Scientific and Clinical External Communications Policy

DND*i* POLICIES

DNDi
Drugs for Neglected Diseases initiative

May 2015

Scope: this Policy applies to any scientific or clinical publication / communication resulting from DND*i* directly-conducted research, or from research funded by DND*i*, or from any publication which includes a DND*i*-affiliated author.

DND*i* believes that the results of its work, treatments for neglected patients, should be accessible with no financial barriers, by contributing to open source initiatives such as public databases and open access journals.

1: DND*i* supports the timely communication of all research it sponsors (discovery, pre-clinical, clinical), and will facilitate the rapid and accurate communication of DND*i*-sponsored research and clinical trial results to the wider scientific and medical communities in the most appropriate and practicable way.

With a view to transparency, the clinical trial protocol should mention the publication policy, and clinical trial results be published in a timely fashion. DND*i* may support communication or publication on its model or other related scientific activities.

2: The publication process will be undertaken by DND*i* and the specific project relevant partners. All scientific and clinical external communications should be submitted by partners to the responsible party within DND*i* at least 20 business days prior to submission to a journal/conference (in the case of abstract submission, 10 days will be sufficient). DND*i* will respond within the review period. In compliance with IP policy, should DND*i* intend to file a patent it will request an additional period of 90 days maximum.

3: DND*i* will ensure:

(a) the scientific integrity of the scientific communication and consistency with information submitted to regulatory and health authorities (when appropriate);
(b) how the communication is compatible with DND*i*'s project objectives (eg. timing and appropriateness of communicating the data from one center in a multi-center study);
(c) whether any information within the communication should be considered for patent application;
(d) how and where the results will be communicated to the wider medical community in the most appropriate, practical, and effective way, as part of a communication plan;
(e) whether the author list reflects appropriately the relative contributions of clinicians, scientists, and other external and DND*i* participants;
(f) whether the results are consistent with other studies within the project;
(g) funding sources in all articles and presentations are acknowledged;
(h) potential conflicts of interest are disclosed in all articles and presentations.

4: DND*i* will grant authors full access to study data.

5: Authorship

a) Criteria for authorship are based on the scientific and academic standards as the following:

- Authorship credit 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; and 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 4 conditions.[i]
- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript. These individuals should fully meet the criteria for authorship/contributor ship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms.
- Acquisition of funding, collection of data, or project management alone does not constitute authorship.
- An individual who contributes significantly to writing a manuscript or to its intellectual content is eligible for authorship and should appear high on the contributor list.

b) Author hierarchy:

- The first author 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 manuscript of quality. Authorship hierarchy should be decided on relative contributions to the intellectual analysis and write-up of a quality manuscript.
- The second and subsequent authors contribute in order after the principal investigator, regardless of affiliation.
- The last two authors, but particularly the last author, is the "principal coordinator", and normally guides the overall orientation and backsup a given study in terms of credibility, regardless of affiliation.
- When the number of authors is particularly high (eg >8), the principal investigator and coordinator should verify those listed satisfy authorship criteria, and those whose contributions should rather be mentioned in the acknowledgement section of the manuscript.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.

c) 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 as follows: "We extend our thanks to *Dr John Smith, Company Name*, who provided medical writing services on behalf of DND*i*".

Financial and material support should be also be acknowledged.

All scientific and clinical external communications that emerge from DND*i*-funded research should include acknowledgement of the role of DND*i*: "This research received funding from / was conducted in collaboration with / in partnership with / etc. the Drugs for Neglected Diseases *initiative*."

6: In accordance with the Declaration of Helsinki, all Clinical Trials will be registered with a recognized clinical trial registry, for example www.clinicaltrials.gov. As such, the site will publish details of DND*i*'s clinical trial activities within the categories specified by the site.

7: This policy applies to any scientific or clinical publication / communication resulting from DND*i* directly-conducted research, or from research funded by DND*i*, or from any publication which includes a DND*i*-affiliated author

8: DND*i* is committed to making its research as widely available as possible, and as such aims to make their research available through "open access" publications. When publications involve disclosure of chemical structures and data, these may be deposited into public databases.

[i] International Committee of Medical Journal Writers: Defining the Role of Authors and Contributors http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html