

Modernizing Clinical Data Capture & Management for Today's and Tomorrow's Trials

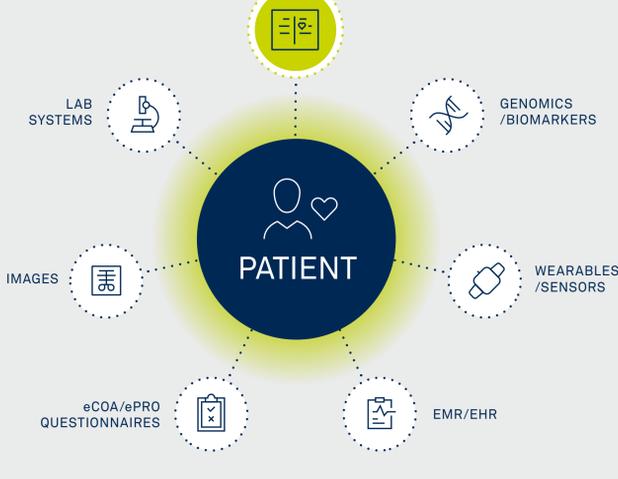
The Clinical Data Landscape Has Changed

Clinical trial data volume has increased seven-fold in the last 20 years¹ to

3.6 million data points in a typical Phase III study.¹

Only approximately 30% of clinical trial data is entered through eCRFs in EDC systems.²

More data is being captured directly from patients and from outside the clinical trial site, driven by the growth in decentralized trials.



¹ Average number of data points in Phase 3 Pivotal trials, 2001-2005 - 0.5 Million, 2015-2020 - 3.5 Million. Source: Tufts CSDD 2020 (data is pre-pandemic).

² Several companies informally surveyed during the SCDM 2018 Leadership Forum stated that over 70% of the data volume (e.g. lab, eCOA, etc.) is not coming from EDC.

...But Clinical Data Management Technologies and Processes Have Not Kept Pace

Aggregating and reconciling data from multiple sources takes huge effort

Integrating different data capture systems and their data is hard

Exhaustive data point by data point review doesn't scale up

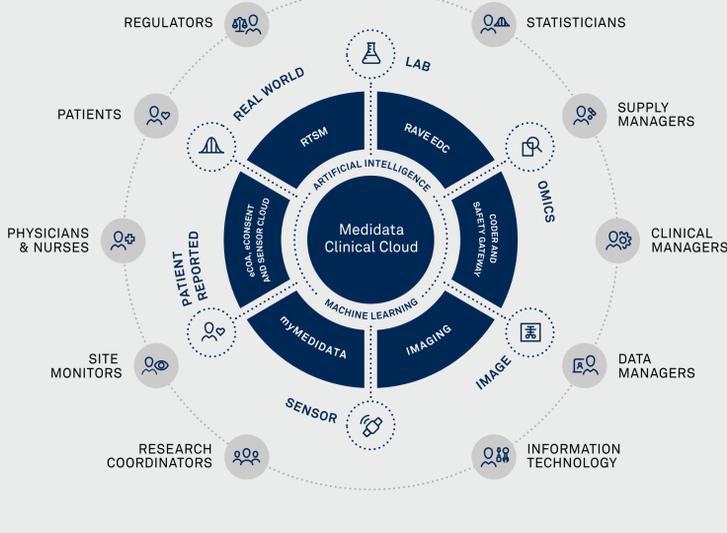
Query-based data cleaning doesn't contribute proportionally to improving data quality³

Database lock and data transformation into submission-ready output are too manual and take too long

³ Risk-based Quality Management in CDM: An Inquiry into the value of generalized query-based data cleaning. Journal of SCDM. Available at: <https://www.jscdm.org/article/id/20/>

Transforming Clinical Data Management Technology to Tackle the Evolving Data Landscape

So how do we modernize clinical data management technologies to manage the new and rapidly evolving data landscape?



