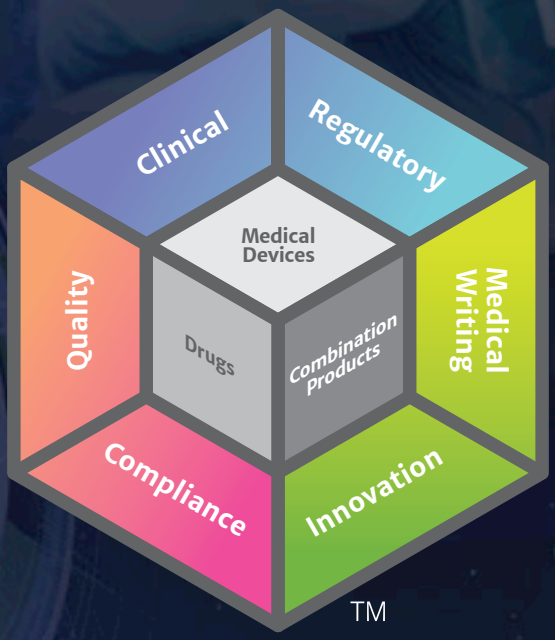
Launch and Thrive.

Clinical Research Strategies Helps
Early- and Mid-stage Life Science Companies
Begin on Solid Footing and Stay Poised for Growth
Throughout their Product Life Cycle.



TM

Clinical Research
STRATEGIES
TM

Built to Think, Evolve & Endure.

Transforming Innovation into Global Opportunities

The CRS team is comprised of accomplished PhD/RPh/PharmD scientists and bioengineers who have extensive problem-solving experience in contract research organizations, life sciences start-ups, academia, medical devices, and large pharma.

CRS distills the complexities of regulatory and research disciplines into accessible terms for life science researchers, executives, entrepreneurs, and investors alike who play a pivotal role in the development of devices, diagnostics, drugs, and biologics. Our goal is to improve our clients' chances of clearing performance hurdles toward successful commercialization or exit.

Putting Clients on a Clear Path to Success

The mission of CRS is to improve business performance of early stage, start-up, and mature businesses with a successful clinical research development plan and strategy.

Our firm supports the entire product life cycle with competent leaders at a reasonable cost and unconstrained by corporate policy.

Project-specific, fit-for-purpose, ad hoc consulting, and staffing clinical trials is what we do best, no matter where companies are in their clinical development program.

CRO services include project management, clinical monitoring, regulatory affairs, medical writing, quality assurance, and medical monitoring.

CRO & Sponsor Staffing
Make sure your clinical trial is on a steady and calculated course for success by avoiding cost over-runs and poor vendor performance.

Compliance, Governance & Due Diligence
Bring a watchful eye and sound decision making to your business for high performance and long-term sustainability.

Clinical & Regulatory Affairs
Put your products on a clear path from development to approval by eliminating hidden surprises and avoiding re-work later.

Risk Management & Quality Assurance
Implement continuous quality improvement and vigilance for your programs while mitigating the risk to your stakeholders.

Policy & Innovation
Manage the complexities of policy adherence and product development, and design your company policies to cultivate innovation.

CRS has Special Contracts with DoD, NIH, DARPA, and others.

Solutions We Provide to Overcome Challenges

- Regulatory Pathway Assessments
- Effective and Efficient Clinical Strategy
- Filling Organizational Gaps
- Business Strategy Clarification / Partnering Opportunities Identification
- Quality Systems Creation / Updates
- EU MDR Compliance Work
- Real-World Evidence (RWE)
- Trial Master File Management and Inspection-Readiness
- First Article Development
- Grant Writing and Support Services
- Redaction Services for Public Domain Posting
- Human Factors / Usability Testing
- Due Diligence
- Trial Rescues

Areas of Expertise

Therapeutic Areas

Aging
Cardiovascular Disease
Central Nervous System (CNS)
Critical Care Medicine
Gastroenterology
Genetics
Infectious Disease
Immunology
Men's Health
Metabolic Disorders
Women's Health
Infant Health
Microbiome
Neurology
Oncology
Ophthalmology
Pediatrics
Precision Medicine
Radiology
Rare Diseases
Respiratory Diseases
Sleep
Wound-Healing

Modalities

Biologics
Combination Products
Digital Therapeutics
In Vitro Diagnostics
Medical Devices
Small Molecules
Software as a Medical Device (SaMD)

Find Case Studies, Research Papers, Published Articles, Webinars, Videos, and More on ClinicalResearchStrategies.com.

