



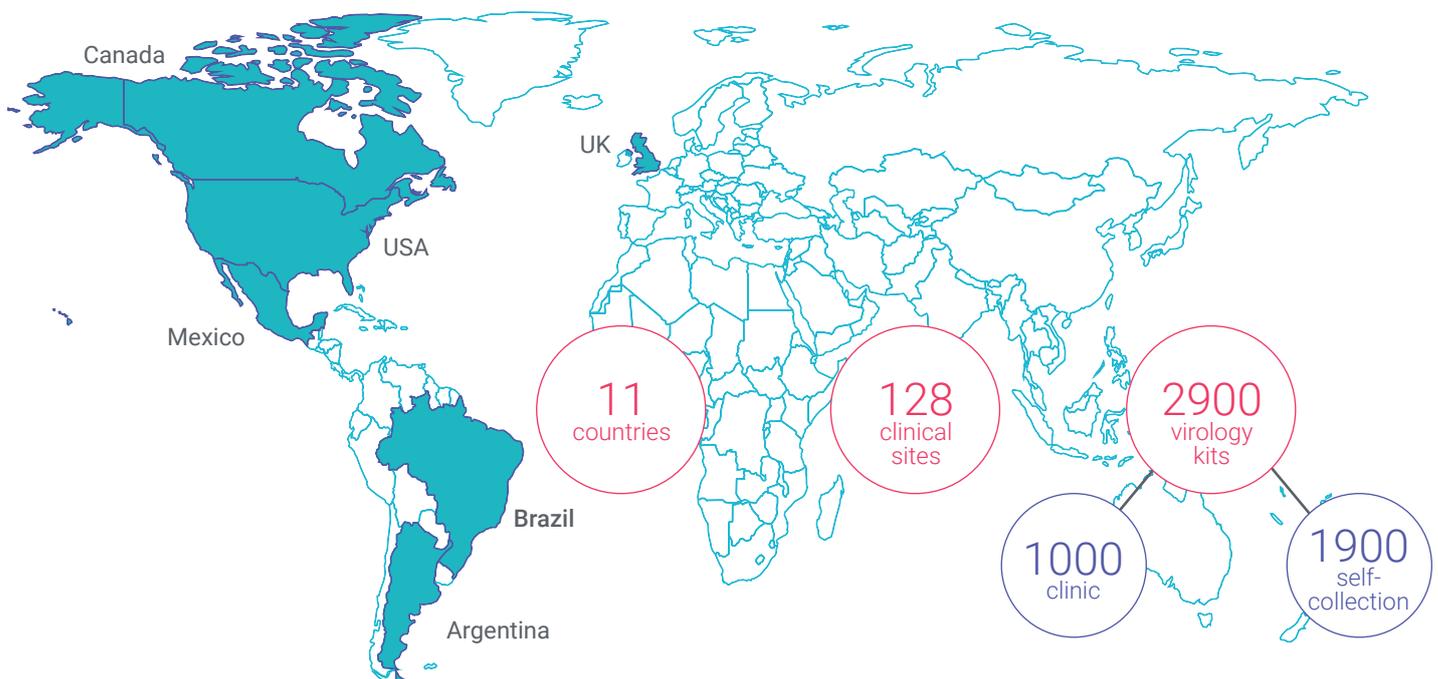
Case Study International Client and Viroclinics-DDL

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. Viroclinics-DDL 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 Clinical Trial Operations and Logistic Excellence laboratory facilities to be analyzed.

Initial Plan



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.



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.

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.

Geography – different countries

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

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.

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'

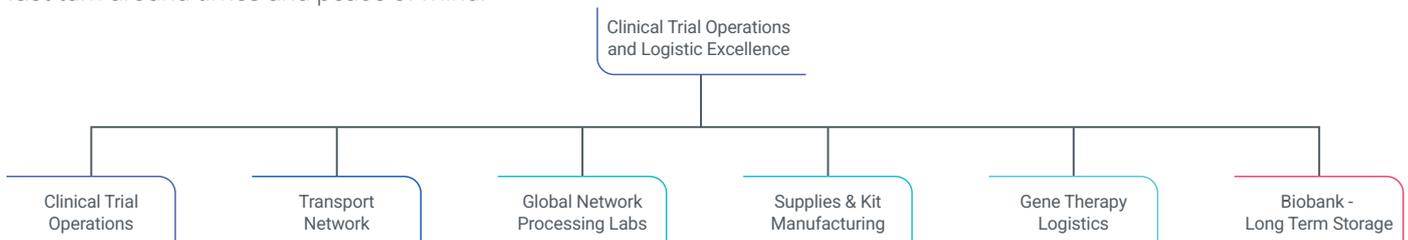
Marc van Puijssen
GM Clinical Trial
Operations and
Logistic Excellence

