Cerba Research

CASE STUDY

Ten-Day Study Start & Custom Test Kit Build at the Height of a Pandemic

Communication, Flexibility, Pragmatism + Resourcefulness Make the Impossible Possible

THE ASK

On the upswing of the COVID-19 pandemic, an ID-focused pharmaceutical client of more than 10 years asked: Can you supply test kits and support for our new study in 10 days?

The client's goal was to evaluate a previously approved drug for safety and efficacy in a new indication — as post-exposure prophylaxis for COVID-19 and other viral respiratory illnesses.

Clearly, time was of the essence. Therapies to mitigate worldwide suffering were desperately needed. Approval was granted under the auspices of the FDA's Coronavirus Treatment Acceleration Program (CTAP) for a Phase III study, which our client was anxious to initiate while the disease prevalence was building and a study population would be easy to recruit.

Central Lab Support Initiated in 10 Days

- Custom Test Kit and NA Distribution
- Central Laboratory Testing
- Database Build

Phase III Study for COVID-19 Prophylactic

- **1,600** Patients Screened
- **1,400** Patients Enrolled
- **30** Sites

For rapid study startup, our client needed custom kit building and distribution throughout North America along with database setup ASAP.

CHALLENGES

Radically Rapid Turnaround

A typical timeline for a project like this would be eight weeks.

Supply Shortages

With demand for hospital PPE outstripping availability and priority going to the care of sick patients and healthcare professionals, supplies for both sample collection and testing were extremely limited.

Customs Delays

Coronavirus altered many customs border policies, declarations, and authorizations, baking in additional time required to accomplish almost every task. These delays and uncertainties unavoidably affected our systems and procedures timelines.

Late Protocol Changes

In response to a last-minute client request, stool PCR testing was added to fulfill an updated FDA requirement. Other amendments included a change from ambient to refrigerated shipping and its resultant cascade of adjustments to the related database, supplies, and manuals.

SOLUTIONS

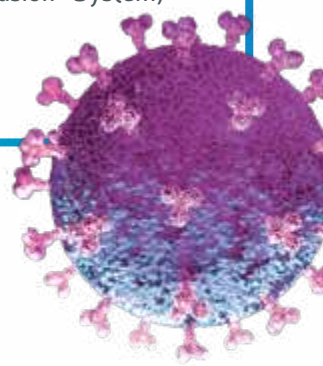
Communication and Transparency

The Cerba Research team quickly realized that the situation would require us to perform dynamically and collaborate with flexibility and understanding to deliver against this timeline. Communication and teamwork were key. Even as many of our lab-based functions and client counterparts were adapting to remote working conditions, the combined teams understood that an unprecedented level of teamwork would be required.

Multiple daily meetings were scheduled to keep hurdles in sight and brainstorm practical solutions. Every day, global internal calls took place early in the morning for some and late in the evening for others. These collaborations drew in staff from project, trial setup, sample handling, and logistics along with associate trial managers, scientific liaisons, and regional heads of project management.

Services Provided by Cerba Research

- Sample management: drug susceptibility testing and blood samples for PKs
- Logistics support
- Safety testing: hematology, biochemistry, and urinalysis
- RT-PCR through GenMark ePlex® Respiratory Pathogen Panel
- Hologic SARS-CoV-2 (Panther Fusion® System) for COVID-19 testing
- COVID-19 testing in stool matrix



Additionally, daily conference calls with client representatives ensured key milestones were being met, such as a shared review of the central laboratory procedure manual by the sponsor and CRO.

Even the project agreement required diligent attention. Working with client counterparts, Cerba's contracts and proposal team completed two separate protocol contracts within the compressed timeline — one, in less than two days.

Flexibility and Persistence

A primary order of business was to stockpile all the necessary supplies to complete the trial. Despite ongoing shortages and supply chain interruptions, the Cerba Research team worked with suppliers and obtained everything needed — with one exception.

At 5 p.m. on a Friday, word came that a shipment of swabs from Belgium was being held by customs with no expected day of release. This was a major setback, because the site supplies were intended to be shipped the following Tuesday. The team first tried sourcing swabs locally, but these did not pass validation within the method SOP of the RT-PCR assay being used.

The problem was solved by dispatching another shipment from the Cerba Research facility in Ghent, Belgium, as a series of smaller-value lots in order to expedite their passage through customs. The in-house kit-building team received the swabs late afternoon on Monday, quickly QC'd them, and started shipping complete kits that evening.

