Data Monitoring Committee Services

Ensuring the Best Decisions are Made for Your Trial

At Cytel, we know that you entrust a great deal of responsibility to your Data Monitoring Committee (DMC), often at the most critical stage of clinical development, the last mile before regulatory submission and registration. Arming your DMC clinicians and statistician with the most accurate and polished report of the safety and benefit profile of your drug or device is critical in assuring that they are positioned to take the right decisions at the right time for your trial.

Towards this end, we leverage our statistical expertise in trial design and implementation in delivering comprehensive DMC support services. Our broad experience supporting DMCs covers small molecules, biologics and medical devices, and spans a multitude of therapeutic areas.

Independent Statisticians:

Our highly qualified statisticians are prepared to present at DMC meetings, having acquired core competencies in several therapeutic areas. Teaming with our expert programmers, they will provide clear, concise, well-organized safety and efficacy reports to the DMC, guiding them through key results and disconcerting safety signals

Experience

Our statisticians have supported hundreds of trials across all therapeutic areas and with dozens of complex designs. Here is a sample of trials that Cytel has supported:

Diabetes	*Cardiovascular Outcome Trial*
Rare Disease	*Adaptive Phase 3 Trial*
Oncology	*Promising Zone Design*
Cardiology	*Population Enrichment*
Acute Renal Injury	*Early Phase Adaptive Dose-Selection*
HIV Orphan Drug	*Adaptive Confirmatory Dose-Selection*
Pediatric Schizophrenia	*Safety Monitoring*
Schizophrenia	*Adaptive Phase 3*
Migraine	*Bayesian Device*
Parkinsons Trials	*Safety for Device Studies*
Bone-health	*Adaptive Phase 3*
Bone-health	*Adaptive Confirmatory Dose-Selection*
Pediatric Dermatology	*Adaptive Confirmatory Dose-Selection*
Anti-Infective	*Blinded Sample Size Re-Estimation*

Our Activities:

DMC Charter:
Our team knows that a well thought out DMC charter provides a clear roadmap for your trial. Following standard regulatory guidance as found in the FDA and EMA Guidances for DMC Support and E9, we will create a DMC charter that provides careful direction for every step of your trial's implementation.

Interim Data Handling:
Our team understands that unexpected challenges sometimes arise when handling interim data. Our expert biostatisticians are well-equipped to handle data that is incomplete, accumulating, unclean, and in the process of arriving from various corners and in different formats.

Reporting:
Our team provides thorough reports of safety and efficacy, and trusted risk-benefit analyses, accompanied by clear and intuitive graphical displays to communicate findings. Concise, comprehensive executive summaries are one of our specialties. Polished SAE reports, updated in real-time, help maintain the integrity of your trial.

Report Distribution:
Our team will distribute DMC reports with due regard for sensitivity and discretion. Our executive summaries, prepared by an accomplished team of statisticians and writers, outline the finer points of safety and efficacy reports in a comprehensive brief.

Interim Statistical Analysis Plans:
We understand that the integrity of your trial depends on adhering to strict regulatory standards. Our team will map all statistical considerations and guidelines, provide an outline of the study design, and make sure that all communications are audited and in regulatory compliance.

Statistical Programming:
Our team can provide programming for TLFs, graphics for predictions, (i.e. Predicted Interval Plots, Enrollment & Events forecasting, etc.,) and proficient defensive programming for unclean or incomplete data sets.

Real-time Data Challenges:
DMCs often need recourse to ad-hoc analyses and on the spot explanations. These evaluations require the same degree of precision, despite the unexpected nature of the requests, and the often unclean data-sets. We provide a team of statisticians that can deliver quality analyses within the confines of these stringent deadlines.

Statistical Expertise:
Our statistical experts can perform the duties of proficient independent statisticians across a range of trials including adaptive, multi-arm, composite endpoint, Bayesian and more. They are also positioned to respond to a range of DMC challenges that may arise unexpectedly.

Independent Statistical Center for Adaptive Trials

Precise and rigorous statistical accomplishment is necessary to maintain the complex regulatory standards for adaptive trials, such as those noted in the FDA Guidance and EMA Reflection Papers on adaptive clinical trials. Cytel's DMC services build on our pioneering work in advanced statistical innovation. We are the leading providers of independent statistical services for designs that use:

- Stopping Boundaries
- Conditional Power Calculations
- Sample Size Re-estimation
- Dose-selection
- Population enrichment

ACES

A good data monitoring committee should allow you to put your trial's integrity on display. Our ACES software has been specifically built to support adaptive trials in compliance with regulatory guidelines. It provides a secure, audit-trailed environment that ensures important communications and decisions are captured for future review, audits, or in the event of any regulatory concerns.

To Learn More - Contact Us
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