

## DATA SHARING AGREEMENT

This Data Sharing Agreement (the "Agreement") is [made effective] as of the [number] day of [month] [year] (the "Effective Date") by and between

(the "Effective Date") by and between

- (1) AstraZeneca AB, a company incorporated in Sweden under no. 556011-7482 with offices at SE-431 83 Mölndal, Sweden ("AstraZeneca"); and
- (2) [[Name of contracting party or individual, corporate entity description, address, ("Researcher")].

### Recitals

- (A) WHEREAS, AstraZeneca and its Affiliates conduct clinical trials;
- (B) WHEREAS, Researcher desires access to certain Clinical Data (as defined below) collected by AstraZeneca or its Affiliates; and
- (C) WHEREAS, AstraZeneca is willing to furnish the Clinical Data to Researcher, upon the terms and conditions set forth herein.

### Agreement

NOW, THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

- 1 Definitions
  - 1.1 "Access System" means the system in which the Clinical Data is made available.
  - 1.2 "Affiliate" means any business entity that, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with, a Party, with "control" meaning in the case of a company, direct or indirect ownership of 50% or more of the voting interest in such company, and in the case of a partnership the right to a share of more than half the assets, or of more than half the income of the partnership.
  - 1.3 "Analytical Tools" includes, but is not limited to, any methodology, statistical methods, formulae or other methods or tools used by Researcher in conducting the Analysis.
  - 1.4 "AstraZeneca Confidential Information" means all information (including, without limitation, patient-level data, Personal Data, research specifications or protocols, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of AstraZeneca that is provided to Researcher in connection with this Agreement, including the Clinical Data.
  - 1.5 "AstraZeneca Uses" means any and all uses of or related to a compound which is owned or controlled by AstraZeneca or its Affiliates on or after the Effective Date, including the compound(s) which was used to generate the patient level data and Clinical Data, which would otherwise be an infringement of any New Intellectual Property. For the avoidance of doubt, a related use includes, but is not limited to, a diagnostic test applicable to a disease treated by the compound or the class to which it belongs.
  - 1.6 "Authorized Person(s)" means any individual, employee, assistant or advisor who will support the Researcher in the performance of the Analysis and require access to the Access System and the Clinical Data. Such Authorized Person(s) act under the Researchers responsibility.

