

## DATA SHARING AGREEMENT

**Effective Date:** \_\_\_\_\_

This Data Sharing Agreement (“Agreement”) is effective as of the Effective Date between EMD Serono Research & Development Institute, Inc., 45A Middlesex Turnpike, Billerica, MA 01821, USA (“EMD Serono R&D”) and

**Name (“Institution”):** \_\_\_\_\_

**Street Address:** \_\_\_\_\_

**City, State, Zip:** \_\_\_\_\_

Institution and EMD Serono R&D are individually referred to as “Party” and collectively as the “Parties”.

### 1. Background.

Whereas:

- EMD Serono R&D is an affiliated business of Merck KGaA, Darmstadt, Germany, a global pharmaceutical company engaged in the research, development, marketing and sale of pharmaceutical products and devices.
- Institution desires access to certain clinical trial data in the possession of EMD Serono R&D or its Affiliates in order to conduct certain research and analyses as further described below.
- EMD Serono R&D is willing to provide access to such data in accordance with its Responsible Data Sharing Policy (a summary of which is publicly available on the website [EMDSerono.com](http://EMDSerono.com)) and the terms and conditions of this Agreement. EMD Serono R&D and Institution intend to establish this Agreement with respect to Institution’s access to such data.

Now therefore, the Parties agree as follows:

**2. Definitions.** The following terms shall have the following respective definitions:

**2.1 “Affiliate”** means any corporation or non-corporate entity which controls, is controlled by or under common control with the Party. A corporation or non-corporate entity, as applicable, shall be regarded as in control of another corporation if (a) it owns or directly or indirectly controls at least fifty percent (50%) of the voting stock of the other corporation or in the absence of the ownership of at least fifty percent (50%) of the voting stock of a corporation, or (b) in the case of a non-corporate entity, if it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable.

**2.2 “Conflict of Interest Statement”** means a statement which is signed and dated by Institution disclosing Institution’s, its Lead Researcher’s and Researchers’ potential and real conflicts of interest that may impact the planning, conduct or interpretation of the analysis, including proposals to manage such conflicts of interest, to be attached to this Agreement as Exhibit D.

**2.3 “Data”** means the specific clinical study reports, clinical study report synopses, clinical study protocols, clinical study results, patient level data, and study level data and data of all kind and in any form relating to the clinical trials listed on Exhibit A.

**2.4 “Data Request”** means Institution’s written request, attached hereto in Exhibit C, that must include the following: a description of the Data being requested, including the hypothesis to be tested; the rationale for the proposed analysis; the analysis plan, including statistical considerations and individuals who will have access to the Data; a list of individuals who will participate as Researchers in the analysis, including a designation of an individual as Lead Researcher; the qualifications and experience of the proposed research team; curriculum vitae for all Researchers; a publication and posting plan; information on how Data will be protected from unauthorized use, access, and disclosure; the source of any research funding; proof of ethics committee approval or commitment to provide proof of approval before any Data is accessed, if necessary; and a statement indicating that the Researcher has a suitable information technology platform compatible with EMD Serono R&D’s to perform the requested analysis.

**2.5 “New Intellectual Property”** means all results of Institution’s analysis, discoveries, developments, inventions (whether patentable or not), improvements, methods of use or delivery, know-how or trade secrets resulting from the Institution’s or Researchers’ use of the Data or performance of the Research Study.

**2.6 “Research Study”** means that specific non-commercial research study prepared and to be performed by Institution and approved by EMD Serono R&D, a description of which is attached hereto as Exhibit B.

**2.7 “Researchers”** means the specific individuals identified by Institution in the Data Request to EMD Serono R&D as having the requisite qualifications and experience to perform the Research Study.

### **3. Data Sharing**

**3.1 Research Purpose and Scope.** EMD Serono R&D shall provide access to the Data to Institution, and Institution shall access and use the Data, solely in order for Institution to perform the Research Study in accordance with the terms and conditions of this Agreement (hereinafter, the “Purpose”), and for no other purpose. Institution shall not download or transfer the data to third parties and shall not access or use the Data for any commercial purposes.

