

Independent Data Access Committee Charter

June 2024

1. Introduction

The goal of WAYFIND-R is to make data available, interoperable and shareable for research to advance precision oncology. WAYFIND-R is an observational, non-interventional, prospective, multi-national, and multicenter cancer registry to collect characteristics and outcomes of patients diagnosed with solid tumors profiled with next-generation sequencing tests (NCT04529122). WAYFIND-R enables the design and hypothesis generation for the conduct of clinical and epidemiological research by providing access to oncology real-world data within the WAYFIND-R® Data Sharing and Collaboration Platform for collaboration, visualization and advanced analytics.

In order to ensure data are requested by qualified individuals and used in a scientific and responsible manner, an Independent Data Access Committee has been set up to review the scientific merit of research proposals submitted by academic researchers. Based on review criteria, the Committee must decide whether the research proposal is appropriate before access to the requested data can be provided. Before applicants can access the requested anonymized, individual participant data within the secure processing environment of the WAYFIND-R platform, a Master Data Sharing and Use Agreement needs to be in place with the applicant's institution. The Committee members are independent from WAYFIND-R data contributors and data requesters and will disclose membership(s) to other Committees or conflict(s) of interest. An Access Manager coordinates administrative tasks to facilitate data access requests by researchers and the dialogue between Roche and the Independent Data Access Committee.

This Charter describes the membership, roles and responsibilities, authority and decision-making processes of the Independent Data Access Committee.

2. Principles Guiding of the Independent Data Access Committee

The principles guiding the set-up of the Committee are:

Independence

Members of the Committee review data access requests from academic researchers based on the scientific merit of the research proposal, which is determined independently from Roche to avoid any publication bias.

Transparency

The Committee makes decisions on data access requests based on decision-making criteria set out in the Committee charter. The Committee documents the main reasons why an application has been rejected or why further clarification is required before decision-making, allowing applicants to see when and why research proposals are rejected.

Diversity

Members of the Independent Data Access Committee represent diverse stakeholders involved in WAYFIND-R, such as healthcare professionals, patient representatives and researchers.

Decisiveness

To make decisions efficiently, the Committee has an uneven number of members to reach a consensus based on defined criteria and timelines for decision-making; in case of discrepancy the Chair will make the final decision.

Technical Expertise

Members of the Committee have relevant subject matter expertise to achieve the required aims of the Committee.

Enabling Research

Members of the Committee will grant access to data to suitably qualified individuals based on assessment of the research proposal and will support data access whenever possible.

3. Independent Data Access Committee Membership

The Independent Data Access Committee consists of three members of whom one member is Chair. These members collectively have the scientific, ethical and medical expertise to review data access requests based on the scientific merit of the applicant's research proposal. This review is performed with due care, skill and ability in accordance with their individual expertise and assessment criteria. However, for topics that fall outside the expertise of the Committee members, Ad-hoc experts may be called into the decision-making process to support the Committee in providing a recommendation. The list of current Committee members can be found on the WAYFIND-R website.

4. Independent Data Access Committee Review Process

Academic researchers requesting access to data submit a research proposal through the WAYFIND-R platform. The Access Manager will complete initial administrative checks within 5 working days before passing the research proposal to the Independent Data Access Committee and will initiate the signing of the Master Data Sharing and Use Agreement with the applicant's institution.

Assessment Criteria to Evaluate Data Access Requests

Each Committee member undertakes a high-level review of the research proposal based on assessment criteria and determines whether there is any reason to reject the applicant's proposal. The assessment criteria defined by the Independent Data Access Committee are:

1. **Clarity and completeness:** The research proposal and the plain language summary are clear and contain sufficient detail.
2. **Methods are suitable:** The research methods and statistical analysis plan (design, methods, analysis and sample size) will meet the scientific objectives.
3. **Relevance and benefit:** The scientific rationale and relevance of the proposed research to medical science, patient care and society are clearly stated (i.e. evaluating any ethical issue to individuals, society or ethnic group).

4. **Conflicts of Interests:** Actual or potential conflicts of interest that may impact the planning, conduct or interpretation of the research are stated, and proposals to manage these conflicts of interest are included.

5. Independent Data Access Committee Decision-making Process

After all Committee members have assessed the research proposal based on the assessment criteria, the final decision on whether the data access request will be approved depends on the Committee member's votes. As part of the decision-making process, each Committee member casts a vote by opting for one of the following three decisions:

1. Approval (with or without comments) for access to the requested data;
2. Rejection of the research proposal with feedback; or
3. Request for major revisions from the applicant before re-review by the Committee.

The voting rules entail that each Committee member has one vote and voting will be conducted through the WAYFIND-R platform. The platform allows the Committee members to provide written feedback on the research proposals and specify whether they approve or reject the proposal or require further clarification. In case of discrepancy between the Committee members' individual votes, the Chair will make a final decision. If there is not a unanimous approval, the Chair decides whether the Committee

1. Approves (with or without comments);
2. Rejects the research proposal with feedback; or
3. Recommends the applicant re-submit and address the revisions.

After receiving the research proposal, Independent Data Access Committee members have 30 calendar days for proposals from WAYFIND-R registry participating institutions, or 60 calendar days for proposals from other academic researchers to complete their review. Revised proposals should be re-submitted by the applicant, and re-reviews by the Independent Data Access Committee will be completed within 30 calendar days from re-submission.

Independent Data Access Committee Review Outcome Notification

Applicants will be notified by email about the Independent Data Access Committee review outcome. Following a research proposal rejection or request for further information, the Access Manager will inform the applicant about the Committee's decision, the rationale behind the decision and any conditions or recommendations.

Before the requested data can be accessed within the WAYFIND-R platform, the applicant and all project collaborators must complete a training on the ethical use of data, and the applicant's institution must sign a non-negotiable Master Data Sharing and Use Agreement. Thereafter, the applicant and project collaborators will be granted access to the requested data for a period of 12 months with a possibility to extend. A plain language summary of approved research proposals will be published on the WAYFIND-R website to increase transparency.