Expertise and Initiative

Another proven strategy at Cerba Research that provided valuable insights in this particular situation was our process of evaluating the client's testing approach and making any recommendations needed. In this case, when the client alerted us to the FDA's requirement for stool testing, we located a lab with a validated process to perform the assay. (The client was notified later when this mandate was reversed).

Cerba Research also added value when we tapped our network to assist with recruitment of health care workers for the study and connected the sponsor with a nonprofit able to help with funding.

RESULTS

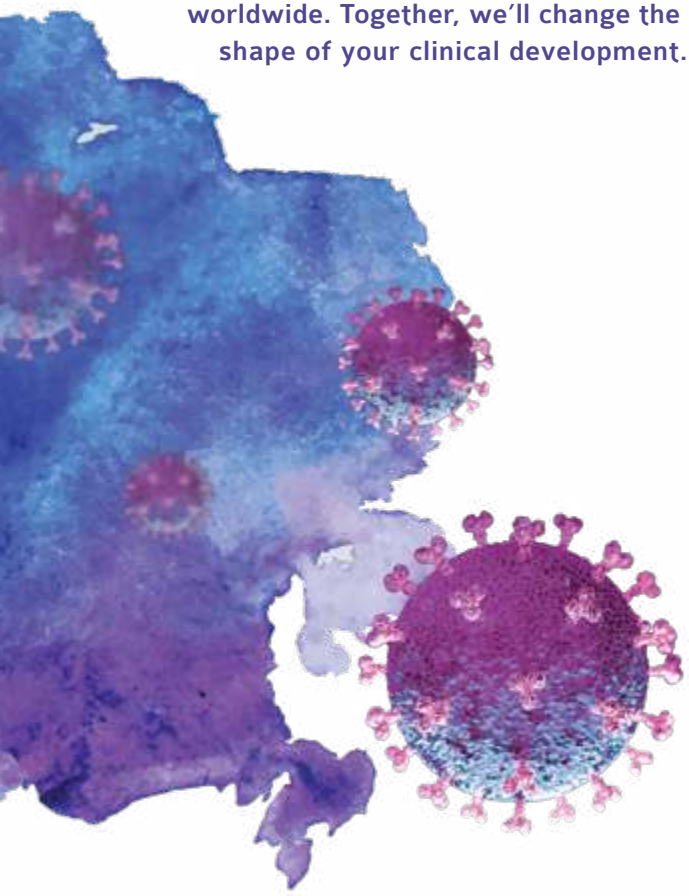
Timeline

TYPICAL TIMELINE [56 DAYS/8 WEEKS]

Motivated by going above and beyond for a long-time client and thrilled to have a hand in the global solution, the Cerba Research team dedicated itself to achieving this extremely ambitious timeline. Factors instrumental in achieving it included:

- Tireless and transparent internal and external communications
- Outstanding organization and management
- Flexibility to adapt to changing needs
- Global scientific experts and logistics network
- In-house kit production
- Highly capable team for building a unified global study database

Start with Cerba Research for integrated clinical laboratory and diagnostic solutions. As your partner, we empower you to bring new life-changing therapies to patients worldwide. Together, we'll change the shape of your clinical development.



Successful 10-day test kit and database build enables speedy initiation of a Phase III trial for a COVID-19 prophylactic therapy despite protocol changes and logistics challenges.

- PATIENTS SCREENED: **1,600**
- PATIENTS ENROLLED: **1,400**
- SITES: **30**
- EXPECTED LPLV: **August 2020**

About Cerba Research

Cerba Research provides the highest quality specialized laboratory and diagnostic solutions while leveraging patient data and scientific insight to shape and advance clinical trials. With our global footprint and access to leading regional labs, data, patients, technology, and partnered resources, we support global biotech, pharma, and IVD organizations to improve the lives of patients around the world.

From the translation of preclinical to clinical, through commercialization, our expert scientists collaborate with you to optimize your therapeutic development and obtain critical insights earlier. We help accelerate your therapies through the development of highly specialized custom assays, deep biomarker expertise, and a passion for scientific innovation across complex therapeutic areas. Our global network of leading, specialty laboratories ensures you have access to quality data and can reach your patients. Together, we'll improve patients' lives around the globe.

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