DNDi
Best Science for the Most Neglected

Request for Proposal

Statistics for DNDi-sponsored or supported Human Subject Research

Dated: 21-Aug-24

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1. DNDi OVERVIEW

Neglected tropical diseases continue to cause significant morbidity and mortality in the developing world. Yet, of the 1,556 new drugs approved between 1975 and 2004, only 21 (1.3%) were specifically developed for tropical diseases and tuberculosis, even though these diseases account for 11.4% of the global disease burden**.**

Founded in 2003 to address the needs of patients with the most neglected diseases, DNDi is a collaborative, patient's needs driven, not for profit drug R&D organization.

Acting in the public interest, DNDi bridges existing R&D gaps in essential drugs for these diseases by initiating and coordinating drug R&D projects in collaboration with the international research community, the public sector, the pharmaceutical industry, and other relevant partners.

DNDi's primary focus has been the development of drugs for the most neglected diseases**,** such as Human African Trypanosomiasis (HAT, or sleeping sickness), visceral leishmaniasis (kala-azar), and Chagas disease, while considering engagement in R&D projects for other neglected diseases to address unmet needs that others are unable or unwilling to address.

The primary objective of DNDi is to deliver new treatments for leishmaniasis, sleeping sickness, Chagas disease, malaria, pediatric HIV, filarial diseases, mycetoma and hepatitis C, and to establish a strong R&D portfolio that addresses patient needs. Expanding upon R&D networks built on South-South and North-South collaborations, DNDi aims to bring medical innovation to neglected patients by developing field-adapted treatments.

In doing this, DNDi has two further objectives:

- Use and strengthen existing capacities in disease-endemic countries via project implementation.
- Raise awareness about the need to develop new drugs for neglected diseases and advocate for increased public responsibility.

For more information, please visit DNDi website: http://www.dndi.org/

2. PROJECT BACKGROUND

DNDi is looking to strengthen and formalize the way that statistics are incorporated into clinical phase R&D projects, replacing the current system of using consultants on an ad hoc basis.

3. SCOPE OF WORK

Statistics support is required both at a project and a trial level.

At the project level:

- Work with teams in the development of target medicine profiles, helping to assess whether targeted efficacy against current standards of care is possible to demonstrate with reasonably sized clinical trials.
- Work closely with projects teams to determine if disease states have changed in such a way that new endpoints or innovative study designs would make development of new treatments feasible.

At the trial level:

- Within a trial team, the statistician provides expert advice on endpoints, estimands, effect sizes, sample size, randomization, blinding and controls, study design, statistical methods including multiplicity, analysis and presentation of the data.
- In addition, the statistician may provide statistical input into Case Report Forms, the IWRS or other randomization process design, the database review, the IDMC charter if applicable, data review during trial conduct and other parts of study conduct as applicable.
- The statistician provides statistical contribution to the study concept, the protocol synopsis, the full protocol, the statistical analysis plan, and the clinical study report.
- N.B. The majority of data management and programming activity will be handled by DNDi's data management centre. The statistician assigned to DNDi will work closely with these colleagues during study start-up and conduct.

Experience beyond interventional clinical trials:

- Able to support teams with the development of study protocols for non-interventional studies, such as epidemiologic studies (prevalence, force of infection etc.).

Potential additional scope of work:

- Designing trials with innovative designs: basket and umbrella trials; platform trials; dynamic borrowing.
- Work with trial teams to develop decision-making tools (e.g. Bayesian conditional power) which support IDMCs in their assessment of the significance of difference in safety and efficacy event rates between trial arms.

Volume of work predicted:

- Approximately 8 clinical trial or study protocols to be developed each year.
- Development of approximately 6 SAPs per year.
- Development of Clinical Study Reports for approximately 4 trials per year.

- Development or revision of 1-2 Target Medicine Profiles per year

Way of working:

- DNDi are happy to consider different approaches according to the following broad requirements:
  - Flexibility to increase or decrease support according to the actual workload of the organization.
  - Dedicated team members assigned to DNDi projects to give consistency to the trial and project teams and to allow statistician to build their knowledge of the diseases in the DNDi portfolio.
  - Will be appropriately qualified for the nature of the work.
  - Will be trained on and follow relevant DNDi SOPs.

