Transformative solutions for the clinical research industry

wcg clinical services™

609.945.0101 / **www.wcgclinical.com**

The pioneer of independent ethical review, WCG drives ingenuity in the clinical research space. Today, WCG's solutions have grown to include a suite of complementary services and technologies that expand the capabilities of the modern research professional through our WCG Clinical Services Division. Within this organization, it is our mission to deliver transformational solutions that stimulate growth, foster compliance, and maximize efficiency for those who perform clinical trials.

WCG Clinical Services is proud to serve the individuals on the frontlines of science and medicine, and the organizations that strive to develop new products and therapies to improve the quality of human health. It is our role to empower them to accelerate advancement, while ensuring that the risks of progress never outweigh the value of human life.

Trusted data on **95%** of all industry sponsored protocols and associated study details

Deep relationships with **2,800+** institutions, including **195** Academic Medical Centers

Enrollment performance on **85%** of all FDA-regulated investigators

Global information, demographics, and contacts for **140k** investigators

On-demand global network of **1,000+** clinical and statistical experts

Sponsor, CRO, and site **verified** industry benchmarking

WCG Clinical Services

WCG is built upon a 50-year legacy of ethical review, growing to what is today a suite of clinical services and technologies that maximize speed and efficiency for those who perform clinical trials.

Study Planning & Site Optimization

- Benchmarking & Analytics
- Site Selection
- Site Feasibility
- Site Contracting
- Site Training
- Site CTMS

Patient Engagement

- Study Marketing
- Patient Identification
- Recruitment & Retention
- eConsent
- Clinical Rater Assessment
- Clinical Outcomes

Scientific & Regulatory Review

- Trial Design Review
- Protocol Design Review
- Data Monitoring Committee
- Endpoint Adjudication
- Drug Safety
- PV

CLINICAL SERVICES PLATFORM

wcg knowledge base™

Delivering unprecedented value to optimize your studies

Regulatory-Grade Data

The WCG Knowledge Base™ is the industry's largest database of site and investigator insights, benchmarks, and competitive performance data.

Broad Ecosystem of Institutional Relationships

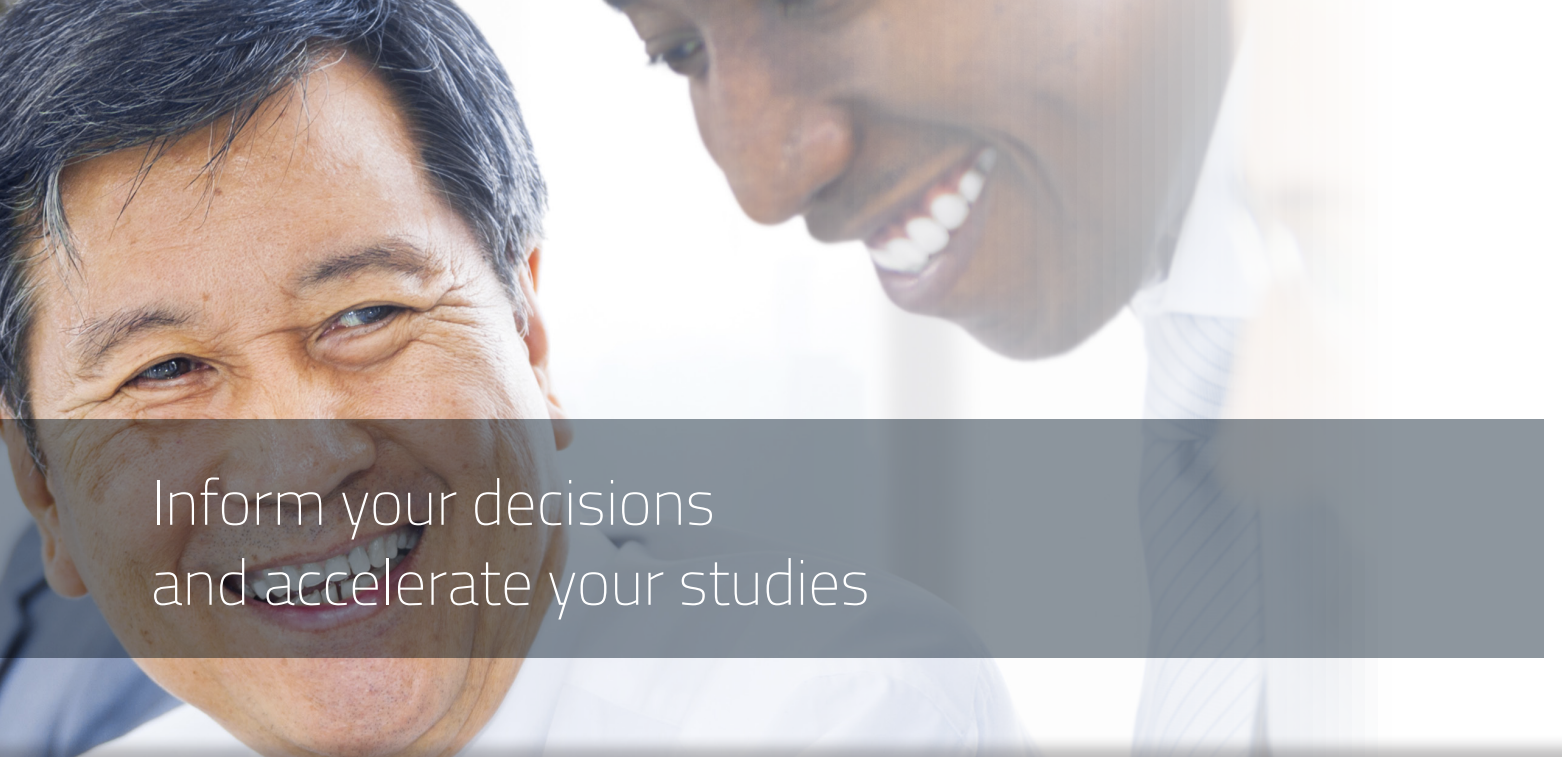
We bring the power of our deep relationships with over 2,800 institutions, including 195 Academic Medical Centers.

