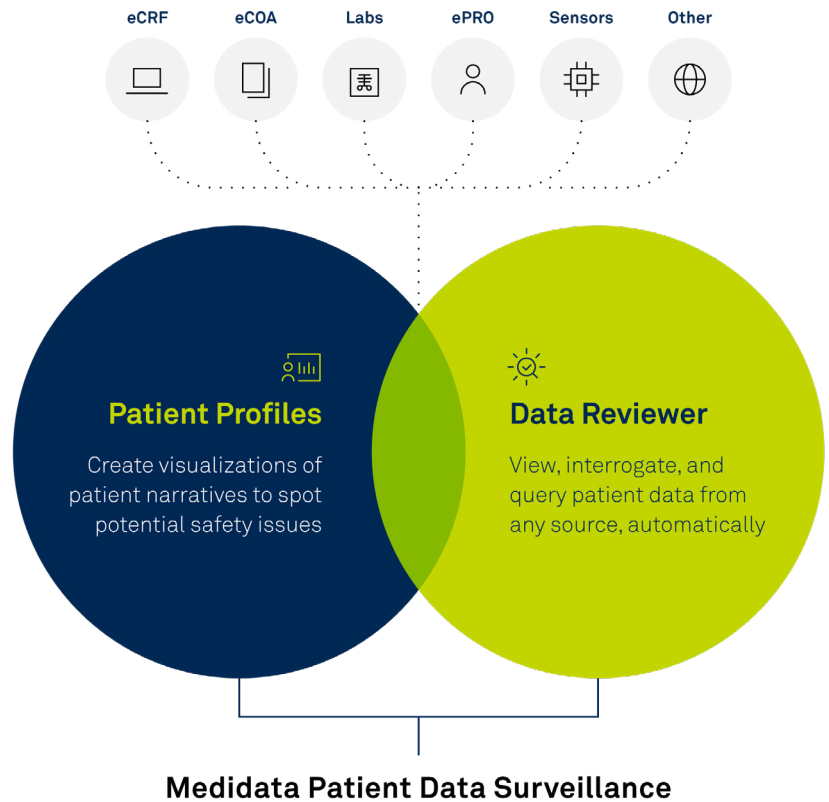# Medidata Patient Data Surveillance
Automate and Accelerate Clinical Data Management Activities

Multiple members of the study team, including clinical data managers, biostatisticians, and medical monitors, work together to manage data completeness and quality, and to ensure patient safety oversight during a clinical trial. Traditional clinical data management approaches suffer from resource-intensive data review and manual query management processes, which can lead to errors and trial delays.

Medidata Patient Data Surveillance is the latest innovation to Rave EDC, combining two powerful data management solutions to simplify complex data investigation across many data sources. The first solution is Patient Profiles, comprehensive patient narratives delivered through easy-to-build and interpret tables, graphs, and visualizations which enable intuitive safety and medical reviews. The second solution is Data Reviewer, which aggregates patient data from many sources for review, interrogation, and AI-driven reconciliation, all from a single location.

eCRF   eCOA   Labs   ePRO   Sensors   Other

Patient Profiles

Create visualizations of patient narratives to spot potential safety issues

Data Reviewer

View, interrogate, and query patient data from any source, automatically

Medidata Patient Data Surveillance

Patient Data Surveillance requires minimal configuration effort and can be implemented in as little as two weeks, allowing you to generate custom profiles and listings in just a few hours.

Benefits

Streamline data cleaning processes

Powerful data review capabilities reduces reliance on custom functions.

