Independent Review Board Charter

Access to patient-level data collected in clinical trials provides opportunities to conduct research that can help advance medical science or improve patient care.

Servier will provide access to patient-level and study-level clinical trial data from interventional clinical trials conducted in patients for medicines and new indications approved in the European Union or the United States on or after 1 January 2014, provided that trials are not part of an ongoing review or are part of a planned submission.

In addition, Servier's data sharing policy includes all interventional clinical studies in patients:

- sponsored by Servier
- with a first patient enrolled as of 1 January 2004 onwards
- for New Chemical Entity or New Biological Entity (new pharmaceutical form excluded) for which development has been terminated before any Marketing Authorization (MA) approval (all indications).

However, requests out of the scope will be reviewed on an individual basis and data provided if materially possible (it may not be possible to provide data from old studies).

Role of the Independent Review Board

All research proposals assessed by Servier will be transmitted to the Independent Review Board:

- for information when fully approved by Servier,
- for review and recommendation when the scientific qualification of the researcher, robustness and scientific merit of the research proposal, is questionable.

Members of the board should provide their best scientific advice on the research proposal and may assist Servier to make its decision. The final decision will be taken by Servier.

Composition of the Independent Review Board

The Independent Review Board is composed of two permanent external experts who are not employees of the company:

- Stephen Senn, PhD - statistics & methodology consultant, Luxembourg
- Cyrus Cooper, Professor of Rheumatology, Director of the MRC Lifecourse Epidemiology Unit, University of Southampton, UK

Additional external experts not employees of the company may be involved depending on the clinical field related to the request.

Review criteria

The Independent Review Board recommendation will be based on a thorough assessment and discussion of relevant criteria.

The Independent Review Board needs to ensure that requests adhere to the highest scientific standards. Board recommendation will be grounded on scientific considerations, for example, the scientific qualification of the applicant to conduct the proposed research in a manner that serves the public 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.

Recommendation-making process

For practical reasons, the recommendation-making process does not require physical presence of all members in a meeting. After the reception of the IRB recommendation, Servier will make a final informed decision.

Servier will strive to communicate the decision and any conditions to the applicant in about 2 to 3 months.

An evolving policy

There are many initiatives currently ongoing to define global standards for data sharing. Servier policies and procedures will evolve accordingly.

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