

Medidata Balance[®] Agile Randomization in the Cloud for Medical Device Trials

Medidata Balance heralds a new generation of cloud-based Interactive Response Technologies (IRT) capabilities.

- New user paradigm based on a simple, highly-configurable interface
- Choice of deployment options: unified with electronic data capture (EDC) system Medidata Rave[®] or as a standalone solution
- Best of cloud-based, agile technology to streamline design and provide real-time visibility into operations

Experience True Study Agility

As sponsors strive to realize greater ROI, clinical trials are increasingly faced with changing requirements and priorities. Traditional interactive voice response (IVR) and interactive web response (IWR) systems were designed to address static, pre-defined requirements. Medidata Balance handles not only pre-defined requirements but also enables changing requirements to be implemented quickly and easily, resulting in greater flexibility in today's adaptive environment. Now, prototypes can be established in hours, setup can be completed in weeks and an arm can be removed mid-study without the need for a vendor change order. Tightly integrated controls accompany this flexibility to ensure all changes are authorized and tracked.

Manage Trial Complexity Simply and Elegantly

Protocol complexity has increased significantly over the years, resulting in a greater range of randomization needs. Medidata Balance enables sponsors to manage complex protocol and operational requirements with ease. For example, sponsors can quickly and easily drop a poor performing study arm and reallocate the resources to other areas of the trial.

A Complete Clinical Trial Solution

Rich features extend from design through operation

- Pre-validated randomization options for permuted block or dynamic allocation
- Simulation of randomization designs for maximum design confidence
- Ability to randomize in real-time from the operating room
- Ability to copy designs instantly among studies
- Fast implementation to better meet the critical path timelines
- Self-generating specification documents and full audit trail
- Single vendor source and support
- Support desk with 24/7 global coverage

Stand-Alone or Unified IRT/EDC Solution

Balance offers a choice of deployment options, allowing sponsors and CROs to choose the method that best suits their study needs. As a stand-alone IRT solution, sponsors and CROs benefit from powerful capabilities on a study-by-study basis. As a unified, pre-validated solution with Rave, the benefits of Balance are experienced through a seamless IRT/EDC system, designed as a *unified, single solution from the ground up*.

New Cloud-Based User Paradigm

As a cloud-based solution that is accessible 24 hours a day, seven days a week, Balance offers sponsors, CROs and sites a simple interface to facilitate study design through to day-to-day operations. Balance delivers powerful configuration capabilities in a clean, intelligent interface that enables clinical Data managers, biostatisticians and other members of the research team to benefit from easy-to-define rules and design. For example, an authorized designer can easily add an arm or factor, modify variables like ratios and probabilities or run a configuration report on demand. Sites also benefit from the simple-to-use Rave interface, resulting in reduced staff training costs and an enhanced user experience.

Robust Randomization Design

Balance offers a choice of pre-validated methods for rapid study planning and start-up. Permuted block studies can be set up in minutes and, with integrated block list generation or the uploading of externally-generated lists, the process is smooth and seamless. For studies using dynamic allocation, Balance offers a built-in, pre-validated algorithm that can be configured in minutes. The built-in simulator enables study teams to immediately analyze the chosen randomization design, comparing the balance achieved using either the permuted block or dynamic methods. For example, randomization design can be adjusted quickly and easily after the trial has gone live, giving greater responsiveness to changing study needs.

About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

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