360° view of all patient data in a unified platform



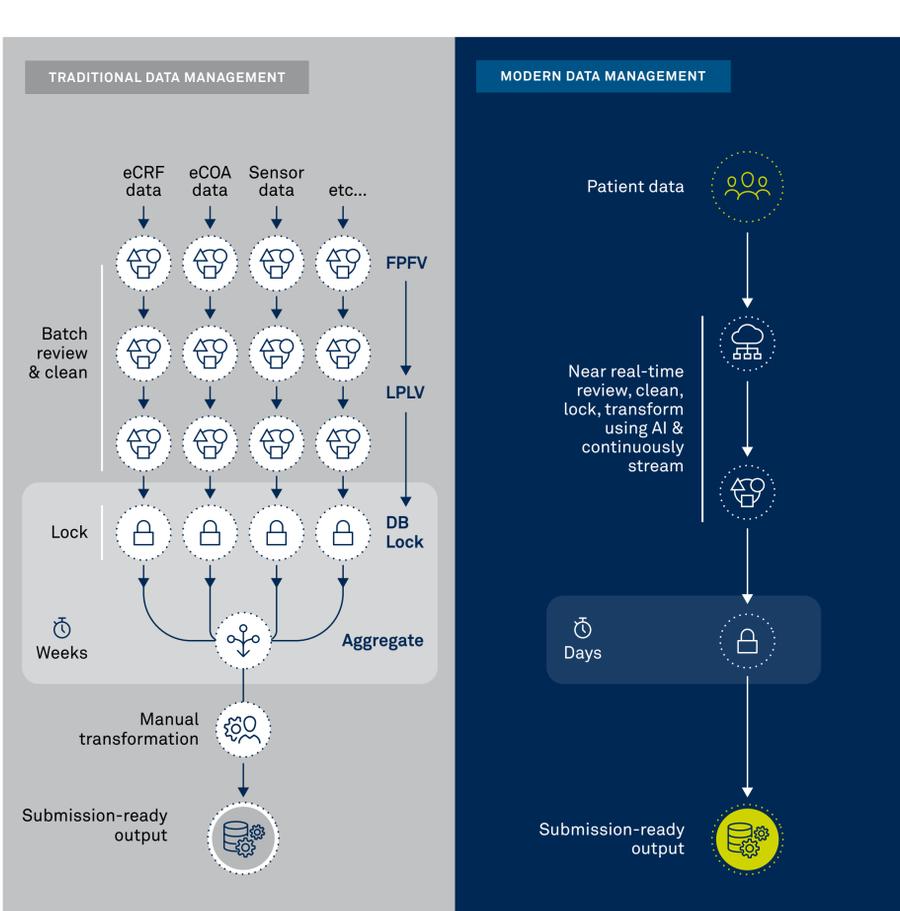
Real-time, automated data review using machine learning, analytics and visualizations



Automated, streamed transformation of data for submission-ready output

Comparing Traditional and Modern Data Management Approaches

Using new clinical data platform and intelligent data analytics technologies will transform clinical data management processes.



Results Achieved by Medidata Customers

64%

reduction in study build time⁴

Database lock in **days not weeks**⁵

80%

reduction in data correction rates⁶

20%-40%

reduction in number of edit checks⁷

50%-55%

of data reviews automated⁵

⁴ Analysis by Medidata Value Team for customer with Rave EDC, Coder, and TSDV; 2019

⁵ Customer sponsored value analysis for Rave EDC, Coder, RTSM, Detect, and TSDV; 2018

⁶ Analysis by Medidata Value Team for customer with Rave EDC, TSDV, eCOA, Coder, and RTSM

⁷ Analysis of customers using Rave EDC and Medidata Detect

“With the Medidata Clinical Cloud™, we have a unified environment for reporting accurate data, reviewing data, and reporting accurate study results. It streamlines the study process for everyone involved—our team, sites, and patients.”

Erin O'Boyle
Head of Clinical Operations,
Rezolute