self-insurance, insurance of a type and in an amount reasonably sufficient to protect against liability hereunder.
   2. The Parties directly insures the risks of damage to its personnel and property involved in the performance of their obligations under the Agreement.
   3. Each Party shall be liable for any damages, material and non-material, or third-party claims that may result from its own negligence, fault or omission within the performance of this Agreement, or caused by an infringement of GDPR for which it is responsible.
   4. The compensation of Data Subjects for damaged resulting from a GPDR violation shall be governed by article 82 of GDPR. Provisions of article 82 of GDPR in force at the signature date of this joint controller agreement have been reproduced below for information:

“*Article 82*

*Right to compensation and liability*

*1.   Any person who has suffered material or non-material damage as a result of an infringement of this regulation shall have the right to receive compensation from the controller or processor for the damage suffered.*

*2.   Any controller involved in processing shall be liable for the damage caused by processing which infringes this regulation. A processor shall be liable for the damage caused by processing only where it has not complied with obligations of this regulation specifically directed to processors or where it has acted outside or contrary to lawful instructions of the controller.*

*3.   A controller or processor shall be exempt from liability under paragraph 2 if it proves that it is not in any way responsible for the event giving rise to the damage.*

*4.   Where more than one controller or processor, or both a controller and a processor, are involved in the same processing and where they are, under paragraphs 2 and 3, responsible for any damage caused by processing, each controller or processor shall be held liable for the entire damage in order to ensure effective compensation of the data subject.*

*5.   Where a controller or processor has, in accordance with paragraph 4, paid full compensation for the damage suffered, that controller or processor shall be entitled to claim back from the other controllers or processors involved in the same processing that part of the compensation corresponding to their part of responsibility for the damage, in accordance with the conditions set out in paragraph 2.*

*6.   Court proceedings for exercising the right to receive compensation shall be brought before the courts competent under the law of the member state referred to in article 79(2).”*

1. **Audit**
   1. If a Regulatory Body (in particular, a Supervisory Authority) notifies one of the Party of an audit or other investigation of the Regulatory Body/Supervisory Authority regarding the Registry, the Party first notified shall promptly inform the other Parties of such notification, including the provision of a copy of any correspondence received from such Regulatory Body/Supervisory Authority with respect to the audit or investigation and provide the other Parties with the audit response or any other comment received immediately upon receipt.

In that event, the Parties undertake to facilitate access to the operating environments for these Regulatory Bodies/Supervisory Authorities and to cooperate fully with each other. The audited Party undertakes not to communicate any information directly to the said authorities without having obtained the prior written consent of the other Party, except in the case of imperative legal or regulatory provisions. For the purposes of the control, the audited Party undertakes to communicate without delay to the other Party all the elements that will be requested from it on this occasion on the medium required by the said authorities.

* 1. Subject to ten (10) working days' notice, the Coordinator reserves the right to carry out any verification that it deems useful to ascertain the HCP’s compliance with its obligations under the Agreement, in particular by means of an audit or control inspection.

The HCP undertakes to respond to the Coordinator's requests for audits and inspections carried out by the Coordinator itself or by a trusted third party that it has selected. In this respect, the HCP shall provide the Coordinator with the necessary documentation to demonstrate compliance with all its obligations under this Agreement and shall make sure that the Users of the Registry will be made available for questions.

The HCP undertakes to cooperate in good faith with any auditor so appointed. It will facilitate the auditors' access to any document or information or other element useful for the proper conduct of the audit mission and will facilitate its mission in particular by answering any questions and granting it access to all the tools and means necessary for the audit. If the conclusions of the audit show that the HCP is in breach of its contractual obligations (i) the 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 in any twelve (12)-month period.

1. **Specific obligations of the Coordinator**

The Coordinator is responsible for making the following information available to the HCP:

* + A list of all the other contributing HCPs to the Registry;
  + A list of all Research Project approved by the Data Access Committee;
  + A list of all published Results and/or presentations that have been made publicly available.
  + Annual activity reports

1. **Specific obligations of the HCP**
   1. The HCP shall, if required and applicable to it, obtain and keep on file any license, approval or similar, necessary for the participation in the Registry.
   2. As the local Controller, the HCP shall fully comply with all national, federal, state, and local legislations and regulations if applicable to it, pertaining to the activities contemplated herein, including without limitation the following: Data Protection Legislation, Clinical Trials Regulation, Regulation EU No 536/2014; 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 on the free movement of such data, and repealing Directive 95/46/EC (GDPR); the principles of ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) E6 and E11, generally accepted professional standards for clinical and research standard of care as well as any guidelines governing the performance of research in the hospital or other place where the data is collected.
   3. The HCP shall ensure with good faith and care the completion of the Database with the Common Data Elements for Rare Disease Registration (CDE) released by the European Commission and other disease-specific elements as described in the Registry Data Dictionary, that are expected to be collected on all Patients.
   4. The HCP undertakes to ensure complete follow-up of enrolled Patients once a year and to provide annual status updates on the Patients enrolled in the Registry using the appropriate questionnaire forms.
2. **Data ownership**
   1. Patient Data are under control of the Patients who give explicit informed consent prior to sharing their Patient Data with the Registry for the agreed Purpose. The Patients shall retain all rights and control on their own Personal Data.

Users Data are under control of the Users who understand that they need to share their Users Data with the Coordinator and Registry Host in order to have an account created in the Registry for purposes deemed legitimate and consistent with the purpose of the Registry and according to the Coordinator’s legitimate interest as stated in article 4 of this Agreement. The Users shall retain all rights and control on their own Personal Data.

* 1. The HCP is responsible for the collection of the Patient Data, which are under its lawful control and acts as the local Data Controller of the HCP Data.

The Registry Host is responsible for the collection of the Users Data, which are under its lawful control and acts as the local Data Controller of the Users Data.

* 1. Except for the rights explicitly granted under this Agreement, nothing in this Agreement will be construed as conferring to the Coordinator any implied right, title deed, exploitation, license right to the HCP Data and will not create any obligation, by implication or otherwise, of either Party to enter into any further Agreement with the other Party.
  2. Registry Data may be used by the HCP or the authorized Research project leader and Recipient within the limits of the Patient informed consent.
  3. Without the authorization of the Data Access Committee, the HCP reserves the right to use the HCP Data for its own purposes in accordance with all applicable national, federal, state, and local statutes, legislations, directives, regulations, and rules, including without limitation the following: Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and its implementing national legislation that will be repealed by the Clinical Trials Regulation, Regulation EU No 536/2014; 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 on the free movement of such data, and repealing Directive 95/46/EC (GDPR); the principles of ICH Harmonized Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) E6 and E11, generally accepted professional standards for clinical and research standard of care as well as any guidelines governing the performance of research in the hospital or other place where the data is collected.
  4. As agreed in the Consortium Agreement, the Members of the Consortium jointly own the database rights to the Database of the Registry.
  5. The HCP will not file, or have filed in the name of third parties in any country, any patent application, or intellectual property rights (copyrights, trademarks,...) claiming the Database or the Registry Data.

