

# **BRISTOL-MYERS SQUIBB DATA SHARING INDEPENDENT REVIEW COMMITTEE (IRC) CHARTER**

Charter Effective Date:  
**October 13, 2017**

**Release v2.0**

## Introduction

This Charter describes the roles and responsibilities of the Independent Review Committee (IRC) for the [Bristol-Myers Squibb \(BMS\) Data Sharing Initiative](#). This program has been initiated by BMS to enhance the transparency of its clinical trial programs and to make available data from clinical trials to qualified researchers for analysis.

### 1. Purpose of Data Sharing Initiative

There is an escalating call for improved transparency in clinical research, particularly by the pharmaceutical industry. This includes the improved communication of clinical trial results and availability of study data to researchers for additional analysis. In response to this movement, the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) released [Principles for Responsible Clinical Trial Data Sharing](#) in July 2013. This includes the following commitments:

- a. Enhancing data sharing with researchers
- b. Enhancing public access to clinical study information
- c. Sharing results with patients who participate in clinical trials
- d. Certifying procedures for sharing clinical trial information
- e. Reaffirming commitments to publish clinical trial results

BMS has initiated a series of efforts to enhance transparency of its clinical trial programs. Specifically, this includes a platform to make data for in-scope clinical trials available to qualified researchers for analysis. Acknowledging the challenges of balancing the risks of disclosure with scientific quality and public perception, BMS has entered into a collaborative relationship with Duke to assist in this endeavor.

### 2. Scope of Data Sharing Initiative

The data sharing initiative pertains to BMS-sponsored Phase I-IV interventional trials in which patients participated. This includes patient-level and study-level clinical trial data, full clinical study reports and protocols from clinical trials conducted in patients for medicines and indications approved in the U.S. and/or EU. Requests are subject to terms necessary to protect patient privacy and respect patient's informed consent.

### 3. Proposal Submission/Research Protocol

Proposals will be submitted electronically via a portal maintained by BMS. The research proposal will include key information on the data request, such as:

- a. Description of the requested data
- b. Hypothesis to be tested
- c. Rationale for the research
- d. Statistical Analysis Plan
- e. Publication Plan
- f. Qualifications and experience of the research team
- g. Potential conflicts of interest
- h. Source of any research funding

#### **4. Independent Review Committee (IRC)**

**To facilitate an independent review process for all submitted proposals, BMS has engaged Duke University, through its Duke Clinical Research Institute (DCRI) to delegate the review and recommendations authority as an outside, reputable academic entity with experience in design, conduct and analysis of clinical trial data.**

##### **Composition of the IRC**

The IRC will be comprised of two co-chairs plus four core members representing three broadly defined areas of expertise; clinical, statistical/data-related and bioethical/protection of human subjects (more detailed information on the members is available by request). To ensure adequate expertise is applied to each review, additional core members or other experts from within Duke or external to Duke may be asked to participate in an IRC meeting at the discretion of the co-chairs.

##### **Qualifications of the IRC Reviewers**

- a. Clinical, statistical, data-related, bioethical or protection of human subjects expertise related to the area of the proposed study
- b. General knowledge of clinical trials
- c. Availability and commitment to the goals and timelines of the program
- d. Remain in good professional standing
- e. Independence from requestor of data or any affiliate(s)
- f. Provide disclosure of potential conflicts of interest that will be reviewed by the
- g. IRC co-chairs, if necessary.

#### **5. Review Process**

BMS will review each proposal for completeness and availability of the data requested and satisfaction of pre-qualification criteria, and may provide a recommendation to the IRC on the feasibility of the request. BMS will inform the requestor if the submitted request for data is out of scope and does not meet pre-specified criteria. Comments generated by BMS staff during this initial review that relate to the evaluation of the proposal will be provided to DCRI for consideration by the IRC. BMS may also suggest to the IRC that the proposal be evaluated following the expedited review process. The following outlines the review process, also summarized in Appendix A.

- a. BMS will compile the proposal materials and send to DCRI project leader via email for review by the IRC.
- b. Upon routine checks for completeness, the project leader will forward the request to the IRC chair.
- c. An IRC Chair will perform an initial evaluation of the proposal to 1) determine if an expedited review, rather than full committee review is acceptable; and 2) determine if subject matter expertise beyond the core IRC membership is required to appropriately review the proposal. The presiding IRC Chair has the sole discretion to invite additional reviewers to participate in the IRC review of a proposal.
  - i. Full committee review meetings will include a chair plus members representing each of the three designated domains to achieve quorum.

- ii. Decisions reached by the IRC when a quorum is achieved will be considered final; subsequent reviews from additional committee members will not be supported.
- iii. Expedited committee review meetings will include the chair plus one other member. If the two members are not unanimous in their recommendation the proposal will go for a full committee review.
- d. Invited members of the IRC may include any individual with the expertise deemed necessary to review a proposal. This may be an employee of Duke University or a subcontractor. Academic faculty status will be typical, but is not required.
- e. After the IRC members have been identified, the project leader will send them all review materials and schedule a meeting, held in person or by a teleconference.
- f. Specific portions of IRC meetings may be 'open' to discussion among IRC reviewers, BMS employees (e.g. statisticians and medical leads familiar with the trial datasets or researcher making the request) and potentially the submitting investigator. A portion of the meeting may be closed to ensure proposals can be freely discussed among IRC reviewers. The IRC will have the final decision-making authority for the disposition of a proposal.
- g. The IRC recommendation will be forwarded to BMS and BMS will communicate feedback on the proposal to the investigator. In the event that a request is not approved or requires revisions, a detailed explanation of the problems with the proposal in its current form will be provided by the IRC.
- h. All decisions regarding data requests will be posted to the SOAR website.
- i. The submitting investigator shall be expected to obtain IRB and/or ethics committee approval or documentation of exemption before performing the research.
- j. The research team will be responsible for entering into a data sharing agreement prior to data being provisioned if the proposal is approved.
- k. BMS will be responsible for provisioning the data to the investigator. DCRI/IRC will be informed of the methods and status of this activity, but will not be directly involved with the implementation of this process.

In cases where a perceived conflict of interest arises (e.g. review of a proposal from a Duke researcher or a request for data from Duke-led studies), experts from outside of Duke may be more appropriate to provide clinical, statistical or ethical insight and will therefore be included in the IRC for review of that particular request. In these situations, one of the Duke IRC co-chairs will work with an external co-chair to determine the potential perception of conflict and the extent to which non-Duke faculty should be included in the review.

## **6. Review Criteria**

The IRC shall ensure that only scientifically appropriate research on clinical trial datasets is approved. The goal is to safeguard scientific validity without creating undue burden by requiring the latest or most sophisticated statistical methodology. The IRC may make requests to BMS or the requester for additional information or clarification that may be needed to adequately review a proposal.

Research protocols will be reviewed using pre-defined criteria, such as:

- a. Is the research question clearly defined with a scientifically valid rationale?
- b. Is there a well-documented and rigorous Statistical Analysis Plan?

- c. If the protocol includes combining data across trials, is there a clear plan to standardize data sets to ensure comparability?
- d. Is there an adequate publication plan to disseminate findings in a peer-reviewed journal or at a scientific meeting?
- e. Has the applicant certified that the stated research purpose has been declared fully and openly and that the research as described will be conducted and reported in good faith?
- f. 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?
- g. Does the research team have sufficient expertise and qualifications to perform the proposed investigation?
- h. Is the privacy of the human subjects whose data will be used as part of this research adequately protected?
- i. Is the request coming from an independent researcher or someone associated with another pharmaceutical company?

After review the IRC will make one of the following recommendations:

- a. Not approved: The proposal is deemed as scientifically invalid or violates human subjects' protection and substantial change would be required to rectify the issues.
- b. Approved: The proposal is approved as submitted.
- c. Revise and resubmit: The proposal holds scientific merit; however, there are issues the IRC will require to be resolved before the proposal can be approved. The IRC will provide detailed feedback to the investigator. Revised proposals will be re-evaluated by the IRC to determine final disposition.

## **7. Final Review of Research Results**

Requesters who received access to BMS data are expected to submit the results or draft publication of the analysis for review by the IRC to assess that the results reported are aligned with the approved analysis plans.

## BMS Data Initiative Review Process

