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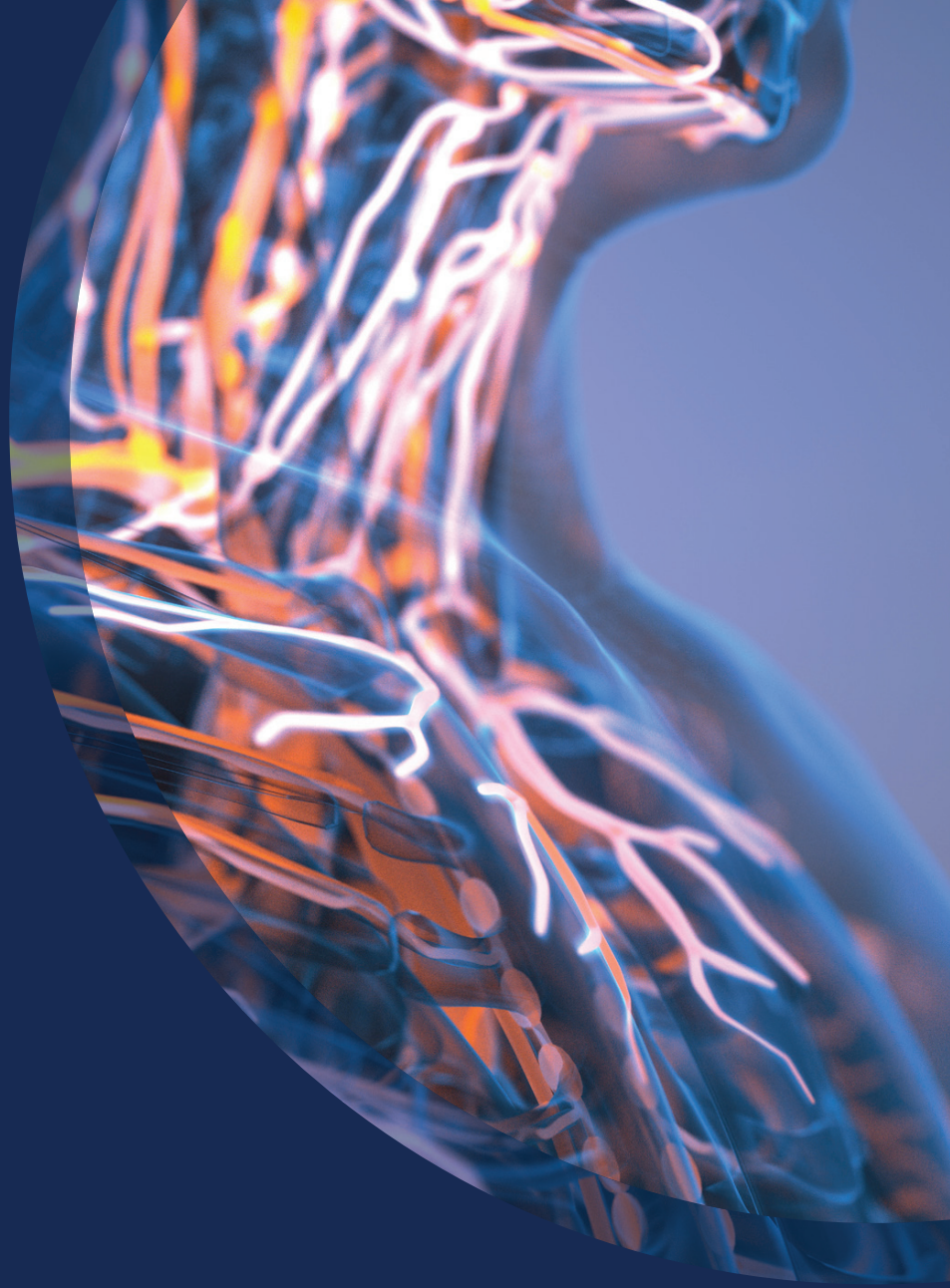

RBQM: The Connective Tissue for Data Quality

7 Ways the Human Body Inspires Better Data Quality in Clinical Trials

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Introduction

Much like the human body, the clinical trial ecosystem is intricately complex, requiring seamless integration for optimal function. This ecosystem is evolving with increasing protocol complexity, a diverse range of active stakeholders, and the necessity for real-time data access, all fostering faster, data-driven decisions.

