



Call for proposals for evaluation of new TB diagnostics and testing strategies

The NIH-funded Initiative for *Feasibility of Novel Diagnostics for TB in Endemic Countries* (FEND-TB) led by Rutgers University and FIND (Grant <u>1U01AI152084-01</u>) invite developers of TB diagnostics to submit proposals for evaluation of early-stage TB diagnostics and novel testing strategies.

The FEND-TB initiative provides access to adaptable and open trial protocols, with the aim to conduct clinical studies, laboratory evaluations of prototype assays, and economic analysis, along with transmission modelling.

Benefits from participating in the FEND-TB initiative

- Free-of-charge independent evaluation in state-of-the-art clinical trials conducted in up to 5 sites across Africa, Asia, and South America for feasibility and evaluation studies
- Rapid feedback on the performance of the technologies and their most effective use in endemic settings
- Laboratory-based evaluation of assays using banked samples before entry to clinical evaluations to assess if prototype modifications are warranted to improve functionality or accuracy
- Economic and transmission modelling to examine the impact of novel TB diagnostic assays on performance of the TB care cascade, long-term health outcomes and cost-effectiveness
- Support from FEND-TB experts to tailor fit-for-purpose product development plans to accelerate evidence generation for policy and regulatory review

FEND-TB accepts submissions from the following test categories

- Non-sputum-based diagnostics and/or sampling strategies for detection of *M. tuberculosis* bacterial and host targets
- Diagnostics developed for Pediatric TB
- Diagnostics developed for subgroups, e.g., HIV-infected individuals
- Sputum and non-sputum-based diagnostics developed for use at the point of care (POC)
- Diagnostics enabling rapid drug susceptibility testing at or near POC

FEND-TB studies will be done at 5 clinical sites encompassing multibacillary and paucibacillary TB, pulmonary (PTB) and extra-pulmonary TB (EPTB), drug susceptible and drug resistant PTB, both sexes and all ages, HIV-positive and negative people, and key comorbidities including diabetes mellitus.

Partner eligibility and selection process

Expressions of interest (EOI) are to be submitted via FIND's <u>Technology Scouting Submission</u> <u>Webform</u>. Please select 'Tuberculosis' as the 'Disease Area' and 'FEND-TB' as the 'Disease Area Subtype' on the form and upload the completed submission template and supporting materials.

Following submission, technologies will be reviewed by the FEND-TB Evaluation Committee, and selected technologies will be invited to a joint development of a tailored project plan.

FEND-TB will review submissions at quarterly intervals and submissions are encouraged as early as possible for planning purposes. The deadline for receipt of EOIs for this round is **31 January 2024**.

If required, FIND can sign a Confidentiality Disclosure Agreement with interested developers prior to their form submission. Please contact us on fend@finddx.org