1. **Results** 
   1. **Ownership of Results**

The HCP retains all rights and interests in the HCP Data.

The Parties agree that Results arising from a Research Project are the property of the Research project leader. In the case, the Research Project is conducted by a Research project leader and one or more consortium members of ERN EURO-NMD, the Results shall be owned by the party generating the results or jointly by the parties generating jointly the results, unless the parties agree otherwise.

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.

* 1. **Use of the Results**

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

For the sake of clarity, the Research project leader of a Research Project understands that the Results does not comprehend Patients’ Data.

1. **Data Access**
   1. The Registry Host provides secured access to the system to authorized Users of the Registry and Recipients. The Registry Host ensures that all the Registry Data is stored on a secured server with appropriate level of encryption as defined in Appendix 4.
   2. The Recipients and Users of the Registry will access to the Registry Data in accordance with the Data Access Policy attached in Appendix 6 (the “**Data Access Policy**”).
   3. The Parties shall reduce access to Registry Data to an absolute minimum, on the basis of necessity and respect the roles assigns to the Recipients and Users of the Registry.
   4. Users of the Registry will have access to their own Patients Data through the Database.
   5. The HCP agrees that HCP Data may be shared with Recipients, in Aggregated or Pseudonymised format, according to the conditions defined in the Data Access Policy.
   6. The HCP is liable for any access to the Registry Data or to the Database by its Users or through its User’s access accounts or credentials. The HCP acknowledges and agrees to notify the Coordinator promptly if any of its Users leave the HCP to allow the Coordinator to revoke related access rights at the effective date of such change. Such notification should be made at the following address: [registry@ern-euro-nmd.eu](mailto:registry@ern-euro-nmd.eu).
2. **Confidentiality**
   1. **General disposition**
      1. All information in whatever form or mode of communication, which is disclosed by a Party (the “Disclosing Party”) to any other Party (the “Recipient”) in connection with Research Projects or in relation with business, affairs, customers, clients or suppliers of the other Party, is “Confidential Information”.
      2. The Recipient hereby undertakes for a period of 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 a Recipient shall take place on a strict need-to-know basis; and
* to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient comply with the confidentiality obligations herein contained with respect to such copy for as long as the copy is retained.
  + 1. The Recipients shall be responsible for the fulfilment of the above obligations on the part of their 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.
    2. The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show by written evidence that:
* the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient’s confidentiality obligations;
* the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
* the Confidential Information is communicated to the Recipient 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 Recipient completely independently of any such disclosure by the Disclosing Party ;
* the Confidential Information was already known to the Recipient prior to disclosure, or
* the Recipient 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.
  + 1. The Recipient 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.

* + 1. 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.
    2. 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.
  1. **Confidentiality of Personal Data**
     1. All Personal Data are considered Confidential Information and must therefore be treated as Confidential Information. The Parties shall impose this duty of confidentiality on all the natural persons and legal entities they engage to process Personal Data, including but not limited to employees, Processors and other Recipients of Personal Data.
     2. The Parties shall keep all Personal Data secret and shall not disclose them to internal or external parties in any way whatsoever, except in cases where:

1. Disclosure and/or transmission of the Personal Data is necessary for the Purpose of the Registry;
2. The Parties are required to disclose, transmit and/or transfer the Personal Data due to mandatory legal provisions or a court order issued by a competent court or on the orders of some other government agency having authority over the Parties, although the Parties shall first notify the other Parties of this requirement.
3. **Publication** 
   1. If Registry Data are used for a report or publication, it must be acknowledged along with the following statement:

“*This study makes use of data provided through the EURO-NMD Registry, which received funding from the European Union’s Health Programme (2014-2020) under grant agreement No. 947598. The EURO-NMD Registry is an initiative of the European Reference Network (ERN) for Rare Neuromuscular Diseases (EURO-NMD) funded by the Eurpoean Comission under the EU4Health programme.*”

* 1. Additionally, authorship in scientific publications emerging from the data collection must follow the criteria set out in the Authorship Policy (Appendix 7).
  2. The Coordinator undertakes to acknowledge the HCP as a data contributor on the public website of the Registry and in all publications resulting from a Research Project.

1. **Entry into force, duration and termination**
   1. **Entry into force**

This Agreement shall begin on the last date of signature by the Parties (the “**Effective Date**”).

A HCP becomes a new Party to the Agreement upon signature of the accession document (Appendix 8) by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

* 1. **Duration and termination**
     1. This Agreement shall continue in full force and effect during ten (10) years.

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

* + 1. However, this Agreement may be terminated in accordance with the terms of this Agreement.
       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 within sixty (60) calendar days of receipt of this notification, the defaulting Party has not performed its obligations, the Agreement may be terminated by operation of law by the Party owing the unperformed obligation. 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.
       2. The Agreement may be terminated, by operation of law, by joint agreement of the Parties recorded in writing.
       3. In the event of refusal of authorization, suspension or withdrawal of authorizations 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 authorization, suspension or withdrawal of authorization, 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.
       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.
       5. Upon expiration or termination of this Agreement, the right to use the Registry Data by the HCP will automatically end.
  1. **Survival of rights and obligations**

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.

1. **Miscellaneous**
   1. **Attachments, inconsistencies and severability**

This Agreement consists of this core text and Appendixes.

In case the terms of this Agreement are in conflict with the terms of the Grant Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments 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.

* 1. **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.

* 1. **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.

* 1. **Notices and other communication**

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 telefax with receipt acknowledgement.

Other communication:

Other communication between the Parties may also be effected 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.

* 1. **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.

* 1. **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.

* 1. **Language**

The language of this Agreement is English.

* 1. **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.

* 1. **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).

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.

* 1. **Appendixes**

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

* **Appendix 1: Details of the Processing and Matrix of responsibilities of the joint controllership**
* **Appendix 2: General Data Workflow**
* **Appendix 3: Informed Consent Form**
* **Appendix 4: Data Security Policy**
* **Appendix 5: Governance**
* **Appendix 6: Data Access Policy**
* **Appendix 7: Authorship Policy**
* **Appendix 8: Accession form**
  1. **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.

