CASE STUDY

Point of care at the point of need: Enabling malaria research

A KEY QUESTION

How did Fortrea and Woodley Trial Solutions enable a remote malaria trial using a decentralized POCT lab model in resource limited sites?

KEYWORDS Malaria, Decentralized Laboratory, Point-of-Care Testing (POCT), Resource-Limited Settings, Remote Sites

Pioneering a decentralized lab solution to access resource-limited regions

Fortrea and Woodley Trial Solutions have teamed up to support a clinical trial investigating a novel therapy for malaria in children and adults, developing an advanced decentralized laboratory solution to access patients in remote parts of Africa and India.

Background

According to the World Health Organization's 2024 **World Malaria Report**, there were an estimated 263 million malaria cases worldwide in 2023, leading to 597,000 deaths. Africa carries the heaviest burden of the disease, accounting for an estimated 94% of total cases. Injectable artesunate remains the gold standard therapy, but the spread of artemisinin-resistant Plasmodium falciparum across some south-east Asian and African countries is undermining future treatment of this life-threatening disease.[1]

In response to this growing threat, the search for effective alternatives has intensified, with a new therapy that rapidly clears parasites—including resistant strains—emerging as a promising candidate.[2] However, conducting clinical trials in low- and middle-income countries where the issue is most widespread can come with many challenges. These may include limited healthcare infrastructure, difficulties in maintaining cold chain logistics for temperature-sensitive supplies, inconsistent access to diagnostic tools and unreliable internet connectivity. Recruiting and retaining participants in remote areas can also be hindered by geographic isolation, language barriers and varying levels of community trust in research initiatives.

Fortrea

The collaboration that has made the trial a reality

- **Fortrea:** Collects and collates the data, as well as managing the overall project, using its experience as a leading global provider of clinical development and patient access solutions to the life sciences industry
- **Woodley Equipment Company:** Supports the trial with biomedical knowledge and technical assistance with tailored training and lab equipment testing
- **Woodley Trial Solutions:** Supports transfer of data from devices to hardware, contributes specialist point-of-care (POC) knowledge and the integration of diagnostic technologies and provides worldwide logistical capabilities
- **Plus:** Multiple POC instrument providers, a third-party software vendor and a dedicated medical courier managed by the combined team

Bespoke point-of-care testing (POCT)

Woodley Trial Solutions and Fortrea are supporting a Phase II clinical trial being conducted across 17 sites in 11 countries—involving more than 200 patients—which aims to investigate the safety and efficacy of a novel therapy in patients with severe malaria. Using central laboratories in the study was not an option, not only for logistical reasons, but also because the political climate in some of the target countries hindered access. Labcorp Drug Development, from which Fortrea was spun out in 2023, approached Woodley Trial Solutions in 2020, having worked with the company in the past and drawn on its POCT experience.[3] Together, they started to develop a POC solution that would be suitable for use in the remote areas in which the study was to be conducted, with the ability to transmit data back to the trial sponsor in real time.

It was at this stage that Steven Karuppan, former Senior Vice President—Global POC Solutions at Woodley Trial Solutions, joined the project, playing a key role in advancing the development and deployment of a tailored POCT solution alongside Fortrea and the trial sponsor. Steven explained, "At first, we explored whether real-time data* transmission produced by devices from different suppliers was even feasible but, eventually, we narrowed down which instruments would be appropriate from both a medical and technical perspective. We found a suitable third-party software vendor and began testing, eventually managing to integrate devices from different manufacturers into a seamless protocol and make them function as if they were designed to work together. This hands-on proof of concept confirmed that live data sharing was achievable, laying the foundation for a full-scale solution tailored to the trial."

Steve also reached out to John Crook, biomedical scientist and Biomedical Technical Manager at Woodley Equipment Company, and the wider team for advice on the best instruments for this particular application. John commented, "We chose a novel hematology analyzer that uses a viscoelastic technology to perform complete blood counts. It requires no maintenance or liquid reagents, making it particularly suitable for remote areas. We use this device to monitor patients during the trial and quickly identify adverse reactions they might have to the drug. We also use a clinical chemistry analyzer—with both hepatic and metabolic testing panels—to test for a range of biochemical markers that, again, monitor if the patient is experiencing any adverse reactions."

