THREAD™

6 Opportunities to Maximize Participant Engagement in Decentralized Trials

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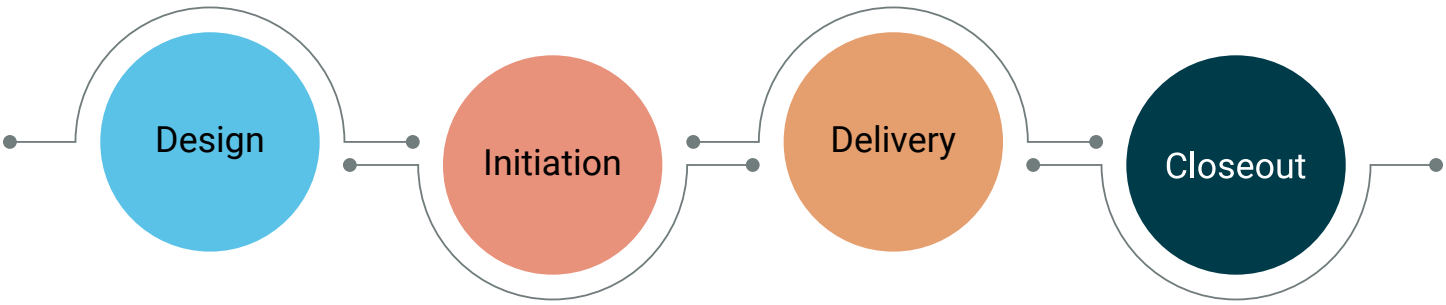
Introduction

Participant engagement in clinical trials has been a long-standing challenge for industry. Some estimates indicate 85% of trials fail to recruit enough participants and 80% are delayed due to recruitment challenges and high dropout rates[1]. The costs to research sponsors of trial delays can be a staggering $600K-$8M per day if that trial is on the critical path to product launch[2]. The participant engagement challenge is complex and often requires multiple mitigation strategies for a single trial. One particularly promising strategy for enhancing participant engagement is the adoption of decentralized approaches in clinical trials. Reducing the number of in-person visits in a clinical trial can mean increasing trial access for the estimated 70% of potential participants living more than two hours away from a study center[3]. Fewer in-clinic visits also increases trial diversity by providing a home visit option, which may appeal more to non-white individuals[4]. However, a decentralization strategy is not enough, and not all decentralized approaches are created equally. Decentralized approaches introduce their own unique challenges, and success requires careful consideration throughout the clinical trial lifecycle from design through closeout. The following report explains how THREAD's Decentralized Clinical Trial (DCT) Platform enables research sponsors to design and execute DCTs that maximize participant engagement through successful trial recruitment and retention throughout the study.

This paper proposes the following six best practices, enabled through THREAD's decentralized clinical trial platform, as impactful opportunities for enhancing participant engagement, and they have been categorized into four phases within a DCT:



Design

1 Perform simulations of your decentralized clinical trial protocol to optimize the participant experience

Decentralized clinical trials operate much more smoothly when the data collection approach informs the selection of trial endpoints and schedule of assessments. Taking this approach allows researchers to identify endpoints that may be captured virtually in a validated manner and potentially reduces the number of in-clinic visits required by a protocol. THREAD's configurable decentralized platform can be used as a simulation tool during protocol development to help research sponsors pressure test their protocol, identify alternative options for validated data collection and optimize the participant experience by selecting endpoints that can be more reliably captured outside of a site setting. The result is oftentimes a much more favorable schedule of assessments that minimizes the number of in clinic visits per protocol, making research more pragmatic for potential participants who are otherwise eligible but cannot accommodate an intensive in-clinic visit schedule.