Expert Clinical & Operational Advisors

WCG services are powered by the combination of our deep clinical expertise and advanced technologies.

Through the combination of our global network, expert services, and verified data, WCG Clinical Services can save an average of

12 months on a 32-month phase III study.



Inform your decisions and accelerate your studies

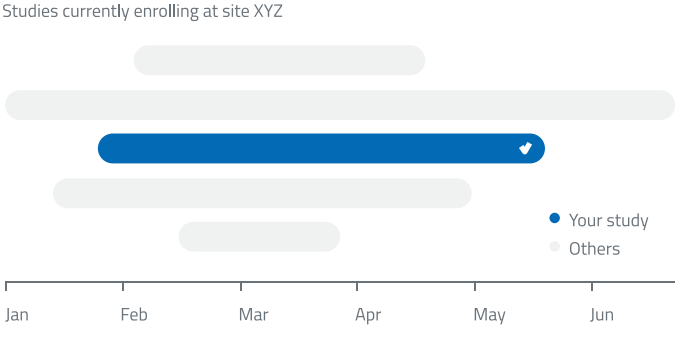
Gain actionable insights to move your study forward with certainty with the WCG Knowledge Base™, our proprietary decision engine with trusted data on 95% of all industry-sponsored protocols and associated study details.

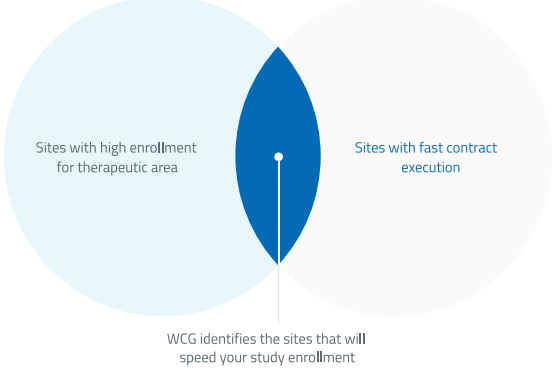
With the WCG Knowledge Base, our clients and partners are accelerating their clinical trial timelines thanks to intelligent, data-driven decisions in each phase of the clinical trial.

Create competitive advantage for your organization.

Sites are the battleground. We have the map.

The WCG Knowledge Base maps out your competition level at each site, so you can proactively deploy strategies to reach your enrollment goals.





Pre-select the right investigators based on historic site performance.

Set up your studies for success from the start. The WCG Knowledge Base lets you zero in on the sites with the best-known performance for the therapeutic area of your study.

Services that align seamless with yours or your CROs processes

WCG is the intersection for all biopharma sponsors, CROs, and sites from around the world who are interested in advancing operations and science through collaboration. We provide unique services in the critical areas of your development program:

Study Planning & Site Optimization

Some 80% of clinical studies run behind schedule, which can dramatically increase costs and decrease product competitiveness.

