11 February 2025

INDEPENDENT REVIEW PANEL CHARTER

INTRODUCTION

Providing Access to Patient Level Data

The aim of the Clinical Study Data Request (CSDR) System is to facilitate broader access to anonymised patient level data from clinical studies and to create a valuable resource for further research. The vision is to ensure the data provided by research participants are used to maximum effect in the creation of knowledge and understanding and to support further medical and scientific research to improve patient care.

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 system. The IRP must decide whether a request is appropriate before access to the data can be provided. An experienced independent consultant acts as 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 three 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 CSDR 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 may, when required, 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 companies involved with the system.

REVIEW PROCESS

Applicants requesting access to data submit a research proposal and application form through the ClinicalStudyDataRequest.com website[1]. All proposals are processed according to the stages set out in the diagram included as an annex. In summary, the IRP secretariat will complete initial administrative checks before passing the proposal to the sponsor Data Sharing Coordinator for “sponsor checks”. Following sponsor checks, the IRP secretariat will then pass the request, together with any relevant information from the sponsor, 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).

[1] https://www.clinicalstudydatarequest.com

Following the review, the IRP secretariat will inform the requestor and study sponsor of the IRP's decision and any conditions or recommendations. Where data are to be made available, the researcher must sign a Data Sharing Agreement (including any conditions), and the study sponsor will make anonymised data available through their chosen access route. The outcome of all requests, together with the reason for any rejection, will be published on the CSDR website.

If a request is declined during the administrative or sponsor checks, the proposal and reasons for decline will be passed to the IRP for information, and published on the CSDR website. It should be noted that it has been agreed that some study sponsors 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 detail about the veto is provided on the CSDR website. The veto must be applied before the IRP reviews a request. In the interest of transparency, full details of any veto, together with the sponsor'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 patientcare
- the ability of the proposed research plan (design, methods and analysis) to meet the scientific objectives
- the publication plan for the research
- the plain English summary is clear with sufficient detail to be understood by a non-specialist
- with the information provided, 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 three 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 sponsors cannot influence individual panel members or overturn or change the decisions of the Panel.

GOVERNANCE AND ADMINISTRATION

- Anaqua has put in place an agreement with each IRP member and therapeutic expert, on behalf of all the study sponsors.
- 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. Study sponsors 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 IdeaPoint.
- 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.
- The CSDR Steering Group will remain responsible for operational issues relating to CSDR and for the development of the system. The IRP Secretariat is a non-voting member of the CSDR Steering Group.

APPENDIX 1: OVERVIEW OF PROCESS FLOWS