How We Define Success

We are with our clients for the long haul — the ups and downs — supported by resilience and pragmatism.

"I am extremely pleased with the exceptional services provided by CRS. Their expertise and guidance have been instrumental in navigating the complex landscape of medical device regulations and clinical trials.

From the moment we engaged their services, the team at CRS demonstrated their deep understanding of the regulatory requirements and their commitment to excellence. They provided valuable insights and strategic recommendations that helped streamline our regulatory processes and ensure compliance every step of the way."

– Nowwell AS / Ella Helgeman, Director, Regulatory Affairs and Quality Assurance

"Based on a recommendation, I reached CRS to prepare a Breakthrough Device Designation submission for the FDA. The CRS team was very responsive, knowledgeable, efficient, and supportive throughout the submission process, and a Breakthrough Device Designation was granted by the FDA within 3 ½ months after first contacting CRS. CRS has also been involved in the development of key strategic research partnerships and collaborations with favorable traction. It has been very rewarding and productive collaborating with the CRS team, and I welcome the chance to work on new projects with CRS as these opportunities arise."

– GenEndeavor LLC / Ricardo Mancebo, PhD, CEO and Founder

"CRS has been an integral partner since the (M2D2) IMPACT accelerator program launched, providing a combination of education sessions and mentorship to help early stage biotech and medtech founders navigate the complex challenges involved with clinical trials. Their case-driven insights and tailored support have been invaluable for startups to become more investor-ready and to de-risk their pathway to regulatory approval."

– M2D2 / Richard Meiklejohn, Innovation Leader

"Our collaboration with CRS has been transformative, setting a benchmark in our clinical trial processes and outcomes.

When we sought an experienced partner to design and manage our medical device clinical trials, CRS emerged as the gold standard ... Their commitment to providing top-notch clinical research strategy and execution has helped us navigate the complexities of medical device clinical trials. We highly recommend CRS to any life sciences company in search of a capable and reliable partner in the clinical research field. With CRS, you're not just getting a service provider – you're gaining a partner committed to your success."

– Entac Medical Inc. / John W. Cromwell, MD, CTO and Founder

"CRS is Firstkind's eyes and ears on US soil. They are a trusted group who brings experience and professionalism to our organization and allow us to function effectively on the other side of the Atlantic. CRS enables Firstkind to maintain compliance with local guidelines and regulations, whilst ensuring recruitment in both post-market clinical follow-up and investigational trials. Overall, our ability to run a clinical program in the United States is due to our relationship with CRS."

– Firstkind Medical / Kieron Day, Head of Clinical Affairs

"CRS has provided critical guidance for helping us understand the FDA approval landscape, develop our strategy through their Regulatory Pathway Assessment, and then helping us every step of the way with the logistics of obtaining FDA approval. They have decades of experience, and it really shows in their expertise and thoroughness. They strive to understand our unique needs and customize their offerings ... CRS has provided quality guidance and made me feel supported every step of the way, and I am so grateful to them!"

– Korion Health / Anna Li, CEO and Founder

"In the last two projects we worked with CRS on, we have been impressed with their industrial expertise, high-quality work product, and fast turnaround time. They went extra miles to cater for our business needs. We are looking forward to working with CRS on the next project!"

– Clinical-stage Oncology Biotech – Belgium/USA

"CRS has invaluable insight into managing CROs for Sponsors, which includes their extensive experience in clinical research. They were able to help us detect what were discrepancies or unnecessary charges, and negotiate more favorable terms in our contract, ultimately saving us over more than a third of a million dollars."

– Ocugenix / Sean McDonald, CEO and Serial Entrepreneur

Clinical Research Strategies
TOP LIFE SCIENCE COMPLIANCE SOLUTION PROVIDERS 2021
AWARDED BY Life Sciences Review

CRS is headquartered in Wexford, PA (greater metropolitan Pittsburgh) and serves international markets with US-based teams in key regions.

Visit ClinicalResearchStrategies.com to learn more, or contact us at 724.272.1245.

Clinical Research STRATEGIES™
Built to Think, Evolve & Endure.

ClinicalResearchStrategies.com