Dermatology
beyond the skin

Version 3.0
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Patient and Scientific Review Board Charter

This Charter outlines the responsibilities of the Patient and Scientific Review Board ("Board"), which is charged with assessing and deciding upon requests from third-party researchers for access to anonymised patient level data ("Data") from LEO Pharma sponsored clinical trials. The purpose of the review process of the Board is necessary to determine that the research proposal has a valid scientific rationale, is non-commercial, and is in the best interest of patients.

The approval of a researcher's request for access to Data shall under no circumstances be considered or interpreted as a recommendation or appraisal of the research proposal either by the Board or by LEO Pharma. The same position applies for the research outcome.

Membership and Composition of the Board

Members of the Board are appointed for a period of one year at a time. The appointment can be renewed each year if the same board member should continue for an additional period. The Chair of the Board is appointed by the Board Members at the first annual meeting and the appointment runs for a year, which likewise can be renewed each year if decided by the board members. Each Board member participates in a personal capacity, and does not represent any organization or institution that he or she may be part of.

The Board consists of five members with different professional backgrounds and experiences. A mixed composition of the Board is important in order to safeguard a comprehensive view on each incoming research proposal. In particular, the composition shall ensure that review and decisions can be taken on rigorous scientific grounds and with a clear benefit of the patients in mind.

Therefore, three seats are allocated to highly senior scientists, out of which one is a statistician, while the two other seats are allocated to two representatives of patient associations.

Responsibility of the Board

The purpose of the Board is to review applications for access to Data from clinical trials sponsored by LEO Pharma and to decide whether to accept or reject such applications or to allow a resubmission. In this respect the Board must determine that Data is to be used for addressing a scientific question in the interest of public health and not for commercial reasons. The Board makes its decisions independently from LEO Pharma.

Responsibility of LEO Pharma

The purpose of the Board is to review applications for access to Data from clinical trials sponsored by LEO Pharma and to decide whether to accept or reject such applications or to allow a resubmission. In this respect the Board must determine that Data is to be used for addressing a scientific question in the interest of public health and not for commercial reasons. The Board makes its decisions independently from LEO Pharma.

Transparency is not an end in itself and it should never be at the expense of protecting an individual patient's privacy. LEO Pharma, as the sponsor of a clinical trial, has made a commitment to patients to protect their privacy by safeguarding their personal data and restricting the use of data from clinical trials to the scope of the informed consent. LEO Pharma has therefore the ultimate responsibility to ensure:

- that access to Data is only granted for research proposals that are within the scope of the patients' informed consent provided by the patient prior to their participation in the clinical trial
- that only anonymised patient level data is made available to the researcher.

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Prior to forwarding research proposals to the Board, LEO Pharma will assess based on the patient privacy items listed above whether the requested Data can be shared with the researcher for the intended research. For detailed information on when LEO Pharma considers a dataset as being appropriately anonymised, please see "Safeguarding privacy of investigated patients".

The Board will receive all requests for Data access but only if the aspects of patient privacy can be secured, will the research proposal be subject to the Board's decision on accessibility of Data.

In cases where LEO Pharma has assessed that the requested Data cannot be delivered within the boundaries of patients' informed consent or cannot be sufficiently anonymised, the Board will also receive a copy of the informed consent form of the respective studies in an anonymised format, together with a clarification of the assessment made by LEO Pharma. In addition, for information purposes, LEO Pharma will forward to the Board possible appeals against LEO Pharma's rejection for access to Data, if any.

If the Board has decided to grant access to the Data, LEO Pharma will prepare anonymised, patient-level datasets. If LEO Pharma, for a particular request and despite its initial assessment, is not able to implement all reasonable steps to maintain anonymity, LEO Pharma will not provide the approved Data. LEO Pharma will be transparent about this decision and inform the Board accordingly.

LEO Pharma will likewise inform the researcher of the issue and provide an explanation for the rejection. It is the responsibility of LEO Pharma to prepare and provide approved Data. The expected timelines for this process is 30 working days from the date of the decision made by the Board, provided that a signed Data Sharing Agreement is in place.

