Medidata and InterMune Work Together to Integrate Clinical and Safety Databases

The Challenge

InterMune is a biotechnology company focused on the research, development and commercialization of innovative therapies in pulmonology and orphan fibrotic diseases. Several years ago, InterMune made the decision to begin utilizing electronic data capture (EDC) for future clinical studies. In addition to looking for an EDC solution that would streamline its clinical research process and enable real-time access to clinical data, InterMune also looked for a system that would integrate with its safety database to:

- Reduce reconciliation of serious adverse event (SAE) data between clinical and safety databases; and
- Eliminate time-consuming and redundant data entry to the drug safety database.

The Solution

After evaluating potential solutions, InterMune determined that the Medidata Rave® system had this functionality. Through the SAE collection and E2B transmission capabilities built in Rave and the functionality of Rave Safety Gateway, InterMune was able to collect all SAE data directly within the EDC system and have it electronically transferred to InterMune's safety database as an electronic E2B file. This process improved the accuracy, speed and visibility of InterMune's SAE collection process, yielding significant savings in time and resources compared to the traditional paper-based processes.

Business Impact

Current manual or paper processes to collect and transmit clinical SAE and SAE-related data from sites to a sponsor's safety database are time-consuming and resource intensive. Moreover, such processes often rely on duplicate data entry and require reconciliation between the pharmacovigilance and clinical databases.

Leverage Medidata Expertise

To facilitate a smooth transition and extract the maximum value from Rave Safety Gateway, Medidata provides a comprehensive consulting workshop to help with the implementation of Safety Gateway. Clients can benefit from Medidata's implementation experience with a full planning and optimization workshop. The workshop will focus on how to transition from a paper-based system to a fully automated, electronic transmission of E2B files from Rave to any E2B compatible safety system.

Topics covered in the workshop:

- Product overview
- Implementation process
- Enablement/common practices
- Key success factors to implementing an EDC-to-safety system electronic process
- Electronic case report form (eCRF) impacts and updates
- Mapping and configuration
- E2B file generation
- Implementation plan

Rave Safety Gateway is a secure, configurable EDC-to-safety system interface that enhances Medidata Rave EDC with advanced SAE collection and E2B transmission capabilities. With Rave Safety Gateway, InterMune has the ability to ensure specific safety process needs are met through comprehensive business rules, which are independently designed to govern parameters specific to a trial's design.

- **Eliminate Reconciliation Between Clinical and Safety Databases**
  Rave Safety Gateway enables InterMune's investigational sites to use the same process and system to collect and communicate SAE data as they do for all other patient data. Rave EDC, the repository for all clinical data, serves as the single source for clinical safety data. By electronically sending safety-related data collected via one source and managed by Rave upfront, it eliminates the need for reconciliation between the clinical and safety databases.
- **Reduce SAE Query Cycles with Improved Visibility and Team Communication**
  The Rave EDC system allows the flexibility for InterMune to permit their safety personnel to view safety-related data directly in the Rave EDC system and raise queries as appropriate.
- **Elimination of Manual Data Entry of SAE Data**
  Safety Gateway dispatches the Rave SAE data to InterMune as an electronic E2B file for processing by its safety database. There is no need for a process of manually sending a handwritten SAE form to a data entry associate for manual entry into the safety database. The elimination of the manual process of entering data into the safety database leads to more productivity, more accurate data and faster case processing.

About Medidata

Medidata Solutions is a leading global provider of cloud-based clinical development solutions that enhance the efficiency of customers' clinical trials. Medidata's advanced platform lowers the total cost of clinical development by optimizing clinical trials from concept to conclusion: from study and protocol design, trial planning and budgeting, site negotiation, clinical portal, trial management, randomization and trial supply management, clinical data capture and management, safety events capture, medical coding to business analytics. Our customers include biopharmaceutical, medical device and diagnostic companies, academic and government institutions, CROs and other research organizations, encompassing 20 of the top 25 global pharmaceutical companies as well as research organizations of all sizes.

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