**3.2 Return or Destruction of Data.** Upon completion of the Research Study and all associated obligations, Institution shall return or destroy, as directed by EMD Serono R&D, all of EMD Serono R&D’s Confidential Information, including the Data, except one copy which may be retained for legal and/or regulatory and/or evidential purposes.

**3.3 No Representations or Warranties or Liabilities / Indemnities on Data Suitability** EMD Serono R&D provides the Data to Institution on an “as is” basis and disclaims all express and implied warranties of any kind, including any warranties of quality, accuracy, timeliness, completeness of the Data, and of merchantability, non-infringement and fitness for a particular purpose. To the fullest extent permitted by applicable law, EMD Serono R&D hereby excludes all liability for and Institution agrees to indemnify EMD Serono R&D and its Affiliates from and against any claim, action, proceedings, damages or payments that may arise as a result of the Institution’s use of Data provided to Institution by EMD Serono R&D, except to the extent caused by the gross negligence or willful misconduct of EMD Serono R&D or its Affiliates.

**3.4 Performance of Research Study.** Institution shall perform, and shall have the Researchers work to perform the Research Study with the highest standards of diligence and in accordance with the generally accepted scientific principles, good analysis practices, and all applicable laws, rules and regulations, including without limitation ethics committee review, patient data privacy and informed consent requirements. Institution shall be considered the study sponsor for all regulatory purposes and the Lead Researcher shall be considered the investigator.

**3.5 Prohibition of Patient Re-identification.** Institution acknowledges that the Data may contain sensitive personal information regarding patients. EMD Serono R&D shall use reasonable efforts to anonymize the Data before providing access to the Institution. Institution shall maintain the Data in such de-identified form and shall not attempt to re-identify any patient.

**3.6 Representation and Warranties.** Institution represents and warrants that it has fully disclosed in the Conflict of Interest Statement any and all potential conflicts of interest, including without limitation those of all Researchers. Institution also represents and warrants that all factual information in the Data Request is truthful, accurate and complete.

**3.7 Drug Safety.** Institution shall EMD Serono R&D immediately (and if required by law, will also inform any regulatory authority) of any safety concerns identified while conducting the Research Study. Institution agrees that EMD Serono R&D 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 Research Study by Institution.

**3.8 Reproduction of the Research Study Results by EMD Serono R&D.** Upon request by EMD Serono R&D, Institution shall provide reasonable access and support to EMD Serono R&D, its Affiliates and designees for the purpose of reproducing the Research Study's results.

**3.9 Approvals.** Institution shall, as a condition to obtaining access to the Data, obtain any regulatory and/or institutional review board ("IRB") or ethics board approvals necessary to conduct the Research Study. Institution understands that it shall not be provided access to the Data unless and until it provides EMD Serono R&D with a copy of any such necessary regulatory and/or IRB/ethics board approvals.

**3.10 Additional conditions.** Institution shall comply with any additional restrictions regarding use of the Data set forth in Exhibit A or elsewhere in this Agreement.

#### **4. Confidentiality.**

**4.1 Confidential Information.** Institution shall hold in confidence EMD Serono R&D and its Affiliates' information relating to its business, operations and products, including but not limited to, Data, any technical information, additional details of the Research Study provided to third party Researchers, know-how, trade secrets, all sensitive, strategic information and method descriptions that it discloses to the Institution in connection with this Agreement ("Confidential Information"), unless such information:

(i) is or becomes generally available to the public other than as a result of disclosure by Institution;

(ii) is already known by or in the possession of Institution at the time of disclosure by EMD Serono R&D;

(iii) is independently developed by Institution without use of or reference to the Confidential Information; or

(iv) is obtained by Institution from a third party that has not breached any obligations of confidentiality.