**Signatures**

**AS WITNESS:**

The Parties have caused this Agreement 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]

**Appendix 1: Details of the Processing and Matrix of responsibilities of the joint controllership**

**Details of the Processing:**

**A. IDENTITY OF THE JOINT CONTROLLERS**

|  |  |
| --- | --- |
| **The HCP:** | **Name**: …  **Address**: …  **DPO’s name and contact details**: … |
| **AP-HP / the Coordinator:** | **Name**: …  **Address**: …  **DPO’s name and contact details**: … |
| **UKLFR / the Registry Host:** | **Name**: …  **Address**: …  **DPO’s name and contact details**: … |
| **RUMC** | **Name**: …  **Address**: …  **DPO’s name and contact details**: … |
| **UPPMD** | **Name**: …  **Address**: …  **DPO’s name and contact details**: … |
| **DDF** | **Name**: …  **Address**: …  **DPO’s name and contact details**: … |
| **AIM** | **Name**: …  **Address**: …  **DPO’s name and contact details**: … |
| **AFM** | **Name**: …  **Address**: …  **DPO’s name and contact details**: … |

**B. DESCRIPTION OF PROCESSING**

|  |  |
| --- | --- |
| *Categories of data subjects whose personal data is processed* | Patients  Users (healthcare professionals) |
| *Categories of personal data processed* | For Patients:  Common Personal Data  Sensitive Personal Data  (See the Registry Data Dictionary)  For Users:  User’s name, institutional email address, institution name, and any relevant institution details |
| *The frequency of the processing (e.g. whether the data is processed on a one-off or continuous basis)* | Continuous processing |
| *Nature of the processing* | For the HCP:  collection, recording, extraction, consultation, use, deletion  For the Members of the Consortium:  Organization, structuring  For the Registry Host:  Storage, extraction, deletion |
| *Purpose(s) of the data process and further processing* | The EURO-NMD Registry is a prospective observational multi-center registry for all rare, paediatric and adult, neuromuscular disease patients, including undiagnosed cases. It is a pan-European, collaborative effort lead by EURO-NMD, an ERN for the thematic grouping of rare neuromuscular diseases (NMDs), to build the first unified NMD Registry in EU.  Collectively affecting an estimated 500,000 EU citizens, NMDs are difficult to recognize and patients experience long delays in diagnosis. No curative treatments yet exist for any NMD and their rarity and diversity pose specific challenges for healthcare and research, and for the development and marketing of therapies.  More than 150 000 patients are estimated to be seen annually by the 84 hospitals in the ERN. While the EURO- NMD health care providers are currently active in more than 120 registries, none of them is used by all EURO-NMD centres. The EURO-NMD Registry will address the fragmentation of data sources and simultaneously provide a registry platform to collect data from all patients treated within the ERN's centres. The purpose of collecting the data is to facilitate, on the one hand, the monitoring and improvement of care quality and outcomes for patients with rare neuromuscular disorders, while providing sufficient and reliable data to launch research and clinical trials, inform policy and regulatory decisions. |
| *The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period* | For Patients Data:  Twenty (20) years maximum from the time of collection for care.  For Users Data:  As long as the User is contributing to the Registry as an employee of the HCP. |
| *The types of Recipients who will have access to the Personal Data;* | Patients Data:  The HCP who collects the Patient Data for its own Patients.  Users Data:  The Registry Host (IT staff) , the Coordinator (management team)  Pseudonymised Registry Data:  Research project leader, other HCP contributing to the Registry, or other body authorized to access the Registry Data by the Data Access Committee for Research Projects.  Aggregated Data:  All natural or legal person, public authority, other HCP, agency or other body authorized to access the Registry Data as outlined in the Data Access Policy. |

**C. COMPETENT SUPERVISORY AUTHORITIES**

|  |  |
| --- | --- |
| **For the HCP:** | Name:  Address:  Website: |
| **For the Coordinator:** | **Name**:  **Address**:  **Website**: |
| **For UKLFR / the Registry Host:** | **Name**:  **Address**:  **Website**: |
| **For RUMC:** | **Name**:  **Address**:  **Website**: |

**D. LIST OF PROCESSORS**

**For the HCP:**

No data processor.

**For the Coordinator:**

No data processor.

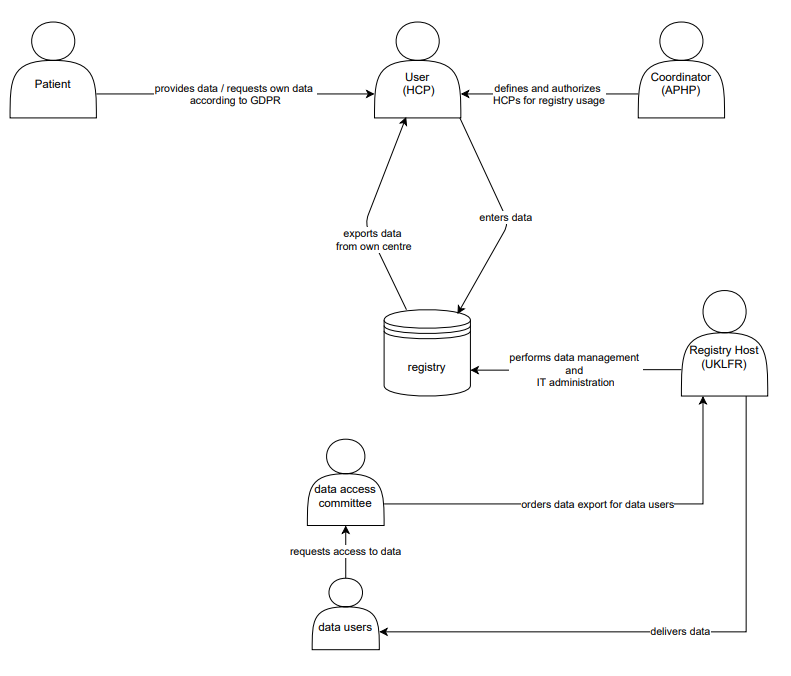
**For the Registry Host:**

No data processor.

