# DATA SHARING AGREEMENT

This Data Sharing Agreement (the "Agreement") effective as of **[insert date]** (the "Effective Date") is between **ALK-Abelló A/S**, Bøge Allé 6-8, 2970 Hørsholm ("ALK") and **[name of researcher]**, **[address]** (the "Researcher"). ALK and the Researcher are hereinafter also referred to individually as "Party" and collectively as "Parties".

**1. BACKGROUND**

1.1. ALK is committed to enhance public health through responsible sharing of clinical trial data.

1.2. The Researcher has requested access to certain clinical trial data for the purpose of conducting a research project.

1.3. ALK is willing to provide the Researcher with access to the clinical trial data under the terms and conditions set forth below.

**2. DATA SHARING**

2.1. The Researcher acknowledges that he/she will not be granted a direct access to the clinical data listed in Appendix A. Instead ALK is willing to make the clinical data listed in Appendix A available to an independent statistician appointed by ALK (the "Consultant"). The Consultant will, at ALK's costs, perform the requested data analysis in accordance with the Researcher's statistical analysis plan provided by the Researcher to ALK (the analysis provided by the Consultant will hereinafter be referred to as the "Clinical Data").

2.2. The Parties will discuss and agree upon an overall timeline for the Consultant's work. ALK is responsible for instructing the Consultant and the Researcher shall direct any requests and questions regarding the Consultant's work and the Clinical Data to ALK. The Clinical Data will be provided to the Researcher by ALK upon the Consultant's completion of the analysis at no charge. The Researcher acknowledges that the Clinical Data is provided as a service to the medical and scientific community and ALK bears no responsibility for the accuracy or content of the Clinical Data.

**3. USE OF THE CLINICAL DATA**

3.1. Subject to and conditional on the Researcher's compliance with this Agreement, ALK grants to the Researcher a limited, non-exclusive, royalty-free license to use the Clinical Data during the term of this Agreement solely to conduct the research specified in Appendix B (the "Research Project"). As between ALK and the Researcher, any title or ownership of the Clinical Data, including any intellectual property embodied therein, remains with ALK.

3.2. (a) The Researcher may only use the Clinical Data:

(i) for the purpose of the Research Project;

(ii) in compliance with applicable laws, rules, regulations, codes of practise and ethical guidelines, including, but not limited to, all applicable laws and regulations relating to data protection and the privacy of subject health information;

(iii) in compliance with ALK's policies and procedure for responsible clinical trial data sharing as stated on the following website: https://www.alk.net/rd/clinical-data-sharing;

(iv) in accordance with the terms and conditions of this Agreement, additional restrictions set forth in Appendix A and ALK's written instructions;

(v) in accordance with any regulatory and/or ethics approvals necessary to conduct the Research Project. The Researcher shall obtain any such regulatory or ethics approvals and shall, upon ALK's request, provide a copy of such approvals to ALK.

(b) The Researcher shall not:

(i) use, or cause or permit the use of, the Clinical Data other than as expressly permitted under this Agreement;

(ii) use, or cause or permit the use of, the Clinical Data or the results of the Research Project for any commercial purposes;

(iii) transfer or distribute the Clinical Data to any third party without the prior written consent of ALK;

(iv) use the Clinical Data in any manner that confers on any third party any proprietary rights in or to the Clinical Data, or that creates obligations to disclose the results generated or derived by the Researcher as the result of the Research Project under this Agreement to any third party (excluding disclosures pursuant to the publication provisions set forth in Clause 8);

(v) seek to re-identify any individual, including without limitation, clinical trial participants and trial staff and/or combine the Clinical Data with other sources of data that would or could lead to the identification of any individual. The Researcher shall maintain the Clinical Data in anonymized form.

(c) The Researcher shall restrict access to and use of the Clinical Data to individuals as:

(i) are directly engaged in performing the Research Project under the Researcher's direct control and supervision (specified in Appendix B) (the "Research Team");

(ii) need to access and use the Clinical Data for purposes of the Research Project; and

(iii) have been informed of the access, use, transfer and disclosure restrictions of this Agreement and are subject to contractual obligations to comply with the same. The Researcher shall be responsible for any violations of this Agreement by the members of the Research Team.

