

# The retention factor

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How medical equipment choices can benefit patients and improve clinical trial retention

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Photography by Isy & Leigh Anderson



## Introduction

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Patient recruitment is a major challenge in designing and managing clinical trials; and retaining participants once a trial commences is just as important. A recent CenterWatch analysis shows that only 70% of participants completed phase 3 clinical trials.<sup>1</sup> Poor volunteer retention can negatively affect a trial by lengthening timelines and inflating costs, as well as reducing the validity of study data and delaying approvals.<sup>2</sup> Recent regulatory changes and an increasingly demanding patient population are making companies look at more patient-centric strategies at the start of the trial. Some of these include better education for patients at the outset,



## What is point of care testing?

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POCT refers to medical testing devices that allow clinicians to take samples and record test results in a hugely reduced time frame, at one time and place – be it the patient’s hospital bedside, their home or a clinical trial site. Medical practitioners and researchers can take samples from patients and receive results as quickly as 15 minutes later, without the requirement to send samples away to labs. Some POCT equipment can be worn and managed by the patients themselves, to streamline monitoring and testing.

Point of care testing equipment is now a fully mature part of the medical equipment landscape, and researchers are starting to see the benefits for their clinical studies.

## *Poor volunteer retention can lengthen timelines and inflate costs.*

as well as the use of point of care testing (POCT) throughout the full course of the clinical study.

This article takes a detailed look at how the use of POCT equipment can have a material effect on the success of clinical trials, specifically as it relates to the challenges of participant retention.

# *POCT equipment has the potential to help companies recruit and retain higher risk patients.*



## **The participant burden**

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As part of a clinical study protocol, participants are usually required to make frequent visits to clinical trial sites for various reasons. They may need to be there for blood tests, to find out the results of laboratory tests, or to pick up new treatment prescriptions. Over time, the frequency of these visits can become a significant burden on volunteers since they may require long-distance travel, time off work and recurrent interruptions to everyday life.

## **Reduced travel time and treatment delays**

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One of the solutions to the participant burden is the use of POCT devices in clinical trials. POCT equipment allows companies to reduce the number of visits a participant needs to make, as well as the associated travel time.

In standard clinical trials, it can take several weeks to obtain laboratory test results, which can also delay the start of patient treatment. As POCT equipment can allow patients to receive their diagnostic results and their treatments as quickly as they would normally receive standard care, participation becomes easier on patients. This in turn has the potential to reduce attrition from trials.

## **High dependency patients**

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Another key benefit of POCT equipment is the potential to help companies recruit and retain higher risk patients; since repeated trips to investigator sites may be very challenging for participants with more advanced conditions. Clinical tests and dosing that are performed at the same visit may therefore help to reduce attendance problems, and improve participant compliance and retention.

## New regulatory requirements

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Recent changes in regulatory requirements in different therapy areas have increased the challenges of recruitment and retention. For example, diabetes clinical trials now require larger sample sizes and for participants' cardiovascular risk to be evaluated.

In addition, many of today's diabetic patients have more complex medical conditions. A number of diabetics admit that they struggle with compliance<sup>3</sup>, which in the context of clinical trials increases the risk of drop-out and loss to follow-up; ultimately leading to missing data.



So companies are looking for ways to reduce participant drop out in diabetes trials, and POCT may have a part to play in resolving this challenge.

*Equipment choices have a vital role to play in optimising study outcomes and maximising participant retention.*

## Increased study efficiency

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Incorporating POCT devices into study protocols allows companies to simplify the process of clinical testing. Some companies are using specific POCT equipment to recruit, randomise and treat patients on the same day. The Mayo Clinic has sponsored a trial looking at the impact of the Abbott iSTAT point of care analyser in the diagnosis and treatment of acute coronary syndrome<sup>4</sup>, and many other trials are looking specifically at how point of care testing can improve clinical outcomes.

There are other benefits too, beyond participant retention for trials – POCT can also allow clinical study managers to keep their project budgets under control by covering several study stages, reducing the costs of repeated patient visits. This increased efficiency can save administration and testing time, and ensure that the trial keeps to its scheduled timelines.

Testing at the point of care can also reduce the risk of losing samples during transportation to laboratories, and avoid potential problems with refrigeration and other global transport logistics.

## Start with POCT in the protocol

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During protocol development, companies should consider how the study design will translate into burden for study participants. These factors include the number of study visits, the complexity of the tasks that the participant must perform, and the convenience of the site location. Each of these issues can contribute to pressure on patients that leads to early discontinuation from the study<sup>5</sup>.

It is important to consider and include the use of POCT in the study protocol itself to optimise the benefits of these clinical devices at each stage of the study. The protocol must also include an adequate lead time to arrange the delivery and use of this equipment before all site initiation visits.



## Summary

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Including POCT as part of the study protocol can improve patient recruitment and retention, particularly by reducing the frequency of visits to clinical study sites. The use of this equipment can also improve the efficiency and productivity of running these trials. In turn, this can reduce the risk of project delay, cost overrun and issues with product approval. As the industry moves increasingly towards patient-centric approaches to research, equipment choices have a vital role to play in optimising study outcomes and maximising participant retention.



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