WCG's Study Planning & Site Optimization service gives you a suite of six solutions you can apply to dramatically accelerate clinical study start-up and completion globally, as well unburden your internal resources.

In nearly every case, these acceleration strategies also reduce complexity, lower costs, drive higher quality study results, and provide a faster path to enrollment.

Patient ID & Recruitment

Many clinical studies experience patient shortfalls initially because potential candidates are frequently never contacted. WCG ThreeWire's dedicated Site Services team adds extraordinary new levels of focus, efficiency, and results to your patient recruitment process.

Our more than 800 Enrollment Assistants™ (EAs) earn WCG ThreeWire an unmatched track record delivering targeted numbers of qualified patients: Improving clinical study enrollment timelines of 33% on average across all therapeutic indications—at a below-average cost-per-enrollment.

Patient Observation & Assessment

WCG's MedAvante-ProPhase and Analgesic Solutions provide services that mitigate the risks of bias, variability, and human error. We achieve that by applying deep scientific expertise to improve the quality of clinical trial outcome data.

Our specific solution is to combine cohesive, interoperable eCOA and accurate, expert clinician services to improve the collection, management, and analysis of clinical study data.

The result is an improvement in the accuracy of clinical assessments — including a reduction of process errors by up to 80%.

Drug Safety & Pharmacovigilance

Ultimately, the key to reliable Adverse Event Processing is strict adherence to regulatory directives and guidance, consistency of data retrieval and documentation, and the high index of suspicion required to identify and assess critical safety signals.

WCG's Vigilaire's seasoned healthcare professionals deliver unmatched expertise in tracking and investigating adverse events. We work with your team to design the systems and processes needed to achieve extraordinary levels of vigilance, as well as documentation you—and regulators—can trust.

Data Monitoring & Endpoint Adjudication

WCG ACI Clinical provides top-tier Endpoint Adjudication and Data Monitoring Committees that deliver reliable and trusted information to support safety decisions around clinical development programs.

By building a global network of 600+ medical and statistical experts to serve as a source of committee members, ACI excels at designing and managing the entire committee process for safety event detection and assessment.

Set up your clinical study sites for success and speed your time to market

A best-in-class suite of services designed to speed study start-up, reduce cost, improve data quality, and ensure compliance. When you engage any of our Study Planning & Site Optimization services, you take advantage of our unmatched connections to all major sponsors and CROs. You also have access to our data on more than 36,000 (of about 40,000) FDA regulated PIs in the U.S., thousands of clinical trial contracts and budgets worldwide, and study performance on 2,800 research institutions in North America.

STUDY & SITE PLANNING

Benchmarking & Analytics

Leverage leading–edge data, products, and services in the form of reports and online tools to inform your clinical development investment and operations strategy.

Site Selection

Match your study's therapeutic approach and protocols precisely to site and investigator performance track records, reducing site identification from the 8-10-week industry average to as quickly as three days.

FAST INITIATION

Site Feasibility

Engage and assess the world's most highly qualified clinical trial sites–and accomplish it 25% faster.

Site Contracting

Our expert legal focus, plus our vast Knowledge Base™ of global contract terms and budget templates cuts your clinical trial negotiating cycles by up to 35%—plus reduces study costs.

STUDY COLLABORATION

Site Training

Launch fully-automated, 24/7 online site training solutions that significantly cut complexity, time, and expense while ensuring full compliance.

Site CTMS

Simplify the management of your entire clinical research portfolio by linking study status, patient enrollment, calendars, budgets, electronic data capture, and more.

Identify patients and jump-start enrollment strategies that exceed your critical milestones

Leveraging our systematic approach and proven success in recruiting patients for clinical trials, WCG has solved some of the greatest enrollment challenges within the hardest-to-reach patient populations on behalf of our clients. In partnering with WCG, you will dramatically accelerate the enrollment performance of your study. With our patient identification and site support services, you can expect predictable success through our unique, deliberate approach to finding the patients you need and enrolling them in the study.

The truth is, most clinical study enrollment delays are caused by a combination of several obstacles: among them, unqualified sites, staffing shortages, protocol design, lack of recruitment skill, and inadequate patient pool.

