Consortium for TB Biomarkers (CTB2) Biorepository

CPTR 2016 WORKSHOP
WASHINGTON DC, APRIL 4, 2016

ON BEHALF OF CTB2
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Funders:

Partners:

CTB2 Biorepository

IDENTIFYING TB BIOMARKERS, ACCELERATING TREATMENTS

Composition:

- 1,000 pulmonary TB patients (currently 685 patients enrolled)
- Samples & clinical data provided at 7 scheduled times; baseline through 12 months post-treatment, plus at recurrence/withdrawal

CTB2 is supported by:

FDA | Bill & Melinda Gates foundation | National Institute of Allergy and Infectious Diseases | TB ALLIANCE | TBTC TB Trials Consortium | ACTG AIDS CLINICAL TRIALS GROUP

CTB2 objective:

- To collect, store and provide biological samples and data from well-characterized, longitudinally-followed, culture-confirmed pulmonary TB patients to support research on biomarkers of TB treatment effect at the late-phase validation stage.

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Samples in the biorepository

- Participants:
  - Adults ≥ 18 years old with newly diagnosed, smear or Xpert positive, culture-confirmed, drug-susceptible pulmonary TB
- Sample and Clinical Data Collection Time Points
  - Baseline; Treatment Weeks 2, 4, 8, 17, 26, 52; Withdrawal or Recurrence
- Outcomes
  - Status determined 18 months after treatment initiation

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Biospecimens available

- Sputum
  - After collection for clinical trial or study purposes. Entire available volume stored, no processing or splitting
- RNA from whole blood
  - 2.5 mL of whole blood collected in PAXGene(R) tube, RNA extracted and stored; Processed for long-term storage into 40 µL aliquots of extracted RNA
- QuantiFERON from whole blood
  - Collected into QuantiFERON tubes (Nil, Mitogen, and TB Antigen); Each tube split into 50 µL aliquots (4 aliquots per tube)
- Plasma
  - Blood collected into 6.0-mL EDTA; Processed and split into multiple 100 µL aliquots
- Urine
  - Spot urine collected into 11-mL container; Processed into multiple 1.0 mL aliquots

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Contributing studies

REMox TB was designed to test whether a moxifloxacin-containing treatment regimen of just four months can cure drug-sensitive TB patients at rates that are non-inferior to those achieved with the standard six-month TB regimen. *99 Patients*

Sponsored by the TB Alliance, the NTP Biostorage Study collects samples according to the CTB2 TB Biorepository standard schedule, and patients continue to be treated at NTP clinics according to NTP norms. *400 Patients*

TBTC Biostorage Study 36A enrolls patients from the Study 36 Platform Study for Assessment of TB Treatment Outcomes. *250 patients*

CTB2 TB Biorepository Participants and Samples

	Number of Patients Contributing Biospecimens and Number of Aliquots Stored as of Dec 2015	Number of Patients Completed, Outcomes Evaluated as of Dec 2015	Number of Patients With Recurrence or Treatment Failure as of Dec 2015	Number of Patients Cured as of Dec 2015	Number of Patients Still in Followup or Clinical Evaluation as of Dec 2015	Number of Patients with Insufficient Followup for Outcome Determination
REMoxTB Clinical Trial	99 Patients; 27,370 Aliquots	99	7	92	0	0
National Treatment Program	400 Enrolled; 116,381 Aliquots	227	10	206	173	11
TBTC Protocol	186 Enrolled; 25,909 Aliquots	0	NA	NA	170	NA
TOTALS	685 Patients; 169,660 Aliquots as of December 2015	326	17	298	342	11

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Total Expected Number of Patients and Samples in Biorepository

	Number of Patients Expceted	Expected Aliquots in Long-Term Storage
REMoxTB Clinical Trial	99	27,370 (Actual)
National Treatment Program	400	123,200
TBTC Protocol 36A Substudy	251	77,308
Other	250	77,000
TOTALS	1000 Patients	304,878 Aliquots in Storage

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Soon to be contributing:

TBTC Study 31: Phase 3 Randomized Clinical Trial of Rifapentine-containing Tuberculosis Treatment Shortening Regimens (S31/A5349). ClinicalTrials.gov Identifier: NCT02410772

250 patients from ACTG participating sites will be enrolled under ACTG A5302 biobankng substudy protocol.

CTB2 Biorepository Key Features

- Consistent Inclusion/Exclusion criteria, Standardized sample collection, processing and storage procedures
- Fisher Bioservices kits and collection tubes
- Comprehensive barcoded tracking of all biospecimens and aliquots
- CTB2 executive committee oversight and governance
  - Including ongoing management of regulatory or shipping issues
- NIH study section approach adopted by CTB2 peer review committee (using NIH guidance on COI and disclosures).

