Category: Clinical Trial Operations (Trial Start-up, Regulatory, Data Management, IITs) – Work in Progress

Collaborative Synergy: Building a Multidisciplinary Team for Digital Protocol Implementation

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1. Background

Clinical trials typically require patients to visit research sites, creating barriers for individuals who live far away, or have other constraints. To address these challenges, Mayo Clinic developed the Clinical Trials Beyond Walls program, which helps decentralize clinical trials through various remote tools. The multidisciplinary team, which includes experts in Operations, Product development, and Data, supports the deployment of decentralized solutions such as remote consent, video visits, device logistics, remote monitoring, remote biospecimen collection, and medication delivery. The program was applied in a Neuro-Oncology study (NCT06377696), aiming to enable full participation in the trial without needing to visit Mayo Clinic for any research-related activities

2. Goals

The primary goal of the *Clinical Trials Beyond Walls* consult service was to deploy decentralized tools in the Neuro-Oncology study, enabling patients to engage in the trial from screening through completion without ever having to come to Mayo Clinic. This approach aimed to make clinical trials more accessible, creating a seamless remote experience, ensuring patient engagement, protocol adherence, and efficient communication between participants and the research team. Crucial to this effort was the collaboration between the Principal Investigator (PI) and the consult service, where the team took the clinical trial protocol and operationalized it through innovative, patient-centric approaches.

3. Solutions and Methods

The Product and Operations team developed the necessary technology for the decentralized trial, including a mobile app that allowed patients to complete cognitive assessments, track medication adherence, and submit study questionnaires. The app included reminders for tasks like refilling medications or preparing for treatments. Additionally, the Product team identified a wearable device, cellular-enabled tablets and developed onboarding materials. User experience team members reviewed all materials to ensure ease of use.

The Data team worked closely with the study team to outline what data would be captured in the electronic data capture (EDC) system versus the patient app, ensuring proper data routing and integration from the start.

The Operations team coordinated the delivery of medications directly to patients' homes and developed workflows for patient engagement through the mobile app. They ensured the IRB application and study budget addressed all decentralized components. Additionally, the

Operations team trained Clinical Research Coordinators (CRCs) to assist patients with the digital tools and set up workflows.

4. Outcomes

The study successfully opened and enrolled its first patient within 24 hours, demonstrating the preparedness of the Clinical Research Coordinators (CRCs) and the effectiveness of the multidisciplinary

team approach. The study has progressed smoothly during the conduct phase, with the consult service continuing to provide support, such as troubleshooting the mobile app, tablets, and wearables.

5. Lessons Learned and Future Directions

A key lesson learned was the importance of a multidisciplinary team with specialized expertise in digital and decentralized trials. The collaboration between experts in operations, product development, and data management ensured the study was successfully launched and continues to run smoothly. Specialized knowledge in digital tools and remote trial management was crucial in addressing challenges and ensuring effective patient engagement. The team plans to incorporate end-of-study interviews and satisfaction questionnaires to gather insights into the patient experience, refining decentralized trial designs.