Data Protection Addendum to the Study AGREEMENT Participating Site – EAN COVID-19 Registry

**Agreement according to Article 26 GDPR**

(hereinafter referred to as “**Agreement**”)

concluded between

1. The European Academy of Neurology, Breite Gasse 4/7, 1070 Wien, Österreich, ZVR 120490024, UID ATU 64517909 (“**EAN**”), an association organized in accordance with public law of Austria, with principal place of business in Vienna, Austria, lawfully represented by First Name Last Name, Acting President of EAN

and

2. INSERT PARTICPATING SITE NAME Head: Name (hereinafter referred to as **“Participating Site”**), lawfully represented by [LEGAL REPRESENTATIVE]

EAN and the Participating Site both jointly hereinafter referred to as “**Joint Controllers**” or “**Parties**”. Each of them hereinafter referred to as “**Party**”

**Preambles**

**WHEREAS** The Joint Controllers concluded Study AGREEMENT Participating Site (“**Study Site Agreement**”) concerning the EAN Neuro-COVID Registry (ENERGY) study (hereinafter also referred to as “**Study**”). EAN acts as organizer of the Study. The Participating Site conducts the Study as set out in the Study Site Agreement and the Protocol (Appendix A of the Study Site Agreement).

**WHEREAS** within the scope of the Study, personal data (hereinafter also referred to as “**Joint Data**”) are processed by the Parties. With regard to some of the processing activities (“**Joint Processing Activities**”) the Parties jointly define the purposes and means so that they act as Joint Controllers within the meaning of Article 26 GDPR. This Agreement defines the Joint Processing Activities, the respective tasks, actual functions and relationships of the Joint Controllers in connection with the Joint Processing Activities and regulates the responsibilities regarding data protection obligations.

Within the context of the Study, personal data of patients will be processed in various process steps. It is the intention of the Joint Controllers to define these process steps as far as possible as separate areas of responsibility of the respective Parties. Therefore, unless otherwise stated in this Agreement, each of the Parties is solely responsible for the compliance with all applicable data protection laws of the data processing in its own area of responsibility.

# Introductory Provisions

In the event of a contradiction between clauses of this Agreement and the provisions of Study Site Agreement or the Protocol, the clauses of this Agreement shall prevail.

In case of doubt, terms used in this Agreement (such as personal data, human subjects, processing, personal data breach, etc.) have the meaning given to them in the EU General Data Protection Regulation 2016/679 (hereinafter also referred to as "GDPR").

Participating Site guarantees that it processes personal data within their respective area of responsibility in accordance with the GDPR and local data protection laws.

# Areas of responsibility of the Parties

## Sole controllership of Participating Site

Participating Site is the sole controller pursuant to Art 4 (7) GDPR for all processing activities involving the collection of clear data from patients, the medical treatment and the patient record. Participating Site guarantees and is responsible for compliance with the applicable data protection laws and other legal provisions.

## Joint controllership of the Parties (Joint Processing Activities)

The Parties are Joint Controllers for the following processing activities:

* Filling out the Case Report Forms and any other form of data collection of the human subject according to the Study Site Agreement and the Protocol.
* Pseudonymization of personal data of each human subject performed by Participating Site for the purposes of the Study
* Record-keeping, access to records and record retention in accordance with the Study Site Agreement and the Protocol.
* The provision of personal data in the central database in accordance with the Study Site Agreement and the Protocol.

## Sole controllership of EAN

EAN is the sole controller pursuant to Art 4 (7) GDPR for the following processing activities:

* Operating the central Database.
* Performance of statistical analysis in accordance with the Study Site Agreement and the protocol.

# Term of Agreement

The term of Agreement corresponds with the term of contract of the Study Site Agreement.

# Purposes and Means

The purposes and the means of the Joint Processing Activities are set out in the Study Site Agreement and the Protocol.

# Consents

Within the scope of the processing activities according to contract points 2.2 and 2.3, Participating Site obtains consents from the human subjects in accordance with the GDPR (in particular Articles 5, 6, and 7 GDPR) and applicable local data protection law in a legally effective manner. Participating Site complies with the rights of the human subjects (e.g. right to revoke consent, etc.).

The declaration of consent is to be drawn-up by Participating Site. Upon request of EAN, Participating Site shall provide EAN with the wording of the declaration of consent and make amendments as requested by EAN.

Participating Site guarantees that it only processes data of human subjects who have given their consent within the Joint Processing Activities.

# Information obligations

Within the scope of the processing activities according to contract points 2.2 and 2.3, Participating Site fulfils the relevant information obligations in compliance with the GDPR (Art 12, 13 and 14 GDPR) and local data protection law towards the human subjects. If Participating Site requires information from EAN, EAN will make it available. Upon request of EAN, Participating Site shall provide EAN with the wording of the documents of information and make amendments as requested by EAN.