**4. CONFLICTS OF INTERESTS**

4.1. The Researcher represents and warrants that he/she has fully disclosed in the Conflict of Interest Statement (Appendix C) any and all real or potential conflicts of interests of both the Researcher and any and all members of the Research Team which could have an impact on the planning, conduct or the interpretation of the Research Project.

**5. ACCESS AND ASSISTANCE TO REPRODUCE THE RESULTS**

5.1. Upon ALK's request, the Researcher shall provide ALK with reasonable access to files and assistance 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 in conducting the Research Project, for the purpose of reproducing the results of the Research Project.

**6. SAFETY FINDING**

6.1. The Researcher shall immediately, and no later than within twenty-four (24) hours, notify ALK and, if required, the relevant regulatory authorities of any safety issues or other safety related concerns identified while conducting the Research Project. Any such notifications must be sent by email to DKHODrug-Safety-HQ@alk.net or faxed to number 0045 4574 8615. ALK may take any actions regarding such safety issues/concerns, including informing competent authorities or healthcare providers or otherwise make the safety issue/concern public, even in advance of the Researcher's publication of the results of the Research Project.

**7. SUMMARY OF RESULTS AND INTELLECTUAL PROPERTY RIGHTS**

7.1. The Researcher shall provide ALK with a summary of the results of the Research Project upon completion of the Research Project.

7.2. The Researcher shall promptly notify ALK in writing of any intellectual property rights, including, but not limited to, discoveries, inventions (whether patentable or not), copyrightable work, data, databases, techniques, ideas, concepts methodologies, improvements, reports and know-how, generated or derived by or on behalf of the Researcher as part of the Research Project or the Researcher's use of the Clinical Data hereunder ("New Intellectual Property").

7.3. The Researcher grants ALK an unrestricted, non-exclusive, perpetual, fully paid-up, royalty-free, unconditional, irrevocable, worldwide license, with full right to sub-license through multiple tiers, to use any New Intellectual Property for all uses, applications, and purposes.

7.4. The Researcher grants to ALK an exclusive option, exercisable by ALK in its sole discretion, for a period of six (6) months from the date of disclosure by the Researcher to ALK of any New Intellectual Property Rights, to obtain an exclusive licence, on commercially reasonable terms in, to and under any and all New Intellectual Property Rights for all uses, applications, and purposes; or, if requested by ALK, to purchase the Researcher's interest therein. Upon ALK's exercise of the option, the Parties shall negotiate in good faith the terms of the exclusive license for six (6) months beginning on the date of exercise of the option by ALK, unless mutually extended by the Parties. If the Parties are unable to agree on the terms of an exclusive license within such six-month period, or if ALK does not exercise the option, the Researcher is entitled to negotiate license terms with third parties, subject to the non-exclusive license granted to ALK pursuant to Clause 7.3 and ALK's first right of refusal under Clause 7.5.

7.5. If the Parties are unable to agree on the terms of an exclusive license within the six-month period set forth in Clause 7.4, or if ALK does not exercise the option to an exclusive license set forth in Clause 7.4, and the Researcher negotiates a license or other transfer of any right, title, or interest with or to a third party to New Intellectual Property, the Researcher shall provide ALK with a copy of such proposed agreement and allow ALK a minimum of forty-five (45) days to enter into an agreement with the Researcher on terms at least as favourable as those of such proposed agreement.

7.6. The Researcher shall ensure that all members of the Research Team are subject to written agreements, which provides for the assignment, without additional consideration, of all rights, title and interests in New Intellectual Property Rights to the Researcher for subsequent licensing to ALK under this Agreement.

**8. CONFIDENTIALITY**

8.1. The Researcher shall treat any and all information and Clinical Data disclosed by ALK to the Researcher (the "Confidential Information") as strictly confidential and shall not disclose it to any third party without the prior written and express consent of ALK, except that the Researcher may disclose the Confidential Information to members of the Research Team in accordance with in Clause 3.2 (c). The Researcher shall treat the Clinical Data with at least the same care and in the same manner as the Researcher's own secret and valuable information but, in no event, less than reasonable care. The Researcher shall immediately notify ALK if the Researcher becomes aware of any unauthorized use, copying or disclosure of Confidential Information. If Confidential Information was disclosed to the Researcher prior to the Effective Date of this Agreement, such Confidential Information must be treated as confidential subject to the terms and conditions hereof.

