**DATA TRANSFER AGREEMENT**

This **DATA TRANSFER AGREEMENT** (**“Agreement*”***) is made effective as of \_\_\_\_\_\_\_\_\_\_\_\_\_\_, 2022 (the **“Effective Date”**)by and between:

[PLEASE PROVIDE PARTY 1 WHO WILL ACT AS A **PROVIDER,** fill in official name of legal entity that is authorized to enter into this agreement, location of principal office and hereby legally represented by (name of legal representative)], who will act as the “Provider”.

[PLEASE PROVIDE PARTY 2 WHO WILL ACT AS A **RECIPIENT,** fill in official name of legal entity that is authorized to enter into this agreement, location of principal office and hereby legally represented by (name of legal representative)], who will act as the “Recipient”.

Each is sometimes referred to herein as a **“Party”** and collectively as the **“Parties.”**

**RECITALS**

**WHEREAS**, [PLEASE PROVIDE THE PURPOSE(S) OF THE PROCESSING OF PERSONAL DATA BY PARTY 1, THE PROVIDER, for example: “The Provider controls personal data of patients on a legal basis. As a caregiver and healthcare institution, the Provider is responsible to collect and process the personal data and health data of each patient and to securely store it in their medical record.”] and whereas the Provider acts as a controller of his processing of personal data;

**WHEREAS**, [PLEASE PROVIDE THE PURPOSE(S) OF THE PROCESSING OF THIS DATA BY PARTY 2, THE RECIPIENT. For example: “The Recipient conducts a study on ???, approved by the ethical committee of ?? on ??. This study was created in order to collect, scientifically analyze this data with the aim of better understanding these diseases and improving the quality of treatment for the patients.] and whereas the Recipient acts as a controller for the processing of data for the purpose of the study;

**WHEREAS,** [IF NECESARRY, PLEASE PROVIDE MORE CONTEXT TO THE COLLABORATION, for example, mention the European Reference Network]

