Procedure on Access to Clinical Trial Data

Overview

We are fully committed to supporting the EFPIA and PhRMA guiding principles on data sharing, including the principle of providing qualified scientific researchers access to anonymized participant-level data and full clinical study reports (CSRs) from MSD's clinical trials to conduct legitimate scientific research. We are also fully participating in the Institutes of Medicine (IOM) global effort to develop principles for responsible sharing of clinical trial data.

Eligibility

Qualified researchers with appropriate competencies who are engaged in rigorous, independent, and novel scientific research can submit a request for participant-level data or a full CSR along with a research proposal to MSD for review. Researchers will be asked to sign a data-sharing agreement prior to receiving access to clinical trial data. The research team must include a biostatistician.

- Conflict of interest will be assessed; data will not be released to individuals with significant conflict of interest or individuals requesting data access for competitive, commercial or legal interests.
- Funding requests are not supported under this procedure.

Application Process

Research proposals must be submitted through the website at http://engagezone.msd.com/ds_documentation.php and must adhere to the requirements for the submission process. The following basic information will be required:

1) Detailed research proposal that includes:
    - Background and rationale
    - Objectives of the research
    - Scientific hypothesis
    - Statistical analysis plan
    - Publication plan
2) Curricula vitae of all researchers, including the biostatistician

Scope of Data

MSD will provide access to participant-level data and CSRs from clinical trials performed by MSD for which results are posted on the clinicaltrials.gov registry (dating back to September 2007) for products or indications that have been approved by regulators in the US and EU. In general, data will be made available for request approximately 18 months after clinical trial completion. Data from phase I trials in healthy volunteers and consumer health care studies are out of scope for this procedure.

There are additional circumstances that may prevent MSD from sharing the requested data:

- MSD may not have the legal authority because the product was co-developed with a partner or obtained from an external partner under a contract that does not permit the disclosure.
- It may be difficult to ensure protection of the privacy and confidentiality of research participants. For example, small trials (e.g., with less than 50 participants) or studies of rare diseases may have too few participants to prevent re-identification of individuals.
- The informed consent or local regulations may not allow for data sharing.
- There may be substantial practical constraints to providing access to the data (for example, size and complexity of databases or resources required to retrieve data from repositories and redact personally identifiable information from relevant documents).

Review Process

Completed applications will be reviewed by MSD with input as needed from an External Scientific Review Board (ESRB) comprised of non-MSD scientists or physicians. Additional details on the governance of the board can be found in the ESRB Charter. Researchers will receive an acknowledgement of receipt, and the request will be evaluated by an internal MSD review committee comprised of subject matter experts in the relevant therapeutic area.

After the request is assessed for feasibility, the MSD review committee will assess the scientific validity of the request and the qualifications of the requesters. If the MSD review committee determines that the request is scientifically valid and the requesters have the appropriate expertise to perform the proposed analysis, then the request will be approved, and data will be shared.
If there are questions or concerns regarding the scientific validity of a data request from the MSD review committee, the request will be forwarded to the ESRB for further review. A recommendation from the ESRB will be communicated to the MSD Steering Committee, which is comprised of the research heads of clinical, regulatory, and biostatistics. The MSD Steering Committee will make the final decision on the data request after consideration of the recommendation from the ESRB. MSD will communicate a formal notification of the status and the rationale to the researcher.

Review Criteria

- Does the proposal include a clearly defined research question and scientific rationale, and is the proposed research relevant to medical science or patient care?
- Is there a well-documented statistical analysis plan?
- For correlative biomarker research, is there a clearly specified and biologically novel hypothesis?
- Is there an ability of the proposed research plan (design, methods and analysis, statistical power) to meet the scientific objectives?
- Is there an adequate publication plan for disseminating the research?
- Is the research applicant willing to disclose any real or potential conflicts of interest that may impact the planning, conduct, or interpretation of the research?
- Does the research team have the expertise, qualifications and experience to conduct the proposed research (e.g., does it include a biostatistician as part of the research team)?

Data Sharing Agreement

Before access to clinical trial data is provided, the researcher must enter into a standard data sharing agreement with MSD. The data sharing agreement commits the researcher to use the data only for the stated research purpose and to not disclose the data to third parties. This is in line with data privacy legislation. In addition, researchers are expected to commit to transparency in the publication of their work.

Anonymization of Data

Protecting the privacy of clinical trial participants is an important obligation of sponsors who conduct clinical trials. Therefore, MSD will take appropriate measures, including anonymization of data, to ensure that participant privacy is safeguarded.

Data Access

MSD will provide researchers with access to anonymized participant-level data needed to address the specific research question consistent with the requirements noted here. If a request for a full CSR is approved, MSD will provide researchers the CSR in a redacted form that is consistent with the need to protect participant privacy and confidential commercial information.

GENETIC OR EXPLORATORY BIOMARKER DATA

Genetic or exploratory biomarker data requires a detailed, hypothesis-driven statistical analysis plan that is collaboratively developed by the requestor and MSD subject matter experts; after approval of the statistical analysis plan and execution of a data-sharing agreement, MSD will either perform the proposed analyses and share the results with the requestor or will construct biomarker covariates and add them to a file with clinical data that is uploaded to an analysis portal so that the requestor can perform the proposed analyses. Participant-level data will not be shared.

An Evolving Procedure

Data sharing principles and processes are evolving, and the procedure outlined here is intended as an initial step, subject to updates as appropriate based on MSD's experience and the recommendations of advisory groups evaluating this issue such as the Institutes of Medicine, regulators, other members of industry, academic institutions, and publishers.

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