

Guiding Principles on the Sharing of Clinical Trial Data

DNDi POLICIES

I. Preamble

DNDi's vision is "to improve the quality of life and health of people suffering from neglected tropical diseases by using an alternative model to develop drugs for these diseases, and by ensuring equitable access to new and field-relevant health tools".

DNDi recognizes the potential value, to researchers in public health and other actors, of the data gathered in the course of its research and development activities. DNDi also recognizes the ethical imperative to share and disseminate its data responsibly in order to contribute to knowledge for the improvement of lives of neglected patients whose needs are often overlooked as research priorities.

II. Scope

This document applies to all final (locked and analyzed) and anonymized patient-level data and clinical study reports on all clinical trials, including Phase I trials, where DNDi as Sponsor owns the generated data.

When DNDi is involved in a study in the capacity other than as the Sponsor, including as a co-sponsor, DNDi will make efforts to have these principles followed by the third parties.

III. Guiding principles

DNDi commits to sharing its clinical trial data in a manner that respects the following principles:

The respect of participants in medical research:

- Through informed consent documents and other procedures as part of a protocol at the outset of clinical research, DNDi will ensure medical confidentiality is fully protected, and the privacy of individuals and the dignity of communities is fully respected when data is collected and, thereafter, shared. Patients will have the rights to refuse data sharing.
- In order to lessen the risk of identification of individuals, especially in the case of rare indications or subgroups where standard anonymization could be perceived as insufficient, DNDi will consider implementing additional methods to ensure data remains anonymous.

Maximizing the benefits to participants and society, while minimizing any potential harm:

- DNDi aims to share its data in order to facilitate, thanks to greater transparency, both the validation of scientific and research results (including negative results), as well as the contribution by other researchers to the creation of additional knowledge.
- DNDi will seek to ensure the sharing of data balances the needs of researchers who generate data, researchers who may wish to re-use the data, and the individuals and communities who participated in health research in the expectation of it leading to broader public health benefits.
- DNDi will seek to minimize potential harm from data sharing, including privacy invasion, biased analyses, unfair and competitive use of data, and the undermining of public trust in and incentives to conduct clinical trials.

IV. Timing and procedures

Prior to data collection:

- Before data collection, clinical trials sponsored by DNDi are registered on public databases such as the US NIH's clinicaltrials.gov or the Pan-African Clinical Trials Registry (PACTR).
- Before data collection, DNDi will also publish on its global website (dndi.org) the synopsis of clinical trial protocols.

Completion of study and prior to publication of results:

- Prior to publication and after study completion, data sharing will be available on a request basis for research projects, based on a final and cleaned database. Requests for access will be examined by DNDi's Scientific Advisory Committee. Criterion to be used by the Scientific Advisory Committee to determine the validity of requests for access to DNDi data include the scientific justification of the request, compliance by the requesting party with ethical considerations, and a commitment from the requesting party to share with DNDi and publish the results of the follow-on research. In addition, the applicant will commit to acknowledge the source of data.
- DNDi will post key results of the research 12 months after completion of the trial.

Upon publication of study results:

- DNDi will publish its studies, whether results are positive or negative, in open-access peer-reviewed journals.
- Data will be shared upon publication of study results, in line with the procedures of major medical journals including Nature, PLOS, BMJ, etc.

V. Implementation

The DNDi Executive Director will ensure the full implementation of this document and put in place, subject where appropriate to Board approval, administrative, financial, technical, and other mechanisms and procedures to ensure its full implementation.

DNDi is a co-signatory of the WHO, May 2017: *Joint statement on public disclosure of results from clinical trials*

VI. Amendments

DNDi retains the right to review, revise, and/or amend this document or any of its terms at its discretion at any time. When warranted and in agreement with the Chair of the Board, the Executive Director will recommend the review, revision or amendment of this document for further approval of the DNDi Board of Directors.

VII. Selected references

- Journal data sharing policies, including for example Nature Research, 2016: *Data Availability Statements and Data Citations Policy: Guidance for Authors*
- Sherpa Juliet database of global funders who require data archiving as a condition of grants
- Wellcome Trust, Higher Education Funding for England, Research Councils UK, Universities UK, 2016: *Concordat on Open Research Data*
- Institute of Medicine, 2014: Discussion Framework for Clinical Trial Data Sharing: *Guiding Principles, Elements and Activities*
- Médecins Sans Frontières, 2013: *MSF Data Sharing Policy*
- WHO, May 2017: *Joint statement on public disclosure of results from clinical trials*

Request for access to DNDi clinical data

<p>Details of requestor including</p> <ul style="list-style-type: none">• name• institutional affiliation• contact details• research CV	
<p>Details of dataset(s) requested including</p> <ul style="list-style-type: none">• nature of data request• study number / identifier / title• indication	
<p>Details of proposed research including</p> <ul style="list-style-type: none">• outline• proposed methodology• funding sources• ethical considerations including approvals sought or to be sought• details of collaborators, sponsor, investigator(s) and institution(s) involved• lay summary• expected outcomes• expected duration	
<p>Plans for publication of results including</p> <ul style="list-style-type: none">• Confirm by signing this box and describe how the Requestor commits to share data and results with DNDi• Confirm by signing this box and describe how the Requestor intends to seek open-access publication	