CROM SOURCE
advise | agree | deliver

Dedicated to Rare Disease 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 14155:2011
conformity confirmed.

Rare Disease Experts

The clinical development of treatments for rare diseases is a task with a number of unique challenges. Ranging from a very small patient population to the wide geographical dispersion of the patients, to the limited medical knowledge of the disease and consequently a small number of specialised sites, and finally to the uncertain regulatory framework.

By definition, one of the biggest challenges is that a rare disease typically affects only a small number of people globally. Standard trial designs are not appropriate to obtain adequate safety and efficacy data from a small number of patients, so alternate designs need to be considered for a rare disease trial.

Creating partnerships with many different stakeholders is important to help find the right patients for the research to be conducted. Working together with patient advocacy groups (PAGs), government agencies, and academia resources we advise our clients on the best strategy and plan to advance their research to find treatments and help those living with a rare diseases.

While rare disease studies follow the same regulations, guidelines, and requirements of all other clinical trials it is important that accurate analysis and planning is done to avoid losing patients and data. This is typically why the monitoring strategy for these types of studies requires a large number of visits in respect to the number of patients involved.

The sites typically involved in rare disease trials are very specialised hospitals. Most of the time these specialised hospitals are not in close proximity to the patients enroled in the trial. Therefore, historically most patients needed to travel to the site, which resulted in them being away from home for several days. This has a tremendous impact on their day-to-day activities and is a financial burden to the patient and their caregivers.

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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

European Headquarters:

Via Giorgio De Sandre, 3
37135 Verona - Italy
Direct: +39 045 8222811

North American Headquarters:

8000 Regency Parkway, Suite 575
Cary, NC 27518 – USA
Direct: +1 919 626 9882

Email: cromsource@cromsource.com

Decentralised Support

However, with the recent adaptation to decentralised clinical trials, it is expected that the patient experience in clinical trials will be easier without the need to travel to the hospital so frequently. This will benefit rare disease trials in a way the industry hasn't seen before. New digital trial platforms can help retain patients for a fraction of the cost that it would take in a traditional trial setting. Modern approaches to trial delivery permit patients from many different geographic areas who could not previously participate due to the ease of access and technology used during the trial. For rare diseases, easing the patient burden is incredibly important for enrolment, retention, and for the patient in general.

Due to the complex nature of rare disease trials, usually there are very specific and complicated examinations and procedures are required. While each trial design is different, it is important to understand the examinations and specific procedures involved and consider which strategies provide the greatest benefit. In our experience it is rarely possible to fully decentralise rare disease trials, but elements of decentralisation can be successfully utilised within a hybrid delivery model. In some cases, a home health nurse may need to be used to collect samples or conduct an exam. In others, a local site may need to be identified if specialised equipment is needed. Finding local and convenient solutions for the patient will ultimately result to higher enrolment and retention.

CROMSOURCE Expertise

CROMSOURCE has a special interest in rare disease studies as this is one of our key areas of focus. Our rare disease study experience includes dozens of studies across all phases and in multiple indications. We recognise the challenges inherent to studies involving rare disease populations and have developed specific strategies for addressing these challenges and mitigating potential risks.

Our entire project team is chosen specifically for your project and has experience working in rare disease, ensuring a fast study start-up and successful study outcome.

About CROMSOURCE

CROMSOURCE is an ISO-certified, international contract research organisation providing a comprehensive portfolio of clinical development services and flexible resourcing solutions to the pharmaceutical, biotechnology, and medical device industries. CROMSOURCE operates offices across all regions of Europe and North America and conducts projects globally. For more information, visit www.cromsource.com

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