

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.

Role of the Independent Review Board

All research proposals within the scope of the Servier Policy will be transmitted to the Independent Review Board:

- for information when Servier agrees with the research proposal;
- for review and final decision when the scientific qualification of the researcher, robustness and scientific merit of the research proposal, ability of the requested data to answer the research question, or the technical feasibility is questionable.

The decision of the Board will be binding.

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 - Head of Competence Centre for Methodology and Statistics at CRP-Santé, 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 decisions will be based on a thorough assessment and discussion of relevant criteria, including an assessment of the proposed research.

The Independent Review Board needs to ensure that requests adhere to the highest scientific standards. Board decisions will be grounded in 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.

Decision-Making Process

For practical reasons, the decision-making process does not require physical presence of all members in a meeting.

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.