DNDi

Best Science
for the Most Neglected

Scientific Communications Policy

DNDi's Policy

Table of Contents

Objective **2**

Scope **2**

Policy **2**

Guiding Principles **2**

Publishing DNDi's scientific work **2**

Internal review and validation **3**

Publication of interim results **4**

Data sharing **4**

Authorship **4**

Criteria for authorship 4

Author hierarchy 4

Representation 5

Acknowledgements 5

Communication **5**

Open Access **5**

Sex and gender equity in research **6**

Conflict resolution **6**

Roles and responsibilities **6**

References **7**

Objective

This policy aims to ensure fair and representative authorship as well as appropriate acknowledgment of donors and partners in high quality scientific communications published by DNDi in a timely, transparent, and open fashion.

Scope

This policy applies to any peer-reviewed publication or other form of external communication related to research conducted, sponsored, or funded by DNDi, and to any external scientific publication or communication that includes a DNDi-affiliated author, whether it originates with DNDi or with a partner. It may take the form of a peer-reviewed article, book or book chapter, conference abstract, presentation, poster or symposium, webinar, grey literature, or other form, and refers to research conducted throughout the entire drug development process, including work such as literature reviews and meta-analyses.

Policy

Guiding Principles

- **Timeliness, transparency, and open access:** DNDi believes that the results of its work should be accessible to everyone, with no financial barriers, through publication in open-source media such as public databases and open access journals. DNDi is a signatory to the World Health Organization's Joint statement on public disclosure of results from clinical trials,[1] which affirms the scientific and ethical importance of timely public disclosure of results from all clinical trials.
- **Fair & representative authorship:** Guided by International Committee of Medical Journal Writers authorship criteria,[2] DNDi strives to ensure that authorship fairly represents those whose work is being published or shared, including partners and staff in countries where research takes place and those whose efforts represent a substantial intellectual contribution to the work. As part of its efforts in diversity, equity, and inclusion, DNDi has indicators for gender parity in lead (first and last) authors of peer-reviewed articles and also reports on the percentage of papers with at least one endemic country lead co-author.

Publishing DNDi's scientific work

DNDi encourages the timely communication of all research it is involved in, at any stage of the R&D and delivery process (i.e., discovery, pre-clinical, clinical, and access/implementation/post-market authorisation), whether quantitative or qualitative, and facilitates the rapid and accurate communication of all DNDi-sponsored research to the wider scientific and medical communities in the most appropriate and practicable way.

In accordance with the Declaration of Helsinki,[3] all of DNDi's clinical trials are registered in a recognized, publicly accessible clinical trial registry, for example, www.clinicaltrials.gov, the Pan African Clinical Trials Registry, or other recognized registry, before recruitment of the first participant.

In keeping with its commitments as a signatory to the World Health Organization's Joint statement on public disclosure of results from clinical trials,[1] DNDi aims to *publish aggregated primary results of all clinical studies within 12 months of study completion (i.e., last patient, last visit) on the selected clinical trial registry or on a pre-print server*.

With a view to aligning expectations and deliverables, partner contracts should reference this policy and any related obligations and commitments. DNDi project leaders should include a discussion of any obligations and commitments at project launch or when partners join a project, to ensure these obligations and commitments are clear. *Aggregated primary results should be published in an open-access peer-reviewed journal within 24 months of the end of the study (i.e., last patient, last visit)*.

In addition to publishing the results of its own and partners' scientific research, DNDi also communicates and publishes on its research and development model and other related scientific activities, and may publish 'think pieces', such as letters to editors, commentaries, and policy or position pieces in the peer-reviewed literature, or other articles of this nature. This are also within the scope of this policy.