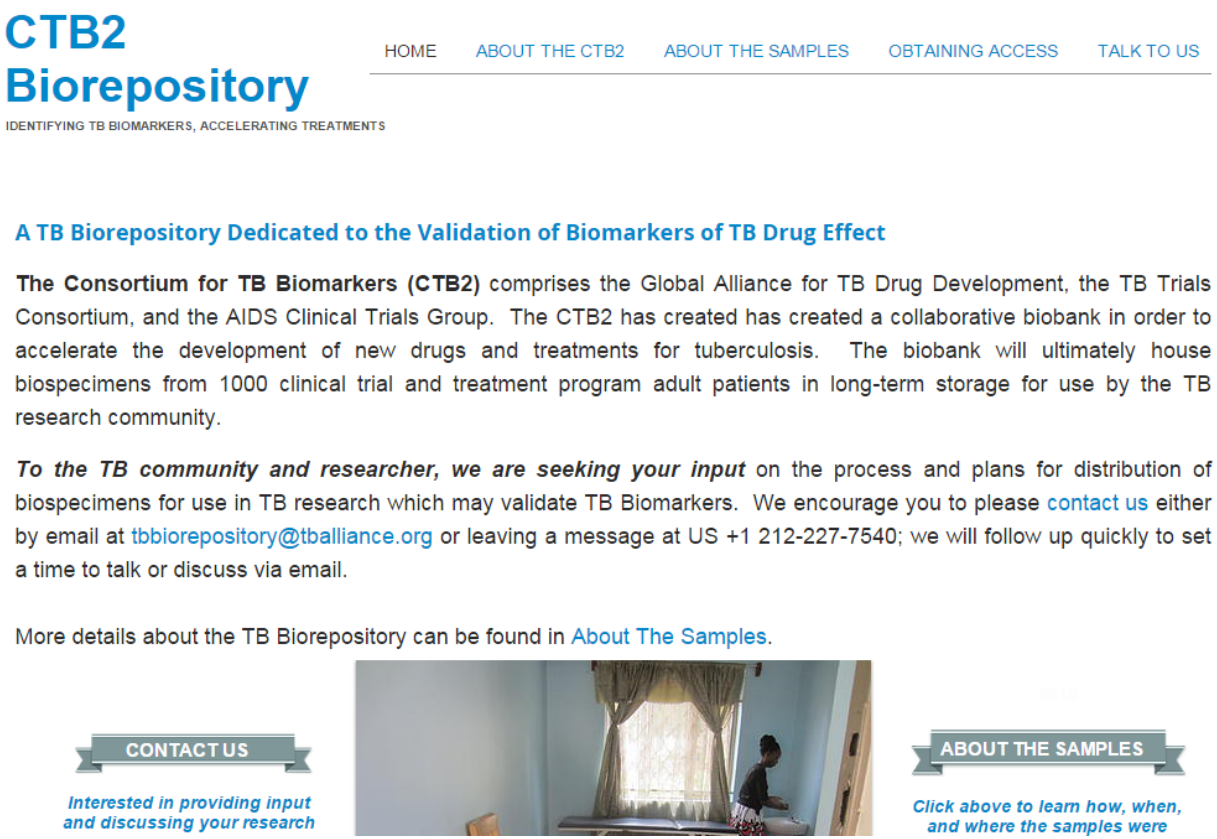
Where to get more information

CTB2 WEBSITE

www.tbbiorepository.org

EMAIL CONTACT

tbbiorepository@tballiance.org



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How to apply for biospecimens

- RFA's announced on www.tbbiorepository.org
  - **Next RFA date: April 29th, 2016**
  - Discussions with CTB2 strongly recommended prior to application submission
  - Review of proposals and determination of awards via CTB2 peer review committee
  - Add your name to the RFA distribution list by emailing your contact details to tbbiorepository@tballiance.org

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Acknowledgements

CTB2 Executive Committee	
Connie Benson	ACTG
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Michael Vjecha	CDC - TBTC
Gerhard Walzl	INDEPENDENT
Frank Weichold	FDA

- **US FDA: 3 year grant (2010-2013)**
- **NIAID: 5-year grant (2012-2017)**
- **Bill and Melinda Gates Foundation (BMGF) for continued support**
- **Participating network sites, and leadership of ACTG, TBTC, TBA**
- **Program Management – Connie Woodlief Moreadith**
- **The patients agreeing to participate and provide samples for research.**