Considerations for Managing COVID-19 Trials

Rapid study start-up is of paramount importance when developing products for the treatment of COVID-19 patients and can make or break the success of a clinical trial. In our over 25 years of experience supporting clients worldwide in developing their products, we have a proven track record of completing complex projects within the agreed timelines. Based upon our expertise coupled with our recent involvement with clients who have started COVID-19 related projects, we are pleased to provide some key elements to consider when setting up your COVID-19 project for success.

Understanding the Regulatory Landscape

During the uncertain landscape of a pandemic, it is important to think outside-the-box while staying compliant with regulations. The first step is to fully understand the relevant guidances and regulations that Regulatory Authorities have issued and continue to keep updated with the release of any new versions or updates.
Refer to:

- "FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency"
- "Guidance on the Management of Clinical Trials During the COVID-19 (Coronavirus) Pandemic" issued by the European Medicines Agency (EMA)
- "Guidance - Managing clinical trials during Coronavirus (COVID-19)" issued by the UK Medicines and Health Regulatory Authority (MHRA).

Planning and Communication

The development of a comprehensive study plan is one of the most critical steps for success. Select a strong project team to define the plan to execute the study, including communication and escalation pathways to support making rapid decisions. This is critical when you involve a CRO or third party vendors in your project. If the CRO has a proactive and problem-solving attitude, they can better support you with the challenges you could face while managing a COVID-19 project.

Site Selection

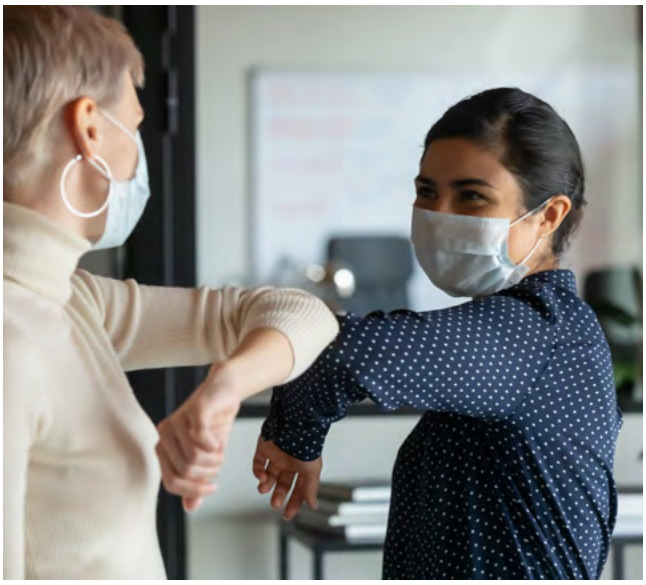
In order to quickly start your trial, you need responsive, fast-acting sites. You should use sites with whom you are familiar and have a history of strong performance. Moreover, if you have already worked with the identified sites in the past this could help reduce time for negotiation of contract and budgets. Up-front questions should be posed to sites to ensure they can comply with the highly compressed timelines for all aspects including regulatory completion and IRB submissions. You should exclude sites that cannot accommodate the shortened timeframes required.

During a pandemic, there are many limitations to having face-to-face monitoring visits. The selection of sites with a proven track record of high quality performance is of vital importance to ensure data integrity. Working with sites that you know and trust makes navigating through this time a little easier. In addition, working with known sites may help streamline steps to activation, such as a combined Pre-Study/Site Initiation Visit or targeted pre-study questions to expedite selection of sites.

Optimisation of Site Monitoring

Due to the many restrictions in place to stop the spread of COVID-19, you will have to be creative to accurately monitor sites to ensure data integrity and patient retention. It is important to create and implement a comprehensive Risk-Based Monitoring plan to specifically document how site performance is being monitored and to ensure that data quality is not being compromised. Taking advantage of the technologies that are now available you could combine remote monitoring and remote

source data verification coupled with the use of ePRO or any wearable devices to capture data. Technology could also be in place to further train staff or to obtain electronic signatures of study documents. To increase patient retention, consider performing home study visits and study medication delivery directly to a patient's home.



Data Management

With potential changes to the study design, visit schedules, assessment methods, and the looming possibility of higher rates of missing or incomplete data, it may become more difficult to provide an unbiased review of the difference between the treatment and control/placebo groups. Keeping these in mind during trial set-up can help highlight any potential issues.

With the day-to-day changes that COVID-19 is bringing to the world in general and healthcare in particular, it is important to start and remain flexible and agile. As a mid-sized CRO, CROMSOURCE is positioned to provide the flexibility needed and the best support to our clients to be successful in this fight.

With experience that spans over 25 years, the core of our business has always been driven by the passion for bringing life-changing and life-saving drugs and devices to those who need them. We are dedicated to help fight COVID-19 with a deep knowledge of the regulatory landscape and our highly experienced operations teams. We can also quickly offer supplemental resources and support via our flexible resourcing department. In CROMSOURCE, we have a dedicated COVID-19 Expert Team guiding our clients to navigate this challenging and changing landscape. According to our motto, "Advise. Agree. Deliver", we advise and agree with our clients the best regulatory and operational strategies and provide guidance on start-up, monitoring strategies, patient safety, and biometrics support.

About CROMSOURCE

CROMSOURCE is an ISO-certified, international contract research organisation providing a comprehensive portfolio of services to the pharmaceutical, biotechnology, and medical device industries. Specialising in clinical development and staffing solutions, we offer a flexible approach to ensure our clients' unique needs are supported. CROMSOURCE is unparalleled in offering an End-to-End Guarantee covering trial timelines, enrolment, and price. CROMSOURCE operates offices across all regions of Europe and North America.

If you would like to learn how we can support you in planning and executing your COVID-19 related project contact us.

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