**DATA TRANSFER AGREEMENT**

This DATA TRANSFER AGREEMENT ("**Agreement**") is made on the date of the last signature (the Effective Date”) by and between

[Provider’s Details](“**Provider**”).

and

[Recipient Details](“**Recipient**”).

Hereinafter Provider and Recipient may individually be referred to as a “Party” and collectively as the “Parties”.

**Recitals**

1. WHEREAS, the Parties have agreed to collaborate in the research project [“*insert project name*”] (“**Research** **Project**”), which is described in Annex 1.
2. WHEREAS, the Research Project has been reviewed and approved by [*hospital/research center/ university*]’s Ethical Committee on the [insert date], with code […].
3. WHEREAS, the Project requires the sharing of patient’s clinical data, including personal information.
4. WHEREAS, Provider has agreed to collect patient’s clinical data, including personal data, and share it with the Recipient for the purpose of developing the Research Project (“**Agreed Purpose**”). The patient’s clinical data, including personal data, which will be shared with the Recipient is described in Annex 2.

**Therefore**, the Parties hereto agree as follows

1. **Definitions**
   1. **“DATA”** shall mean patient’s clinical data, including Personal Data, collected and pseudonymised by Provider and shared with the Recipient for the Agreed Purpose.
   2. **“DATA PROTECTION LAWS”** shall mean 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, and repealing Directive 95/46/EC (“**General Data Protection Regulation**” or “**GDPR**”), the Spanish Organic Law 3/2018, of December 5, on Data Protection and Guarantee of Digital Rights (“**LOPDD**”), and any other applicable law or regulation.
   3. **“PERSONAL DATA”** shall mean any information relating to an identified or identifiable natural person (“**DATA SUBJECT**”); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person; and for the purposes of this Agreement includes patient’s Data Concerning Health.
   4. **“DATA CONCERNING HEALTH”** shall mean Personal Data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status.
   5. **“DATA CONTROLLER”** shall mean the natural or legal person, which, alone or jointly with others, determines the purposes and means of the processing of Personal Data.For the purposes of this Agreement, Data Controller is the Provider.
   6. **“DATA PROCESSOR”** shall mean a natural or legal person which processes Personal Data on behalf of the controller. For the purposes of this Agreement, Data Processor is the Recipient.
   7. **“DATA SUBJECT CONSENT”** shall mean any freely given, specific, informed and unambiguous indication of the data subject's wishes by which he or she, by a statement or by a clear affirmative action, signifies agreement to the processing of Personal Data relating to him or her**;** and for the purposes of this Agreement obtained through Patient Informed Consent Forms (ICFs) in full compliance with the requirements established by Data Protection Laws.
   8. **“PERSONAL DATA PROCESSING”** shall mean any operation which is performed on Personal Data, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure, or destruction.
   9. **“PSEUDONYMISATION”** shall mean 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 organisational measures to ensure that the Personal Data are not attributed to an identified or identifiable natural person.
   10. **“COMMERCIAL PURPOSES”** shall mean the sale, lease, license, or other transfer and/or the use of the Data to and/or by a for-profit organization.
   11. **“CONFIDENTIAL INFORMATION”** shall mean any and all proprietary or confidential scientific, technical, financial or business information that is identified as confidential or that is clearly recognizable as confidential to a reasonable person with no special knowledge of the disclosing Party’s activities in whatever form (written, oral or visual). The Data, confidential information relating to the Data and all references to Data Subjects are CONFIDENTIAL INFORMATION.
2. **Object**

This Agreement governs:

1. Pseudonymisation of Data by Provider.
2. Transfer of Data from Provider to the Recipient.
3. Use of Data by the Recipient within the Agreed Purpose and sharing of the results with Provider.
4. Ownership and protection of the results of the Research Project.
5. Publication of the results of the Research Project.
6. **Data Subject Consent and pseudonymisation of Data** 
   1. Provider represents that it has obtained all necessary consents and authorizations to allow the Recipient to process the Data for the Agreed Purpose, in full compliance with Data Protection Laws and any other applicable law and regulations.
   2. Provider represents that Data transferred to the Recipient has been duly pseudonymised.
   3. The Recipient acknowledges and accepts that it will receive the Data duly pseudonymised, being impossible to identify the Subjects without additional information in the exclusive possession of Provider, and to which the Recipient shall not have access.
7. **Transfer of Data** 
   1. Provider shall, subject to the terms of this Agreement, use all reasonable efforts to provide the Recipient with sufficient Data, as available, for the Recipient to conduct the Research Project.
   2. Provider and the Recipient shall be deemed as Data Controller and Data Processor, respectively, under the terms established by *Regulation (EU) 2016/679 of 27th April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data* (hereinafter, the “GDPR”) and other applicable laws.
   3. The Recipient shall use the Data only within the Research Project as detailed in Annex 1, expressly excluding any other use and especially of a commercial nature.
   4. The Recipient shall not distribute or release the Data to any other location and/or to any other person other than its Representatives who require access to the Data strictly for the purposes of the Research Project, without Provider’s prior written consent.
   5. The Recipient shall not authorize any third party or sub-contractor to process the Data without Provider’s prior written consent, and such third party or sub-contractor entering into a contract with the Recipient including terms and conditions which are not less restrictive than those established herein, and on the condition that the processing of the Data pursuant to such contract shall terminate on the earlier of termination or expiry of this Agreement; or the end of the Research Project.
   6. ALL DATA IS PROVIDED “AS IS” AND TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, DATA PROVIDER HEREBY DISCLAIMS AND EXCLUDES ANY AND ALL REPRESENTATIONS, WARRANTIES, CONDITIONS OR OTHER TERMS, WHETHER WRITTEN OR ORAL, EXPRESSED OR IMPLIED, WITH RESPECT TO THE DATA, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.
   7. The Recipient shall strictly comply and ensure that its Representatives comply with the GDPR and other applicable data protection laws and regulations.
   8. The Recipient shall process the Data only on the written instructions of Provider unless otherwise required to do so by European Union, Member State law, or other legislation to which the Recipient is subject to; in such a case, the Recipient shall inform Provider of that legal requirement before processing the Data, unless that law prohibits such information on important grounds of public interest.
   9. The Recipient shall inform Provider without undue delay if it believes it has been given an instruction which does not comply with the GDPR and other applicable laws and regulations.
   10. The Recipient shall not analyze or make any use of the Data in such a way that might lead to the re-identification of any Data Subject or compromise the anonymity of any Data Subject in anyway.
   11. The Recipient shall not copy, sell, transfer, supply, distribute or release any of the Data to any third party, without the prior written consent of Provider.
   12. The Recipient shall use appropriate security measures and safeguards to preserve the integrity of the Data, preventing any loss, damage, or destruction thereof and any unauthorized access or disclosure, which shall not be less restrictive than those required under Data protection Legislation as amended from time to time; and in particular shall:
8. deny unauthorized access to data processing facilities in which personal data is processed or used (physical access controls);
9. prevent unauthorized persons from using data processing systems (access controls);
10. ensure that authorized users only have access to the data to which they have access rights, and that personal data cannot be read, copied, modified or deleted by unauthorized persons during processing or use, and after storage (user-access control);
11. ensure that personal data cannot be read, copied, modified or deleted by unauthorized persons during electronic transmission or during their transport or their storage on data carriers, and that it can be verified and established at which points a transmission of personal data by data transmission equipment (transmission control) is foreseen;
12. ensure that it can be subsequently verified and established whether and by whom personal data are entered, modified or deleted in the data processing systems (input control);
13. ensure that personal data which are processed on behalf of Provider can be processed only in accordance with Provider’s instructions;
14. ensure that personal data are protected against accidental destruction or loss (availability control); and
15. ensure that data collected for different purposes can be processed separately.
    1. The Recipient shall assist Provider in ensuring compliance with its obligations under the GDPR and other applicable laws and regulations with respect to security, breach notifications and management, impact assessments and consultations with supervisory authorities or regulators and assist, where applicable, Provider in responding to any request from a Data Subject.
    2. The Recipient shall notify Provider without undue delay (and in any event within 48 hours) in the event of an actual or reasonably suspected data breach under the Data Protection Legislation and, at its sole cost and expense, undertake all remediation efforts necessary to rectify and prevent a recurrence of such data breach.
    3. The Recipient shall assist Provider in consulting with the Data Protection Authority in circumstances where there is an unmitigated high risk to the Data.
    4. The Recipient shall use reasonable efforts to notify Provider within five (5) business days, or as soon as possible thereafter, of any request received from a Data Subject to exercise rights under GDPR and other applicable laws and regulations, such as to access, rectify, amend, correct, share, delete or cease processing his or her personal data.
    5. The Recipient shall, at Provider’s written request, and without delay, either securely delete or securely return to Provider all the Data that Provider has shared with it in such form as Provider reasonably requests after the earlier of:
16. the expiry or termination for any cause of this Agreement;
17. the end of the Research Project;
18. the withdrawal of Consent by the Data Subject; or
19. the processing of the Data is no longer required for the purposes of the Research Project.