Case Example

For a planned DCT in a rare genetic disease, THREAD and the Sponsor conducted a live simulation of the participant and site experience with a participant and Principal Investigator (PI). The simulation consisted of going through study application invitation, app registration, in-app activities, and conduct of a Telehelath visit. The THREAD platform enabled participant questionnaires (validated ePRO), study drug dosing diary, and video visits with the Study Doctor. At the conclusion of the simulation, the participant and PI provided immediate feedback through a moderated forum.

As a result, the hands-on simulation allowed the participant and PI to provide in-depth, tangible feedback around their experience with the technology, specifically for: ease-of-use, preference versus on-site and paper use, benefits/efficiencies gained through the technology, areas for improvement and general consideration from their perspective. These insights were incorporated by the sponsor into a more participant centric protocol.

"A customer came to us with a very nuanced and difficult protocol that required more work for participants and caregivers than we thought necessary. We were able to build a simulation of the platform to show them where the weak spots might be that would cause drop outs. The result was a protocol overhaul that included more participant interaction and assistance through the app interface that simplified data and information collection experience." **T Hephner, Head of Business Development at THREAD**

Initiation

2 Maximize your enrollment reach with a trial-specific recruitment website

A core element of success in participant recruitment is ensuring that as many trial eligible participants are aware of the clinical trial as possible, and that they can easily self-identify as candidates to save time and money during the recruitment process. THREAD's Participant Web, a web-based recruitment tool, allows researchers to generate a study-specific participant landing page with an embedded pre-screener that can be paired with digital advertising for the clinical trial to increase clinical trial awareness. Qualified participants are then routed to a research site for enrollment (in the case of a hybrid decentralized trial) or followed up virtually for consenting (in the case of a fully decentralized trial). Participants are given feedback in real time as they progress through the study screening form to determine whether they are eligible or ineligible. In the case of eligibility, participant information is transmitted to the appropriate PI for consent form completion and enrollment within minutes.

Decentralized Study

Customer - Medical Device Case Study

Background

Digital recruitment with pre-screening to Virtual Visit for screening, eConsent, enrollment, onboarding and triggered device cohort shipment

Continuous data collection via surveys, ePRO and medical device in between Virtual Visits

Series of scheduled Virtual Visits where surveys were completed in real-time, medical device data was reviewed and site data capture forms were completed

Key Metrics and Results

<4 months — Recruitment completed in **< 4 months** vs the standard projection

60% time savings — Time required for recruitment was 60% less than industry benchmark

95% retention rate — Participant **retention above 95%** from eConsent to final Virtual Visit

25% cost savings — Cost savings of approximately **25%** compared to similar study budget

3 Optimize participant recruitment through a nuanced and flexible recruitment partnership strategy

Clinical trial recruitment is supported across the development landscape by a wide range of specialist companies. Partnerships with recruitment specialists are even more important for decentralized research, particularly for a fully decentralized trial, which has no research site involvement, and therefore no site-driven participant relationship networks to support recruitment. However, a 'one-size fits all' approach to partnering in the recruitment space won't work. Many recruitment specialists take different approaches to recruitment and offer unique focus areas that require unique partnerships. For instance, some recruitment companies operate leveraging privileged access to participant communities and may be more successful recruiting within certain therapeutic areas, while other recruitment companies use linked, real-world data to identify participants who are focused within a geographic area and who align with the underlying data sets. THREAD's Recruitment Partnership Program engages a wide range of recruitment specialist companies to ensure that the right partner is aligned with the right clinical trial profile to support enrollment success.

"A one-size fits all approach to partnering doesn't work for clinical trial recruitment as recruitment companies have unique approaches that yield greater success in certain geographies and therapeutic areas over others. Having a wide network of partners allows THREAD to bring the right partner to the right trial to support the best enrollment outcomes." **Joss Warren, Head of Partnerships at THREAD**

Delivery

4 Incorporate technologies that facilitate simple and easy trial engagement for participants and caregivers.

A trial that is overly cumbersome for participants or their caregivers drives participant fatigue and ultimately participant loss. Simplification of trial protocols at the design stage is an important step to minimizing the risk of participant fatigue. Adoption of technologies that reduce the trial burden on participants is also essential to reduce this risk. THREAD's unified platform enables the deployment of trial technology that allows researchers to engage and capture validated endpoint data from participants in their home, or wherever is most convenient for them, through platform features like telehealth, sensor and wearable integration, eConsent and ePRO.

