Rapid results to determine the course of treatment

30 YEARS
SMARTER EQUIPMENT SOLUTIONS

Clinical trial	**Woodley Trial Solutions implements POCT to streamline a clinical trial investigating a new treatment for HeFH**
Total number of patients	62
Global sites	14 sites across the US and Germany
Robust protocol	Double-blind study using advanced data encryption
Patient centric testing	POCT yielded results in minutes without causing inconvenience to patientsg

A randomized, double-blind, placebo-controlled, parallel-group study was performed to evaluate the efficacy and safety of alirocumab in patients with heterozygous familial hypercholesterolemia (HeFH). HeFH is a genetic disorder that results in elevated levels of low-density lipoprotein cholesterol (LDL-C), which can lead to heart disease, myocardial infarction or stroke if left untreated. Traditionally, treatment is through lipid apheresis, an invasive therapy that removes cholesterol from the blood – much like dialysis in patients with end-stage kidney failure. However, lipid apheresis cannot curb the early onset atherosclerotic cardiovascular disease caused by HeFH, and is invasive and obstructive to patients requiring constant therapy, leading to the investigation of alirocumab as an alternative treatment.

The main objective of this study was to assess how alirocumab, administered every two weeks, affected the frequency at which patients with HeFH required lipid apheresis. Participants had to be adults with HeFH currently undergoing weekly or bi-weekly lipid apheresis for at least eight weeks prior to the screening visit.

The key challenges

Logistical

The clinical trial included 14 sites in the US and Germany, and required an accurate and reliable method to screen LDL-C values. Woodley Trial Solutions has extensive experience in supplying equipment to both lab-based and point-of-care testing (POCT) for clinical trials in over 150 countries worldwide. The team handled all the logistics for the trial, and supplied a custom device – developed in partnership with the manufacturer exclusively for this trial – to rapidly evaluate LDL-C values. Staff on every trial site received hands-on, certified training to ensure they felt comfortable with how to use the device, and benefitted from ongoing technical support, enabling all doctors and nurses to quickly troubleshoot any issues and focus on their patients.

Technical

All patients were screened during their first visit to determine baseline LDL-C levels, which were then used to decide whether lipid apheresis was required in subsequent visits. Results were needed quickly for the safety of the patient, and to ensure lipid apheresis was only administered in patients needing the expensive procedure. Therefore, POCT was chosen over processing in central labs to speed up time-to-results and remove inconsistencies between each trial site.

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A bespoke device was modified from an existing lipid panel that showed other parameters, including total cholesterol, high-density lipoprotein cholesterol and triglycerides. As only LDL-C values were of interest to the medical team, the software was edited to omit the superfluous information. The results of each blood test were displayed as six-digit codes to ensure that neither the patient nor medical personnel knew the actual values. They were then sent to a third party for decryption, which determined whether there was an increase of 10 per cent or more from baseline observations, allowing rapid reporting of a simple 'yes' or 'no' answer determine whether lipid apheresis should be administered.

Summary

Woodley Trial Solutions streamlined the clinical trial process to evaluate the effect of alirocumab on LDL-C levels in patients with HeFH, helping to determine whether this new treatment could reduce the frequency of lipid apheresis in these patients. Using POCT for screening and ongoing monitoring provided rapid, accurate and consistent results, with encryption further improving the robustness of the trial. The deployment of innovative POCT technologies like this requires not only technical knowledge and supply chain efficiencies, but also vast regulatory know-how to be able to implement these time-saving solutions to trial sites across the world.

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