



# Premium IDMC Services

## Ensure Patient Safety and Data Integrity

An Independent Data Monitoring Committee (IDMC) or Data and Safety Monitoring Board (DSMB) can be the difference between a trial that protects patients and delivers credible data and one that regulators and investors don't trust. But when you can't have access to unblinded information, how can you make sure your IDMC does its job?

Partner with IDDI for the expertise needed to seamlessly run your IDMC, keep patients safe, and maintain the utmost data integrity.

## Safeguard Your Clinical Trial

IDDI's IDMC services provide succinct, structured reports that clearly show your intervention's risk-benefit profile. IDDI also serves as a liaison between you and the committee, helping them efficiently identify safety trends and make well-informed recommendations.

But unlike with generalist CROs or consulting statisticians, IDDI's services are powered by:

### True Biostatisticians

We keep trial integrity at the forefront, catching and reducing risks before they become problems. We also independently partner with the chairperson to manage the IDMC, adapting reports as safety or efficacy trends emerge and autonomously responding to ad hoc requests so you can trust that critical oversight is fast, unbiased, and centered on the best interests of the patients and the study.

### Dedicated Partnership

As your clinical data science partner, we seamlessly handle every aspect of the interim data monitoring process while making efficacy and safety crystal clear.

### 20+ Years of IDMC Experience

Many IDDI experts have served as voting IDMC members, giving us unmatched insights into what committees need. Without seasoned oversight, unexpected events can derail a trial, but our expertise ensures the IDMC has the right data at the right time, so you can act in the trials' and patients' best interests.

### Continuous Improvement

We're committed to enriching the IDMC member experience with improvements such as innovative graphs and analysis methods that make data review easier, dynamic interfaces for real-time safety assessments, and including patient advocate members in committees.

**1,000+**  
IDMC meetings  
supported

Partner  
with IDDI for  
uncompromising  
excellence in IDMC  
services.

Get Started

# Efficiency and Ease at Every Step

As your independent statistical reporting group, we take care of every administrative and organizational IDMC task, so the IDMC can focus on the data and provide prudent study recommendations.



## Set Up

- Trial design and protocol development:
  - Methodology for interim analysis or adaptive design components to be reviewed by a committee
- Member contract management, including:
  - Member identification and training
  - Confidentiality and financial disclosure
  - Payment and invoicing
- Write the IDMC charter
- Write the IDMC statistical analysis plan (SAP), including monitoring boundaries development
- Prepare the IDMC report template, including mock tables, listings, and figures
- Schedule, coordinate, and run a kick-off meeting before the first patient is enrolled



## Programming

- Program and quality control all analyses in the IDMC report
- Produce dry run reports and review with the sponsor as needed



## Meetings

- Schedule, coordinate, and run IDMC meetings
- Ensure secure, firewalled meeting structure to maintain blinding and independence
- Produce and distribute open/closed IDMC reports in concise, easily interpretable, and secure formats
- Proactive management of ad hoc requests, including prompt preparation of additional analyses and scheduling of ad hoc meetings without compromising study blinding
- Assist IDMC Chair with preparation, delivery, and archiving of IDMC recommendations



## Close Out

- Reconciliation of ad hoc requests
- Coordination of close out meeting with IDMC and the sponsor to share top-line results and committee suggestions with sponsor for regulatory strategy or future trial development
- Archiving

The IDMC unblinded team is fully independent from the sponsor and study team. Firewalls and thorough blinding procedures prevent bias, meeting critical regulatory requirements.

**When every data point represents a patient, accuracy and integrity aren't optional – they're everything. That's why it's IDDI's IDMC services.**

[Talk to an Expert](#)



IDDI is a trusted clinical data science partner. With 35+ years of research-driven experience, we combine therapeutic expertise, biostatistical leadership, and regulatory insight to mitigate risk from design to registration and beyond. We deliver uncompromising excellence in biostatistics, strategic consulting, clinical data management, IDMCs, and supporting eClinical technologies, because when every data point represents a patient, perfection is the only option. Learn more at [IDDI.com](https://www.iddi.com).