

**DATA SHARING AGREEMENT**

Between LEO Pharma A/S and [insert name of Researcher]

This Data Sharing Agreement (“**Agreement**”) effective as of the date of the last signature (the “**Effective Date**”) is entered into by and between

**[Name of researcher]**

[Address]

(“Researcher”)

And

**LEO Pharma A/S**

Industriparken 55

2750 Ballerup

Denmark

(“LEO”)

(“Researcher and LEO are also referred to individually as “**Party**” and jointly as “**Parties**”)

## 1 BACKGROUND

**Whereas** LEO is committed to be transparent with respect to its clinical trials and is therefore willing to provide access to anonymised patient level data sets from clinical trials sponsored by LEO to qualified researchers, under the prior condition of i) a study proposal with a valid scientific rationale and which is non-commercial and in the best interest of patients; and ii) a signed data sharing agreement.

**Whereas** Researcher desires access to certain patient level data in order to conduct rigorous, independent scientific research as further described below.

**Now therefore** LEO and Researcher have entered in to this Agreement with respect to Researcher’s access to patient level data.

## 2 DEFINITIONS

2.1 “**Agreement**” shall mean this Data Sharing Agreement and its appendices.

2.2 “**Confidential Information**” shall have the meaning as set out in Clause 7.1.

2.3 “**Data**” shall mean the anonymised patient level data from the LEO sponsored clinical trial(s) listed in Appendix 1, to which the Researcher is provided access to.

2.4 “**Effective Date**” shall mean the date described above.

2.5 “**LEO Affiliates**” shall mean all entities controlled by LEO, meaning the ownership or control of the shares representing 50% or more of the voting shares of such entity or the ability in fact to control the management decisions of such entity.

2.6 “**LEO Website**” shall mean the [www.leo-pharma.com/Home/Research-and-Development/Clinical-trial-disclosure.aspx](http://www.leo-pharma.com/Home/Research-and-Development/Clinical-trial-disclosure.aspx) website.

2.7 “**New Intellectual Property**” shall have the meaning as set out in Clause 6.1.

2.8 “**Patient and Scientific Review Board**” shall mean the board, as described on the LEO Website, reviewing the Research Proposals and approving the providence of the requested patient level data.

2.9 “**Project**” shall mean project described in the submitted Research Proposal.

2.10 “**Research Proposal**” shall mean the research proposal submitted by Researcher and approved by the Scientific Review Board attached as Appendix 2.

- 2.11 “**Research Team**“ shall mean the Researcher and all research team members listed in the Research Proposal.

### **3 DATA SHARING**

- 3.1 LEO will provide Researcher with access to the Data. Access is given exclusively for the purpose of enabling Researcher to conduct the Project.
- 3.2 All Data made available to Researcher will be anonymised at LEOs discretion in accordance with the LEO Pharma Principles of Anonymisation of Clinical Trial Data (available on the LEO Website), and any commercial confidential information of LEO or third parties, to whom LEO has contractual obligations, will at LEOs discretion be redacted.
- 3.3 The amount of Data to be made available to Researcher will be limited to the minimum necessary to reasonably achieve the scientific objectives of the Project.
- 3.4 LEO shall attempt to provide access to the Data within 30 days from the Effective date. How Data will be provided to Researcher shall be the sole consideration of LEO.
- 3.5 Once access is provided, the Data will be available for a 24-month period.
- 3.6 LEO makes no representations or warranties regarding the suitability of the Data provided to Researcher for the Project
- 3.4 In the event LEO is not able to implement all reasonable steps to maintain anonymity for relevant trial subjects and/or if the Research Proposal is not within the scope of the patients’ informed consent, LEO will neither be able nor obliged to provide the requested patient level data to Researcher. LEO will inform Researcher of the issue and provide an explanation of the rejection.

