CALL FOR APPLICATIONS

EVALUATION OF THE MSF TB-PRACTECAL CLINICAL RESEARCH PROJECT

APPLICATION DEADLINE: 25 October 2022

Médecins Sans Frontières/Doctors Without Borders (MSF) is an international medical humanitarian organisation providing quality medical care to people in crises around the world, regardless of religion, ethnic background, or political views. Our fundamental principles are neutrality, impartiality, independence, medical ethics, bearing witness, and accountability.

The **Vienna Evaluation Unit**, based in Austria, is one of three MSF units tasked with managing and guiding the evaluation of MSF projects. For more information see http://evaluation.msf.org/

Subject/Mission	**TB-PRACTECAL Clinical Research Project**
Expected start	**November, 2022**
Duration	Final deliverables to be submitted by end of January, **2023**
Application Requirements	1) A proposal containing an initial version of evaluation matrix and the expected budget[1] (total estimated workload: 30 consultancy days). 2) A cover letter highlighting applicants' experience with similar past assignments (max 1 page). 3) CV(s). 4) One example of past evaluation report in a similar context or topic. Applications should be sent to veuapplication@vienna.msf.org
Deadline to apply	**25 October 2022**

[1] Please specify the gross amounts and applicable VAT/tax rates (or indicate if a VAT exception applies) in the budget proposal. Please note that MSF Austria is not part of the EU's Reverse Charge VAT mechanism. Do not include field data collection/travel costs, as they will be calculated separately based on MSF policies.

CONTEXT

MSF has been advocating for better more effective treatment for drug-resistant tuberculosis (DR-TB) since the late 1990s. The side effects of the medicines people currently take for DR-TB are often described as worse than the disease itself. Patients take up to 20 pills a day, alongside painful injections in some countries, with treatment lasting up to 18 months. Over the course of their treatment, some patients are unable to go to work, socialise, or even visit public places. Their lives are put on hold. And after all that, only about half of people with DR-TB are cured.

DR-TB also tends to affect people from some of the most disadvantaged communities MSF works with. In many cases, people do not know what life will hold for them in over a year's time when their treatment is due to end. It is in this context that TB-PRACTECAL was conceived (2013) and launched (2017) by MSF-OCA. TB-PRACTECAL is a drug-resistant tuberculosis research programme encompassing a randomised clinical trial (RCT) and three sub-studies (Economic Assessment, Patient Reported Outcomes, and Pharmacokinetic/Pharmacodynamics).

The RCT is a multi-centre, open label, multi-arm, randomised, controlled, phase II-III trial, evaluating short treatment regimens containing newly approved drugs bedaquiline and pretomanid in combination with existing and re-purposed anti-TB drugs for the treatment of biologically confirmed pulmonary multidrug-resistant TB (MDR-TB).

The clinical trial was implemented in Uzbekistan, Belarus, and South Africa, and enrolled 552 patients from January 2017 to March 2021. The trial was stopped early (~85% target sample size) due to the new drugs showing significant improvements in efficacy and safety compared to the control standard of care treatment. All patients in the trial were followed up for a minimum of 72 weeks post randomisation until August 2022. The clinical trial and the three sub-studies completed data collection in Q3 2022 and will carry out final analysis during Q4 2022. The project is currently scheduled to end in Q1 2023.

Given that the project is concluding in the next months, there is an opportunity to evaluate the project to provide MSF-OCA and the wider MSF movement valuable learning from the undertaking of a 10-year, 35m euro research project.

EVALUATION PURPOSE, OBJECTIVES, AND QUESTIONS

This is a summative (process) evaluation. The scientific outcomes of the trial have been assessed and published as part of the RCT, and they will be included as point of reference to assess the effectiveness of the intervention. There are also other sub-studies ongoing that include an economic assessment, patient reported outcomes, and aspects related to pharmacokinetics/ pharmacodynamics. Although these aspects will be out of the scope of this evaluation, the decision of having these studies will be considered when assessing the overall design of the intervention.

The **objectives** of the evaluation are:

1. To provide an evidence-based assessment of the strengths and weaknesses of the design decisions and implementation of TB-PRACTECAL. These include, but are not limited to, decision processes to implement the intervention, design, choice of sites and partners, investments, etc., both in terms of internal implementation (governance, project design, monitoring, financial management, HR strategy, etc.) and how it has interacted/ related to the wider MSF-OCA programmatic and medical strategies and operations from 2013 (designed) until 2022.
2. To provide an information resource for the future design and implementation strategy of MSF-OCA clinical research activities, including the evaluation of the funding mechanism.
3. To provide a coherent transparent record of how MSF implemented this project (for external audiences).

