Conducting High Quality TB Clinical Trials in China

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Topics to be covered

- TB epidemic in China
- Current TB clinical trial capacity
- Advantages and challenges
- Recent NIAID activities
A few facts about TB in China

- China has the **second largest TB epidemic** in the world (only after India) and it also has the **most** MDR-TB patients.

- After the spread of SARS, the TB control system was strengthened significantly.

- The economic prosperity has led to dramatic funding increase for TB control in recent years.
## Pulmonary TB cases in 2010

<table>
<thead>
<tr>
<th></th>
<th>Smear+ cases</th>
<th>Smear- cases</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>New</strong></td>
<td>429,800</td>
<td>420,300</td>
<td>904,000</td>
</tr>
<tr>
<td><strong>Drug Experienced</strong></td>
<td>54,000</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### MDR/XDR-TB epidemic in China

<table>
<thead>
<tr>
<th></th>
<th>New (%)</th>
<th>Retreat (%)</th>
<th>Total (%)</th>
<th>Estimated cases /year</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MDR-TB rate among TB patients</strong></td>
<td>5.71</td>
<td>25.6</td>
<td>8.32</td>
<td>120,000</td>
</tr>
<tr>
<td><strong>XDR-TB rate among TB patients</strong></td>
<td>0.47</td>
<td>2.06</td>
<td>0.68</td>
<td>10,000</td>
</tr>
</tbody>
</table>

Topics to be covered

- TB and TB control systems in China
- **Current TB clinical trial capacity**
  Advantages and challenges
- Recent NIAID activities
## On-going TB clinical trials in China

<table>
<thead>
<tr>
<th>Drug</th>
<th>Period</th>
<th>Sponsor</th>
<th>Study sites</th>
</tr>
</thead>
<tbody>
<tr>
<td>OPC-67683</td>
<td>2008-</td>
<td>Otsuka Pharmaceutical Co. Ltd</td>
<td>Beijing, Shanghai, Shenzhen</td>
</tr>
<tr>
<td>TMC-207</td>
<td>2010-</td>
<td>Johnson &amp; Johnson Pharmaceutical Ltd</td>
<td>Beijing, Shanghai, Shenzhen</td>
</tr>
<tr>
<td>Moxifloxacin</td>
<td>2011-</td>
<td>TB-Alliance</td>
<td>Beijing, Tianjing, Shanghai</td>
</tr>
<tr>
<td>Clofazimine</td>
<td>2010-</td>
<td>Beijing Chest hospital</td>
<td>Beijing, Chongqing</td>
</tr>
</tbody>
</table>
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- Current TB clinical trial capacity
- Advantages and challenges
- Recent NIAID activities
China was chosen because it has the largest urban patient population in the world - providing a vast patient pool - in addition to a huge network of hospitals with over 2.5m doctors, nurses and technicians, all on significantly lower salaries than their western counterparts.

China, despite its bureaucracy, government red tape and questions over intellectual property, has stolen the top spot from India who is seemingly more active in this arena and more in tune to the needs of the West.
Advantages conducting clinical trials in China

- Large patients population: 1 million new PTB cases/year
- Low cost: 1/3 or 2/3 in comparison to Western Countries
- Excellent condition and resources in many major hospitals
- Increased disease awareness and enthusiasm for international collaborations
- Numerous clinical trials in other fields of medicine
- Strong support from MOH, SFDA, CMA, CDC
  - National Key Technology R&D Program (11th and 12th Five year Plan): New anti-TB drugs R&D clinical evaluation platform
Chengdu Infectious Disease Hospital

100% patient word occupancy!
New Chengdu Infectious Disease Hospital
Beijing Chest Hospital
Beijing TB and Lung Cancer Institute

- Established in 1955
- 250 TB beds
- 250 beds for lung cancer
- 100% occupancy
- Several international clinical trials
Shanghai Chest Hospital

- Established in 1933
- 250 TB beds
- Leading TB education institution and international collaboration center
- Negative ventilation
Tianjin Chest (HaiHe) Hospital

- 04年抗击SARS后组建海河医院

Over 800 patient beds
Annual income 150 million Chinese Yuan
New technologies treating TB

肺结核空洞介入

Dr. Li Liang
Tianjin CDC
Guangzhou Chest Hospital
GeneXpert in Guangzhou Chest Hospital
Shenzhen Donghu Hospital
TB, Hepatitis, and HIV

- Adjacent to HK
- Live diseases: 200 beds; 210,000 patient visits
- TB: 120 beds, 30,000 patient visits
- HIV/AID: 23 beds, 50,000 patient visits
- Perhaps it has the most advanced equipment and technologies among hospitals in China
Challenges conducting clinical trials in China

- Lack of clinical trial infrastructure (6/206)
- Ethical and DSMB committees
- Regulatory barriers
- Language insufficiencies
- Culture differences
- Concurrent alternative medicines
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“The success of our joint TB research program would not be possible without the continued support and cooperation of the United States and Chinese governments working at the national and provincial levels to bring together expertise and collaboration opportunities …..”

“I look forward to a future when US-China leadership in combating TB, through concrete projects such as our joint research partnership in Henan, makes significant, transformative advances in the diagnosis, treatment, and management of TB worldwide …..”

Anthony S. Fauci
China Daily, 2011-03-24
Building an international collaboration with NIH and others in TB clinical research
April 15, 2011, Beijing
TB Clinical Research Consortium

- Members: China TB experts and international consultants

- Mission:
  - To establish, support, and facilitate global collaborations for international standard multi-center clinical trials.
  - To harmonize standard approaches for high quality clinical TB studies
  - To engage partnerships and training activates
Current NIH sponsored HIV/TB international clinical research sites
Projected Future Clinical Trial Sites

Current NIH sponsored HIV/TB international clinical research sites
Thanks and Questions