That's why any attempt to accelerate enrollment using a single strategy is likely to fail. That's also why WCG's Patient ID & Recruitment services use a holistic strategy, applying proven tools to bring your clinical study's enrollment up to speed rapidly. With these services in place, we can help reduce average enrollment timelines by 33% across all therapeutic indications.

Study Marketing

We reach patient populations efficiently via demographic, psychographic and geographic targeting, and build awareness with advertising, online marketing, and social media.

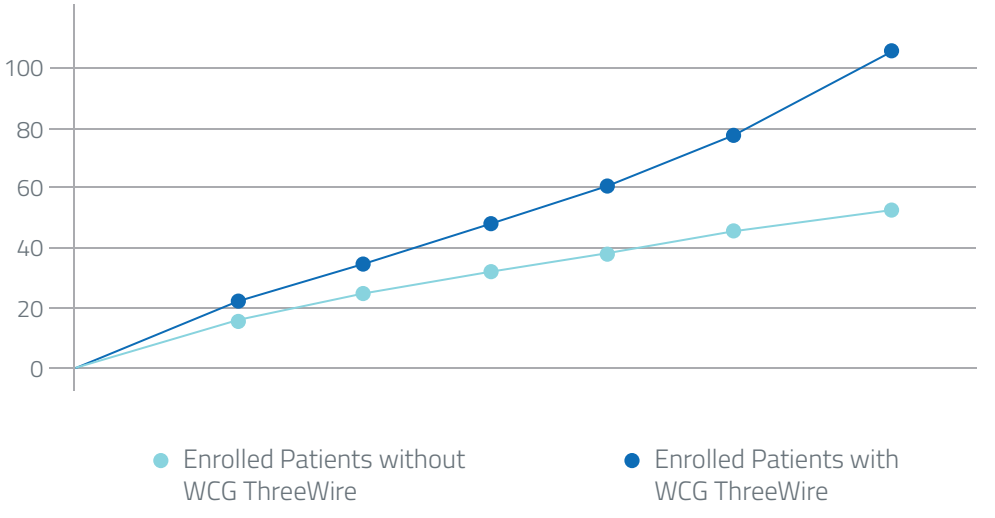
Patient Identification

Jumpstart clinical study enrollment with more focused, cost-efficient chart review. Our dedicated team frees up your site staff, rapidly identifying qualified patients so your trial begins and stays on schedule.

Recruitment & Retention

Once you identify likely study patients, don't risk shortfall. Ensure you reach—and maintain—target enrollment by using our dedicated, highly efficient recruitment and retention specialists.

ENROLLMENT BY TIME



Improve signal detection and reduce clinical trial error rate, all while engaging patients throughout the lifecycle of a study

The high and costly failure rate of clinical trials is due in large part to imprecise endpoint measurements and high patient dropout rates that add noise and impair signal detection. WCG's MedAvante-ProPhase and Analgesic Solutions provide services that mitigate the risks of bias, variability, and human error. We achieve that by applying deep scientific expertise with innovative technology to improve the quality of clinical trial outcome data by 80%.

CLINICIAN SERVICES

Independent Ratings

Our network of expert clinicians remotely administers and scores assessments to minimize bias and variability.

Accurate Pain Reporting (APR)

Accurate pain reporting is crucial to study success, but 20% to 30% of subjects enrolled in a pain trial are unable to report their pain accurately. Having trained over 30,000 subjects, our clinicians deliver evidence-based, validated training solutions.

Clinical Data Analytics

Our statistical and data experts work with our clinical scientists to open unique windows into a study's progress.

Rater Qualification & Certification

Our training minimizes variability across groups of raters and prepares clinicians effectively and efficiently for a study.

Placebo Response Reduction

The PRR training program provides training for study monitors, study staff, and study subjects to encourage neutral expectations from subjects, establish the "research alliance", provide examples and scenarios to help study staff understand as well as practice how to interact verbally and non-verbally with subjects.

Independent Review

Our clinicians over-read selected assessments to improve quality of administration and scoring.

STUDY TECHNOLOGIES

Virgil Investigative Platform

Our Virgil platform tracks all eClinRO, eObsRO and ePRO, resulting in standardized assessments, more accurate signal detection, and more reliable data quality.

WCG ConsentNow

WCG's eConsent solution both automates and humanizes the informed consent process—dramatically reducing costs and risks, while increasing patient knowledge, satisfaction, and retention.