- 1.7 “New Intellectual Property” means all discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery, know-how, or trade secrets which are made by Researcher or any Authorized Person(s) as a result of the conduct of the Analysis or the use of any information provided to Researcher or any Authorized Person(s) by AstraZeneca under this Agreement.
- 1.8 “Parties” means AstraZeneca and Researcher and “Party” shall mean either of AstraZeneca or Researcher.
- 1.9 “Personal Data” has the meaning in Directive 95/46/EC or its superseding text and includes any information that directly or indirectly identifies a living person, such as and not limited to, age, birthdate, race or ethnicity and health information.
- 1.10 “Review Board” means an institutional review board, independent ethics committee or other group formally designated by Researcher to review, approve the initiation of, and conduct periodic review of, any Analysis.
- 1.11 “Scientific Review Board” means the review board appointed by AstraZeneca or its Affiliate from time to time that review and approve research proposals made by researchers.
- 2 Data Sharing
- 2.1 AstraZeneca agrees to provide the Researcher with access to patient-level data from the clinical studies listed in Exhibit A (the “Clinical Data”) through the Access System for the sole purpose of the analysis according to Researcher’s research plan (the “Analysis”) attached as Exhibit B and for no other purpose. Researcher agrees that Clinical Data provided by AstraZeneca are AstraZeneca Confidential Information.
- 2.2 Upon written request by the Researcher, AstraZeneca may grant access to the Clinical Data and the Access System to an Authorized Person(s), subject to the terms of this Agreement. Researcher represent and warrant that any Authorized Person(s) shall at all times comply with the terms of this Agreement, including without limitation this Section 2, Section 3 and Section 4, and that Researcher duly notifies any Authorized Person(s) of all applicable requirements under this Agreement in accessing the Clinical Data and the Access System.
- 2.3 Upon the request of access to the Clinical Data and the Access System and continuously during the term of this Agreement, the Researcher and any Authorized Person(s) shall disclose to AstraZeneca any potential and real conflict of interest that may impact the planning, conduct or interpretation of the Analysis.
- 2.4 AstraZeneca shall deliver to Researcher and any Authorized Person(s) a unique login and password for use specifically by such Researcher or Authorized Person(s). Access to the Access System shall require the person accessing the Access System to enter a valid login and password. Researcher shall be responsible for maintaining the confidentiality of each login and password and shall ensure that only the individual for whom the login and password was created use such login and password when accessing the Access System. Researcher shall promptly notify AstraZeneca if it learns or suspects that a login and password may have been compromised or disclosed to a third party. AstraZeneca may suspend the use of any login and password if it reasonably believes that such login and password may have been compromised and/or that the person using such login and password is not in fact an authorized individual under this Agreement. Researcher will acknowledge receipt of access to the data and the data meets the requirements of the Researcher within thirty (30) days to AstraZeneca.
- 2.5 DISCLAIMER. ALL CLINICAL DATA AND ASTRAZENECA CONFIDENTIAL INFORMATION PROVIDED BY ASTRAZENECA ARE PROVIDED “AS IS” AND, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, ASTRAZENECA HEREBY DISCLAIMS AND EXCLUDES ANY AND ALL REPRESENTATIONS, WARRANTIES, CONDITIONS OR OTHER TERMS, WHETHER WRITTEN OR ORAL, EXPRESSED OR IMPLIED, WITH RESPECT TO THE CLINICAL DATA AND ASTRAZENECA CONFIDENTIAL INFORMATION, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE. DISCLAIMER. TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, SAS Software

Limited, HEREBY DISCLAIMS AND EXCLUDES ANY AND ALL REPRESENTATIONS, WARRANTIES, CONDITIONS OR OTHER TERMS, WHETHER WRITTEN OR ORAL, EXPRESSED OR IMPLIED, WITH RESPECT TO THE ACCESS SYSTEM, INCLUDING ANY REPRESENTATION OR WARRANTY OF QUALITY, PERFORMANCE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.

- 2.6 NOLIABILITY. TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ASTRAZENECA AND SAS Software Limited SHALL NOT BE LIABLE TO RESEARCHER OR ANY AUTHORIZED PERSON(S) WHETHER FOR BREACH OF CONTRACT, NEGLIGENCE OR OTHERWISE, WITH REGARD TO THE PROVISION OF PROVIDING ACCESS TO CLINICAL DATA OR THE ACCESS SYSTEM .

### 3 Conditions of Access

- 3.1 The Clinical Data and the Access System and any derivative work product, including without limitations notes, reports, summaries, and mental impressions(a) shall be used by the Researcher and any Authorized Person(s) exclusively for the Analysis ;(b) shall not be used by or delivered by the Researcher or any Authorized Person(s) to or for the benefit of any third party without the prior written consent of AstraZeneca; (c) shall not be downloaded, copied or transcribed to any other medium, system or the like by the Researcher or any Authorized Person(s); (d) shall not be used by Researcher or any Authorized Person(s)for any commercial purpose, including in any product for commercial use or distribution or for the purpose of producing any such product or providing any such service or clinical trial work, or to otherwise pursue a financial benefit (whether on behalf of the Researcher or for a third- party); (e) shall not be used by the Researcher or any Authorized Person(s) in combination with any other data other than those explicitly set forth in Exhibit B attached hereto (whether commercially available or otherwise); and (f) shall not be reverse engineered, reverse assembled or decompiled by the Researcher or any Authorized Person(s).
- 3.2 The granting of accesses to the Clinical Data and the Access System by AstraZeneca to Researcher or any Authorized Person(s) under this Agreement shall not transfer any rights to or in the Clinical Data and/or the Access System to the Researcher or any Authorized Person(s).
- 3.3 Researcher shall use, and shall cause any Authorized Person(s) to use, the Clinical Data and Access System in compliance with all applicable laws, rules, regulations, guidelines and requirements.
- 3.4 If AstraZeneca has reasonable belief that Researcher or Authorized Person(s) is in breach of their obligations under this Agreement, AstraZeneca shall have the right, subject to advance reasonable written notice, to audit and inspect Researcher's and the Authorized Person(s)'s facilities, internal practices, systems, books, records, agreements, policies and procedures relating to the use or disclosure of Clinical Data pursuant to this Agreement.
- 3.5 Researcher shall notify AstraZeneca in writing of any use or disclosure of Clinical Data not permitted by this Agreement within twenty-four (24) hours of becoming aware of such unpermitted use or disclosure. Researcher agrees to use its best efforts to mitigate any harmful effect known to Researcher that is caused by a use or disclosure of Clinical Data by Researcher in violation of the terms of this Agreement.
- 3.6 If required with respect to the Analysis, Researcher shall provide to AstraZeneca documentation verifying review and approval by the applicable Review Board of the proposed Analysis prior to conducting the Analysis.
- 3.7 Researcher agrees to provide access and reasonable assistance to AstraZeneca to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis.
- 3.8 Researcher agrees that it will inform AstraZeneca immediately of any potential new adverse

