

Why outsource administration of your safety oversight groups?

Reasons why outsourcing your DSMBs, CECs, and Medical Monitoring is a smart choice.

Utilizing an independent, third party outside of the sponsor organization for managing safety monitoring groups offers several benefits. A CRO can ensure high quality safety oversight through independence, consistency and organization, credibility and experience, attention to detail, flexibility, availability, and timeliness.

Having a CRO can establish a “firewall” between the Sponsor and the safety management boards, therefore freeing the sponsor and study of any additional scrutiny for potential for bias. An independent CRO to administrate also promotes objectivity that benefits the safety of the subjects and the integrity of the trial. A CRO that offers administration of safety monitoring groups will have well-established processes and follow these for your study-specific requirements.

The CRO can also offer another layer of independence through assessing Conflicts of Interest (COI), managing member agreements, and managing member compensation. An independent administrator brings consistency and organization through standardized procedures and because managing safety boards are their primary concern.

Rather than having a DSMB or CEC that tries to run itself with physicians who are already busy, a CRO is available to deliver reliable results in a timely manner. Medical Monitors have the support they need to focus on providing expert safety reviews. Critical timelines, reports, notifications, and follow-ups don't get behind and are maintained seamlessly. Specialists can focus then on their areas of expertise without distraction. And if finding a convenient meeting location is an issue, a CRO can organize remote or local sessions. This also offers the flexibility to work with individuals from across the country and around the globe, providing a greater network of respected therapeutic expertise to use for a study.



IMARC has developed a list of best practices, summarizing the benefits of outsourcing your safety oversight groups. A DSMB, CEC, or Medical Monitor is an investment in safety and data integrity that goes beyond checking a box. Seek qualities in your safety management team that will be sure to add value to your important study.



Selection of Suitable Members

- Define 'suitable' for the project
- Establish criteria for expertise needed
- Collect and assess any disclosed conflicts of interest
- Collect credentials (CVs, licenses) and verify employability
- Complete onboarding and training of selected members



Protection of Study Confidentiality

- Obtain agreement from members to maintain confidentiality of reviewed information
- Select supporting tools to help ensure confidentiality, such as controlled access file sharing systems, and a secure physical or electronic system for retaining documents
- Remind group members of confidential nature of their role at subsequent meetings



Charter Development

- Add study details to template, including pre-determined requirements such as protocol-defined stopping rules for safety
- Request input from members and sponsor for review schedule, data to be reviewed, and any notification or stopping criteria
- Define responsibilities and timelines as needed



Conduct of Meetings

- Plan, host, and document meetings and follow-up items
- Coordinate logistics for remote or in-person meetings
- Develop relevant templates for meeting minutes, attendance, and recommendations and/or adjudications as needed



Ongoing Administration

- Facilitate and document other correspondence or adjudications
- Handle requests for information from IRBs
- Track and resolve follow-up actions
- Distribute notifications from the sponsor to members and track responses
- Update Charters as needed
- Maintain members' documentation and update as needed (CVs, licenses, COI forms)