



Medidata Launches New Functionality to Enable Holistic Risk-Based Quality Management for Clinical Trials

The launch of Medidata Risk Management, coupled with updates to Medidata Detect, round out a full suite of unified RBQM solutions, built on the Medidata Clinical Cloud™

New York, New York – April 12, 2021 – Medidata, a Dassault Systèmes company, announces [Medidata Risk Management](#), the latest addition to its [Risk-Based Quality Management](#) (RBQM) suite, a holistic group of solutions designed to streamline the adoption of proactive clinical operations oversight activities. These include centralized monitoring, reduced source data verification (SDV) and source data review (SDR), remote source document review, and implementation of decentralized trial activities.

RBQM practices enable clinical operations teams to remain flexible and agile within the complex environments of the ever-changing clinical development landscape. Available today, Medidata Risk Management is the foundational step to enable a comprehensive RBQM strategy. Built on the [Medidata Clinical Cloud™](#) and fully integrated with Medidata's centralized monitoring tool, Medidata Detect, Medidata Risk Management supports sponsors and contract research organizations (CROs) as they identify critical data and processes, associated risks, and implement mitigation strategies as defined within ICH E6 (R2). And, with recent updates to Medidata Detect, now study teams can also compare site differences across all participants to easily uncover trends or anomalies and determine whether there are discrepancies in data collection or integrity to be investigated.

“The COVID-19 pandemic propelled sites, sponsors and CROs to adopt remote and risk-based approaches to assure the safety of trial participants, maintain compliance with good clinical practice (GCP), and minimize risks to trial integrity,” said Lisa Moneymaker, vice president of Clinical Operations Technology at Medidata. “Our goal has been, and remains, to drive innovation and solutions in this space, so that we are able to support sponsors and CROs with the capabilities they need in their clinical operations toolbox —so that they are best able to support sites and patients.”

Instead of managing risk assessments in siloed spreadsheets, Medidata Risk Management's library of templates allows study teams to collaborate for greater efficiency. These templates include the TransCelerate Risk Assessment and Categorization Tool (RACT), a Medidata-authored COVID-19 Risk Assessment, and a Decentralized Trials template, authored and developed by the Association of Clinical Research Organizations (ACRO), that can guide

companies on the specialized concerns and focus areas, as they move into the decentralized and virtual trial space.

Medidata Risk Management was built on the Medidata Clinical Cloud, providing access to a suite of solutions to streamline data capture, data management, trial planning and management, and analytics. The solution adopts the Quality by Design (QbD) approach to monitor leading indicators of quality, including Quality Tolerance Limits (QTLs) and Key Risk Indicators (KRIs), prior to the start of a clinical trial. This proactivity ensures the defined risk control mechanisms are effective in mitigating the identified risks.

Risk Management integrates directly with Medidata [Detect](#), so study teams can proactively monitor known risks and identify anomalies, trends, and even unknown risks earlier with real-time data flow and on-demand data updates. Detect uses the KRIs and QTLs from the Risk Management solution to develop issue management dashboards and provide visibility to anomalies that can be drilled into for additional details. Now study teams can proactively evaluate issues that fall outside the tolerable range to determine if corrective action is needed.

Medidata is driving technology to support excellence in trial execution, enabling companies to achieve digital oversight, which the company sees as the future of Clinical Operations. The goal is to help CROs and sites create efficiencies and prioritize patient safety, while the sponsors can invest in innovative solutions for worldwide health and streamline time to market.

Medidata is a wholly owned subsidiary of Dassault Systèmes, 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.

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THE MEDIDATA RBQM SOLUTION: MODULAR & SCALABLE

