# Case Study

# Rapid Start-Up for a US Based Study for COVID-19

## Description

COVID-19 testing study

Primary Endpoints: The purpose of the study was to test the client's COVID-19 assay testing kit against the standard of care kit to ensure the validity of the outcome data of the testing kits.

Services: CROMSOURCE was engaged for the following services:

- Site Feasibility and Selection
- Full Site Monitoring
- Site Enrolment
- Trial Master File
- Project Management
- Regulatory Submissions
- Adverse Event Management

Indication: Diagnostic / Infectious Disease (COVID-19)

**Study Duration**
Start-Up: 10 days (all 9 sites)
Recruitment: 4 months
Close Out: 1 month (based on client direction)

**Clinical Sites**
9

**Patients**
Total patients contracted was 3,000

**Regions**
United States

## Introduction

CROMSOURCE was contacted by a mid-size biotech company based in the US to conduct a COVID-19 testing study recruiting up to 3,000 patients within a one month period. Due to the timely importance of this study during the pandemic it was imperative that start-up be accelerated and that recruitment began immediately. This would allow us to take advantage of the high positivity rates of COVID-19 in many regions that had not implemented universal guidance documents and/or regulations regarding social distancing and mask wearing.

This study involved nine sites in the US who were engaged to enrol 3,000 presumed positive COVID-19 patients during the peak of COVID-19. Each patient was to present with at least two COVID-19 symptoms as defined by the Center for Disease Control (CDC) within the prior three days, provide a brief history of illness and if known exposure. The patient was to submit for nasal pharyngeal, oral pharyngeal or nasal swabbing. Each patient had three samples taken at the visit, at least one sample had to be a nasal pharyngeal sample. The sites were to store samples either on dry ice or in a -70 °C freezer until shipment. The samples were shipped to the client designated lab and control samples were shipped to their local lab for comparator testing. The study aimed to have at least a 10% positivity rate across all of the patients tested.

## The Challenges

- The client required an accelerated start-up for a COVID-19 testing study in order to collect samples from 3,000 patients within a one month period. The client expected recruitment to begin within two weeks of contract execution.
- Site selection was dependent upon the ability to recruit presumed positive COVID-19 patients for testing.
- Many states already offered free testing regardless of symptoms, and most symptomatic patients presented to their local medical doctor.
- Areas of high positivity were able to flatten the curve through containment measures, and the pool of patients available to effectively enrol the study became reduced.

## Operational Plan

CROMSOURCE tracked the COVID-19 positive rates by US states and cities to determine where the curve was rising and utilised our known site network to recruit in specific cities where the likelihood of positive cases was high in advance of study award, during the RFP process. We solicited feedback from each centre on:

- Ability to recruit patients in a rapid manner
- Ability to utilise a pre-defined central Institutional Review Board (IRB)
- Ability to provide all required regulatory documents within four hours of notification of study award
- Ability to execute contract and budget within 24 hours of receipt
- Ability to host a combined phone Pre-Study Visit (PSV)/Site Initiation Visit (SIV) within a one day notification
- Ability to recruit 60-80 patients in any given week

Additionally, CROMSOURCE developed draft documents such as: monitoring manual, PSV/SIV template, site checklists, source data tools and communication and project plans in order to be able to begin execution immediately upon study award.

CROMSOURCE reviewed daily trends in positivity rates at the city level in multiple high positive states and kept open communication with the known network of sites in order to quickly activate new sites. CROMSOURCE also sought out Urgent Care centres or emergency care settings that we had previously worked with for participation as these facilities consistently had patients that had COVID-19 symptoms who were present for testing.

CROMSOURCE also reviewed the following daily:

- Site current performance with enroled patients
- Site adherence to study procedures and entry of data
- City Intensive Care Unit (ICU) admissions (up or down)
- Trends in admissions to ICU

## Considerations

There are many aspects of rapid study start-up that should be carefully considered to be successful. The team should be prepared to identify and mitigate risks in a controlled manner quickly and efficiently in order to execute the project deliverables while also ensuring that all actions are ICH/GCP compliant and in alignment with regulations.

An important strategy in a rapid start-up situation may include executing a combined PSV/SIV which assumes that the site is already selected. It is therefore, important to utilise a network of trusted sites with whom previous experience is present, otherwise at the combined visit there is a risk that the site is not qualified and a last minute replacement site may need to be selected.

Another consideration may be executing the SIV prior to IRB approval or prior to contract/budget execution. This approach was utilised in this study due to the need of the rapid start-up and due to the pandemic situation, however, close relationships with your sites are key in order to work around a standard SIV process that is normally conducted after IRB approval.

All considerations and/or risks need to be thoroughly thought out and planned for prior to execution as some may cause additional costs and timeline delays.

## Result

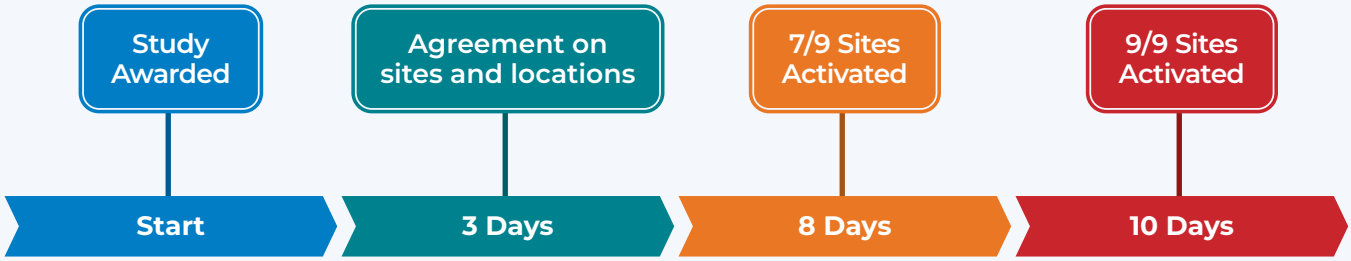
Due to the preparation that was done pre-award and the rapid execution of all elements simultaneously, CROMSOURCE was able to activate seven out of nine sites within five days of the client agreement on the sites and locations and within eight days of study award.

The first site began screening patients five days from selection with the remaining six sites to begin the following business day.

The final two sites were up and running two business days following the first batch of sites achieving full activation and recruitment of nine sites within ten business days of study award.

## Notable successes

- **Nine sites active within ten days of contract signature.**
- **Rapid recruitment began on day three from site contract execution.**
- **Successful enrolment achieved for data submission to FDA.**




## Quote from Client

*"I wanted to take a pause and thank you for the great work you have done since we awarded the project. The progress on site activation is unprecedented, you have brought up 9 sites in a matter of days, and the level of responsiveness and diligence of the entire team has been on point.*

*On behalf of the entire team a big thank you!"*

## About CROMSOURCE

CROMSOURCE is an ISO-certified international provider of outsourced services to the pharmaceutical, biotechnology and medical device industries, specialising in clinical development and staffing solutions. CROMSOURCE was founded in 1997, over 25 years ago. Its successful growth has been built on stability, integrity, and high levels of customer satisfaction, all of which contribute to a high rate of repeat and referral business. We have grown steadily, but responsibly, to become an organisation of over 350 organised and well-trained experts.


### CROMSOURCE Quality

ISO 9001:2015 multi-site certified quality management system
ISO 14155:2020 conformity confirmed

### 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

www.cromsource.com