While all are vital individual components, a clinical trial ecosystem only reaches its full capability when all parts are fully connected and working together. Like a body system out of sync, a disconnected ecosystem drives data and workflow silos that lead to quality, safety, and operational inefficiencies like increased costs, wasted resources, and delayed timelines.

The clinical trial ecosystem is made up of several moving parts:

- Massive amounts of generated data
- Increased protocol and operational complexity
- Active stakeholders

And requires:

- Data integration and access in real time
- Faster, data-driven, personalized decisions and actions
- Cross-functional flexibility and adaptability

With RBQM strategies, these silos are disbanded and trials become interconnected and, ultimately, lead to greater success.

Just as our body is only functional when all parts work together in harmony, RBQM can serve as the connective tissue of a given trial. Consider each element in the RBQM framework in the context of the human body's system:

1. **Quality by Design** acts as our immune system, interconnected with aggregated real-time data and actions
2. **The risk management system** acts as the brain of operations
3. **The data points** acts as the blood flowing through all parts of a trial
4. **The data platform** acts as the heart pumping the blood, or data, to various stakeholders in all parts of the organization
5. **Monitoring** acts as the senses, equipping stakeholders with the ability to identify risks
6. **Mitigations** acts as the medicine
7. **Self-regulation and adjustment** balancing trials acts as the homeostasis and equilibrium

Drawing parallels with the human body, this eBook explores "7 Ways the Human Body Inspires Better Data Quality in Clinical Trials" to enhance cross-functional flexibility and adaptability while addressing costly inefficiencies of disconnected systems.

1

Quality by Design Principles

The Trial's Immune System

Innate Immunity

Innate immunity to trial challenges begins with the very genesis of the trial—protocol design. From defining clear endpoints to outlining rigorous inclusion criteria, Quality by Design (QBD) ensures that the trial is built on a solid foundation, establishing a first line of defense against potential challenges.

Burden Reduction

Much like the body's need to manage stressors and minimize strain to maintain overall wellbeing, QBD principles emphasize the importance of reducing patient and site burden as early as the protocol design phase. Recognizing the significant demands placed on both patients and research sites, QBD advocates for strategies that streamline processes, minimize unnecessary complexities, and optimize resource allocation.

This may involve implementing patient-centric approaches to reduce the burden of study participation, simplifying study procedures, and enhancing communication and support for research sites. By alleviating the burdens faced by patients and sites, researchers can enhance recruitment and retention rates, improve data quality, and ultimately enhance the overall success of the trial.

Fit-for-Purpose

Another vital component of a trial's immune system is fit-for-purpose data strategy. Purposeful data strategy guides us through the maze of information to extract meaningful insights and drive informed decisions.

The QBD approach gathers a diverse array of stakeholders, extending beyond Sponsor organizations to investigators, site staff, and patients. Each group contributes unique perspectives and historical insights crucial to a trial's success.

Adaptive Immunity

Additionally, as our body's adaptive immune system fortifies itself over time by recognizing and swiftly neutralizing familiar threats, our historical data strengthens our defenses. QBD works similarly.

By looking at what we've previously learned from other studies, we can use QBD principles to fight common pitfalls. Ultimately, this accumulated knowledge empowers us to identify and mitigate risks more efficiently, minimizing complexities, redundancies, and patient burdens along the way.

2

Risk Identification and Management

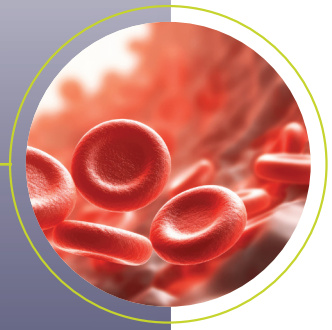
The Trial's Brain

As our brains have evolved, we've moved beyond solely relying on the amygdala, which processes primal emotions such as anger, avoidance, defensiveness, and fear. Instead, our neocortex enables us to analyze risk.

In the context of clinical trials, the process of Risk Identification mirrors the function of our neocortex, empowering us to draw upon past experiences to comprehend risks and devise effective mitigation strategies.

As the central repository, Risk Identification in clinical trials relies on critical thinking and historical insights to inform mitigation strategies, rather than relying on mere checklists. Sensing and collecting information from various stakeholders across the organization reflects the interconnected functions of the human body, emphasizing the importance of ongoing vigilance and collaboration.

