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 Rave EDC system had this functionality. Through the SAE collection and E2B transmission capabilities built in Rave EDC 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. Rave Safety Gateway is a secure, configurable EDC-to-safety system interface that enhances 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.

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 Rave 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 EDC 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

- **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 EDC 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**
  Rave 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.

The Platform of Choice for Clinical Research

The Medidata's 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, you are now on a truly unified platform.

About Medidata

Medidata is leading the digital transformation of life sciences, creating hope for millions of patients. Medidata helps generate the evidence and insights to help pharmaceutical, biotech, medical device and diagnostics companies, and academic researchers accelerate value, minimize risk, and optimize outcomes. More than one million registered users across 1,400 customers and partners access the world's most-used platform for clinical development, commercial, and real-world data.

Medidata, a Dassault Systèmes company (Euronext Paris: #13065, DSY.PA), is headquartered in New York City and has offices around the world to meet the needs of its customers.

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