Development of CDISC Tuberculosis Data Standards

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Structure of Presentation

TB Landscape

TB Data Standards Pilot

Application to other Areas

Discussion Points
TB Landscape

No new TB drugs submitted in 8 years

Drug-resistance to current therapies

The need to accelerate new TB drug development

The case for TB data standards
TB Data Standards Pilot

Objective: To advance CDISC TB data standards, establishing a common language for TB efficacy data, and thereby benefiting the TB community.
Pilot Key Participants

- Jane Diefenbach - PharmaStat LLC / CDISC
- Quintiles
- Centers for Disease Control and Prevention
- Phase Forward
- Octagon Research Solutions
- Formedix
- Pinnacle 21
- FDA
- Duke Translational Medicine Institute
### Trial Summary

TB Legacy study - non-standard data

- Trial duration: mid-1990’s to early 2000’s
- Pulmonary Tuberculosis
- Phase III
- >1000 patients at different sites / countries
TB Data Standards Pilot

**Method**

- De-identified the legacy data (by CDC)
- Parsed data from text fields (identified AEs)
- Assigned reference ranges to labs
- Prepared, coded, mapped data
- Applied TB specific standards
- Performed verification/conformance checks (Third party)
TB Data Standards Pilot

Challenges

- Data collected in a non-standard format is difficult to map to SDTM
- Gaps in raw data led to SDTM compliance issues and data imputation
- Non-standard structure of raw data (wide files and form based, not domain based) led to mapping challenges
Deaths recorded in several places led to inconsistencies

Not enough specificity to define the MS and MB domains. Data elements and additional qualifiers were needed. Example: Colony Forming Units (CFU) to quantitative cultured bacteria

Implementation issues

Data / conversion issues

Issues could have been avoided if legacy data collection standards were better

Identified missing data elements
## TB Data Standards Pilot

### Lessons Learned

- Variation in application and interpretation of standard
- Gaps in the standard
- Variations of conformance (need for guidelines)
- Need for experts who are well versed in SDTM to convert and use standard
- Need to implement standards upstream
- CSR could not be 100% reproduced
TB Data Standards Pilot

Guidance needed
Enhance Standards with FDA Feedback
Integrate therapeutic guidance into CDISC
Guidance document to apply the standard
TB Data Standards Pilot

Application / Benefits

- Lessons learned can be applied to other therapeutic area standards
- Identification of potential future standardization initiatives (e.g., data collection)
Why Does this Matter?

• Advance the development of new medicines for patients
  – Standard (e)CRFs
  – Standard analyses and report tables
  – Cross study integration
  – Accelerated regulatory review

Improved Quality + Accelerate Timelines = Better Drugs Faster
Discussion Points

• Is enough being done with respect to therapeutic standards (e.g., recent CDISC draft oncology standards)?
• Should there be a larger focus on efficacy domains?
• How do we get the FDA, pharma, CROs, NIH, HL7 and CDISC talking about these topics? Should there be more pilots done?
• Need for more collaboration across the industry (user networks, conferences)
Feedback Assessment

• Please Complete Evaluation!!
Thank You!

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