Internal review and validation

DNDi will follow internal procedures to ensure:

(a) the scientific integrity of the scientific communication and consistency with information submitted to regulatory and health authorities (when appropriate);
(b) that all claims made regarding the efficacy and safety of an IMP are supported by data and consistent with data shared with regulators and ethics committees;
(c) the compatibility of the communication with DNDi's project objectives (e.g., timing and appropriateness of communicating the data from one centre in a multi-centre study);
(d) any relevant information within the communication is considered for a patent application;
(e) the results are communicated to the wider medical community in the most appropriate, practical, and effective way, as part of a communication plan;
(f) the author list appropriately reflects the relative contributions of clinicians, scientists, and other external and DNDi participants (see 'Authorship' below);
(g) the results are consistent with other studies within the project;
(h) funding sources in all articles and presentations are acknowledged;
(i) donors requiring prior agreement for acknowledgement in writing and/or use of their logo are contacted within the agreed timelines (e.g., 10 business days for BMGF);
(j) potential conflicts of interest are disclosed in all articles and presentations;
(k) presentations are appropriately formatted and in the latest slide format.

All scientific communications produced by partners with a DNDi-affiliated co-author (i.e. DNDi employees and consultants – not board or SAC members) should be submitted by partners to the designated project focal point within DNDi for internal review and validation at least 20 business days prior to submission to a journal (for manuscripts) or 10 business days prior to submission to or presentation at a conference or meeting (for abstracts, presentations, and posters). DNDi will respond within the review period. These review deadlines must also be respected for internally produced communications.

- Scientific communications related to study results (e.g., manuscripts, abstracts, posters, slide presentations) must be reviewed and approved, prior to submission, by the relevant R&D heads and directors, fundraising, and scientific communications (according to DNDi's internal procedure, currently a SharePoint validation tool [4]).
- Disclosure of human participant research must be reviewed and approved by the Medical Director.

- Disclosure of human participant research where the data are interim or the CSR is not complete must be approved by the R&D director.
- For any data that has not yet been publicly disclosed, the lead author should obtain agreement from the corresponding DNDi executive management (e.g. R&D Director for R&D) prior to its submission, presentation, or dissemination.
- Partners must be informed before disclosure if the results are material to their interests.

Publication of interim results

Interim results may only be published if indicated as part of the plan in the study protocol and must include language emphasising the provisional nature of the data.

Data sharing

DNDi will grant authors full access to study data. Data will be shared externally according to the DNDi data-sharing policy and procedure.[5]

Authorship

Criteria for authorship

- Following the criteria of the International Committee of Medical Journal Editors,[2] inclusion as an author should be based on: 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; 3) final approval of the version to be published; and 4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Authors should meet all four conditions.[2]
- When a large, multi-centre group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript, normally before the study starts. These individuals should fully meet the criteria for authorship defined above.
- Acquisition of funding, collection of data, or project management alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify for authorship should be listed.

Author hierarchy

- The first author in a paper reporting on study results should be the principal investigator of the scientific or clinical results described – this person coordinates/implements the research, carries out the "intellectual analysis" and directly writes or oversees (e.g., in cases where medical writers are contracted for drafting) a high-quality manuscript. Authorship hierarchy should be decided based on relative contributions to the intellectual analysis and write-up of a high-quality manuscript.
- The second and subsequent authors should be listed in order of contribution after the principal investigator, regardless of affiliation. Where that contribution is equal, alphabetical order may be used. The last two authors, but particularly the last author, is the principal coordinator, who normally guides the overall orientation and backs up a given study in terms of credibility, regardless of affiliation.

Representation

- DNDi strives to ensure that leadership roles in country-specific projects and studies are held by staff and partners from endemic countries. Consequently, DNDi co-authored papers should include authors, and usually lead authors, from relevant endemic countries, including where a manuscript concerns the results of a clinical trial.
- Where publications are commentaries or opinion pieces, position or policy papers, letters in response to articles, or other 'think pieces', authorship should be appropriately representative, with consideration given, e.g., to regional representation, gender, and the inclusion of those whose perspective is important and relevant but who may be excluded from the typical list of those deemed to be experts.

Acknowledgements

- Individuals who do not qualify for authorship but who have made significant contributions should be acknowledged, their contribution specified, and informed of such. Writing assistance should be acknowledged, for example, "We extend our thanks to *Writer's name*, *Company Name*, who provided medical writing services on behalf of DNDi".
- Financial and material support should also be acknowledged. All scientific and clinical external communications that emerge from DNDi-funded research should include acknowledgement of the role of DNDi: "This research received funding from/was conducted in collaboration with/in partnership with/(or similar) the Drugs for Neglected Diseases initiative."

