Real World Data Informed Clinical Development via Modeling and Simulation

Zhaoling Meng

Gates MRI
E-mail: zhaoling.meng@gmail.com

Abstract: Historical clinical trials, electronic health records (EHR) and patient population survey provide rich information for the clinical development and enable the project planning going beyond simple assumption-based sample size justification. Modeling and clinical trial simulations (CTS) are frequently utilized to integrate these information with project knowledge and assumptions to provide quantitative assessments and scenario testing in the study and sometime project development design, increase the study/project probability of success (POS) and maximize resource input and outcome benefit balance. This talk presents case studies to illustrate the utilization, especially in complex decision-making situations. First example presented the use of Claims data in supplementing available clinical knowledge and designing a Cardiovascular (CV) safety outcome study. 2nd example illustrated the use of historical study results and targeted disease population survey to run various Phase 3 scenarios and balance the predicted benefit and cost considering a large Phase 2 result uncertainty in a vaccine study setting.