WCG CLINICAL

The Top 5 Benefits: Outsourcing Expert Committee Management to an Independent Provider

Shaena Kauffman, Executive Director, Operations EAC

Today's clinical development landscape is seeing more and more clinical trial designs that include a specialized oversight component on accumulating data that utilizes medical and/or statistical experts who operate within a committee structure according to charter-defined rules and procedures.

Due to evolving practices and increased regulatory attention on Expert Committee operations, trial sponsors must recognize both the importance and the benefits of outsourcing their committee management functions to an independent provider.

In this article you will see the top 5 benefits of utilizing an Independent Expert Committee.

CLEAR FIREWALL

MEMBER RELATIONSHIPS

NO PERCEPTION OF BIAS

QUALITY CONTROL ON TRIAL

TIME AND COST SAVINGS

1 CLEAR FIREWALL

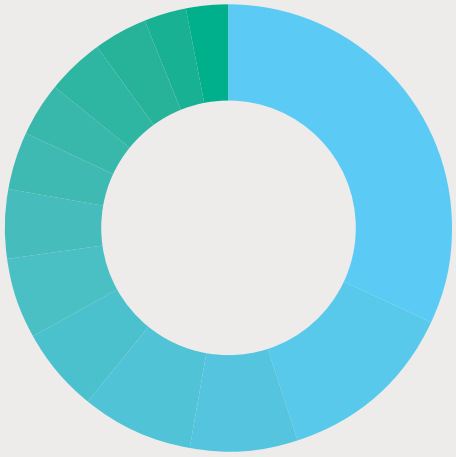
As part of their responsibilities, Data Monitoring Committees (DMCs) have access to unblinded data, whereas Endpoint Adjudication Committees (EACs), often access blinded data. Everyone involved with unblinded data must be entirely independent from the clinical trial operations, and must be separate from the group or vendor managing the EAC, due to blinding considerations as the information could influence actions and risk the integrity of the trial. This is taken very seriously by the regulatory agencies as well as most quality assurance and compliance groups. Some sponsors and CROs attempt to use separate teams for trial management as well as DMC management and EAC management but this still introduces a risk to the program as the teams could easily converse with one another. Outsourcing DMC and EAC management to a separate independent provider that specializes in managing independent expert committees helps eliminate that risk.

2 MEMBER RELATIONSHIPS

Sponsor relationships with their committee members can be a sensitive topic. Committee members are often selected for their expertise in the field of study and sponsors may therefore feel strongly that they should always have positive interactions with these members to maintain their connection to the product.

This dynamic makes it very challenging for sponsors to appropriately pushback and manage the members so it is a better option for sponsors to keep an arms-length relationship with the members while relying on a third-party company to set expectations with members, manage disputes, make payments, etc.

WCG's Global Expert Network of 1200+ Expert Clinicians and Statisticians with a Variety of Therapeutic Specialties



- Other
- Cardiovascular
- Multiple Scleroris
- Hematology; Medical Oncology
- Critical Care Medicine; Pulmonar Disease
- Gastroenterology
- Nephrology
- Rheumatology
- Hematology
- Pulmonary Disease
- Medical Oncology
- Infectious Disease
- Vascular Neurology

3 NO PERCEPTION OF BIAS

The clinical development industry upholds the scientific integrity of clinical trials and the research process. Whether substantiated or not, there is a common perception of bias when oversight functions are managed by the same group managing a trial because there is a conflict of interest between taking difficult and/or costly actions to do what is right for a trial versus doing what will propel the drug forward to the next milestone. In the absence of an independent, objective and unbiased company managing regulatory agencies have been known to take additional precautions to ensure validity of the trial results and committee conduct.

4 QUALITY CONTROL ON TRIAL

Because DMCs are tasked with reviewing study data throughout the trial, they can also serve as a quality control check on the trial itself. For example, DMCs may identify data outlier trends specific to particular study sites that could point to fraudulent conduct and warrant further investigation. If these types of situations arise with a committee that is managed by a sponsor's internal clin-ops resource, in addition to the countless of other responsibilities on their plate, the trends may go unnoticed and uncorrected. However, independent specialty providers focus deeply on metrics in the trial process, as well as trends in both data reporting and member voting, allowing for midcourse corrections with the early identification of risks.

5 TIME AND COST SAVINGS

Expert Committee management can be a complex process with multiple moving parts. The industry has seen many "rescue" committees salvaging trials with poorly conducted committees, numerous trials that were unnecessarily stopped by mismanaged DMCs and so on. On top of the significant time and cost delays in getting these drugs to market, many CROs scramble to keep up with the complexity of committee management and end up with negative profit margins on their projects. By comparison, independent specialty groups tend to have deep staff expertise to guide clients through a well-documented, cost-effective process that is measured and frequently reported on throughout the project to ensure the most value for the budget.

WCG is a global leader of solutions that measurably improve and accelerate clinical research. Biopharmaceutical and medical device companies, contract research organizations (CROs), research institutions, and sites partner with us for our unmatched expertise, data intelligence, and purpose-built technology to make informed decisions and optimize study outcomes, while maintaining the highest standards of human participant protection. WCG raises the bar by pioneering new concepts, reimagining processes, fostering compliance and safety, and empowering those who perform clinical trials to accelerate the delivery of medical therapies and devices that improve lives. For more information, please visit wcgclinical.com or follow us on Twitter @WCGClinical or LinkedIn.

wcgclinical.com