Dedicated to Medical Devices Research

The CROMSOURCE Advantage

- **Consistent quality systems** across the entire business
- **Executive oversight** that provides the highest level of attention
- Consistent **on-time**, **on-budget** project delivery
- **Low employee turnover** resulting in consistency and continuity across the program
- **Global Presence. Local Expertise.**
- Big enough to perform large, global trials, yet small enough to offer the **flexibility** and **attention to customer focus**

CROMSOURCE Quality

ISO 9001:2015
multi-site certified quality management system.

ISO 14155:2020
conformity confirmed.

CROMSOURCE is highly qualified to assist you during all phases of product development, through the approval process with the FDA and regulatory authorities, and with post-marketing requirements.

For over 25 years, CROMSOURCE has been helping clients conduct successful trials. We offer strategic regulatory consulting for medical devices companies in multiple markets from initial regulatory strategy, preparing and compiling submissions, to post-market commercialisation.

Our Numbers Speak for Themselves

We have completed hundreds of Class II and III medical devices trials and have a repeat business rate of >80%. We pride ourselves on building great relationships with our clients through successful clinical trials.

Our specialist medical devices staff has decades of combined medical devices clinical research experience. You can rely on our expertise in areas from simple pilot studies to large, complex trials across multiple countries and for your pre- and post-market needs.

CROMSOURCE delivers the support you need with milestones that are guaranteed.

Broad Therapeutic Experience

CROMSOURCE has experience with medical devices across many classes spanning a diverse range of therapeutic areas and indications.

Our experienced project managers and CRA's are assigned to your project based on their experience in your specific therapeutic area, ensuring a fast study start-up and a higher-quality study outcome.

Our Expertise Ensures Your Success

CROMSOURCE has developed a stringent methodology to help sponsors identify the highest enroling countries and sites during the feasibility stage. Our unique Feasibility Plus™ approach is provided to potential clients without obligation at the RFP stage and is the foundation of our ability to offer sponsors a guaranteed timeline, enrolment and budget.

Working closely with our clients, **CROMSOURCE** identifies geographic areas well known for their prevalence of the targeted indication. All regulatory requirements are reviewed and timelines are developed for each country to ensure the best regulatory strategy.

CROMSOURCE works directly with the most successful sites in recruiting patients. Sites are only considered if they have proven they can deliver a combination of high enrolment, high retention and quality data.

CROM SOURCE
advise | agree | deliver

Our End-to-End Guarantee

- Guaranteed study start-up time
- Guaranteed enrolment
- Guaranteed price without CRO-initiated changes in scope
- Guaranteed database lock date

How can CROMSOURCE do this?

- Realistic and highly detailed feasibility analysis
- Operational excellence within a cohesive team

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All the Services You Need, Where You Need Them

With offices throughout the US and Europe, CROMSOURCE deploys the resources you need in the countries you select. We have strong relationships with regulators, sites, and principal investigators in those countries, facilitating study start up and data quality.

We offer our clients the following services:

- Feasibility
- Project Management
- Clinical Operations
- Biometrics
- Regulatory Affairs
- Safety
- Medical Affairs
- Medical Writing
- Flexible Resourcing Solutions

Why CROMSOURCE

- Medical Devices expertise and experience
- Operational excellence based on more than 25 years of experience
- The only “End-to-End Guarantee” in the industry
- Detailed knowledge of sites, investigators, KOLs

Performance Guaranteed

CROMSOURCE is the only CRO to offer clients a performance guarantee. We will start and complete the study on-time, enrol the agreed number of patients, and do it for the price originally agreed upon.

GLOBAL PRESENCE, LOCAL EXPERTISE.