4. RFP INSTRUCTIONS

4.1. General information

- DNDi invites you to submit a single proposal covering the services described in Section 3.
- The issuance of this Request for Proposal in no way commits DNDi to make an award. DNDi is under no obligation to justify the reasons of its choice following the competitive bidding. DNDi could choose not to justify its business decision to the participants of the RFP.
- DNDi reserves the right to:
  - Reject any proposal without any obligation or liability to the potential service provider.
  - Withdraw this RFP at any time before or after the submission of bids without any advance notice, explanation or reasons.
  - Modify the evaluation procedure described in this RFP.
  - Accept another proposal than the one with lowest cost.
  - Award a contract on the basis of initial proposals received without discussions for best and final offers.
  - Award a contract to only one supplier or allocate them to different suppliers according to what DNDi will consider necessary.
- Late submission proposals will be rejected.
- DNDi reserves the right to request additional data, information, discussions or presentations to support their proposal. All bidders must be available to discuss details of their proposal during the RFP process.
- All offers should be submitted in an electronic format.
- The proposed timelines below indicate the process DNDi intends to follow. If there are changes to this timeline, DNDi will notify you in writing.

4.2. Timelines

Process steps	Responsible party	Timelines
Launch RFP	DNDi	21.AUG.2024
Questions sent to DNDi	Provider	28.AUG.2024
Return LoI signed	Provider	28.AUG.2024
DNDi's awswers to questions	DNDi	02.SEP.2024
Submission of proposals	Provider	16.SEP.2024
Bidders' preselection notification	DNDi	27.SEP.2024

Bid defense meetings	DNDi & Provider	01.OCT.2024
Due Diligence for finalists	DNDi	18.OCT.2024
Project award notification	DNDi	08.NOV.2024

4.3. RFP processes and contact information

All bidders may request further clarifications regarding this RFP by addressing their questions in writing to the dedicated key contacts identified below. These questions should be submitted to DNDi according to the above-mentioned timelines and by using the attached form (Annex 2).

In order to keep a fair bidding process, questions related to this RFP will only be answered in a document shared with all the bidders according to the above-mentioned timelines.

All emails and documents must be sent to:

Topics	Contact person	Title	Contact information
Contractual & Business aspects	Bruno Discini	Procurement Manager	bdiscini@dndi.org
Project lead	For general Questions: Craig Tipple For stats specific questions: Lois Larsen	Medical Director Senior Statistics Consultant	ctipple@dndi.org llarsen@extern.dndi.org

4.4 Format and content of the proposal

Responses to this RFP must be in English and should contain the following information:

- A cover letter including:
  - Name and address of the service provider
  - Name, title, phone number and email address of the person authorized to commit contractually the service provider
  - Name, title, phone number and email address of the person to be contacted in regards of the content of the proposal, if different from above
  - Letter signed by a duly authorized representative of the company

- **Administrative information**
  - Business Company information: directors and officers, creation date, corporate headquarters, locations, business turnover of the past 3 years (global and in the field of service provided), headcounts (global and in the field of service provided), general services provided, customer's reference, pricing strategy for an NGO.
  - Any other relevant information enabling DNDi to assess the opportunity of contracting with your company.

- **A technical proposal**
  - Detailed proposal explaining how your company approach will enable DNDi team to

meet trial timelines, deliverables and ensure quality results as per the input required (detailed above).
    - Project Management approach
    - High level Risk management plan detailing potential risks and mitigations
    - Inclusion of anonymized of CV(s) of statisticians who would be assigned to work with DNDi.
- **A financial proposal**
    - Budget to be provided for all activities detailed in section 3 (Direct and Pass Through Costs). Costs to be provided in Euros.

4.5 Conflict of Interest

The Company shall disclose any actual or potential conflicts of interest.

5. CRITERIA FOR SELECTING SERVICE PROVIDERS

The decision to award any contract as a result of this RFP process will be based on Service Providers' responses and any subsequent negotiations or discussions. The decision-making process will consider the ability of each service provider to fulfil DNDi's requirements as outlined within this RFP and the cost of the offer.

Proposals will be assessed against the main following criteria but not limited to:

- **Technical criteria**
    - Project approach, methodology, customer tailoring and planning.
    - Experiences/skills, level of company representatives assigned to this project.
    - Quality and applicability of proposal presentation.
    - Customer references
- **Capacity to deliver**
    - Reasonable timelines
    - Project management capabilities (Profile of staff involved)
    - Past experience with similar work
- **Financial criteria**
    - Budget with full details of your offer including fixed costs and pass through costs (if applicable). If any activities performed by subcontractors should be clearly indicated (as well as the names of the relevant companies)
    - Realistic costing of the proposal with NGOs rates where possible

6. ANNEXES

Annex 1: Letter of Intent
Annex 2: Q&A Form