propharma

WHITEPAPER

Safety Services: Critical Component of Clinical Trials

Nowhere in clinical trials is the risk-reward aspect more widely considered than in Safety Services. There are two primary questions to answer when selecting the Safety services to subcontract to a pharmacovigilance vendor.

The first is to identify which component parts are worth a solid investment of money over time and which will be less impactful to the program.

Second, sponsors are challenged with determining which additional services, beyond the required elements, will augment the final data package of the investigational product and which will have provided no further value.

Armed with those decisions, navigating the murky waters of selecting a safety services provider can still be tricky, so let's examine a few elements that sponsors should investigate when contemplating outsourcing safety services:

- Experience
- Flexibility and proactivity regulatory knowledge
- Technology platform, technical expertise and dedicated safety systems resources
- Communication skills
- Ability to provide safety services throughout the full drug or device life cycle
- Cost

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle

http://www.propharmagroup.com/

info@propharmagroup.com

Experience Level

Don't settle for only the answers a vendor chooses to share. Instead, ask the questions that dig deeper and get to the root of what truly matters.

A commonly asked question in sponsor-vendor discussions is whether every Pharmacovigilance (PV) team member has the ideal number of years of industry and therapeutic experience to match an upcoming clinical trial. While this is important, a more critical – yet rarely asked – question is about the experience level of the Quality Check (QC) team. This team plays a pivotal role in shaping the SAE narrative and resolving queries, ultimately influencing the quality of the final output.

Another frequently asked metric is the PV vendor's case processing quality percentage, which is typically defined by the number of errors identified during QC. But what about the mistakes that go unnoticed during QC and remain in the final report submitted to the sponsor? Does the PV vendor even track that?

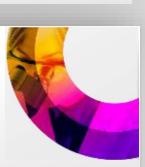
These are the kinds of questions that can distinguish a surface-level assessment from a truly informed vendor evaluation.

Sponsors shouldn't settle for the surface-level answers a vendor chooses to provide—especially regarding something as critical as pharmacovigilance. Instead, it is essential to ask the right questions—those that dig deeper and uncover the insights that truly impact trial success.

One commonly asked question from sponsors is whether each Pharmacovigilance (PV) team member has the ideal number of years of industry and therapeutic experience aligned with the sponsor's upcoming clinical trial. While important, a far more revealing question would be: What is the experience level of the Quality Check (QC) team? This is the stage where serious adverse event (SAE) narratives and queries are critically evaluated and shaped so knowing the experience level for these team members seems far more important.

Similarly, sponsors often ask about quality percentages for case processing—typically defined as the average number of errors per case identified during QC review. However, a more strategic and meaningful question would be: How many errors go undetected during QC and remain in the final report submitted to the sponsor? And, perhaps most importantly, does the vendor even track that data?

The answers to these more insightful questions can reveal whether the vendor's team is able to deliver the high-quality outputs needed for a complex trial Investing in a highly skilled, highly trained PV team—particularly at the QC level—can yield significant long-term benefits. For example, well-written SAE narratives can be directly incorporated into the Clinical Study Report (CSR) without requiring revision, thus streamlining report development and reducing cost and time needed.



Flexible and Proactive Capabilities

You might expect that any CRO that offers safety services will be able to handle the basic essential functions of Safety Plan development, safety database management, case processing, narrative writing, and SAE reporting.

- Can they do this globally?
- Do they know the legal obligations of clinical trials to identify when sites are not conducting the trial ethically?
- Can they manage the complexity of multiple protocols or when sponsors make changes mid-trial? Worse yet, does that automatically mean a change order?
- Are they responsive and do they proactively seek out ways to help you?
- Can they help with medical opinion expertise and clinical event classification management if needed?
- Can they maintain the project from the early phase through post-approval?

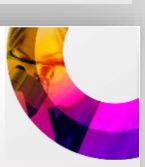
Chances are that while your clinical trial starts only needing the basics, somewhere along the path, things may change. Having a PV partner who is nimble and prepared to adjust is key to the study's success. You may not have to invest now in an adjudication committee or global literature surveillance services, only the basics; things may change somewhere along the path.

