



Independent

Data Monitoring Committees

A helpful guide through ACI Clinical's DMC approach

Expert Committees for Clinical Trials

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About ACI Clinical



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.

Intro Meeting Agenda

- Team Introductions
- Project Scope Review
- Communication Flow
- Ideal Member Profile Discussions
- Roles and Responsibilities for Startup Deliverables
- Project Timelines
- Biometrics Planning (SAP, Mock Displays)
- Meeting Schedules
- Expectations
- Questions

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.

Planning for Success



Startup Meetings

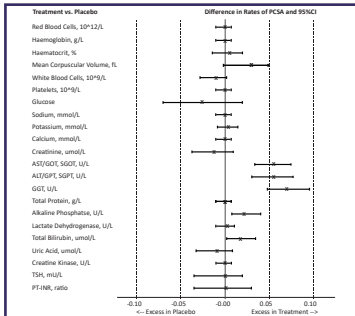
ACI follows a Project Management driven approach to DMC management. Following the Introductory Meeting, a communication plan will be created and a short series of startup meetings will be scheduled by the Project Manager. These meetings address key startup decisions:

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

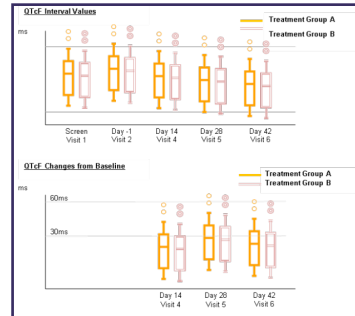
The startup phase concludes with a Kick-off meeting between ACI, the study Sponsor, and the DMC Members to finalize all documentation and understanding of the DMC purpose and process.

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.



Forrest Plot showing treatment differences



Box Plot showing descriptive statistics

Moving into Maintenance



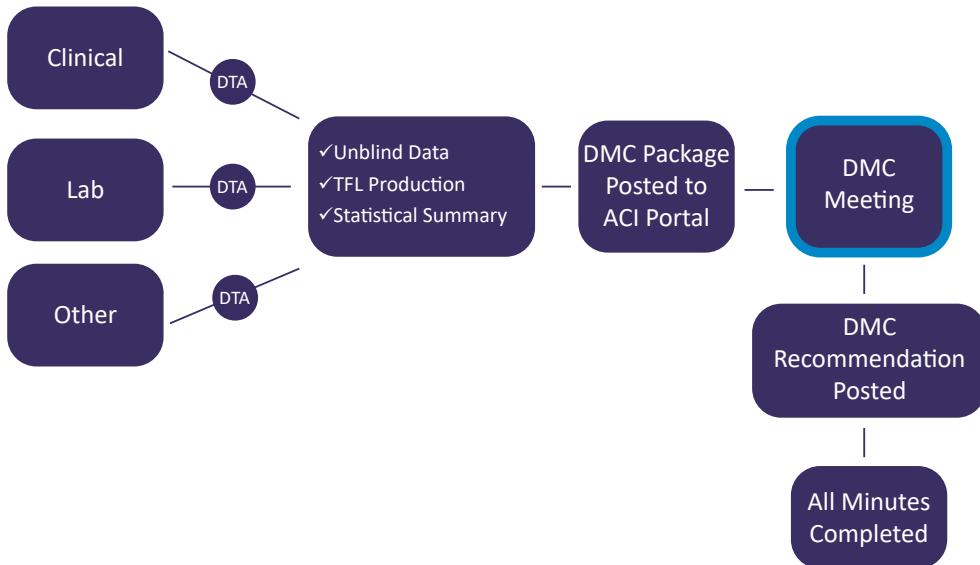
During the maintenance period, ACI is responsible for managing all core elements of DMC operations and associated deliverables:

- Data Receipt
- Display Generation
- DMC Meeting Scheduling and Facilitation
- DMC Meeting Documentation

Data Sources

ACI Preparations

DMC Meeting



Keeping You Connected



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.

Home Project Code: ACI_Project 1

New Announcements
new announcement or edit this list

Title	Created	Created By
Welcome to the <Sponsor Name> DMC Portal!	5/4/17	ACI Admin

Study Documents
New Upload

Name	Modified By
Protocol	ACI Admin
Charter	ACI Admin
Statistical Analysis Plan	ACI Admin
Investigator Brochure	ACI Admin

SAE Reports
New Upload

Name	Modified By
Patient 001_Event 07	ACI Admin
Patient 023_Event 03	ACI Admin

DMC Calendar
new event or edit this list

Title	Date
First DMC Meeting	6/27/2018 10:00 AM
Second DMC Meeting	7/29/2018 10:00 AM
Third DMC Meeting	11/7/2018 10:00 AM

Relevant Links
new event or edit this list

- The Establishment and Operation of Clinical Trial Data Monitoring Committees

Study Contact Information
new contact or edit this list

Last Name	First Name	Business Phone	Email
ACI	Admin	(484) 429-7200	info@aciclinical.com
ACI	Admin	(484) 429-7200	info@aciclinical.com
ACI	Admin	(484) 429-7200	info@aciclinical.com

DMC Member Project Code: ACI_Project 1

DMC Meeting Documents
New Upload

Name	Modified By
Closed Session Meeting Minutes	ACI Admin
Current DMC Meeting Report	ACI Admin

DMC Member Discussion
new event or edit this list

Title	Created	Created By
Elevated Liver Enzymes	5/4/17	ACI Admin

Sponsor Involvement



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



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