National Centre for Communicable Diseases

Mongolian TB Coalition

# TREAT TB
# MDR-TB Clinical Trials Capacity Building Webinar Series

## Challenges with MDR-TB Clinical Trial Implementation – Sponsor and Site Perspectives

**Regulatory Requirements – Import and Export Permits**

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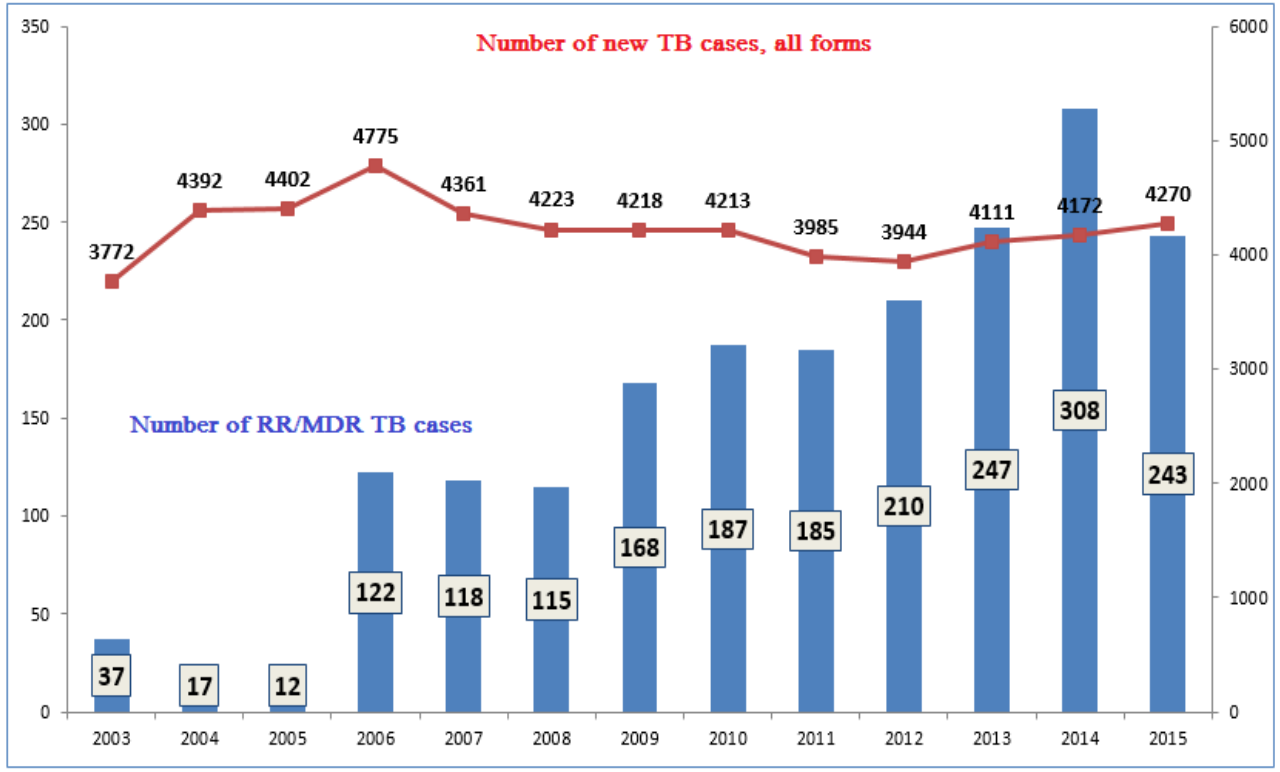
# Outline

- Overview of site
- Strategies, Challenges, and Lessons Learned
  - Regulatory Approvals
  - Import Permits
  - Export Permits
- Conclusions

# Overview of Site


## Number of MDR/RR-TB cases notified (2003-2015)



# STREAM site: National Centre for Communicable Diseases (NCCD)

- Established in 1986 with the help of Russians
- 7 hectares land
- 23 separate buildings
- TB hospital joined in 2001
- National TB Reference Laboratory

# Regulatory Approvals

**Challenges related to the Regulators:**

- Lack of experience with clinical trials
  - Concern of patients safety
  - Concern with reporting (Protocol deviations, SAEs)
- Critics related to the trial protocol and Patient information sheets
  - Wording, not site specific etc.
  - Rationale for the major amendments in the Protocol

- Concern to accept some of the amendments:
  - Pressure from the public on issues related to children (Harvard vit D study)

# Regulatory Approvals

- **Challenges related to the trial sponsor:**
  - Frequent amendments to the study Protocol and related documents (2 times since the Stage 2 approval was obtained)
  - Some major amendments are not so relevant to the site (Permissible ART)
  - Translation of study documents and back translation
  - Sample storage
- **Challenges related to the site:**
  - Pressure on the site to obtain approvals
  - Preparation of approval applications
  - BDQ is not registered on the essential drug list of the country
  - Attempts to register BDQ

# Regulatory Approvals

- **Strategies to streamline processes for obtaining approvals and ensure reporting requirements are met:**
  - Meeting with all stakeholders before the trial initiation (MoH, Ethics committee, NTP, hospital administration, clinic staff, WHO, Global Fund)
  - Programme-based trial activities
  - Obtain hospital administration support
  - Quick response to the regulatory requests
  - Progress reporting (paper reports, briefing, annual meetings)
  - Respect and to abide to the national regulations
  - Good attitude towards working together and listening to their critics, comments well
  - Site openness

# IMP Importation

- **Challenges:**
  - BDQ is not registered on the National Essential Drug List, however BDQ was included in the updated TB guidelines in 2017
  - Customs clearance require several visits to the customs
  - Previously applications were done as paper applications (access)
  - Several official letters to be sent to the respective government agencies
  - Communication with all parties involved
  - Incomplete IMP documentation (Certificate of Origin, correct address, weight for each item)
  - Equipment sent through DHL

# IMP Importation

- **Strategies to streamline IMP importation:**
  - Stakeholders meetings before the trial initiation, e.g. MoH, Ethics committee, NTP, WHO, Global Fund, hospital administration, clinic staff
  - Hospital administration and NTP support
  - Working close relation with the NTP and reporting, meeting

  - Second line drugs were supported by the Global Fund and the NTP had an experience of obtaining drug importation license
  - Experience of site pharmacists working for NTP (MDR TB drug focal point)
  - Local courier experience
  - Inclusion of BDQ in the WHO essential drug list in 2015
  - Customs fee

# Export Permits

- **Challenges:**
  - Regulatory authorities are cautious exporting bio samples
  - Restrictive airline policy to carry Category A bio samples
  - Decontaminated samples (Cat B):
    - Increased number of samples
    - Workload to lab staff
    - Many export permits
    - Process of obtaining permits require time
  - No feed back to the local lab about exported samples

# Conclusions

- Importance of the trial to be programme-based and the main staff to have experience working with the NTP and MDR TB patients at the national level
- Involvement of all stakeholders at the beginning and informing and reporting them about the progress of the trial
- Regular safety reporting
- Creation and maintenance of good collaboration with the hospital, NTP, as well as donors (WHO, GF)
- Partnership of government and non-government organisations (National Centre for Communicable Diseases and Mongolian TB Coalition)
- Team work of dedicated staff with good attitude
- Good communication and patience

# Questions