

Strengthening laboratory quality management towards accreditation for National Tuberculosis Reference Laboratory (NTRL)

PR43849

Terms of Reference (ToR)

Background on Save the Children

Save the Children is the leading global independent organisation for children. Save the Children believes every child deserves a future. Around the world, we work every day to give children a healthy start in life, the opportunity to learn and protection from harm. When crisis strikes, and children are most vulnerable, we are always among the first to respond and the last to leave. We ensure children's unique needs are met and their voices are heard. We deliver lasting results for millions of children, including those hardest to reach.

We do whatever it takes for children – every day and in times of crisis – transforming their lives and the future we share.

Our vision: A world in which every child attains the right to survival, protection, development and participation.

Our mission: To inspire breakthroughs in the way the world treats children, and to achieve immediate and lasting change in their lives.

Our values: Accountability, ambition, collaboration, creativity and integrity.

We are committed to ensuring our resources are used as efficiently as possible, in order to focus them on achieving maximum impact for children.

Background information/context

National Tuberculosis Reference Laboratory (NTRL) is the apex institution of national tuberculosis laboratory network in Nepal. The NTRL is located within the premises of National Tuberculosis Control Center (NTCC) and provides a wide range of TB laboratory services including sputum smear microscopy, GeneXpert testing, TB culture and drug susceptibility testing through both phenotypic (solid and liquid culture) and genotypic (line probe assay) methods.

It is crucially important to have a laboratory quality assurance system in place for a TB reference laboratory as it provides specialized laboratory services and any error in a laboratory result will adversely affect diagnosis and clinical management of a TB patient. Implementation of a quality management system (QMS) in laboratories leads to improved quality of diagnostic tests and better patient care. The importance of quality assurance in TB laboratory services has been further highlighted due to the emergence of the multi-drug resistance tuberculosis (MDR-TB) which requires a precise diagnosis for a successful clinical management. Moreover, quality-assured tuberculosis laboratory services are critical to achieve national goals for tuberculosis prevention and care.

TB laboratory services provided by the NTRL have been reviewed and assessed by various laboratory experts at different times. One of the key recommendations made by all the reviews is to strengthen

the NTRL by implementing a quality management system (QMS).¹ The QMS is implemented by complying with the requirements of the international quality standard for medical laboratories such as ISO 15189. Different tools and processes have been developed to implement the QMS in a laboratory, examples include GLI Stepwise Process towards TB Laboratory Accreditation, Laboratory Quality Stepwise Implementation (LQSI) tool developed by WHO and Strengthening Laboratory Management Toward Accreditation (SLMTA) tools. SLMTA program provides a structured approach to implementing QMS particularly for TB services.

The NTRL requires technical assistance from an expert or a group of experts to implement the QMS. It is unlikely that experts experienced in implementation of laboratory QMS are available in Nepal. Therefore, an international consultant or a consulting firm having expertise in the relevant area is required to conduct this activity.

Objective

The objective of assignment is to support NTRL in implementing a Laboratory Quality Management System (QMS) towards accreditation.

Specific objectives:

1. Provide technical support to NTRL in implementing a laboratory Quality Management System (QMS)
2. Conduct a Training of Trainers (ToT) on implementation of laboratory Quality Management System (QMS) toward accreditation

Location and official travel involved

The supplier will be required to travel to NTRL in Bhaktapur, Nepal. Any required travel will need pre-approval by SCI in accordance with SCI's Travel Policy.

Services the Supplier will provide

The consultant will

- Conduct a preliminary review of current practices related to laboratory QMS (audit) at National TB Reference Laboratory.
- Develop a SLMTA or equivalent program to include adaptation of existing local lab tools, job aids and supplementary materials specific to the national tuberculosis reference laboratory.
- Develop a detailed plan and a harmonized checklist for implementation of laboratory QMS at NTRL. The plan will be based on GLI's Stepwise Process towards TB Laboratory Accreditation/WHO's LQSI tool /SLMTA or Stepwise Laboratory Improvement Process Towards Accreditation (SLIPTA).
- Develop a training program (including training materials) so as to train NTRL lab staffs on laboratory Quality Management System (QMS).
- Conduct a ToT on laboratory QMS for selected laboratory professionals in Nepal to implement QMS in TRLs and TB QC units in provinces.
- Conduct onsite coaching and mentoring for NTRL staff for the successful implementation of QMS which will ultimately lead to accreditation (ISO 15189) of NTRL.

¹ Report of the Joint Monitoring Mission for Tuberculosis (2019); Mission Report - Supranational Reference Laboratory Munich-Gauting (2018)

- Conduct required visits to NTRL to provide support for stepwise implementation of laboratory QMS based on existing tools such as SLMTA, LQSI tool or GLI tool.
- Conduct a workshop to finalize Standard Operating Procedures (SOPs) and TB laboratory quality manual.
- Prepare a detailed report on implementation of laboratory QMS at NTRL.

