

## **DATA SHARING AGREEMENT**

This DATA SHARING AGREEMENT (this “Agreement”) is effective as of \_\_\_\_\_, 20\_\_\_\_ (the “Effective Date”) between \_\_\_\_\_ (“Researcher”), located at \_\_\_\_\_ and GlaxoSmithKline, LLC, with offices located at 5 Crescent Drive, Philadelphia, PA 19112 and Five Moore Drive, Research Triangle Park, NC 27709 *or* GlaxoSmithKline Research and Development Ltd, with offices at 980 Great West Road, Brentford, Middlesex, TW8 9GS (“GSK”).

### **BACKGROUND**

GSK and its affiliates develop, manufacture, distribute, and sell pharmaceutical and healthcare products. Researcher desires access to certain data collected by GSK in order to conduct certain analyses as further described below. GSK and Researcher intend to establish this Agreement with respect to Researcher’s access to GSK data.

### **DEFINITIONS**

“GSK Confidential Information” means all information (including, without limitation, patient-level data, research specifications or Protocols, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of GSK or GSK’s affiliates that are provided to Researcher in connection with this Agreement.

“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 in connection with the use of GSK Confidential Information under this Agreement.

“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.

“GSK Uses” means any and all uses of or related to a compound which is owned or Controlled by GSK on or after the effective date, including the compound(s) which was used to generate the patient level 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. DATA SHARING**

(a) GSK and Researcher agree that GSK will provide the Researcher with access to patient level data from the GSK-sponsored clinical studies listed in Exhibit A for the sole purpose of analysis according to Researcher’s approved research plan (the “Analysis”) attached as Exhibit B and for no other purpose. Researcher agrees that data provided by GSK are GSK Confidential Information. GSK makes no representations or warranties regarding the suitability of the data provided to Researcher for the Analysis.

(b) Researcher agrees that it will only use GSK Confidential Information for the

approved Analysis and associated obligations and will not download or transfer the GSK Confidential Information from the GSK access system for either the approved use or other uses.

(c) Researcher agrees to provide access and reasonable assistance to GSK to utilize and implement any Analytical Tools for the sole purpose of reproducing the Analysis.

(d) Researcher agrees that it will inform GSK immediately (and will also inform any regulatory authority) of any safety concerns identified as part of the Analysis. Researcher agrees that GSK may take action regarding such safety concerns, including informing regulatory authorities or healthcare providers, or otherwise making the safety concern public, even in advance of publication of the Analysis by Researcher.

(e) Researcher agrees to comply with any additional requirements identified by the Independent Review Panel which approved the Analysis plan, listed in Exhibit C.

## **2. CONFIDENTIALITY**

(a) GSK Confidential Information and all tangible expressions, in any media, of GSK Confidential Information are the sole property of GSK. Researcher agrees not to use GSK Confidential Information for any purposes other than the purpose(s) described in this Agreement. Researcher agrees not to disclose GSK Confidential Information to third parties except as necessary for the purpose(s) described in this Agreement and under an agreement by the third party (with the exception of regulatory authorities notified of Analysis results) to be bound by the obligations of this Section. Researcher shall safeguard GSK Confidential Information with the same standard of care that is used with Researcher's confidential information, but in no event less than reasonable care. At any time upon the request of GSK, all tangible expressions, in any media, of GSK Confidential Information in Researcher's possession shall be delivered to GSK, or at GSK's option, destroyed.

(b) The obligations of confidentiality and limited use under this Section shall not extend to any information:

(i) which is or becomes publicly available, except through breach of this Agreement;

(ii) which Researcher can demonstrate that it possessed prior to, or developed independently from, disclosure under this Agreement;

(iii) which Researcher receives from a third party which is not legally prohibited from disclosing such information; or

(iv) which Researcher is required by law to disclose, provided that the other party is notified of any such requirement with sufficient time to seek a protective order or other modifications to the requirement.

(c) The obligations of this Section shall survive this Agreement for a period of fifteen (15) years after the Effective Date.

