

# Ensuring Unbiased Oversight: The Case for Independent Expert Committee Management

Expert committees are a critical component in the success of a clinical trial. By turning to third-party providers to manage these services, sponsors can enhance trial credibility, mitigate risks, reduce bias and the perception of bias, and drive operational efficiencies.

Data Monitoring and Endpoint Adjudication Committees are groups of independent medical and/or statistical experts charged with a specific set of oversight activities related to a development program.

Data Monitoring Committees (DMCs) go by a variety of names, including Data Safety Monitoring Boards and Data Safety Boards. All clinical trials require safety monitoring, but not all require a DMC.

The DMC experts sit at arm's length from a clinical trial and look at the overall trial or clinical program data as it's unfolding. Unlike the sponsors and study CROs (contract research organisations), the DMC has access to unblinded data that it reviews for early indicators of safety problems.

An Endpoint Adjudication Committee (EAC) – also called a Clinical Endpoint Committee – adjudicates suspected events to determine if they meet event definitions, per the Charter. This panel of independent adjudicators often reviews blinded data to give their expert opinion on patient-level safety or efficacy events of interest according to predefined rules outlined within the Charter.

Sponsors may opt to manage these committees in-house, outsource to a CRO, or outsource to a specialty provider. While the first two options are viable operationally, they can create unnecessary risk, increased cost, and operational inefficiencies. Outsourcing expert committee management to a specialty provider with committee management expertise can be the best option from a regulatory, ethical, and business perspective.

### The Value of Independent Review: Eliminating Bias

While it can prove challenging to keep the EAC and DMC independent from the clinical trial sites, participants, and the sponsor, it is critically important to do so. Maintaining third party independence between the committee and sponsor can greatly reduce the risk of bias and perceived bias compared to a sponsor managing a committee directly. Committee management and the related processes also add a level of complexity to trial conduct and benefit from expert management.

This is especially true for DMCs, which have access to unblinded data. Each person involved with unblinded data must be separate from clinical trial operations because the information could – even

unintentionally – influence their actions and put the trial's integrity at risk. Relying on a CRO to manage the DMC could increase risk in that domain because the CRO might also be responsible for monitoring and running the trial and developing the final analysis.

### Protecting Sponsor/Expert Relationships

This firewalled approach can help sponsors maintain relationships with industry experts and key opinion leaders, that often serve on independent committees. Since it is important to preserve these relationships, there are clear benefits to engaging an independent specialty provider to set expectations, manage disputes, and handle compensation. This approach enables sponsors to protect their relationships and the integrity of the trial.

### Quality Control Through Committee Management

Independent specialty providers can offer an additional level of quality control for trials. For example, DMCs review study data and can provide quality control checks on the trial itself in areas such as data timeliness and cleanliness. Specialty providers focus on trends in data reporting and study progress, allowing for timely recommendations or midcourse corrections and early identification of risks.

### Selecting the Right Provider to Achieve Efficiencies

Working with an experienced provider can save time and money. Building the committee infrastructure – such as a web-based adjudication platform, process guidelines, and charters – requires a significant investment of time and financial resources. Sponsors can save time and money by partnering with a provider that has existing infrastructure, systems, and templates.

Conducting due diligence during the partner selection process will ensure the provider has the qualifications, experience, and resources to effectively manage the EAC or DMC.

Successful vetting begins with asking the prospective provider some key questions:

- **Timeline Management:** What mechanisms do you have to monitor timelines and ensure timeline compliance? Do you have additional resources to expedite processes that will enable the sponsor to hit key milestones?
- **Member Management:** Can you describe your experience and strategies to manage the actions and tasks required of the members to ensure critical timelines are met? What mechanisms do you have to measure committee member satisfaction and engagement? Managing the committee members and the required actions of the members is critical.
- **Audit Support:** What mechanisms do you have to answer regulatory agency questions? What is your experience hosting



audits of EACs and DMCs? What level of support will you provide for audits? Look for a provider that has a depth of expertise supporting and hosting audits, specifically those related to expert committee management.

- **Operational Efficiencies:** What operational efficiencies are available as we grow this program? Look for a provider who can find operational efficiencies and cost savings for a high-volume program. As programs grow or protocols are added, the right provider should be able to scale the program leveraging existing systems, processes, or documents.
- **Reporting & Data Access:** How will I view status reports and access the results of my committee? What is the turnaround time and how will it be measured? How do you manage member spend reporting and payments? Having access to your data when you need it is critical and working with a provider that understands your reporting needs is essential.
- **Staff Expertise:** Can you tell me about the project team that will be managing the expert committee? Can you tell me about coverage plans and staffing size to support this project as it scales? Will the staff working on this DMC or EAC work exclusively on expert committee projects? When outsourcing

expert committees, look for a provider who is as much an expert consultant as they are a provider managing the operational tasks of the project. Qualified providers should have a depth of experience managing expert committees and ensuring the project team has the required expertise and training is critical.

