Independent Data Monitoring Committees

A helpful guide through ACI Clinical’s DMC approach

Expert Committees for Clinical Trials

www.aciclinical.com | info@aciclinical.com | +1 (484) 429-7200
ACI Clinical was founded in 2001 as an independent specialty group within the clinical research industry. For more than a decade, we have focused on driving best practices in managing Independent Expert Committees – such as Data Monitoring Committees (DMC), Endpoint Adjudication Committees (EAC) and Safety Assessment Committees (SAC) – in order to provide clinical trial sponsors with a highly efficient process based on established best practices and more than 15 years of experience.

Our employees care deeply about achieving performance excellence and customer satisfaction in everything we do. Internal core competencies are focused in:

- Project Delivery
- Statistical Analysis
- Programming
- CDISC Data Standards/Conversion
- Clinical Consulting
- Up-to-Date Knowledge of Regulatory Thinking for Committee Conduct

ACI Clinical operates globally having supported hundreds of projects and compounds in nearly all therapeutic areas for Pharma, Biotech, Academia, Device, and CROs. When combining our internal expertise with our Global Academic Expert relationships and committee-supportive technologies, ACI excels in providing strategic guidance and reliable execution as a valued partner in support of any client’s committee projects.

**About This Guide**

The descriptions within this guide reflect ACI Clinical’s best practices for DMC management. We have worked under a wide variety of DMC models and have flexibility to meet additional Sponsor requested services. Please discuss any further needs with your Project Manager.
Planning for Success

During startup, ACI’s experienced project teams will drive the DMC setup and implementation in order to help sponsors structure the most efficient process based on each project’s unique needs. We recognize that smooth project collaboration begins with the first step, and we invite your team’s input on all major decisions in the setup.

**Introductory Meeting**
Each new project begins with an Introductory Meeting between ACI's project team and the Sponsor's project team. This initial meeting agenda allows for a comprehensive overview of the startup phase to align everyone's understanding of the deliverables, assigned responsibilities and expectations from the very beginning.

**DMC Member Recruitment and Approvals**
DMC Member recruitment and approvals is a collaborative effort whether members are identified by Sponsors or sourced from ACI’s Global Network of prominent academic medical and statistical experts. Our Member Services department is dedicated to the support of our global experts throughout the lifecycle of projects to manage the administrative aspects on their behalf and ensure their satisfaction with the process.

ACI will hold qualifying calls with each candidate to determine their rates, confirm interest/availability, collect their financial disclosures, and perform conflict of interest vetting. Qualified Member CVs will be sent to the Sponsor for final approval prior to ACI contracting and managing subsequent payments.
Startup Meetings
ACI follows a Project Management driven approach to DMC management. Following the Introductory Meeting, a communication plan will be created and a short series of startup meetings will be scheduled by the Project Manager. These meetings address key startup decisions:

• Meeting 1 - Member Identification and Data Transfer Planning
• Meeting 2 - Draft DMC Charter Review
• Meeting 3 - Review of DMC Statistical Analysis Plan and Displays

The startup phase concludes with a Kick-off meeting between ACI, the study Sponsor, and the DMC Members to finalize all documentation and understanding of the DMC purpose and process.

Statistical Analysis Plan and Mock Output Shells
Under our full-service model, ACI will develop the DMC Statistical Analysis Plan (SAP) and DMC-specific displays (examples below) from our library of Tables, Figures and Listings (TFLs) that were designed to simplify DMC member review based on clinically-oriented presentation of the data. Alternatively, ACI can receive the Sponsor/CRO programs under a hybrid model to unblind and rerun for the DMC.
Moving into Maintenance

During the maintenance period, ACI is responsible for managing all core elements of DMC operations and associated deliverables:

- Data Receipt
- Display Generation
- DMC Meeting Scheduling and Facilitation
- DMC Meeting Documentation
ACI Clinical provides all DMC Members and Sponsors access to our secure, role-based, web-based DMC Portal. The Portal's Home page is available to all parties and it includes study documents, DMC meeting schedule, contact information, and open session minutes.

The DMC Member Area is only available to the DMC members. It includes previous DMC closed session minutes and the current meeting's data displays.
ACI ensures that a firewall is properly maintained for any unblinded data and related discussions in order to protect the trial's integrity. During the maintenance period, Sponsor involvement is focused in three areas:

1. Attendance at DMC Meeting Open Sessions
2. Receipt of DMC Recommendation Post-Meeting
3. Review and Approval of Open Session Minutes

**DMC Minutes**
ACI Clinical's Project Managers are specially trained in the sensitivities of DMC Meeting Minutes. We provide concise, action-based minutes for both open and closed session meetings in regulatory-appropriate language.

### Open Session
- Introductions
- Review Previous Action Items
- Blinded Clinical Status
- Protocol Update
- Blinded Safety Update
- Other Business
- Action Items

### Closed Session
- Introductions
- Review Previous Action Items
- Unblinded Data Review Discussion
- Summary Agreement on Recommendations
- Next Meeting Scheduling
- Action Items
A Successful Closeout

**Final Transfer, Archival, and Portal Access Removal**
After receiving notification that the study database has locked, the ACI Project Manager will provide the final portal archive and final transfer of all DMC data, programs, and documentation. DMC Portal access for all users will be removed at this time.

**Debrief Meeting**
The ACI Project Manager will schedule a final meeting to confirm all materials were received as expected and to request feedback on the project. The DMC members can also be included at the Sponsor's preference to advise on further development.

**Continuing Partnership**
ACI Clinical will remain available after the project to answer questions and support items needed for any regulatory audits or submissions. In our effort to build long-term, mutually beneficial relationships with our clients, there may be operational efficiencies that we can carry forward to future projects together. Please ask about our Preferred Provider benefits as well. We look forward to working with you on this project as well as any projects in the future!

Consistent Processes
Consistent Results
Programmatic Efficiencies
Predictable Cost Forecasting and Billing
Specialized Third Party Independence
Efficient Project Setup and Execution