Study AGREEMENT Participating Site – EAN COVID-19 Registry

This Study Site Agreement (**“Agreement”**) effective as of signature date is made 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 Prof. Claudio L. Bassetti, 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 Participating Site hereinafter individually or collectively referred to as **“Party”** or **“Parties”.**

**Preambles**

**WHEREAS** EAN shall act as organizer of the EAN Neuro-COVID Registry (ENERGY) study with tasks and duties as described in this agreement, and the protocol.

**WHEREAS** the AIM of the study is to provide epidemiological data on neurological manifestations in patients with COVID-19 infection reported by neurologists.

**WHEREAS** EAN will collect, analyse and publish the data and the results of the study.

**WHEREAS** Participating Site will register patient data via a database provided by EAN.

**WHEREAS** EAN will nominate a working group/committee that will take over all responsibilities on behalf of EAN of the study, as outlined in the protocol (Appendix A).

**WHEREAS** Participating Site is willing to conduct the Study at its site located in Country (the **“Country”**) as further set out in in the Protocol (Appendix A), and Participating Site is willing to conduct the Study and to assume the delegated responsibilities according to the Protocol (Appendix A) under the supervision and direction of its employee Title Firstname Lastname, City, Country(hereinafter **“Site Investigator”**), or such replacement as may be named pursuant to Section 2;

**Therefore**, Parties agree the following:

1. EAN RESPONSIBILITIES
	1. EAN shall respect and follow all applicable laws, rules, regulations and guidelines of any type, and all legislation and guidelines regarding the privacy of persons and the protection of personal data. (collectively: “Laws and Regulations”).
	2. EAN shall be the international coordinator of the Study.
	3. EAN will provide Participating Site with documents, to the extent necessary to perform the Study, except those which are specific for the country or which need to be in the native language, all as set out in the protocol. (Appendix A).
2. Participating Site RESPONSIBILITIES
	1. Participating Site shall respect and follow all Laws and Regulations. The Study at Participating Site will be coordinated by Site Investigator. If, for any reason, Site Investigator is unable or unwilling to continue to serve as Site Investigator, an appropriate and qualified successor will be appointed by Participating Site after having consulted EAN.
	2. Participating Site shall perform the obligations as delegated to the Participating Site in the Protocol (Appendix A) and possible related SOPs.
	3. As far as necessary, Participating Site shall draft and provide documents required in and specific for the country the Participating Site is situated in as set out in the Protocol.
3. FINANCIAL SUPPORT AND STUDY MATERIALS
	1. Other than the Protocol and related Study information/instructions as outlined in the protocol (Appendix A), EAN will not provide any financial sponsorship to Participating Site, and no equipment or materials required for the conduct of the Study by Participating Site. Participating Site warrants that it has sufficient resources available (including materials and personnel) to conduct the Study.
	2. Participating Site shall ensure that it has an adequate supply, at its own costs, of all drugs and/or materials and/or equipment (if applicable) for the purpose of performing the Study as required in the Protocol.
4. OWNERSHIP AND USE OF STUDY DATA

Ownership

* + 1. **CRFs.** All case report forms and other data (including without limitation, written, printed, graphic, video, image, and audio material, and information contained in any computer database or computer readable form) created or developed during the course of the Study by Participating Site (excluding source records) (the **“Data”**) shall be the property of EAN, which may utilize the Data in any way it deems appropriate, subject to and in accordance with applicable Laws and Regulations and the terms of this Agreement.
		2. **Database.** EAN shall collect the Data of all participating sites in a central database (hereinafter **“Database”**) as described in the protocol. EAN shall be the owner of the Database and all intellectual property rights therein.
		3. EAN shall have unrestricted access to all Data relevant to the Study under the terms and conditions of this Agreement. All Data shall be provided to EAN in accordance with the Protocol (Appendix A) and case report forms. Participating Site and Site Investigator warrant that all Study Team members under Applicable Law or by each having executed a written agreement with Participating Site assign to Participating Site all right, title and interest in and to all data, in order that Participating Site may fully assign the rights to EAN as provided above. However, Participating Site may use all Data generated by Participating Site for its internal non-commercial research purposes only, subject to the provisions regarding publications and confidentiality of this Agreement.