drug reaction assessed by the Researcher as having a reasonable possibility of casual relationship between an adverse event identified as part of the Analysis and the AstraZeneca drug(s) as part of the Clinical Data provided under this Agreement AND not previously reported in publicly available European Union (EU) product labelling. Researcher agrees that AstraZeneca may inform regulatory authorities or healthcare providers, or otherwise make the information reported by the Researcher under this Section 3.8 public, even in advance of the Publication of the Analysis by Researcher.

- 3.9 Researcher agrees to comply with any additional requirements identified by the Scientific Review Board which approved the Analysis plan, listed in Exhibit C.
- 4 Confidentiality
- 4.1 Subject to Sections 4.2 and 4.3, Researcher shall at all times keep confidential the Confidential Information. Researcher shall safeguard the AstraZeneca's Confidential Information with at least the same level of care as it affords to its own Confidential Information of the same type but in no event less than reasonable care, and shall not use AstraZeneca's Confidential Information for any purpose other than expressly described in this Agreement and in Exhibit B. Researcher agrees not to disclose AstraZeneca's Confidential Information to any third parties, except to any Authorized Person(s) or as otherwise expressly permitted under this Agreement, without AstraZeneca's prior written consent and provided that any such third parties, including Authorized Person(s), are contractually bound by obligations of confidentiality at least as restrictive as those contained in this Agreement and obligations not to use AstraZeneca's Confidential Information for any purpose other than as expressly authorised in this Agreement and in Exhibit B.
- 4.2 The obligations on Researcher set out in Section 4 shall survive the expiry or termination of this Agreement, but shall not apply to any information which:
- 4.2.1 was in Researcher's possession (with full right to disclose) prior to receiving it from AstraZeneca, as demonstrated by written records;
- 4.2.2 is public knowledge otherwise than as a result of any breach of this Section or any similar Section in any other relevant agreement; or
- 4.2.3 Researcher can demonstrate was developed independently without reference to the AstraZeneca Confidential Information, or was received from a third party who had the right to disclose such information in a non-confidential manner.
- 4.3 Researcher may disclose Confidential Information to the extent required by a court of competent jurisdiction, by a governmental, supervising or regulatory body, or otherwise in order to comply with all applicable laws, rules, regulations, guidelines and requirements (including freedom of information legislation), provided always that (i) to the extent it is legally permitted to do so, the Researcher gives AstraZeneca as much notice of such disclosure as possible; and (ii) the Researcher complies with the AstraZeneca's reasonable directions for taking legally available steps to resist or narrow such requirement (at AstraZeneca's reasonable expense) and in any event restricts the disclosure to only those parts of the Confidential Information lawfully required to be disclosed.
- 4.4 Except as expressly permitted by this Agreement, neither Party shall make any public announcement relating to this Agreement or the transactions covered by it or mention or otherwise use the name, insignia, symbol, trademark, trade name or logotype of the other Party or its Affiliates in any publication, press release, promotional material or other form of publicity without the prior written approval of that Party in each instance. The restrictions imposed by this Section 4.4 shall not prohibit either Party from making any disclosure that is required by applicable law.
- 4.5 At any time upon the request of AstraZeneca, all tangible expressions, in any media, of

