futureproofing
CLINICAL TRIALS

Chapter 2:

The Potential of Decentralization

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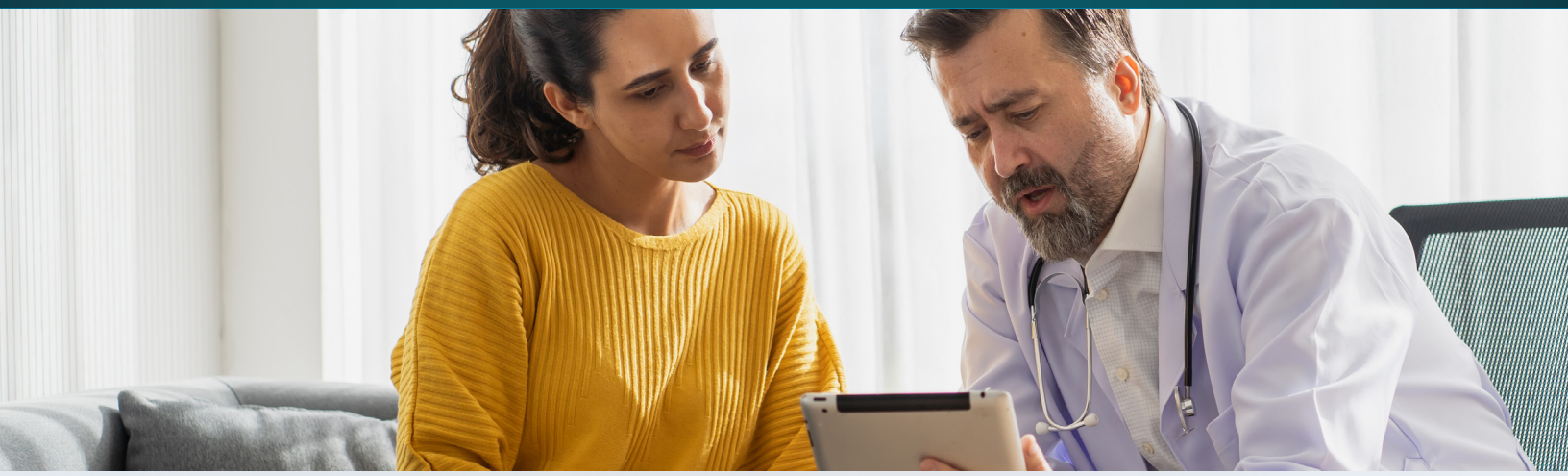

In this series, we are exploring the key opportunities that exist to optimize and futureproof clinical trials. Our objective is to support the strengthening of the clinical trial process for better recruitment and enrollment, improving understanding of the potential of crucial medicines among a broad representation of patients and ultimately accelerating the progress of medication submissions for approval by the U.S. Food & Drug Administration (FDA) so they may benefit patients in need.

As a recap, we have highlighted 3 key limitations in the current clinical trial model that are hindering the progress of crucial treatments getting to healthcare providers and patients:

Diversity & Representation:
Inequitable representation in trials leads to incomplete data and biased findings.[4]

Recruitment & Enrollment:
Approximately 80% of clinical trials fail to meet enrollment deadlines, risking delayed benefits for patients and costing sponsors $600,000 to $8 million per day.[2,3]

Implementation & Management:
Challenges in trial location, participant understanding, and discontinuations can compromise outcomes.