Record-Keeping and Access to Records

Participating Site shall maintain complete and accurate written or otherwise revorable records, accounts, notes, reports, data and examinations (**“Records”**) relating to the Study and the Protocol which will be used to prepare and submit Study Subject case report forms to EAN, as detailed in the Protocol.

Record Retention

Participating Site shall retain, maintain and archive the essential documents related to the Study for the period defined according to applicable laws, but not for less than for 10 years after publication of the results of the study in a way that ensures that they are readily available, upon request, to the Competent Authority, and for monitoring and auditing purposes and in order to prove compliance with good scientific practice.

Informed consent

Participating Site shall ensure that each human subject enrolled in the Study (**“Study Subject”**) by Participating Site has given specific consent in writing for the use of and access to Study Data as described in this Agreement, for the purpose to conduct the Study as set out in the Protocol and for associated monitoring and auditing purposes.

1. CONFIDENTIAL INFORMATION
	1. “Confidential Information” means, information, data and material of any nature belonging to a Party and disclosed by one Party (the “Disclosing Party”) to the other Party (the “Receiving Party”), either directly or indirectly, in connection with this Agreement, which is personal data relating to any patient or Study Subject of Participating Site or his or her treatment or medical history, or which is other information that reasonably should be deemed as Confidential Information of the Disclosing Party, or which is a trade secret, including know how, whether disclosed before or after execution of this Agreement, except the information specified in Section 5.2. below. Confidential Information may be written or spoken, and orally disclosed Confidential Information shall be noted as such and confirmed in writing within 15 days following oral disclosure. The obligations of confidentiality concerning Confidential Information, which is not personal data, shall survive for a period of five (5) years following termination or expiry of this Agreement. The obligations of confidentiality of this Section 5 regarding Confidential Information which is personal data shall remain in full force and effect after termination or expiry of this Agreement in accordance with applicable personal data protection laws.

Disclosure of Confidential Information

* + 1. Each Party shall use the other Party’s Confidential Information only in the conduct of the Study and shall return to the Disclosing Party all written Confidential Information at the request of the Disclosing Party.
		2. Neither Party shall disclose Confidential Information to any third party, without prior written consent of the other Party, and shall take all reasonable precautions to prevent the disclosure of Confidential Information to third parties.
		3. Participating Site will oblige Site Investigator and Study Team members to comply with the provisions of this Section 5.
	1. The provisions of Section 5.2. do not apply to any Confidential Information which:
		1. the Receiving Party can demonstrate by written records was known to the Receiving Party prior to receiving that Confidential Information from the Disclosing Party;
		2. is generally known to the public or which becomes generally known to the public through no act or omission on the part of the Receiving Party; or
		3. is lawfully obtained by the Receiving Party from sources independent of the Disclosing Party and who, to the best of their knowledge after due inquiry, have a lawful right to disclose such Confidential Information.
	2. Subject to the Receiving Party’s obligation to notify Disclosing Party of the disclosure requirement in a timely manner so that Disclosing Party may, at its own expense, take appropriate steps to protect its proprietary rights, specifically authorized is the disclosure of Confidential Information:
		1. under obligation of law, regulation or court order, provided the information disclosed is necessary to comply with legal requirements, and confidentiality is maintained to other third parties;
		2. to the EC/IRB, Competent Authority, and representatives of the health-care inspectorate or a medicines evaluation board;
		3. as part of publication of the results of the Study based on Study Data, subject to the provisions of Section 6 of this Agreement, regarding publications and disseminations of results.
1. PUBLICATION
	1. Participating Site will, and will oblige Site Investigator and other Study Team members to, comply with the provisions of this Section 6. Participating Site agrees that the first publication of the results of this Study shall be made according to the protocol. This first publication shall be coordinated by EAN, as described in the Protocol or SOPs. The results of the final analysis as well as all analyses that deal with the primary and secondary endpoints listed in the Protocol will be initiated and/or authorized by EAN.
	2. For a period of at least three years following Study completion or termination, Participating Site may request access to the Data in the Database to perform further analyses. EAN shall not unreasonably deny or delay its consent to such request, and shall maintain an adequate research policy, for such requests.
2. PUBLICITY

EAN will not use the logo or name of the Participating Site, Site Investigator, nor of any member of the Participating Site’s Study Team, for promotional purposes or in any publicity without the prior written approval of an authorized representative of Participating Site, such approval not to be unreasonably withheld. Participating Site will not, and will ensure that the Site Investigator and Study Team members do not, use the name or logo of EAN or of any of its employees, nor the name of the Study, for promotional purposes or in any publicity without the prior written approval of EAN, such approval not to be unreasonably withheld.