The regular exercise of sharing information across the board keeps communication strong and ensures rapid mitigation response to future issues.



3

Data, Data, and More Data

The Trial's Blood

While we focus on processes, tools, and subsets of stakeholders in RBQM discussions, the true lifeblood of a clinical trial is data. Over the past decade, clinical trial data volume has witnessed an unprecedented surge, growing tenfold.*

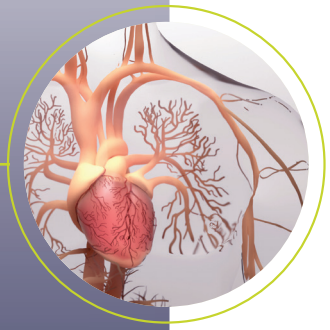
On average, Phase 3 studies now grapple with an overwhelming 3.6 million data points.*

Just as blood continuously circulates throughout the body, data must flow continuously and be readily available in real time to support the RBQM framework. Without robust, real-time data, our ability to effectively apply various risk monitoring tools and derive insights is severely limited.

This necessitates a data-driven culture—one that encompasses not only data itself but also the technology, organizational support, and change management required to foster a culture of data-centricity.

A robust and continuous flow of data is indispensable for driving informed decision-making and identifying potential signals of risks in clinical trials, just as a healthy bloodstream is essential for the body's optimal function.

* CSDD [Tufts Center for the Study of Drug Development]. 2021. January/February Tufts CSDD Impact Report: Rising Protocol Design Complexity is Driving Rapid Growth in Clinical Trial Data Volume. January/February, 23(1).



4

Data Platform: Acquisition and Aggregation

The Trial's Circulatory System

Made up of the heart, blood vessels, and blood, the circulatory system is responsible for pumping blood from the heart to the lungs to fill with oxygen. It controls our our life, and without it, we're left on life support—relying on instruments like extracorporeal membrane oxygenation machines to breathe and circulate blood for us.

Like the circulatory system, clinical trial data must flow in a cohesive and predictable path. Having a data platform where you can aggregate and acquire data from multiple sources allows you to keep off life support.

By providing the same data to all users in a fit-for-purpose format, tailored to their specific needs and responsibilities, the data platform supports users in their roles, aligning with RBQM principles.

Interconnected workflows, deep links, and unified data access empower users to connect across functions, ensuring that data flows uninterrupted and that the trial operates at its fullest potential. Like the circulatory system coordinates the circulation of blood throughout the body, the unified data platform orchestrates the flow of data, ensuring that the trial remains healthy.

5

Data and Risk Surveillance

The Trial's Sensory System

With blood—or data—flowing uninterrupted, our sensory system becomes heightened. In a clinical trial, we are able to better monitor data quality, site performance, and patient safety in real-time through advanced analytics, intuitive visualizations, and purpose-built tools for each stakeholder.

While our senses alert us to potential dangers, such as red flags or warning signs at the first sign of trouble, in a clinical trial we can now pinpoint issues at various levels of granularity like data point, patient, site, or study. This increased awareness enables us to anticipate and address known risks quickly and effectively, should they be isolated or systemic.

Using automated workflows and AI algorithm tools further sharpen detection and accuracy, allowing us to identify risks faster and detect anomalies earlier, before risk becomes an issue.

Strategies for continuous and automated monitoring of data integrity and quality, site performance, and patient safety free up valuable time for stakeholders to focus on interpretation and resolution. With vigilant surveillance of potential issues and previous actions, AI facilitates an accelerated path to clean, quality data.

6

Mitigation Actions

The Trial's Medicine

Mitigation Actions in clinical trials are like medicine—aimed at averting potential risks before they escalate into major issues. Much like personalized medicine tailors treatment to individual patients, mitigation strategies are customized to the type and level of risk at hand.

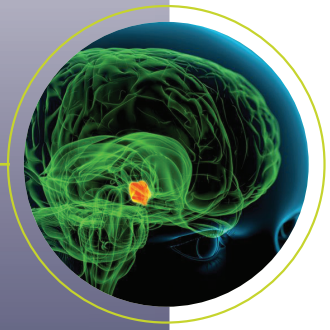
Instead of employing a one-size-fits-all approach, trial teams observe closely, increase monitoring, provide supportive therapy and training, or even resort to hospitalization and quarantine when necessary, selecting the right intervention for the specific risk.

