Game-changing solutions transforming clinical trials

30 YEARS
SMARTER EQUIPMENT SOLUTIONS

Clinical trial	Woodley Trial Solutions brings success to POCT prescreening
Total number of patients	4,000
Global sites	850 sites in 45 countries across five continents
Screen failure rate	Reduced from 70 % to 50 %
Expenses	Halved compared to central lab testing
Time taken for testing	<10 minutes compared to 48 hours with central lab testing
Correlation to central lab values	eGFR: 97 % UACR: 85 %
Investigator acceptance of, and satisfaction with, POCT	81 %

This clinical trial was a randomized, double-blind, placebo-controlled study conducted on 4,000 patients around the world. Its main objective was to evaluate the effect of atrasentan – a selective and potent inhibitor of the endothelin A receptor – on certain renal analytes in individuals with diabetes and chronic kidney disease. The phase II studies initially relied on central laboratory testing to prescreen prospective subjects with two parameters: estimated glomerular filtration rate (eGFR) and urine albumin creatinine ratio (UACR). However, the investigator sites were often hampered by logistical challenges, and screen failure rates were extremely high. When it came to the phase III registration trial, it was decided to prospectively implement testing at the point of patient care, to see if this action would make the enrollment process more efficient, and improve the workflow of the trial.

The key challenges

Logistical

The trial needed to establish a simultaneously fast and responsive prescreening service at 850 sites, spread over 45 countries. This included all aspects of testing, from equipment delivery and training of staff, to ensuring fast and consistent reporting of results, along with full technical support to minimize downtime. In addition, the project required a multi-faceted approach that included not only digital communication, but physical traveling to different destinations to engage staff and adapting to working in different cultures.

Woodley Trial Solutions was perfectly placed to provide this service, with extensive global experience of lab-based and point of care (POC) trials. The team coordinated all efforts at all sites, holding certified theoretical and hands-on workshops on the POC devices for the on-site staff during planned investigator meetings, travelling to sites regularly, and scheduling monthly webinars to ensure compatibility of testing, and to allow for changing personnel. The instruction manuals and user interfaces were delivered promptly in multilingual formats and follow-up support for all user issues was provided by email, phone and, if required, in person. Data was compiled electronically from all sites to ensure the rapid and reliable acquisition of results and performance analysis.

Technical

Consistency of results was essential to ensure the seamless functioning of the trial and so it was important to be able to monitor the reportable range of each instrument. It was also critical to forecast the number of tests that would be needed globally – and plan timely deliveries – anticipating the screen failure rate, the test box size, and the expiry dates on the kits.

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The Woodley Trial Solutions specialists advised what equipment to use for the prescreening, including Siemens CLINITEK® urine analyzers and Nova Biomedical StatSensor® creatinine and eGFR meters, along with test reagents and other quality control materials. The company's implementation and commercial teams then worked in tandem to ensure the availability and appropriate functioning of every device at all sites. The reproducibility of results was upheld by internal strategic drivers, such as replacing faulty equipment, calibrating analyzers, and a fast-track response to feedback from all trial sites.

The breakthrough results

The solutions provided reduced the screen failure rate of the trial from 70 % in phase II down to 50 % in phase III. Good conformity with results was achieved – eGFR: 97 %, UACR: 85 % – and an impressive 81 % of investigators were happy with POCT. In addition, the cost per patient was reduced by almost 50 %, and enrolment was far quicker. Data was effectively captured from all on-site devices and sent securely to an electronic document coordinator, helping to minimize operator and transcription errors, and allowing the data to be easily stored and be accessible for further studies.

The bottom line

Timely access to expertise and information is crucial to aligning the logistics of clinical trials of any size, and it also requires the deployment of flexible and efficient technologies like POCT and digitally-enabled workflows. POCT is reshaping how testing is performed; it represents a huge step towards patient-centricity, and offers a more cost-effective solution to CROs and sponsors, especially for prescreening. Woodley Trial Solutions' operational excellence and automated management of data, with its end-to-end product delivery workflow, makes it the go-to company for supporting any size of trial, even for large operations illustrated here.

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