THREAD®

The Impact of Hybrid Study Designs in Post Marketing Research

RWE case study utilizing DCT and Central PI models

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The transformative impact of patient-centric, hybrid study designs, with a particular focus on applications in rare diseases, aims to address the challenges posed by patient dispersion and participation burden in traditional site-based research. Integrating decentralized technology solutions and prioritizing patient needs demonstrates how modernized study designs can revolutionize researchers' ability to generate meaningful insights from real-world clinical studies.

Introduction

Post-marketing research, especially for rare diseases, plays a vital role in understanding the long-term effectiveness and safety of therapeutic interventions. However, the unique characteristics of rare diseases, such as patient dispersion and participation burden, present substantial challenges for traditional site-only research designs. In many cases, these approaches become cost-prohibitive due to the involvement of healthcare professionals (HCPs). Moreover, patients and HCPs increasingly prefer digitally enabled remote participation. The solution to these challenges lies in hybrid study designs that leverage patient-centric approaches.

The Central PI Model

The central PI model represents a significant shift in the way post-marketing research is conducted. Key features of this model include:

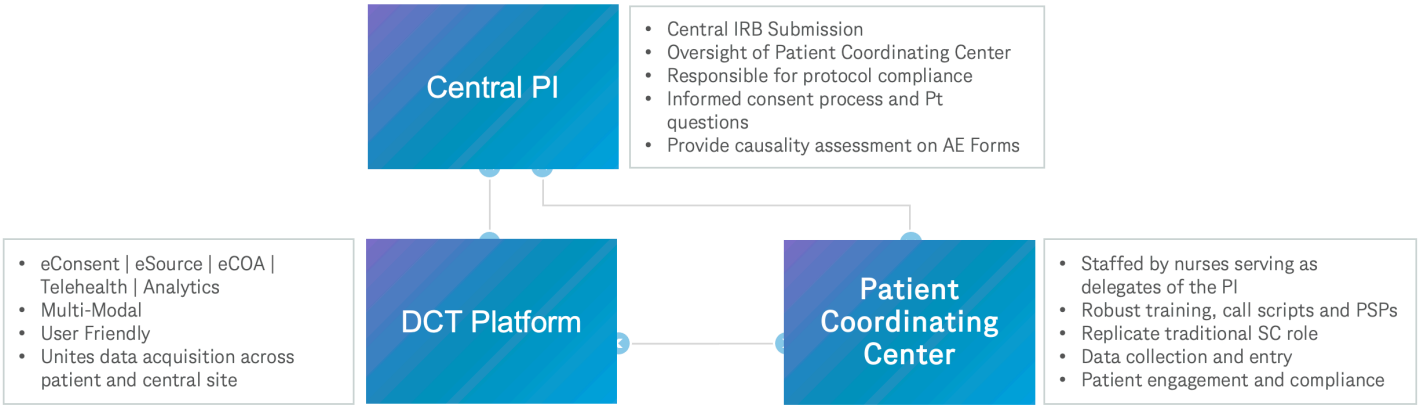
Experienced PIs: Seasoned Principal Investigators oversee consent, monitoring, and reporting, ensuring the highest standards of patient care.

Cost-Effective: This model offers a more cost-effective alternative to traditional site-based research.

Faster Enrollment: Leveraging eConsent and telemedicine, the central PI model facilitates rapid patient enrollment.

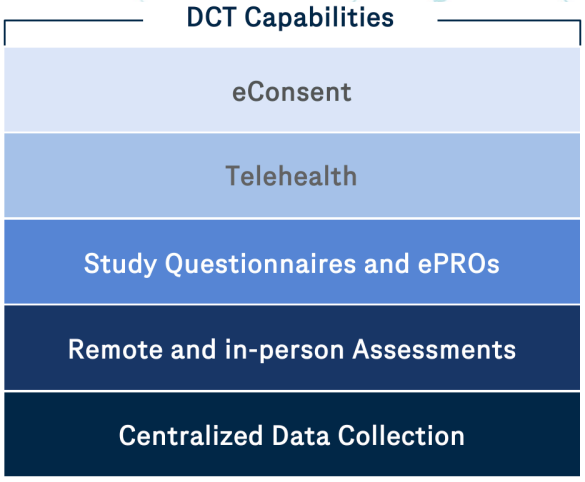
Centralized Data Oversight: Continuous data quality oversight and compliance are maintained through centralized data and safety reviews.

Expertise: Comprehensive functional expertise in virtual, hybrid, and pragmatic designs, along with product and therapeutic knowledge, particularly in specialty products, rare, orphan, and complex diseases.



Hybrid DCT Study Designs

Hybrid designs offer the dual advantage of increased patient participation and more efficient research processes. By allowing patients to take part from their homes, these designs enhance recruitment and retention rates while collecting real-world data. They also ease the burden on clinical sites and investigators, potentially accelerating research timelines. In essence, hybrid decentralized studies optimize patient engagement and research rigor, yielding benefits for both participants and researchers.



