



General Manager Clinical Trial Services & Logistic Excellence and Global Head of Logistics, Sample Handling & CTOS

Creating a vaccine that is entirely plant-based, is a noble plan and completely in line with the current spirit of the times. One of our clients set out to do it. However, in order to have the test results you need, you need strategic partners – not just suppliers. Cerba Research is such a strategic partner. Together with their client, they could get the results needed to develop this unique plant-based vaccine for SARS-CoV-2.

The mission

To develop this vaccine, our contact person, wrote a study protocol to best describe this challenge. In a nutshell, our client set up a randomized, observer-blind, placebo-controlled, phase 2/3 Study to assess the safety, efficacy, and immunogenicity of a recombinant coronavirus-like particle COVID-19 vaccine in adults 18 years of age or older. The initial plan was to get samples from 11 countries, 128 clinical sites using 2900 virology kits. These samples were scheduled to go to the Viroclinics-DDL laboratory facilities to be analyzed.

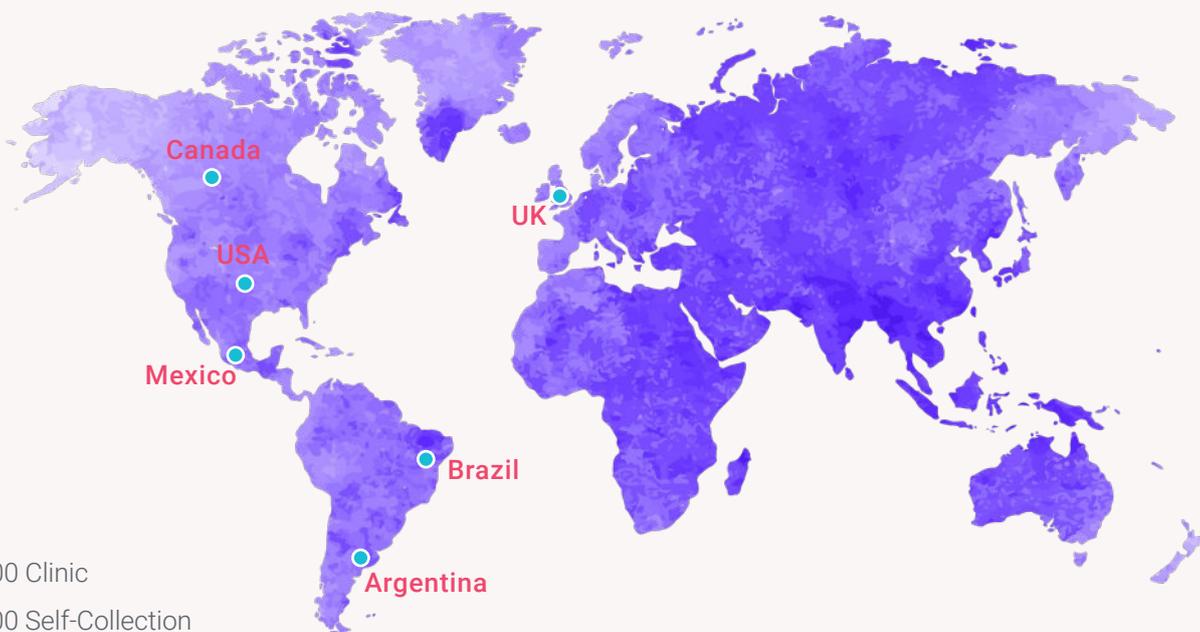
Initial Plan

11
Countries

128
Clinical
Sites

2900
Virology
Kits

1000 Clinic
1900 Self-Collection



The challenge

The study was well-thought out by all parties involved. Unfortunately, not everything went according to plan. Consequences were that all parties involved, had to rethink strategy, and adjust where necessary to perform the study according to previously set guidelines. It goes to show that having a strategic partner and constant communication are key to get results needed.

Our hurdles to overcome

Upscaling kit production and distribution

The number of kits needed were dramatically increased during the study. A lot of samples had to be collected from all over the world. Beforehand, it was decided that approximately 2900 kits were needed. In the end, more than 111.000 kits were used. To meet this demand, kit production had to be quickly increased in as little time possible. Not only production proved to be a challenge, distribution and collection also had to be arranged.

Down Scaling Clinical Sites

Because the list of countries changed, the number of clinical sites used had to be downscaled. This can be done, provided there is swift and profound communication with all sites involved. 128 clinical sites were prepared for kit collection and in the end 85 sites were actually used.

Geography – different countries

The countries where sample collection was scheduled, also changed. And needless to say, the strategy had to be adjusted.

This trial was scaled-up in the South America region in a very complex context. We faced issues with customs and the emergence of a new SARS-CoV-2 variant. Samples were shipped from sites to our central laboratory for PCR testing. Then all positive samples were shipped to a specialist laboratory for sequencing using the Athena Pipeline for SARS-CoV-2 variant determination. After the trial the samples were stored long term in our specialized freezers.

In conclusion: Success is tailor made

When it comes to this industry, there is no 'one size fits all approach'. It's important to think in solutions, not in constraints. It's vital to make sure any communication is efficient and as clear cut as possible. Potential issues at sites should be detected and resolved early in the process. Another thing that's essential, is the ability to respond to fluctuation in demands. This means scaling up and down. Always make sure there are enough kits available to collect a sample.



'Success is tailor made'

Marc van Pruijssen

General manager Cerba Research

Viroclinics-DDL, a Cerba Research Company

As a virology contract research organization, we serve the biopharmaceutical community with our preclinical, clinical diagnostic, research & development and clinical trial logistics services. Our extensive experience with clinical and preclinical studies for viruses, including our specialty in respiratory viruses, puts us at the forefront for supporting the development of vaccines, antibodies and antiviral compounds targeting viral infectious diseases.

Cerba Research

At Cerba Research we provide world-class clinical research to help life science companies successfully develop the predictive and precision medicines of the future and help people live healthier lives. We support you with industry-leading excellence in oncology, virology, vaccine development, immunology, and cell and gene therapy.

Want more information?

Check <https://cerbaresearch.com/clinical-trial-services/logistic-excellence/> or send me an email via marc.vanpruijssen@cerbaresearch.com.

Cerba Research Clinical Operations

Clinical Trial Operations

Transport Network

Global Network Processing labs

Supplies & Kit Manufacturing

Gene Therapy logistics

Biobank - Long Term Storage

Our Track Record

Our Performance

10,000

Controlled Deliveries

Our Reach

Shipment from
2500+

Different Location
Globally

Our performance

Production of
135,000

Kits Annually

Our Reach

38

Operational Processing
Labs Globally

Our Service

80+

Different Type of Kits

Our performance

150,000

Inbound Samples

Our Reach

70+

Countries

Our performance

Study Activation Under

4 Weeks

Learn more about Viroclinics-DDL contributions to vaccine and antiviral development :

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