

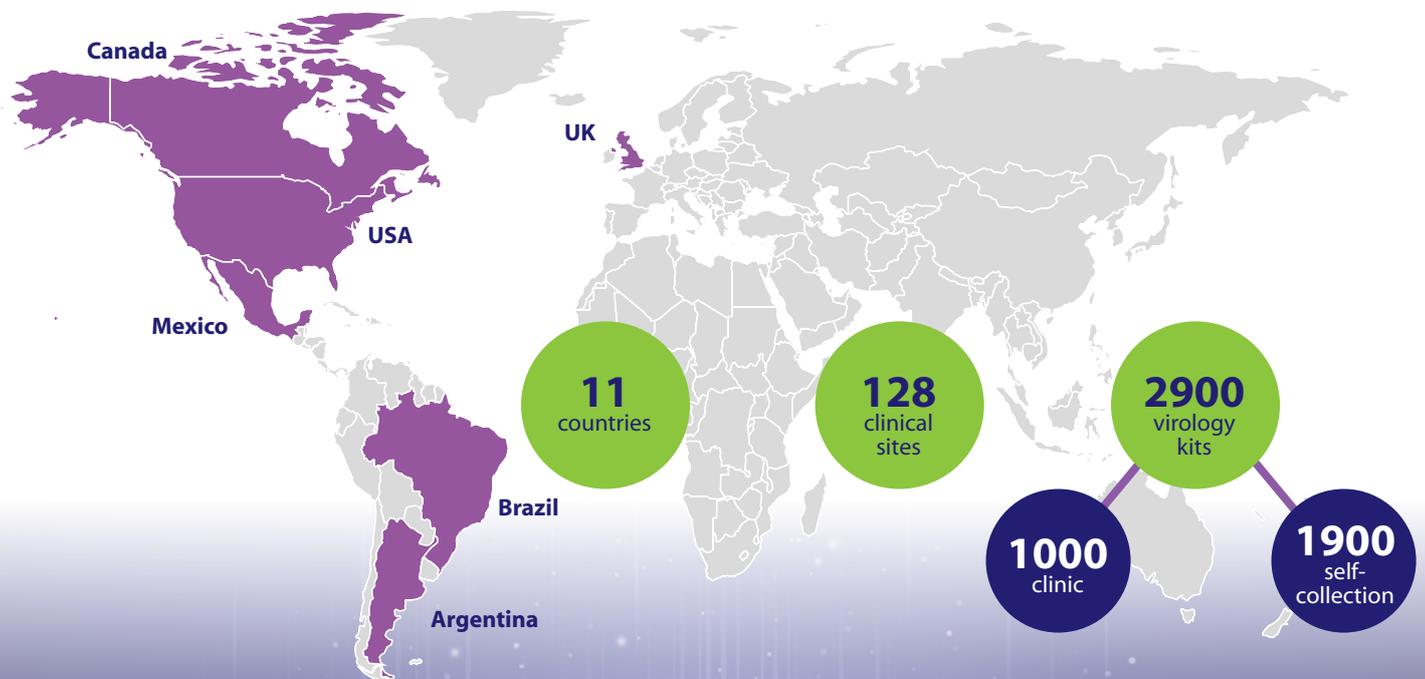
# Case Study – International Client and Viroclinics Xellerate

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 Xellerate 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



## 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.

### 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.

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 Puijssen

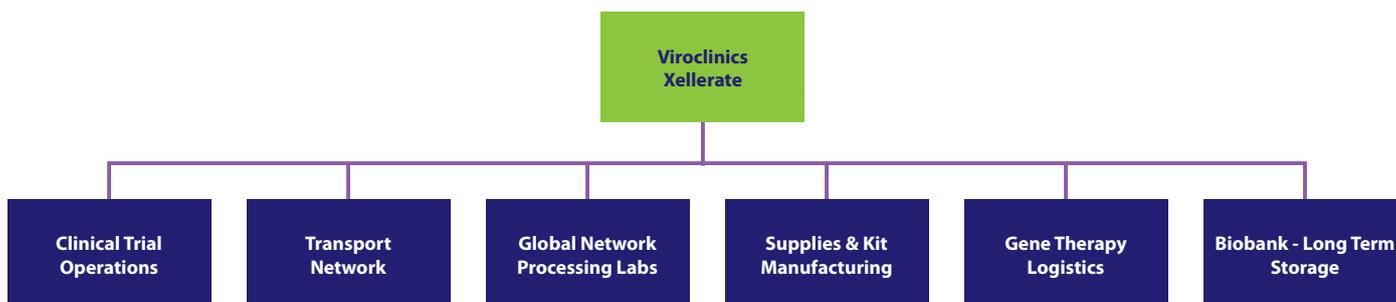
General manager Viroclinics Xellerate

### Viroclinics-DDL, a Cerba Research Company

*This company focuses on improving Global Health and accelerating preventive and therapeutic solutions*

### Viroclinics Xellerate

*Viroclinics Xellerate 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 38 partnering (processing) labs all over the world, Xellerate 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 ensures that all data is to be used successfully in analysis.*



## Want more information?

Check [www.viroclinics.com/ctos](http://www.viroclinics.com/ctos) or send me an email via [vanPuijssen@viroclinics.com](mailto:vanPuijssen@viroclinics.com).

# Our Track Record

OUR  
PERFORMANCE

**10,000**

Controlled  
Deliveries



OUR  
REACH

Shipment from  
**2500+**  
Different Locations  
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:

[www.viroclinics.com](http://www.viroclinics.com)