AstraZeneca's Confidential Information in Researcher's or an Authorized Person(s)'s possession or control shall be delivered to the AstraZeneca or, at AstraZeneca's option, irretrievably destroyed. In any event, upon completion of the research purposes specified in Exhibit B, Researcher shall, and shall cause any Authorized Person(s) to, irretrievably destroy all copies of AstraZeneca's Confidential Information within Researcher's or an Authorized Person(s)'s possession or control. Researcher shall complete such destruction within one hundred and eighty (180) days of completion of the research purposes specified in Exhibit B. Researcher shall issue corresponding deletion instructions to any third parties authorized by AstraZeneca to have access to AstraZeneca Confidential Information for the purposes set forth in Exhibit B.

- 4.6 Researcher acknowledges and agree that any transfers of value under this Agreement may be subject to disclosure pursuant to physician payment transparency legislation, European Federation of Pharmaceutical Industries and Associations ("EFPIA") transparency reporting requirement and any other AstraZeneca's transparency obligations.

## 5 Intellectual Property

- 5.1 Researcher will notify AstraZeneca, promptly and in writing, of any New Intellectual Property. Researcher hereby grants to AstraZeneca a perpetual, non-exclusive, royalty-free, worldwide license for AstraZeneca Uses with right to sublicense (with an exclusive option, to be exercised within one hundred eighty (180) days from notice of the New Intellectual Property to negotiate in good faith an exclusive, fee-bearing, worldwide license with right to sublicense) to all New Intellectual Property which Researcher may have or obtain, without additional consideration from AstraZeneca. If additional assistance from the Researcher is requested beyond the rights provided by the non-exclusive license, Researcher will provide reasonable assistance to AstraZeneca, upon commercially reasonable terms that are at least as favorable to AstraZeneca as the terms agreed with any other licensee for such assistance, to facilitate AstraZeneca in fully utilizing any New Intellectual Property.

- 5.2 If AstraZeneca exercises its option to negotiate an exclusive license, AstraZeneca and Researcher will exclusively negotiate in good faith, for up to one hundred eighty (180) days or such mutually agreeable longer period, regarding commercially reasonable terms for an exclusive, worldwide, fee-bearing license, including the right to sublicense, for AstraZeneca and its Affiliates to make, have made, use, sell or otherwise dispose of the subject matter of the New Intellectual Property or products incorporating the subject matter of the New Intellectual Property subject to any non-exclusive licenses granted in Section 5.1. In the event that AstraZeneca does not exercise its option to negotiate an exclusive license or in the event Researcher and AstraZeneca fail to agree to commercially reasonable exclusive license terms following good faith negotiation, Researcher may negotiate further non-exclusive license terms with third parties. Any such terms shall be consistent with the non-exclusive license granted to AstraZeneca in Section 5.1 above. Should any terms be agreed with a third party in accordance with this section, then for five (5) years after the effective date, Researcher will notify AstraZeneca, within thirty (30) days of the effective date of any such agreement, of the identity of the third party.

- 5.3 Researcher agrees to obtain written agreements with Authorized Person(s) which assign, without additional consideration, all rights, title and interests in New Intellectual Property to Researcher for subsequent licensing to AstraZeneca. The obligations of this Section shall survive termination of this Agreement.