Reduce time and cost for performing data review

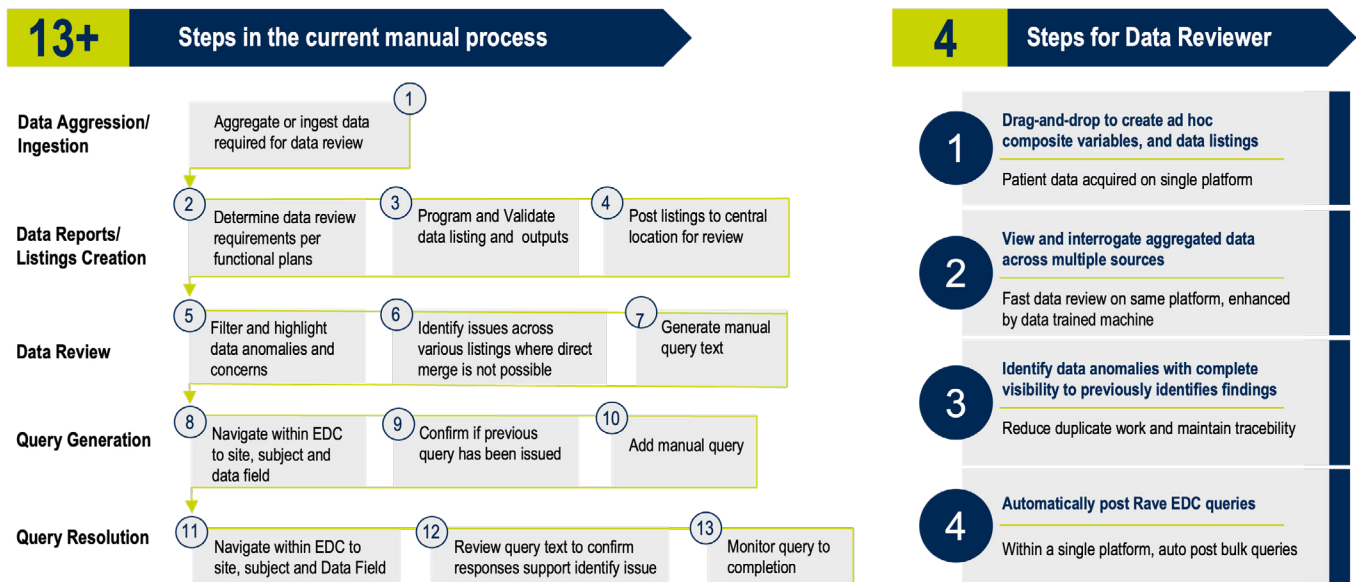Embedded AI and automation streamline complex data reconciliation.

Generate deeper insights

Understand the full patient journey using Patient Profiles with direct links to Rave EDC.

Features

- Supports many patient data sources, including labs, eCOA, sensor/wearable data, and safety data

- Submit queries in bulk and manage their status in one place

- Refresh data daily with direct links into Rave EDC from profiles and queries

- Focus patient profiles on areas of interest with graphs, side-by-side timeline views, and custom flags

- Create ad hoc composite variables and data listings with no programming and save as templates for future use

- Automate complex data reconciliation with AI

- Track patient cleaning status in real-time dashboards

Drastically Reduce Manual Data Review Timelines

13+ Steps in the current manual process

Data Aggression/ Ingestion
1. Aggregate or ingest data required for data review

Data Reports/ Listings Creation
2. Determine data review requirements per functional plans
3. Program and Validate data listing and outputs
4. Post listings to central location for review

Data Review
5. Filter and highlight data anomalies and concerns
6. Identify issues across various listings where direct merge is not possible
7. Generate manual query text

Query Generation
8. Navigate within EDC to site, subject and data field
9. Confirm if previous query has been issued
10. Add manual query

Query Resolution
11. Navigate within EDC to site, subject and Data Field
12. Review query text to confirm responses support identify issue
13. Monitor query to completion

4 Steps for Data Reviewer

1. **Drag-and-drop to create ad hoc composite variables, and data listings**
Patient data acquired on single platform

2. **View and interrogate aggregated data across multiple sources**
Fast data review on same platform, enhanced by data trained machine

3. **Identify data anomalies with complete visibility to previously identifies findings**
Reduce duplicate work and maintain traceability

4. **Automatically post Rave EDC queries**
Within a single platform, auto post bulk queries

The Medidata Advantage

As the landscape of data acquisition has grown, the industry requires new approaches to clinical data science that support the pace and expansion of data sources, and deliver automated workflows for data and discrepancy management. Patient Data Surveillance is part of our comprehensive data and risk surveillance solution Medidata Detect, and is unified with Rave EDC. This streamlines data cleaning and quality oversight processes in a single system, resulting in improved collaboration between data management and clinical operational teams. While other vendors offer point solutions that must integrate into a broader landscape, Medidata offers a modular, interconnected, platform-based set of capabilities to deliver significant efficiencies in cost, workflows, and future-proofed innovation.