

Medidata Rave Safety Gateway Speed and Accuracy in Safety Data Capture

Rave Safety Gateway is a configurable EDC-to-safety system interface that streamlines end-to-end workflow management of 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 is built on the Rave Clinical Cloud's unified platform, which enables a single source of truth for all study-related data across your entire portfolio. This adds advanced AE and SAE collection and E2B transmission capabilities to the Medidata Rave EDC platform. Leveraging Rave Clinical Cloud's unified data platform 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. This can be accomplished because once data is entered, the platform masters and populates it throughout the end-to-end suite of Rave applications.

Reduce Data Query Cycles and Database Reconciliation

By using a single system to capture all patient data, Rave Safety Gateway extracts the appropriate data from Rave EDC 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, substantially shortening query cycle times and reducing 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.

A Complete Clinical Trial Solution

Medidata 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

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, Safety Gateway extracts relevant safety data and simultaneously issues email notifications to predefined personnel.

Streamline Post-Marketing Expedited Reporting

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

Configure Business Rules and Work Flow

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.

Medidata Rave Clinical Cloud

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

The Platform of Choice for Clinical Research

The Medidata 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 and excel sheets, you are now on a truly unified platform.

About Us

Medidata is leading the digital transformation of life sciences, with the world's most-used platform for clinical development, commercial and real-world data. Powered by artificial intelligence and delivered by the #1 ranked industry experts, Medidata helps pharmaceutical, biotech, medical device companies, and academic researchers accelerate value, minimize risk and optimize outcomes. Medidata and its companies, Acorn AI and SHYFT, serve more than 1,200 customers and partners worldwide and empower more than 150,000 certified users every day to create hope for millions of patients. Discover the future of life sciences: www.medidata.com

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