8.2. The obligation of confidentiality set out in Clause 8.1 shall not apply to Confidential Information which the Researcher can demonstrate: (i) is or becomes generally available to the public otherwise than by reason of breach by the Researcher of the provisions of this Agreement; (ii) is known to Researcher and is at the Researcher's free disposal (having been generated independently by the Researcher or a third party, in circumstances where it has not been derived directly or indirectly from ALK) provided that documentary evidence of such knowledge is furnished by the Researcher to ALK within thirty (30) days of receipt of demand for such proof; or (iii) is subsequently disclosed to the Researcher without obligation of confidence by a third party owing no such obligations to ALK in respect of that information.

8.3. In the event that the Researcher determines, upon legal advice in writing, that it is legally compelled to disclose any Confidential Information, the Researcher shall provide ALK with prompt notice of such request or requirement in order to enable ALK to object to the relevant governmental entity or court of law regarding the required disclosure. The Researcher shall use all reasonable efforts to obtain confidential treatment of Confidential Information required to be disclosed and shall disclose only that portion of the Confidential Information that is legally required to be disclosed.

8.4. The Researcher shall not make any statement on ALK's behalf or concerning ALK to the press, media, investors, brokers, banks, financial analysts and/or other person unconnected with ALK without the prior approval of ALK.

8.5. The obligations set out in this Clause 8 shall survive for a period of fifteen (15) years after the termination of this Agreement.

**9. PUBLICATION**

9.1. Upon the Research's publication of the results of the Research Project, ALK shall have the right to disclose a summary of the Research Project on the ALK website or other websites owned and maintained by ALK.

9.2. The Researcher shall publish the results of the Research Project for publication in a peer-reviewed journal or otherwise make the results publically available as set forth in the publication plan set out in Appendix B.

9.3. The Researcher shall provide ALK with copies of any intended publication or other public disclosure relating to the Research Project or the Clinical Data by or on behalf of the Researcher within thirty (30) days before submission for publication or publicly disclosing such information, to give ALK the opportunity to (i) provide input regarding medical and scientific accuracy or supplementary scientific information, (ii) object to the inclusion of any Confidential Information and (iii) review for patentable subject matter.

9.4. The Researcher shall ensure that any publication or public disclosure of any results display the strengths and weaknesses of the research methodology. The Researcher shall provide ALK with a reference citation upon publication or other public disclosure, and may use ALK's name solely for the purpose of the data and study attribution.

**10. DISCLAIMER**

10.1. The Researcher acknowledges that the Clinical Data is provided `as is´ and without any representation or warranty, express or implied, as to the accuracy or completeness, including, without limitation, any implied warranty of the suitability of the Clinical Data for the Research Project, or any warranty that the use of the Clinical Data will not infringe or violate any patent or other proprietary rights of any third party.

**11. INDEMNIFICATION AND LIABILITY**

11.1. ALK and/or the Consultant shall not be liable for any claims related to the Researcher's possession or use of the Clinical Data. The Researcher shall indemnify, defend and hold harmless ALK, the Consultant and any of ALK's affiliates, directors, officers and employees against any and all loss, liability, claim, or action arising out of or resulting from any third party claim, suit, action, or proceeding that arises out of or results from the Researcher's breach of this Agreement; or the Researcher's possession or use of the Clinical Data.

No Party shall have any liability towards the other Party for any indirect, special, incidental or consequential loss, damage, costs or expenses of any kind including, but not limited to the loss of business opportunity, loss of the use of any data or information, or loss of revenue, savings or profit in connection with or arising out of this Agreement, even if the other Party shall have been advised of the possibility of such damages, unless such loss, damage, costs or expenses were caused by the defaulting Party's gross negligence or intentional misconduct.

**12. TERM AND TERMINATION**

12.1. This Agreement comes into effect on the Effective Date and remains in force until the last publication has been published in accordance with the Researcher's publication plan set out in Appendix B, unless terminated earlier in accordance with Clause 12.2.

