

CASE STUDY

HOW CERBA RESEARCH HELPED ADVANCE A PHASE IIB STUDY IN THE MIDDLE OF A PANDEMIC AND BREXIT

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A two-country clinical trial that involves a nasopharyngeal swab and two assays sounds relatively straightforward. But when you're conducting a study during a global pandemic and Brexit, nothing is simple.

A combination of creative logistics, careful planning, and a strong customer relationship allowed Cerba Research to keep sample processing for a novel COVID-19 treatment on track in the middle of extraordinary upheaval.

The Case:

A randomized, controlled Phase IIB clinical trial to evaluate the safety and efficacy of the sponsor's drug for high-risk subjects with mild COVID-19. The subject population enrolled a total of 600 men and women aged 18 years and over, recruited in the U.S. and the U.K., and initially included 25 U.S. sites and 10 U.K. sites. However, as COVID-19 continued to impact investigator and site availability and patients' willingness to visit sites, the sponsor moved to a decentralized model.

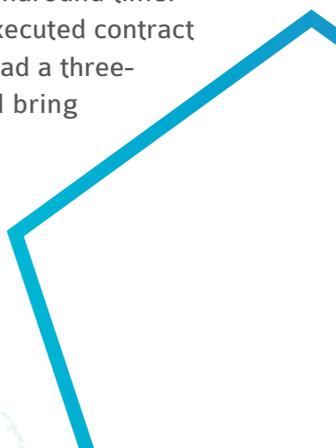
Once the sponsor randomized patients into the trial, a "COVID in a Box" kit was delivered to patients' homes. Patients could then decide whether to participate on-site or remotely using telemedicine. Most chose the latter.

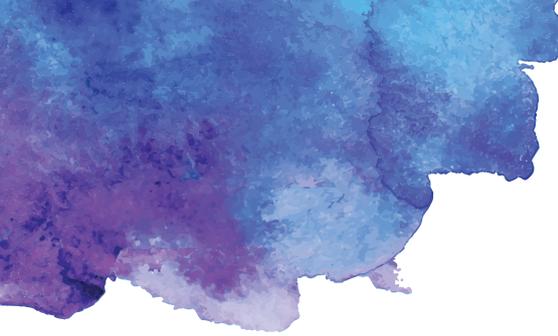
Once the patient supplied the sample and repacked the box, an agent from Marken, the preferred courier, arrived within the hour to collect the sample. Both agent and patient followed a strict process using physical distancing and personal protective equipment (PPE) during the handoff.

The Challenge:

The sponsor had an ultra-quick turnaround time. For example, it requested a fully executed contract one week after the award. It also had a three-month window to ship supplies and bring sites online.

According to our stability testing, samples had a maximum room temperature stability of 72 hours





between collection and testing. Samples had to move fast, and shipments coming through U.K. ports were at their peak due to Brexit concerns.

How We Responded:

Cerba Research had a strong preexisting relationship with the sponsor. The high level of established trust allowed us to obtain approval and execute all contracts quickly.

Kit production for the U.K. sites took place at Cerba Research's central lab in Ghent, Belgium. Kit production for the U.S. sites occurred at our New York facility. Staff from other departments came in to help manually assemble kits. Others worked evenings and weekends. With teamwork, the necessary collection materials, requisition forms, and PPE were kitted into each COVID in a Box in as short a time as possible. Necessary random batch QC checks were performed before we forwarded the kits to the U.K. investigator sites in bulk.

Concerned about the short stability window, our lab in Johannesburg, South Africa, conducted an additional long-term stability experiment on the Abbott m2000sp sample preparation platform using the Seegene Allplex 2019 kit. Based on this data, we were able to extend the stability of the samples from 72 to 96 hours. Marken managed all inbound shipments. No samples were lost to stability issues.

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Top Takeaways:

- **Get all legal and vendor onboarding agreements in place early, perhaps prospectively.** Even with necessary agreements in place, responsiveness and goodwill will help smooth the process.
- **Find practical solutions to sponsor challenges.** Cerba Research experts in two different continents came together to find a way to overcome Brexit-related logistical challenges and execute within a tight timeline.
- **Bring in your central lab partners early.** During preliminary conversations, we can evaluate assay stability, lab capacity, logistics, screening timelines, and other important aspects of your study. Early involvement helps us develop strategies to advance your research sooner.
- **Build a relationship of trust.** Cerba Research's reputation — built on robust governance paired with open, transparent conversation and a commitment to do whatever it takes to keep studies on time and on budget — allowed us to get the rapid client buy-in required to deliver under challenging circumstances.

For more than 35 years, this commitment is why organizations worldwide choose Cerba Research: the central lab centered on you.