Summary:

CRDF Global is seeking a Subject Matter Expert (SME), specializing in Tuberculosis (TB) preclinical and clinical research, to serve as a program manager in support of the coordination and implementation of new TB drug/regimen development plans as well as development and validation of new biomarkers carried out by the National Institutes of Health (NIH). The SME will work in conjunction with CRDF Global and Program staff at the National Institute for Allergy and Infectious Diseases (NIAID) Division of AIDS (DAIDS) to coordinate planning among major stakeholders and research groups to ensure rapid and efficient collaborative research efforts both nationally and internationally. Qualified candidates should have experience facilitating productive collaborations across governments, funding agencies, academic institutions, pharmaceutical/biotech companies, and TB clinical research networks. The anticipated contract start date is September 26th, 2022 with a period of performance of one year.

Scope of Work

- Support the coordination and implementation of new TB drug/regimen development plans as well as development and validation of new biomarkers
  - Provide scientific and technical leadership for oversight of TB drug discovery and preclinical projects, ensuring timely and quality technical performance
  - Review current literature and provide clinical and scientific information from a wide range of sources to support the development and coordination of plans and projects
  - Maintain current knowledge and understanding of ongoing developments in TB biology and research and development in industry and academia
  - In collaboration with DAIDS staff, evaluate and support the identification and selection of appropriate compounds and product candidates for TB drug development
  - Devise and implement TB therapeutic project development coordination strategies/plans/activities, sharing, and agreements on specific tasks and responsibilities in a team setting
  - Develop and implement detailed project management plans for appropriate activities with milestones/timelines, communication channels/contact persons, responsible parties, as applicable
  - Identify needs, gaps, and opportunities for improving the effectiveness and efficiency of coordination of research activities
  - Develop and implement strategic approaches to address existing research gaps
  - Support the development and preparation of requests for applications (RFAs) to address gaps

- Support communication and coordination efforts to avoid unnecessary duplication and promote collaborative research efforts nationally and internationally
  - Support the coordination of cross-NIAID research efforts with DAIDS/DMID staff, the AIDS Clinical Trials Group (ACTG), and other DAIDS/DMID TB research grantees/contractors
  - Facilitate discussions among other TB drug/combination regimen developers and organizations, both clinical and preclinical (e.g., Pharma/non-profit, Clinical Trial Networks, other applicable national and international agencies, etc.)
  - Coordinate with DAIDS staff to facilitate interactions and coordination of activities for TB intervention and development research
  - Serve as Executive Secretary for the TB Drug Combination Clinical Development Planning Forum
  - Attend and participate in national/international scientific meetings/conferences to stay abreast of current research findings and to interact with other groups/investigators to promote coordination and potential collaborations
Monitor progress and oversee project deliverables and timeliness
- Evaluate project performance and ensure cooperation among stakeholders
- Ensure timely progress, quality, effectiveness, efficiency, and impact
- Advise DAIDS program management of deficiencies and problems
- Devise and implement corrective actions needed to achieve specified results
- Produce reports, documents, presentations, and responses to requests for information as required in planning and implementation of projects/strategies

Anticipated Timeframe:
Anticipated Contract start date is September 26, 2022. Contract period of performance will be for one (1) year, with a possibility for renewal.

Proposal Requirements:

Each proposal must include:
- Statement of Interest and Technical Capabilities (including list of RFP related capabilities and applicable past experience and publications as relevant).
- Cost proposal: description of pricing and cost factors (e.g. hourly rates, fixed-cost pricing on standard services, etc.) that the contractor would be willing to negotiate.
- CV(s) of Subject Matter Expert(s)
- List of recent experience in the RFP Subject Matter area and applicable references/past performance
- Any Small or Disadvantaged Business Designations (Veteran Owned, HUB Zone, Women Owned, Disadvantaged Businesses) and/or NAICS Codes

Timetable:
August 15th       RFP Questions due
August 16th       RFP Questions & Answers released
September 6th     RFP submissions due
Week of September 12th     Interview Panel
September 19th   Contracted Expert Selected
September 26th   Contract start date

Contractor Selection Criteria:

CRDF Global will select the contractor that provides the best value in terms of overall price as well as quality of proposal, past performance, and other intangible factors. CRDF Global reserves the right to accept or reject any and all proposals, and to negotiate terms of any subsequent agreements at its own discretion.

The contractor should have proven experience working in a research leadership capacity within an academic/pharmaceutical/biotechnology company or other international agency.

A successful proposal will highlight the following qualifications:
- Master’s degree, or an equivalent combination of education and experience, with advanced training in clinical research, epidemiology, or public health
- Minimum 5-10 years working experience in a research leadership capacity within an academic/pharmaceutical/biotechnology company or other international agency
- Expert knowledge of tuberculosis (TB) preclinical and clinical research
- Knowledge of ICH guidelines and Good Clinical Practices (GCP)
- Experience and working knowledge of FDA/EMA policies regulating clinical trials
• Ability to work effectively independently and across multidisciplinary teams
• Experience facilitating productive collaborations across governments, funding agencies, academic institutions, pharmaceutical/biotech companies, and TB clinical research networks
• Strong communication, presentation, and interpersonal skills

CRDF Global prioritizes a safe and collaborative work environment in which diversity, equity, and inclusion is championed and discussed. CRDF Global provides equal employment opportunities to all qualified individuals without regard to age, race, color, religion, sex, sexual orientation, and gender identity, national origin, protected veteran, or disabled status. We are dedicated to creating and maintaining a respectful work environment that is safe, engaging, and comfortable for all.