### **4 REQUIREMENTS FOR ACCESS**

- 4.1 Researcher agrees that the Data provided by LEO are LEO Confidential Information as set out in Clause 7 and are subject to the confidentiality obligations of this Agreement. Researcher agrees to only use the LEO Confidential Information in accordance with this Agreement and any specifications or additional requirements, if any, set by the Patient and Scientific Review Board in the approval and/or separate requirements document attached as Appendix 3.
- 4.2 For the access of Data Researcher agrees
- (a) to inform LEO immediately, and no later than within twenty-four (24) hours, of any safety concerns identified as part of Researches analysis of the Data and promptly provide to LEO all information required to be provided to the relevant regulatory authorities. Researcher agrees that LEO may take action regarding such safety concerns, including informing competent authorities or healthcare providers or otherwise make the safety concern public, even in advance of the publication of the analysis by Researcher;
  - (b) to provide to LEO access and assistance to enable LEO to understand, implement and utilize any analytical methods and/or tools including, but not limited to, any methodology, statistical methods, formulae or other methods or tools used by Researcher in conducting the analysis, for purpose of reproducing the results of the Project;
  - (c) following publication cf. Clause 4.2 (b) above, to provide other researches with additional details of the analysis on request and to provide access and reasonable assistance to those researchers to utilize and implement any analytical tool for the sole purpose of reproducing the results of the Project, however subject to appropriate provisions to protect Confidential Information;
  - (d) to handle and process personal data in accordance with any applicable national legislation regulating data protection. The Researcher shall be obligated to initiate all necessary technical and administrative security measures in order to safeguard that personal data shall not accidentally or illegally be destroyed, lost or impaired, and that such personal data shall not be disclosed for unauthorized persons, be abused or in any other respect processed contrary to the relevant legislation;

- (e) not to establish or de-identify the identities of clinical trial participants and/or to combine the Data with other sources of data that would or could lead to the identification of any individual;
- (f) not to download, save, edit, copy, print, transfer or reverse engineer the Data except to the extent required to conduct the Project.

4.3 Further, the Researcher represents and warrants

- (a) that the Project or any results and data generated according to the Project will not now or at any point in the future be used by the Researcher, any member of the Research Team, or any third party for commercial purposes;
- (b) to have fully disclosed any and all real or potential conflicts of interests for both Researcher and any and all members of the Research Team which could have an impact on the conduct or the interpretation of the research conducted under the Project;
- (c) to obtain any regulatory and/or ethics approvals necessary to conduct the Project;
- (d) to conduct the Project in compliance with any and all applicable law, regulation and any written instructions from applicable ethics committee or institutional review board; and
- (e) to ensure that all members of the Research Team are subject to contractual obligations to comply with the obligations set forth in this Agreement.

## 5 PUBLICATION

- 5.1 Researcher permits LEO to publish the lay summary of the Research Proposal and the publications plan on the LEO website or other website owned and maintained by LEO. Researcher agrees to submit the results of the Project for publication in a peer-reviewed journal or otherwise make the results publically available as described in the publication plan set out in Appendix 2. The publication shall appropriately disclose the strengths and weaknesses of the methodology used in the Project. At the time of submission Researcher agrees to provide LEO with a copy of the manuscript. Following publication, Researcher permits LEO to publish the summary results of the Project on the LEO website or other website owned and maintained by LEO.
- 5.2 Researcher shall provide LEO with a reference citation upon publication.
- 5.3 Researcher agrees to comply with any additional requirements or provisions regarding publication of the results generated from the Project as set forth in Appendix 3.

## 6 IP RIGHTS

- 6.1 Researcher shall promptly notify LEO in writing of any new intellectual property, including but not limited to discoveries, inventions (whether patentable or not), copyrightable work, data, reports and know-how generated based on the Project ("New Intellectual Property").
- 6.2 Researcher hereby grants LEO and LEO Affiliates a perpetual, non-exclusive, royalty-free, world-wide license, with the right to sub-license, to use for any purpose all New Intellectual Property which Researcher may generate or obtain from the Project or in relation hereto. Researcher undertakes to provide to LEO reasonable assistance at reasonable cost to help LEO in fully utilizing any New Intellectual Property for any purpose LEO may see fit.
- 6.3 On the initiative of LEO, LEO and Researcher shall exclusively negotiate in good faith, for up to two hundred (200) days or such mutually agreeable longer period, regarding commercially reasonable terms for an exclusive, worldwide, fee-bearing license, including the right to sublicense, for LEO and its Affiliates to use New Intellectual Property for any purpose.
- 6.4 Researcher agrees to obtain written agreements with the members of the Research Team and Researcher's employees, agents and subcontractors which assign, without any additional consideration, all rights, ti-

tle and interest in New Intellectual Property to Researcher for subsequent licensing to LEO. The obligations of this clause shall survive the termination of this Agreement.