**4.2 Use and Disclosure.** Institution represents and warrants that it shall use the Confidential Information only for the Purpose. Institution represents and warrants that it shall not use the Confidential Information for any other purpose. Institution represents and warrants that it shall disclose the Confidential Information only to the Researchers or those individuals identified in its Research Study and shall not disclose or its Affiliates the Confidential Information to any other third party except: (a) it is reasonably necessary for the purpose of performing the Research Study, (b) EMD Serono R&D has consented to it in writing, and (c) the third party is bound by agreement to all obligations of this Agreement as it is the case for the Institution. Institution shall be responsible for any use or disclosure of the Confidential Information by any such third parties. Further, Institution shall impose all obligations under this Agreement on its employees, affiliates, and all third parties who (only with the consent of EMD Serono R&D are assisting

with, working on or involved in the conduct of the Research Study.

**4.3 Standard of Care.** Institution shall protect the Confidential Information using not less than the same care with which it treats its own confidential information, but at all times using at least reasonable care. Institution shall (i) implement and maintain appropriate privacy and security measures to prevent unauthorized access to, use or disclosure of, the Confidential Information, (ii) promptly notify only EMD Serono R&D of any unauthorized access or disclosure of the Confidential Information, and (iii) cooperate with EMD Serono R&D in the investigation and remediation of any such unauthorized access or disclosure.

**4.4 Provision of personal data via EMD Serono R&D's website and Data Privacy.** Institution gives permission to EMD Serono R&D and its Affiliates and their designees and service providers, to collect, use, process and hold Institution's data and information on the Research Study, including: (i) Institution's name, address and other contact details; (ii) name(s) and contact details of (a) Researcher(s) and other personal data included in (a) curriculum vitae(s), (iii) Research Study title, scope and intent; (iv) requested Data; (v) the date of the Data Request; (vi) funding source; (vii) affiliation with any third parties that might lead to conflict of interest, (viii) the author(s), the title and the source of the Publication as defined below, for the following purposes: (a) maintaining this Agreement; (b) satisfying legal or regulatory requirements, if any; (c) statistical reporting, (d) creation of data sharing platform account for Researcher(s). Recipients of personal data according to this Section may also be established in countries outside the EU or the European Economic Area subject to an adequate protection, especially by the use of EU Standard Contractual Clauses.

**4.5 Information about processing of personal data.** Institution shall inform the Researchers and those individuals identified in its Research Study about processing of their Personal Data by EMD Serono R&D and its Affiliates for the purposes of this Agreement so that EMD Serono R&D and its Affiliates comply with its information requirements under applicable data protection laws; where Institution is reasonably missing details to provide

complete information, EMD Serono R&D will provide such information upon request. Institution confirms that it has obtained any necessary consents of the Researchers and those individuals identified in its Research Study, to collect, use, process, hold and transfer their personal data and information for the purpose of requesting Data via EMD Serono R&D's website using the Data Request, and for the purpose of maintaining this Agreement. Where Researchers and other affected individuals want to exercise their rights under data protection laws, they can contact EMD Serono R&D's data protection officer at [privacy@emdgroup.com](mailto:privacy@emdgroup.com).

**4.6** For purposes of Section 4.4 (d) above, Institution shall obtain consent from Researcher(s) who is/are assigned by Institution to access the Data. Researcher(s) can provide consent by signing Attachment E.

**4.7 Monitoring and Inspection.** Institution shall afford EMD Serono R&D and their representatives and designees reasonable access to Institution's facilities, to Data as well as to any other documents and documentation so as to permit EMD Serono R&D and its Affiliates to monitor compliance with this Agreement (including after termination of this Agreement).

**5. Independent Contractors.** The relationship between the Parties is that of independent contractors. The Parties shall not enter into any agreements or incur obligations on behalf of either Party without prior written consent from the other Party.

