**DATA TRANSFER AGREEMENT**

This **DATA TRANSFER AGREEMENT** (**“Agreement*”***) is made effective as of \_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2020 (the **“Effective Date”**)by and between Universitätsklinikum Hamburg-Eppendorf, represented by its Board of Directors with its conducting centre, the 1st Department of Medicine, located at Martinistraße 52, 20246 Hamburg, Germany (**“UKE”**), and [PLEASE PROVIDE], located at [PLEASE PROVIDE] (“**INSTITUTION**”). Each is sometimes referred to herein as a **“Party”** and collectively as the **“Parties.”**

**RECITALS**

**WHEREAS**, UKE is a consortium partner to the European Union funded European Reference Network for rare liver diseases (“**ERN-RARE-LIVER**”) and has taken up the role of establishing an international European Registry (“**Registry**”) for capturing data on patients with rare liver diseases in order to collect and scientifically analyze such data with the aim of better understanding these diseases and improving the quality of treatment for the patients.

**WHEREAS**, INSTITUTION has advance knowledge in the treatment of patients with rare liver diseases and is willing to collect and transfer for the aforementioned purpose data evaluating patients rare liver diseases;

**WHEREAS**, responsible coordinating investigator for UKE is Prof. Dr. Christoph Schramm (“Coordinating Investigator”) and responsible investigator at Institution is … (“Investigator”).

