



TRANSFORMING CLINICAL OPERATIONS

Data and Advanced Analytics to Power Action Across the Trial Continuum

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INTRODUCTION



Empowering Clinical Operations with Intelligent Technology

Clinical operations play a critical role in the planning, execution, and management of a clinical trial, from study design and planning to successful study start-up and execution, to final study close out. As the complexity of clinical trials and data collection increases, clinical operations must keep pace to meet regulatory requirements, patient safety, and trial timelines. Traditional approaches which rely on point solutions and siloed analytics are no longer fit-for-purpose, resulting in inefficient data re-entry and delayed insights. Today's study teams need more intelligent feedback from the technology they use, and in turn they are asking more of technology partners.

Today's users must be empowered with user-friendly technology that reduces clicks, increases access to data insights, and orchestrates end-to-end workflows that cross traditionally siloed systems.

1



THE NEXT GENERATION OF CLINICAL OPERATIONS

One Unified Platform



Medidata's Clinical Operations solutions improve study timelines on a platform driven by connected workflows and data-driven intelligence, coordinating and managing the various aspects of clinical trials whether they are traditional, hybrid, or fully decentralized. Medidata's technology spans the entire clinical trial lifecycle and is built on a unified platform where data is entered once and used in many places.

Medidata is the only provider that offers a comprehensive [decentralized clinical trial \(DCT\)](#) program that allows sponsors and CROs to prepare for and analyze high volumes of data at scale.



2

CONNECT USERS ACROSS THE CLINICAL TRIAL LIFECYCLE

Driving Faster Clinical Trial Decisions with High Quality Data

Medidata transforms clinical operations workflows through the [Medidata Clinical Cloud®](#), the industry's only unified platform dedicated to clinical research that provides a single data ecosystem for users to interact across capabilities. By centralizing trial data and clinical operations technology on a single platform, sponsors and CROs can move from insight to action more quickly.

Medidata enables optimized clinical trial operations by surfacing actionable data intelligence that informs study team activities. This is achieved by embedding powerful analytics where they are needed most—within core clinical operations workflows—by bringing insights directly to the frontlines of decision-making, driving the highest quality data while significantly mitigating risk.

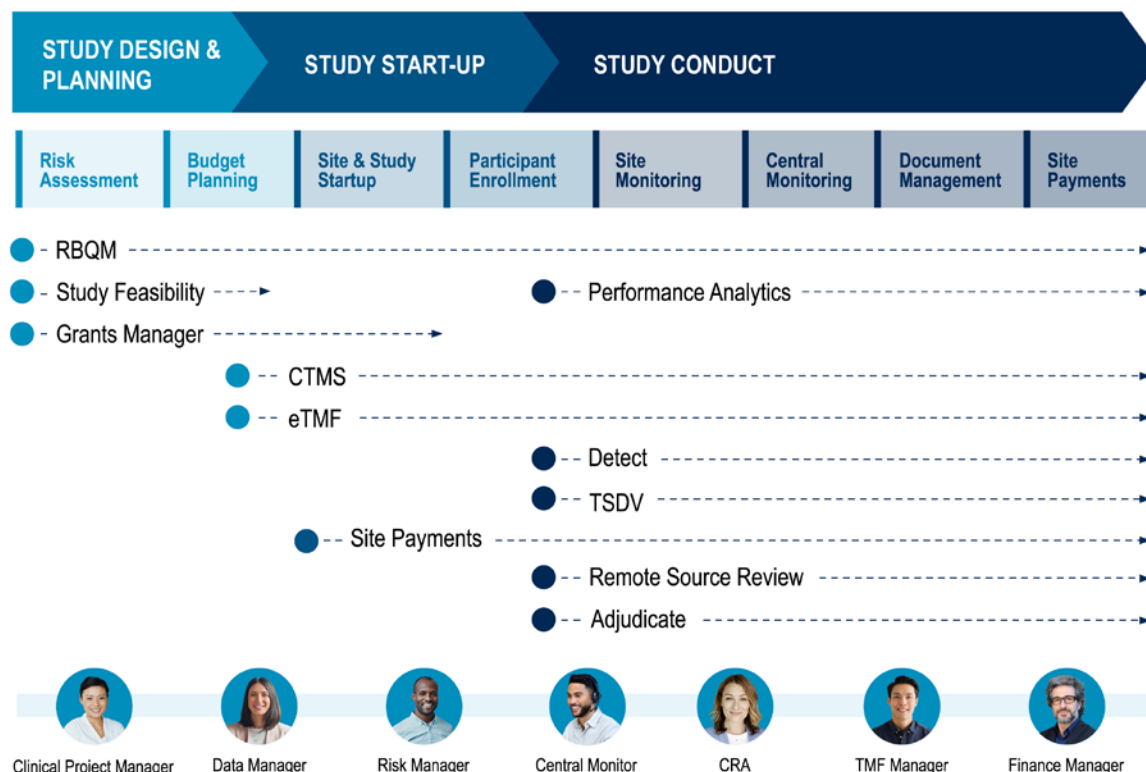
[Watch our Clinical Operations video here to learn more.](#)

