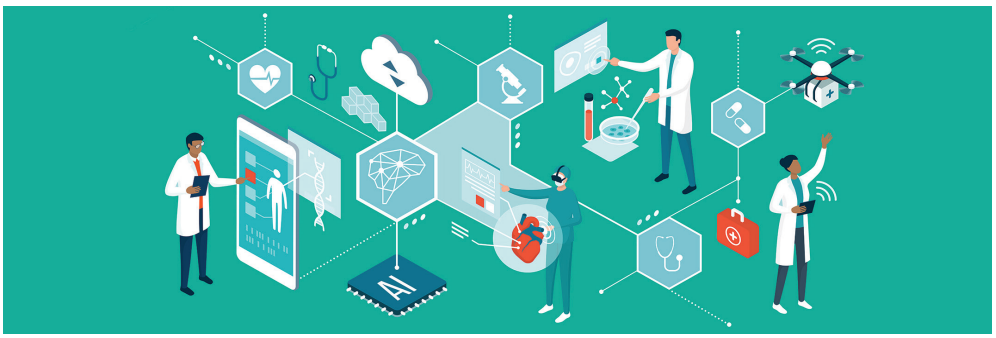

30 YEARS
SMARTER EQUIPMENT SOLUTIONS

Point-of-care testing in clinical trials

Introduction

Point-of-care testing (POCT) allows diagnostic tests to be performed near the study subject, so samples can be taken and analyzed while the patient is present rather than sending them to a central laboratory and waiting for results. But what constitutes a point-of-care (POC) test or device, and how do you know what is most appropriate for your trial? How do you ensure that all users have the right training? And what about regulatory compliance? This white paper looks at the unique demands of POCT and discusses everything you need to consider to set you on the pathway to success.

What is a POC device?

POC analyzers – also known as *in vitro* diagnostic (IVD) devices – can be defined as any medical device used for the analysis of samples such as blood and urine, from large analyzers in central laboratories to small monitors kept at a patient's home. The challenge lies in choosing the right option for your specific trial needs.

When would you use POCT?

POCT is a valuable complement to centralized testing, offering fast turnaround times, convenience, ease of use and, in many cases, portability. Testing can be standardized across sites, and laboratory quality results obtained from any sample size. One of its most important applications is rapid screening of potential trial participants, where it can help to lower screen failure rates and increase the rate of enrolment, all with comparatively fewer visits. POCT may also be used to boost safety measures before a study drug is given, for example, checking that a participant is in good health, eliminating any potentially interfering factors, and monitoring for alcohol or drugs of abuse.

When time is of the essence

Some studies require testing of analytes that are labile or have a short half-life. In these cases, transport to a central laboratory is simply not feasible; a delay in sample transfer would degrade the analyte, calling the results into question. POCT is the only practical solution for these analytes. Once a study is underway, the drug development protocol may require frequent checks of a specific endpoint analyte, for instance, glucose, prothrombin time/international normalized ratio (PT/INR), hemoglobin or estimated glomerular filtration rate (eGFR). POCT gives virtually instant results and treatment can be adjusted immediately, while the patient is still on site. It has also proved essential for trials targeting infectious diseases during the COVID-19 crisis; patients needed to be recruited while they were infectious.

Saving time and money

Clinical trials run for long periods of time, typically at a cost of four to five million USD per month. But what if that time could be reduced by analyzing the sample at the investigative site instead of a central lab? Taking sample transfer delays out of the equation can significantly reduce the time to results, leading to shorter turnaround times and, ultimately, bringing a drug to market more quickly. Every month saved represents significant financial savings, making POCT a serious contender for any sponsor planning a clinical trial.

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Choosing the right device for your trial

Devices must be carefully chosen, based on the trial protocol and all the available analyzer options. A knowledgeable partner, such as Woodley Trial Solutions, can help you to identify the most appropriate instruments and, once you've made your choice, can arrange for the fully calibrated and validated system to be installed. To ensure correct operation and regulatory compliance, we can also help with all necessary training.

Case studies

Reducing screen failures in a large global study of chronic kidney disease

- Prescreening eGFR and urinary albumin-to-creatinine ratio (UACR)
- Woodley supplied 850 sites in 45 countries
- Provided devices, consumables, controls and certified training
- 4,000 patients successfully screened
- Test results in less than five minutes
- Good conformity with lab results – eGFR 97 %, UACR 85 %
- Screen failures reduced to less than 50 %
- Investigators acceptance of, and satisfaction with, POCT 81 %[1]

Testing C-reactive protein (CRP) to help confirmation of rare pericarditis

- Global, double-blind, placebo-controlled, randomized study
- Rapid identification of episodes of pericarditis and treatment with the study drug
- Turnaround times were: central lab 48 hours; local lab 1 hour; POCT system 15 minutes
- Woodley provided training, support and logistics

Encrypted POC lipid test aids decision-making

- Blinded low-density lipid (LDL) measurements for phase III trial
- Patients in US and Germany with heterozygous familial hypercholesterolemia
- Standardized testing method for encrypted LDL
- On-site apheresis based on the decrypted LDL value
- Turnaround times were: central lab 48 hours; POCT system 10 minutes
- Woodley provided POC solution

Collection of sweat samples for cystic fibrosis (CF) drug development

- 60 site US/EU phase II study
- Measuring changes in chloride levels in sweat
- Required a standardized way to collect sweat samples to send to the central lab for testing
- Woodley provided training and support, and managed the complex inventory and logistics

Dry blood spot training app boosts test performance

- Study was hampered by poor dry blood spot collection technique
- Problem was compounded by a cumbersome training program and global import restrictions
- Woodley worked with the CRO and the sponsor to identify a globally available alternative
- A mobile training app streamlined site proficiency testing
- App was successfully used in three separate studies, resulting in 100 % usable data
- Additional benefits of reducing courier fees and the need to oversee sampling

Summary

POC analyzers and devices have much to offer the clinical trials sector, as the rapid delivery of results lets investigators make decisions on the spot. Working with a company such as Woodley Trial Solutions, with extensive knowledge and expertise in the field, as well as logistical capabilities, can smooth the way. Whether you need advice, POC devices and supplies, technical support or training, we're here for you, working quietly in the background to deliver everything you need, wherever in the world you need it, in a timely manner.

[1] Heerspink HJL, Andress DL, Bakris G, et al. Baseline characteristics and enrichment results from the SONAR trial. *Diabetes Obes Metab.* 2018;20(8):1829-1835. doi:10.1111/dom.13315

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