Request for Proposal

Global Clinical Safety Services

Dated: July 3, 2023
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1. DNDi Overview

Neglected tropical diseases (NTDs) continue to cause significant morbidity and mortality in lower and middle income countries. 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. 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. Since the start of the COVID-19 pandemic DNDi has engaged a rapid response, coordinating a major clinical trial initiative in Africa, Asia and South America (ANTICOV) as well as engaging in major repurposing and novel anti-viral discovery approaches.

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.

With 350 employees of 37 nationalities located in nine offices on four continents (Switzerland, Kenya, DR Congo, Rio, New Delhi, Kuala Lumpur, New York, Tokyo, South Africa. DNDi is committed to diversity, equity, and inclusion as essential parts of our culture and key drivers of our success.

DNDi is not a medicine authorization holder for any of the medicines it develops and does not engage significantly in post-approval pharmacovigilance activity.

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

DNDi is seeking for one PV service provider with or without replacement of its drug safety database provider. This is to ensure DNDi continues to maintain a safe and compliant drug safety system which supports registration activity for its medicines and trial activity in sometimes challenges settings in LMICs. If justified, there could be 2 PV services providers (case processing and medical writing) in addition to the safety database provider.

2.1. Scope of Work

The scope of pharmacovigilance support services to be provided will include case processing; expedited reporting and exchanges with DNDi’s partners; safety database administration and maintenance and medical writing as per the list of activities mentioned below.

2.1.1. List of activities to be performed

The activities to be conducted by the PV Service provider are the following:

- Coordination of its own team:
  - DNDi project management, Vendor team training (e.g. DNDi protocols, product reference safety information, and DNDi process/Safety Management Plans...).

- Supporting global safety regulatory intelligence including all countries where DNDi has clinical trial activity. Minimally, this should include the EU, UK and USA (and DNDi would be in charge of covering other countries).

- Safety Database:
  - Maintenance of safety database (Currently BaseCon*; now acquired by ABcube) for each clinical trial in scope, including: database administrator role for user access management, training, new patch validation, configuration for new products, product xEVMPD registration/maintenance, clinical trials, reporting rules, listings and summary tabulations.
  - Safety database MedDRA and WHODrug upgrades.
  - Generation, review and monthly distribution of SAE and other ICSR listings.

*BaseCon (https://basecon.com/basecon/safetybase-interchange/) is the safety database currently used by DNDi (n=600 ICSRs). The use of this technology (or ABcube after data migration) will be preferred to another database. If another safety DB is proposed by the vendor, technical and detailed costs information (set-up fees, migration or re-entry of legacy ICSRs, annual/user/upgrade/ICSRs fees) should be provided to DNDi.

- Case processing of initial and follow-up SAEs/other ICSRs into the safety database:
  - Including: acknowledgment of receipt, urgent query, triage, data entry, Quality Control, coding, narrative writing/draft assessment
(causality/expectedness) and request of clarifications (draft queries) prior DNDi review and approval, case finalization (CIOMS or MedWatch) and safety database and release.

- Review and approval of study specific safety management plans (SMPs) and SAE reconciliation plans prepared by DNDi.
  - This may extend to the preparation of study specific safety management plans (SMPs) or SAE reconciliation plans as per DNDi templates.
- Handle clinical trial SAE reconciliations as per study specific SAE reconciliation plan.
- Maintenance of a service provider/DNDi common portal for general project documentation (including maintenance of case processing and key safety documentation filing).
- Filing & archiving safety-related documents (common portal).
- Safety regulatory reporting:
  - Expedited reporting: Registration and reporting/submission of ICSRs to CAs in US, EU/UK (Regulatory authorities and Ethics Committee), if required (as described in study specific SMP).
  - Handle Development Safety Update Report (DSUR) reporting to local Health Authorities and EC (in US, EU/UK), if required (as described in study specific SMP).
  - Provide to DNDi monthly submissions compliance tracker and annual KPI.
- Exchanges with DNDi partners
  - Manage ICSRs exchanges with partners based on PV agreements and as described in study specific SMP).
  - Manage reconciliation of ICSRs exchanges with DNDi partners (as per PV Agreements).
  - Provide to DNDi monthly exchange compliance tracker.
- Medical Writing:
  - Prepare required DSURs, as per DNDi PV SOPs and SMP
- Support DNDi during GCP audits (Internal or by partners) or regulatory inspections.
- Optional: coordination of translation (French, Spanish, Portuguese to English) handled directly by vendor or outsourced.

