RePORT- China

China Tuberculosis Clinical Trial Consortium (CTCTC)

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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.
Site locations(7)

Bei Jing
Tian Jin
Chang Sha
Zhen Jiang
Shen Zhen
Wu Han
Fu Zhou
## RePORT-China CTCTC Characteristics -2
### Parent Studies

<table>
<thead>
<tr>
<th>Area</th>
<th>Description of Study</th>
<th>Enrollment target</th>
<th>Sponsor</th>
<th>Start date</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DS Treatment</strong></td>
<td>Efficacy of shorter course chemotherapy for new smear positive drug susceptible pulmonary tuberculosis</td>
<td>3,900</td>
<td>China Ministry of Science and Technology (MOST)</td>
<td>Sep.2016</td>
<td>Enrolling</td>
</tr>
<tr>
<td><strong>MDR-TB Treatment</strong></td>
<td>Real world MDR-TB cohort study</td>
<td>500</td>
<td>MOST</td>
<td>Jan.2018</td>
<td>Preparation</td>
</tr>
</tbody>
</table>
| **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 collecting protocol on use for DS-TB cohort

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

Note: B/L=baseline; Tx= Treatment; F/R/W=failure/ relapse/withdrawal
We are actively exploring cohort B parent study.
Thank you!