QDSS

A statistical, predictive central surveillance system for clinical trial monitoring. It differs from standard RBM in that it is evidence based and focuses on factors that may impact "Assay Sensitivity" (the ability to differentiate placebo from drug)

MADDERS®

This standardized system - in conjunction with the FDA-ACTIION initiative - fills a need for standardized approaches to quantifying potential abuse in clinical trials.

- Virgil platform deployed in **53** active or completed studies
- More than **5,000** site application tablets
- More than **30** countries worldwide
- More than **305,000** electronic outcome assessments
- Administered to nearly **29,000** subjects

Leading Clinicians Who Translate Science to Operational Excellence

A team of highly experienced clinicians brought together to provide guidance to properly design & conduct clinical trials.

Each has extensive experience in the initiation and conduct of their own research, which can be applied to your program.

Their measurement science is applied through the actual conduct of your study to ensure an efficient and successful trial.

wcg™

Andrew J. Cutler, MD

Expertise: Attention Deficit Hyperactivity Disorder (ADHD) and Psychiatry

UF UNIVERSITY of FLORIDA

Leslie Citrome, MD, MPH

Expertise: Schizophrenia and Psychosis

NEW YORK MEDICAL COLLEGE
A MEMBER OF THE TOURO COLLEGE AND UNIVERSITY SYSTEM

Christoph Correll, MD

Expertise: Child and Adolescent Psychiatry

DONALD AND BARBARA ZUCKER SCHOOL of MEDICINE AT HOFSTRA/NORTHWELL

Michael R. Liebowitz, MD

Expertise: Social Anxiety Disorders

COLUMBIA UNIVERSITY IN THE CITY OF NEW YORK

James E. Galvin, MD, MPH

Expertise: Non-Alzheimer's Disease Dementias and Neurobehavior

FAU
CHARLES E. SCHMIDT COLLEGE OF SCIENCE
Florida Atlantic University

Philip Scheltens, MD, PhD

Expertise: Alzheimer's Disease

VUmc VU University Medical Center Amsterdam

Leo Verhagen Metman, MD, PhD

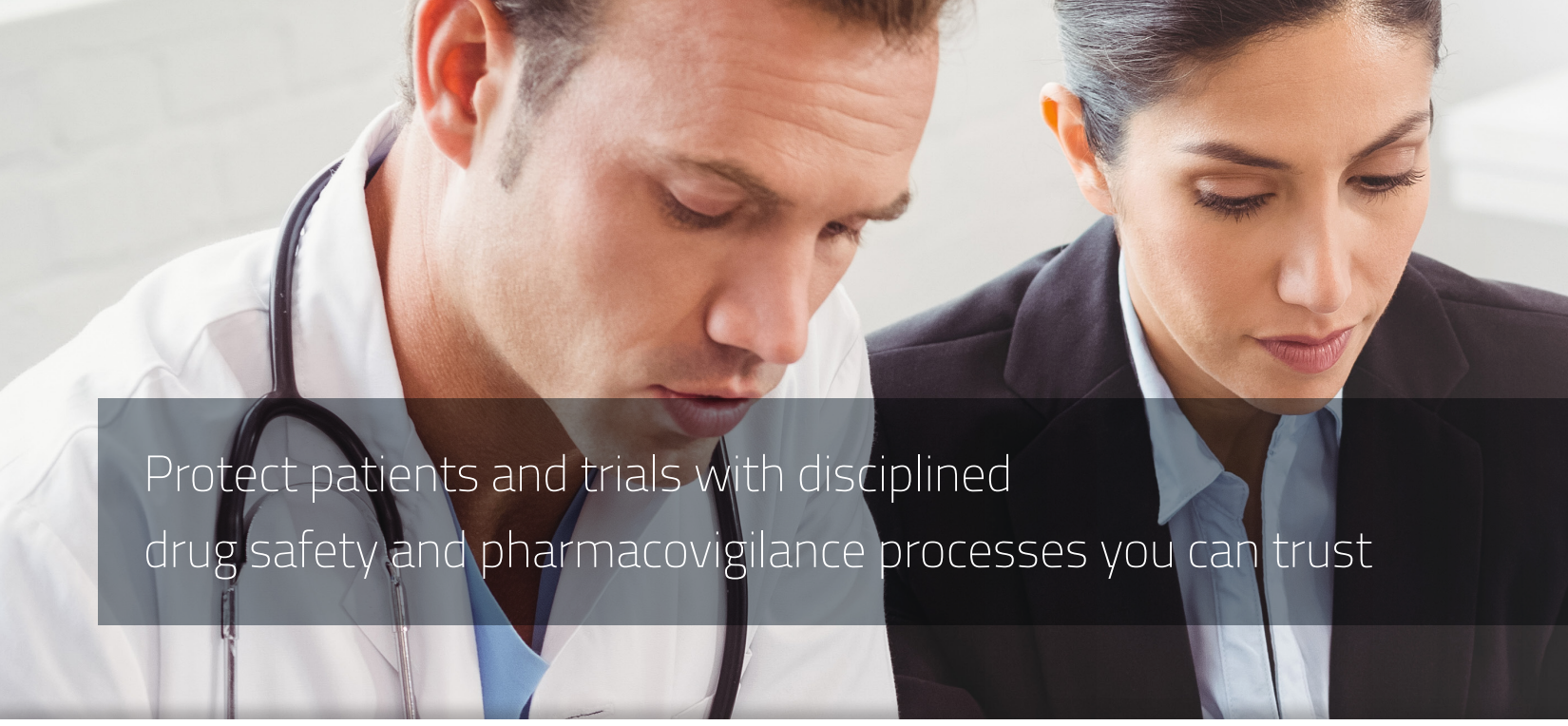
Expertise: Parkinson's Disease

RUSH UNIVERSITY MEDICAL CENTER

Scott J. Hunter, PhD

Expertise: Neurodevelopment, Autism and Rare and Orphan Disorders

THE UNIVERSITY OF CHICAGO



Protect patients and trials with disciplined drug safety and pharmacovigilance processes you can trust

Successful pharmaceutical development — achieving safety results that protect both your investment and your patients—requires astute management of adverse event (AE) monitoring, analysis, and reporting. Ultimately, the key to reliable Adverse Event Processing is strict adherence to regulatory directives and guidance, consistency of data retrieval and documentation, and the high index of suspicion required to identify and assess critical safety signals.

WCG's Vigilare seasoned healthcare professionals deliver unmatched expertise in tracking and investigating adverse events. We work with your team to design the systems and processes needed to achieve extraordinary levels of vigilance, as well as documentation you—and regulators—can trust.

