

Standard 'Call For Proposals' (CFP)

Improving Quantification and Forecasting of New Drugs and Regimens based on Updated Guidance and Trial Results

Introduction and Background

UNOPS has hosted Stop TB Partnership Secretariat as of 1 January 2015. The Stop TB Partnership ("STBP"), under the direction of the Executive Director is leading the way to a world without tuberculosis (TB), a disease that is curable but still kills three people every minute. Founded in 2001, the Partnership's mission is to serve every person who is vulnerable to TB and ensure that high-quality treatment is available to all who need it.

As a key initiative of the Stop TB Partnership, the goal of the Global Drug Facility (GDF) is to facilitate world-wide, equitable access to TB medicines and diagnostics across both public and private sectors. This goal is achieved through management and coordination of market activities for the full portfolio of TB medicines and diagnostics, strategic procurement and innovative logistics solutions, technical assistance and capacity building for TB programmes in better pharmaceutical management practices, and accelerated uptake of new TB medicines, regimens, and diagnostics.

GDF, through this Call for Proposal (CFP), invites proposals from qualified organizations interested in receiving grant support to develop and implement tools that will help improve GDF's approach to quantification and forecasting of new drugs and regimens.

In the past five years, two new medicines have received conditional approval by Stringent Regulatory Authorities for the treatment of drug-resistant TB. The approvals were followed by interim guidance from the World Health Organization (WHO) on how to use these new drugs, including the dose, the frequency of administration, the duration of treatment, which patient populations would benefit and recommendations on monitoring for safety. However, the Drug-Resistant TB Scale-Up Treatment Action Team (DR-TB STAT) estimates that between July 2015 and July 2017, less than 5% of patients who could benefit from these new drugs actually received them.

Additionally, more evidence has emerged on how these drugs and shorter regimens could be used, including:

- The WHO guidance on use of delamanid in children as young as six years old
- The WHO best practices for off-label use of both bedaquiline and delamanid:
 - In children and pregnant women
 - For extrapulmonary TB
 - When there are limited treatment regimen options, including due to extensive resistance patterns to second-line drugs and patients with drug intolerance or adverse events
 - For a longer treatment duration (more than 24 weeks)
 - In combination (both new medicines) in a single regimen
- WHO Recommendations on the use of shorter regimens
- Results from multiple observational and interventional clinical trials

With new patient populations eligible, more variability on duration of treatment, the possibility to use both drugs in combination, and the introduction of shorter regimens, the complexity of quantification and forecasting for the new drugs and regimens increases. These changes create a risk that countries may have fewer drugs than originally quantified resulting in either slowed or delayed enrolment, the need for emergency orders or possible stock out situations. All of this could lead to a further gap in access to treatment.

The objective of this CFP is to identify an organization with a proven track record working in drug-resistant TB, particularly with new drugs, which can develop tools to improve the quantification and forecasting approach to new drugs.

1. General instructions for proposal submission

How to submit?

Grantees are requested to submit their complete application as per the grant application instructions provided in the CFP and in an electronic form (PDF) as well as an accessible format (word/excel) to the below e-mail address.

Mr Philipp Hodel
Portfolio Officer
UNOPS Geneva Office
philipp@unops.org

When to submit?

Deadline: Tuesday, 12 December 2017, 18:00 (Geneva time)

2. Eligibility criteria as per project agreement

Grant Proposals must not exceed USD 215,000, any amount over the ceiling must be co-financed by the selected organization.

The minimum eligibility criteria are:

- A. Not-for-profit international or national non-governmental organizations.
- B. Demonstrated experience and expertise in:
 - Clinical management of drug-resistant TB with new drugs and/or new regimens;
 - Facilitating introduction of new tools for the diagnosis, prevention and/or treatment of TB; and,
 - Experience in coordinating multi-stakeholder technical inputs, consolidating, analysing and presenting results.
- C. Presence and/or network to carry out the project activities in multiple countries, as needed
- D. Good relationships with key stakeholders in the TB space, including but not limited to delivery agencies, funders, normative agencies, and regulatory bodies.
- E. Administrative, financial, and technical capacity to carry out the project activities within the time frame required.

3. Description of scope of work

The scope of work of this grant aims to develop validated tools to improve quantification and forecasting for new drugs and regimens for drug-resistant TB over the course of one year.

