Dermatology
beyond the skin

Version 3.0
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Patient and Scientific Review Board Charter

The Charter outlines the responsibilities of the Patient and Scientific Review Board ("Board"), whose task is to judge requests from third-party researchers for access to anonymised patient-level data ("Data") from LEO Pharma-sponsored clinical trials. The purpose of the Board review is to determine whether 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

Each member of the Board is appointed for one year at a time. 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 organisation or institution that he or she may be part of.

The Board consists of five members with different professional backgrounds and experience. A mixed composition of the Board is important to safeguard a comprehensive review of 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 to patients in mind.

Therefore, three seats are allocated to highly senior scientists, including one statistician, while the two remaining seats are allocated to 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 the Data are 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

Transparency is not an end in itself and should never come at the expense of an individual participant's privacy. LEO Pharma, as the sponsor of a clinical trial, has made a commitment to trial participants 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 informed consent provided by the participant prior to their participation in the clinical trial
- only anonymised patient level data are made available to the researcher.

Prior to forwarding research proposals to the Board, LEO Pharma will assess and decide whether the requested Data can be shared with the researcher for the intended research, based on the participant privacy requirements listed above.

The Board will receive all requests for Data access, but only if the participant privacy can be secured will the research proposal be assessed by the Board.

In cases where LEO Pharma has assessed that the requested Data cannot be delivered within the boundaries of participants' informed consent or cannot be sufficiently anonymised, the Board will receive a copy of the relevant informed consent forms 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.

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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 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 supports the Board by preparing and forwarding 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".

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 correspond with the researcher about administrative matters, e.g. to inform about decisions or request additional information required by the Board.

PROCEDURES FOR THE BOARD

The Board will meet on a quarterly basis, with two face-to-face meetings and two virtual/web-based meetings per year. At the meetings, the Board will discuss the reviewed research proposals and grant or deny access to the requested Data. All decisions will be made publicly available on LEO Pharma's clinical disclosure website after the requesting researcher has been informed.
Research proposals for review and decision will be forwarded to the Board along with any relevant study-specific documents. The documents must 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 if the research proposal submitted is found to be incomplete.

If 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 according to his or her own expertise.

The review will include:
- general (formal) assessment
- patient's view
- scientific view
- methodology assessment.

When deciding whether 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 base its decision on the scientific rationale of the proposed research. To this end, the Board must determine whether the question/study is clearly defined and whether the Data can be appropriately analysed using the methods described and the statistical analysis plan provided.

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 analytical methods, and statistical analysis plan must be valid and support the proposed research in a coherent and rational way.

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

3. Publication plan:
The research proposal must contain a valid 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.

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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 influence 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 of the research proposal; Data access granted.
2. Rejection of the research proposal; Data access denied.
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, 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, this can be stated in the decision minutes based on a request from this member.

Board members who are prevented from attending a meeting must submit his or her recommended decision to the Chair no later than two working days ahead of the meeting. The decision will be prepared in writing by the Chair. Following agreement by all Board members, the Chair will forward the signed decision 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.