DON'T DO IT ALONE

To De-Risk Your Next Trial, Seek Outside Expertise

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Whether the focus is endpoint adjudication, aggregate data monitoring or safety assessment, the clinical and device development industry clearly understands the value of establishing expert scientific committees to provide oversight on study data. These expert committee assessments provide validation on clinical data as additional support for regulatory submissions and commercial strategy. What is less well understood, however, is the importance of independent expertise.

Without independent expertise, sponsors risk biased decision-making, conflicts of interest, potential clinical delays and squandered resources that could otherwise be avoided.

MORE THAN JUST EXPERTS

Expert committee optimization demands expertise—people with the right committee-specific training and experience, plus the right processes and technology. This involves many elements, including having the infrastructure to onboard the right medical or statistical experts at the right time, automating manual processes, deploying well-defined, regulatory-grade documentation and communication flows, and using partners with deep expertise to pull it all together and proactively manage the committees toward their intended purposes.

WHY USE AN OUTSIDE PARTNER?

Sponsors often don't realize how much work is involved in creating these committees—building the technology, creating an effective Charter, predefining criteria for the endpoints being monitored, etc. As a result, many sponsors initially try to handle expert committees in house or turn it over to the study CRO as these seem to be the easy and logical choices. There are better options! As a sponsor, do you really want to divert resources from your high-pressure clinical trial startups to operationalize all the elements that need to happen to ensure you have good independent oversight?

The same applies to handing it off to the study CRO. You wouldn't want the CRO that is managing the operational aspects of your trial to also be responsible for providing an independent perspective. The sponsor and the study CRO must keep focused on all of the critical activities at the heart of the clinical trial; they may not see the signals the same way an independent expert would.

There's another important reason to hand off scientific review to a third party: *The appearance of objectivity.*

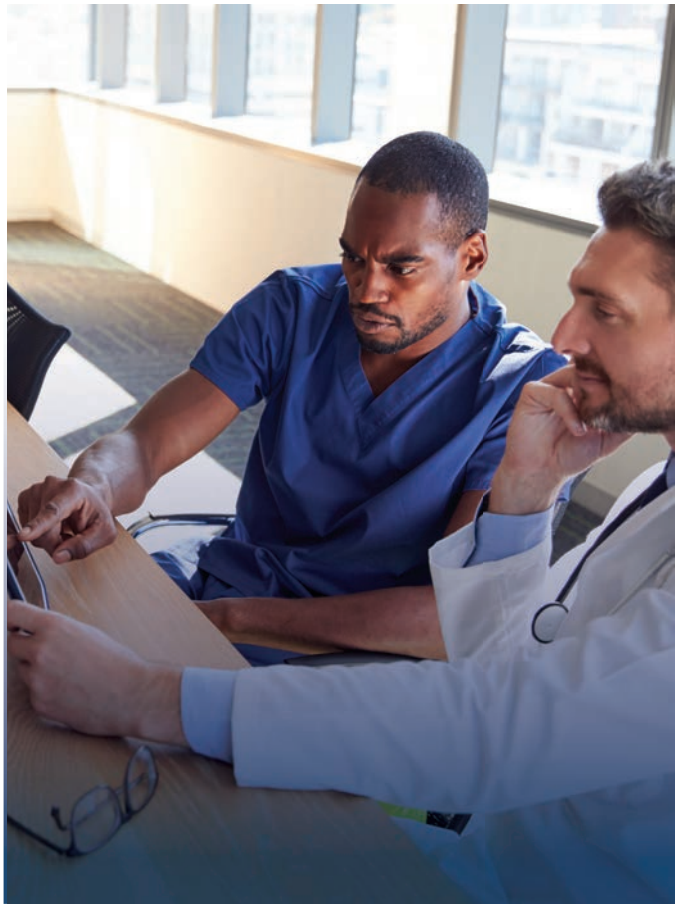
Sponsors and CROs are committed to the scientific integrity of clinical trials and the research process. But they have an inherent conflict of interest between making difficult—and often costly—actions to do what is right for a trial vs. taking the actions that will propel the drug forward to the next milestone. This feeds the common perception of bias when oversight functions are managed by the same group managing a trial.

To address this, some sponsors and CROs create separate teams for trial management and committee management. This is better than no action at all, but it still runs the risk of bias and conflicts. Moreover, it does little to address the *perception* of bias.

GUIDANCE ACROSS THE LIFECYCLE

Our experience shows—and common sense dictates—that planning committees at the onset of clinical trial design, rather than during trial conduct, provides better insights and value. The later you bring in the expertise, the less useful it may be for a strategy that is already underway. You want access to these insights throughout the lifecycle of the development program. This allows you to receive key input at program design that can have huge impacts to protocol effectiveness, and to detect signals during the course of the clinical trial that help decide whether, and how, to keep moving forward. Expert committee oversight can serve as a helpful QC mechanism on study conduct to help identify issues early on. Early identification of trends enables opportunity for critical modifications that may avoid an unnecessary shut-down. On the other hand, expert oversight can also help trials fail faster when needed to avoid cost and resource burden.

Plus, it doesn't need to stop at the end of the trial. Although historically expert committees have commonly focused on prospective review of clinical trial data, companies are now gaining valuable, competitive advantage producing insights from approaching committees at a program-level and/or applying retrospective reviews of data from select trials. Thoughtful deployment of committees in the post-marketing phase has enabled companies to organize, define and gain insightful expertise to bridge from clinical to



commercialization—and beyond.

REGULATORY EDGE

Few regulatory mandates exist on the use of expert committees; however, regulators have increased mentions of independent expert committees in recent guidance.

In addition, several publications with regulator authorship have come out of private-public efforts, such as the Cardiac Safety Research Consortium (CSRC) and Clinical Trials Transformation Initiative (CTTI), that define current thinking on Endpoint Adjudication/Data Monitoring Committee best practices and expectations for conduct for both drug and device studies.

The ICH E6 R2 guidelines make no explicit mention of expert committees. However, sponsors can address the requirements for timely risk detection and mitigation through well-designed committees. Specialized expertise in committee design allows sponsors to construct expert committees as a strong foundational support tool to help advance a given regulatory or commercial strategy.

BEYOND COMMITTEES

Sponsors that recognize the value of outside expertise often focus only on formal, structured committees. Committees—and individual committee members—can be beneficial beyond their structured use as EACs, DMCs and SACs. They can be sounding boards for strategic insights around new trial areas, protocol development, trial challenges and potential areas of risk.

Expertise opens doors. Sponsors can look at ways to incorporate independent medical thinking early on to answer key questions. Such insight can prevent sponsors from investing time and money in something that may not bring value.

Scientific review isn't a one-size-fits-all endeavor. Sponsors have different needs. Many development programs do not even need a committee. They may just need that one therapeutic expert to look at that one particular signal that has the team concerned.

FIND THE RIGHT PARTNER

The right partner will be flexible, working across your entire portfolio, across one therapeutic area or for a single trial. There are several companies purposefully independent from clinical trial conduct that specialize entirely on the thoughtful setup and management of Expert Committees. Boutique statistical shops often help manage independent Data Monitoring Committees, and specialized software companies can help equip teams for Adjudication activities.

WCG's deeply experienced scientific leadership team combines more than 200 years of collective industry expertise in designing specialized clinical oversight and statistical solutions. Engage Independent Expert Endpoint Adjudication and Data Monitoring Committees in a strategic manner to identify methods for retrospective and prospective evaluations that may improve competitive advantage and bolster regulatory submissions.

To learn more about our Endpoint Adjudication and Data Monitoring Committee Solutions, click the links below:

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