Due to the complexity of TB-PRACTECAL, the evaluation will be organised in five sub-studies, each focusing on a specific aspect of the process. These sub-studies will be linked to each other, and data shared when

necessary to make evaluation inferences. The proposed evaluation sub-streams are a) RCT design, b) governance, c) implementation, d) partnerships and communication, e) ethical dilemmas.

The role advertised in this CfA is for the evaluation team member responsible for sub studies a) RCT design, and e) ethical dilemmas.

To achieve the evaluation objectives, the following questions are proposed for each of the two sub-studies:

EQ1. How appropriate was the design of an RCT and three sub-studies in relation with the TB-PRACTECAL objectives?

The appropriateness will be assessed against the intervention outcomes, constrains and failures. The evaluation will consider the context in which decisions were made at the time of the design of the intervention. Actual programme components and outcomes, rather than the intended ones, will be considered.

EQ2. Were there alternative designs that could have produced additional benefits?

Linked to the previous question, the evaluation will explore alternatives to the chosen design, if any, and elaborate on potential advantages and disadvantages. To assess potential alternatives, the evaluation will consider aspects related to the population studied, randomisation of participants, blinding, cost, data analysis, etc. As an example, decisions linked to MSF operational involvement - as compared to just funding a third party specialised in Clinical Research to deliver results - will be part of the discussion.

EQ3. What were the mechanisms designed to manage risks (medical, project, organisational) and were they fit for purpose?

Under this question the evaluation will consider the mechanisms in place to identify, assess, mitigate, and review risks. Some of the aspects to consider will be related to the complexity of the study, the participation/ or lack of it of vulnerable populations, standard practices in selected sites, etc. In addition to documenting risks and their management, the evaluation will identify risks that were identified but not included in the formal mechanism. This will help understand the thought process and describe barriers and constrains in the process.

EQ 12. What were the main ethical dilemmas that were anticipated and which ones were not? What are the lessons learned?

This question will explore key dilemmas faced by different structures of the project (Governance, HQ, field, participants, partners, etc.) and what the outcome was. The evaluation will consider these aspects within the contextual challenges of humanitarian interventions. The MSF ERB "Framework for Ethics review" will be used as a guide.

EQ 13. What were the mechanisms in place to resolve the ethical dilemmas and what were the results?

Linking with the previous question, the evaluation will analyse the mechanisms that were in place and how they functioned, in case of all (or selected if too many) identified dilemmas.

EQ 14. What are the implications at various levels (organisation, partners, and society) of MSF committing to this type of intervention?

This question will draw from information collected in most of the earlier questions to infer what the positive and negative implications on the short, medium, and long terms are.

METHODOLOGY AND DATA SOURCES

Evaluators are expected to elaborate a methodology based on remote and on-site data collection methods, including:

- Interviews with key stakeholders, (e.g., national staff, present and former TB advisor(s), Medical Coordinator(s), Head of Mission(s), (Medical) Operations Manager(s), Operations Advisor(s), Advocacy Manager(s), Ministry of Health partners, World Health Organization members, Access Campaign).

- Desk review of Mission documents, detailing changes over time as well as how activities have been adjusting to the needs of the patients and the gaps observed when working with the MoH.

EXPECTED OUTPUTS

An inception report outlining the scope, workplan, timeline, methodology and limitations will be provided by mid-November 2022.

A first draft report is expected by mid-January 2023.

A final report with findings, discussion and recommendations is expected by the end of January 2023.

A PowerPoint presentation to accompany the evaluation findings should be prepared by the evaluator(s) for ease of presenting findings. Results will be presented to the Commissioners team, field Missions, Cell and the VEU stakeholders shortly after presenting the final report.

PROFILE / REQUIREMENTS FOR APPLICANTS

Applicants should have the following qualifications and experience:

- Minimum 5 years' experience with RCTs or clinical trials in resource constrained settings
- Minimum 5 years' experience with MDR-TB
- Strategic outlook and thinking
- Knowledge of the role of medical research and innovation
- Strong understanding of humanitarian principles
- Excellent knowledge of English (spoken and written); Russian not compulsory but a strong asset
- Excellent analytical and writing skills
- Experience in negotiations/work with MoH in resource constrained countries