Note: based on available services, vendors suggestions and BID meetings, adjustments can be made to scope of work based best suitability to support DNDi projects.

2.1.2. Expected reporting

- Organize regular TC (1 hour/monthly) with minutes preparation.
- Monthly compliance (ICSRs reporting and exchanges with the partners) and annual KPIs.
• Organize ad hoc technical or management meetings as necessary.

3. RFP Instructions

3.1. General Information

a. DNDi invites you as a Service Provider to submit a proposal in regards of this RFP for Clinical Safety Services.

b. This entire RFP and all the related discussions, meetings, information exchanges and subsequent negotiations that may occur are subject to the confidentiality terms and conditions of the Intent to Participate attached as Annex 1.

c. All bidders are required to complete and send in return the Intent to Participate letter signed.

d. The issuance of this current Request for Proposal in no way commits DNDi to make an award. DNDi is under no obligation to justify the reasons of its service provider’s choice following the competitive bidding. DNDi could choose not to justify its business decision to the participants of the RFP.

e. 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 other proposal than the lowest one.
   • Award a contract based on initial proposals received without discussions for best and final offers.
   • Award all services to only one supplier or allocate them to different suppliers according to what DNDi will consider necessary.
   • Confirm the award after the results of the qualification GCP audit.

f. DNDi and the selected service provider will be required to adhere to DNDi’s donor’s requirements including:
   • Frequency and format of financial and technical reporting.
   • Access to financial records and audits.
   • DNDi to own the resultant intellectual property.
g. Late submission of proposals is subject to rejection.

h. DNDi reserves the right to request additional data, information, discussions, or presentations to support the proposal. All bidders must be available to discuss about details of their proposal during the RFP process.

i. All offers should be submitted in an electronic format and in English.

j. A proposed time plan set out below indicates the process DNDi intends to follow. If there are changes to these timelines, DNDi will notify you in writing.

### 3.2. Timeline

<table>
<thead>
<tr>
<th>Process steps</th>
<th>Responsible party</th>
<th>Timelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Launch RFP</td>
<td>DNDi</td>
<td>July 4th 2023</td>
</tr>
<tr>
<td>Send back signed Letter of Intent</td>
<td>Service Provider</td>
<td>July 17th 2023</td>
</tr>
<tr>
<td>Questions send to DNDi</td>
<td>Service Provider</td>
<td>July 17th 2023</td>
</tr>
<tr>
<td>DNDi responses to Q&amp;A</td>
<td>DNDi</td>
<td>July 21st 2023</td>
</tr>
<tr>
<td>Send the Proposal</td>
<td>Service Provider</td>
<td>August 4th 2023</td>
</tr>
<tr>
<td>Bid defense meetings</td>
<td>DNDi &amp; Service Provider</td>
<td>Aug 21st-25th 2023</td>
</tr>
<tr>
<td>Due Diligence (finalists)</td>
<td>DNDi &amp; Service Provider</td>
<td>Aug 31st-1st Sept 2023</td>
</tr>
<tr>
<td>Qualification GCP</td>
<td>DNDi</td>
<td>Mid Sept 2023</td>
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<tr>
<td>Award supplier</td>
<td>DNDi</td>
<td>End of Sept</td>
</tr>
<tr>
<td>Start Service</td>
<td>DNDi &amp; Service Provider</td>
<td>Q4’2023</td>
</tr>
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</table>

### 3.3. RFP Processes and contact information

#### 3.3.1. Instructions

All bidders may request further clarifications in regards of this current RFP, by addressing questions in writing to the dedicated key contacts identified below in English. These questions should be submitted to DNDi at the date mentioned in the section 3.2. of the RFP.

In order to keep a fair bidding process, all the questions will only be answered in a document shared with all the bidders on the date indicated in section 3.2 of the RFP.
To submit your questions, please use the form attached as Annex 2.

3.3.2. Confirmation of intent

Please transmit your intent to participate by using and signing the document attached in Annex 1.

Each bidder is required to provide DNDi with a written confirmation of intent or decline to participate by the date as indicated in the section 3.2.

