eSource:
The Evolution of Clinical Trial Data Capture

What is eSource?

According to the FDA, eSource, or electronic source data, is simply data recorded initially in an electronic format. eSource includes, as examples, a site entering data directly into an EDC or an EMR/EHR system, an EDC system importing data from a laboratory system, a patient filling out an ePRO form on their mobile device, and blood pressure data collected on a wearable sensor.

Why is eSource Important?

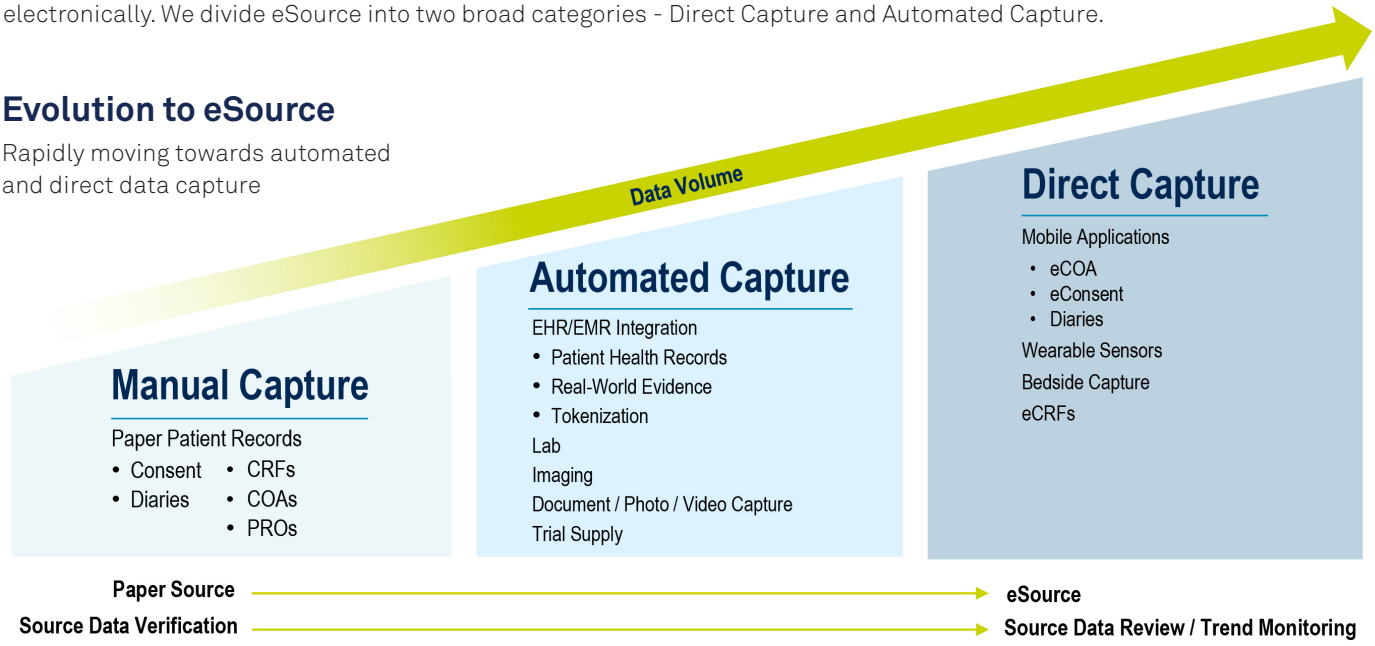
Today's clinical trial sites typically complete paper visit forms or bedside charts, and patients often complete paper diaries or questionnaires, all of which need transcribing into the EDC system. The reliance on paper source documents leads to transcription errors, unnecessary data duplication, and burdensome source document verification processes.

eSource offers the opportunity to significantly reduce or eliminate paper records and these manual, inefficient processes. It also enables sites, sponsors, and CROs to collect comprehensive data faster and more frequently to provide more significant insights into the patients' condition and the safety and efficacy of the investigational product.

