



## External Scientific Review Board (ESRB) Charter

### Providing Access to Patient-Level Data

Merck is committed to the EFPIA/PhRMA Transparency and Clinical data sharing principles, including the principle of providing qualified scientific researchers access to patient-level data from Merck's clinical trials to conduct legitimate scientific research.

In accord with this commitment, Merck will provide access to patient-level data to qualified researchers with a scientifically valid research proposal regarding clinical trials performed by Merck for which results are posted on clinicaltrials.gov (dating back to September 2007). Data will be made available upon request from studies conducted for approved products and indications that have been approved by regulators in the US and EU. An External Scientific Review Board (ESRB) comprised of non-Merck scientists will assist Merck in assessing the scientific validity of data requests. For details of the procedure for submitting data requests and the overall review process, please refer to the Merck Policy for Clinical Trial Data Access.

Protecting the privacy of patients who participate in clinical trials is an important obligation of those who conduct clinical trials and therefore Merck will take appropriate measures, including anonymization of data, to ensure that patient privacy is safeguarded.

### Purpose of the External Scientific Review Board

The External Scientific Review Board will

- 1) Review the scientific validity of research proposals and help ensure the data are used in a scientific and responsible manner.
- 2) Provide advice and feedback on the experience gained through this initiative to help guide the future development of the process.

This charter provides the responsibilities and decision making processes of the ESRB in relation to research proposals and access to patient-level data.

A Merck internal review committee made up of subject matter experts in the relevant therapeutic area will perform an initial feasibility assessment and scientific review of in scope data access requests. Any request approved by Merck will not require review by the ESRB.

### Composition

The ESRB will be comprised of scientists or physicians who are not employees of Merck and who have experience in conducting or reviewing clinical trials. The members of the ESRB will select a Chairperson.

### Scope

The ESRB will review proposals that are sent by the Merck internal review committee for reasons or questions of scientific validity or the qualifications of the requesters. The role of the ESRB will be to review the application with regard to the scientific validity of the request and qualifications of the requesters and make a recommendation to Merck as to whether the proposal should be approved or not.



The ESRB conducts a high level review of the research proposal, based on the following criteria:

1. Is the research question or hypothesis clearly defined with a scientifically valid rationale?
2. Is there a well-developed Statistical Analysis Plan?
3. Is there an adequate publication plan to disseminate findings in a peer reviewed journal or scientific meeting?
4. Has the applicant declared that the research as described will be conducted and reported in good faith?
5. Is the applicant willing to declare all professional interests, affiliations, possible conflicts of interest and all sources of support for the research as part of the dissemination of their results?
6. Does the research team have sufficient expertise, including a statistician and qualifications to perform the proposed investigation?

Based on this review, the ESRB makes a written recommendation with a rationale to Merck on whether or not to approve the proposal.

#### **ESRB Process**

The ESRB will seek consensus among its members, but if that cannot be achieved, its recommendations will be made on the basis of a simple majority vote from its members.

The Chairperson communicates in writing the ESRB's recommendation, including the rationale, and any conditions, where applicable, to the Merck Steering Committee, which is comprised of the research heads of clinical, regulatory and biostatistics. The Merck Steering Committee will make the final decision on the data request after consideration of the recommendation from the ESRB.

#### **An Evolving Policy**

Data sharing principles and processes are evolving and the policy and process outlined here is intended as an initial step, subject to modification based on Merck's experience and the recommendations of advisory groups evaluating this issue, such as the Institute of Medicine working group.

Merck will reimburse members of the External Scientific Review Board fair market value fees for their time and expertise and disclosures of other work with Merck, if any, will be disclosed. Board members will review research proposals in a personal capacity, not as representatives of their respective organizations or institutions.