

TB Clinical Diagnostics Research Consortium (CDRC)

**A New Resource for Development of
TB Diagnostics**

Confidence in the field of TB diagnostics, in general, has been undermined by inordinate variability in test performance due to inadequate study designs, small sample sizes, poorly characterized clinical populations, inadequate quality control of laboratory endpoints, lack of a standard prototype and researcher bias

Banoo S, *Nat Rev Micro* 2006

What we are:

- **Consortium of scientists, clinicians, support personnel**
- **Affiliated with experienced clinical trials sites in TB endemic countries**
- **Established by NIAID contract awarded September 30, 2009**

Mission

- To provide data on the performance of investigational diagnostics **AND** *their potential impact on TB management algorithms in endemic countries*
- To inform and advise scientists, manufacturers

CDRC – *Early* in Developmental Pipeline

***Feasibility studies* validate proof of principle and provide adequate preliminary data to warrant initiation of test development.**

(*Evaluation studies* of a product that has completed development, design-locked, ready for scaled-up manufacture)

Who we are:

J. Ellner	Principal Investigator	Boston Med Ctr
S. Dorman	Co-PI, Director of Clinical Studies	Johns Hopkins
M. Perkins	Chief Scientific Officer	FIND
D. Alland	Scientific Director	UMDNJ
L. Moulton	Director of Biostatistics	Johns Hopkins
D. Hom	Director of Operations	UMDNJ
C. Barry	Chief, Intramural TB Research	NIAID
N. Dianis	Project Leader	Westat
R. Chaisson	Ad Hoc	Johns Hopkins
B. Kampmann	Director Pediatric Studies	Imperial College

Other Key Personnel

K. Lacourciere	Project Officer, NIAID
C. Sizemore	TB Program Officer, NIAID
Dikoe Makhene	Director of Protocol Review, NIAID
External Advisory Board	TBN

Where we work - Clinical Sites:

Infectious Diseases Institute, Makerere University	Kampala, Uganda	Y. Manabe M. Joloba R. Mugerwa
Núcleo de Doenças Infecciosas, Universidade Federal do Espírito Santo	Vitoria, Brazil	R. Dietze M. Palaci
University of CapeTown	Cape Town, South Africa	M. Nicol H. Zar
International TB Research Center	Masan, South Korea	R. Cho C. Barry, III

Clinical Sites

Site	HIV Prevalence	Drug Resistance
Brazil	-	-
Uganda	+	-
S Korea	-	+
S Africa	+	+

What we do:

- **Non-interventional clinical studies in appropriate populations**
- **Evaluate new diagnostics, advise scientists and manufacturers**
- **Coordinate activities with other NIH contracts, TBTC, other networks**

We would like to be:

- **Resource to TB community; advice to scientists, small businesses, manufacturers**
- **Develop novel approaches to testing diagnostics within the clinical algorithm**
 - **special populations**
 - **value-added of tests**

What we do *not* do:

- **Support development of diagnostics or clinical trials infrastructure**
- **Perform interventional trials**
- **Perform registration trials**

How to Contact Us:

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- J. Ellner – jerrold.ellner@bmc.org
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- D. Alland – allandda@umdnj.edu
- Respond to RFPs