**Matrix of responsibilities of the joint controllership**:

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Responsibility** | **The Coordinator** | **The Registry Host** | **The Members of the Consortium** | **The HCP** |
| **Definition of the characteristics of the Processing** |  |  |  |  |
| 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 |  |  |
| Maintaining documentation of the Processing | X | X |  | X |
| Performing data extraction from database | X | X |  | X |
| **Generic obligations** |  |  |  |  |
| 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 |
| **Aspects relating to the Registry** |  |  |  |  |
| 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 |  |  |
| 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 | **X** | X |  |  |
| **Information and consent of the Persons concerned** |  |  |  |  |
| 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 |
| **Management of the requests of the Data Subjects** |  |  |  |  |
| 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 Processing to the Joint Controllers, Processors and Recipients | X | X |  | X |
| **Privacy Impact Assessment** |  |  |  |  |
| 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 |
| **Data breaches** |  |  |  |  |
| 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 |
| 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 |

Appendix 2: General Data Workflow

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**Appendix 3: Informed Consent Form**

## **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. 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](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[[2]](#footnote-2). * 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 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](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. |

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| **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.  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. |

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| **PROTECTION** |

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| **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 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](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 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[[3]](#footnote-3). 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 at least 20 years. |
| 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 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. |

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| **ADDITIONAL INFORMATION** |

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| **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)

|  |
| --- |
| INFORMED CONSENT  Patient First and Last Name:………………………………………………..…………………………...  Date of Birth (dd/mm/yyyy):…../……/….…….. ID number:……………………….…………… |

|  |
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| 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. |

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| **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 and/or clinical study related to my condition** [my child/the patient condition]**.** |
|  |  | **I CONSENT** to provide my email address and be contacted to complete questionnaires about my health [the health of my child/the patient] and receive news and updates about the registry. |
| Email address:…………………………………………………………………………………………… | | |

|  |  |
| --- | --- |
| **PATIENT [PARENT/LEGAL GUARDIAN]**  Date and Signature: | **MEDICAL DOCTOR / AUTHORISED WITNESS**  Full name:  Position:  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 policy describes the data security measures incorporated in the EURO-NMD Registry, including the collection, use of and access to data, all of which are conduct in full compliance with the European General Data Protection Regulation (GDPR)[[4]](#footnote-4) and national laws and regulations pertaining to data protection and data privacy.

The EURO-NMD Registry is a patient registry for all rare, paediatric and adult, neuromuscular diseases. It is a pan-European, collaborative effort led by EURO-NMD, an ERN for the thematic grouping of rare neuromuscular diseases, to build the first unified NMD Registry in the EU.

The purpose of the EURO-NMD Registry is to improve the quality of care and outcomes for NMD patients across Europe, while providing sufficient data to launch research and clinical trials, inform policy and regulatory decisions.

The Registry received funding from the 3rd EU Health Programme and was jointly developed by a consortium of organisations: · Assistance Publique–Hôpitaux de Paris (AP-HP), · University Medical Centre Freiburg (UKLFR), · Radboud University Medical Center (Radboudumc), · World Duchenne Organization (UPPMD), · Duchenne Data Foundation (DDF), · Institute of Myology (AIM), · French Muscular Dystrophy Association (AFM-Téléthon).

The EURO-NMD Registry is a registry maintained on REDCap, a web-based database developed by Vanderbilt*.* The REDCap server is housed in a secure central facility of the University Medical Centre Freiburg (UKLFR) and maintained by UKLFR IT staff.

All data transmitted to, or extracted from, the registry platform is protected using SSL/TLS encryption. The registry platform limits personally identifiable data to Patient’s Date of Birth, Gender, information about their clinical and genetic diagnosis and the name of their treating centre of care, other potential identifiers, including, but not limited to, Patient Name, Patient Email Address, or National Identification Number, are not part of the registry.

Access to the REDCap server is password-protected and passwords are encrypted, and can only be accessed by approved registry staff who sign a Confidentiality Agreement whereby they undertake to maintain the confidentiality of any data that they access in the Registry.

Hospitals and users of the registry are responsible and liable for all data which they submit into the online system and must ensure compliance with all relevant ethical and privacy standards. To access the online database, hospital users must be affiliated to a centre part of the EURO-NMD network of healthcare providers and have an approved user account, which requires explicit approval by the principal investigator of the involved centres. In addition, hospitals must obtain approval by their relevant national or local governance authority and ethics committee to participate in the registry and have an agreement with the registry establishing the terms of participation including, but not limited to, the requirement to obtain consent for data processing and to apply pseudonymization before entering any data into the registry. The re-identifying key is kept at the local site and securely stored in such a way that re-identification of individuals is only possible by clinicians caring for patients.

Hospital staff shall transfer data to the Registry central database by entering data manually on associated data entry forms or by importing data from CSV (comma-delimited) files via the REDCap user interface. Variables are entered according to the guidance provided in the EURO-NMD Registry Data Dictionary. The initial data collection occurs at routine clinical visits and follow up data of participants are updated annually. Data are entered longitudinally and for each visit a set of data entry forms, consisting of a minimal dataset which is common across all diseases and sites, are presented. Hospital staff can only enter required information into the EURO-NMD Registry web tool.

Information held by the Registry is confidential, and access to data is restricted based on user role. A hierarchical access authorization system is implemented and web access is only provided at an individual level using two-step verification protected user accounts. All requests for local user accounts must be approved by the hospital Coordinator/representative from the same organisation on behalf of which the user is requesting access. Only authorized users at hospital sites will have direct access to the Registry and they can only access data from patients treated at their own site. Hospitals can use the online tool to produce summary data reports, export data for local analysis, and monitor and compare their performance to other participating hospitals.

The procedure for making a request for data by a third party is outlined more extensively in the EURO-NMD Registry Data Access Policy. In summary, data access request by third parties are made in writing through an online Data Access Request Form. Only pseudonymized or aggregate data can be provided to third parties on approval by the Registry’s Steering Committee and/or the Data Access Committee (DAC). Data is provided to applicants for approved studies only after the approval processes have been met and a Data Transfer Agreement has been signed.

Provision of data for linkage studies and commercial purposes is only possible if patients have specifically given permission for their pseudonymized data to be shared and combined for those purposes. Likewise, requests seeking to use the Registry to recruit participants for other relevant research projects may be met, where registrants have consented to being contacted again for this purpose. Consenting registrants will be contacted by their treating clinician. Registrant contact details are not released to researchers.

The registry is based on Consent. However, to confirm compliance with the principles set forth in article 35 of GDPR, the Coordinator, on behalf of the Members of the Consortium, completed a Privacy Impact Assessment (PIA) for the Registry database. This document is kept on file and will be reviewed regularly together with this Data Security Policy to ensure compliance with newly ratified legislation or institutional policies. Any changes will be communicated to all hospitals using the Registry platform, as well as authorized users, and other relevant stakeholders.

