Critical Considerations for Clinical Trial Safety Reporting Investments

Naturally, safety event reporting and pharmacovigilance (PV) should be subject to detailed regulatory scrutiny as evidenced from the Food and Drug Administration (FDA) overseeing the protection of human subjects and improving trial conduct by ensuring appropriate safety procedures are in place. It's critical that the right information reach the right constituents for reporting adverse events in a clinical trial.

In this article, we will cover some of the key aspects that impact clinical trial safety reporting processes, such as excessive reporting by sponsors and the need to automate and intelligently integrate siloed information to facilitate safety document distribution. Non-integrated clinical trial training and communication can negatively impact safety letter notification, regulatory document exchange, and cross-reporting between studies. There are also challenges involved in pharmacovigilance information technology. We will delve into a real-life use case for the effective distribution of critical drug safety event information. Centralised and automated SUSAR distribution has proven to be effective for delivering safety compliance information to sponsors, CROs and research sites.

Pharmacovigilance IT and Business Process Support

Throughout the drug development life-cycle, pharmacovigilance IT and business process support are critical components to ensure both drug and device safety. Clinical Research Organisations (CROs), pharmaceutical and medical device companies must proactively work and collaborate with all stakeholders to ensure a systematic approach to safety monitoring and reporting. This has helped to support the evolution of safety document distribution and technology breakthroughs, such as safety data communications hubs, portals, dashboards, etc. They centralise and automate distribution to increase the speed of clinical trials without compromising on safety and accuracy.

The need for an increased collaborative approach, combined with a constantly changing regulatory landscape, has brought about additional requirements for managing risks. For instance, the industry has transitioned from passive to active safety surveillance and automated document distribution activities. Advanced technology in the form of communications hubs or smart portals can easily and seamlessly deliver documents to a variety of recipients within a specific timeframe, using predefined methods of delivery and in required formats, flawlessly. It is important to take into account the relevant global, regional or local regulations that apply, together with applicable internal business requirements by utilising quantitative methods to leverage data from all available sources (including Clinical Trial Management Systems).

The Role of a Safety Data Communication Hub

Pharmaceutical companies and CROs that utilise a safety data communication hub for drug safety document management today, are transforming the way in which they connect sponsors, CROs and sites across the clinical trials ecosystem. There has been a paradigm shift to more advanced technology like this, which is safeguarding companies and bringing greater efficiencies than ever before. They are alleviating troubling inspections that can be risky and lead to penalties. Issues with sponsors burdening sites with needless or redundant reports of safety issues that have little to no relevance to the site can finally be eliminated. Cost savings can be achieved by no longer needing the trial staff to investigate whether a report of adverse events should be submitted to their institutional review board (IRB), a designated committee that protects the rights, safety and well-being of humans involved in a clinical trial, by reviewing all trial aspects and approving its start-up.

It is no wonder that safety reporting is one of the largest hidden costs in the clinical trial industry. By simply decreasing any unnecessary safety letter distribution, cost savings can equate to millions of dollars. From our experience, we are finding that more than 50 percent of sites are spending 72-plus hours of staff time. This is time that could be invested in patient care. Additionally, we have found safety reports can average about $23 each to produce with budget expenses ranging about $40–$45 per report. Of course, these estimates can change depending on whether they involve global clinical trials where economies of scale can result or depending on how the trial unfolds in terms of its complexities. By reducing the complexities of safety reporting through the use of new technology for drug safety document management, substantial savings can be made through streamlining the reporting process and alleviating the burden on sites, CROs and sponsors.

One CRO's Perspective

In conversation with a Clinical Research Manager at a full-service global CRO they mentioned that they have successfully received from the FDA, as well as other international regulatory agencies, approval of more than 85 products since 2000.

There has been tremendous benefit gained by replacing the legacy cloud-based collaboration platform with a "Smart Portal" that automates the sending of safety documents to the right people involved in a clinical trial, instead of multiple manual steps, as required with the previous solution. The CRO's involvement in more than one trial meant that they could expect to receive an average of 75 reports daily from some 3-4 hub users per individual site.

With so many reports being generated and so many users utilising the information on a regular basis, this gives added importance to gaining auditable reporting and compliance tracking – all of which is handled through the hub where information can be centralised, and distribution of safety letters automated. The hub also groups messages where applicable. For example, in a large oncology program, there are multiple protocols, for the same compound, so by grouping messages together, sites receive only one safety alert and are not flooded with emails. This has also enabled the CRO to automate cross-reporting between multiple studies, a critical activity that the CRO struggled with previously.

By centralising safety reporting within the organisation, they fixed their inability to track everything from every recipient, an instrumental activity for the clinical operations (CO) team who are working with the clinical sites directly. Now the CO teams no longer have to maintain compliance in another system but rather

can do it through the same application doing the delivery. This has eliminated hours of lost time weekly and substantially reduced overspending.

Safety documents like SUSARs, line listings and development safety update reports (DSURs) can be quickly sent and accessed by all recipients including sites, ethical committees or ECs and IRBs – thus reducing the number of outgoing messages. This is a great time savings when you factor in the CRO has about 200–300 internal users and thousands of site recipients. The safety documents can be automatically distributed using the embedded country rules and recipients' language preferences. Out-of-the-box settings can be configured to user preferences, which helps in faster adoption and easier training, especially for large, global organisations. Safety reporting is a compound-level vs. study-level activity within drug safety operations. The hub handles study-level distribution using an approach that limits over-distribution especially when those sites are working on multiple studies with the same compound.

Putting Actionable Insights into Practice

In essence, the large CRO referenced said they advanced the automation of their drug safety document distribution process and appreciated that documents could be uploaded once and immediately made available to all appropriate recipients. The company was able to put actionable insights into practice and be able to track which recipients did what and when. By drilling into data sets, it was possible to see if particular countries, sites, users or studies are falling short of expectations regarding their obligations. Ultimately, it gave them better oversight on compliance and access information to potentially determine where targeted training may be needed for certain groups as well as possibly assessing whether wider issues exist at a site so that they can mitigate general risks.

To Conclude

Innovative approaches to safety reporting processes should include monitoring and alert mechanisms to enable full compliance and also eliminate overspending together with comprehensive audit trails. Processes that build on existing safety delivery methods should also seamlessly implement and not require extensive site staff training. Often it is deemed instrumental to a clinical trial to achieve higher levels of user acceptance, automated compliance and save resources. Thus, why market research has shown that around 85% reduction in costs can be achieved along with a 90% reduction in resource requirements while experiencing compliance rates above 97% when able to fully automate the document distribution process. All of which gives credence to re-evaluate current in-house systems for safety compliance.

Tim Billington

T. Billington, Chief Sales Officer at pharmasol, which provides pharmacovigilance hosting services, and software, to their pharmaceutical and CRO customers. (www.pharmasol.de). He has been working in the pharmaceutical industry for more than 20 years. Starting his career at a CRO within data management and project management he then moved to Oracle where he led a number of global clinical software implementation projects. In 2001, he moved to pharmasol, where he co-developed the rapidLIVE implementation approach for accelerated application deployment. He now leads the sales team at pharmasol across all areas of the business.

Email: tim.billington@pharmasol.de