and securely delete existing copies unless storage of any Data is required by applicable law.

* 1. The Recipient shall maintain complete and accurate records and information to demonstrate compliance with its obligations under the GDPR and other applicable laws and regulations.
  2. The Recipient shall contribute to audits and inspections conducted by a Data Protection Authority or Provider or its nominee.
  3. No transfer of any Data shall be made outside the European Economic Area (EEA) or a country or territory under an EU Commission Adequacy Decision unless prior written consent is given by Provider, and the appropriate safeguards under the GDPR are adopted by the Parties.

1. **Property and license to the Data**
   1. Property and any other rights to the Data are retained by Provider.
   2. Subject to the terms and conditions of this Agreement, Provider hereby grants to the Recipient a royalty free, non-exclusive, revocable, non-transferable licence to use the Data solely for the Agreed Purpose and for no other purpose.
2. **Intellectual Property**
   1. Nothing in this Agreement shall be construed as an assignment or transmission of any industrial and/or intellectual property rights, including without limitation any and all patents, applications for patents, trade secrets, rights of publication, and any other worldwide intangible or tangible right related to the Data belonging to Provider and/or to third parties, which are not granted herein (hereinafter, “Intellectual and/or Industrial Property Rights”).

* 1. Where the research involving the Data results in any invention, Recipient and/or Recipient’s researcher/s shall promptly disclose this development to Provider in writing and in confidence. Recipient and Provider shall decide in common about the ownership, taking in due consideration Provider’s contribution to the invention through its Data, and applicable patent law. Decisions about all further proceedings, such as filing of a patent application or exploitation, shall be made after ownership is determined.

* 1. In any event, protection of Intellectual and/or Industrial Property Rights relating to Results shall observe the moral rights of the inventors or authors, expressly including the right to be mentioned as inventors or authors.

* 1. The transfer of Data shall not be construed as to grant an option or license to the Recipient under any patent, trade secret or other rights now or hereinafter held by Provider, other than the non-exclusive, non-transferable, revocable right to use the Data for the Agreed Purpose.

* 1. Provider shall have a royalty-free, worldwide, non-transferable, non-exclusive license to use any Recipient’s results for research and non-commercial purposes.

