Secure data transfer from CGM device to CRO during diabetes study

30 YEARS
SMARTER EQUIPMENT SOLUTIONS

Clinical trial	**Drug impact assessment on hypoglycaemia in adults with type 1 diabetes**
Total number of patients	168
Global sites	19 across USA and Canada
Technological expertise	Identification and provision of CGM devices with appropriate regulatory clearances
Innovative partnership	Working with data management platform for ongoing training, support, and fully compliant data storage and distribution

This phase 2a randomized, double-blind, placebo-controlled clinical trial aimed to assess the impact of a new drug on hypoglycaemia in adults with type 1 diabetes.

Across 19 different sites in USA and Canada, this trial aimed to determine whether a new drug lowers the number of nocturnal low-blood sugar events ('hypos') experienced by adults with type 1 diabetes. Data was gathered over two four-week periods, with participants wearing a continuous glucose monitoring (CGM) device sourced and supplied by Woodley Trial Solutions. The study had seven outcome measures, including incidence of nocturnal hypoglycaemia, incidence and severity of adverse events, and glucose time below range.

Providing dedicated expertise

Technology identification and provision

After in-depth discovery conversations, Woodley Trial Solutions' expert team identified, sourced, and supplied the trial organisers with appropriate market leading CGM devices and additional connectivity equipment. By quickly recognising the client's preferred CGM device was not regulated for use in Canada, Woodley Trial Solutions swiftly suggested and sourced an appropriate alternative – with no impact on quality.

Innovative and all-encompassing data support

Woodley Trial Solutions' support in identifying appropriate CGM devices was further enhanced by a long-standing innovative partnership with data management platform Glooko. This synergistic collaboration ensures both the CGM hardware (managed by Woodley Trial Solutions) and associated software (Glooko's platform) are implemented together to ensure participant data is collected efficiently and stored securely with the highest levels of cyber protection. Combined, this provided the trial's CROs with an all-encompassing, technology-driven service specifically designed to enable the trial to proceed smoothly and at pace.

Enhanced training and knowledge sharing

Glooko provided extensive platform training to ensure all stakeholders could effectively navigate the technology in a way that best suits their needs. This trial saw Glooko offer both in-person and virtual training sessions to site leads and, on occasion, participants. Woodley Trial Solutions simultaneously delivered training on how to set up and use the CGM hardware, ensuring that participants understood battery life and the importance of having a mobile device readily available for Glooko's platform to automatically receive generated data. At the culmination of Woodley Trial Solutions' training, participants felt comfortable replacing the sensor, reapplying the device, and checking that data is still syncing after that process. This is critical to ensure the ongoing feasibility of the study, and provide CROs and trial sponsors with the reassurance they need that weeks of potential data gathering will not prove futile due to user error. Woodley Trial Solutions' specialist Project Management team also completed Glooko training, enabling them to offer further expertise and support where needed.

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

woodley TRIAL SOLUTIONS

A truly insightful and responsive partnership

As the trial progressed, Woodley Trial Solutions and Glooko continued to work to deliver on the project's overall goals. The synergy between the two companies has developed to such an extent that we collectively understand how to overcome challenges and complement each other in providing a ground-breaking supply solution for CGM in diabetes trials. From the outset, Woodley Trial Solutions provided end-to-end project management, including inventory tracking, supplier management, expiry dates and trackers, labelling and packaging, budget reconciliations, regular meetings, and high-level quarterly business reviews (QBRs). 24/7 hardware tech support was also provided throughout the study, ensuring the trial was not stalled by avoidable delays. At the same time, Glooko's ingenious data dashboards helped the trial's site coordinators and medical monitors to surface data that enabled the identification of each participant's study phase, as well as potential adverse events that helped determine if a participant was eligible for randomisation.

Summary

Over a 16-week study period, this clinical trial gathered important data on the impact of a new drug on hypoglycaemia in adults with type 1 diabetes. Its primary outcome measure was the incidence of nocturnal hypoglycaemic events lasting at least 15 minutes for participants receiving the trial drug compared to those receiving a placebo. Three secondary outcome measures were monitored: the number of participants experiencing adverse events; the glucose time below 54 mg/dL (as %) compared to participants receiving the placebo; and the number of hypoglycaemic events at any time lasting for at least 15 minutes. Finally, three other outcome measures were also monitored: glucose time in range (70-180 mg/dL, %) compared to placebo; mean glycemic variability; and mean glucose concentration. Gathering complex medical data is a challenging task, but in this instance the trial organisers knew they could rely on the expertise, innovation, commitment, and integrity of two world-leading partners – Woodley Trial Solutions and Glooko – operating in tandem to deliver a truly remarkable service.

24/7 hardware tech support was also provided throughout the study, ensuring the trial was not stalled by avoidable delays. At the same time, Glooko's ingenious data dashboards helped the trial's site coordinators and medical monitors to surface data that enabled the identification of each participant's study phase, as well as potential adverse events that helped determine if a participant was eligible for randomisation.

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

woodley TRIAL SOLUTIONS