# Handling the rights of the human subject

Participating Site must respond to all requests of human subjects for exercising their rights and the communication with human subjects within the scope of the Joint Processing Activities, including the right to access (Art 15 GDPR), rectification (Art 16 GDPR), erasure (Art 17 GDPR), right to restriction of processing (Art 18 GDPR), right to object to processing (Art 21 GDPR) and right to data portability (Art 20 GDPR), the right not to be subject to a decision based exclusively on automated processing - including profiling - (Art 22 GDPR), the notification obligation (Art 19 GDPR) or comparable rights under local data protection law, are handled by Participating Site.

Participating Site informs EAN in the event of a request by a human subject within this clause within three days.

# Personal Data Breach

Each Joint Controller must inform the other Joint Controller immediately of any personal data breach in connection with the Joint Processing Activities. This information shall at least include:

a) a description of the nature of the personal data breach including if possible, the categories and approximate number of human subjects concerned and the categories and approximate number of personal data records concerned;

b) the likely consequences of the personal data breach;

c) the measures taken or proposed to be taken by the controller to address the personal data breach, including, where appropriate, measures to mitigate its possible adverse effects.

If the supervisory authority contacts a Joint Controller with regard to a personal data breach in connection with Joint Processing Activities, the Joint Controller shall also inform the other Joint Controllers without delay.

The Joint Controllers shall assist each other and provide each other with all necessary information relating to personal data breach.

Notifications and communication shall be agreed in advance with the other Joint Controller.

# Further Data Protection Obligations

Each Joint Controller is obliged to ensure compliance with the data protection principles (Art 5 GDPR) for the processing activities to be carried out by him and to implement suitable technical and organisational measures pursuant to Art 24 para. 1 GDPR, Art 32 para. 1 GDPR and to update them regularly.

In particular, it is agreed:

##### The Joint Controllers are obliged to document the Joint Processing Activities in accordance with the requirements of the GDPR (if applicable) so that they can meet their accountability obligations.

##### The Joint Controllers are obliged to document the Joint Processing Activities in their records of processing activities in accordance with the provisions of Art 30 GDPR or comparable obligations under local data protection law (if applicable).

# Making available the essential contents of this Agreement

Participating Site shall inform the human subjects concerned by the Joint Processing Activities of the substantial contents of this Agreement. In doing so, at least a description of the actual functions and relationships of the Joint Data Controllers towards the human subjects, the information on the distribution of responsibilities (contract points 4 to 9) must be made available to the human subjects.

# Confidentiality

Participating Site, its employees and any other third parties engaged by it are required to keep personal data from the Joint Processing Activities and other information of EAN; provided to it on the basis of the Study or this contractual relationship confidential, notwithstanding other legal duties of confidentiality.

Participating Site hereby represents and warrants that the persons authorised to perform the Joint Processing Activities are reliable and adequately trained in respect of their compliance with this Agreement and applicable data protection law.

Participating Site hereby represents and warrants that the persons authorised to perform the Joint Processing Activities, in particular the persons in charge of data input in the central Database, have given an undertaking of confidentiality and of compliance with legal data secrecy or are subject to an appropriate legal duty of confidentiality.

# Breach of joint responsibility

If a Joint Controller processes joint data for purposes other than those defined jointly in contract point 2.2. of the Agreement, he shall himself be controller within the meaning of Article 4(7) of the GDPR for this processing activity. In this case he shall be solely and unrestrictedly liable to third parties. In addition, he shall indemnify and hold harmless the other Joint Controller from and against any and all disadvantages (e.g. claims, damages, expenses and costs), including those of an non-material nature, which arise or may arise for him or them as a result of this processing activity. This also applies to the defence against such disadvantages, irrespective of whether they are justified or unjustified and irrespective of the legal basis on which they are based.

# Information and coordination obligations

The Parties shall support each other in good faith and free of charge in the performance of their respective data protection obligations and shall inform each other without request and without delay of any relevant developments that could affect the performance of the data protection obligations of one of the Parties.

Upon request of a Party, the other Party shall promptly provide any information from its own area of responsibility that the requesting Party needs to fulfil its own data protection obligations.

Statements, notifications and other communication with supervisory authorities, courts, human subjects or other third parties concerning data processing subject to joint responsibility must be coordinated in advance with the other Party (insofar as this is reasonable under the circumstances and legally permissible).

If claims for damages, fines or other sanctions or measures based on data protection laws are threatened or asserted against a Party, the other Party must be informed thereof without delay. Without prior written agreement with regard to the Study Site Agreement with the other Party, no substantive statement shall be made to claimants or authorities (in particular no acknowledgement, confession or comparable declarations).

The Parties shall inform each other immediately and in full if errors or irregularities in data processing or violations of provisions of this Agreement or applicable data protection law (in particular the GDPR) are identified.

**IN WITNESS WHEREOF**, Parties have executed this Agreement by their respective officers hereto duly authorized on the day and year hereinafter written.

**EAN:**

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|  |  | Date: |  |
|  | First name Last name  EAN President |  |  |

**EAN:**

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|  |  | Date: |  |
|  | First name Last name  EAN Past President |  |  |

**EAN:**

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|  |  | Date: |  |
|  | First name Last name  EAN Executive Director |  |  |

**Participating Site:**

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|  |  | Date: |  |
|  | First name Last name  Head of Clinic |  |  |