Automate Safety Data Transmission 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 by automating collection of AEs and SAEs (entered by your sites into Rave EDC), and preparing safety cases in the industry-standard E2B format for transmission to your safety system.

Product Benefits

Rave Safety Gateway extracts relevant adverse event data from Rave EDC (per configured mappings) and generates files in the industry-standard 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
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 of the processing of safety case data.

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.