However, the variety, volume, and velocity of data that is now possible to collect via eSource present new challenges. How do you verify data that has no source document? How do you spot missing data or anomalies in millions of data points? Traditional monitoring and data management methods are no longer suitable.

How Does Medidata Think About eSource?

Medidata believes that the future of clinical trial data is to capture data as close to the patient as possible, electronically. We divide eSource into two broad categories - Direct Capture and Automated Capture.



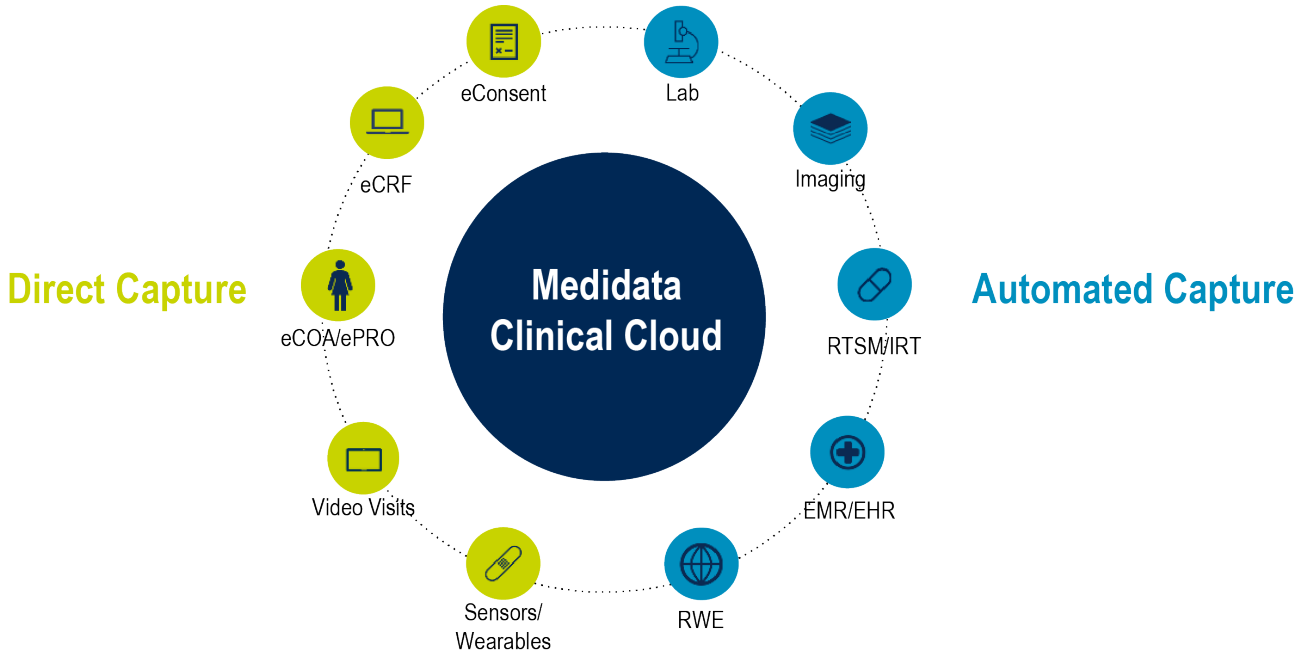
Direct Capture includes any electronic clinical data collected directly from a patient (via eCOA/ePRO or sensors) or entered by the site staff straight into the EDC system.

Automated Capture includes any eSource data where the clinical data is initially captured in a different electronic system (e.g., Imaging, Lab, EHR/EMR, tokenized patient data) and then replicated within the EDC system.

As the volume of data captured via eSource increases, monitoring and data management processes need to adapt to be relevant to how and where the data is collected and scale to detect and clean data issues without extra resources.

Why Medidata for eSource?

Only Medidata offers a broad range of direct and automated capture eSource solutions in a single, unified platform.