"DCT Technologies like Telehealth not only make participation in studies simpler by removing the burden of in-person visits, they help make participation a routine part of daily life. Just as they would jump on a FaceTime call with a friend or check the score of a game, they do the same to speak with their study doctor and complete study activities. And best of all, it's centered around what's most convenient for them." **Todd Harnett, Director of Delivery at THREAD**

5 Keep your clinical trial front-of-mind for participants through notifications

As participants move through the clinical trial, it's important to ensure they are routinely reminded of their obligations under the trial protocol to maximize adherence and ensure high quality trial data. THREAD's platform enables regular participant notifications that are pushed to their preferred device as a simple reminder to complete an assessment or plan for a trial visit. THREAD study applications are widely accessible across Android and Apple devices and trials can be delivered through a bring-your-own-device (BYOD) or trial-provisioned device approach.

"Participants and their caregivers using their own phone or tablet to receive notifications, enter data and have telehealth visits with their study team is much more convenient than visits to the sites. We have seen studies with participants in wheelchairs that live hours from a study site who are now able to participate in studies that they wouldn't have been able to with the traditional model." **Jennifer Price, Executive Director of Data & Analytics at THREAD**

Closeout

6 Communicate the study results to your trial participants

At the conclusion of the clinical trial, it's appropriate to share summary information about the results of the trial with participants. While research sponsors will share information publicly through established channels as directed under FDAAA 801 and the Final Rule, these channels may not be frequently accessed by trial participants. As such, research sponsors should consider alternate modes of communication. THREAD's DCT Platform allows researchers to send on-demand email messages to participants, a tool that can be used at trial closeout to thank participants for their involvement, update them on the results of the study and inform them of the overall impact the study results will have on the broader community. Communicating with participants in this way acknowledges the sacrifices participants make to be involved in research, and encourages their willingness to become involved with research studies in the future.

Case Example

Active communication of study results can also be approached as a strategy for maximizing participant engagement during a study. For a large registry that THREAD is supporting, THREAD is developing a real-time analytics dashboard to summarize how participants and their caregivers are interacting with the registry as well as anonymized information about the broader registry population. This level of transparency offers participants and caregivers a unique opportunity to become more actively involved in research and tangibly demonstrates how their contributions to the registry, along with the contributions of other participants, are expanding the body of scientific knowledge for their disease in real time.

Conclusion

Decentralized approaches help address clinical trial participation barriers that traditional models have been unable to solve, unlocking new opportunities for improved recruitment by involving participant populations that are historically under-represented in clinical research. Decentralized approaches also enhance retention across the board, but implementing decentralized features alone is not enough. Decentralized technologies must be deployed strategically in order to have the intended effect of maximized participant engagement, and they must be carefully considered from clinical trial design and recruitment, all the way through closeout. THREAD's DCT Platform has been designed with the participant in mind and provides researchers with the flexibility and functionality to use decentralized technology to drive successful outcomes.

To learn more about how THREAD can help you design and deliver a decentralized clinical trial that maximizes participant engagement schedule your tailored simulation at THREADresearch.com

Citations:

[1] https://www.biopharmadive.com/spons/decentralized-clinical-trials-are-we-ready-to-make-the-leap/546591/

[2] https://www.antidote.me/blog/25-useful-clinical-trial-recruitment-statistics-for-better-results

[3] https://www.biopharmadive.com/spons/decentralized-clinical-trials-are-we-ready-to-make-the-leap/546591/

[4] https://www.antidote.me/blog/25-useful-clinical-trial-recruitment-statistics-for-better-results