## **6. Compliance Obligations.**

**6.1** EMD Serono R&D intends to conduct its business in accordance with environmental, labor and social standards and to abide by the standards set forth in the EMD Serono Code of Conduct and Human Rights Charter (available at [www.EMDSerono.com](http://www.EMDSerono.com)). Institution shall comply, and shall ensure that its subcontractors comply, with reasonably comparable environmental, labor and social standards. Institution further acknowledges and ensures that Institution and its subcontractors are familiar with the provisions of the U.S. Foreign Corrupt Practices Act ("FCPA"), UK Bribery Act and applicable local bribery and corruption laws,

and shall not take or permit any action that will either constitute a violation under, or cause EMD Serono R&D or its Affiliates to be in violation of the provisions of the FCPA, UK Bribery Act or applicable local bribery and corruption law, environmental, labor and social standards and the EMD Serono Code of Conduct and Human Rights Charter (collectively "Improper Conduct").

**6.2** In addition to any other rights EMD Serono R&D may have under this Agreement, if Institution notifies EMD Serono R&D of, or EMD Serono R&D otherwise has a reasonable suspicion of, the occurrence of Improper Conduct, EMD Serono R&D may inspect or have inspected by an independent auditor the premises, books and records of Institution relevant to Improper Conduct for the purpose of ensuring compliance by Institution of its obligations under this section entitled "Compliance Obligations." Institution shall promptly notify EMD Serono R&D in writing of such events.

**6.3** Should EMD Serono R&D gain sufficient evidence that Institution or its subcontractors are in breach of the foregoing, EMD Serono R&D may terminate this Agreement immediately by written notice to Institution.

## **7. Property Rights**

**7.1** Non-Exclusive License. Institution shall notify EMD Serono R&D promptly and in writing of any New Intellectual Property. Institution hereby grants to EMD Serono R&D and to its Affiliates a perpetual, non-exclusive, royalty-free, worldwide license (with the right to sublicense) to all rights, title and interest which Institution may have or obtain in any New Intellectual Property, without additional consideration from EMD Serono R&D. Institution will provide reasonable assistance to EMD Serono R&D, upon commercially reasonable terms that are at least as favorable EMD Serono R&D as the terms agreed with any other licensee for such assistance, to facilitate EMD Serono R&D in fully utilizing any New Intellectual Property.

**7.2** Option. Institution hereby grants to EMD Serono R&D and to its Affiliates an exclusive option, to be exercised in writing within one hundred eighty (180) days following receipt of

notice of the New Intellectual Property, to obtain an exclusive, fee-bearing, worldwide license (with right to sublicense) to all or at EMD Serono R&D's election, a portion of the rights, title and interest which Institution may have or obtain in any New Intellectual Property. Following any exercise of such option, EMD Serono R&D and Institution shall exclusively negotiate the financial terms if such license in good faith, for up to one hundred eighty (180) days or such mutually agreeable longer period. If EMD Serono R&D or an Affiliate does not exercise the option to an exclusive license, or if Institution and EMD Serono R&D fail to agree to commercially reasonable financial terms of the license following good faith negotiation, then Institution may negotiate license terms with third parties. Any such terms shall be consistent with the non-exclusive license granted to EMD Serono R&D in section 6.1 above. Should any terms be agreed with a third party in accordance with this section, then for five (5) years after the Effective Date, Institution shall notify EMD Serono R&D, within thirty (30) days following the Effective Date of any such agreement, of the identity of the third party.

**7.3** Records. Institution shall obtain written agreements with Institution employees, agents, and subcontractors which assign, without additional consideration, all rights, title and interests in New Intellectual Property to Institution for subsequent licensing to EMD Serono R&D.

