

Synchronized Committee Management
Solutions for Faster, Better Outcomes

Aligned Action



The Smart Way to Get Better Results

Quintiles provides a high level of experience, expertise and customer service to the entire clinical trial process. This is especially true for our oversight group management service.

We offer a complete range of services, from managing a single oversight group, to coordinating and integrating multiple oversight group processes on the same trial, to managing all aspects of a customer's oversight group management operations. Our services include design, recruitment and management of:

- > *Data Monitoring Committees (DMCs) / Data Safety Monitoring Boards (DSMBs)*
- > *Endpoint Adjudication Committees / Clinical Event Committees (CECs)*
- > *Core Laboratories*
- > *Advisory committees*

Managing oversight group processes presents unique challenges in study planning and resourcing, to which Quintiles brings solutions based on industry-leading best practices. Because their requirements are detailed, oversight groups can add complexity to trial communication and data flow processes. And because their processes can be interdependent, the complexity level increases when multiple oversight groups are working on a single trial.

Integrated Solutions

Quintiles applies its reach, resources and experience to the execution of oversight group processes, offering both leadership and support in the following areas:

- > *Identification, screening, qualification and selection of committee members and core laboratories*
- > *Development of relationships with therapeutic experts, thought leaders and key opinion leaders (KOLs)*
- > *Process design including workflows, committee charters and site manuals*
- > *Endpoint reporting and adjudication CRF design*
- > *Committee meeting planning and coordination*
- > *Expert endpoint dossier processing*
- > *Ongoing reconciliation of endpoint data and core laboratory assessments*
- > *Tracking and status reporting*
- > *Contracts, payments and reimbursement*

Quintiles' finely tuned, integrated oversight group management services give you the insight and support for quality results your studies require in *the New Health*.

Reduced Complexity

Quintiles offers customers the only complete solution to today's complex oversight group management challenges. We provide one central contact with the knowledge and expertise to centrally manage, coordinate and integrate the complex requirements that are integral to the support and successful execution of oversight group processes.

Quintiles has spent years managing oversight group processes all over the world.

An increasingly complex regulatory environment demands the highly specialized resources, best practices and depth and breadth of clinical and regulatory experience only Quintiles offers. You receive comprehensive benefits as we help:

- > *Provide direction, where others in clinical trial management positions may be unfamiliar with oversight group processes and requirements*
- > *Free up sponsor staff to concentrate on core duties*
- > *Reduce cycle time*
- > *Prevent expensive delays (our endpoint adjudication processes average an extremely low 1% rate of requests for additional documentation)*
- > *Improve communication, dataflow, event reporting and coordination*
- > *Synchronize the needs of different oversight groups to achieve study milestones*

Quintiles has conducted over 225 studies with these components, including processing over 120,000 endpoints for adjudication and managing over 150 DMCs.

Oversight Groups Explained

Data Monitoring Committees (DMCs)/Data Safety Monitoring Boards (DSMBs)

These are designed to independently review clinical trial safety and efficacy data to ensure the trial's safety, ethical integrity, validity and scientific merit. After this review, they make recommendations to the sponsor regarding the continuation of the trial. In addition, they sometimes perform formal interim analyses. Most DMCs include 3 or 5 independent members (MDs, biostatisticians, other advisors).

Endpoint Adjudication Committees/Clinical Events Committees (CECs)

These independently review study event data for potential clinical efficacy and/or safety endpoints. They confirm and document the potential endpoints which meet established protocol criteria. This ensures that the endpoint outcomes are as consistent, accurate and unbiased as possible. Most adjudication committees include 4 to 6 independent members.

Core Laboratories

Core laboratories independently identify and document laboratory-based endpoints that meet established protocol criteria. Use of a core laboratory process controls for variability in investigator-determined endpoint classifications and ensures that the endpoint outcomes are as consistent, accurate and unbiased as possible.

Advisory Committees

Also known as expert panels, steering committees, advisory boards, scientific advisory committees, etc., they collaborate with the sponsor on various aspects associated with the development and execution of a clinical trial program and/or a specific protocol. They provide insight into existing pre-clinical/clinical trial data and recent publications, assist with the identification of new angles for potential research and advise regarding specific aspects of protocol design.

Contact Us:

In the U.S.: +1 866 415 3145

International: +800 7627 5382*

On the web: www.quintiles.com/safety

Email: clinical@quintiles.com

*Not toll-free in all countries



Navigating the new health