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

1. **Scope of the Agreement**
   1. Scope of this Agreement is the [RETROSPECTIVE/PROSPECTIVE] collection and transfer of data of one controller (i.e. the Provider) to another controller (i.e. the Recipient).
   2. The Provider has used reasonable efforts to determine that the Recipient is able to satisfy its legal obligations under this Agreement.
   3. The Recipient will only receive de-identified data (i.e. data without any 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). The Provider will be responsible for this de-identifying.
   4. This Agreement does not cover the transfer of any samples, fluids or tissue or other material of similar nature.
   5. This Agreement does not cover the transfer of personal data outside the EEA.
2. **Conduct and Responsibilities** 
   1. The Parties shall fully comply with all applicable laws, legislations, directives, regulations and rules pertaining to the activities contemplated herein, including without limitation the following: Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on good clinical practice in the conduct of clinical trials on medicinal products for human use and its implementing national legislation, the patient rights legislation, requirements of the competent EC as well as generally accepted professional standards for clinical and research standard of care.
   2. The Recipient will inform the Provider of every discovery, irregularity that might have an impact on the health or wellbeing of a patient. The Provider will assess the necessity of informing this patient.
   3. The Recipient will comply with the applicable legislation. Recipient will have in place appropriate technical and organizational measures to protect the Data against accidental or unlawful destruction or accidental loss, alteration, unauthorized disclosure or access, and which provide a level of security appropriate to the risk presented by the processing and the nature of the Data to be protected.
   4. The Recipient will only process the transferred Data for the purposes as set out in this Agreement. It will not disclose or transfer the Data to a third party controller located outside the European Economic Area (EAA).
   5. Before the Recipient can transfer the Data he received under this Agreement to a third party, the Provider must give his written consent.
   6. The Parties agree that this Agreement or the enrolment of patients into the Registry does not influence the specific treatment of that patient by Provider. Therefore Provider remains fully and solely responsible for the treatment of its patients.
   7. If a regulatory body notifies Provider or Recipient of an audit or other investigation regarding the registry or provided Data, 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 the other Party immediately upon receipt.
3. **Financial Terms**
   1. Each Party shall perform its obligations under this Agreement at its own cost, unless stated otherwise.
4. **Ownership of and Use of Data; Intellectual Property**
   1. Provider is and shall remain the owner of the Data. The Provider hereby grants to Recipient a non-exclusive, royalty-free, personal, non-assignable license to use the Data and Confidential Information solely for helping to analyze the Data.
   2. If the [IF APPLICABLE: Study] which involves the Provider’s Data and the related Confidential Information results in an invention, improvement or substance, whether or not patentable (“Invention”), Recipient and Provider will have the right to use such Inventions and Results for their own and internal non-commercial research (non-commercial meaning the absence of revenue from third parties)
   3. Unless a delay is required to protect Intellectual Property Rights or publication in a peer-reviewed journal, Recipient shall fully and promptly, i.e. within 3 months, disclose in writing to the Provider all Data, if legally permitted, that may be of interest for inclusion in the Provider’s database. Submission of those Data to the Provider does not affect the requirement for Recipient to maintain their own research records.
   4. If a valorization of the research results can be considered, Recipient will promptly inform Provider. The Parties will immediately take appropriate measures to preserve this potential valorization and will start negotiations in view of concluding an agreement with respect to this valorization, including an agreement on intellectual property rights. The agreement can attribute the right of valorization and/or the intellectual property rights to Recipient, to Provider or to both in a given proportion.   The Parties shall negotiate in good faith, taking into account the specific contributions of each Party to the research that is subject to valorization.   Every agreement within this scope stands on its own and will have no bearing on other research to be valorized.
5. **Publication** 
   1. Any Publication of the obtained Data by Recipient shall be subject to the prior review and written consent of such Publication by the Provider.
   2. All the publications and communications regarding the Study Results will mention the participation of both Parties in the Study.
6. **Liability** 
   1. Each Party shall be liable to the other Party for damages it causes by any breach of this Agreement. Liability as between the Parties is limited to actual damage suffered. Punitive damages (i.e. damages intended to punish a party for its outrageous conduct) are specifically excluded.
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 de-identified Registry Data. For purposes of this Article, each Party may be a **“Submitter”** and/or **“Recipient”** of Confidential Information. Each Party 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 other Party, neither Party 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 a Submitting party shall remain the property of the Submitting party. Upon the written request of this Submitting Party, all such tangible Confidential Information of Submitter, whether in hard copy or electronic form, shall be promptly returned to the Submitting Party 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.

1. **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 shall have the right, without prejudice to its other rights or remedies, to terminate this Agreement for any reason or no reason upon thirty (30) days written notice to the other Party.
   3. The Parties shall have the right, without prejudice to its other rights or remedies, to terminate this Agreement upon written notice with immediate effect, if at any time the other Party breaches any terms of this Agreement.
   4. Recipient’s right to use the Provider’s Data shall expire upon the expiration of this Agreement. After expiration or termination of this Agreement, Recipient will receive a reasonable delay to delete or return, at the choice of the Provider, all the Data that it has gathered, processed and received in connection to this Agreement.
   5. Provisions which, by their nature, shall continue to apply after the term of this Agreement shall survive expiry or termination of this Agreement.
2. **Governing Law**
   1. The validity, interpretation, and performance of this Agreement will be determined in accordance with the laws of Belgium.
   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 of Brussels, Belgium.
3. **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 Provider:**

**PLEASE PROVIDE THE CONTACT INFORMATION OF THE DATA PROCESSING OFFICER**

**If to Recipient:**

**[PLEASE PROVIDE THE CONTACT INFORMATION OF THE DATA PROCESSING OFFICER]**

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, but not limited to, the GDPR 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 processing of personal data, the maintenance, the use, the transmission or other activity concerning patient records and the confidentiality of personal and medical data.
  2. This Agreement may be changed only by a written Agreement 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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| [Name Provider]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  on behalf of…  read and acknowledged.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | [Name Recipient]  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  on behalf of …  read and acknowledged.  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |