Scientific review board charter

Background

It is ALK's policy to disclose clinical trial results openly and accurately for any ALK sponsored clinical trial regardless of development phase or outcome. ALK is committed to EFPIA's and PhRMA´s "Principles for Responsible Clinical Trial Data Sharing" guidelines in a manner that safeguards the privacy of patients, respects the integrity of national regulatory systems, and protects proprietary information.

This charter defines the responsibilities of the scientific review board (herein-after "board"), the purpose of which is to assess research proposals for access to clinical trial data. The board evaluates the legitimacy of the research purpose, the qualification of the researcher, the adherence to data protection principles, and potential conflicts of interest.

Members of the board

The board members represent different areas of medical or scientific expertise to ensure a broad and rigorous scientific view on the research proposals. ALK appoints one of the members as chair of the board. The identities of the members and their affiliations with ALK are posted on the ALK website. The members do not represent any organisation with which they may be affiliated and their obligations cannot be delegated.

ALK will facilitate the day-to-day operations of the board, including administrative review of the research proposal for completeness, preparing the meetings and documentation packages for review, and communication with researches on behalf of the board.

Review process

Initially ALK will evaluate a research proposal for administrative completeness. If complete and if not readily accepted by ALK, the board will evaluate the request. The board will receive a copy of relevant documentation, together with the assessment made by ALK.

The board must evaluate whether the clinical data are to be used for novel and legitimate research, addressing a scientific question that can help advance medical science or improve patient care, and not for commercial reasons.

During the review process, each member of the board will review the research proposals, diligently taking into account his or her own expertise. The review criteria shall include a general assessment, the patient's perspective, a scientific perspective, and a methodology assessment.

During the review process, the board shall assess the following items:

1. Scientific objective: The research proposal must contain a research plan that explains the scientific rationale for the analysis and its relevance to medical research and/or patient outcomes.
2. Study design: The analytical methods and statistical analysis plan must be valid and support the proposed research in a coherent way with the ability to meet the scientific objectives.
3. Publication plan: The research proposal must contain a proposal for a publication plan demonstrating that the researcher intends to publish the results of the study in a peer-reviewed scientific journal or otherwise make the results publically available.

4. Qualifications of the researcher: The researcher must be qualified to perform the described study.
5. Conflicts of interest: Any real or potential conflicts of interest must be disclosed, as this could have an impact on the conduct or interpretation of the research.

Board meetings

The board will meet (face-to-face, by phone and/or web-based) on a quarterly basis to discuss and decide whether to grant access to the requested analysis, report or protocol. ALK will share relevant documents to the board members no later than 20 workings days before each meeting. ALK employees will participate in the meetings to provide administrative assistance, but not be part of the decision. If no new applications have been received 30 days prior to the next scheduled meeting, the meeting may be cancelled.

If a board member is prevented from attending a meeting, he/she is required to submit a recommendation to the board chair before the meeting. At least 2 board members must be present at the meeting.

As a general rule, decisions of the board shall be made by consensus. If it is not possible to reach consensus, the decision shall be made on the basis of a majority vote.

Following agreement by all board members, the chair prepares the decisions of the meeting in writing, which shall be approved by all members of the board. Within 7 working days, the chair sends the approved decision to ALK, who communicates the decision to the researcher.

Data sharing

If the board grants access to the clinical trial data, ALK will provide the clinical trial protocol, the redacted clinical trial report, or the outcome of the statistical analysis to the researcher, as relevant.

ALK is responsible for ensuring that access to clinical trial data is consistent with data protection principles and in accordance with the patients' informed consent provided in relation to their participation in the clinical trial. In addition, ALK is responsible for ensuring that sharing of data is within legal restrictions, including contractual provisions for data collected in collaboration with third parties.

If ALK for a particular request and despite its initial assessment, is not able to implement all reasonable steps to maintain anonymity, ALK will not provide the clinical trial data and will inform the board accordingly. ALK will inform the researcher of the issue and provide an explanation for the rejection.

Compensation

Members of the board are compensated for their time and expertise. Compensation follows fair market value based on national requirements and disclosure follows the health-care professional transparency regulations, when applicable. In addition, ALK covers the costs for travel, accommodation and meals (according to national requirements) in connection with the face-to-face board meetings.