Access to Clinical Research Information Board Charter

Background

Consistent with the joint PhRMA/EFPIA Principles for Responsible Data Sharing, AbbVie (the Company) is committed to sharing upon request from qualified scientific and medical researchers, patient-level clinical trial data, study-level clinical trial data, and protocols from clinical trials in patients for medicines and indications approved in the United States (US) and the European Union (EU), as necessary to facilitate legitimate scientific and medical research.

The Access to Clinical Research Information Board (ATCRIB), which is subject of this Charter, is an integral part of the systems and processes that have been designed and implemented by the Company to handle requests from third parties, including independent researchers, to access such data and information in a timely, manageable, and transparent fashion.

The Company recognizes that there may be different ways for access to be provided. It is expected that with experience gained this initiative will be a learning system that undergoes modifications to further improve the process through which the Company grants access to data.

Purpose of the ATCRIB

The ATCRIB is the Company's external decision body involved in the process of sharing data and information with certain external parties. The primary responsibility of the ATCRIB is to reassess denials to third-party requests for access to clinical trial data and information, where such denials have been based on Company judgments regarding the scientific qualification of the requestors, and/or robustness and scientific merit of the research proposal underlying the request, and/or the ability of the available data to answer the research question. ATCRIB decisions either ratify or reverse the original denial decision from the Company based on scientific merit. They are final and binding for the Company.

Composition

The ATCRIB is composed of five external experts who are not employees of the Company. A Company representative will schedule and facilitate the conduct of ATCRIB meetings, but does not participate as a voting member. All members of the ATCRIB must be qualified, with the necessary experience and expertise to assess the merits of access to data and document requests received by the Company on scientific grounds.

They are selected by the Company and must be free of any conflict of interest that would interfere with their ability to serve on the ATCRIB in an impartial and objective manner. ATCRIB members should be selected to cover all of the following areas of expertise: medical and drug development sciences, statistics, epidemiology/outcomes research, and public health.

All members will be reimbursed fair market value compensation for their efforts serving as a member of the ATCRIB. Board members serve for two years, which can be extended. One member will be elected by ACTRIB to serve as Chair of the board. ATCRIB members may serve other companies in the same function.

The ATCRIB members may be supported by subject matter experts (SME). SMEs will be made available by the Company to support ATCRIB members in their deliberations as needed, *e.g.,* by evaluating specific requests, by providing specific expertise or by answering defined questions of members regarding specific requests. SMEs have no voting rights. External SMEs will be reimbursed fair market value compensation for their efforts supporting the ATCRIB.

Arriving at a Decision

Company denials of third-party requests for access to clinical trials data and information communicated to the ATCRIB will be accompanied by the associated rationale for denial, including the specific reasons for denial of access on scientific merit. ATCRIB decisions should be based on a thorough assessment and discussion of all relevant criteria, including a full assessment of the proposed research supporting the third-party request for access to clinical trial data and information. To arrive at a final decision, the ATCRIB may also discuss and clarify details on requests with requestors.

The ATCRIB needs to assure that that requests for access to data and information and accompanying and supportive research proposals adhere to the highest scientific standards. ATCRIB decisions shall be grounded in scientific considerations; *e.g.,* the scientific qualifications of the requestor to conduct the proposed research in a manner that serves the public health interest, the adequacy of the research proposal to answer the proposed research question, the relevance of the proposal to public health, and, after reviewing the requested data, the ability or need of the available data to answer the research question.

The five external members have equal voting right, and the Company representative has no voting right. All voting members of the ATCRIB must vote, after the conclusion of deliberations, to either ratify or reverse a Company decision to deny access to a requestor on scientific grounds. Members have to decide with a 'yes' or a 'no' vote. Decisions require the simple majority of the ATCRIB votes.

Should an ATCRIB member have a conflict of interest that would impact their ability to serve in an objective and impartial manner in connection with a specific request, that member has to indicate this conflict and shall not participate in consideration of the request.

For practical reasons, decision-making does not require physical presence of all members in a meeting, and voting members do not have to vote all at the same time. At least three votes must be available for a decision. In case of a tie decision, the Chair has the right to make the final decision.

All decisions the ATCRIB makes are final and binding to the Company.

Process Flow

The Company representative organizes ATCRIB meetings. Meetings should be scheduled appropriately to enable prompt reviews of denials. ATCRIB meetings may be conducted via teleconference.

ATCRIB decisions shall be communicated promptly to requestors, in writing with vote results and a summary of the reasons articulated by the ATCRIB explaining its final decision.

When requests are approved by the ATCRIB, i.e. the previous decision of the Company is reversed, data and information shall be shared with requestors, following execution of any data sharing agreements (DSA) with the requestor. The ATCRIB decision-making process shall be documented internally.

The Company website contains a description of the data request and review process, and the identity of the external scientists and healthcare professionals who participate in the ATCRIB, including any existing relationships with any such individuals and the Company.

The Company website will include summary tables including descriptive statistical parameters of the total number of requests, those granted, and those denied.