Experience and skill set required

- At least 7 years of experience in strengthening Quality Management System (QMS) of health laboratories, preferably of TB reference laboratories in low- and middle-income countries.
- Strong knowledge and skills on implementation of at least one of the laboratory QMS tools such as WHO's LQSI tool, SLMTA or GLI's Stepwise Process towards TB Laboratory Accreditation or Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA).
- Experience of ISO 15189 accreditation of health laboratories.
- Sound knowledge of health laboratory issues in low- and middle - countries.
- Demonstrated ability of planning, reviewing, analyzing and report writing.
- Excellent written and verbal communication skills in English
- Working knowledge of Nepali will be an added advantage

Education

- A minimum of post-graduate degree or other advanced university degree in the field of health laboratory sciences. PhD in related field preferred.

Expected Deliverables

The consultant will be responsible to provide the following documents to NTCC and SCI

1. Report on the preliminary review of current practices related to laboratory QMS (audit) at NTRL
2. A detailed plan for implementation of laboratory QMS at NTRL
3. A complete training package on laboratory QMS
4. Report on the ToT on laboratory QMS conducted for selected laboratory professional in Nepal
5. Quality manual, complete sets of Standard Operating Procedures (SOPs), documents and records developed for implementation of laboratory QMS at NTRL
6. A detailed report on the implementation of QMS at NTRL

Timeline

Estimated Commencement Date: February 21, 2022

Estimated End Date: May 15, 2022

Estimated Level of Effort (LoE): 60 days

Acceptance

All deliverables to be accepted by SCI Project Lead within 14 days of delivery date.

Payment information

The Fees are inclusive of all costs, overheads, and expenses, including travel, subsistence and accommodation.

Payment can be made on instalment basis after completion of each deliverable or on mutual agreement with winning bidder.

Save the Children shall pay correctly rendered invoices (a) upon completed delivery of the goods or performance of the services in accordance with the contract or (b) within 45 days from the date of invoice (**whichever is later**).

Proposal Evaluation Criteria and Scoring Criteria

Parameter	Description
Essential Criteria	<ul style="list-style-type: none"> For Company/Institution/Organization: The proposing consultant should be registered as per the prevailing act of the country. This is not applicable for international individual consultant. At least 7 years of experience in strengthening Quality Management System (QMS) of health laboratories. Experience of implementation of at least one of the laboratory QMS tools such as WHO's LQSI tool, SLMTA or GII's Stepwise Process towards TB Laboratory Accreditation. Post-graduate degree or other advanced university degree in the field of health laboratory sciences.

S.No.	Criteria	Major Topic	Score Weightage
I	Capability	<p>Qualification and Experience proposed consultant</p> <p>Qualification: 5% PhD in the field of health laboratory sciences Yes = 5, No = 0</p> <p>Relevant Experience: 30%</p> <p>Experience in strengthening Quality Management System (QMS) of health laboratories: 10% 7 to 10 years = 5% More than 10 years = 10%</p> <p>Experience of ISO 15189 accreditation of health laboratories: 10% One Accreditation = 5% 2 to 3 Accreditation = 7% More than 3 = 10%</p>	35%

		Experience working in TB reference laboratories: 10% Yes =10% No = 0	
2		Proposed approach and methodology Excellent: 5%, Very Good: 3%, Good: 2%, Poor: 0%	5%
3		Interview / Presentation (For shortlisted bidder/s only)	10%
4	Sustainability	The bidder demonstrates experience and understanding of local context and community. Experience working in Low- and Middle-income countries Yes = 10% No = 0	10%
5	Commercial	Budget (Total cost for the assignment). Score in inverse proportionate basis (which means lowest total cost will get highest score).	40%

How to apply for the services:

Proposal Submission Guideline/Required Documents

- Proposal Submission Deadline- **8th February 2022**
- Required Documents-
 - Filled out Consultancy Proposal Form (enclosed with this ToR)
 - CV(s) of the proposed consultant(s) with full date of birth in dd/mm/yyyy format.
 - **For firms (International):** Copies of registration documents as per the prevailing act of the country.
 - **For Individuals (Foreign Nationals):** Copy of passport and CV.
 - **For both (International Firms and Individual Foreign Nationals):** Copy of relevant professional license / registration in their own country or international registration (if applicable).

If an individual is a full-time staff member of another organization, a no objection/consent letter signed by the organization head must be submitted along with the proposal. This is not applicable for proposals sent through a firm.

Proposals should be submitted via email to nepal.bids@savethechildren.org

The proposal submitted in another email address will not be consider in the process. (Please note that, consultant must not cc / bcc / forward proposals to any other email addresses).