Training

John and his team then developed a custom kit to provide alongside the instruments—including blood collection tubes and consumables, as well as a printer and router for online access—meaning that sites would have everything they needed to test their patients. They essentially created a decentralized lab solution for each site, standardizing the equipment and techniques to generate robust data for the study. Part of this package was a comprehensive training program that included either in-person or online education, or both, with all the information personnel on site needed to confidently test patients. John described the sessions, "We were doing online

* Real-time data refers to the seamless, near-immediate delivery of patient data from multiple integrated hardware sources to the end-user, enabling rapid clinical decision-making.

training in Manchester, often with a translator to confirm everything was understood. You could see the staff on site appreciated the sessions, and they were really engaged throughout. We also developed bespoke user guides; we didn't use the manufacturers' manuals but rather developed a tailored step-by-step guide of how to use the devices for this application."

"The training was interactive as well," Sara Miller, Biomedical Scientist for Product Development and International Sales Support at Woodley Equipment Company, added. "We had cameras set up at both ends, allowing teams to perform the tests simultaneously; local staff even volunteered to have their blood drawn and to run samples in real time. The sessions were highly effective and, by the end, the teams on site felt confident and well prepared."

Sustained collaboration and support

Woodley Trial Solutions and Fortrea continue to support the sites throughout the trial, so that when issues arise they can collaborate with the on-site teams remotely and address any challenges. John continued, "We have set up multiple channels to communicate with the trial sites, including a portal on our website and email. We regularly receive phone calls with technical questions that we can immediately respond to, while sites sometimes just need that little bit of reassurance that they are doing something correctly. We essentially give these remote areas that same level of service that sites around the corner could expect from us."

Fortrea's role in the trial is primarily involved with data management, supporting the transmission of data from the sites to the sponsor in an efficient and secure manner. Any issues are promptly flagged and resolved together with Woodley Trial Solutions. A Fortrea project manager emphasized the strength of the collaboration, "The team at Woodley Trial Solutions has taken the lead role in liaising with sites during the study, and we work closely together for smooth communication between all parties. If any problems come up, they always respond swiftly, enabling site visits to continue with minimal disruption. This joint effort is especially important in managing the inevitable technical issues related to POC devices or data transmission. We really appreciated this support throughout the trial."

Kirsten Pendlebury, Project Manager at Woodley Trial Solutions, echoed the significance of this collaborative approach, working closely with Fortrea to have seamless coordination across teams and allowing the study to progress with minimal disruption. Kirsten explained, "Working with Fortrea has been an excellent experience. We've built a genuine, solution-focused collaboration rooted in mutual respect and shared goals. Each team has delivered complementary strengths to the trial, which has been paramount to its success."

"The collaboration has been vital to tackle the logistical challenges of running a clinical trial across remote and resource-limited sites in sub-Saharan Africa and India. We manage everything from procuring and importing temperature-sensitive reagents and consumables, to supplying ancillary items across 17 trial sites, including gauze swabs, pipette tips and printer rolls. These sites are located in 11 countries, each with their own customs regulations, infrastructure capacities and language requirements, which often require tailored solutions. We really had to make sure everything was lined up—from getting import licenses approved to ensuring delivery quantities were correct—and plan everything well in advance."

"We also act as importer of record (IOR) where necessary, which helps to streamline customs clearance and comply with local regulatory requirements in each country. As some of the deliveries require cold storage, we chose to use a dedicated medical courier that can safely store temperature-sensitive items if they are held up at customs. This helps to ensure the integrity of critical supplies is maintained, and patient visits can continue without interruption. There is little room for error in a trial like this, with every delay having real consequences on the ground. This is why we've taken such a hands-on, proactive approach, which has ultimately been a big factor in the success of the study."

Scaling new frontiers in global clinical research

As the global health landscape continues to evolve, there is growing recognition of the need to bring clinical research into underserved regions. A senior director at Fortrea commented, "Global health organizations are seeking guidance on how to conduct clinical trials in resource-limited settings. These environments often lack the technologies and infrastructure typically required for complex studies, which can restrict what's achievable on the ground. However, the decentralized lab testing solution used in this study helps to access patient populations previously out of reach. The potential to take this model and apply it to future clinical trials is huge, as it provides a framework for conducting studies in low- to middle-income countries that are historically wrought with challenges. This enables the inclusion of a wider demographic and the ability to study infectious diseases in dire need of effective therapies, such as Ebola and Zika virus disease."

Conclusion

This trial represents a landmark achievement in overcoming the operational and logistical barriers of running clinical research in remote settings. The collaboration between Woodley Trial Solutions, Fortrea, the pharmaceutical client and various third parties resulted in the development of an innovative decentralized lab solution backed by steady support, allowing patients who live in the areas most affected by malaria to participate in the study. This approach offers not only hope, but also a scalable and impactful framework for carrying out critical research where it is needed the most.

Learn more at:
fortrea.com/therapeutics/infectious-disease-vaccines

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