Broadest Range of Direct Capture Solutions

Direct Capture means that you don't have to transfer the data from disparate systems or view/verify the eSource data in another application or system.

Our patient-facing data capture solutions (e.g., eConsent, eCOA/ePRO, Video Visits, Sensors) are part of our unified platform, the Medidata Clinical Cloud. No other provider offers the breadth of data capture solutions connected to a unified platform.

For example, data captured directly from a patient via eCOA/ePRO is automatically available within Rave EDC, alongside summaries of Sensor data.

You can verify all eCOA data from the patient or site directly in Rave EDC. Only Medidata can offer this with our unique unification of EDC and eCOA capabilities.

Effortless and Accurate Automated Capture Solutions

Automated capture means your data originates in one electronic system and then is replicated - automatically - within your EDC system. Medidata's unified platform, the Medidata Clinical Cloud, enables automated capture from 3rd party data sources and unifies it with data captured directly within Medidata applications.

For example, lab data is automatically captured from central or local labs and brought together in Rave EDC with imaging results automatically transferred from Rave Imaging.

The Medidata Clinical Cloud ingests data from any 3rd-party imaging, eCOA/ePRO, RTSM/IRT, ECG, or other systems/devices.

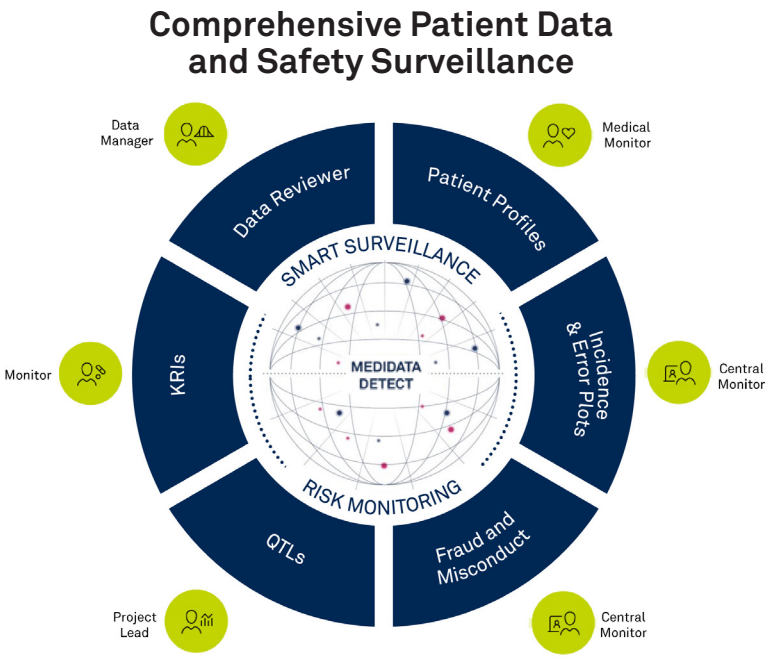
In 2022, sites will be able to quickly and easily find and capture data within their EHR/EMR system to populate form fields in Rave EDC with a few clicks.

Cutting-Edge Data Review and Monitoring Solutions

Only Medidata offers automated workflows and advanced analytics as part of our unified platform to help you manage the increasing volume of eSource data and eliminate manual data review and monitoring processes.

Instead of using programmers to aggregate datasets and build listings and spreadsheets to perform and track data reviews, Medidata Detect aggregates data from multiple sources for easy review and interrogation.

Detect enables data managers and monitors to centrally reconcile and review the complete data set. Detect applies machine learning and analytics to automatically detect unusual patterns, outliers, and anomalies in the data, with action taken in real-time via centralized issue management.



Your Partner for eSource

Only Medidata has the eSource coverage, unified platform, centralized data review, and advanced analytics capabilities to improve the patient experience and enable CROs and sponsors to deliver high-quality data faster and more efficiently.

Ultimately, Medidata's eSource capabilities help our customers accelerate clinical trial results and bring smarter treatments to patients sooner.