Communication

At the request of the R&D Director, all scientific and clinical external communications that emerge from DNDi-funded research are documented by the Scientific Communications team. DNDi authors must inform Scientific Communications when a manuscript or abstract is accepted and keep them up-to-date about publication dates to allow for strategic communications planning and dissemination.

Open Access

DNDi is committed to making its research available as widely and as rapidly as possible. Three routes to this are currently available:

- Gold open access: the author pays a fee to an open access or a hybrid journal, article is instantly available for readers.
- Green open access: the author submits their accepted manuscript to a public repository, there is often an embargo period and some journals charge a fee.
- Pre-printing: the submitted manuscript is deposited to a preprint server; a peer reviewed version is not freely available.

Pre-printing is strongly recommended for **all** DNDi research and is consistent with our commitment, as a signatory to the World Health Organization's Joint statement on public disclosure of results from clinical trials,[1] to *publish aggregated primary results of all clinical studies within 12 months of study completion (i.e., last patient, last visit) on the selected clinical trial registry or on a pre-print server*.

All research will be routinely made available through 'gold' open access. Where this is not possible, 'green' open access within 6 months of publication is acceptable; authors are responsible for uploading the author accepted manuscript to the repository within the time limit.

In exceptional cases for non-human subject research (e.g., partners without funds), on the condition that the manuscript is submitted to a pre-print server, open access publishing is not required.

Please refer to the DNDi policy on sharing and secondary use of human subject research data for further details about the disclosure of primary results of human subject research.[5]

Authors are responsible for checking the specific requirements of their funders and the open access publishing options at their chosen journal.

- Project budgets must include funds to pay for open access fees, which vary widely by journal and can be high, requiring advance planning.
- The individual requirements of funders must also be met. These are subject to change, so refer to the latest guidance.
- When publications involve disclosure of chemical structures and data, these may be deposited into public databases.

Sex and gender equity in research

The results of clinical trials should be reported, as far as possible, according to the sex and gender equity in research (SAGER) guidelines.[6] These provide a comprehensive procedure for reporting of sex and gender information in study design, data analysis, results and interpretations of findings.

Conflict resolution

Any dispute arising out of or in connection with external scientific communication shall be settled:

- when external partners are involved, in accordance with the dispute resolution provisions set forth in, or with the law applicable to, the contract executed with such partners;
- when DNDi employees are involved, by the Executive Director.

Roles and responsibilities

The main roles involved in this process include:

- Scientific Communications: ensures validation of external scientific communications.
- Directors and Heads of Disease: validation of external scientific communications.
- Fundraising: checking funding statements to ensure all relevant donors are acknowledged and their agreement obtained when required.
- Authors of external scientific communications:
    - Prepare, submit for internal review, and submit for external publication documents according to this policy.
    - In case of green open access, upload the accepted manuscript to a repository within the time limit.
    - Inform Scientific Communications about manuscript/abstract acceptance
- Project leaders:
    - Communicate with partners about obligations and commitments described in this policy.
    - Ensure budget is set aside for open access publishing.
- R&D: approval of publication of interim results or results from a study without a finalized CSR.
- Medical directors: approval of publication of results from human participant research.

References

1. World Health Organization. Joint statement on public disclosure of results from clinical trials. 2017 https://cdn.who.int/media/docs/default-source/clinical-trials/ictrp-jointstatement-2017.pdf?sfvrsn=adad9dc4_2
2. International Committee of Medical Journal Writers. Defining the Role of Authors and Contributors. Accessed 05 Mar 2025. http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
3. World Medical Association. Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Participants. 1964 https://www.wma.net/policies-post/wma-declaration-of-helsinki/
4. DNDi. Communications resources/Sci Comms validation tool.
5. DNDi policy on sharing and secondary use of human subject research data.
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