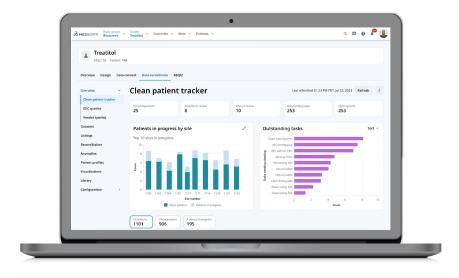


Medidata Clinical Data Studio

Unlock the True Power of Clinical Trial Data



Medidata Clinical Data Studio is a transformative Al-powered data quality management experience that brings study teams together with access to data from all your clinical data sources. Built with a user-friendly, no/low code environment, it leverages automation and Al to streamline data aggregation, standardization, and management workflows so that multiple users can act on real-time data in ways that reduce burden, shorten review timelines, increase quality, reduce risk, and improve patient safety. Clinical Data Studio unlocks efficiencies and accelerates clinical discovery by supporting a wide variety of use cases for clinical data managers, clinical operations, medical monitors, clinical programming, and other data stakeholders.

Benefits



Reduce Technical Burden and Deliver Value Sooner

IT and Clinical Programming teams configure Clinical Data Studio in as little as three days. Data from multiple Medidata and non-Medidata sources are quickly and efficiently integrated to make them available for review and analysis sooner.



Review, Reconcile, and Action Data Issues Faster

Clinical data management teams reduce data review cycle times by up to 80% per cycle with automation and AI-assisted data review and reconciliation. Medical and safety monitoring teams reduce patient profile review times by up to 50% with comprehensive patient narratives at their fingertips.



Manage, Monitor, and Mitigate Data Quality Risks More Efficiently

Clinical operations teams manage and monitor site, country, and study-level risks with QTL (Quality Tolerance Limit) and KRI (Key Risk Indicator) dashboards and automated statistical monitoring. Critical data quality issues are detected and mitigated sooner.



Features



Data Ingestion, Standardization, Transformation, and Export

Data from non-Medidata sources are easily ingested, validated, and standardized. Data setsn from Medidata and non-Medidata sources are integrated and transformed to activate them for data review, safety review, and monitoring tasks, all in a no/low-code experience.



No-code Listings, Automated Queries, Al-assisted Data Reconciliation, and Clean Patient Tracker

With Clinical Data Studio, data review listings are built without programming. Review status is tracked, Rave EDC queries are automatically generated and posted, and non-Medidata data vendor queries are resolved, all with a single online experience. Progress towards clean data is tracked in the Clean Patient Tracker dashboard, eliminating ad-hoc reports and spreadsheets.



Patient Profiles, Data Visualizations, and Oncology Analytics

Comprehensive patient profiles and ad-hoc data visualizations are created without programming. A RECIST (Response evaluation criteria in solid tumors) 1.1 dashboard enables a quick review of oncology study patients' disease progression (tumor burden).



Risk-based Quality Management (RBQM)

Critical data and risks are identified, managed, and monitored with QTL and KRI dashboards and graphs. Machine learning and graphical analytics help spot data anomalies and unusual trends, enabling central monitors to detect and mitigate site performance, compliance, and data quality issues.

90%

Faster to Build Listings

80%

Faster Data Review (per cycle)

50%

Reduction in Patient Profile Review Time

85%

Faster to Configure KRIs

Efficiencies Realized with Clinical Data Studio

*Medidata internal analysis

The Medidata Advantage

Built on the <u>Medidata Platform</u>, the industry's leading clinical research platform, enabled by a scalable, flexible, open, and real-time streaming data architecture, Clinical Data Studio uniquely delivers a unified data quality management experience for all clinical data, multiple roles, powered by automation, AI, and advanced analytics. With Clinical Data Studio, you can get started quickly and get value faster without extensive implementation timelines and ongoing managed service fees.