The foregoing notwithstanding, Parties may disclose the existence of this Agreement and the role of the other Party for financial transparency purposes, and to comply with Applicable Laws and Regulations or other legitimate request.

1. TERM AND TERMINATION
	1. The term of this Agreement shall commence on the date upon which this Agreement is executed by both Parties and shall remain in effect, for the duration of the Study, unless terminated in accordance with this Section 8.2. The term may be extended by a written amendment to the Agreement signed by both Parties.

Termination

Either Party may terminate this Agreement upon 30-days written notice to the other Party or upon written notice to the other Party with immediate effect in the following events:

* + 1. if, through no fault of a Party, the Study does not receive official approval from the EC or Competent Authority, or this approval is permanently revoked;
		2. any material breach of or failure to comply with any of the terms or conditions of this Agreement or Protocol by the other Party, which breach or failure, if capable of remedy, is not remedied within thirty (30) days after notice from the aggrieved Party demanding such remedy, and provided the termination is in reasonable proportion to a termination for such cause;

Survival

Any provision of this Agreement which by its nature or implication (including in respect of any accrued rights and liabilities) is required to survive the termination or expiry of this Agreement shall remain in full force and effect upon termination or expiry of this Agreement without regard to whether the Parties have fully performed their obligations under this Agreement, and, as the case may be, during a time period mentioned in each respective section.

1. MISCELLANEOUS

Entire Agreement

* + 1. This Agreement, including those documents attached hereto as Exhibits or referenced herein, constitutes the entire understanding of EAN, Participating Site, EAN Investigator, and Site Investigator
		2. In the event of any inconsistency between the terms of this Agreement and the terms of any Exhibit attached hereto such as the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Study.
		3. No changes, amendments, or alterations shall be effective, unless in writing and signed by both Parties. If for any reason a court of competent jurisdiction finds any provision of this Agreement, or portion thereof, to be unenforceable, that provision of this Agreement shall be enforced to the maximum extent permissible so as to effect the intent of the Parties, and the remainder of this Agreement shall continue in full force and effect.

Failure by either Party to enforce any provision of this Agreement shall not be deemed a waiver of future enforcement of that or any other provision.

* + 1. In case Participating Site uses a translated native language version of documents for the Study and/or of this Agreement, this English language version Agreement shall remain the wording document and the terms of this English language Agreement shall prevail over the translated documents.
	1. Arbitration

Any controversy, claim or dispute arising out of or relating to this Agreement, shall be settled through binding arbitration conducted in accordance with the WIPO Arbitration Rules. All arbitration proceedings shall be conducted in the English language. The Arbitration panel shall consist of three arbitrators, one selected by Participating Site and one selected by EAN. The first two arbitrators shall select the third arbitrator. The place of arbitration shall be Vienna, Austria. The award and any order of the arbitrators shall be in writing, in the English language, and shall be final and binding on both Parties to such arbitration.

Notice

Any notice required to be given under this Agreement shall be sent to the other Party by certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties as set forth below, and shall be deemed given as of its date of receipt, which shall be no later than five (5) days after the date of postmark. Notice shall be given to each Party at the address set forth below, or such address a Party may indicate:

**To SPONSOR:**

European Academy of Neurology
Headoffice
Breite Gasse 4/7

1070 Vienna, Austria
E-mail: headoffice@ean.org

With copy to: sander@ean.org

**To Participating Site:**

Name of Institute / Hospital

Department

Street

Zip City

Country

E-mail address:

1. Assignment

This Agreement shall not be assignable in whole or in part by either Party.

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

**EAN:**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Date: |  |
|  | Prof. Dr. Claudio L.A. Bassetti EAN President |  |  |

**Participating Site:**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | Date: |  |
|  | First name LastnameHead of Clinic |  |  |