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| **Data security measures for the European Registry for Rare Neuromuscular Diseases (EURO-NMD Registry)** | |
| * *Measures of pseudonymisation and encryption of personal data:* | * *pseudonymisation is not part of the EURO-NMD Registry. A patient ID is generated automatically by the REDCap-system. Allocation lists for patient ID – name are not part of the REDCap-database of this project and must be stored separately.* |
| * *Measures for ensuring ongoing confidentiality, integrity, availability and resilience of processing systems and services* | * *Confidentiality: All data access is done using authentication and authorization. Each HCP user can only access patients from his/her own site (REDCap Data Access groups)* * *Integrity:*    + *SSL-certificate proves identity of REDCap-system and protects data transfer*   + *REDCap Logging-Module lists all changes made to this project, including data exports, data changes, and the creation or deletion of users* * *Availability and resilience: System is hosted in a redundant computer center and monitored (alerts for system offline, high CPU usage, high memory usage, disk space).* |
| * *Measures for ensuring the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident* | * *90 days backup for the whole virtual machine that hosts the REDCap-system and for individual files / all data on the system. Backups are physically separated from the runtime environment.* |
| * *Processes for regularly testing, assessing and evaluating the effectiveness of technical and organizational measures in order to ensure the security of the processing* | * *General yearly testing of restoring data from backup* |
| * *Measures for user identification and authorization* | * *users have to apply for an account on the system. ERN coordinator approves requests. Once approved, accounts are set up in REDCap. Expiration date, password rules, account deactivation after too many incorrect login-attempts or inactivity, separate authorization on project-level (Roles, Data Access Groups)* |
| * *Measures for the protection of data during transmission* | * *SSL-encryption* |
| * *Measures for the protection of data during storage* | * *Controlled access to REDCap-database only for authorized and trained personnel* * *antivirus* * *firewalls* * *intrusion detection* * *weekly and on-demand system- and software-updates* |
| * *Measures for ensuring physical security of locations at which personal data are processed* | * *stored in university hospital computer center which complies to german KRITIS-Verordnung for critical infrastructure* |
| * *Measures for ensuring events logging* | * *event-logging is automatically done by REDCap-system* |
| * *Measures for ensuring system configuration, including default configuration* | * *only REDCap LTS versions* * *system changes are documented* * *installation protocol and configuration checks* |
| * *Measures for internal IT and IT security governance and management* | * *IT is managed in compliance with University Medical Center IT standards (regular meetings, regulated responsibilities, security operations team at university medical center Freiburg)* |
| * *Measures for certification/assurance of processes and products* | * *Clinical Trials Unit Freiburg is a certified ECRIN-datacenter* |
| * *Measures for ensuring data minimization* | * *usage of Key Performance Indicators to ensure that all data items collected will be used in data analysis* |
| * *Measures for ensuring data quality* | * *REDCap data quality rules for live plausibility-checks and warnings for implausible values* * *datatype-validation* * *branching-logic* * *use of standardized instruments / CRFs* |
| * *Measures for ensuring limited data retention* | * *registry design has been curated by domain-experts and cleaned / harmonized afterwards so that only information relevant for the project-purpose is being collected* |
| * *Measures for ensuring accountability* | * *Clinical Trials Unit Freiburg has procedures for data protection related issues (SOPs, rules for data breaches, data protection officer)* |
| * *Measures for allowing data portability and ensuring erasure* | * *data and metadata can be exported in multiple widely used formats (PDF, CSV, R, SPSS, SAS, CDIDC / XML, turtle, owl,…)* * *data erasure is possible for registry users directly in the REDCap-system; complete data removal from backups as well automatically after 90 days* |
| * *For transfers to (sub-) processors, also describe the specific technical and organizational measures to be taken by the (sub-) processor to be able to provide assistance to the controller and, for transfers from a processor to a sub-processor, to the data exporter* | * *no sub-processor defined yet* * *data transfer is generally done via controlled procedures (data encryption, use of local cloud-platforms)* |

**Appendix 5: Governance**

The EURO-NMD Registry is a patient registry for all rare, paediatric and adult, neuromuscular diseases. It is a pan-European, collaborative effort led by EURO-NMD, an ERN for the thematic grouping of rare neuromuscular diseases, to build the first unified NMD Registry in the EU.

The purpose of the EURO-NMD Registry is to improve the quality of care and outcomes for NMD patients across Europe, while providing sufficient data to launch research and clinical trials, inform policy and regulatory decisions.

The Registry received funding from the 3rd EU Health Programme and was jointly developed by a consortium of organisations: · Assistance Publique–Hôpitaux de Paris (AP-HP), · University Medical Centre Freiburg (UKLFR), · Radboud University Medical Center (Radboudumc), · World Duchenne Organization (UPPMD), · Duchenne Data Foundation (DDF), · Institute of Myology (AIM), · French Muscular Dystrophy Association (AFM-Téléthon).

The Coordinating Centre of the ERN EURO-NMD (AP-HP) is the owner of the EURO-NMD Registry. The University Medical Centre Freiburg (UKLFR) is responsible for hosting the Registry server and database.

The EURO-NMD Registry governance structure comprises the following bodies:

The **EURO-NMD Coordinator**, who acts as the Registry lead on behalf of the Network and provides oversight to the Registry’s operations.

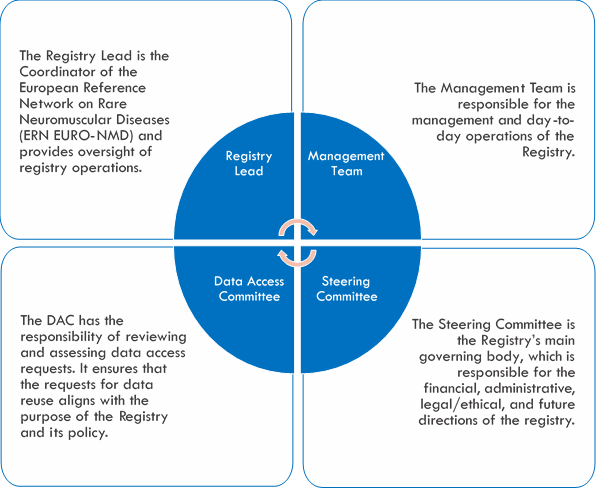
The **Steering Committee (SC),** constituted by the EURO-NMD Coordinator and members of the EURO-NMD Registry Consortium, is the Registry’s main governing and decision-making body. It provides strategic direction and ensures that agreed policies and procedures are followed. The SC works closely with EURO-NMD Executive Committee, where each thematic Work Group of the Network is represented.

