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OTC IVD Studies - Is a decentralized trial design right for you?

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Decentralized vs. Traditional Trial Designs for OTC In Vitro Diagnostics: What's the Right Approach?

A well-designed clinical trial is critical to demonstrating the safety, effectiveness, and usability of any diagnostic device, particularly for over the counter (OTC) indications. In recent years, decentralized trials have gained popularity. These newer designs bring the trial to the patient vs the patients going to clinical trial sites. The inclusiveness of more patients from different backgrounds, lower costs in some cases, speedy enrollment, and access to more patients in general have been part of the appeal to this design, contributing to the popularity. However, decentralized models are not a good fit for all studies, and there should be several considerations to see if this model works well for an OTC indication.

Key Questions That Drive Trial Success

- ***Is the study conducted in real-world consumer settings that reflect how the test will actually be used?***
- ***Can untrained users understand and follow the instructions to collect specimens, run the test, and interpret results accurately?***
- ***Do the results show strong agreement with a laboratory reference method across diverse users and use conditions?***
- ***Are there existing OTC cleared tests on the market for your intended indication? How were their clinical studies conducted?***
- ***What is the sample type for your test? Is it one that consumers are already accustomed to collecting at home in other OTC products?***

1. Enrollment Timing and Disease Stage

In decentralized studies, participants often enroll well into their illness, reducing the diagnostic window in the case of an infectious disease test. Unlike patients who visit healthcare professionals (HCPs) early in their symptoms, decentralized participants may delay reporting until symptoms are moderate or persistent. This lag can reduce diagnostic sensitivity, compromise endpoint accuracy, and introduce recall bias in self-reported symptom onset. However, if the analytes being tested are for a chronic condition, the diagnostic window is not as critical and could be an efficient way of sample collection.

2. Regulatory Expectations for Objective Evidence

Regulatory agencies require objective, verifiable, and reproducible data, not subjective feedback like "the line looked faint." In-person observation at clinical sites allows trained staff to confirm correct test execution, interpret results consistently, and ensure reliable usability data. This level of quality assurance is difficult to achieve remotely. Some designs use video to oversee the collection, but this method might not be acceptable to the FDA. Also, sending a healthcare provider to conduct a home visit could make the trial design more expensive and less efficient than brick and mortar sites in some cases.

3. The Need for Controlled Observation - Simulated at Home Environment

While regulatory agencies expect OTC IVD data to reflect real-world use, it must still be collected under controlled observation most of the time. At-home environments are inherently variable, affected by lighting, noise, distractions, or multiple users. Even video monitoring cannot replicate the oversight achievable in a controlled clinical setting. This lack of control reduces confidence in both usability and interpretability of results.

4. Technology and Accessibility Barriers

Decentralized trials depend on participants having reliable technology access and digital literacy. This can unintentionally exclude older adults and others less comfortable with technology, limiting generalizability and potentially biasing the study population. On the other hand, if you're seeking a patient population that is difficult to reach, far from sites, or in rural settings, sometimes, a decentralized approach can open paths to more diverse patient populations.

5. Sample Integrity and Handling Risks

At-home sample collection introduces risks in technique, timing, and handling. Improper storage or shipping can compromise sample integrity, particularly reference method sample collection, typically performed by an HCP. Shipping individual samples from participants' homes adds cost and variability compared to controlled batch processing from clinical sites. Consider your sample type, the stability, and whether the sample needs to be kept at a certain temperature so that results are repeatable. Some sample types are stable for long periods of time and fare better in decentralized settings.

6. Efficiency and Cost Considerations

While decentralized designs promise faster enrollment, they often increase operational complexity, requiring apps, logistics management, and participant support systems. In contrast, traditional brick-and-mortar sites offer established infrastructure, trained staff, and efficient coordination that often make them more reliable and cost-effective for OTC IVD trials. It depends on which way the study is carried out, the cost, trial design, and other factors which way is best for your test.

7. Conclusion

All of these factors should be assessed for your study design, budget, and timeline to market. While decentralized trial designs can offer greater convenience, broader reach, and may in some cases reduce costs or accelerate enrollment, they do not always guarantee these advantages. Likewise, they may not deliver the data quality, oversight, or regulatory confidence needed to support OTC diagnostic clearance.

Considering a Clinical Trial for an OTC IVD test?

With deep expertise in IVD studies, we bring a thorough understanding of FDA guidance, offering the knowledge and confidence essential for successful, compliant research partnerships. ***The Studybox Research team has supported multiple sponsors in designing & executing successful OTC studies and can help determine the optimal trial design for your product.***

Therapeutic Areas Include:

- Infectious Disease
- STD/STI Detection
- Hematology
- Drugs of Abuse
- Antimicrobial Susceptibility (AST)
- Gastrointestinal Health
- Women's Health
- Cardiovascular Disease
- Biothreat

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