Medidata Rave® Safety Gateway Speed and Accuracy in Safety Data Capture

Rave Safety Gateway is a configurable EDC-to-safety system interface that enables safety and data managers to collect and transmit safety data from investigational sites to a safety system, efficiently and accurately.

Timely reporting of serious adverse events (SAEs) in clinical trials is critical to sponsors and contract research organizations (CROs). Additionally, the new European regulatory requirements for post-marketing expedited reporting are making the timely reporting of non-serious adverse events (AEs) more pressing. However, paper-based processes used to collect AE and SAE data from sites are inefficient, requiring manual data re-entry into safety reporting systems, and are costly, time-consuming and error-prone.

Rave Safety Gateway adds advanced AE and SAE collection and E2B transmission capabilities to the Medidata Rave EDC/CDM platform. Leveraging Rave's flexibility and the vast amount of safety-related data collected in EDC, Rave Safety Gateway significantly improves the accuracy and speed of safety data collection and transfer to safety systems, for both pre-marketing and post-marketing studies.

Reduce Safety and Clinical Databases Reconciliation

By using a single system to capture all patient data, Rave Safety Gateway extracts the appropriate data from Rave according to configured mappings and outputs files in the industry-standard E2B format, which can be processed by any E2B–compatible safety system. This fully electronic, end-to-end solution ensures a single "source of truth" and reduces reconciliation efforts to resolve discrepancies between safety and clinical databases, yielding significant savings in time and resources for sponsors.

Automatically Notify Predefined Personnel

Rave Safety Gateway addresses the time-sensitive nature of safety data reporting. Immediately upon sites entering new or follow-up safety data in the EDC system, Rave Safety Gateway extracts relevant safety data and simultaneously issues email notifications to predefined personnel. Customizable email content provides important case information to safety teams.

Key Features and Benefits

Rave Safety Gateway is a secure, online interface between EDC and safety systems that integrates investigational sites with safety and data management teams.

- Provides end-to-end solution to capture safety data within EDC
- Automates safety data collection and communication processes
- Generates output files in standard E2B format
- Provides context-sensitive help and access to a product knowledge portal
- Provides safety team with direct visibility into EDC data
- Associates one or more events into a single safety case
- Offers configurable, reusable business rules
- Includes fully auditable mapping and data activities

Rave Safety Gateway

Configure
- E2B mappings
- Business rules and data selection criteria

Capture & Notify
- AE/SAE data in EDC
- Notification of predefined personnel
- Follow-up information in EDC

Manage
- E2B content
- Site queries
- Follow-ups
- Data transfer to safety system

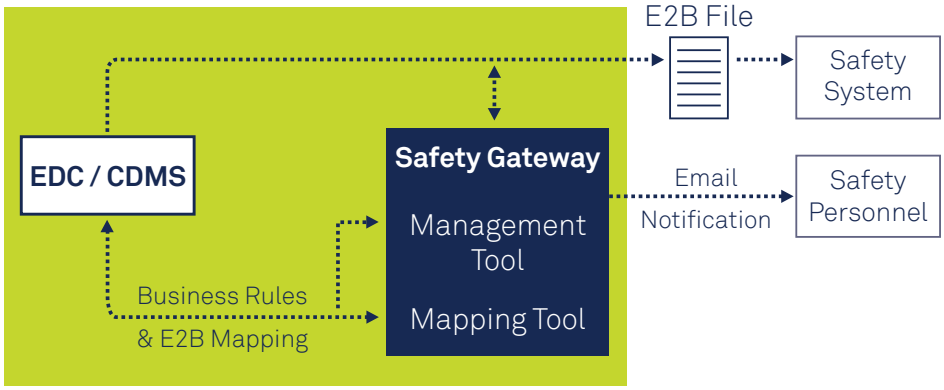
Reduce Safety Data Query Cycles

Rave Safety Gateway substantially shortens query cycle times and reduces the number of queries safety staff need to issue sites to fully triage cases. Not only is the safety team spared re-keying of safety data into the safety system, they also leverage Rave's robust data management capabilities to reduce the amount of incomplete or inaccurate data, which often leads to repetitive query resolutions. Common data visibility for both safety and site staff can greatly speed case data processing.

Streamline Post-Marketing Expedited Reporting

Beginning in July 2012, some European countries are requiring applicants and holders of European marketing authorizations to report non-serious adverse reactions within 90 days. Rave Safety Gateway helps pharmas meet this new requirement by allowing the transfer of both serious and non-serious safety case data from Rave to their safety system.

Configuration and data flow



Configure Business Rules and Workflow

Business rules can be defined to govern case follow-up or time windows for extracted data, such as medical history or concomitant medication. Manual override allows safety personnel to review the extracted data and select which is to be included in the E2B file prior to its creation and transmission to the safety system. When E2B Plus is supported by the safety system, Rave Safety Gateway can extract supplementary data not covered by the E2B standard. All mapping and data activities in Rave Safety Gateway are logged for audit purposes.

Streamlined Safety Reporting

Rave Safety Gateway works in parallel with Medidata Rave EDC and Medidata Coder, offering a real-time solution to further streamline the safety reporting process. Once an AE and corresponding case data is captured in Rave EDC, verbatim(s) requiring coding is sent to Coder in real time. Upon receiving the coding decisions from Medidata Coder, Rave Safety Gateway will automatically send the coding information as part of the case data file defined per the extraction rules.

About Medidata

Medidata is reinventing global drug and medical device development by creating the industry's leading cloud-based solutions for clinical research. Through our advanced applications and intelligent data analytics, Medidata helps advance the scientific goals of life sciences customers worldwide, including nearly 850 global pharmaceutical companies, biotech, diagnostic and device firms, leading academic medical centers, and contract research organizations.

The Medidata Clinical Cloud® brings a new level of quality and efficiency to clinical trials that empower our customers to make more informed decisions earlier and faster. Our unparalleled clinical trial data assets provide deep insights that pave the way for future growth. The Medidata Clinical Cloud is the primary technology solution powering clinical trials for 17 of the world's top 25 global pharmaceutical companies and is used by 16 of the top 20 medical device developers—from study design and planning through execution, management and reporting.

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