Responsibility of secretariat

The secretariat facilitates the performance of the Board, which includes preparing the meetings and the review packages, sending invitations, booking flights and hotels, and attending parts of the meetings. The responsibility also covers the reception and handling of the two request forms used by the requesting researchers: "Data Feasibility Form" and "Research Proposal for Access to Data"

Research proposals for review and decision by the Board are directly forwarded to the Board after screening to ensure inclusion of all necessary documents in the proposals.

The support of the secretariat is purely operational and the secretariat may not make any recommendations or in any other way interfere in the discussions or decisions of the Board. The secretariat will not participate in the closed Board sessions (e.g. when the Board makes its final decisions on the requests).

The secretariat will only be in contact with the researcher with regard to administrative matters, to inform about decisions or if requested to do so by the Board.

Procedures for the Board

The Board will meet on a quarterly basis with two meetings arranged as face-to-face meetings while the other two meetings will be virtual/web-based. At the meetings, the Board will discuss the reviewed research proposals, and make a decision on whether to provide access to the requested Data or not. All decisions on granting access will be made publicly available on LEO Pharma's corporate website. The decision will be posted after informing the decision to the requesting researcher.

Research proposals for review and decision will be forwarded to the Board along with appropriate study-specific documents. The documents have to be accessible for the Board members at **latest 20 workings days** ahead of the next meeting. Upon the Board's request, the secretariat can contact the researcher and request additional documents or information in order to have the research proposal completed prior to the Board meeting.

In the case that no research proposals for Board assessment have been received by LEO Pharma **30 working days** prior to the next scheduled meeting, the Board meeting will be cancelled.

Review Process and Requirements

During the review process each member of the Board shall review the research proposals diligently taking into account his or her own expertise.

The review criteria to consider are the:
- General (formal) assessment
- Patient's view
- Scientific view
- Methodology assessment

When deciding whether or not to grant access to the requested Data, the Board must determine that the Data will only be used for addressing a relevant scientific question in the interest of public health and not for commercial reasons. The Board shall make its decision whether to provide access or not on the basis of the scientific rationale of the proposed research. In this respect the Board must determine whether the question/study is clearly defined and an appropriate analysis of the Data can actually be achieved by the provided statistical analysis plan and described methods.

During the review process, the Board shall assess the following items:
1. Scientific objective: The research proposal must contain a comprehensive research plan which explains the scientific rationale of the analysis and its relevance to medical research and/or patient outcomes. The study design, the described analytical methods and statistical analysis plan must be valid and support the proposed research in a coherent and rational way.

2. Benefits of the patients: The research proposal must state how the patients will benefit from the outcome of the research.

3. Publication plan: The research proposal must contain a valid proposal for a publication plan signifying that the researcher(s) intends to publish the results of the study in a peer-reviewed scientific journal or otherwise make the results publicly available.

4. Qualifications of the researchers: The researcher/research group must be qualified to perform the described analysis/study.

Where research groups or patient associations wish to collectively access the Data, the names and CVs of all members of the research group or patient association shall be included in the proposal. At least one statistician (degree in statistics or a related discipline) shall be designated as part of the research team.

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.

6. Patient confidentiality: The research must not be designed in a way that can reveal the identity of the study patients.

7. Safety: The researcher must state that LEO Pharma will be informed within 24 hours of any potential safety concerns identified.

8. References: The names of three independent experts in the field shall be provided, whom the Board could consult, if needed, on the scientific merit of the proposal.

Decision Making Process

Each member of the Board can make one of three recommendations based on the review:
1. Approval to provide access
2. Rejection of the research proposal
3. Resubmission possible.

As general rule, decisions of the Board shall be made by consensus. If in exceptional circumstances it is not possible to reach consensus, then the Chair can decide that the decision will be made by majority vote with all five members present. It is not possible to veto a decision, but if a member of the Board cannot agree with the majority decision, then this can be stated in the decision minutes based on a request from this member.

Board members who are prevented from attending a meeting are required to submit his or her decision recommendation, to the Chair, no later than two working days ahead of meeting.

The decision will be prepared in writing by the Chair. Following agreement by all Board members, the Chair forwards the signed decision paper to the secretariat within 7 working days after the meeting. The decision of the Board will be communicated by the secretariat to the researcher within 15 working days of the Board meeting.

Compensation

Members of the Board are compensated for their participation in the Board. Compensation reflects fair market value. Apart from compensation, LEO will also cover the costs for travel, accommodation and meals in connection with the Board meetings.