Medidata Balance Randomization Design & Simulations

Instructor Led Training Agenda

Course Description: <Medidata Balance Randomization Design & Simulations focuses on creating and configuring trial simulations for a study using the pre-validated randomization methods available in Balance. Specifically, this course will review two main randomization methods:

- Dynamic Allocation;which allocates treatments to subjects based on the imbalance of treatments
- Permuted block, which randomizes subjects to block randomization lists

This class is a 4 hour Virtual Instructor-Led training that will walk through both randomization concepts with hands-on exercises, and analyze the simulated outputs based on the randomization design.

Approximate Duration: 4 hours[1]

Module	Topic
Welcome (10 min)	Objectives
Balance Refresher (15 min)	Demo of iMedidata Study Creation Roles and Permissions in Balance
Randomization (30 min)	Introduction to Randomization Overview of Randomization Designs in Balance Differences in Randomization Approaches Balance Study Setup Wizard
Configuring Randomization (30 min)	Adding Study Arms Adding Randomization Factors Strata

[1] Duration listed is approximated, and does not reflect activities, simulations or assessments.

Module	Topic
Randomizing Subjects from Rave (20 min)	Randomizing Subjects into Balance from Rave EDC
Break (15 min)	Break
Dynamic Allocation Randomization (20 min)	Dynamic Allocation Concept and Methods Types of Dynamic Allocation Randomization
Dynamic Allocation Simulations (30 min)	Setting up & Executing Simulations Reviewing Simulations Results
Permuted Block Randomization (30 min)	Permuted Block Concept and Methods Selecting Stratification in Balance Pre-Allocating blocks in Balance Adding Study Arms in Permuted Block Studies Enabling stratification & Pre-Allocation in Balance
Creating Permuted Block Randomization Lists (30 min)	Uploading a Randomization List Mapping a Randomization List Generating a Randomization List Viewing Randomization Lists & Blocks
Summary (10 min)	Summary