## 6 Publication

- 6.1 Subject to Section 4, Researcher agrees to post a summary of the Analysis plan on a publicly available internet register or website prior to conducting the Analysis. Researcher agrees to post summary results of the Analysis on the same publicly available internet register or

website within one year of completing the Analysis and, thereafter, to permit AstraZeneca to post a summary of the Analysis results on any publicly available internet register maintained by AstraZeneca. Subject to Section 4, Researcher also agrees to submit the results of the Analysis for publication in the peer-reviewed literature (a "Publication") in a timely and complete manner as described in the Publication plan attached as Exhibit D, with such Publication appropriately including citations or register identification numbers for the studies used in the analysis and discussing the strengths and weaknesses of the Analysis methodology and interpretation. Researcher shall submit to AstraZeneca a copy of the summary results of the Analysis at the time of posting the summary results as well as a copy of any proposed Publication fifteen (15) days prior to of submission to a scientific congress or journal. Upon the request of AstraZeneca, Researcher shall remove any material that is AstraZeneca Confidential Information from the Publication.

Additionally, Researcher shall provide AstraZeneca a reference citation upon publication. Researcher agrees, following publication, to provide other researchers with additional details of the Analysis on request and to provide access and reasonable assistance to those other researchers to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis. The obligations of this Section shall survive termination of this Agreement.

## 7 Sunshine Act requirements

- 7.1 Any physician licensed to practice in the U.S. and any U.S. teaching hospital is a "Covered Recipient." A "Payment or Transfer of Value" is any payment or transfer of value as defined in the U.S. Physician Payment Sunshine Act (42 USC 1320(e)(10)), and implementing regulations (42 CFR 403.900 et seq.), and includes compensation, reimbursement for expenses, meals, travel, medical journal reprints, study drug, study supplies and medical writing and publications assistance. Institution acknowledges and agrees that any direct or indirect Payments or Transfers of Value to Covered Recipients are subject to transparency reporting requirements, including disclosure on AstraZeneca's website. Institution shall not contract with or make any Payment or Transfer of Value to a Covered Recipient on behalf of AstraZeneca without AstraZeneca's prior written approval. All payments to U.S. physicians will be made according to a centrally managed, pre-set rate structure based on a fair market value analysis conducted by AstraZeneca. Institution acknowledges and agrees that any request for payment of, or reimbursement for, a Payment or Transfer of Value to a Covered Recipient will require that Institution provide AstraZeneca with detailed expenditure information in a manner that conforms to the requirements set forth in AstraZeneca's Data Requirements for Payments and Transfers of Value to Covered Recipients, available at <http://www.astrazeneca-us.com/astrazeneca-purchasing-general-terms-and-conditions> (on that website, click on the "US Sunshine Act/Open Payment Data Requirements). Documentation concerning Payments or Transfers of Value to a Covered Recipient must be maintained by Institution for nine years.

## 8 Representations and Warranties

- 8.1 Researcher represents and warrants that Researcher or any Authorized Person(s) does not have, and will not enter into, any legal or contractual obligations that would prevent them from complying with their obligations under this Agreement, including without limitation, the obligations of Section 5. Researcher further represents and warrants that Researcher has the authority to enter into this agreement and the authority to bind any Authorized Person(s) to the terms of this Agreement.
- 8.2 Researcher acknowledges the importance of data privacy of individuals to whom accessed data may relate, and Researcher commits, and shall cause any Authorized Person(s), to comply with all applicable data privacy legislation, not to attempt to identify subjects, and

not to combine accessed data with other sources of data that would lead to the identification of any individual.

8.3 Researcher represent and warrants that entering into this Agreement and performing the Analysis hereunder does not, and shall not, cause the Researcher or any Authorized Person(s) to be in noncompliance with any policy or procedure of any institution or entity with which the Researcher is affiliated. ;

8.4 Researcher acknowledge that Researcher and Authorized Person(s) have been selected to conduct the Analysis because of their experience, expertise and resources and Researcher acknowledge that Researcher and Authorized Person(s) will not offer, pay, request or accept any bribe, inducement, kickback or facilitation payment, and will not make or cause another to make any offer or payment to any individual or entity for the purposes of influencing a decision for the benefit of AstraZeneca;

8.5 The Researcher warrant that Researcher or any Authorized Person(s) have not engaged in any conduct that has resulted or may result in a criminal conviction, nor are they currently excluded, debarred, suspended, or otherwise ineligible to participate in government health care programs in any country. The Researcher agree to notify the AstraZeneca immediately in the event Researcher become aware that Researcher or any Authorized Person(s) is investigated by any regulatory authority.

