Ludwig Institute for Cancer Research Turns to Medidata and EXTEDO for End-to-End Pharmacovigilance Solution

The Challenge

The Ludwig Institute for Cancer Research is a nonprofit research organization committed to improving the control of cancer through integrated laboratory and clinical research, and novel therapeutic strategies based on the emerging understanding of cancer. Ludwig runs clinical oncology trials based on discoveries made by its researchers that are focused on exploring the therapeutic modalities of cancer vaccines, targeted antibodies and small molecule inhibitors. During these trials, Ludwig captures data from trial participants, including serious adverse events (SAEs), which must be understood, distributed, triaged and reconciled in order to maintain a high level of patient safety.

Faced with the standard, paper-based SAE reporting process and a growing number of international studies, Ludwig sought to automate and optimize their system. An automated system would eliminate manual data entry and reconciliation of the safety and clinical databases.

The Solution

The Ludwig Institute chose to create a complete, end-to-end SAE solution by enabling and configuring Medidata Rave Safety Gateway, Medidata's electronic data capture (EDC)-to-safety-system interface, with EXTEDO's PcVmanager, a drug safety management solution built specifically with open data standards in mind. This cross-vendor solution leverages the E2B standard for SAEs using an AS2-compliant electronic data interchange (EDI) service, allowing a fully electronic workflow from data entry to Medwatch/CIOMS creation, complete with an integrated Rave query system for resolving any questions between Ludwig and the clinical sites. PcVmanager's gateway can also be configured to submit electronically to the FDA and EMA in addition to partners. With EXTEDO providing a fully centralized safety database, this integration allows all medical coding to occur directly in Rave. Any user with coding questions can utilize Rave's flexible query workflows before sending the coded safety data on to PcV manager.

Better for the Sponsor

All data is entered directly in Rave, including the narrative, MedDRA coding, edit checks and query responses. This allows a single source of truth and an almost instantaneous feedback loop with the sites. This simplified process should lower the number of queries and completely remove the laborious reconciliation process at the end of the trial.

Faster for the Site

Sites no longer need to fax or email duplicated SAE information to Ludwig. They are up to speed on the new system very quickly, as the new system is the standard Rave EDC interface with which they are already familiar. A simple one-sheet quick start is all that is necessary to train them on the new PV process. They are reminded to resolve any SAE queries each time they access Rave to enter additional trial data. In the same way, monitors are able to more easily verify data entered by the site.

One Fully Electronic Workflow

- From adverse event data entry to medical coding, triage, analysis and agency communication, all safety events follow a common electronic workflow.
- Duplicate data between EDC and Pharmacovigilance (PV) forms is not necessary. All SAE data is entered directly into Rave.
- Both Rave and PcVmanager provide reports with consolidated views of all SAEs available in a fully transparent fashion.
- PcVmanager continues the thread of electronic workflow for each SAE with the ability to recode, classify, review, categorize and submit.

SAE Reconciliation Reduced

- SAE queries can be resolved quickly using the standard Rave query workflows.
- Affiliates and large partners are able to use a familiar query interface in Rave, and are able to see at all times the latest version of the safety data.
- Little to no reconciliation effort is necessary at the end of each trial, saving hours to weeks in reconciliation time.
- There are significant savings in time and resources with the implementation of a seamless, electronic SAE reporting process.

About EXTEDO

EXTEDO is the key software and service solutions provider in the field of regulatory information management. EXTEDO's focus is on optimizing clients' eRegulatory business processes. The company's enabling technology, the EXTEDOsuite, is unique in that it covers the complete regulatory landscape including: product registration planning & tracking, submission management, pharmacovigilance management, labeling management and document management. Today EXTEDO serves over 700 customers in 60 countries, including the EMA and more than 25 regulatory authorities worldwide.

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