**NOW, THEREFORE**, in consideration of the foregoing the Parties agree as follows:

1. **Scope of the Agreement**
   1. Scope of this Agreement is the prospective collection and transfer of data by Institution and the use of such Data by UKE for the ERN-RARE-LIVER.
   2. The Data to be obtained and transferred is specified in the list of data items, enclosed as Annex I to this agreement and will be collected by way of an electronic case report form provided by UKE.
   3. This Agreement does not cover the transfer of any samples, fluids or tissue or other material of similar nature.
2. **Conduct and Responsibilities** 
   1. Institution is responsible to obtain and maintain any license, approval or similar, necessary for the participation in the Registry. UKE has obtained approval by its competent Ethics Committee (Ethikkommission der Ärztekammer Hamburg) and is willing to provide the same for reference to support application by Institution. Institution shall fully comply with all applicable national, federal, state, and local statutes, legislation, directives, regulations, and rules pertaining to the activities contemplated herein, including without limitation the following: (i) Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 and its implementing national legislation, 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 - GDPR) the ICH GCP, requirements of the competent EC as well as generally accepted professional standards for clinical and research standard of care.
   2. According to local regulations, Institution is responsible for obtaining an informed consent from each participant before enrolling the respective patient into the Registry and before transferring any data from that patient. To that regard Institution shall use the patient information and consent form as approved by its competent ethics committee/IRB. The consent shall cover inter alia the transfer of pseudonymized data (i.e. removing all sensitive personal data, including but not limited to patient names, initials, dates of birth, and other personally-identifiable information, and leaving visible a coded subject number) to UKE and for use within scientific research projects approved by the ERN-RARE-LIVER Management Board (“MB”) as specified in 4.2.
   3. Institution shall provide the personnel and equipment (hardware) necessary for participation in the Registry.
   4. UKE will provide the electronic data capture system (software) (“**eCRF**”) and be responsible for the storage of transferred data and administration of user rights.
   5. The Parties agree that this Agreement or the enrolment of patients into the Registry does not influence the specific treatment of that patient by Institution. Therefore Institution remains fully and solely responsible for the treatment of its patients.
   6. Institution shall ensure timely completion of the eCRF as defined and after the patients visit and have the responsible Investigator be available for query resolution.
   7. Institution shall use best endeavors to enroll all patients treated who fulfill the inclusion and none of the exclusion criteria into the Registry.
   8. Institution agrees that upon prior notice UKE or its designees on behalf of ERN-RARE-LIVER will in accordance with applicable data protection laws, including but not limited to GDPR, and the patient informed consent be granted access to all documents necessary for auditing and monitoring purposes and that the responsible Investigator be available for questions.
   9. If a Regulatory Body notifies Institution, or UKE of an audit or other investigation of the Institution regarding the Registry the Party first notified shall inform the other Party promptly of such notification, including providing a copy of any correspondence received from such Regulatory Body with respect to the audit or investigation and provide the audit response or any other comments by the Regulatory Body to UKE immediately upon receipt
3. **Financial Terms;**
   1. Institution receives no remuneration for the participation in the Registry.
4. **Ownership of and Use of Data; Intellectual Property.**
   1. Institution is and shall remain the owner of the data obtained for the Registry (“**Registry Data**”).
   2. Upon prior approval by the MB Registry Data may also be provided to any other body making an access request to the MB solely for the purpose of performing scientific research projects approved the MB.
   3. Any Intellectual Property (including copyright and inventions) created by either Party shall belong to that Party. In case of a common creation of Intellectual Property by both Parties the Parties shall decide in common about the further use and responsibilities of either Party in consideration of the goals of ERN-RARE-LIVER.
   4. Neither Party will, without the prior written consent of the other Party, use in advertising, publicity, or otherwise, the name, trademark, logo, symbol, or other image of the Party or that Party’s employee or agent except as required under applicable governmental laws, rules and regulations.
5. **Publication.** 
   1. Any Publication of the Registry Data shall be subject to the prior review of such Publication by the MB and according to the publication rules of the ERN-RARE-LIVER. UKE is not allowed to make any Publications unless within the scope of section 4.2 above.
6. **Indemnification.** 
   1. UKE hereby agrees to defend, indemnify and hold Institution harmless from and against any and all liability, loss, costs (including reasonable attorneys’ fees) and damages (collectively, **“Losses”**) which Institution may incur by reason of any third party claim asserted against Institution attributable to the use by UKE of the pseudonymized Registry Data; provided, however, that UKE shall not be obliged to indemnify or defend Institution to the extent such Losses are attributable to (i) breach by Institution of this Agreement or of applicable laws, rules, or regulations or (ii) negligence or willful misconduct by Institution or its employees or contractors, as applicable, in the conduct of the Registry or in the collection, preparation, or analysis of the de-identified Registry Data.
   2. INSTITUTION hereby agrees to defend, indemnify and hold UKE harmless from and against all claims and Losses which UKE may sustain or incur arising out of or attributable to (i) any breach by INSTITUTION of this Agreement or of applicable laws, rules, or regulations or (ii) any negligence or willful misconduct by INSTITUTION or its employees or contractors, as applicable, in the conduct of the Registry or in the collection, preparation, or analysis of the pseudonymized Registry Data provided, however, that Institution shall not be obliged to indemnify or defend UKE to the extent such Losses are attributable to (i) breach by UKE of this Agreement or of applicable laws, rules, or regulations or (ii) negligence or willful misconduct by UKE or its employees or contractors when using the Registry Data.
7. **Confidentiality.**
   1. **“Confidential Information”** shall mean each Party’s confidential information, inventions, know-how, or data disclosed pursuant to this Agreement or in performance of the Registry**.**  Notwithstanding the foregoing, Confidential Information does not include the pseudonymized Registry Data. For purposes of this Agreement, each Party may be a **“Submitter”** and/or **“Recipient”** of Confidential Information. Recipient shall employ the same degree of care to keep all Confidential Information confidential as it employs with respect to its own Confidential Information of like importance. Without the prior written consent of the Submitter, Recipient shall not disclose any Confidential Information to any third parties, except the staff of Regulatory Bodies as required by applicable law.
   2. All Confidential Information disclosed by Submitter shall remain the property of Submitter. Upon the written request of Submitter, all such tangible Confidential Information of Submitter, whether in hard copy or electronic form, shall be promptly returned to Submitter or destroyed; provided, however, that Recipient may retain one copy of such Confidential Information in a secure location for purposes of identifying its obligations under this Agreement.
   3. The obligation of Recipient as to confidentiality and non-use set forth in this Agreement shall continue for seven (7) years following disclosure of such Confidential Information, but shall not apply to any portion of the Confidential Information that:

a. is or becomes public or available to the general public otherwise than through the act or default of Recipient; or

b. is obtained by Recipient from a third party who is lawfully in possession of such Confidential Information and is not subject to an obligation of confidentiality or non-use owed to Submitter; or

c. was previously known to Recipient prior to disclosure to Recipient by Submitter under this Agreement, as is evidenced by written records, and not obtained or derived directly or indirectly from Submitter; or

d. is independently developed, discovered or arrived at by Recipient without use of the Confidential Information.

