Amalgamation of Safety data in Global clinical trials: Enticing solutions

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A US Based biotechnology company with innovator products for cardio-vascular diseases.

Business Challenge: The Client was running clinical trials for an investigational product across the globe. Since many CROs were involved for data collection and processing for their respective clinical trials, the final data was hard to compile together and reconcile for the overall safety evaluation.

Services Provided: Transition of safety data originating from all the clinical trials for the same investigational products to a centralized Argus safety data base in a harmonized format. End to end case processing, SAE reconciliation, DSUR, IB updates, and medical monitoring services are being provided to the client now.

KEY BUSINESS NEED

The Client was running its clinical trials in different regions of the world like North America, EU, Latin America and various Asian sites. Since there were huge, diversified areas, many CROs and Clinical trial vendors were involved. From a safety point of view every CRO was processing the SAEs in their own safety data bases. This led to challenges in the preparation of DSURs, IB updates and Signal management as the safety data was not lying in a consolidated manner.

BUSINESS SOLUTION

Our client had clinical trials running across the globe. In order to comply with the Global regulations, it's imperative to harmonize PV systems and consolidate safety information of the investigational medicinal products. Our client had multiple stake holders who were fulfilling the obligations at a local level, but the information was not get collected in a harmonized manner at a central pool.

AWINSA implemented a centralized Argus safety data base and did the migration of all the SAEs from the clinical trials run by different CROs using a robust migration plan. The migration was done in a phased manner with the risk-based approach which involved migration of the closed SAE cases first followed by the open SAE cases (non SUSARs) followed by the migration of SUSAR cases.

The migration was done for 7 different clinical trials for the same investigational medicinal product and was carried out in 2 months. The presence of all the SAEs in the centralized safety base helped in making the processes of signal management, IB update, DSUR preparation much easier.

WHO WE ARE

Planning for a paradigm shift in the delivery of Pharmacovigilance services, AWINSA Life Sciences aims to provide end to end PV services including in its ambit both clinical trial and post marketing services. Manned by people with discernment and an eye for quality, we at AWINSA Life Sciences ensure astute analysis of safety reports so that clinical scenarios emerge in perspicuity

Intricate and deep-rooted knowledge of the subject and the international regulations will ensure that you are delivered services of the highest order within the stringent timelines.

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