



Case Study – Viroclinics Xellerate fights Spinal Muscular Atrophy 7 days a week



Viroclinics Xellerate – where the medical world meets the world of logistics

The world seems smaller in this digital era, information can reach you within a second. However, logistics still poses a challenge in our business. Serum or blood samples that have been collected anywhere in the world, must go to either a partnering laboratory or our facilities in Rotterdam. And when it comes to treatment for babies, serum samples must be handled with the utmost speed and special care. We mention babies because of a life changing therapy Viroclinics-DDL is taking part in; the fight against Spinal Muscular Atrophy.

The treatment

So how do we treat this disease? One of the treatments is based on gene therapy. This treatment – which is given by a viral vector – is one of the possible treatments for this disease. It contains a replica of the missing gene. The viral vector passes into the motor neurons in the spinal cord and restores function of the missing gene, which then produces proteins necessary for nerve function and controlling muscle movements. It's given via a one-time intravenous infusion which is administered on a patient for over an hour. This single injection helps newborn babies with SMA to develop close to normal and saves their lives. This treatment is being approved in many countries around the world. One of the pivotal steps to evaluate the eligibility of a patient with SMA for the treatment with gene therapy is the presence of antibodies against the viral vector.

What is SMA?

Spinal Muscular Atrophy or SMA is a rare genetic (inherited) condition caused by a missing or non-functioning (mutated) SMN1 gene. This condition results in rapid and irreversible loss of motor neurons. This then affects main muscle functions like breathing, swallowing and basic movements. Since these neurons control muscle movements throughout the body, a lack of it could cause paralysis, severe muscle weakness, loss of movements and newborns with the most severe type, will without treatment, die at a young age.

The Guthrie test makes early diagnosis of SMA possible. Time is of the essence for diagnosis and treatment so this technique allows us to be ahead of the curve for diagnosis and treatment.



Our added value

You can imagine that each serum sample potentially represents a baby's life. Therefore, any logistical challenges must be overcome quickly and smoothly. There is a lot at stake. That's where our extensive expertise and knowledge come in. We have a proven track record in a wide variety of services varying from serum samples collections from over 50 countries, quick delivery to our Rotterdam site for immediate laboratory testing which will tell if antibodies are an eventually contra-indication for gene therapy, logistics of sampling kits to hospitals and laboratories. For this service we work with multi-disciplinary teams from Viroclinics Xellerate and our departments of Clinical Virology Services and R&D in Rotterdam.

How common is SMA?

Orphan Disease

SMA is a rare disease.

That's why they call this an orphan disease.

Newborn

1 in 10,000 newborns have it.

Genetic defect

About 1 in 54 people carry the genetic defect of SMA.



Two carriers

Two carriers have a 25% chance of having a child with SMA.

Daily, these teams work closely together to bring in the patient samples, have them tested, check and report the results immediately, **7 days a week**. The next steps for the service, considering that the treatment is being approved in more countries and new markets, keep on opening, will be cooperation with external laboratories. This will allow Viroclinics Xellerate to centralize and simplify sampling and logistical processes for the regions where difficulties were being faced previously, therefore decreasing transit times for the samples making the treatment available faster.


The goal and ultimate challenge is to minimize the time from sample collection to reporting results to the physician. SARS-Cov-2 still has a huge influence on the process, regarding closed borders and other major restrictions. Unfortunately, wars and conflicts are also to be mentioned. Sometimes challenges already begin in the very first stage, like finding dry ice for transportation. It is very impactful to work on this project. Because we are of course aware that every sample is a baby's life; a life that we might be able to save. Sometimes a delay of one day, may already be too late. So, pace and efficiency are utterly important. It's amazing to see the achievements, how this project is growing and developing.

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 40 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.



References

Pharma Intelligence & ASGCT, Gene, Cell, & RNA Therapy Landscape: Q2 2022 Quarterly Data Report (2022)

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Our Track Record

OUR
PERFORMANCE

20,000

Controlled
Deliveries



OUR
REACH

Shipment from
3,500
Different Locations
Globally



OUR
PERFORMANCE

Production of
180,000
Kits Annually



OUR
REACH

40
Operational Processing
Labs Globally



OUR
SERVICE

80+
Different Type
of Kits



OUR
PERFORMANCE

175,000
Inbound
Samples



OUR
REACH

70+
Countries



OUR
PERFORMANCE

Study Activation
Under
4 Weeks



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