

Outsourcing Pharmacovigilance: Use a secure web-base interface to develop a collaborative partnership between Sponsor and CRO

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ABSTRACT

Since the beginning of Pharmacovigilance adventure in the 60's following the wave of congenital disorder caused by Softenon (thalidomide), the safety of the patient has been driving organizations to be more and more aware of the safety profile of any medication. Additional clinical trials with more detailed protocol and risk evaluation focus, additional ways of data collections, additional legislation for the company to follow to make certain no similar disaster happens. To help sponsors and authorization holders to cope with the safety surveillance activity of their medications, guidance's, legislations, and instructions have been developed and improved to improve data collection, harmonies and distribute the safety information widely.

However, the drawback is that the development of a pharmacovigilance system, the set up and its maintenance may turn out to be time consuming and expensive, especially for small or minor companies newly in place which has to follow all the requirement at once while other have had many years of adaptation and improvement along with the regulation changes.

Outsourcing pharmacovigilance, completely or partially, appears to answers some of constrains the safety surveillance activity presents at different levels. Involving third parties in this can provide you expertise, flexibility regarding workload and cost control.

To improve safety surveillance, data accuracy, respect of timelines and patient safety, communication between partners is the key. The information must be exchanged fast, be available at all time by all involved stakeholder and tracked efficiently

The use of secured data sharing environment is one of the recent tools which can improve this communication between partners all around the world. Above shared repository new features can be developed to fulfill communication and data exchange needs. Alerts and automatic actions from those systems can ease case management, track efficiently any exchanges and improve the process to focus on the safety surveillance, signal detection and risk/benefit assessment.

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