Chaired by the EURO-NMD Coordinator, the SC takes its decisions on the basis of consensus, if not by absolute majority. The SC follows the operational procedures defined in the EURO-NMD Registry Consortium Agreement. The composition of the SC will be reviewed periodically and its appointed representatives updated as required.

The **Management Team**, under the guidance of the EURO-NMD Registry SC, is responsible for the daily management and the day-to-day operations of the Registry. This group is composed of members of the ERN EURO-NMD coordination office based in Paris, who are responsible for the overall management of the Registry, and the operational management team based in Freiburg, composed of IT experts and data managers, with overall responsibility for data operations and maintenance of the data entry system.

Additionally, a **Data Access Committee** (DAC) has been established to review and assess data access requests submitted by third parties in accordance with the EURO-NMD Registry Data Access Policy.

In the event that the Registry or the Network are discontinued for any reason, the data will remain the responsibility of the EURO-NMD Registry SC. This SC has the responsibility to make sure that data collected through the EURO-NMD Registry will be stored securely and preserved for a period of 10 years.



**Governing Structure of the EURO-NMD Registry**

**Appendix 6: Data Access Policy**

This Data Access Policy (DAP) document applies to the European Reference Network (ERN) Registry for Rare Neuromuscular Diseases (EURO-NMD Registry). It covers the composition of the Data Access Committee (DAC) as well as the entire process to be followed for requesting access to the data captured in the EURO-NMD registry.

## **Background**

The EURO-NMD registry is the European registry for all patients (paediatric and adults) with rare neuromuscular diseases (NMDs). The registry is affiliated to the European Reference Network for rare neuromuscular diseases (ERN EURO-NMD).

The aim of the registry is to improve quality of care, including the diagnosis, treatment and prognosis of patients with rare neuromuscular disorders and to enable research by gathering data from a large number of NMD patients and providing regulated data access following this Data Access Policy.

The EURO-NMD registry consists of a collection of common data elements for all patients followed at the participating Healthcare Providers (HCPs) of the ERN EURO-NMD combined with disease-specific data elements for all thematic disease groups covered by the ERN EURO-NMD. It incorporates the set of common data elements for rare disease registration released by the European Platform on Rare Disease Registration (EU RD Platform CDE), key performance indicators (KPIs) of care processes and patient-reported outcome measures (PROMs).

The EURO-NMD registry complies with the legal, ethical and privacy standards required within Europe. Patient data is protected in full compliance with the European Union (EU) regulations on the processing and free movement of personal data as well as with all pertinent national laws and regulations of the Member States. Written informed consent for participation in the registry is obtained from all patients and personal identifiers are removed and replaced by a pseudonym prior to data being submitted to the Registry.

The registry database and data are hosted in the European Union. The Registry is hosted at: Clinical Trials Unit, Faculty of Medicine and Medical Centre, University of Freiburg, Freiburg, Germany. The centres participating in the EURO-NMD Registry have concluded an agreement on joint protection responsibility according to art. 26 of the General Data Protection Regulation (GDPR).

For more information see: <https://registry.ern-euro-nmd.eu/>.

## **Tasks of the Data Access Committee**

The overall aim of the Data Access Committee (DAC) is to promote the research use of the data that are being collected in the EURO-NMD registry through a transparent and simple approach ensuring the long-term sustainability of the project. The DAC should advise on the maintenance of the highest levels of custodianship of the data. Whilst it should have a good knowledge of ethics and data protection, it should not act as another ‘research ethics committee’ which is a responsibility that rests at the level of the data controllers. The DAC should:

* Check that the proposed work complies with the terms and conditions of the ethics approval provided to the EURO-NMD registry.
* Look for evidence that the third-party requesting data is appropriately qualified for use of the data.
* Advise on improving the projects and any overlaps with ongoing projects.
* Ensure that the effort of all those involved is appropriately acknowledged.
* Aim to respond to all data requests promptly.
* Communicate to the requestor with appropriate feedback.
* Be aware of their own conflicts of interest.
* Treat all data requests confidentially.

## **Composition of the Data Access Committee**

The current composition of the Data Access Committee (DAC) consists of the Steering Committee of the EURO-NMD Registry project and the Chairs from each of the 5 thematic disease groups covered by the ERN EURO-NMD on an ad-hoc basis.

The EURO-NMD Registry project Steering Committee consists of the following members:

|  |
| --- |
| Neurologist and Coordinator of the ERN EURO-NMD (Chair): Teresinha Evangelista, Pitie Salpetriere University Hospital (AP-HP), Paris. |
| Neurologist and Scientific Coordinator of DM-Scope Myotonic Dystrophy Registry: Guillaume Bassez, Pitie Salpetriere University Hospital (AP-HP), Paris. |
| Neurologist and Clinical Advisor of the ERN EURO-NMD: Antonio Atalaia, Pitie Salpetriere University Hospital (AP-HP), Paris. |
| Neurologist and Chair of the ERN EURO-NMD Research Advisory Board: Hanns Lochmüller, University Medical Centre Freiburg (UKLFR). |
| Bioinformatics expert: Peter-Bram t’Hoen, Radboudumc University Medical Center Nijmegen |
| IT specialist: Adrian Tassoni, University Medical Centre Freiburg (UKLFR) |
| FAIR data expert: Nawel Lalout, Radboud University Medical Center (Radboudumc) |
| Patient representative and ERN EURO-NMD ePAG: Dimitrios Athanasiou, World Duchenne Organization (WDO) |
| Patient representative and Chair of the World Duchenne Organization: Elizabeth Vroom, World Duchenne Organization (WDO) |
| Patient representative and Chair of the ERN EURO-NMD Patient Advisory Board: Francois Lamy, French Muscular Dystrophy Association (AFM-Téléthon) |
| Patient Representative, AI expert and Chair of the Duchenne Data Foundation: George Paliouras (DDF) |
| Project Manager: Paraskevi Sakellariou (DDF) |
| Data manager: Dagmar Wandrei, University Medical Centre Freiburg (UKLFR) |
| Project and Communication manager: Suzie Ann Bakker, Duchenne Data Foundation (DDF) |
| Senior Project Manager of the ERN EURO-NMD: Carla D’Angelo, Institute of Myology, Paris (AIM). |

## **Registry authorized users**

The EURO-NMD registry is a web-based platform subject to role-based authorization privileges and controls. Access of authorized users to the registry is controlled by assignment of a secure, individualized password. Authorised users are issued with a unique username and password enabling them the appropriate level of access to the system