* 1. Notwithstanding the foregoing, Recipient shall be permitted to disclose Confidential Information pursuant to a requirement of law, regulation, rule, act, or order of any governmental authority or agent, provided that Recipient: (i) gives Submitter prompt notice of such fact so that Submitter may obtain a protective order or other appropriate remedy concerning any such disclosure and/or waive compliance with the non-disclosure provision of this Agreement; (ii) fully cooperates with Submitter in connection with Submitter’s efforts to obtain any such order or other remedy; and (iii) discloses, where disclosure is necessary, only the minimum Confidential Information legally required to be disclosed in order to comply, whether or not a protective order or other similar order is obtained by Submitter. The Confidential Information supplied shall remain confidential for any other purpose.

8. **Data Protection**

The parties shall adhere and comply with data protection regulations (including but not limited to GDPR). The further handling of personal data, especially patient data, is the scope of Annex 1 to this Agreement.

**9. Term & Termination.**

* 1. The term of this Agreement shall commence as of the Effective Date and shall continue indefinitely, unless terminated earlier pursuant to Sections 8.2 or 8.3.
  2. Either Party may terminate this Agreement for any reason or no reason upon thirty (30) days written notice to the other Party.
  3. Provisions which, by their nature, shall continue to apply after the term of this Agreement shall survive expiry or termination of this Agreement.

**10. Governing Law.**

* 1. The validity, interpretation, and performance of this Agreement will be determined in accordance with the laws of Germany.
  2. The Parties shall first attempt to settle any and all disputes arising out of or in connection with or relating to the execution, interpretation or performance of this Agreement through good faith negotiation before resorting to the competent courts at the place of the defending party which courts shall have exclusive jurisdiction.

**11. General Provisions.**

* 1. All legal notices, aside from invoices, to be given by either Party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties at their respective addresses first set forth above to the attention of:

**If to INSTITUTION:**

[PLEASE PROVIDE]

**If to UKE:**

Universitätsklinikum Hamburg-Eppendorf

1st Department of Medicine

Attn.. Prof. Dr. Christoph Schramm

Martinistraße 52

20246 Hamburg

Germany

or to such other address as a Party may designate from time to time to the other. Any notice shall be effective as of its date of receipt.

* 1. The Parties shall comply with all applicable laws and regulations governing the privacy and security of patient information, including the 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), as applicable, and any other laws, rules, or regulations relating to the maintenance, use, transmission or other activity concerning patient records and confidentiality of personal and medical data.
  2. This Agreement may be changed only by a writing signed by both parties. This equally applies to the change of this clause
  3. In the event that any one or more of the provisions in this Agreement shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, and all other provisions shall remain in full force and effect. The Parties shall negotiate in good faith a provision that is valid, legal and enforceable and that comes closest to the original intent of the Parties:

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives to be effective as of the date indicated above.

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| Universitätsklinikum Hamburg Eppendorf  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  i.V. Dr. Ralf Krappa /  i.V. Dr. Matthias Iding  on behalf of its Board of Directors  read and acknowledged.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Prof. Dr. Christoph Schramm  Coordinating Investigator | Institution.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  on behalf of …  read and acknowledged.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  XXX  Investigator |

Annex 1: Data Protection

**§ 1: Parties and Subject of processing, Purpose**

(1) Parties to this Annex are Institution and UKE.

(2) The parties shall adhere and comply with data protection regulations (including but not limited to GDPR). This Annex provides for the further specification of the cooperation in terms of data protection. In case of discrepancies between this Annex and the main agreement, this Annex shall prevail.

(3) The purpose of the processing is to conduct a registry including its relevant documentation. Data of the participating patients, including special categories of personal data, as well as data of employees of the parties are processed by both parties to the extent necessary for the processing purpose. The more detailed type of data of the study participants to be processed is specified in the study protocol in the respectively valid version.

**§ 2: Duration of the Annex, special right of termination, right of retention**

(1) This Annex shall continue to apply beyond the termination of the Agreement to conduct the registry, until the end of processing of personal data under the Agreement. The separate ordinary termination of this agreement is excluded. The right to termination for good cause remains unaffected.