3



FROM INSIGHT TO ACTION

Clinical Operations Processes on the Medidata Platform



Benefits of Medidata's Clinical Operations Solutions

- Data-driven insights enabling confident study planning, greater trial diversity, and accelerated enrollment
- Holistic data surveillance driven by analytics and AI that automatically identifies data anomalies for higher data integrity
- Trial management which integrates monitoring, document management, and issue management workflows in a single data-powered solution
- Comprehensive RBQM capabilities, which improve efficiency while ensuring data integrity and patient safety by focusing efforts on risks to critical data and processes
- Financial management that accelerates budget to payment timelines by harmonizing clinical data with financial data in real time



CLINICAL OPERATIONS EXCELLENCE WITH MEDIDATA

Intelligent Trials

Increase confidence in decision making across a clinical trial's life cycle with insights from [Medidata AI Intelligent Trials](#), to bring treatments to patients faster and reduce costs. Leveraging the industry's largest clinical and operational dataset, Intelligent Trials enables study teams to more confidently plan for trial success, including establishing and meeting diversity goals. Once the trial is underway, Intelligent Trials can help you stay agile by diagnosing issues earlier within a dynamic trial landscape to gain a competitive edge.

Solutions include:

- [Study Feasibility \(with Diversity module\)](#)
- [Performance Analytics](#)

Trial Execution and Oversight

Simplify the operations and management of clinical trials, optimize physical and virtual interactions with sites, and optimize event adjudication with intelligent workflow automation and data-powered insights.

Solutions include:

- [CTMS](#)
- [eTMF](#)
- [Adjudicate](#)
- [Detect](#)
- [Remote Source Review](#)

CLINICAL OPERATIONS EXCELLENCE WITH MEDIDATA

Risk-based Quality Management (RBQM)

A connected platform of capabilities that provides near real-time insights into critical data, allowing teams to focus resources on what's most important in the study. End-to-end solutions allow users to holistically manage risk, improve data quality, and ensure patient safety with [risk-based capabilities](#) that shorten trial timelines, reduce overall costs, and improve trial outcomes.

Solutions include:

- [Detect](#)
 - [Risk Management](#)
 - [Patient Data Surveillance](#)
 - [Key Risk Indicators \(KRIs\)](#)
 - [Quality Tolerance Limits \(QTLs\)](#)
 - [Centralized Statistical Monitoring](#)
- [Targeted SDV](#)
- [Remote Source Review](#)

Clinical Trial Financial Management (CTFM)

Make smarter and faster financial decisions with Medidata's [Clinical Trial Financial Management](#). Powered by data, CTFM pairs Grants Manager Planning and Contracting with Site Payments to power Sponsors and CROs with an end-to-end financial management solution. From study budget planning to site budget negotiations and site payments, CTFM ensures financial visibility through your entire study life cycle.

Solutions include:

- [Site Payments](#)
- [Grants Manager](#)

Professional Services for Clinical Operations

Medidata deploys deep internal expertise to manage key clinical processes, reducing FTE burden and improving ROI. Medidata's experts ensure that all trial processes are optimized and help sponsors and CROs attain the maximum value from their investments in Medidata solutions.

TRANSFORMING CLINICAL OPERATIONS

Discover more about Rave Clinical Operations by clicking here.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 2,000+ customers and partners access the world's most trusted platform for clinical development, commercial, and real-world data. Medidata, a Dassault Systèmes company (Euronext Paris: FR0014003TT8, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers. Discover more at www.medidata.com and follow us [@medidata](https://twitter.com/medidata).

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