

# Medidata Balance<sup>®</sup> Change Management Service

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## Expedite Medidata Balance Adoption:

Medidata Balance Change Management Service helps sponsors realize the full value of their Balance investment, helping to rapidly enable system utilization and avoid the costs and long implementation timelines associated with full-service vendors.

Engagement starts with review and documentation of the current RTSM operating model baseline and a risk assessment profile to ensure that the client's specific requirements are met. The future RTSM operating model is then established and gaps are assessed to understand the required capabilities for a smooth transition. Finally, the service includes detailed and careful prioritization and planning to identify how and when Balance should be adopted across the client's clinical trials.

## Document current RTSM operating model baseline to address sponsor implementation requirements

A critical component of the change management program is to understand the current operating model being used with full-service RTSM vendors. The sponsor-specific baseline is documented by identifying current organizational roles and responsibilities, business process enablement and workflows, and data and information capture.

## Review existing process documentation and stakeholder interviews to capture current operating model

By leveraging previous analysis and existing documentation, the baselining of the current RTSM operating model is expedited, ensuring the focus is on areas that require further analysis. Inclusion and engagement of relevant stakeholders through a structured interview process helps identify friction points in the current model, as well as fosters buy-in for the change management effort.

## Establish risk assessment profile to identify harmful risks

One of the key success factors in adopting Balance as an internal core competency is identifying and managing risks that typically hinder successful uptake and production implementation. That's why risk mitigation is a core theme to the change management program, ensuring business continuity as part of the transition to Balance. Our experience has indicated that sponsors who incorporate a comprehensive risk management approach into their Balance implementation program start using the solution earlier in the life cycle, while experiencing fewer start-up and production issues.

# Medidata Professional Services

**Medidata professional services** offer unmatched expertise in clinical trials and broad expertise across study phases and therapeutic areas. Whether you are a leading multinational sponsor, an innovative medical device start-up or a CRO, Medidata professional services has the skills and experience to meet your needs.

**Medidata Study Implementation Service** delivers fast, flexible, optimally designed trials. Our proven methodology and consultative approach will save you time and money.

**Medidata Sponsor Enablement Service** lets you continuously realize the full value of your Medidata solution. Training and mentoring enable you to take full ownership of your clinical trial systems and process.

**Medidata CRO Support Service** extends the full expertise of Medidata professional services to our CRO partners.

**Medidata Strategic Consulting Services** offer expertise in outsourcing governance, protocol design review, trial design and randomization, risk-based monitoring strategies and more.

## Conduct as-is business process workshop to finalize current RTSM operating model

The results of the analysis and interview phase are presented to the stakeholder team as the final step in the baselining process. This workshop is designed to modify or add to the initial process and workflow delineation, and ensure that the final output accurately reflects the current state. This is also an opportunity to validate the identified “pain points” in the organization that need to be addressed in the new operating model.

## Ensure expedited Balance uptake and successful production implementation

The intended outcome for the Balance change management program is to expedite production utilization, allowing sponsors to realize a positive ROI as early as possible in the Balance implementation life cycle and position the organization for success. In order to achieve this goal, organizational enablement and transition to an efficient, streamlined model is a critical success factor. This phase utilizes the current RTSM baseline operating model to identify the gaps and required capabilities for the new Balance operating model.

## Visioning and capability identification to incorporate best practices

Visioning sessions are conducted with each stakeholder organization to identify the new capabilities that will be introduced to implement and support Balance studies. Leveraging experience from over 80 clients who have successfully implemented Balance, we establish a proposed Balance operating model that incorporates these new capabilities and best practices as the future RTSM operating model.

## Gap assessment to understand required capabilities for model transition

With the current and future RTSM operating models defined, the gap between existing and future capabilities is assessed to determine the organizational, process and potential IT changes required. The level of effort to close each gap is quantified, along with an initial prioritization of each capability through stakeholder engagement and input. Short-term wins are also identified, as well as longer-term capabilities needed to achieve the future-state vision.

## Future-state workshop to agree and finalize new operating model

The final step in the future-state operating model process is to present the results of the visioning and capability assessment phase to the stakeholder team. This workshop again allows Medidata and stakeholders to modify or add to the initial process and workflow delineation, agree on the prioritization of capabilities and ensure that the final baseline accurately reflects the input for the future state process. The final output from the workshop sessions is the agreed baseline of the Balance operating model and the relative prioritization of capabilities required to transition the organization to the new operating model.

## Strategic Consulting Services

By powering a significant portion of the world’s clinical trials, Medidata has developed unique expertise in R&D change management and business process optimization. Available strategic services include:

### **Risk-based monitoring**

Reduce trial costs and increase site quality by developing a strategic monitoring program based on effective risk assessment and categorization.

### **Facilitated study design and review**

With optimal protocol and study design you can streamline and enhance trial processes and decrease your overall study cost and complexity.

### **Outsourcing and CRO governance**

Reduce costs and risk through optimal outsourcing governance, CRO selection and data-driven management processes.

### **Supply chain optimization**

Reduce costs and create a demand-driven supply chain. Apply best practices in packaging design, supply distribution strategy, external network integration and randomization design.

### **Business transformation**

Drive best practices and optimal study design through business transformation, change management and analytics and benchmarking.

## Ensure business continuity through risk assessment, implementation planning and stakeholder readiness

One of the primary risks to successful Balance adoption is the lack of proactive assessment and planning needed to efficiently run Balance studies. By identifying and enabling mitigation strategies for identified risks, ensuring that relevant functions are prepared to transition to the new operating model and developing a roadmap for both pilot phase and production Balance execution, the overall risk to business continuity is greatly reduced.

## Capability prioritization and implementation roadmap to assimilate Balance as a core competency

The capabilities identified during the visioning workshop provide the foundation for the implementation roadmap required to introduce the new operating model into the organization. By identifying the immediate needs, longer-term capabilities and organizational impact for these changes, plans to assimilate these new capabilities can be proactively conducted utilizing a resource constraint model to ensure the greatest benefit and risk mitigation.

## Portfolio review and planning to agree and establish future Balance utilization

Initial assessment of the sponsor's drug program portfolio for Balance applicability is included as part of the change management services. This includes recommendations for a pilot phase for initial Balance utilization, as well as identification of potential longer-term studies for a full production phase. A decision tree is utilized to ensure an objective analysis on a study-by-study basis.

## Readiness assessment to ensure successful organizational transition

The last piece of the Balance change management process is to ensure stakeholders are fully equipped with the knowledge and skill set to move forward with their new RTSM operating model. This allows a holistic approach to ensuring business continuity and expediting Balance uptake. By focusing on the key changes required for each stakeholder group, readiness criteria are established for each functional area to ensure a successful transition.

## Medidata Support for Success

The Medidata professional services team is ready to help your life science organization realize the full potential of the Medidata Clinical Cloud. We offer industry-leading expertise in clinical trial processes and technology, and broad knowledge and skills across study phases and therapeutic areas. To get started, contact your Medidata account manager or services project manager, or email us at [MedidataConsulting@mdsol.com](mailto:MedidataConsulting@mdsol.com).

## 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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