Risks are to trials as potential diseases are to the human body. Each requires a distinct prophylactic approach. Traditionally, we may have employed blanket strategies such as 100% Source Data Verification (SDV), regardless of the risk profile. But when armed with data-driven insights, precision medicine principles are applied to risk monitoring and mitigation, optimizing strategies to be more targeted, intelligent, and efficient.

Precision medicine in risk mitigation entails flexing new approaches to match the unique characteristics of each risk. Drawing a parallel to the human body, we don't administer flu shots year-round; rather, we activate them when the risk of infection is higher. Monitoring protocols are adapted to align with the seasonality and nature of specific risks.

While traditional monitoring methods suffice for many known risks, some elusive threats require more advanced detection methods. Here, centralized monitoring and heightened surveillance serve as our advanced senses, equipping us to uncover hidden risks and respond accordingly.

By embracing a layered, proactive, and cross-functional approach to risk mitigation, trial teams can stay ahead of potential issues and ensure the safety and integrity of the trial. Precision medicine principles guide us in selecting the most effective strategies to mitigate risks and safeguard the success of the trial.



7

Data Balance and Stability

The Trial's Homeostasis

From alterations in heart rate and body temperature to key processes like digestion and circulation, our body makes numerous micro adjustments to everyday internal and external stimuli in order to maintain equilibrium. Without them, the body is subjected to health issues and imbalances. RBQM balances trials in a similar way.

Just like the body, data homeostasis in the RBQM framework involves continuous monitoring, regulation, and adaptation to changes.

RBQM ensures trial data homeostasis in key ways:

- **Stability in Data Quality** through data transformation and standardization processes
- **Balance in Data Integrity** through ensuring constant and accurate data
- **Adaptation to Changes** in trial conditions, shifting data management strategies when necessary to ensure balance
- **Continuous Monitoring and Regulation** of data quality, applying corrective actions, and adjusting transformation standards as needed to maintain data stability
- **Optimal Functioning and Decision-making** by ensuring that the information used for those decisions remains consistent and reliable
- **Resilience to Disturbances** that occur—whether due to data anomalies or deviations—to quickly identify and correct these issues

By integrating the concept of homeostasis into the management of data within the RBQM framework, the proper balancing acts are in place to maintain data integrity.

Conclusion

Much like a healthy human body, a connected trial ecosystem driven by RBQM principles and a data-driven culture delivers quality, safety, and operational efficiencies.

When any disconnect or interruption poses a risk to the integrity and success of the trial, it's vital that every aspect works in harmony. From protocol design to data collection, monitoring, and analysis, RBQM principles powered by solutions like Medidata Clinical Data Studio create a cohesive unit that delivers reliable, comprehensive, high-quality data. Leveraging solutions like Medidata Clinical Data Studio allows us to proactively embed quality risk management into daily operations. These tools enable stakeholders to identify abnormalities, visualize insights, and take quick, informed actions.

Quality-by-Design

Built to embed quality risk management into daily operations to proactively reduce the likelihood of errors that matter

Scalable, Connected Workflows

Flexible to your current processes and solutions and grow with you as your study needs change

AI/ML and Smart Analytics

Powerful anomaly detection and smart visualizations quickly turn insights into actions

Real-Time Actionable Insights

Real-time data delivers the insights you need to take action quickly

Applying an RBQM framework serves as the true connective tissue of clinical research and paves the way for transformative advancements in clinical trial optimization.

RBQM:
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About Medidata

Medidata is powering smarter treatments and healthier people through digital solutions to support clinical trials. Celebrating 25 years of ground-breaking technological innovation across more than 33,000 trials and 10 million patients, Medidata offers industry-leading expertise, analytics-powered insights, and the largest patient-level historical clinical trial data set in the world. More than 1 million registered users across 2,200+ customers trust Medidata's seamless, end-to-end platform to improve patient experiences, accelerate clinical breakthroughs, and bring therapies to market faster. The company is a wholly owned subsidiary of Dassault Systèmes (Euronext Paris: FR0014003TT8, DSY.PA), which with its 3DEXPERIENCE platform is positioned to lead the digital transformation of life sciences in the age of personalized medicine with the first end-to-end scientific and business platform, from research to commercialization. Medidata is headquartered in New York City and has been recognized as a Leader by Everest Group and IDC. Discover more at www.medidata.com and follow us **@medidata**.

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