Request for proposals

Pharmacovigilance Support

Dated: 11th January 2016
# Table of Contents

1. Context and purpose .................................................................................................................. 3
   1.1. DNDi Overview .................................................................................................................. 3
   1.2. Objective of the request ................................................................................................. 4

2. Scope of work ............................................................................................................................ 5
   2.1. Activities ......................................................................................................................... 5
   2.2. Estimated volume for 2016-2018 .................................................................................. 5
   2.3. Project Timelines ........................................................................................................... 5

3. RFP instructions ......................................................................................................................... 6
   3.1. General information ......................................................................................................... 6
   3.2. Confirmation of Intent ...................................................................................................... 6
   3.3. Conflict of Interest .......................................................................................................... 6
   3.4. Questions ......................................................................................................................... 6
   3.5. RFP Timelines .................................................................................................................. 7
   3.6. Format and content of the proposal ................................................................................. 7

4. Appendices ................................................................................................................................ 8
1. Context and purpose

1.1. DNDi Overview

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.

The primary objective of DNDi is to deliver new treatments for HAT (sleeping sickness), Leishmaniasis, Chagas disease, Paediatric HIV, specific Helminth infections, HCV and Mycetoma (since 2015), 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: www.dndi.org

DNDi Portfolio snapshot (Dec. 2015)
DNDi Clinical Operations overview

As of January 2016, DNDi conducts around 15 clinical trials, from phase 1 to 4, including for New Chemicals Entities (NCEs) for 5 diseases (Leishmaniasis, Sleeping Sickness or human African trypanosomiasis, Chagas disease, Paediatric HIV, and Filarial diseases).

Those clinical operations take place in 12 countries, with the support from DNDi Regional Offices, located in Rio (Brazil), Kinshasa (DR Congo), Nairobi (Kenya), and Delhi (India).

In 2016-2017, DNDi will expand the number of its clinical trials to 23, and will address new diseases (Mycetoma, Hepatitis C).

1.2. Objective of the request

DNDi pharmacovigilance activities, which are correlated to its clinical operations, are expected to grow in the coming years.

To continue ensure safety and compliance to the best standards to its patients and stakeholders, DNDi will adjust its pharmacovigilance set-up established a few years ago to address such activities.

DNDi is seeking an organization that could support the growth of DNDi pharmacovigilance activities, with a transversal and consolidated approach (multi-diseases and cross-regional approach).

The scope of pharmacovigilance support services to be provided will include case processing, expedited reporting, and safety database administration.
2. Scope of work

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

- Coordination of its own team (Project management, CRO team training on DNDi protocols, products, and Safety Management Plans)
- Set-up and maintenance of safety database (BaseCon\(^1\)) for each study in scope (including database administrator role for user access management, training, patch validation, etc.)
- Case processing of initial and follow-up SAEs and pregnancy reports into the safety database (including triage, data entry, Quality Control, coding, narrative writing, case finalization, translation request)
- Write the first narratives (CIOMS)
- Registration and reporting/submission to Regulatory authorities and Ethics Committee, if required
- Handle safety reconciliations
- Generate, review and distribute monthly SAE and pregnancy report listings
- Prepare Development Safety Update Report (DSUR) and handle reporting to local Health Authorities and EC if required
- Filing & archiving safety-related documents

2.2. Estimated volume for 2016-2018
From Q2 2016, 15 studies will need PV support. Those will be conducted in 12 countries.
With an assumption of SAE rate of 10% (of patients recruited) and of 4 follow-up per SAE, the estimated needs to cover the period from Q2 2016 to Q2 2018 are the following:

- 80 SAEs
- 320 follow-up (4 per SAE)

This estimate does not include the PV needs to be covered for new studies to start in between (Mycetoma, HCV). It can so be considered as a low estimate. A similar trend is expected for the next 4 years.

2.3. Project Timelines
The activity is expected to start in April 2016. The agreement to be concluded will be of a duration of two years, to be then renewed/adjusted according to DNDi needs.