Innovative Approach

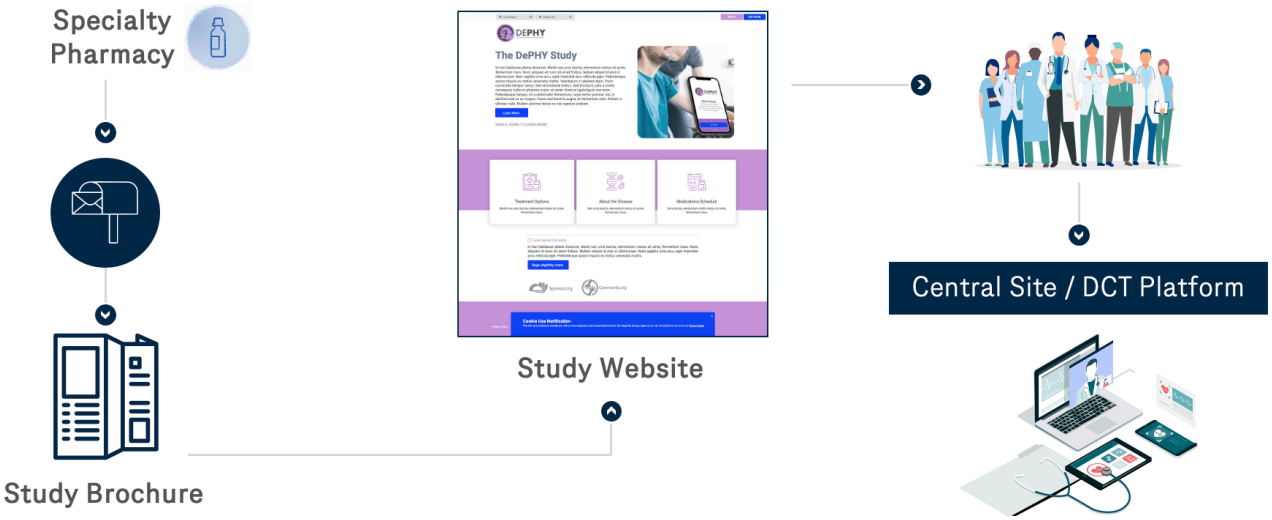
A case study was presented at the DIA Global Annual Meeting 2023 where THREAD, UBC and the sponsor showcased a solution to generate real-world evidence on the long-term effectiveness in rare disease patients. A primary challenge was to enroll 200-500 patients, which initially relied on 30 traditional sites.

How can we design a trial that is more inclusive, patient-centric, forward-thinking, engaging, accessible, and adaptive for patients with disease related challenges?

The answer was to leverage a patient enrollement and engagement model that combined recruitment tactics with a central site and decentralized platform, embracing an inclusive and adaptive framework.

Remote Screening: Telehealth and eConsents were employed to enable a remote screening experience, extending the trial's reach and access.

Virtual Visits: Additional site visitations were transitioned into virtual visits, creating a true hybrid decentralized clinical trial (DCT) approach to reduce patient burden and enhance retention.



The Results

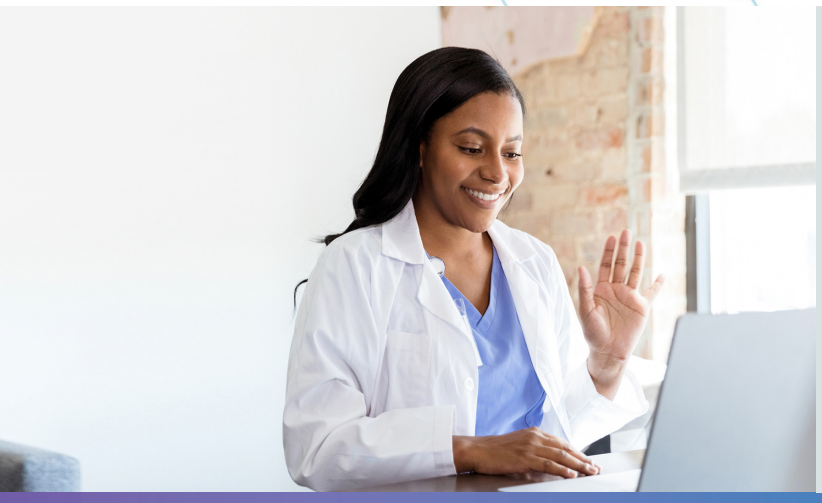
The impact of this modernized hybrid study design was striking:

25 Traditional brick-and-mortar sites enrolled 90 patients in the first 18 months. **While the 1 Central PI site enrolled 30 patients in just 3 months.**

This illustrates how patient-centric, hybrid study designs, have the potential to revolutionize post-marketing research. By prioritizing patient needs and reducing participation burdens, these approaches not only enhance patient experiences but also accelerate enrollment and data generation.

The study's success in addressing rare diseases sets a precedent for similar designs across all therapeutic areas, promising significant advancements in treating life-threatening conditions. The future of clinical research is undoubtedly more inclusive, diverse, and patient-centered.

A single Central PI site
recruits 50 times faster than a traditional site



Learn more about a joint offering to augment traditional studies with a Central PI model from UBC and remote data capure via THREAD's comprehensive platform.

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