Global Pharma Bridges the Gap Between Data Management and Pharmacovigilance with Medidata Rave Safety Gateway

The Challenge

A global life sciences organization, which has brought treatments to market for the improvement of human and animal health, engaged in an initiative to significantly improve clinical productivity. This industry leader typically has hundreds of new treatments in development at a time in all trial phases. The capture, triage and reporting of serious adverse events (SAEs) by local and central pharmacovigilance (PV) groups is a critical process that runs concurrently with data management.

In the company's traditional SAE capture process, as data was entered into its Medidata Rave electronic data capture (EDC) system the investigator would fill out a paper form to identify the SAEs, as well as any relevant medical history, labs, concomitant medications and other relevant test results. This form was then faxed or mailed to a local PV office for data entry and processing and sent to the central PV organization, requiring duplication of data entry and additional reconciliation at the trial's end. Questions or clarification about the SAE then required a direct email or phone call to the investigator.

As a global organization, the sponsor needed a more efficient way to ensure its safety data was captured cleanly and with reduced redundancy through the use of a single data source with up-to-date SAE information and more formal control over data entry, as well as a more collaborative, better-flowing process between the clinical data management (CDM) and PV teams.

The Solution

The sponsor chose to connect Rave Safety Gateway, Medidata's EDC-to-safety-system interface, with their in-house, existing pharmacovigilance database. This new process allows investigators to enter all SAE data directly into Rave, which then transmits it in E2B format to an ancillary system. This system generates an XML file for automated electronic data transfer into the central PV database and a PDF copy of the SAE in a user-friendly format. The PDF is made available to the local PV office for further processing to the central PV organization, and additional copies of the PDF report are distributed to the investigator and the responsible clinical research associate (CRA), as well as optionally to the study medical expert.
Changes to the SAE for follow-up are clearly highlighted with original data side-by-side in the PDF copy. Cycle time for SAE reports, formerly one to two

A GLOBAL PHARMACOVIGILANCE PROCESS

A big part of the success formula for the company's Rave Safety Gateway implementation is their adherence to common standards, as well as its phased implementation approach.

- System integrations require an up-front agreement on data standards, and the E2B+ format supported by Safety Gateway is a critical piece of this puzzle, allowing the systems to work in harmony even with additional custom attributes that extend the standard E2B specification.
- A phased approach to implementation has allowed its data management team to fully support the electronic generation of SAE reports in PDF format for the local and central PV offices. These PDFs are automatically generated by the system, providing a familiar format and annotating clearly any changes made against the original electronic copy. Future phases of the implementation will support a fully electronic process through the local offices.

days, is now 10 minutes, saving the investigator hours of time in filling out forms and rechecking already entered and verified clinical data.
If the PV team has questions for the investigator, they simply open a Rave query using a hyperlink directly to the relevant data, and query resolution is routed by Rave through the PV team and answered. Duplication of queries between data management and PV is a non-issue, as the set of existing queries and their resolutions are visible. This improves collaboration between the two groups, keeping the data immediate and available right after First Patient First Visit (FPFV) and moving all tasks up-front and early.

Business Impact

ALWAYS ONE VERSION OF THE TRUTH

- Duplicative data entry is avoided by sites and sponsors that use Rave SAE data as their single source of truth. Data entry errors are largely avoided, and discrepancies are limited to the monitored electronic case report form (eCRF) process that is in place.
- Reporting provides a consolidated view of all SAEs, transparently showing changes, the initial report and all follow-ups.
- Many SAE tracking reports are no longer necessary, as the latest SAE information is always available.
- Reconciliation effort is significantly reduced at the end of each trial.

FASTER CYCLE TIME, FROM WEEKS TO MINUTES

- A typical one to two day wait time (with peak delays of weeks) for the SAE report to be submitted and routed is reduced to 10 minutes, saving the investigator hours of unnecessary effort with each SAE.
- All involved PV teams get a clear copy of the safety information for further processing. In follow-up reports, changes are clearly highlighted, and the entire process is automated.
- If partner assistance is needed during a busy period, they can be brought in to support SAE management overflow with very little switching effort involved.

ALWAYS ON THE SAME PAGE

- SAE and query information is bi-directional, so globally separated teams no longer work in silos. The study data management and pharmacovigilance teams work more closely and effectively using Rave query management and the Safety Gateway E2B transmission.