Trial Decentralization Approaches to Consider

- **Site Design & Selection**
- **eConsent**
- **Participant-informed study design**
- **Remote intervention**
- **Study task reminders**
- **Social media recruitment**

In our first chapter (to read, click here), we explored the application of cutting-edge integrated intelligence methods that promise to support the remediation of current limitations and challenges. As we look to evolve the current model, the next area we will explore is decentralization, and the many opportunities that sponsors may consider in order to increase the inclusivity of their clinical studies. Historically underrepresented populations may be disproportionately affected and burdened by the logistics of clinical trials. Medical researchers and the US FDA have proposed that decentralized approaches may ease the burden of clinical trial participation and potentially improve recruitment and retention of diverse patients.[4-6]

The Potential of Trial Site Decentralization

Decentralizing trial sites involves conducting clinical trials in diverse locations closer to participants' communities rather than centralized clinical settings, or utilizing novel technologies that will enable trial administration and monitoring to be completed at home. Both of these methods aim to improve accessibility, participant diversity, and data quality. By making trials more accessible, a greater number of people who might typically face barriers—like doubts about clinical settings, travel restrictions, or physical limitations—are able to overcome those challenges and take part.[6]

Decentralized trials and tools such as online recruitment and electronic informed consent, as encouraged by the FDA, 7 can be one strategy to aid minority participation and foster diversity while decreasing burden.[8]

1. Retail Partnerships

Retail collaborations are proving beneficial for clinical trial sponsors who aim to broaden participant pools and streamline management by conducting trials in local communities where patients feel at ease. These collaborations hold the potential for expanded recruitment, improved enrollment, and better representation.

Major national chains collaborate with sponsors to enhance accessibility, diversity, and convenience. The proximity of these retail locations to patients' residences reduces apprehension, increases willingness to participate, and simplifies local patient identification, compared to current methods.6 Furthermore, the familiarity of these organizations and locations has the potential to improve patient education and understanding, as they are staffed by members of the patients' communities, with whom they interact on a more regular basis.

Results of a qualitative study of US-based patients and investigative sites further support that retail pharmacy collaborations could enhance clinical research by providing convenience, improving public awareness, and increasing patient diversity. Minimizing stigma surrounding clinical trials, through the increasing prevalence of retail pharmacies, was yet another benefit identified. These insights were gathered from interviews with patients and site personnel and highlight the potential for retail pharmacy collaboration to contribute to retail pharmacy viability and engagement as investigative sites.[9]

2. Remote Technologies

Vulnerable groups, especially patients with rare diseases, can benefit from decentralized access to clinical trials.[10] By integrating remote and decentralized technologies into healthcare and research settings, these trials become more accessible and tailored to meet these patients' needs. Digital health tools for remote monitoring facilitate broader recruitment and lessen reduce the burden on patients, addressing travel concerns in a post–COVID-19 landscape. Additionally, technologies such as telehealth, electronic clinical outcomes assessments (eCOA), electronic patient-reported outcomes (ePRO), electronic diaries (eDiaries), image capture, voice capture, and wearables (with Internet of Things - IoT) have the potential to enhance data consistency by minimizing bias and enabling more frequent or continuous data collection without requiring patient travel. This approach expands trial participation to individuals who may otherwise be deterred by concerns about clinical environments, travel difficulties, or physical limitations.[6] Additional recommendations by the Trial Innovation Network (TIN), which was started by the National Center for Advancing Clinical and Translational Science to address critical roadblocks in clinical research and accelerate the translational research process, include eConsent, participant-informed study design, remote intervention, study task reminders, social media recruitment, and return of results as additional decentralized approaches. TIN has consulted on over 400 clinical trials across the nation and found that there were several benefits and achievements of remote methods, including reduced participant and trial site burden, broader reach of participation and multicenter trial efficiency.[7]

Decentralization is just one opportunity that harnesses cross-industry collaboration as a way of bringing together the best minds and resources, fostering innovation and efficiency in clinical trials. In the next installment of this series on futureproofing clinical trials, we will explore enhanced communication strategies designed to improve recruitment, engagement, and retention, while supporting improved representation and equity to ensure that trials are inclusive and reflect the diverse populations they aim to serve.

All these efforts, especially when combined, offer the promise of improving our clinical trial model and evolving our systems for the greater good.

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To learn more about the ways in which JPA Health is applying strategic thinking and proprietary research to improving clinical trial recruitment and implementation efforts, please reach out to **Kelly McNeil at kmcneil@jpa.com**.

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