\(^1\) BaseCon is currently used by DNDi, as a safety database. The use of this technology will be preferred to another database.
3. RFP instructions

3.1. General information

DNDi invites you, as a service provider, to submit a proposal for Pharmacovigilance support and associated services, to support DNDi pharmacovigilance activities described above.

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

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.

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 on the basis of 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
- Request additional data, information, discussions or presentations to support their proposal. All bidders must be available to discuss about details of their proposal during the RFP process.

Late submission proposals are subject to rejection. All offers should be submitted in an electronic format.

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 to participate by the date as indicated in the section 3.5.

Confirmations of intent should be sent by email to Mr. Guillaume Drapeau (contact details below).

3.3. Conflict of Interest

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

3.4. Questions

All bidders may request further clarifications in regards of this current RFP, by addressing its questions in writing, to: Guillaume Drapeau, Operations Coordinator (gdrapeau@dndi.org)

To submit your questions, please use the form attached as Annex 2.
3.5. RFP Timelines

<table>
<thead>
<tr>
<th>Process steps</th>
<th>Responsible party</th>
<th>Timelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>RFP launch</td>
<td>DNDi</td>
<td>11 January 2016</td>
</tr>
<tr>
<td>Intent to participate letter sent back to DNDi</td>
<td>Service Provider</td>
<td>14 January 2016</td>
</tr>
<tr>
<td>Technical Appendix sent to interested bidders</td>
<td>DNDi</td>
<td>15 January 2016</td>
</tr>
<tr>
<td>Q&amp;A sent to DNDi</td>
<td>Service Provider</td>
<td>20 January 2016</td>
</tr>
<tr>
<td>DNDi responses to Q&amp;A</td>
<td>DNDi</td>
<td>22 January 2016</td>
</tr>
<tr>
<td>Reception of proposals</td>
<td>Service Provider</td>
<td>28 January 2016</td>
</tr>
<tr>
<td>Notification to Pre-selected Bidders</td>
<td>DNDi</td>
<td>2 February 2016</td>
</tr>
<tr>
<td>Bid Defense Meetings</td>
<td>DNDi / Service Provider</td>
<td>4 and 5 February 2016</td>
</tr>
<tr>
<td>Bidder selection</td>
<td>DNDi</td>
<td>19 February 2016</td>
</tr>
<tr>
<td>Contract signature</td>
<td>DNDi / Service Provider</td>
<td>18 March 2016</td>
</tr>
</tbody>
</table>

The timelines proposed above indicate the process DNDi intends to follow. If there are changes to this timelines, DNDi will notify you in writing.

3.6. Format and content of the proposal

Given DNDi’s requirements, describe how your approach and staff will enable your team to meet timelines, insure quality results, and minimize expenses, considering DNDi’s clinical operations.

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

- Company profile
  - Management team, history and key contacts
  - Key figures (PV revenue and headcounts for the past 3 years, locations in Europe)
  - General services provided and specific expertise in Pharmacovigilance
  - Customer’s reference in related area
  - Specific business approach with NGOs
  - Any other relevant information enabling DNDi to assess the opportunity of contracting with your company

- Technical proposal
  - Detailed proposal explaining how your company’s approach will enable DNDi team to meet project timelines and ensure quality results
  - Proposed project team (CVs)
  - Proposed tools and methodology
  - Any other relevant information

- Financial proposal
  - Comprehensive financial proposal detailing activities, estimated workload and associated costs
  - Fixed costs and estimated pass-through costs
  - Daily rate for additional services per type of skills/profiles
  - Potential additional costs
Bidders are invited to disclose any activities to be performed by subcontractors. Thanks to clearly state the name of those sub-contractors and the valuable advantage for DNDi (reasons why outsourcing and why this/those company/ies).

4. Appendices
   - Appendix 1: Intent to participate letter
   - Appendix 2: Q&A Form
   - Appendix 3: Technical appendix (to be communicated to bidders after receipt of the Intent to participate letter)