■ COMPANY PROFILE



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BVMA member since 2010 Audits passed in 2010, 2013, 2016, 2019 and 2022



A ClinChoice Company



https://www.cromsource.com/

History and Mission

CROMSOURCE, a ClinChoice company, is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialized in clinical development and flexible resourcing solutions. CROMSOURCE delivers tailored, full-service clinical development solutions with offices across Europe, North America, and the APAC region. We seamlessly move biopharmaceutical products from first in human through all subsequent phases of pre- and post-approval research internationally with a flexible approach that ensures we support the unique needs of each client.

Highlights

Global Coverage

With offices and expert staff across the key regions of Europe. North America and Asia-Pacific, CROMSOURCE delivers trials globally through local expertise and high levels of customer focus

Bridge Across the Atlantic

CROMSOURCE has a strategic focus on supporting European clients wishing to include North America within their clinical development programmes. Our expert teams in Europe, Canada and the United States work closely with our clients at every step.

Decentralised Clinical Trials

CROMSOURCE has the capability and experience to provide the optimal solution for fully decentralised or hybrid approaches to clinical trial delivery.



Services

Clinical Development Services

- Feasibility / Site Selections
- Clinical Operations: Project Management & Monitoring
- Regulatory Affairs and Medical Monito-
- Medical Writing: Protocols, CIP
- Ouality Assurance Audits
- Pharmacovigilance / Materiovigilance
- Data Management and Statistics
- Drug and Vendor Management
- Regulatory for US/EU (eg. CER, PMCF, consulting for FDA Pre-IND/IDE)
- Legal Representative US/EU
- Consultancy for customized solutions to optimize product development, minimize costs and time to market for novel therapies and medical device
- IT: Customized Tools & Resources (eg. THeCRF, TheDiary; TheSurvey)
- Flexible Resourcing Solutions (FSP model or short and/or long-term or permanent staff)

Early Phase Services

- ADMF studies
- Bioavailability
- Bioequivalence
- Dose ranging/multiple dose tolerance
- Drug-drug interactions
- First in Human (SAD, MAD)
- Food effect studies
- Patient Studies
- Pharmacokinetics/pharmacodynamics
- Proof of Concept
- OTc studies



