Summary of EMD Serono's Responsible Data Sharing Policy

1. Rationale and Objective

In accordance with the European Federation of Pharmaceutical Industries and Associations (EFPIA) and the Pharmaceutical Research and Manufacturers of America's (PhRMA) *Principles for Responsible Clinical Trial Data Sharing*, EMD Serono believes that as a biopharmaceutical company, the sharing of information related to company sponsored clinical trials is central to our mission. The sharing of clinical trial Information enables the medical and scientific community to further develop the medical and scientific knowledge base and permits the public to make informed healthcare decisions.

However, because information from company sponsored clinical trials may include confidential personal information and proprietary company information, EMD Serono must ensure that information is provided only in response to legitimate scientific and medical requests and that information disseminated outside of the company properly protects all confidential and proprietary information. All clinical trial information must further be provided only in accordance with applicable laws and codes.

2. Information Shared With Researchers

Following approval of a new product or a new indication for an approved product in both the European Union and the United States, EMD Serono will share study protocols, anonymized patient level, and study level data and redacted clinical study reports from clinical trials in patients with qualified scientific and medical researchers, upon researcher request, as necessary for conducting legitimate research.

Such data will only be shared after a new product or a new indication for an approved product has been approved in both the European Union and the United States after 1 January 2014. Data will not be shared for products and indications approved prior to the effective date of this Policy. In addition, data will not be shared with EMD Serono competitors.

2.1 Requirements for Researchers' Requests

Researcher requests for information must be in writing and include:

- 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;

Address line one
Address line two
Tel: +00 (0)00 0000 0000
Fax: +00 (0)00 0000 0001

- 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 vitas for all Researchers;
- A publication and posting plan;
- Information on how data will be protected from unauthorized use, access, and disclosure;
- A conflict of interest statement describing any potential conflicts of interest, including potential competitive use of the data;
- 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 sufficient information technology platform compatible with EMD Serono's.

2.2 Evaluation of Researchers' Requests

Researchers' requests will be evaluated initially by an internal committee at EMD Serono, which may decide to approve the request. If the EMD Serono committee denies the request, the request will be escalated to the EMD Serono Scientific Review Board for a second review (de novo). The Board shall include scientists and/or healthcare professionals who are not employees of EMD Serono. The Board shall be responsible for reviewing the request to determine whether the request meets the criteria for researcher qualifications and legitimacy of the research purpose, notwithstanding the denial by the EMD Serono committee.

When evaluating the qualifications of the Researcher, the Board must verify the Researcher's identity and determine whether the Researcher is appropriately qualified to perform the proposed research. The Board may consider a variety of factors bearing on a Researcher's qualifications, including without limitation:

- The Researcher's training and/or experience;
- Whether the Researcher is associated with an organization with appropriate research governance and management systems; and
- The extent and complexity of the proposed research.

When evaluating the legitimacy of the research purpose, the Board may consider a variety of factors, including without limitation:

- The scientific/medical merit of the request, including any unmet medical need;

- The existence of a clear research hypothesis designed to provide meaningful information or conclusions;
- Whether a statistician with a degree in statistics or person with relevant statistical knowledge or a related discipline is part of the research team;
- Whether results will be published;
- Whether the sole purpose of the request is to address a question or conduct an analyses in the interest of public health;
- Whether adequate measures are specified for the protection of Clinical Trial Information, specifically individual patient data, from unauthorized use, disclosure, and access; and
- The potential competitive use of the requested data.

When evaluating a request, the Board may assume that any requestor might intend to use the requested information to help gain approval of a potentially competing product. While EMD Serono is open to third parties entering into agreements to co-develop products with EMD Serono, EMD Serono's Policy is not intended to, and shall not be used to, provide an alternative co-development pathway to such third parties.

2.3 Data Sharing Agreement

After approval of a request and prior to the transfer of any information, the researcher must enter into a Data Sharing Agreement ("DSA") with EMD Serono. The standard DSA which must be entered into is posted on EMD Serono's website.

2.4 Data Access

EMD Serono shall notify researchers as to how the requested data will be provided. Different types of data may be provided to researchers in different ways. Under appropriate circumstances, EMD Serono may require that a researcher access data only on the company's data sharing platform. EMD Serono is not obligated to provide researchers with software or a platform to analyze the requested data or otherwise re-format data.

3. General Public

Following approval of a product and indication in both the European Union and the United States, EMD Serono will make publicly available Clinical Study Report synopses that were filed with regulators on or after January 1, 2014. All synopses disclosed under EMD Serono's commitment shall respect patient privacy, as well as third party agreements, and shall be redacted of all confidential commercial information.

4. Study Participants

In order to help inform and educate patients about the clinical trials in which they participate, EMD Serono will work with regulators to adopt mechanisms for providing a factual summary of clinical trial results and make the summaries available to study participants.

5. Website Information

EMD Serono will certify on a publicly available website that the company has established policies and procedures to implement the company's data sharing commitments. EMD Serono will further publicly post its data request review process, as well as the identity of the Board, including any existing relationships with external Board members.

6. Scope

EMD Serono's commitment applies to all clinical trials sponsored by EMD Serono and its affiliate companies, wherever in the world they are conducted. This commitment does not affect or alter other EMD Serono commitments with respect to public disclosure of clinical trial designs and clinical trial results or publishing clinical trials results in publications.