

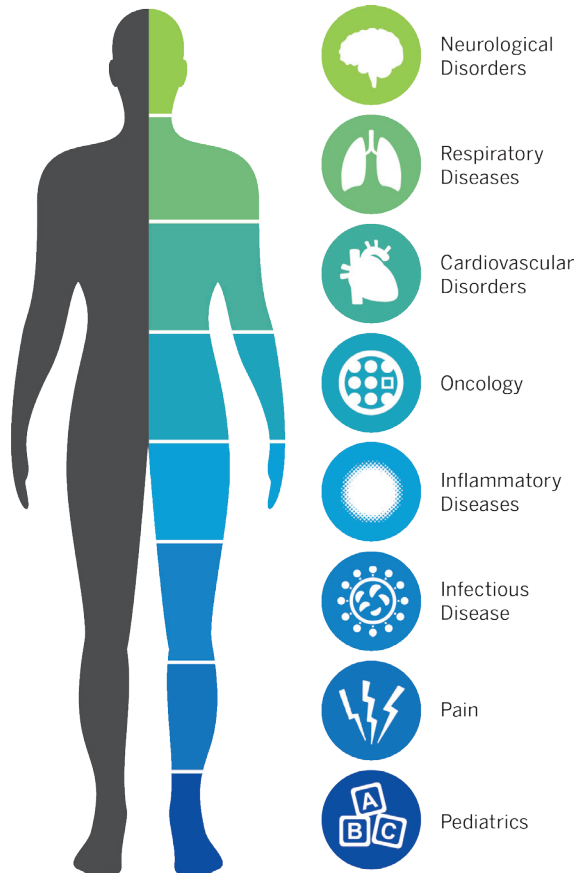
Data Monitoring Committee Support

Our Data Monitoring Committee support services include:

- Committee member recommendation and contracting
- Preparation of the DMC charter
- Specification and preparation of interim analyses
- Designing and programming DMC reports
- Presenting open and closed DMC reports
- Completing meeting minutes
- Providing Institutional Review Board (IRB) notification documents
- Coordinating DMC meeting arrangements

Axio coordinates and manages DMC projects to fit the specific requirements of each clinical study and serves as **client liaison** to the DMC, providing some or all of the support services needed to facilitate its operation. To promote optimum review of our clients' interim study data by their DMCs, we have developed a distinctively **user-friendly, easily referenced report format** and other innovations that ensure the clear presentation of data. Axio staff are highly trained to serve as **independent statisticians** for DMCs. We apply our training and deep DMC experience to provide **turnkey solutions** for monitoring patient safety and ensuring trial integrity.

As one of the world's leading providers of DMC support services, Axio offers broad-based DMC expertise across all major therapeutic areas.



Axio has supported clients in the planning and management of more than 200 Data Monitoring Committees in all major therapeutic areas—making us one of the foremost companies in this field.

Drafting, Programming, and Testing of Clear Tables, Listings, and Figures

Axio can help you design clear and concise tables, listings, and figures to be included in the DMC reports and provide your DMC members with mock versions of these report elements so they can provide their input prior to programming. Based upon the approved mock tables, listings, and figures, Axio will develop and test programs using SAS to produce the report elements required for the DMC reports.

Specialists in Overcoming the Challenges of Analyzing Unpolished Data

Axio's experience with mid-study data gives us the flexibility to work successfully with unclean or incomplete data. Our biostatisticians are accustomed to real-time data and are trained to find and respond to anomalies, outliers, data errors, and alterations to data structures. Upon receipt of treatment codes and kit numbers, we can perform a reconciliation to confirm all patients' kits match the treatment code. We also scan study results to determine whether efficacy and safety findings appear to be consistent with the treatment groups. We are accustomed to handling these problems on a large scale and have developed systems and processes to efficiently handle the issues that inevitably arise.

Our professionals are also well versed in overcoming the challenges associated with crafting Interim Analysis Plans detailing the calculations and data displays required for each interim examination of the trial data. Stopping boundaries are adjusted as needed for each interim look at the actual data. We have extensive experience with tricky endpoints such as time to disease progression, time to failure of local control, relapse, and composite cardiovascular endpoints.

Building a Better DMC Report

Axio has developed advanced report formatting programs that enable the creation of PDF files containing a fully linked table of contents. Our years of experience supporting hundreds of DMCs have also made us experts in selecting the appropriate content to be included in your reports. Distracting or irrelevant report elements are omitted, allowing your DMC members to thoroughly review your report in a time-efficient manner.

Practiced Presentation of Open and Closed DMC Reports

The Axio biostatistician working on your trial can attend your DMC meetings to present the materials and answer questions about the data or analyses in a professional manner. If requested and appropriate, our biostatisticians can provide additional analyses to the DMC membership to aid them in their oversight role, even during the closed session.

We are keenly aware of the importance of maintaining confidentiality and study integrity in DMC meetings. Our statisticians are specifically trained on how to interact closely with a study team without giving verbal or nonverbal cues about treatment arm results.

Coordinating DMC Meeting Arrangements

Axio's highly experienced team can smoothly manage all the planning and logistics required for both in-person and teleconference meetings, including travel, hotel, and catering arrangements for your DMC events. We make ourselves available for DMC teleconferences at any hour of the day or night.

It is our practice to send out meeting notices well in advance, to follow up with reminders, and to have a staff member ready to contact and assist DMC members who have not dialed in to a teleconference when expected. We prepare and distribute an agenda—and ensure that all agenda items are covered during the meeting.

Working With Your Study Team and Your DMC

Many companies are new to DMC procedures. We invite you to consider a visit to your company by one or more of our DMC statisticians. They can show your team how to support your DMC—and what is of interest to DMC members. We can help you understand what goes on behind closed doors and recommend how everyone can interact with one another to make the DMC experience as effective as possible.



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