DMC™

Data Monitoring Committee (DMC) Services

Ensure Independent, Expert Oversight of Interim Clinical Trial Data

Each research trial is different, with unique data safety monitoring plans, endpoints, and statistical designs. Advarra's worldwide network of biostatistical and medical experts take time to carefully understand your trial and collaboratively build and administer your data monitoring committee (DMC) or data safety monitoring board (DSMB).

Independence | Compliance | Experience | Performance

- Improve trust and safety with independent trial oversight
- Conform with U.S. Food and Drug Administration (FDA) and EU European Medicines Agency (EMA) guidelines for DMCs
- Leverage a global network of 1,500+ statisticians, medical, and other research professionals
- Rely on 20+ years' proven experience in independent DMC administration
- Experience truly collaborative charter development and member selection
- Get committee meeting results within one business day after scheduled meetings

Solutions for all Therapeutic Areas and Trial Designs

No matter the trial complexity, we design your DMC to provide the appropriate independent oversight to support participant safety and statistical evaluations. We can support studies involving:

- Blinded designs
- Complex endpoints
- Lengthy duration
- Virtual trial modalities
- Real world evidence
- Decentralized trial modalities
- Worldwide data
- Medical devices
- All therapeutic areas

Charter Development

Create a solid foundation for your DMC by starting the charter development process as early as possible. Our expert statisticians and DMC administrators work collaboratively with the sponsor's or contract research organization's (CRO's) clinical and biostatistical teams to establish an appropriate charter. We take time to gather your input and ensure the committee's work will conform to U.S. FDA and EU EMA guidelines.

Independent Committee: Truly Integrated Service

While the DMC reviews interim clinical trial data independently from Advarra's other independent oversight and review services (IRB, IBC, EAC), an experienced, integrated services team oversees the overall process. Reviews are coordinated to avoid delays during study startup and throughout the trial. Your dedicated client success partner gets to know your study team and program to provide an unmatched level of knowledgeable, responsive support.

Enhanced Security

Your critical trial data is protected at every step by our state-of-the-art data protection technologies. Advarra's DMC administration systems are compliant with all applicable international privacy regulations including HIPAA, GDPR, PIPEDA, and FDA Part 11.

Expert Consulting

Want help developing your statistical plans, endpoints, or the overall trial? Our experienced network of industry professionals can assist.

SOAR™ for DMC

Advarra's secure, compliant, flexible and audit-ready platform is specifically configured for your project.

- Compatible with any electronic data capture (EDC) or similar clinical records system
- Secure biostats working environment
- Complete audit trail and secure audit ready document repository

Independent DMC Statistical Center

Need expert support with your trial's DMC-related statistical analysis?

Leverage Advarra's decades of statistical experience to design the protocol's overall DMC statistical analysis plan (SAP), including necessary programming and validation to complete the tables, listings, and graphs (TLGs) necessary for the DMC.

Services include:

- Develop DMC SAPs
- Create SAS derived dataset programs
- Create TLG programs
- Conduct validation of SAS programming per 21 CFR Part 11 standards
- Prepare periodic statistical reports for the DMC per SAP
- Serve as unblinded statistician(s) on the DMC

While our DMC Statistical Center typically works with the Advarra-administered DMC, we can also prepare TLGs for DMCs administered by other parties.

your data monitoring committee?

Contact businessdevelopment@advarra.com to get started.