



## Call for trial partners:

Multicentre clinical study to assess the performance of the Bioneer Q-RFIA PCR kit on IRON qPCR for M/XDR-TB detection to inform WHO policy

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April 2020

## **Background**

FIND ([finddx.org](http://finddx.org)) is soliciting applications for trial sites interested in evaluating the performance of the **Bioneer Q-RFIA PCR kit on IRON qPCR** for rifampicin, isoniazid, fluoroquinolone, and aminoglycoside resistance detection.

The partnership between FIND, Bioneer and the International Tuberculosis Research Centre (ITRC, Korea) is addressing the need for an M/XDR-TB diagnostic solution for patients in settings with a high burden of drug-resistant TB through the development, evaluation and introduction of the cartridge-based Bioneer Accupower Q-RFIA PCR kit on the IRON qPCR instrument.

We are aiming to perform a prospective evaluation of this new assay to assess the clinical performance of the Bioneer Accupower Q-RFIA PCR kit on the IRON qPCR device in settings of intended use and inform global and national policy decision-making.

This call is to identify trial partners and sites to conduct assessments of the clinical performance of this diagnostic assay. FIND will provide both technical and financial support for the trials.

### **Requirements for the trial sites are as follows:**

- Must be located in low- or middle-income countries in a setting with a high burden of TB and MDR-TB
- Must be able to enroll approximately 350 participants within an eight-month period
- Must have an on-site laboratory or nearby referral laboratory where routine TB testing is available (including smear microscopy, GeneXpert and phenotypic DST)
- Must have a good laboratory and trial infrastructure and/or experience with previous diagnostic trials
- Sites with access to stored sputum samples from individuals with drug-resistant TB who have consented for their remnant samples to be used for research purposes will be preferred

Must be able to conform with good laboratory and clinical practice (GCLP/GCP)

### **Timelines:**

- Expression of interest (cover letter) and site description form ([provided separately](#)) are to be submitted by **31 May 2020** by e-mail to [margaretha.devos@finddx.org](mailto:margaretha.devos@finddx.org)
- A first round of selection will be carried out and the results will be announced mid-June 2020.
- FIND will perform site assessments of shortlisted sites
- Decision on the final site selection will be done by end-July 2020.
- Site initiation and enrolment is expected to start in January 2021.

This call will close on 31 May 2020. Send your submissions before **17:00 CEST on 31 May 2020** to:

Margaretha de Vos – [margaretha.devos@finddx.org](mailto:margaretha.devos@finddx.org)

For further questions, please contact:

Margaretha de Vos – [margaretha.devos@finddx.org](mailto:margaretha.devos@finddx.org)

Adam Penn-Nicholson – [adam.penn-nicholson@finddx.org](mailto:adam.penn-nicholson@finddx.org)