How a Top Pharma Client Transformed Its Safety-Reporting Process, Saving $11.2m in One Year

Overview

Expedited Safety Reporting may be the most inefficient aspect of clinical trials today. Sponsors, CROs, and some technology providers have taken an approach of distributing all safety reports to all sites – leading to sponsors being out of compliance with most country's regulations, overburdening sites, and burying important patient safety information. The system needs a complete overhaul. It can be done, but it requires the willing to invest in change.

Sponsors bombard sites with safety notifications, much of them unnecessary and not in compliance with individual country rules. The sites risk being overwhelmed to the point they miss the critical patient-safety information. Some sites have even quit participating in a sponsor's trials due to this bombardment followed by the sponsor requiring them to read and acknowledge duplicate or unnecessary safety. Sponsors, too, become overwhelmed. For large trials, they must keep up with hundreds of different—and constantly evolving—country- specific rules.

Then there's the issue of global harmonization. Keeping track of different—and constantly evolving—country-specific rules leaves sponsors and CROs overwhelmed.

Without the right systems in place, it's impossible to comply with all the various regulatory requirements. The entire process of this "brute-force distribution" is costly, non-compliant, and ripe for error. Patient health is the most important issue, but far from the only one. Over-reporting can lead to regulatory repercussions, delays, fines, loss of site relationships, and cost-over-runs.

In 2014, a leading biotech company decided to upgrade its safety document distribution system to address some of these issues. After researching several options, the biopharma company chose WCG's SafetyPortal.

The Challenges

IN NEED OF RESCUE

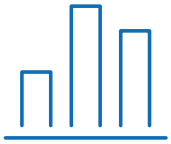
In 2014, the company urgently needed to replace its safety document distribution system. The existing one was failing them: Safety alerts were not going out in a timely fashion, making the company non-compliant.

OVERDISTRIBUTION

The company was distributing too many safety reports in an effort to be cautious. Sites spend hours each week tracking, reading, reconciling and archiving safety reports, activities that significantly increase monitoring costs and take time away from patients. Further, over-distribution is actually documented non-compliance with a country's requirements NOT to send certain expedited safety reports to their investigators.

A NEW GLOBAL PRESENCE

The lack of global harmonization in safety reporting rules became an increasing burden as the company expanded its presence. The information required, and documents considered important, vary by country. Ethics committees also have different needs. As they expanded into Europe and Asia, they were suddenly faced with an array of different regulations. They couldn't show compliance with each country's safety document distribution requirements.



GROWING PAINS

The company was growing rapidly. By 2016, it was generating roughly a million safety alerts annually across 40 oncology trials. It needed a more sophisticated and advanced safety portal.

A NEED FOR OVERSIGHT & TRANSPARENCY

Rapid expansion dramatically increased the need for oversight and transparency of the safety reporting process.

DIFFERENT DATA FEEDS

The company, with three separate clinical trial management systems (CTMS), needed a way to seamlessly integrate the data feeds.

SITE RELIEF

Trial sites were being inundated with reports to the point they were losing hours a week that could be better focused on recruitment and retention.

Solutions Implemented

In 2017, WCG began implementing SafetyPortal to address:

GLOBAL HARMONIZATION

WCG's SafetyPortal harmonizes regulations for >113 countries. That allowed the company to distribute safety letters based on what each country's laws specify or the needs of a particular IRB or ethics committee. Because the system is continually updated, the client remains in compliance: Each site receives all the notifications it needs and only the ones it needs.

STREAMLINED REPORTING

To avoid regulatory issues, the company had been overdistributing reports—massively. WCG was able to eliminate virtually all over-distribution and in the process cut their notification volume in half.

DATA INTEGRATION

Unlike some other software service vendors, WCG is also a systems integrator, so it was able to seamlessly connect the three CTMS feeds.

TRANSPARENCY

SafetyPortal gives the sponsor complete transparency; it can click a button and see how many Investigators and sites are compliant, when they last logged on and who hasn't acknowledged what.

WORKFLOW ENGINE

The WCG SafetyPortal workflow engine simplifies and streamlines its SDD process. WCG automated the entire safety reporting process, providing a user interface to the SafetyPortal workflow engine that was simple enough—even for business users without an IT background—to configure by using picklists for each country-alerting rule.

REDUCED SITE BURDEN

SafetyPortal saves Investigators hours each week by eliminating unnecessary safety letters. That, combined with its clean interface, allows Investigators to focus their time on research, not on trying to access the dashboard.

Conclusion

Since 2014, for this one client, WCG SafetyPortal has powered safety reporting across 300 studies for 17,000 users, with more than 7 million distributions. With WCG SafetyPortal, this biotech company cut its reporting in half, allowing it to better deploy its resources and dramatically reduce the administrative burden on its sites and study teams, while complying with global and local safety reporting regulations. Sites had more time to devote to patients and the company saved $11.2 million within one year of go-live.

Within 1 year this client saved $11.2 million through SafetyPortal