The planned grant activities will be as follows:

- Propose and in conjunction with GDF and other Stop TB Partnership Secretariat teams as needed, finalize a set of initial target countries with high background resistance to second-line medicines (e.g., would likely benefit more from new drugs) and low background resistance to second-line medicines (e.g., would likely benefit more from shorter regimens) to provide as broad as possible applicability to develop PSM tools;
- Develop an assessment tool to collect baseline data at the country level that would feed development of more refined quantification and forecasting which may include existing country guidance on new drugs (dose, duration, patient population, etc.) and regimens (drugs, doses, duration, patient population, etc.), the actual approach to use of new drugs and regimens (if different from the recommended approach), targets for treatment set by donors and other relevant information;

- In coordination with other partners (e.g., GDI and subgroups), use the assessment tool to collect data on the initial target countries; consolidate and analyse the information to develop a forecast model that accounts for the different identified approaches to treatment;
- Develop country-level forecasts for these products and regimens (annual, rolling), update these forecasts quarterly, collect actual consumption (quarterly) and compare to the forecast, identify barriers to uptake, coordinate with GDF and other partners on any significant barriers, delays or other issues that may affect procurement;
- Refine the model and update required country level inputs to improve the model as necessary (model should be flexible enough to account for changes to treatment recommendations over the grant period and beyond);
- Based on the validated model, develop a PSM tool/guide/job aid to assist GDF and country programmes to more accurately quantify and forecast new drugs and regimens (e.g., could be used to improve quantification and forecasting platforms such as QuanTB and others);
- Provide trainings to GDF staff and consultants on using the developed PSM tools, including support on country missions as appropriate;

Deliverables (may include, but are not limited to, the following):

- A validated model for estimating number to be enrolled in different treatment regimens and durations.
- A PSM tool/guide/job aid to improve quantification and forecasting of new drugs and regimens.
- Quarterly needs forecasts and actual enrolment across target countries for new drugs and regimens.

4. Evaluation process

In line with UNOPS evaluation principles of fairness, transparency and integrity, an independent Grant Evaluation and Selection Committee will be responsible for the review of proposals and the Grantee selection.

A two-stage procedure will be utilized in evaluating the proposals, with evaluation of the technical component being completed prior to any budget component being considered. The budget component will be evaluated only for those applicants whose technical component meets the requirements for the CFP. Any non-compliant proposal may automatically be eliminated from the evaluation process.

The technical component, which has a total possible value of 100 points, will be evaluated using the following criteria:

Technical Criteria	Maximum Score
Nature of the proposing organization, legal status (registration with government approved authority), and organizational and financial capacity (annual financial statements, membership and affiliation to association or umbrella groupings).	20
Demonstration of experience in introducing new commodities for TB, clinical excellence in drug-resistant TB.	30
Proposed project approach, work plan of activities, timelines and grant budget	40
Identified major risk factors that could result in the grant activities not producing the expected results (internal/external) and proposed risk mitigation measures	10
Maximum Score: Technical Component	100

Only proposals that have a Technical Component receiving more than 70 points out of the potential 100 points shall be considered for financial evaluation.

Financial proposals will be evaluated following the completion of the technical evaluation.

A detailed budget breakdown covering all costs and only costs which directly relate to efficiently carrying out the grant activities shall be submitted. Grant overheads may not exceed 10% of the total budget.

A grant will be awarded to the grantee with the most attractive combination of technical and financial proposals.

5. UNOPS Grant Support Agreement

The UNOPS Standard Grant Support Agreement (GSA) containing UNOPS General Conditions for Grant Support Agreements (*Annex D of the [UNOPS Grant Support Agreement template](#)*) is herewith attached. The GSA constitutes an integral part of this CFP as it is mandatory to accept this agreement with its conditions before submitting a proposal.

6. Interest / Grantee Application template

If your organization is interested in submitting a grant proposal in response to this CFP, please kindly submit a grant application in pdf as well as an accessible format (word/excel) addressing the technical and financial requirements outlined in sections two to four of this CFP.

My organization _____ is hereby formally interested in the advertised grant program/component and is submitting a proposal within the established timeframe.

Authorized signature: _____

Title: _____

Date: _____