Please, note that the "intent to participate letter" is a standard document which DNDi cannot afford negotiating due to project priorities, time and resources dedication. This template is based on several years of experience working with suppliers and contains widely acceptable terms in RFPs.

Confirmations of intent should be sent by email to Bruno Discini (contacts details below).

<table>
<thead>
<tr>
<th>Questions types</th>
<th>Contact person</th>
<th>Title</th>
<th>Contact information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contract &amp; Technical Aspects</td>
<td>Bruno Discini</td>
<td>Procurement Manager</td>
<td>Email: <a href="mailto:bdiscini@dndi.org">bdiscini@dndi.org</a></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Phone: +55 21 97139 4461</td>
</tr>
</tbody>
</table>

3.4. 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.
  - Signature of this letter done by a duly authorized representative of the company.
  - Acceptance of the consultation principles as detailed in section 3.1.

- A technical proposal
  - Detailed proposal explaining how your company approach will enable DNDi team to meet project timelines and ensure quality results.
  - Proposed vendor team composition with the CVs of the key staff.

- A financial proposal
  - Budget with a detailed cost break down for each activity (with unit cost) to be performed.
• All costs expected to occur shall be clearly indicated and even the taxes if applicable for DNDi/NGOs.
• Pass-through costs shall be quoted and indicated in a very clear way.

○ **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 NGO.
  • Any other relevant information enabling DNDi to assess the opportunity of contracting with your company.

### 3.5. Conflict of Interest

The Company shall disclose any actual or potential conflicts of interest in the Intent to Participate letter.

### 4. 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, subsequent negotiations or discussions and a successful audit. 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:

#### 4.1. Technical criteria
- Records of audits/inspections of the facilities/processes.
- Safety DataBase (BaseCon) knowledge and expertise.
- If applicable, other safety DB knowledge and expertise (& associated costs) in addition to cost of legacy data migration (covering migration plan).
- IT security (including disaster plan, business continuity).
- Data protection according to EU regulations.
- Outcome of GCP PV audit.

#### 4.2. Capacity to deliver
- Project management capabilities and experience.
- Past experience with similar activities.
- Experience with DNDi/NGOs or start-up companies.
- Feedback from references.
• Profile of key staff involved (CVs).

4.3. **Financial criteria**

• Realistic costing of the proposal with NGO rates when possible.

5. **Proposal, Requirements, Deliverables and Timelines**

5.1. **Proposal Requirements**

Following the issuance of the RFP, all interested bidders are invited to submit a proposal that describes:

• General information of the company as described in section 3.4
• Technical and financial proposal as described in section 3.4. Budget with full details of your offer including fixed costs and Pass-Through Costs. We recommend the use of DNDi template inserted as Annex 3.
• Project team involved.
• List of tasks and responsibilities.

In addition, please provide us with complementary information on:

• Standard QA package recommended by the Service Provider (e.g., audits, QC procedures etc.).
• Proposals for monitoring scope and schedule.
• Options to front-load activities in order to gain time (e.g., change management plan if applicable).

5.2. **Deliverables**

DNDi is willing to contract drug safety services for a period of 3 years (Q4 2023 to Q4 2026).

- Project Monthly teleconference: 36
- Number of active Clinical Trials: 10
- Number of planned Clinical Trials: 10
- Number of Safety Management Plans: 10
- Number of significant update of Safety Management Plans: 20
- Number of Products: 12
- Number of EVMPD product registration: 5
- Number of EVMPD product maintenance: 10
- Number of initial ICSRs: 120
- Number of Follow-up ICSRS (assuming 5/initial ICSRs): 600
✓ Number of electronic submissions of ICSRs to Authorities: 40
✓ Number of manual submissions of ICSRs to Authorities: 10
✓ Number of SAE Reconciliation Plans: 10
✓ Number of SAE Reconciliations: 25
✓ Number of ICSRs to be exchanged with Partners: 500
✓ Number of monthly listings (one by product): 360
✓ Number of DSURs: 25
✓ MedDRA Update of safety database: 6
✓ WHO Drug update of safety database: 6
✓ Training of DS&PV team on safety DB (incl. refresh): 12
✓ Support during PV audit or inspection: 2

5.3. Timelines

Beginning of the service: planned in Q4’2023
For further details, please see section 3.2.

6. Annexes

Annex 1: Intent to Participate letter
Annex 2: Question Form
Annex 3: Budget template