## **3. INTELLECTUAL PROPERTY**

(a) Researcher will notify GSK, promptly and in writing, of any New Intellectual Property. Researcher hereby grants to GSK and to GSK's Affiliates a perpetual, non-exclusive,

royalty-free, worldwide license for GSK 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 for GSK Uses) to all New Intellectual Property which Researcher may have or obtain, each without additional consideration from GSK. Researcher will provide reasonable assistance to GSK, upon commercially reasonable terms that are at least as favorable to GSK as the terms agreed with any other licensee for such assistance, to facilitate GSK in fully utilizing any New Intellectual Property for GSK Uses.

(b) If GSK exercises its option to negotiate an exclusive license for GSK Uses, GSK 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 GSK and GSK's 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 for GSK Uses. In the event that GSK does not exercise its option to negotiate an exclusive license, or in the event Researcher and GSK fail to agree to commercially reasonable exclusive license terms following good faith negotiation, Researcher may negotiate further non-exclusive license terms with third parties for GSK Uses. The Researcher may negotiate license terms with third parties for non-GSK Uses. Any such terms shall be consistent with the non-exclusive license granted to GSK in section 3(a) 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 GSK, within thirty (30) days of the effective date of any such agreement, of the identity of the third party.

(c) Researcher agrees to obtain written agreements with Researcher employees, agents, and subcontractors which assign, without additional consideration, all rights, title and interests in New Intellectual Property to Researcher for subsequent licensing to GSK. The obligations of this Section shall survive termination of this Agreement.

#### **4. PUBLICATION**

Researcher agrees to post a summary of the Analysis plan on a publicly-available internet register or website prior to conducting the Analysis, and to post summary results of the Analysis on the same publicly-available internet register or website within one year of completing the Analysis. 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 disclosing the strengths and weaknesses of the Analysis methodology. Researcher shall submit to GSK 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 within five (5) days of submission to a scientific congress or journal. Additionally, Researcher shall provide GSK with a reference citation upon publication. In the event GSK submits Analysis results to regulatory authorities with the potential to impact product labelling, Researcher agree that GSK may post a summary of the Analysis results on GSK's Clinical Trial Register. 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.

**5. INDEPENDENT CONTRACTOR**

The relationship of the parties is that of independent contractors. Neither party is the partner, joint venturer, or agent of the other and neither party has authority to make any statement, representation, commitment, or action of any kind which purports to bind the other without the other's prior written authorization.

**6. ASSIGNMENT**

GSK may assign its rights and duties under this Agreement without Researcher's consent. Any assignment by Researcher is valid only upon the prior written consent of GSK. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the parties and their permitted successors and assigns.

**7. REPRESENTATIONS AND WARRANTIES**

(a) Researcher represents and warrants that it does not have, and will not enter into, any legal or contractual obligations that would prevent it from complying with its obligations under this Agreement, including without limitation, the obligations of Section 3.

(b) Researcher represents and warrants that it has the authority to bind to the terms of this Agreement any individual proposed by Researcher to have access to GSK data, and that the term "Researcher" shall apply to all such individuals.

(c) Researcher represents and warrants that it will obtain any regulatory or ethics approvals necessary to conduct the Analysis.

(d) Researcher acknowledges the importance of data privacy of individuals to whom accessed data may relate, and commits 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. GOVERNING LAW; VENUE**

This Agreement shall be governed by and interpreted in accordance with the laws of Delaware *or* England and Wales.

**9. ENTIRE AGREEMENT**

This Agreement represents the entire and integrated agreement between the parties and supersedes all prior negotiations, representations or agreements, either written or oral, regarding its subject matter.

**GlaxoSmithKline:**

**Researcher:**

By: \_\_\_\_\_

By: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**Attachments:**

Exhibit A – Clinical Trial Listing

Exhibit B – Analysis Plan

Exhibit C – Independent Review Panel Requirements

Exhibit D – Publication Plan

Sample