#### **Ensure Alignment Before Startup**

Early alignment between the sponsor and vendor is crucial. Developing high quality systems, processes and documentation up front will increase the project quality and efficiency and help to mitigate downstream issues. Successful partnerships are built on strong relationships, open communication, clear goals, and accountability.

- **What are the critical time points (e.g., interim analyses, database locks, DMC meetings)?** Be clear on key milestones at each step of the journey, making sure they are documented with expectations. This ensures all stakeholders are aware of and working towards meeting critical deliverables throughout the lifecycle of the project.
- **Who are the key decision makers?** When developing an expert committee there are numerous documents, forms, and

systems that need to be reviewed and aligned between the sponsor and vendor. Ensure the right people are in the right discussions and approval processes up front, to eliminate downstream issues.

- **Who is responsible for what tasks?** Roles and responsibilities should be well documented in the Charter or project guidelines. Strategically delineating task ownership between the sponsor and vendor is a critical discussion that should be held early. When making these decisions, aim to have the parties with the most experience and expertise owning each task or process to ensure operational success. For example, leveraging an EAC vendor with a depth of experience in EAC event identification can help to ensure high accuracy, quality, and a clear strategy that can be documented for regulatory authorities.
- **What are the communication and escalation pathways between the sponsor and vendor?** Define escalation pathways upfront and revisit them often. Is the process working as expected? Do the right people have access to vital information? Are delays or obstacles escalated to the appropriate parties to drive results? How is success measured and what does success look like? Use these data to drive results.
- **Who requires access to the adjudication results?** It's important to make this clear from the beginning. Who needs the data? Are data transfer agreements in place to ensure the appropriate party receives the data?

## Managing Committee Members

The right partner not only knows how to manage a committee; they know who to select to join it. An expert provider should have a vast network of committee members with a wide range of therapeutic expertise to draw upon.

The member selection process should ensure that the right members are chosen from the outset. The vendor should ensure the members have appropriate licensing, training, and expertise, with no conflicts of interest. Additionally, the members must have sufficient availability to be able to commit to the requirements of the committee and necessary turnaround times. Often members participate in a committee in addition to their job as a physician, so ensuring they have enough time to participate is critical for the project's long-term success and retention of members.

Expert committees should always be designed, structured, and managed with the members' experience in mind. Members want to be part of a high functioning, organised committee, engaged in interesting work and scientific problems. To drive results with the committee in mind, consider the following:

- **Set expectations:** Give committee members detailed guidance on roles, responsibilities, and operating procedures. This information should be well documented in the Charter. Make sure each member understands and agrees to the expectations and requirements – including availability – well before the first meeting or start of adjudication.
- **Prepare:** Provide the right data, in the right format, at the right time. Deliver data and meeting materials far enough in advance to allow members to thoroughly prepare for the meeting.
- **Respond:** Promptly answer committee questions and concerns, ensure clear escalation procedures are defined, and that committee members have access to staff when they need



them. This not only reduces member frustration, but it can also reduce delays.

- **Provide seamless administration:** In short, make things easy for the committee members. Committee members should be able to focus on the key responsibilities outlined in the Charter leveraging their medical and statistical expertise with minimal time spent navigating administration or technology issues. The members should receive seamless onboarding, contracting, and compensation.
- **Seek feedback:** Leverage member experience and feedback to drive efficiency and improve the process. Seek feedback and engage with the committee members throughout the project's lifecycle.

## Efficient, Safe and Unbiased

Sponsors rely on expert committees and when managed well, these committees enhance trial integrity, bolster efficiency, mitigate risks, and safeguard patient safety. Managing expert committees well takes expertise, effort, and experience. EACs and DMCs are complex, and sponsors need a partner they can consult with, not merely a vendor who performs outsourced tasks. Sponsors need a specialty provider with committee expertise, and years of regulatory and operational experience, who can navigate those challenges, make recommendations, and provide guidance.

The right partner helps sponsors ensure clinical integrity and regulatory compliance, attain operational and financial efficiencies, and achieve clinical trial success.

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