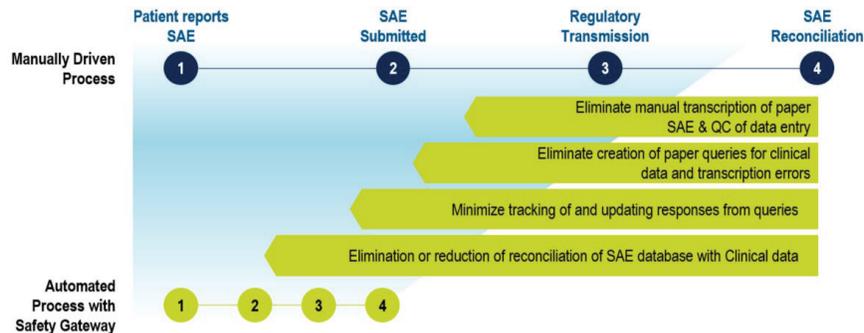


Automate Clinical Safety Data Management with Precision and Speed

A patients' safety in the clinical trial process is of paramount importance. Using paper forms, unreliable faxes, or disconnected systems to collect and transmit adverse event (AE) or serious adverse event (SAE) reports from sites to a safety system is slow and error-prone, wastes time and could put patients at risk.

[Rave Safety Gateway](#) addresses these challenges for safety monitoring in clinical trials by automating collection of AEs and SAEs (entered by your sites into [Rave EDC](#)), and preparing safety cases in the industry-standard ICH E2B format for transmission to your safety system.

Eliminate Safety Transmission Delays with Rave Safety Gateway



Product Benefits

Rave Safety Gateway extracts relevant adverse event data from Rave EDC and generates files in the industry-standard ICH E2B R2 and R3 formats that can be consumed by an external safety system.

The benefits of this automated approach include:

Accuracy

- Transcription errors are eliminated as AE data is entered once into Rave EDC and automatically transferred to the safety system
- Verbatims in AE reports can be coded using [Rave Coder](#) with 98% accuracy in automatically suggested coded terms

Speed

- Data duplication and reconciliation are eliminated, reducing review cycles and queries
- If AE data in Rave EDC is not signed off within a specific period, Safety Gateway automatically transmits the data to the safety system, including updates to existing AE reports

Reduced Burden

- The burden of safety data entry, query and reconciliation efforts for sites, data managers and safety teams is reduced

Features

Configurable Mapping of EDC Fields to Safety Case Tags

The Mapping tool enables the mapping of form fields in Rave EDC to E2B R2 and R3 tags and monitors those fields to detect data entry.

Automatic or Manual Transmission

The Management tool defines whether AE data is automatically exported into E2B files or sent to the Management tool for review, selection and approval before export.

Timed Trigger Transmission

Timed Trigger Transmission is a fail-safe mechanism to ensure timely reporting of AEs and SAEs. If, after a pre-defined period of time, AE/SAE data has not been signed off by the Principal Investigator, it is automatically transmitted to your safety system.

Notifications

When data is received or exported by Safety Gateway, and the receipt of the E2B file by the safety system is acknowledged or unacknowledged after a defined period of time, user groups or individuals can receive email notifications, to alert them to these events.

E2B Plus

If the external safety system supports E2B Plus, supplementary data is extracted that is not covered by the E2B standard.

The Medidata Advantage

Rave Safety Gateway is integrated with the most commonly used clinical data management system, Rave EDC, to streamline and improve the accuracy and timeliness clinical safety data management.

Safety Gateway supports the ICH E2B (R2) and E2B (R3) standards for the electronic transmission of safety case reports, enabling it to work with any compliant safety system to improve safety monitoring in clinical trials.