中国结核病临床试验合作中心
China Tuberculosis Clinical Trial Consortium (CTCTC)

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RePORT INTERNATIONAL COORDINATING CENTER

RePORT- China
China Tuberculosis Clinical Trial Consortium (CTCTC)

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RePORT-China CTCTC Characteristics -1
Background

- Joined RePORT International in Jan., 2017 and is established on CTCTC platform.
- Co-Funded by consortium, sites and NIH CTCTC project. Parent studies are funded by Chinese Ministry of Science and Technology.
- Specimen stored at participating sites.
- Coordinating and data management center is located in Beijing Chest Hospital.
- Currently not participating cross-consortium projects, but are interested.

Map of China and the Report-China pilot study sites

Site locations(7)

Bei Jing
Tian Jin
Chang Sha
Zhen Jiang
Shen Zhen
Wu Han
Fu Zhou

RePORT-China CTCTC Characteristics -2
Parent Studies

Area	Description of Study	Enrollment target	Sponsor	Start date	Current Status
DS Treatment	Efficacy of shorter course chemotherapy for new smear positive drug susceptible pulmonary tuberculosis	3,900	China Ministry of Science and Technology (MOST)	Sep.2016	Enrolling
MDR-TB Treatment	Real world MDR-TB cohort study	500	MOST	Jan.2018	Preparation
New Drug Introduction and Protection project (NDIP)	• Develop a mechanism • Effectiveness and safety evaluation of BDQ-containing regimen • Pharmacological Vigilance of BDQ	1000	Gates Foundation and Janssen Company	Nov.2017	Preparation

Common Protocol Status: Cohort A

- Identified Shorter DS-TB treatment trial as parent study.
- Common Protocol has been translated into Chinese and reviewed by sites.
- Operation manual and CRF printed and sent to sites.
- Site visits conducted to evaluate capacity and provide on-site training. (Dr. Ryoo of Westat and CTCTC central team)
- Discussion with sites was held and sample collection scheme were modified to fit the parent study (i.e. 18-week treatment).
- One site is enrolling (Changsha). Effort is ongoing to support initiation at other sites.

Specimen colleting protocol on use for DS-TB cohort

Specimen type	Collection volume(ml)	Collection time points	Reagent for stability(ml)	Cryopreservation volume/tube(ml)	No. of tubes
Whole blood RNA	2.5	B/L,M1,M2,End of TX or TX F/R/W	6(already in the tube)	2	4
Whole blood DNA	4	B/L	0	1	2
Serum	6	B/L,M1,M2,End of TX or TX F/R/W	0	0.5	4
Urine	50	B/L,M1,M2,End of TX or TX F/R/W	0	10	4
Sputum	3-5ml	B/L,M1,M2,End of TX or TX F/R/W	1(manual adding)	1	4
MTB isolate	Actual amount	B/L,M1,M2,End of TX or TX F/R/W	8(manual adding)	2	4

Note: B/L=baseline; Tx=Treatment; F/R/W=failure/ relapse/withdrawal

Common Protocol Status: Cohort B

We are actively exploring cohort B parent study.

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Thank you!