1. **Confidentiality**
   1. A Party receiving Confidential Information from the other Party (the “Receiving Party”) will use all reasonable endeavours not to disclose to any third party any Confidential Information from the Party providing such Confidential Information (the “Providing Party”), nor use for any purpose except as expressly permitted under this Agreement. These obligations of confidentiality do not apply to Confidential Information which:
2. was lawfully in the Receiving Party’s possession or control prior to the date of disclosure; or
3. was in the public domain or enters the public domain through no improper act of the Receiving Party’s or any of the Receiving Party’s employees, staff, officers, and agents; or
4. is disclosed to the Receiving Party from third sources having no obligations of confidentiality *vis-à-vis* the Providing Party; or
5. was independently developed by the Receiving Party without use of the Confidential Information provided by the Providing Party, as evidenced by contemporaneous written records; or
6. must be disclosed in compliance with court orders, regulations, or statutes.
   1. The Recipient agrees to preserve the confidentiality of Data pertaining to Data Subjects. In particular, the Recipient undertakes not to use, or attempt to use the Data to deliberately compromise or otherwise infringe the confidentiality of information on Data Subjects and their respective rights to privacy.
   2. These obligations of confidentiality and non-use shall survive termination of this Agreement for a period of five (5) years. For the avoidance of doubt, Data that directly or indirectly identifies a Subject and information related to a Data Subject shall remain confidential indefinitely.
7. **Publications**
   1. Publication of the results of the Research Project may be made by each Party and the authorship of the publication will be determined in accordance with the standard academic practice. Each Party will acknowledge the contributions of the other Parties as scientifically and academically appropriate. Recipient shall name Provider’s Principal Investigator as co-author of any publication and be cited as the source of the Data, according to the respective contribution of Data to the publication and as scientifically appropriate.
   2. Where a Party (the “Publishing Party”) desires to publish or make an oral presentation of the results of the Research Project and such publication or presentation refers to the Data, the Publishing Party will provide the other Party (the “Reviewing Party) with a manuscript of the paper to be published or presented forty-five (45) days prior to the intended date of submission for publication or presentation. The Reviewing Party shall have thirty days from the date of the communication to review the proposed publication or presentation to ensure that no Confidential Information is inadvertently disclosed nor disclosed in violation of the Reviewing Party’s contractual obligations *vis-à-vis* third parties, and to make any further comments. If requested in writing the Publishing Party shall withhold the publication or presentation for up to an additional ninety (90) days from the date of the Revieing Party request to allow for the filing of a patent or other intellectual property right application or the taking of such measures as the Reviewing Party deems appropriate to establish and preserve its proprietary rights in the information and the material being submitted for publication or presentation.
8. **Term**
   1. This Agreement shall be effective as of the last date of signature by the Parties ("Effective Date") and shall terminate two (2) years afterwards or on the earlier of the following:
9. the date of completion of the Research Project; or
10. upon thirty (30) days written notice of termination by either Party to the other Party, which notice of termination may be provided with or without cause.
    1. This Agreement will terminate immediately upon any material breach of a provision of this Agreement unless the Party in breach has remedied the material breach within 30 (thirty) days of receiving notice of such breach.
    2. The Parties accept that the changing ethical framework of human genetic research may lead to: (i) alteration to the provisions of this Agreement, in which case the Parties may accept such alterations or terminate this Agreement by prior written consent and reasonable efforts to agree upon an amendment of this Agreement; or (ii) the withdrawal of this Agreement in extreme circumstances.
    3. Upon completion of the Research Project or in the event that a Party decides not to continue with the Research Project or in case of early termination of this Agreement, any Data, not used in the Research Project will be either destroyed by the Party or, at the request of the providing Party, returned to the providing Party at its expense.
    4. Notwithstanding the aforementioned, any provision of this Agreement related to confidentiality and/or Data protection shall survive the expiration and termination of this Agreement to the extent applicable statutory law requires a longer confidentiality period.
11. **General** 
    1. Each of the provisions of this Agreement is separate and severable and enforceable accordingly. If at any time any of the provisions is held to be void or unenforceable, the validity or enforceability of the remaining provisions shall not be affected. If any provision is held to be void or unenforceable, the Parties agree to substitute any such provision with a valid enforceable provision which achieves to the greatest extent possible the economic, legal and commercial objectives of the invalid or unenforceable provision.
    2. This Agreement represents the entire agreement between the Parties with respect to the subject matter therein and supersede all prior representations, agreements, arrangements, and undertakings with respect thereto whether written or oral. This Agreement may only be amended in writing signed by duly authorised representatives of the Parties.
    3. Neither this Agreement nor any subsequent discussions between the Parties shall create any obligations other than those expressly stated herein. Nothing in this Agreement shall oblige either Party to enter into any further agreement with the other in relation to the subject matter of this Agreement.
    4. All notices given by a Party to the other pursuant to this Agreement shall be in writing and may be delivered by email, or pre-paid post, registered courier, by hand to the address at the beginning of this Agreement.
12. **Governing Law**

This Agreement shall be subject to the laws of [country]. All disputes arising between the Parties in connection with this Agreement which the Parties cannot settle amicably shall be finally settled by the courts of *[city, country]*.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their authorized representatives.