## **8. Publication of Results**

**8.1** By Institution. Institution shall post a summary of the Research Study on a publicly-available internet register or website prior to conducting the Research Study, and to post summary results of the Research Study on the same publicly-available internet register or website within one year of completing the Research Study. Institution also agrees to submit the results of the Research Study for publication in the peer reviewed literature or at a scientific congress (a "Publication") in a timely and complete manner, with such Publication appropriately disclosing the strengths and weaknesses of the Research Study methodology. Such Publication shall comply with all applicable standards and guidelines including those of the International Committee of Medical Journal Editors. Institution shall submit to EMD Serono R&D an advance copy

of the Research Study summary and summary results prior to posting the summaries, as well as an advanced copy of any proposed Publication at least sixty (60) days before submission to a scientific congress or journal for the purpose of reviewing the summaries and Publication for confidential or proprietary commercial information. Upon EMD Serono R&D's request, all such confidential or proprietary commercial information shall be removed from the summaries and publication. Additionally, Institution shall provide EMD Serono R&D with a reference citation upon publication. Institution will assist EMD Serono R&D in obtaining re-prints of the Publication.

**8.2 By EMD Serono R&D.** If EMD Serono R&D or an Affiliate submits Research Study results to any regulatory authority with the purpose or effect of changing any product labeling or approvals, Institution agrees that EMD Serono R&D may post a summary of the Research Study results on a public website and/or website hosted by EMD Serono R&D or its Affiliate for posting Research results. Institution agrees, following publication, to provide other researchers with additional details of the Research Study on request, provided that all confidential and proprietary commercial information of EMD Serono R&D and its Affiliates shall be removed from the additional details, 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 Research Study.

## **9. Term and Termination.**

**9.1 Term.** The term of this Agreement shall commence as of the Effective Date and continue until all obligations under the Agreement have been fulfilled, unless terminated earlier upon notice by EMD Serono R&D at any time.

**9.2 Survival.** Termination or expiration of this Agreement shall not relieve either Party of any obligation or liability accrued prior to the termination date. The obligations of the Parties under the Sections entitled: Confidentiality, Property Rights, Publication of Results, Survival, Assignment, and Miscellaneous shall survive termination of this Agreement.

**10. Assignment.** The rights and obligations of Institution under this Agreement are personal to Institution and may not be assigned or subcontracted to others without EMD Serono R&D's written consent. EMD Serono R&D may assign this Agreement in whole or in part without Institution's consent.

**11. Miscellaneous.** This Agreement and all claims related to it shall be governed by the laws of Massachusetts, without regard to its choice or conflict of law provisions. This Agreement is the entire agreement between the Parties relating to the subject matter hereof and supersedes all prior agreements between the Parties relating to the subject matter hereof. Facsimile signatures shall have the same effect as originals. This Agreement may be executed in counterparts.

[Signatures begin on next page.]

IN WITNESS WHEREOF, duly authorized representatives of the Parties have executed this Agreement as of the Effective Date.

**Institution**

**EMD Serono Research & Development  
Institute Inc.**

Signature: \_\_\_\_\_

Signature: \_\_\_\_\_

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

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

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

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

**EXHIBIT A**

**SPECIFIC CLINICAL TRIAL(S) AND DATA TO BE PROVIDED**

EMD Serono R&D has agreed to provide Institution access to data from the following clinical trials sponsored by EMD Serono R&D and/or its Affiliate(s):

Full protocol name: \_\_\_\_\_

Protocol number: \_\_\_\_\_

Ct.Gov identifier: \_\_\_\_\_

EMD Serono R&D has agreed to provide access to the following specific data from the above-listed trial(s) [DRAFTING NOTE: delete all types of data which have not been authorized by EMD Serono R&D for a specific request]:

1. Full clinical study report
2. Clinical study report synopsis
3. Clinical study protocol
4. Clinical study results
5. Patient level data (defined in Responsible Data Sharing Policy as “Information on individual patients collected during the course of a clinical study and recorded on Case Report Forms, including, but not limited to, demographic data, laboratory results, baseline characteristics, drug concentration data, biomarker and pharmacogenetic data, and adverse events. Patient Level Data shall not include any medical, clinical, regulatory, or legal interpretations, explanations, or conclusions.”)
6. Study level data (defined in Responsible Data Sharing Policy as “Patient Level Data that has been amalgamated, compiled and tabulated, manipulated, stratified or otherwise organized into study-level data sets to be used in interpreting the outcome of a study. Study Level Data is usually presented in tabular, graphic, or statistical form showing averaged, stratified, or patterned presentations of study data. This data shall not include any medical, clinical, regulatory, or legal interpretations, explanations, or conclusions.”)
7. Summary information of data (in case where co-development agreements or other agreements or other legal restrictions prevent EMD Serono R&D from sharing particular data).

Additional restrictions regarding use of Data (if any):



**EXHIBIT B**

**RESEARCH STUDY PLAN**

Under Data Sharing Agreement dated [     ]

[insert Institution Research Study Plan]

**EXHIBIT C**

**DATA REQUEST**

**EXHIBIT D**

**CONFLICT OF INTEREST STATEMENT**

*[Please add any potential conflicts of interest with the proposed research for each member of the research team. A "conflict of interest" is considered to be financial and/or non-financial relationships that could be perceived to influence the planning, conduct or interpretation of the research. Wherever conflict of interests exist these have to be elaborated in the table below]*

**Name of researcher:** [Insert name]

FINANCIAL CONFLICTS:	
Board membership	[Insert conflict or N/A]
Consultancies	[Insert conflict or N/A]
Employments	[Insert conflict or N/A]
Grants	[Insert conflict or N/A]
Patents	[Insert conflict or N/A]
Royalties	[Insert conflict or N/A]
Stock/shares	[Insert conflict or N/A]

**Name of researcher:** [Insert name]

FINANCIAL CONFLICTS:	
Board membership	[Insert conflict or N/A]
Consultancies	[Insert conflict or N/A]
Employments	[Insert conflict or N/A]
Grants	[Insert conflict or N/A]
Patents	[Insert conflict or N/A]
Royalties	[Insert conflict or N/A]
Stock/shares	[Insert conflict or N/A]

**Name of researcher:** [Insert name]

FINANCIAL CONFLICTS:	
Board membership	[Insert conflict or N/A]
Consultancies	[Insert conflict or N/A]
Employments	[Insert conflict or N/A]
Grants	[Insert conflict or N/A]
Patents	[Insert conflict or N/A]
Royalties	[Insert conflict or N/A]
Stock/shares	[Insert conflict or N/A]

**Name of researcher:** [Insert name]

FINANCIAL CONFLICTS:	
Board membership	[Insert conflict or N/A]
Consultancies	[Insert conflict or N/A]
Employments	[Insert conflict or N/A]
Grants	[Insert conflict or N/A]
Patents	[Insert conflict or N/A]
Royalties	[Insert conflict or N/A]
Stock/shares	[Insert conflict or N/A]

**Name of researcher:** [Insert name]

FINANCIAL CONFLICTS:	
Board membership	[Insert conflict or N/A]
Consultancies	[Insert conflict or N/A]
Employments	[Insert conflict or N/A]
Grants	[Insert conflict or N/A]
Patents	[Insert conflict or N/A]
Royalties	[Insert conflict or N/A]
Stock/shares	[Insert conflict or N/A]

**Attachment E**

**Consent for Submission of Personal Data  
to Service Provider Hosting the Data Sharing Platform(s) of  
EMD Serono Research & Development Institute, Inc. ("Company") and/or its Affiliate(s)**

I consent to the submission of my personal data (title, name, contact details and information regarding my professional qualifications) to the service provider(s) which is (are) engaged by the Company and/or its Affiliates for hosting the Company and/or its Affiliates' data sharing platform and for creation of my data sharing platform account.

I am entitled to withdraw this consent at any time with future effect.

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

Signature: \_\_\_\_\_

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

Location: \_\_\_\_\_