

Reliable delivery of equipment amid unprecedented global pressures



Clinical trial	Woodley Trial Solutions supplies equipment for a decentralized clinical trial investigating a new treatment for patients with transthyretin amyloidosis cardiomyopathy
Total number of patients	632
Global sites	90 sites across the world
Sturdy supply chain	Fast delivery of equipment amid the COVID-19 pandemic and Brexit
Minimized downtime	Rapid device replacement to ensure patient visits were met

A randomized, double-blinded and placebo-controlled study with parallel assignment was performed to evaluate the effect of a new treatment for patients with transthyretin amyloidosis cardiomyopathy (ATTR-CM). ATTR-CM is an under-recognized cause of heart failure in older adults, characterized by deposits of amyloid protein fibrils on the walls of the left ventricle. This makes the walls stiff, causing the heart to lose the ability to relax and fill with blood, or squeeze to pump blood out, which results in serious health issues, especially as the left ventricle is the main pumping chamber of the heart.

There is currently no cure for ATTR-CM, but treatment can slow down disease progression and alleviate some of the symptoms. This study aimed to assess the efficacy of a new medication, using an already approved drug as a reference, in patients with hereditary ATTR-CM. Inclusion criteria were adults aged between 18 and 85 years, with a documented diagnosis of ATTR-CM and a medical history of heart failure, including at least one hospitalization. The study was decentralized, and the equipment – including Clinispin HOROZON 6 Flex centrifuges and CardioPad ECGs – was shipped directly to nurses' homes. The nurses would bring the equipment during their patient visits to administer the medications in a blinded method, and perform the testing required for the clinical trial.

The key challenges

Logistical

Supplying equipment for such large-scale projects always comes with its challenges and, in this instance, logistics were further complicated by the global pandemic and Brexit. Woodley Trial Solutions anticipated the changes that Brexit would bring to the supply chain network, and worked proactively to mitigate them, implementing new strategies by early 2020. This included a strategic distribution partnership on EU soil in the Netherlands – where equipment could be stored and distributed in a timely manner – and reviewing stock levels weekly to ensure devices were there when needed.

Even greater care was taken when packing the equipment, including extra safety measures to protect both staff and clients, such as mask wearing and using gloves when handling the instruments to limit the risk of contamination. With these measures in place, Woodley Trial Solutions was one of the few global companies that could still offer the same service amid the emerging and continuously evolving restrictions.

The ever-changing regulatory landscape during the COVID-19 pandemic, which often differed between each country, presented unprecedented challenges to running a trial with multiple global sites. Trying to stay ahead of this regulatory maze was near impossible, and required great flexibility and all the company's experience in supplying decentralized clinical trials.

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Minimizing downtime

The company's attention to detail and willingness to go above and beyond the remit, combined with vast experience in supporting clinical trials, ensured the study ran as smoothly as possible. Part of this service-centered mindset was keeping a stock of instruments at various locations – ready to be shipped anywhere in the world – to quickly replace equipment when maintenance was required. This helped to minimize downtime if equipment needed calibrating or if there were unexpected issues, as replacement devices were sent in advance, instead of waiting for maintenance or recalibration of the original item. This significantly benefitted the client – with cost-effective and seamless upkeep of the equipment – and the patients, as it helped to meet appointment times without delay, so they could continue to receive treatment in the comfort of their home.

Summary

Woodley Trial Solutions was able to continuously provide the mandated equipment for this study, adapting to and resolving the parallel challenges of Brexit and the COVID-19 pandemic with precision. ATTR-CM is a life-threatening disease without a cure, and so the importance of completing this clinical trial without unnecessary delays was of the utmost importance to accelerate the possibility of future therapies. Taking a decentralized approach was hugely beneficial, helping one of the final phases in drug discovery to proceed in a timely, cost-effective and, most importantly, patient-centric manner.

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