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
Dr. Bazra Tsogt

National Centre for Communicable Diseases
Ulaanbaatar, Mongolia
July 10, 2018
Outline

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