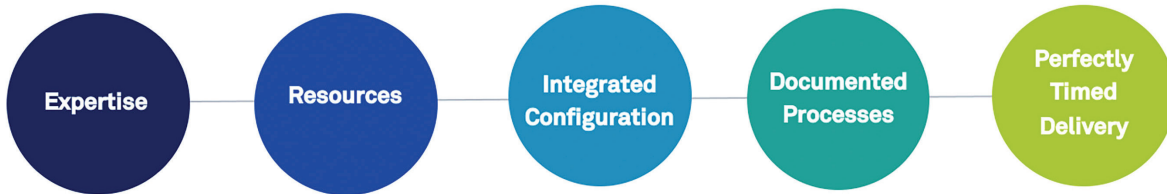


Medidata Professional Services - Optimize Randomization and Trial Supply Management



Medidata’s Professional Services RTSM (Randomization and Trial Supply Management) experts have a deep understanding of the IRT/RTSM industry. We partner with you every step of the way to ensure your RTSM processes are optimized by providing recommendations and best practices so you can achieve the highest value from our unified platform, the Medidata Clinical Cloud™. Professional Services support can range from full build and execution to Live Study Management™ (LSM), where we partner with you to execute some or all of your study conduct and trial supply requirements. Medidata Professional Services also specializes in supply management and will guide you towards the most impactful supply strategy to meet your goals. We evaluate and recommend the best approaches to minimize costs and waste and ensure that all your patients are treated as scheduled.

Benefits

The Medidata Professional Services RTSM team has extensive experience with managing RTSM solutions in clinical trials of all indications and phases.

Extension of Your Team

- Works with you to ensure success at every phase of implementation
- Provides insights and recommendations on randomization, dispensation and supply management needs.
- Adjusts support according to your needs

Deep Expertise

- Developed and executed supply management strategies across every study type and size
- Managed 100s of adaptive trial and mid-study variations
- Proposed recommendations derived from insights into best practices
- Translate design considerations based on visibility into EDC

RTSM Innovation Insight and Support

- Manages and support Direct-to-Patient studies and trial virtualization
- Manages and supports integrations with any depots or forecasting vendors
- Provides updates on all study metrics and trends

Customer Satisfaction

- We are committed to your study success and satisfaction
- Dedicated RTSM SMEs from study kick-off to study close-out
- Ranked highly by our customers (see quote on next page)

Product Benefits

The Medidata Professional Services RTSM team has extensive experience with managing RTSM solutions in clinical trials of all indications and phases.

Study Maintenance

- Packlist or randomization list uploads
- Cohort management and cap adjustments
- Supply plan changes and additions
- Inventory and expiry updates
- Lot/QP release

Project Management

- Status meeting attendance with your team
- Generation of RTSM reports for status meetings
- Mentorship on best use of system and advisement on any study design changes associated with future protocol amendments

Operational Support

- Available 24/7/365 for any RTSM-related issue
- Emergency unblinding capability

Medidata Live Study Management Ensures Efficiency

Medidata's Live Study Management Services partners with you to reexecute some or all of your study conduct and trial supply requirements, including:

- **Consulting Services** - Consulting support for everything from study designs for randomization to dispensation to all facets of supply management
- **Oversight of Study Progress** - Monitoring of study progress on an ongoing basis, including enrollment and trial supplies while making recommendations to changes in supply strategies
- **Support for Protocol Amendments** - Protocol amendment review while recommending and implementing study changes to the original design
- **Manage Study Changes** - Opening/ closing cohorts while the study is underway, adjusting patient caps for cohorts, and study design and supply strategies/plans

“The SCTU Data Management team has accelerated their digital transformation utilizing the Medidata unified platform and professional services support to deliver complex COVID-19 AGILE platform trials using Rave EDC, RTSM and eConsent in weeks instead of months.”

Susannah Condie, Head of Clinical Data Management
Southampton Clinical Trials Unit, University of Southampton

The Medidata Advantage

The Medidata Professional Services RTSM team has the experience, knowledge and passion to ensure that your RTSM trial experience is positive and successful. From our deep understanding of different randomization algorithms to complex dosing and titration treatments to making recommendations, to how best to supply sites and patients with supplies, we will work tirelessly to optimize and provide the value of the Medidata platform and the unification between Rave EDC and Rave RTSM.

Medidata, a Dassault Systèmes company, is leading the digital transformation of life sciences.

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