

Development of New Tuberculosis Treatment Regimens-- Scientific and Clinical Trial Design Considerations

July 19, 2017

Panel Discussion Topics (AM Panel Discussion):

- 1) To what extent can nonclinical studies be used for demonstrating the contribution of each component of a new regimen before advancing to clinical studies?
- 2) What are some important pharmacokinetic considerations in TB regimen development/populations of interest in order to better optimize dosing/target exposure?
- 3) How can biomarkers and diagnostic tools be used to accelerate TB drug development in Phase 2/3 studies?

Panel Discussion Topics (PM Panel Discussion):

- 1) To what extent can clinical studies be used for demonstrating the contribution of each component of a new regimen?
- 2) What are current efforts regarding additional training/adding sites that can aid in performing EBA studies? How can ethical/other considerations around EBA studies (such as use of monotherapy) be addressed?
- 3) What types of drug regimens should be prioritized in various populations, including children, pregnant women and the elderly? What are some specific challenges with regard to regimen development in such populations?
- 4) Please comment on current trial design challenges and next steps in studying better tolerated and shortened regimens with regard to enrichment strategies, generalizability of results, special populations, evolving treatment guidelines and other factors.
- 5) What can be done to facilitate collaborative efforts for all stages of drug development, including capacity building at trial sites?