

Independent Review Panel Charter Facilitated by the Wellcome Trust for Vivli

INTRODUCTION

Providing Access to Patient Level Data

The mission of Vivli is to promote, coordinate, and facilitate scientific sharing and reuse of clinical research data through the creation and implementation of a sustainable global data-sharing enterprise. Vivli acts as a neutral broker between data contributor, data user and the wider data sharing community. Vivli has harmonized governance, policy and processes to facilitate data sharing for users and contributors. The Vivli platform includes an independent data repository, in-depth search engine and a cloud-based, secure analytics platform. The ultimate vision of Vivli is to advance human health through clinical research data sharing, thereby respecting and honoring the contributions of clinical research participants.

In order to ensure data are requested by qualified researchers and used in a scientific and responsible manner, an **Independent Review Panel (IRP)** has been set up to review the scientific merit of research proposals submitted through the platform, for members who choose to use the Wellcome Trust facilitated IRP. For these members, the IRP must decide whether a request is appropriate before access to the data can be provided. In order to ensure the panel is truly independent from the Data Contributors who request the services of the IRP, the Wellcome Trust has taken responsibility for the appointment and operation of the IRP. The Trust will also administer the IRP secretariat. This Panel Charter sets out the responsibilities of the IRP and the decision-making process.

Independent Review Panel Membership

The panel consists of a Chair and five members with a range of expertise, including statistics, conducting clinical trials, ethics and a lay perspective. The list of current members can be found on the Vivli website. Panel members will review research proposals in a personal capacity, with due care, skill and ability in accordance with their individual expertise.

The IRP will be augmented by an expert pool to provide therapeutic expertise; individuals from this pool will be invited by the IRP secretariat to review relevant research proposals. The appointment and operation of the IRP is independent from the Vivli data contributors who engage the IRP.

REVIEW PROCESS

Applicants requesting access to data submit a research proposal and application form from Vivli. Vivli will complete initial administrative checks before passing the proposal to the Data Contributor(s) for “feasibility checks”. For those Data Contributors who engage the IRP, Vivli will then pass the request, together with any relevant information from the data contributor, to the secretariat who then sends it to the IRP and any relevant therapeutic expert for review.

Each panel member undertakes a high-level review of the research proposal and determines whether there is any reason to reject the proposal. This review must be completed within 30 days of the

proposal being sent to the IRP (unless the Panel requires further information).

Following the review, the IRP secretariat will inform the requestor and Data Contributor(s) of the IRP's decision and any conditions or recommendations. Where data are to be made available, the researcher must sign a Data Use Agreement and the Data Contributor will make anonymised data available through a Vivli secure research environment. The outcome of all requests, together with the reason for any rejection, will be published on the Vivli website.

If a request is declined during the administrative or Data Contributor checks, the proposal and reasons for decline will be passed to the IRP for information and published on the Vivli website. It should be noted that it has been agreed that some Data Contributor(s) may, in exceptional circumstances, veto a request to access data where they feel there is a potential conflict of interest or an actual or potential competitive risk. Further information about members data access policies are outlined on their individual member's page. In the interest of transparency, full details of any veto, together with the Data Contributor's justification, will be made available on the website and the IRP will also be informed.

IRP review: assessment criteria

Panel members will undertake a high-level review to assess:

- the scientific rationale and relevance of the proposed research to medical science or patient care
- the ability of the proposed research plan (design, methods and analysis) to meet the scientific objectives
- whether the proposal has potential to produce information that will enable identification of individual research participants
- the publication plan for the research
- real or potential conflicts of interest that may impact the planning, conduct or interpretation of the research and proposals to manage these conflicts of interest
- qualifications and experience of the research team to conduct the proposed research.

IRP review: decision-making process

Each panel member makes one of four recommendations:

1. Approval to provide access to the requested data
2. Rejection but with advice to re-submit the research proposal to address specific aspects
3. Rejection of the research proposal

The panel can also request more information before making a recommendation. Where panel members recommendations differ, the panel should seek consensus through discussion, but the Chairman will make the final decision. Three members will constitute a quorum. The Data Contributors cannot influence individual panel members or overturn or change the decisions of the Panel.

GOVERNANCE AND ADMINISTRATION

- The Wellcome Trust has put in place an agreement with each IRP member and therapeutic expert on behalf of all the Data Contributor(s).
IRP members and therapeutic experts are paid for their time and expertise in reviewing proposals. Payments are on a per review basis, with an annual review to assess demand. Vivli administers fees on behalf of the Data Contributor(s). Data Contributor(s) will disclose all payments to IRP members and therapeutic experts.
- The IRP Secretariat will provide guidance on the IRP's role and all necessary support to the IRP members and therapeutic experts. Initial training to use the system will be supplied by Vivli.
- The panel will operate virtually on an ongoing basis but will have a face-to-face meeting (or teleconference) once a year.
- IRP members will initially be appointed for a two-year term. After two years, the membership will be updated on a rotating basis, to help ensure consistency and continuity.