

Rave Safety Gateway

Enhance Safety Data Transmission with Precision and Efficiency

Patients' safety in the clinical trial process is of paramount importance to pharma sponsors and the sites conducting the trial. Paper forms and unreliable faxes are slow, costly, and error-prone, wasting time and putting patients at risk. Medidata's Rave Safety Gateway addresses these challenges through automated data capture, tracking, and transmission that results in fewer errors, less data reconciliation, and improved patient safety.

Rave Safety Gateway transmits adverse event data from Rave EDC to a safety system using the E2B (R2) industry standard. Rave Safety Gateway significantly improves the accuracy and speed of safety data collection from investigational sites and the transfer of that data to safety systems for both pre-marketing and post-marketing studies. Safety Gateway also provides the flexibility to apply organization-specific business rules to data prior to transmission, transmits extracted data in real-time or in scheduled batches, and alerts safety staff when these extractions occur.

Innovation Leads to Better Outcomes

Managing the adverse event (AE) and serious adverse event (SAE) data transmission and reporting process requires precision, accuracy, timeliness, and attention. In many trials, the rate of AEs and SAEs is high, and the time spent addressing these events by a study/site manager is significant. In many cases, process workflows require extensive data review and uploads, import of safety data from external safety systems, reconciliation, and review/approval of data and any coding linked to these AEs/SAEs.

Data Managers, Coders, and Safety Specialists should not spend their limited time compiling safety reports. Rather, they should focus on reviewing these reports to ensure consistency and accuracy between EDC and safety systems. Rave Safety Gateway facilitates this process through time-triggered case and safety transmission reports. The time trigger helps organizations adhere to regulatory reporting requirements and to improve patient safety. Safety transmission reports allow organizations to review data transmissions prior to incorporation into a safety system.

UPTO

39%

FEWER SAFETY QUERIES TO THE SITES

APPROXIMATELY

30%

OF SAFETY RELATED QUERIES AUTOMATICALLY GENERATED BY THE SYSTEM

THE PLATFORM OF CHOICE FOR CLINICAL RESEARCH

The Medidata's Rave Clinical Cloud is the cutting-edge platform that transforms the clinical trial experience for patients, sponsors, CROs, and research sites. Designed with a unified data platform, the Rave Clinical Cloud creates a single source of truth for all study-related data. Simply put, enter data once and let the platform master and populate it throughout the end-to-end suite of Rave applications. Optimize operational execution, decrease the data entry and maintenance burden, and reduce the number of clinical systems across your study teams. Throw away your list of passwords, you are now on a truly unified platform.

Harness the Intelligence of the Medidata Platform

Rave Safety Gateway is built on the Medidata Rave Clinical Cloud, a unified data platform, which provides a single source of truth for all study-related data across your entire portfolio. Rave Safety Gateway ensures that identified AE/SAE data are transmitted successfully the first time, eliminating the need for timely review cycles and reconciliation. This is accomplished because once data is entered, the platform masters and populates it throughout the end-to-end suite of Rave applications.

Rave Safety Gateway provides enhanced features related to Coding Suggestions and Time Triggers, combining automatic transmissions with real-time parameter settings to code adverse events, medical history events, and concomitant medications. Powered by Rave EDC and partnered with Rave Coder, Rave Safety Gateway provides greater efficiency and streamlines workflows for sites and end-users alike.

A Complete Safety Management Solution

The power of Rave Safety Gateway is further enhanced by its connection to Coding Suggestions, a component of Rave Coder, which increases coding productivity and accuracy (up to 98%) when coding adverse events (MedDRA) and concomitant medications (WHODrug Global). Coding Suggestions leverages an algorithm to suggest coding decisions for AE and CM verbatims to the MedDRA and WHODrug dictionaries, respectively. Coding suggestions reduce manual coding by up to 50%, accelerating AE and SAE coding. Together, Rave Coder and Safety Gateway provide your organization faster and more accurate tools to prepare and transmit safety cases to improve patient safety.

- Robust tool to aggregate AE/SAE data into a single safety case
- Easy identification of EDC data for extraction
- Automatic transmission of extracted safety data
- Built-in alert features to notify staff when extractions occur
- Increased savings by streamlining workflow and improving safety data collection accuracy

Medidata Rave Clinical Cloud™

Cloud-based clinical research solutions | Innovative technology | Data-driven analytics
Reduced costs | Improved time to market | Faster decisions | Minimized risk

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 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

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