Enabling the efficient distribution of these adverse event documents is our proprietary SafetyPortal technology. This system–developed over a decade ago in conjunction with a large pharma organization–automates document distribution which in turn improves accuracy, drives down costs, and ensures patient safety.

WCG's SafetyPortal not only streamlines safety document distribution, but also ensures that only those who need to see any given document receive it. This efficiency reduces wasted time and expense, and it improves site response to safety notices. In fact, over a five year period, WCG SafetyPortal saved a large pharma $250 million dollars.

Eliminate Waste

SafetyPortal helps sponsors and CROs categorize safety reports granularly, so they're matched precisely to recipients' need-to-know.

Monitor Global Regulations

WCG's SafetyPortal permits automated, continuous monitoring of regulatory distribution requirements for 110 countries, so you're always compliant for every site.

Accountable Processes

Documents are distributed immediately, securely and cost-effectively—all within a tight, trackable system allows you to monitor distribution instantly—and remain audit-ready day and night.

Reduce the risk of safety concerns throughout the life of your study with an expert , independent committee

There is a growing trend across a wide variety of therapeutic areas and medical device studies to adjudicate critical endpoints, outcome events, and even inclusion/exclusion criteria that determines whether patients are eligible for a specific study. Similarly, there is a need for independent, Data Monitoring Committees to provide recommendations to a sponsor on whether a trial can be continued, modified, or stopped due to safety concerns of what study data shows. That's why, with a clinical, expert review, you can achieve quality clinical trial outcomes and reduce inconsistencies or bias in clinical trial data.

With WCG's Committees and processes, we help the biopharma and device industry to lower the risk of variation in important clinical trial outcome events for submission to regulatory agencies.

When you need thorough insights, turn to a network of 600+ global experts

Our committees are run by a dedicated team of more than 600 medical, statistical, and safety experts who serve as advisors to clinical trial sponsors, academic experts and regulatory agencies. Their main objective is to reduce the variation in important clinical trial events and ultimately mitigate risk and enhance patient safety in clinical trials.

Sponsors who tap into WCG's network committee:

- Achieve consistent, global data collection
- Catch safety issues early on
- Assess risk with event findings
- Bolster regulatory strategy prior to submission
- Gain expanded labeling
- Drive increased adoption through publication support
- Gain a competitive advantage over other products