The following broad groups of stakeholders will require access to the EURO-NMD registry platform:

|  |  |
| --- | --- |
| Registry Coordinator & Management Team | Has full access to all data and provides access to authorized users |
| Hospital Coordinators (principal investigators) | Has full access to all cases at their centre and approves or denies access requests from centre users. |
| ERN Workgroup leads | Has full access to all cases of the disease group covered by the relevant workgroup. |
| Clinical Contributor | Has full access to all the cases of their center and approves or denies access requests from local team members. |
| Patient | Has access to their own individual data. Can complete on-line questionnaires, gain information and understanding of what has been done with their data (who had/has access to their data and for which purpose). |

## **Stakeholders entitled to Request Registry Data**

The following stakeholders are entitled to request data from the EURO-NMD registry in order to contribute to projects whose objectives are directly connected to improve healthcare provision to individuals living with rare neuromuscular diseases:

* Researchers contributing to the EURO-NMD registry
* Patients contributing own data to the EURO-NMD registry
* Non-contributing researchers
* Pharmaceutical companies
* Health authorities
* Policy, supervisory or regulatory agencies
* Payers/insurers
* Non-Governmental Organisations
* Patient organizations

**Note:** Private companies data access should be submitted to the negotiation and execution of a separate agreement.

## **Categories of requestable data**

The stakeholders entitled to request registry data can request the following type of data:

|  |  |
| --- | --- |
| Aggregated data | 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; |
| Individual-level data | All data derived from the Registry Data that are attributable to an individual Patient. |

The data access authorisation levels can be found in detail in Annex A. All data access requires authentication.

All data in the registry are pseudonymized, in the definition of GDPR; the registry does not contain directly identifiable data elements. The pseudonymization key lies with clinical contributors. Stakeholders that are given access to the data should not make any attempt to identify a participant in the registry.

## **Ownership of the data**

In the EURO-NMD registry, the patient participant (who is the ‘data subject’) is the primary owner of the data and must give explicit informed consent prior to participation in the Registry and to the use of such data for research and other purposes. In case the patient participant is under the age of majority, or if the data subject is physically or legally incapable of giving consent, parent(s) or legal guardian(s) is/are the primary owner(s) of the data and are authorised to provide consent for the data collection and all processing activities.

The institution of the clinician participant who has entered the data is the owner of the data of that patient participant.

When processed, the data become research data and are then the intellectual property of the investigator.

The healthcare provider hosting the Coordinating Centre of the ERN EURO-NMD is the owner of the EURO-NMD registry platform.

## **Research and data analysis**

The Registry is funded within the 3rd Health Programme of the European Union and receives support from the World Duchenne Organisation (WDO), Duchenne Data Foundation (DDF), Institute of Myology (AIM), and the French Muscular Dystrophy Association (AFM-Téléthon).

The data in the EURO-NMD registry shall undergo analysis at regular intervals by the Project Management Team for detailed data consistency evaluations. This analysis will focus on overall data accrual, content, quality, and headline descriptions of care. This analysis will not require approval from the DAC but shall be performed closely with oversight of the DAC to provide progress reports.

All other analysis will require completion of a Data Access Request Form to be reviewed by the Data Access Committee where appropriate and the signing of a Data Transfer Agreement regulating the terms and conditions for the use of data, including:

* Commitment to ensure that the data will be used for the purpose intended and approved
* Commitment to respect the EU legislation
* Commitment to no attempt to re-identification
* Commitment to no attempt to directly contact the patients.

Prior to any application being prepared/submitted, investigators should first review the data elements and data dictionary posted on the Registry website to verify that critical data are available for their proposed study. In addition, proposals must not have any major overlap with other approved research proposal. A list of previously approved research proposals, or studies that are in progress, are available on the Registry website.

## **Process for seeking access to the data**

* Applicants shall need to complete the online Data Access Request Form for every proposed research question/project.
* The EURO-NMD registry Management Team will undertake an initial review within 3 weeks of submission and forward to the DAC; if the application has not been satisfactorily completed, the management team will request clarification or further information.
* The DAC meets on a monthly basis. Applications which are complete and have addressed all applicable clarifications will be discussed at the next available DAC meeting.
* The DAC shall provide their feedback using the Feedback Form within one week of the meeting. The DAC may ask the requesting investigator for clarifications related to their proposals before a final decision.
* Following approval, applicants shall need to sign and comply with the Data Transfer Agreement.
* If a fee is requested to access the data, the management team will notify the applicant prior to release of prepared data.
* Some requests will not require DAC review but must still be made in writing, on the appropriate form, stating the need and purpose of the request.
* In case the contents of a new application overlap with an existing active application, the investigators of the two applications will be jointly advised to discuss the overlap.

The Registry only provides access to data for which:

* documented and valid informed consents have been obtained from patients (or their legal representatives); when an industry representative applies for data, only data from patients who consented to commercial use will be granted; and
* required documentation regarding requests for Access to Registry Data is received, on the appropriate forms, including but not limited to the data access request form; and
* DAC approval has been obtained to allow investigator(s) to access and use the data for a specific study proposal (if required); and/or
* Ethics’ committee or institutional review board authorization has been obtained as required by Investigator prior to initiating the research as required.

**Note**: Requests seeking to use the Registry to recruit participants for a study or for additional data collection should be addressed to the Steering Committee.

All documents are accessible on the EURO-NMD registry website (<https://registry.ern-euro-nmd.eu/>) and through the EURO-NMD registry project management team.

## **Governance review**

This document will be reviewed every two years from the implementation but may be reviewed and updated more frequently as required, e.g. in the event of operational changes or following significant changes to any applicable laws.