## **7 CONFIDENTIALITY**

- 7.1 LEO shall be the sole owner of all and any information of LEO, its Affiliates and/or under the control of LEO that are provided to the Researcher under this Agreement, including but not be limited to patient level data, protocols including any study definition documents and other study specifications, and any other scientific, technical, trade and/or business information or materials (whether or not patentable), know-how and trade secrets of LEO, its affiliates and/or under the control of LEO (“Confidential Information”).
- 7.2 Researcher shall maintain the Confidential Information in confidence and shall not disclose, directly or indirectly, Confidential Information to any third party (person or entity) unless expressly agreed upon in writing with LEO, in which case Researcher shall advise such third party that such information is strictly confidential and shall require their compliance in writing with the terms of this Clause 7. Researcher shall maintain Confidential Information properly protected against theft, loss and unauthorized access, including through password protection where access is by electronic means. Researcher shall immediately notify LEO if Researcher becomes aware of any suspected or actual unauthorized use, copying or disclosure of Confidential Information.
- 7.3 The confidentiality and non-use obligation shall not apply to Confidential Information that:
- (a) at the time of disclosure, is already in the public domain through no fault of the Researcher;
  - (b) after disclosure, becomes a part of the public domain by disclosure through no violation of this Agreement;
  - (c) Researcher is able to prove, has been lawfully in the Researcher’s possession prior to any disclosure under this Agreement;
  - (d) is hereafter lawfully disclosed by a third party to Researcher, where such third party did not acquire such information under a still effective obligation of confidentiality to LEO.

Researcher shall immediately and without any delay inform LEO by a written notice if Researcher is of the opinion that any Confidential Information received is included in the information under this Clause. If disputed Researcher shall have the burden of proofing that the information received is included under Clause 7.3.

- 7.4 If Researcher is required to disclose Confidential Information by an order or action of a governmental agency, authority or court LEO shall be informed as soon as reasonably possible and Researcher shall furnish only that portion of the Confidential Information which is legally required, and shall exercise all efforts required to obtain confidential treatment for such information.
- 7.5 The confidentiality and non-use obligation under this Agreement shall expire, for each item of Confidential Information, at such time as such information is no longer maintained in confidence by LEO or if it falls within the limitations of Clause 7.3 above. Upon completion of the Project, expiration or termination of this Agreement for any reason, the Researcher shall promptly stop making use of Confidential Information and shall return to LEO all Confidential Information and destroy any copies and reproductions thereof. The Researcher acknowledges that the return, deletion or destruction of any and all Confidential Information does not release it from its confidentiality and non-use obligations under this Agreement.
- 7.6 If Confidential Information was disclosed to the Researcher prior to the Effective Date of this Agreement, such Confidential Information shall be treated as confidential subject to the terms and conditions hereof.

## **8 INDEMNIFICATION**

- 8.1 Researcher shall indemnify, defend and hold harmless LEO and any of LEO’s Affiliates, directors, officers, and employees against any and all claims, expenses, losses, damages, or liabilities arising from any third party claim or suit brought against LEO relating to any breach of this Agreement by Researcher, including breach or misstatement of representations and/or warranties made under this Agreement.

**9 TERMS AND TERMINATION**

- 9.1 This Agreement shall come into force on the Effective Date. The Agreement shall remain in force until the Researcher has fulfilled all of Researcher’s obligations in this Agreement, however, no longer than 24 months after the Researcher first was granted access to the data under this Agreement.
- 9.2 LEO shall have the right to at any time and for any cause to terminate this Agreement by notice to the Researcher.
- 9.3 The following clauses shall survive the termination or expiry of this Agreement: 4, 5, 6, 7, and 8.
- 9.4 Researcher shall upon termination of this Agreement or completion of the Project promptly stop making use of the Data and either destroy or return to LEO any LEO confidential Information in Researcher’s possession.

**10 MISCELLANEOUS**

- 10.1 Assignment. Researcher is not allowed to assign any of it rights and duties under this Agreement without the written consent of LEO. LEO may assign its right and duty under this Agreement without Researcher’s consent.
- 10.2 Governing Law, Venue and Dispute Resolution. This Agreement shall be governed by the laws of Denmark without regard to the conflict of law provisions.

In the case of a dispute arising from or in connection with this Agreement, the Parties shall try to solve all disputes out of court prior to resorting to any legal action. If the Parties are unable to resolve the dispute amicably within reasonable time, the dispute shall be brought before the City Court at Glostrup, the domicile of LEO, Denmark.

- 10.3 Nothing shall restrict the right of either Party to bring an action for injunctive relief in any court with jurisdiction to hear this matter.

**11 SIGNATURES**

- 11.1 This Agreement is signed in two (2) original copies. Each Party has received a copy.

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**LEO Pharma A/S**

**[Name of Researcher]**

\_\_\_\_\_  
Date

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Name (Capital letters)

\_\_\_\_\_  
Name (Capital letters)

\_\_\_\_\_  
Title

\_\_\_\_\_  
Title

**Appendices:**

Appendix 1 – [Data Feasibility form or List of Clinical Trials, for which Data have been granted access]

Appendix 2 – Research Proposal

Appendix 3 – Approval and Requirements from Patient and Scientific Review Board