CRDF Global pledges to prioritize sponsorship of diverse events and panels of experts whenever possible.

Submission:

Proposals should be submitted to procurement@crdfglobal.org & coconnor@crdfglobal.org, no later than 5:00 PM ET on Tuesday September 6. Proposals should be submitted as electronic documents in PDF, Word or Excel format.

Background:

CRDF Global is an independent nonprofit organization founded in 1995 in response to the collapse of the Soviet Union and the threat of large-scale proliferation of weapons technology from the region. With support authorized by the Nunn-Lugar Act of 1991 and the Freedom Support Act of 1992, as well private foundation contributions, CRDF Global embarked on bolstering the global scientific community and fostering alternatives to weapons research.

In the past 25 years, our work has expanded to address ever-changing global concerns, but our commitment to ensuring the success of our partners remains the same. We are a leading provider of flexible logistical support, program design and management, and strategic capacity building programs in the areas of higher education, CBRNE security and nonproliferation, border security, cybersecurity, global health, technology entrepreneurship, and international professional exchanges.

With offices in Arlington, VA; Kyiv, Ukraine; and Amman, Jordan, CRDF Global’s diverse staff and networks of local community and government stakeholders deliver tailored programs that meet specific regional needs in over 100 countries across the globe.

Vision Statement:
Our world, healthy, safe, and sustainable.

Mission Statement:
Safety, security, and sustainability through science, innovation, and collaboration.

Values:
We do the right thing.
We care about each other and the people we work with.
We work together to deliver excellence

CRDF Global provides equal opportunities to all qualified individuals without regard to age, race, color, religion, sex, sexual orientation, gender identity, national origin, protected veteran, or disabled status. We are committed to prioritizing an inclusive and collaborative space in which diversity and equity is discussed, championed, and supported.
We acknowledge and honor the fundamental value and dignity of all individuals. We pledge ourselves to creating and maintaining an environment that respects diverse traditions, heritages, and experiences.

More information is available at [www.crdfglobal.org](http://www.crdfglobal.org).

**Solicitation Terms & Conditions:**

**Right to Select Suppliers.** CRDF Global reserves the right to negotiate with and select all qualified suppliers at its own discretion and is not obligated to inform suppliers of the methods used in the selection process. CRDF Global reserves the right to dismiss any and/or all suppliers from the bid process and reject any and/or all proposals.

**Obligation.** This RFP does not bind nor obligate CRDF Global in any way. CRDF Global makes no representation, either expressed or implied, that it will accept or approve in whole or in part any proposal submitted in response to this RFP. CRDF Global may reward, in whole or in part, the proposal at its sole discretion.

**Notification.** CRDF Global will notify bidders following completion of the evaluation process, as to whether or not bidders have been awarded the contract. The only information regarding the status of the evaluation of proposals that will be provided to any inquiring bidder shall be whether or not the inquiring bidder has been awarded the contract. CRDF Global may, at its sole discretion, inform any inquiring bidder of the reason(s) as to why it was not awarded the contract.

**Binding Period.** Following the due date of submission of this Proposal, the pricing included in this RFP shall be binding upon the supplier for the duration of the contract.

**Hold Harmless.** By submitting a response to the RFP, bidder agrees that CRDF Global has sole discretion to select any and/or all suppliers. During or following the conclusion of this process, bidders waive their rights to damages whatsoever attributable to the selection process, materials provided, supplier selection, or any communication associated with the RFP process and supplier selection.

**Transfer to Final Contract.** The terms and conditions of the RFP, including the specifications and the completed proposal, will become at CRDF Global’s sole discretion, part of the final contract (the "Agreement") between CRDF Global and the selected bidder. In the event that responses to the terms and conditions will materially impair a bidder’s ability to respond to the RFP, bidder should notify CRDF Global in writing of the impairment. If bidder fails to object to any condition(s) incorporated herein, it shall mean that bidder agrees with, and will comply with the conditions set forth herein.

**Exceptions.** Any exceptions to the terms and conditions or any additions, which bidder may wish to include in the RFP, should be made in writing and included in the form of an addendum to the applicable Section in the RFP.

**CRDF Global Proprietary Information.** Supplier agrees that all non-public information contained in this document and communicated verbally in reference to this RFP by CRDF Global shall be received for the sole discretion and purpose of enabling the supplier to submit an accurate response to this RFP. The information contained in this RFP and disclosed during the course of negotiations and communications are proprietary in nature and under no circumstances to be disclosed to a third party without prior written consent from CRDF Global.

**Supplier Proprietary Information.** Information contained in the response to this RFP will be considered proprietary in nature if marked "confidential" or "proprietary". Such marked documents will not be disclosed to third parties outside CRDF Global with the exception of retained consultants under contractual confidentiality agreements.