Integration of Pharmacometric and Statistical Analyses using Clinical Trial Simulations to Enhance Quantitative Decision Making in Clinical Drug Development

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Workshop Description

This workshop outlines a general framework in which clinical trial simulations are employed integrating both pharmacometric and statistical analyses to support trial design and quantitative decision making in drug development. Specifically, predictive pharmacometric models are used as data-generation models to simulate data, while data-analytic models as specified in the statistical analysis plan are used to analyze the simulated data, and to apply a quantitative data-analytic decision rule. Various probability metrics including probability of achieving the target value (PTV), probability of success (POS), and probability of a correct decision (POCD) are proposed to support study design recommendations and quantitative decision-making. A case study is presented to illustrate the clinical trial simulation methods and procedures described in this article.

Training Objectives

1. Learn how to formulate quantitative decision rules using confidence interval criteria.

2. Understand the concept of assurance or probability of success and how it differs from statistical power.

3. Understand the distinction between confidence intervals and prediction intervals and how to perform stochastic simulations using pharmacometric models to construct such statistical intervals.

4. Learn how to apply clinical trial simulation procedures to evaluate various probability metrics including PTV, POS, and POCD to support study design recommendations and quantitative decision-making.