Establishing the long-term safety and efficacy of a novel treatment for hemophilia A

30 YEARS
SMARTER EQUIPMENT SOLUTIONS

Clinical trial	**Woodley Trial Solutions delivers ultrasound systems to support a clinical trial investigating a new treatment for hemophilia A**
Global sites	13 sites worldwide, including USA, France, UK, Taiwan, Italy, Netherlands and Canada
Smooth changeover	Efficient handover from one CRO to another ensured trial continued uninterrupted
Meeting medical device requirements	Trouble-free importation of regulatory-compliant equipment

This clinical trial was a phase 3, open-label interventional study of a new treatment for patients with severe hemophilia A, and was followed by an extended study to confirm its long-term safety and efficacy. Patients with hemophilia A have a genetic deficiency in clotting factor VIII, which causes increased bleeding. While there is no cure for hemophilia, treatment with clotting factors – either as a prophylactic or, in mild cases, in response to prolonged bleeding – usually allows people with the condition to live a normal life.

The main objective of this study was to establish the efficacy of intravenous administration of efanesoctocog alfa as a treatment for hemophilia A. Eligible patients were enrolled onto either a weekly prophylaxis treatment regimen for 52 weeks or, alternatively, received the drug on demand for 26 weeks, followed by a prophylaxis treatment regimen for a further 26 weeks. The trial was subsequently extended to evaluate the long-term safety and efficacy in previously treated patients.

The key challenges

Logistical

The clinical trial included 13 sites globally, each of which required a specific ultrasound technology. Medical devices must comply with various regulations, both local and national – for example, the European Medical Device Regulation – and these are subject to change. Woodley Trial Solutions drew on its extensive regulatory knowledge to ensure the ultrasound systems were compliant for use at all the trial sites. A diverse range of system-specific accessories was also sourced, including tangible hardware – such as transducers, mobility carts, travel cases and battery packs – and various software packages. These were obtained from a number of third-party suppliers – as is often the case to meet special regulations for each country – ensuring that they were compliant and able to be used for the trial, and that all relevant documentation was in place prior to importation. Furthermore, the ultrasound equipment and accessories were carefully tested at each trial site. This made sure that all the devices were fully functional, and left in the optimal state to support the study and its patients.

A change of CRO

During the course of the trial, the study transferred from one CRO to another, as one phase came to an end and the next began. This called for the combined experience of Woodley Trial Solutions' project management and contracts teams, who efficiently handled all internal communications, and quickly grasped the particularities of working with the new CRO. This smooth changeover was essential to ensure patient visits continued uninterrupted, technical support remained available, and unnecessary and expensive delays to the trial were avoided.

Summary

Woodley Trial Solutions sourced and supplied bespoke ultrasound equipment from a reputable manufacturer. The company ensured the equipment complied with all regulations, was accompanied by the required documentation to streamline shipping, and was approved for use in the clinical trial. Woodley Trial Solutions was also able to use its expertise in the field to ensure a smooth transition from one CRO to another, liaising with all parties involved to safeguard the uninterrupted continuation of the trial.

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