Change is Inevitable: Flexible IRT Systems and Effective Product Consultants Are Keys to Coping with Change

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There are three certainties in life – death, taxes, and clinical protocol amendments. All joking aside, if anyone has conducted or been part of a clinical trial that was completed with no protocol amendments, that would be the exception to the norm. Generally, professionals who support clinical trial research operate under the expectation that a clinical protocol *will* be amended, and the only question is *how many times* it will be amended.

A common question we hear from those who are newer to clinical research is, "Why don't sponsors take the time to get the protocol right the first time?" Experience has shown there are several factors, and we will tackle two of them in this article.

Speed

Most professionals are in clinical research because they want to be involved in developing products that help improve patient quality of life or even better, cure diseases or conditions. While we all share the same mission, ultimately, there will be competition among sponsor companies to be the first to gain product approval with hopes of capturing larger market share. So, the main construct of a clinical protocol, its hypothesis and endpoints, will be clear but other aspects may need to be fluid and require changes during a trial. If a sponsor tried to perfect protocol language before beginning a study, it will likely see its competition speed ahead.

Protocol Type

Certain types of protocols will require change based on what a sponsor is trying to achieve. For example, there could be a clinical protocol that is in phase 1 or phase 2 where four doses of a product are being compared. During clinical trial conduct, what if the clinical data showed that one of the doses was not being tolerated by patients and therefore was not safe? On the other hand, at interim analysis what if the clinical data showed that three doses were proving to be somewhat effective and only one of the doses was proving to be very effective? In either case, the clinical protocol could be amended based on real-time clinical trial data.

In late phase studies, especially oncology, we have seen more protocol designs that compare an investigational product (IP) or a combination therapy to current standard of care. Such protocol designs may be in a master protocol format that would expect amendment. Perhaps a sponsor sees their IP being used in different indications and each indication has a unique timeframe. Perhaps trial design has different products being added, dropped, or distribution ratio altered based on clinical trial results at various interim analyses. Protocol change is inevitable.

Flexible System

Knowing that clinical protocols will change, clinical technology providers need to consider how their system offerings can efficiently and effectively handle the data. Sponsors can benefit from a self-service feature on the user interface or quick system changes by the IRT provider to handle typical IRT changes, such as adding cohorts, adding or removing drug/product managed in the system, and prioritizing which batches/lots are sent to clinical sites first.

For those who have managed clinical study amendments using IRT, most will agree that the biggest hurdle is related to implementation timelines and costs. To be fair, complex protocol amendments can require the same amount of work (or more) as an initial IRT system build depending on the infrastructure and approach of the IRT provider. If the technology provider takes the time to ensure its platform can handle their most common change requests in an efficient way, it will help break down the perception of a big hurdle when a protocol amendment requires a system change.

Consultation is Crucial

While a clinical technology provider needs to offer a robust, flexible system, they also need to ensure that their product consultants fully understand the system's capabilities to provide the greatest value to their customers. To start, a product consultant can help proactively plan during the study startup and system design phase based on experience in a therapeutic area, indication, trial design, and more. The consultant's experience helps them anticipate certain changes that may come up during a trial and can build flexibility into their initial system release. As is the case with most protocol amendments, there is a direct correlation between the amount of change needed to the system and the impact to the sponsor's cost and timeline.

There are times when the sponsor gives its provider specific instructions for what needs to change in the IRT. Good consultants who understand clinical trials will do more than follow orders. They will listen to the sponsor's needs in relation to the clinical protocol AND the sponsor's business process to assess appropriate options. The sponsor's business process is one critical consideration that typically is missed by even the best consultants. It is important for both IRT providers and sponsor companies to remember that what works for one may not work for another.

There are many clinical technology providers who have fantastic product offerings and people. They each have their differentiating characteristics, and many have user interfaces that are appealing to the eye. Sponsors who are looking at new technology providers need to look beyond the façade and assess what is underneath as well. Do not get excited by the term 'configurable system'. Instead, propose scenarios to the provider that could impact your clinical trial and ask how their system would handle those situations. Expect your product consultants to ask many questions to ensure they are providing the right system for your clinical protocol. Ultimately, the combination of a solid technology infrastructure with experienced consultation is a recipe for success in coping with inevitable system change.

About the Authors

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About YPrime

With more than a decade of focused work with eClinical systems, YPrime is a provider of technology and services that expedite clinical trial data management. Cloud-based interactive response technology (IRT) and electronic clinical outcome assessment (eCOA) platforms enable greater speed, precision, and integration in clinical trial management. YPrime's technology and service offerings enable sponsors to move faster and more efficiently to their next development milestone.