Having a PV partner who is nimble and prepared to adjust is key to the study's success. For example, you may not have to invest now in an adjudication committee or global literature surveillance services. Still, the security of knowing you have options available when you need them is priceless.

Regulatory Knowledge

It's well known that health authorities have differing timelines and reporting requirements, not to mention the variety of ethics committee requirements globally. To ensure project compliance, PV teams need to be well-versed in this area since the timeliness and quality of the data submitted to the health authorities impacts approval decisions, the approval timeline, and ultimately impacts affects the costs to get a product to market.

Asking the standard questions in this case will not get to the core of the information needed here. Instead of asking whether a CRO can perform submissions to the FDA or EudraVigilance for example, dig into the process by asking how they maintain and ensure current regulatory intelligence information, for example, dig into the process by asking how they retain and ensure current regulatory intelligence information and how this is shared with your project team. Ask how they prepare and submit periodic safety reports and how they complete EudraVigilance or MHRA registrations.



The good news is that regulatory intelligence information can be purchased from another PV vendor, so even if your current PV team does not have what it takes, you can still reduce your risk of non-compliance by providing the proper information to them.

Technology and Tech Expertise

Consider someone who understands very little about the mechanics of their car and relies entirely on their trusted mechanic to ensure it functions properly. That individual would not be well-suited to work for a ride-sharing company, where passengers depend on the reliability and safety of the vehicle. If they're unable to diagnose or fix even a minor issue, how dependable could they truly be in that role?

Following that same logic, how dependable would a PV vendor be who does not understand how to make backend changes to their safety database or finetune the strategy threads of the literature search tool in use? These days, the number of different systems, platforms, and applications available within PV is astounding, but technology is not the same as tech expertise. Having a PV vendor who can quickly make changes within Argus is critical instead of waiting two to three weeks for Oracle to get around to your service ticket.

For some organizations, technology is seen as an imperative. But in pharmacovigilance, deep technical expertise is not just important—it is critical. Regardless of the platform selected to manage the collection, assessment, and reporting of serious adverse events, the pivotal variable is an experienced team of specialists supporting every aspect of the system: from implementation, integration, and migration to system upgrades, validation, and, if applicable, direct hosting of the environment. Even the most robust safety processes can falter without the proper expertise to maintain the technology solution.

An efficient technology backbone, maintained by a knowledgeable and experienced team—is essential for reducing costs and ensuring data quality and timely reporting to partners and regulatory agencies. Is this an area where early investment pays off? Without question. Absolutely!

With careful planning, Sponsors only need to build a safety database one time for all their products, for all of their reporting, through the full lifecycle of their drugs and devices. By ensuring an internal team is in place to upgrade and safeguard that database, there is no need ever to migrate the data elsewhere.

Communication Skills

Clinical trials rarely follow a perfect path – there are always some challenges that some challenges always occur along the way. Identifying and addressing these challenges proactively is necessary before they doom a study. Communication and transparency are key to working with the investigative sites, identifying new processes, and resolving issues.

Your safety team may be managing multiple protocols for which there could be hundreds of outstanding queries and ongoing tasks with the sites related to expedited events being reported. You will want a team that communicates thoroughly and promptly.

Ask what their systems are for handling open case listings and query reports, what templates are already in place, what training is standard for the project team, and how do the cross-functional teams operate. Their answers to these questions will help you know if this is the right team for you.

Costs

Once you have asked all your questions and gathered all of your data, be sure to compare your priorities with the capabilities of each vendor your questions and gathered your data, be sure to compare your priorities with each vendor's capabilities. This last task will not only make the decisions easier but will point to areas where a deeper investment is required for the success of your program. Sometimes you do get what you pay for, so find the team that fits your needs, is experienced, flexible to adapt to changing parameters, offers consistent communication, and technology that is well-managed; it will gain efficiencies that will help to bring your study in on-time and within budget.

Pharmacovigilance should not be so difficult. We're here to make it easier for you; we're ProPharma.

For more information on how we can support your clinical trial, please visit www.propharmagroup.com.