**Annex A: Stakeholders entitled to request data & data access authorization levels.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| Stakeholder | DAC permission required | Cohorts | Data elements | Data  access level | Authentication | Fees |
| Contributing researcher | **No** | **Own patients** | **All** | **Individual-level** | **Yes** | **No** |
| **No** | **All patients** | **All** | **Aggregated** | **Yes** | **No** |
| **Yes** | **All patients** | **All** | **Individual-level** | **Yes** | **No** |
| Contributing patient | **No** | **Own data** | **All** | **Individual-level** | **Yes** | **No** |
|  | **No** | **All patients** | **All** | **Aggregated** | **Yes** | **No** |
|  | **Yes** | **All patients** | **All** | **Individual-level** | **Yes** | **No** |
| Non-contributing researcher | **No** | **All patients** | **All** | **Aggregated** | **Yes** | **No** |
| **Yes** | **All patients** | **All** | **Individual-level** | **Yes** | **No** |
| Industry | **No** | **All patients consenting to commercial use** | **CDE** | **Aggregated** | **Yes** | **Yes** |
| **Yes** | **All patients consenting to commercial use** | **CDE + selected disease history/ intervention/ outcome data** | **Individual-level** | **Yes** | **Yes** |
| Health Authorities | **No** | **All patients** | **CDE** | **Aggregated** | **Yes** | **No** |
| **Yes** | **All patients** | **CDE + selected disease history / intervention/ outcome data** | **Aggregated** | **Yes** | **No** |
| Policy, supervisory or regulatory agencies | **No** | **All patients** | **CDE** | **Aggregated** | **Yes** | **No** |
| **Yes** | **All patients** | **CDE + selected disease history / intervention/ outcome data** | **Individual-level** | **Yes** | **No** |
| Payers/insurers | **Yes** | **All patients** | **CDE** | **Aggregated** | **Yes** | **Yes** |
| Non-Governmental Organisations | **Yes** | **All patients** | **CDE** | **Aggregated** | **Yes** | **Yes** |
| Patient Organisations | **No** | **All patients** | **All** | **Aggregated** | **Yes** | **No** |
| **Yes** | **All patients** | **All** | **Individual-level** | **Yes** | **No** |

**Appendix 7: Authorship Policy**

This document describes the guidelines for the publication of work generated using any of the data stored on the EURO-NMD Registry. It applies to all individuals requesting to use and wishing to publish any form of publication based on data that have been provided to the EURO-NMD Registry, including (but not limited to) manuscripts, abstracts, posters and presentations.

This policy does not apply to site-specific data and, as such, contributing hospitals are free to publish their own data at any time with acknowledgement of the EURO-NMD Registry as per section below.

**Acknowledgement**

The EURO-NMD Registry should be acknowledged in any form of publication using data provided by the EURO-NMD Registry using the following wording:

This study makes use of data provided through the EURO-NMD Registry, which received funding from the European Union’s Health Programme (2014-2020) under grant agreement No. 947598. The EURO-NMD Registry is an initiative of the European Reference Network (ERN) for Rare Neuromuscular Diseases (EURO-NMD), funded by the Eurpoean Comission under *the EU4Health programme* and coordinated by Assistance Publique - Hôpitaux de Paris (AP-HP).

In recognition of the effort that data contributors made in collecting and providing the data to the Registry, it is also a requirement to acknowledge contributions to the data collection. Where possible, publications based on data held by the Registry will include a list of local site Principal Investigators (PIs) from hospitals participating in Registry, as part of a study collaborators list if they have not been involved as co-author.

**Authorship criteria**

Authorship on scientific publications emerging from registry data may be required when investigators associated with contributing hospitals make substantial contributions to a published study. Authorship credit should be based on the International Committee of Medical Journal Editors (ICMJE, http://www.icmje.org/)

The ICMJE currently recommends the following criteria for authorship credit:

1. Significant involvement in study conception/design, data collection, or data analysis/interpretation;
2. Involvement in drafting or revising manuscript;
3. Approval of final version of manuscript for publication; and
4. Responsibility for accuracy and integrity of all aspects of research.

Authorship may be granted to at least one representative from centres that have contributed data to the Registry within the period covered in a proposed study, this may be done through a group authorship, e.g. the “EURO-NMD registry investigator group”. The EURO-NMD unit lead will be invited to participate and/or to nominate a member of their team to be part of the writing committee for that paper and therefore qualify for co-authorship. To ensure co-authorship status, everyone who agrees to participate on the writing committee must make valuable contributions to the study consistent with ICMJE authorship guidelines. Centre designated co-authors who are unable to meet the obligations of authorship will be named in the Acknowledgement.

Typically, one or two potential authors would be selected per centre, but the number of selected authors will depend on the size of the study and the number of centres. When necessary, the criteria for defining the number of co-authors per centre will be the number of included patients; e.g. if a centre is among the five centres with the largest numbers of cases in the study or contributes 10% or more of the cases. In special cases, only centres that contributed data for substantial numbers of patients meeting the eligibility criteria for a study will be solicited to join the Writing Committee.

The sequence of listing of the co-authors will follow the number of included patients in the publication per site; otherwise, authorship ranking will be based on the value and extent of contribution to the manuscript. If the number of authors is restricted by a journal, authorship may be attributed to the “EURO-NMD Registry” with authors names explicitly identified anywhere else in the text of the article as the members of the writing group for the article.

For studies which had been proposed by investigators from participating hospitals, two co-authorships will be accepted from the investigating centre which submitted the data request. The principal investigators should be appointed as the first author. Only active investigators (minimum 50 complete documented entries) may submit data requests for projects intended for publication.

If hospitals wish to publish comparisons of local hospital data with the Registry published data (including data published in the Registry annual report) then the EURO-NMD Registry must be acknowledged in the appropriate way as described above.

Investigators who uniquely use data published on the EURO-NMD website may do this without co-authorship with centres investigators as long as they reference correctly the EURO-NMD Registry website.

Appendix 8: Accession Form

**ACCESSION of a new Party to**

**EURO-NMD Registry Data Sharing Agreement, version […, YYYY-MM-DD]**

**[OFFICIAL NAME OF THE NEW PARTY]**

**hereby consents to become a Party to the EURO-NMD Registry Data Sharing Agreement identified above and accepts all the rights and obligations of a Party starting [date].**

**ASSISTANCE PUBLIQUE HOPITAUX DE PARIS, the Coordinator**

**hereby certifies that the Members of the Consortium have accepted the accession of [the name of the new Party] to the Data Sharing Agreement starting [date].**

**This Accession document has been done in 2 originals to be duly signed by the undersigned authorised representatives.**

**[Date and Place]**

**[INSERT NAME OF THE NEW PARTY]**

**Signature(s)**

**Name(s)**

**Title(s)**

**[Date and Place]**

**ASSISTANCE PUBLIQUE HOPITAUX DE PARIS**

**Signature(s)**

**Name(s)**

**Title(s)**

1. 2014/286/EU: Commission Delegated Decision of 10 March 2014 setting out criteria and conditions that European Reference Networks and healthcare providers wishing to join a European Reference Network must fulfil [↑](#footnote-ref-1)
2. 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 biomedical research (2005); the [“standard contractual clauses for the transfer of personal data to third countries” (EU) 2021/914](https://eur-lex.europa.eu/legal-content/DE-EN/TXT/?from=DE&uri=CELEX%3A32021D0914) and **…. <please include any other applicable law>** [↑](#footnote-ref-2)
3. 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. [↑](#footnote-ref-3)
4. 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 on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) [↑](#footnote-ref-4)