EURO-NMD
Registry Hub
European Reference Network
for neuromuscular diseases

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 [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 [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 [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 [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 [title], [name].

ASSOCIATION INSTITUT DE MYOLOGIE (AIM), a French not-for-profit organisation, organized under the French Law of July 1, 1901, established in 47-83 BOULEVARD DE L'HOPITAL, 75651 PARIS, France, VAT number: FR75483754347, represented for the purposes of signing the Agreement by [title], [name].

ASSOCIATION FRANCAISE CONTRE LES MYOPATHIES (AFM), a French not-for-profit organization, organized under the French Law of July 1, 1901, having its headquarters at 47-83 Boulevard de l'Hopital, 75651 Paris Cedex 13, France, and its principal offices 1 RUE DE L'INTERNATIONALE, 91000 EVRY COURCOURONNES, France, VAT number: FR00775609571, represented for the purposes of signing the Agreement by [title], [name].

This document is part of the project 'EURO-NMD Registry' co-financed by the European Commission under the Third Health Program (grant agreement 101055286). The EURO-NMD Registry has also received funding for 5 months from the EU4health program (grant agreement 101085084) and will continue to be funded for the 2023-2027 period under the call EU4H-2023-ERN-IBA.

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 [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,

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a) 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.

b) In order to support research on rare diseases, the European Commission has launched 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.

c) 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.

d) 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**").

e) 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

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of Annex II to Delegated Decision 2014/286/EU.[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).

f) 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

1.1. 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.

1.2. Additional definitions

"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 ;

[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

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"**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;

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	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

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	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.

2. 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.

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

3.1. 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.

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3.2. 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.

3.3. The Parties shall not collect more Personal Data than strictly necessary for the Purpose.

3.4. The Parties agree on the specification of the Processing and on their respective responsibilities, as described in Appendix 1, and the data entry and export process used in the Registry, as depicted in the Data Flow Diagram in Appendix 2.

4. Lawfulness of Processing of Registry Data

In order to ensure the lawfulness of the Processing of 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.

5. 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.

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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.

6. Data Subject rights

6.1. 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.

6.2. 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.

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6.3. 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.

6.4. 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.

7. Security measures

7.1. 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).

7.2. The Parties agree to implement the technical and organizational security measures as described in Appendix 4.

7.3. 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.

7.4. The Coordinator will set up the Registry help desk to support the HCP, which can be contacted at registry@ern-euro-nmd.eu.

8. Contracting with Processors

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8.1. Each Party hereby warrants that any Processing performed by a third party on its behalf is governed by a contract in accordance with article 28 of GDPR.

8.2. 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 industrial 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.

8.3. 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.

8.4. The obligations arising from this Agreement shall also apply to those who process Personal Data under the Parties' authority, such as the Parties' Processors they have contracted.

8.5. The Coordinator has the right to inspect the data processing agreement(s) referred to in article 8.1 at all times.

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

9.1. The 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

9.2. 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

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clauses of the European Commission, in order to ensure that the level of protection of Patients guaranteed by the GDPR is not undermined.

9.3. The Users' Data will not be transferred to any third country outside the EU or international organization.

10. Privacy impact assessment

10.1 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.

10.2 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.

10.3 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.

10.4 The Parties shall assist each other, where necessary, in the performance of their respective privacy impact assessments.

11. Data Breach

11.1 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.

11.2 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;

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- The categories of Personal Data that was subject to the Data Breach and the approximate number of individuals and Personal Data affected;
- The name and contact information of the Parties' Data Protection Officer and/or any other point of contact from whom additional information may be obtained;
- A description of the likely consequences of the security breach;
- A description of the measures to remedy the security breach, including, if applicable, measures to mitigate any adverse effects;
- Any other information that the other Parties may reasonably request regarding the security breach.

11.3 If the Parties are notified of a Data Breach, they shall consult each other on the consequences and potential consequences for all Parties.

11.4 The Parties shall notify each other of the latest developments regarding the Data Breach.

11.5 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: [insert address]

11.6 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).

11.7 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).

11.8 Each Party shall be separately responsible for reporting a Data Breach to the Supervisory Authority if a Data Breach occurred under its responsibility.

11.9 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.

11.10 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.

11.11 Each Party is separately responsible for recording Data Breaches in a register.

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12. Complaints

12.1 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).

12.2 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.

12.3 Generally, the Parties inform each other, on a confidential basis, about all complaints received.

13. Records of processing activities

13.1 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.

13.2 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.

14. Duration of Processing, Data storage and Data disposal

14.1 **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, regarding the data collected prior to discontinuation the Steering Committee shall determine whether the data shall be destroyed, returned to the

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HCPs they originate from or other options to maintain the data for research in accordance with applicable privacy law and regulations.

14.2 **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.

14.3 **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.

15. Liability

15.1 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.

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15.2 The Parties directly insures the risks of damage to its personnel and property involved in the performance of their obligations under the Agreement.

15.3 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.

15.4 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.*

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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).”

16. Audit

16.1 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.

16.2 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-

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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.

17. 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

18. Specific obligations of the HCP

18.1 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.

18.2 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.

18.3 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.

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18.4 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.

19. Data ownership

19.1 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.

19.2 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.

19.3 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.

19.4 Registry Data may be used by the HCP or the authorized Research project leader and Recipient within the limits of the Patient informed consent.

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19.5 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.

19.6 As agreed in the Consortium Agreement, the Members of the Consortium jointly own the database rights to the Database of the Registry.

19.7 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.

20. Results

20.1 **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.

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20.2 **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.

21. Data Access

21.1 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.

21.2 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**").

21.3 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.

21.4 Users of the Registry will have access to their own Patients Data through the Database.

21.5 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.

21.6 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.

22. Confidentiality

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22.1 General disposition

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

22.1.2 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.

22.1.3 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.

22.1.4 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;

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- 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.

22.1.5 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.

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

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

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

22.2 Confidentiality of Personal Data

22.2.1 All Personal Data 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,

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including but not limited to employees, Processors and other Recipients of Personal Data.

22.2.2 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:

i. Disclosure and/or transmission of the Personal Data is necessary for the Purpose of the Registry;

ii. 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.

23. Publication

23.1 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.*"

23.2 Additionally, authorship in scientific publications emerging from the data collection must follow the criteria set out in the Authorship Policy (Appendix 7).

23.3 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.

24. Entry into force, duration and termination

24.1. **Entry into force**

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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.

24.2. **Duration and termination**

24.2.1 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.

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

24.2.2.1 In the event of total or partial non-performance by one of the Parties of any of its obligations, the Party noting such non-performance shall send the defaulting Party notification by registered letter with acknowledgement of receipt setting out the breach of the obligations of the Agreement. If 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.

24.2.2.2 The Agreement may be terminated, by operation of law, by joint agreement of the Parties recorded in writing.

24.2.2.3 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.

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

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24.2.2.5 Upon expiration or termination of this Agreement, the right to use the Registry Data by the HCP will automatically end.

24.3. **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.

25. Miscellaneous

25.1 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.

25.2 No representation, partnership or agency

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

25.3 Force Majeure

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

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

25.4 Notices and other communication

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.

25.5 Assignment and amendments

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

25.6 Mandatory national law

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

25.7 Language

The language of this Agreement is English.

25.8 Applicable law

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

25.9 Settlement of disputes

The Parties shall endeavor to settle their disputes amicably.

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

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.

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

25.10 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**

25.11 Signature

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

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]

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