12.2. Either Party has the right to terminate this Agreement:

(a) on thirty (30) days' prior written notice to the other Party; or

(b) by written notice to the other Party having immediate effect in the event of the other Party being in material breach of any of the terms or condition of this Agreement, and, only where such breach is capable of remedy, failing to remedy such breach within fourteen (14) days of written notice requiring such breach to be remedied.

12.3. Immediately upon any termination or expiration of this Agreement, the Researcher shall stop using the Confidential Information and within fourteen (14) days from such termination or expiry, at ALK's option, return or destroy any Confidential Information.

**13. GOVERNING LAW AND JURISDICTION**

13.1. The laws of Denmark, without giving effect to its principles of conflicts of law, govern any dispute or claim arising out of or in connection with this Agreement.

13.2. Any dispute or claim arising out of or in connection with this Agreement must be finally settled by Danish arbitration in accordance with the "Rules of Procedure of the Danish Institute of Arbitration". The place of arbitration must be Copenhagen, Denmark and the arbitration proceedings must be conducted in the English language. The arbitration proceedings and the awards rendered must be confidential. Reference to arbitration is without prejudice to the rights of a Party to seek an injunction or other emergency interim relief before any court of competent jurisdiction.

**14. MISCELLANEOUS**

14.1. Survival. The rights and obligations of each of the Parties under any provision of this Agreement, which by its terms, is intended to survive beyond the term of this Agreement, including, but not limited to, Clauses 3, 5, 6, 7, 8, 9, 10, 11, 12.3, 13 will survive any expiry or termination of this Agreement.

14.2. Independent Contractors. In making and performing this Agreement, the Parties are acting and will act at all times as independent contractors, and nothing contained in this Agreement will be construed or implied to create any agency, partnership or employer and employee relationship between the Parties. At no time shall any Party make commitments or incur any charges or expenses for or in the name of any other Party, other than as expressly set forth herein.

14.3. Power to Enter into the Agreement. Each Party represents and warrants to the other that it has the legal right and power to enter into this Agreement, to extend the rights and licenses granted to the other in this Agreement, and to fully perform its obligations hereunder, and that the performance of such obligations does not conflict with its charter documents or any agreements, contracts, or other arrangements to which it is a party.

14.4. Assignment. Neither Party may assign this Agreement in part or in whole to any third party without the prior written consent of the other, save that ALK may assign this Agreement to any of its affiliates or to the successor (including the survivor company of any consolidation or merger) or assignee of all or substantially all of its business.

14.5. Counterparts. This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which shall constitute one and the same document. The exchange of copies of this Agreement and of signature pages by facsimile or Portable Document Format (PDF) transmission shall constitute effective execution of this Agreement as to the Parties so delivering such pages and may be used in lieu of the original Agreement for all purposes. Signatures of the Parties transmitted by facsimile or Portable Document Format (PDF) shall be deemed to be their original signatures for all purposes.

**15. LIST OF APPENDICES:**

**Appendix A:** Description of the Clinical Data to be provided
**Appendix B:** Description of the Research Project
**Appendix C:** Conflict of Interest Statement

| **For and on behalf of ALK-Abelló A/S** | **[Name of Researcher]** |
|---|---|
| **Signature** | **Signature** |
| **Date** | **Date** |
| **Name (capital letters)** | **Name (Capital letters)** |
| **Title** | **Title** |

# APPENDIX A

ALK has agreed to provide the Researcher access to data from the following ALK sponsored clinical trials:

ALK Trial ID(s):

Full Protocol name(s):

EudraCT/CT.gov number(s):

ALK has agreed to provide access to the following specific data from the above-listed trial(s) **[INSERT DATA WHICH HAVE BEEN AUTHORIZED BY ALK FOR THE SPECIFIC REQUEST]. The data will be provided in the form of an analysis prepared by an ALK designated consultant who will analyse the data in accordance with the statistical analysis plan provided by the Researcher.**

Additional restrictions regarding use of Clinical Data (if any):

# APPENDIX B

**[Insert Project Plan, including Publication Plan and Statistical Analysis Plan]**

# APPENDIX C

**[Conflict of Interests Statement]**