(2) Either party may terminate the main contract and this Agreement at any time without notice ("Extraordinary Termination") if the other party commits a serious or continuing breach of data protection legislation or the terms of this Annex. A serious breach shall be deemed to have occurred in particular if one party fails to fulfil or has failed to fulfil to a considerable extent the obligations specified in this Annex, in particular the agreed technical and organizational measures.

(3) The parties are entitled, without influence on the contractual obligations, not to provide or transmit any further personal data to the other party if and to the extent that there are doubts about a legal basis for this. This may arise in particular if changed legal or factual circumstances lead to a new legal assessment, e.g. the first or changed requirement of justification pursuant to Art. 44ff GDPR or a declaration of consent used does not justify the processing. Such circumstances may also arise from official or court orders as well as publications of the supervisory authorities. In such case the Parties work together on the clarification of the legal basis and finding a provision/legal basis that comes closest to the scientific goal.

**§ 3: Responsibilities**

(1) Unless otherwise agreed below, each of the party ensures compliance with the statutory provisions, in particular the legality of the data processing operations it carries out. Each party is responsible for the processing carried out by itself. Actions and processing by data processors of one party shall be attributable to this party. Personal Data shall be forwarded by Institution via eCRF directly to UKE in Germany. Where UKE has engaged a CRO the same is a data processor for UKE in the sense of Art 28 GDPR.

(2) The parties shall take all necessary technical and organizational measures to ensure an adequate level of protection of the data pursuant to Art. 24, 32 GDPR and to ensure the rights of the data subjects, in particular according to III. Chapter GDPR, within the statutory periods at any time.

(3) The UKE is solely responsible for the technical and organizational measures related to the eCRF. This also includes the responsibility for a transmission path complying with the requirements of Art. 32 GDPR.

(4) The Institution is solely responsible for the processing of all data within the scope of treatment, in particular in the patient file. The Institution is also responsible for the factually correct input of personal data into the eCRF as well as the necessary correction.

(5) Furthermore, the UKE is responsible for the data processing in the eCRF and the subsequent data processing, provided that no sharing of data with third parties will take place without the consent of the Institution to that particular use of the data.

(6) Existing statutory responsibilities shall remain unaffected.

**§ 4: Point of contact, ensuring the rights of data subjects**

(1) The Institution shall act as a contact point for the data subjects. The Institution forwards inquiries which cannot be answered or processed to the UKE and the UKE's answer to the data subjects; this should be done in pseudonymised form using the registry-specific identification number. The Institution is not responsible for the proper processing by the UKE, nor does it owe advice on this matter. However, each party should inform the other if it believes that the other party is acting unlawfully.

(2) The Institution shall obtain from the data subject the Informed consent that allows for the sharing of the data with UKE and for further research. UKE provides a sample form that Institution may use but has to adapt to the applicable legislation and standards of its competent Ethics Committee.

(3) The Institution shall provide the data subject during enrollment with the information pursuant to Art. 13, 14 GDPR as well as information as to which party fulfills what data protection obligations, especially regarding compliance with data subject rights and information obligation, and shall explain it where necessary. This information shall be part of the patient information form.

(4) In addition, both parties are independently responsible for the implementation and adherence of the data subjects rights with regard to the data processed by them or their data processors.

**§ 5: Obligations regarding processing**

(1) The parties must inform each other immediately and completely if they discover errors or irregularities with regard to data protection regulations during the examination of the processing activities and/or the order results.

(2) The Parties shall keep a record of its individual processing activities within the meaning of Art. 30 ( 1) GDPR. They shall assist each other in drawing up such a record.

(3) The Parties have in respect to its individual processing steps, the information obligations resulting from Art. 33, 34 GDPR towards their respective supervisory authority respectively the data subject affected by a violation of the protection of personal data

(4) If a data protection impact assessment in accordance with Art. 35 GDPR is required, it shall be carried out under the responsibility of the UKE and the relevant documents shall be made available to the Institution. The Institution has to support the UKE.

**§ 6: Liability**

(1) Art. 82 GDPR shall remain unaffected. This agreement does not justify any claim by data subjects or other third parties nor shall it constitute a joint or several liability of the Parties.

(2) Within the internal relationship, each party shall be liable to the other party for the damage caused by the processing for which it is responsible. This shall also apply with regard to fines imposed as a result of circumstances for which this party was responsible.