WCG Partners with Major Japanese Pharmaceutical Sponsor to Unify the Management of Safety Records and Increase Compliance

WCG's SafetyVigilance® Online Safety Event Solution Delivers Quality and Efficiency to Unify Enterprise Trial Management and Meet Regional Guidelines and Regulations

OVERVIEW

A Japan-based pharmaceutical sponsor partnered with WCG to assess the impact of WCG® online safety event delivery solution, Investigator Space within the sponsor's enterprise safety event processes. Across studies, CRAs reported complexities with current adverse event documentation processes including: difficulty tracking records and getting investigators to review and acknowledge safety letters and misplacement and/or misfiling of emails containing adverse event documentation. The sponsor evaluated several solutions, but only WCG SafetyVigilance® was equipped to meet all of the sponsor's requirements.

> We appreciate that Japan has some of the most stringent regulations for the communication of adverse events. We are excited to partner with a Japanese company to help address these regulations and offer solutions like SafetyVigilance® that help improve efficiency of these processes.
>
> **DAVE YOUNG, WCG**

THE CHALLENGE

Improve CRA efficiency by automating processes and time consuming non-value-added activities for adverse event documentation

Ensure compliance and reduce likelihood of errors associated with CRA turnover and misfiling of emails

Meet and exceed sponsor requirements and complexities of working within stringent PMDA regulations

RESULTS

INCREASED COMPLIANCE

Implementation of SafetyVigilance® significantly improved quality of adverse event documentation with improved processes, tracking methods and automatic recording within this system. This allowed both the study teams and CRAs to track all records and gain visibility to documentation for a more unified management of adverse events, leading to a **62% increase** in enterprise compliance within 18 months.

SafetyVigilance® has full support for the unique 15 and 30 day PMDA reporting and predictability requirements in Japan. This allowed the sponsor to stay on top of changing regulations, ensuring they were always in compliance with local country rules.

We engaged WCG in 2017 to develop an enterprise approach to safety letter delivery for increased compliance while simultaneously reducing the amount of administrative burden facing the Pharmacovigilance team. The results have been significant: enterprise compliance increased from 30% to 92% within 18 months.

VP, TOP PHARMA CLIENT

REDUCTION IN ADMINISTRATIVE BURDEN

SafetyVigilance® reduced working hours by eliminating redundant and non-value-added processes. SafetyVigilance® also ensured accurate and automated recording of documentation to support adverse events across the entire enterprise.

Safety event processes were optimized, giving principal investigators more control. With the implementation of SafetyVigilance®, most activities were automated, allowing PIs to complete them within the system, eliminating work formerly done by CRAs and allowing the PIs more control over the process, resulting in improved accuracy and timeliness of documentation.

PLANS FOR THE FUTURE

The sponsor to expand use of SafetyVigilance® to all studies with both internal and CRO based CRAs

The sponsor plans to leverage WCG training modules to help manage risk-based monitoring activities, train site staff and CRAs using InvestigatorSpace® – WCG online training platform

The sponsor plans to integrate SafetyVigilance® with other systems such as Medidata (EDC), VeeVa (eTMF), Master Control (Document Management) and Oracle (Argus)

The sponsor plans to eliminate all physical paperwork and manual processes