

Supply of connected devices for decentralized clinical trial



Clinical trial	Decentralized study to assess safety of drug administered to children with congenital hyperinsulinism
Total number of patients	44
Global sites	Ten across USA, Germany, Israel, and the UK
Connected devices	Sourcing, supply and set-up of hi-tech devices across four different territories.
Ongoing partnership	After experiencing the comprehensive nature of Woodley Trial Solutions' support, the client-supplier relationship continues today.

This phase 3 open-label decentralised trial assessed the safety and efficacy of a drug administered to children with congenital hyperinsulinism.

Across 10 different sites in USA, Germany, Israel, and the UK, this trial aimed to assess the long-term safety and efficacy of a drug administered to 44 children (aged six weeks to 13 years) with congenital hyperinsulinism. The study had one primary outcome measure – the number of adverse events up to Month 1; during Month 1 to 3; and in each three-month period for the first year – with a further 15 secondary outcome measures also being monitored.

Going the extra mile

Technology identification and advice

As with many decentralised clinical trials, when data is gathered remotely and then transmitted to a central location, the CRO required support and assistance in ensuring that all connected devices were primed for use within the territories in which they would operate. Woodley Trial Solutions offered a personalised identification and sourcing service, tailored to supply only the highest quality on-budget digital cameras, memory cards, laptops, and MiFi devices for each relevant country. We took care to work within the organiser's budget, adding value by meticulously analysing coverage versus budget assessments to ensure clients costs were always effectively balanced against performance. We also completed essential imaging of the laptops to ensure all crucial data collection software were correctly installed and ready to use. By taking care of details like that within a series of tight deadlines, the trial was able to begin on its scheduled start date without any delay or interruption.

Consistency in equipment and data

It was a trial requirement for all data to be accessible by the CRO from a remote, central location. This meant that a range of considerations had to be made, beyond simply the sourcing and supply of connected devices. To ensure consistency across all gathered data, our team worked hard to identify universal solutions wherever possible. For example, the Kodak PIXPRO FZ53 compact camera was recommended for all sites in the study. But each camera was sourced locally, ensuring they were equipped with the correct plugs for their operating environment.

Dedicated project management service

From the start, Woodley Trial Solutions delivered a fully responsive service that enabled the trial's rapid roll-out. Our dedicated project management service provided the trial organisers quick answers to any queries they had. Our logistical expertise ensured each site could rely on timely deliveries. And our calibration team worked tirelessly to ensure all equipment was ready to use from the moment it landed on site. Core equipment like fridges, freezers, and temperature dataloggers were calibrated and supplied alongside the trial's connected devices, demonstrating our ability to provide a best-in-class service across all requirements. At every possible turn, Woodley Trial Solutions went above and beyond to add value and offer a service that extended in its scope and impact beyond solely the supply of trial equipment.

Woodley Trial Solutions managed a significant number of bulk shipments during the project, consistently ensuring the client had full visibility and a granular understanding of lead times, delivery schedules and budget allocation.



Summary

Thanks to Woodley Trial Solutions' dedication and ability to provide a fully comprehensive service, the trial is now actively gathering critical data crucial for the ongoing treatment of congenital hyperinsulinism in children. This important work has been able to happen at speed, with the trial organisers being so impressed by Woodley Trial Solutions that an ongoing partnership has developed across multiple decentralised clinical trials.

UK Office
t: +44 (0)8456 777001

e: hello@woodleytrialsolutions.com
www.woodleytrialsolutions.com

USA Office
t: +1 800 471 9200

 [Woodley Trial Solutions](#)
 [@WoodleyTrialSol](#)

