Project Coordinator
FEND-TB Project

Organization:
FIND is an international non-profit organization based in Geneva, Switzerland. The organization is dedicated to activities that result in 1) new diagnostic tools; 2) expanded access to these tools; and 3) strengthened diagnostic testing capacity for poverty-related diseases in low- and middle-income countries.

Background:
Feasibility of Novel Diagnostics for TB in Endemic Countries (FEND-TB) is a global, multicenter research project that will encompass a strong partnership between investigators at academic institutions in the US and at FIND across 5 clinical research sites in India, Peru, South Africa, China, and Uganda. FIND is the leading organization globally in TB technology scouting and has extensive knowledge of global stakeholder priorities in TB diagnostics and input into policy decisions. The FEND-TB project encompasses an advanced diagnostic technology scouting component, analytical laboratory evaluation of the most promising TB diagnostics, and an innovative study plan involving continuous enrolment across clinical protocols in five countries over five years. The rigorous but efficient study strategy will incorporate new early stage assays for development and evaluation of diagnostic accuracy.

Location: New Delhi

Job description:
FIND is looking for a consultant who will:

- Work with the trial site principal investigator (PI) and provide required support for facilitating timely approvals by the Institutional Committees. This will include:
  - Completion, compilation, and submission of necessary documents for institutional approvals
  - Following up and promptly resolving any queries raised by the institutional committees
- Work with the trial site PI and provide required support for facilitating timely HMSC and regulatory approvals. This will include:
  - Completion, compilation, and submission of necessary documents for HMSC and regulatory approval
  - Following up with ICMR and promptly resolving any queries raised by the HMSC
  - Following up with CDSCO and promptly resolving any queries raised
- Lead on trial set up in India, including development of specific plans, forms or SOPs that may be required for the study
- Manage set activities within the trial and ensure progress towards pre-determined goals.
- Set-up and maintain Trial Master Files and prepare Trial Manual based on the requirements in the Trial Protocol
- Support the development of training materials for site provide follow-up training to sites and/or PI as required
- Conduct clinical trial quality assurance/compliance central and on-site monitoring (including but not limited to verification of compliance with Trial Manual instructions and source data verification) and provide prompt feedback to supervisor
- Ordering, tracking and managing investigational products, trial materials, consumables, equipment etc.
• Facilitate recruitment of study staff at the trial site and monitor their work performance
• Support the team in the development and implementation of corrective action plans when a confirmed quality/compliance/risk issue is identified
• Assist with coordination and troubleshooting on supply of investigational product to sites.
• Escalate observed potential risks, issues, non-conformances where necessary
• Assist in preparation for audits and inspections
• Conducting regular site visits, coordinating project meetings and writing visit reports
• Attend symposiums, conferences, continuing-education training and able to write manuscript for publications
• Performs miscellaneous job-related duties as assigned

Desired qualifications and experience:
• Advanced scientific degree (MSc or higher) in a relevant scientific background (e.g. epidemiology, microbiology, molecular biology, immunology, applied biology etc.) with a track record of published studies. Postgraduate degree/diploma in clinical trials would be preferred
• Good technical understanding of diagnostics would be an asset. Previous experience in TB and/or other infectious diseases would be preferred
• Ability to work independently, coupled with management and organizational skills with at least 3 years relevant experience in clinical trial planning, execution and monitoring, preferably diagnostic trials
• Knowledge of GCP and the ethical and regulatory framework for clinical trials
• Previous experience of coordinating HMSC and regulatory approvals would be preferred
• Excellent time management skills, able to prioritize tasks and set goals efficiently
• Basic computer applications like Word, Excel and PowerPoint, plus knowledge of electronic data capture (EDC) and experience with CRF development
• A team-oriented approach with strong written and oral communication skills
• Performs other duties as assigned by management / line managers

Nature of appointment:
The selected candidate will initially be offered a six-month consultancy contract from the date of assignment. The position will be extended subject to satisfactory performance, project extension and fund availability.

Compensation:
The gross remuneration budgeted for the position shall be commensurate with the qualifications, experience and salary history of the selected candidate.

Deadline to send your application:
Please mail a motivation letter, a detailed resume and three references to HR-IN@finddx.org by 7 June 2020

(But don’t wait until the deadline! We will start screening right away and if we find the right person, we will stop searching.)

Please note that only applicants meeting the profile requirements will be personally contacted. Applications sent by recruitment agencies will not be considered.