Viroclinics-DDL, a Cerba Research Company

Viroclinics operates at a global level, being the preferred virology testing laboratory for several of the top-10 Biopharmaceutical companies. Viroclinics-DDL operates at a global level, being the preferred virology testing laboratory for several of the top-10 Biopharmaceutical companies.

Clinical Trial Operations and Logistic Excellence

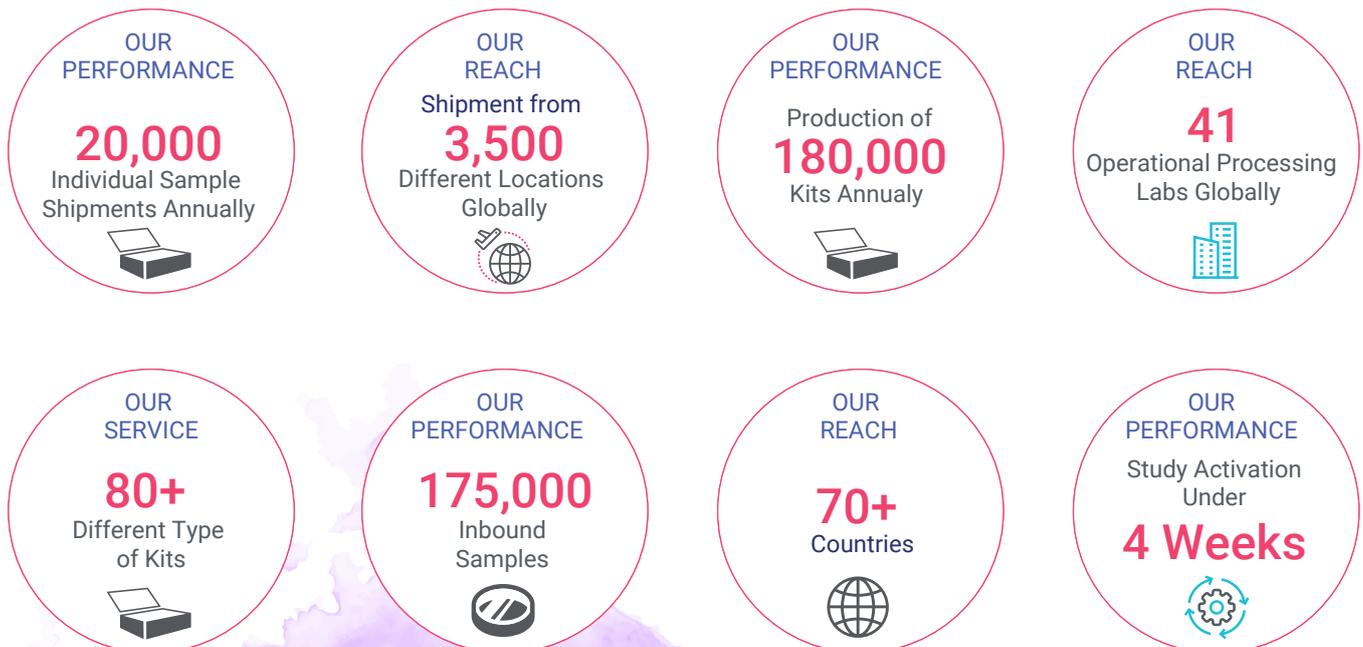
Clinical Trial Operations and Logistic Excellence is a separate business unit within Viroclinics-DDL that helps biotech and pharmaceutical companies with global logistics during phase 2 / phase 3 in clinical trials. With 41 partnering (processing) labs all over the world, we can guarantee 100% on time delivery and successful data management. For any kind of sampling, kits are custom-built, distributed, and retrieved with a track and trace code to be analyzed in our facilities. After a study, samples can be stored short-term or long-term in a bio bank. A 24/7 helpdesk is available for all studies to ensure fast turn around times and peace of mind.



Want more information?

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

Our Track Record



Learn more about Viroclinics-DDL's contributions to vaccine and antiviral development: www.cerbaresearch.com

