Real-time measurements at the point of care help speed up clinical trials

30 YEARS
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Clinical trial	Woodley Trial Solutions plays a vital role in POC identification of pericarditis episodes
Total number of patients	86
Global sites	50 sites across Australia, Israel, Italy and the United States
Time taken for testing	15 minutes compared to 48 hours with central lab testing, or 1 hour at a local lab
Correlation to local lab values	Parallel analysis with local lab values showed good agreement between results
Patient centric testing	On-site testing enabled faster identification of a pericarditis episode and enrollment onto the study, and earlier administration of the study drug

This clinical trial was a double-blind, placebo-controlled, randomized-withdrawal design study with open-label extension in 86 subjects with symptomatic recurrent pericarditis. Interleukin-1 has been implicated as a mediator of recurrent pericarditis. A Phase II trial of rilonacept, an interleukin-1α and interleukin-1β cytokine trap, had previously shown evidence of its effectiveness in resolving pericardial inflammation, enabling progression to a Phase III study. The objective of the Phase III clinical trial was to test the primary hypothesis that rilonacept would lead to a lower risk of recurrence of pericarditis than a placebo.

Patient eligibility for both the Phase II and Phase III trials was determined by measurement of the inflammatory marker C-reactive protein (CRP) during a symptomatic recurrence of pericarditis. While this can be achieved using either a central or local lab, the methods are not standardized, and it can take up to 48 hours to receive the results. This led to a pilot study of point-of-care testing (POCT) for CRP during the Phase II trial. POCT was subsequently implemented for Phase III, enabling standardized on-site CRP testing, to identify an episode of pericarditis and appropriate treatment with the study drug.

The key challenges

Logistical

One of the biggest trial challenges was that patients had to be in flare at the time of enrolment onto the study. A fast, standardized service was required to enable patients to be screened at the point of care, to confirm a pericarditis episode and establish eligibility to participate in the trial. POCT would not only enable immediate enrolment onto the trial, but also allow the study drug to be administered without delay, and monitoring of the patient's CRP levels in real time.

A rapid screening solution suitable for implementation across 50 sites in four countries was required. This needed to include everything from delivery of equipment and consumables to training of staff, to ensure fast and consistent reporting of results. Full technical support was also essential to minimize any downtime. Woodley Trial Solutions was perfectly placed to provide this service, with extensive experience of both lab-based and POC trials equipment in over 150 countries worldwide. The team recommended the Abaxis Piccolo POC chemistry analyzer, which was piloted at a single site during the Phase II study, and subsequently chosen as the preferred method to standardize procedures across multiple sites for Phase III.

Woodley Trial Solutions arranged delivery of both the equipment and consumables, including submission of all necessary documentation.

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This was particularly challenging in Israel, where the instrument was not yet registered, requiring specialist knowledge to achieve prior approval from the Ministry of Health. The team also organized certified theoretical and hands-on workshops on the device during planned investigator meetings – with online training for those unable to attend – as well as webinars. Follow-up support was provided for all user issues via email and telephone.

Technical

A successful clinical trial depends on accurate, precise and consistent results. In turn, this requires reliable delivery of the necessary consumables to global sites, taking into consideration the number of tests required – including an allowance for the screen failure rate – the test box size, and the expiry dates on the kits.

Woodley Trial Solutions' specialists provided everything required for the successful eight-month pilot of POCT during the Phase II trial – including the instrument, consumables, training and support services – and this was then rolled out to other participating sites for Phase III. Correct operation of the POC device was certified through on-site quality control testing at every investigator site prior to starting patient testing, and verified by Woodley Trial Solutions to ensure results were comparable. The team also coordinated the timely delivery of tests to each site, including liaising with local distributors.

Fast results in real time

The Phase II POCT pilot study showed that screening results were comparable with those from the local lab, and could be delivered in just 15 minutes – a 45 minute time saving. This enabled on-the-spot determination of a patient's eligibility for the trial, speeding up the enrollment process. Following this success, POCT was implemented in Phase III. Confirmation of a pericarditis episode was obtained in minutes, and the subject enrolled onto the trial and treated with the study drug far sooner than would otherwise have been possible. CRP levels were then followed in real time to monitor the effectiveness of the drug.

Better all round

Timely, accurate and precise delivery of results is key to the success of any clinical trial, and flexible and efficient technologies such as POCT have a great deal to offer both investigators and study subjects. POCT is patient-centric, delivering real-time results that offer convenience for study subjects and a fast, standardized and cost-effective solution for CROs and sponsors. Woodley Trial Solutions is ideally placed to deliver everything required for successful POCT – instruments, consumables, training and technical support – wherever in the world it is needed, making it the go-to company for supporting clinical trials.

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