#### 9 Governing Law

9.1 This Agreement and the rights and obligations of the parties hereunder shall be governed by, and construed under, the laws of the Sweden without reference to its principles of choice of law. All disputes pertaining to this Agreement shall be decided by a court located in Sweden, and Company hereby consents to personal jurisdiction in such courts.

#### 10 Term and Termination

10.1 This Agreement shall commence upon the Effective Date as shown above and shall continue until the Analysis is completed, unless this Agreement is earlier terminated in accordance with this Section 10 but in no event shall the term of this Agreement exceed twelve (12) calendar months unless done by an approved amendment sixty (60) days before expiration of this Agreement.

Please note that Amendments are reviewed in special circumstances only where unmitigable issues may arise beyond the parties control.

10.2 This Agreement may be terminated by either Party upon thirty (30) days written notice to the other Party.

10.3 Upon expiration or earlier termination of this Agreement, Institution shall (a) subject to Section 4.1, return to AstraZeneca all Confidential Information (except one copy of such Confidential Information may be retained for archival purposes). Termination of this Agreement shall not affect any rights and obligations of the parties that accrued prior to termination.

#### 11 Miscellaneous

11.1 The Parties recognize that any threatened breach or breach of Sections 5, 4 or 6 may cause irreparable harm that is inadequately compensable in damages and that, in addition to other remedies that may be available at law or equity, AstraZeneca is entitled to seek injunctive relief for such threatened or actual breach.

11.2 Neither Party shall assign this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, however, that AstraZeneca shall have the right to assign or otherwise transfer this Agreement to its Affiliates or to any successor in interest.

11.3 This Agreement and the attachments constitute the entire agreement and understanding

between the parties with respect to the subject matter hereof and supersede all prior oral and written agreements, understandings, promises and representations with respect thereto. Notwithstanding the content of any purchase order, sales agreement or other document or record, whether issued before or after the Effective Date, the provisions of this Agreement shall govern and any conflicting, inconsistent or additional terms contained in other documents or records shall be null and void. In the event of any conflict or inconsistency between an Attachment and this Agreement, the terms of this Agreement shall govern except as specifically included in the Attachment.

- 11.4 No amendment, modification or waiver of any of the terms of this Agreement shall be deemed valid unless made in writing and duly executed by authorized representatives of both parties. Each Party shall have the right to enforce the Agreement in strict accordance with its terms. The failure of either Party to enforce its rights strictly in accordance with terms shall not be construed as having in any way modified or waived same
- 11.5 Invalidity or unenforceability of any provision in this Agreement shall not affect the validity or enforceability of any other provision.
- 11.6 All provisions of this Agreement which, in accordance with their terms, are intended to have effect after termination or expiration of this Agreement shall survive termination or expiration of this Agreement.
- 11.7 This Agreement may be executed in two or more counterparts, each of which shall be deemed an original and all of which shall together be deemed to constitute one agreement. The parties agree that execution of this Agreement by industry standard electronic signature software or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each Party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

IN WITNESS WHEREOF, the parties intending to be legally bound, do hereby execute this Agreement on the date stated opposite that Party's signature and represent that the individuals executing this Agreement have the authority to bind their respective entities.

[INDIVIDUALS'S FULLNAME]

ASTRAZENECA CONTRACTING ENTITY

By:

By:

Name:

Name:

Title:

Title:

Organization:

Date:

Date:

[INDIVIDUALS'S FULLNAME]

By:

Name:

Title:

Organization:

Date:



Attachments:

**Exhibit A** – Clinical Trial Listing

**Exhibit B**- Analysis Plan

**Exhibit C**- Scientific Review Board Requirements

**Exhibit D**- Publication Plan

