Life Sciences Case Study

PROJECT OVERVIEW

From Prototype to Launch: Creating a Novel Digital Tool to Facilitate Phase 3 Clinical Trials

A rare genetic disease biopharmaceutical organization engaged Clarkston Consulting to help develop a digital strategy and a novel solution to support the company's clinical and data operations needs due to its rapid scale-up.

As the company prepared to ramp up Phase 2 and Phase 3 clinical trials, there was a clear need to move away from manual processes and Excel spreadsheets into a centralized platform that would facilitate the patient enrollment process and key interactions across physicians, primary investigators, and different functional owners within the organization.

Historically, the client experienced inefficiencies as part of the patient referral process across different clinical trials. Specifically, many manual processes were involved, communication between functions was often redundant, and the organization lacked a single point of truth to orchestrate critical activities across clinical operations, medical liaisons, data operations, and area development managers. To solve this, Clarkston was brought in to help reinvent and reimagine what a potential new strategy and novel digital solution could do to streamline the patient referral process.

The journey started with a strategic "art of the possible" lens that required input from a variety of stakeholders, including clinical operations, research and development, regulatory and compliance, field teams, IT, data operations, major clinical research organizations (CROs), and IRT providers. From there, Clarkston developed digital prototypes to rapidly iterate on what a potential solution could look like and allow all involved parties to visualize and experience the new workflows in a tangible way.

The project culminated with Clarkston supporting the development and creation of a web-based digital tool that streamlined workflows and helped this biopharmaceutical organization expedite patient enrollment. As a result, more than 10,000 eligible patients for this rare disease were screened by healthcare providers (HCPs) and principal investigators (PIs) across >40 sites in North America, resulting in the successful enrollment of patients across both Phase 2 and Phase 3 trials. For our client, a single source of truth that unified internal and external stakeholders continues to prove invaluable in managing the success of the company's patient enrollment, as well as the critical cross-functional collaboration across clinical operations, data operations, medical science liaisons (MSLs), and field operations.

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INDUSTRY:

Biopharma

PRODUCTS AND SERVICES :

Rare genetic diseases

PRIMARY OBJECTIVES:

- Define the problem and structure the necessary steps required to get to a future solution that met the needs of a wide array of internal and external stakeholders
- Enable HCPs and PIs to identify potentially eligible patients to join clinical studies and refer patients for trial consideration
- Empower clinical operations and MSLs with centralized and structured data flows to understand enrollment from a variety of sources (e.g., HCPs, biobanks, CROs, IRTs, others)
- Improve patient and HCP engagement via scalable processes to optimize speed and quality of clinical trial enrollment
- Support current and future clinical trial enrollment
- Further qualify patients who might be eligible for existing and/or future commercial drugs

RESOLUTION:

- Clearly articulated the vision of the digital tool to create organizational alignment and understanding of what the ultimate solution would look like
- Defined the most critical challenges and barriers to overcome as part of the digital ambition
- Developed working digital prototypes to help all functions experience and visualize the tool prior to its actual development
- Determined potential patient journey flows (e.g., data flows, interaction with different clinical trials, patient repository, data disposition, etc.) and how different functions within the organization would be impacted
- Gathered in-depth requirements across key stakeholders including business partners, HCPs, and third-party partners (CRO, IRT, and data providers).
- Developed technical landscape diagrams to show desired future-state architecture
- Led vendor selection process to identify digital partner to build the tool based on a working digital prototype, agreed-upon designed specifications, and the necessary data (technical and regulatory) requirements
- Acted as product managers post-development of the new digital tool, owning the product vision, strategy, backlog, and development sprints

KEY BENEFITS:

- Successfully launched tool that has touched >10,000 rare disease patients across >40 sites in North America
- Leveraged agile principles to align on what the MVP solution would look like prior to investing in the actual development of the tool
- Accelerated and streamlined the referral process for eligible patients into clinical trials
- Provided greater transparency on all eligible patient records across the organization, including clinical operations, data operations, MSLs, field teams, HCPs, and PIs
- Allowed end-users to view patient status and eligibility results in real-time with full adherence to quality and regulatory standards
- Enabled key stakeholders to manage the status for each cohort study in a centralized platform

clarkston CONSULTING

More than 10,000 rare disease patients referred through the bespoke digital tool

Agile product and project management techniques allowed for supporting the on-time and on-budget launch of the digital tool while elevating the clients' digital capabilities

Successful integration with key providers (gobal CROs, IRTs, and biobanks) continues to push near real-time data to all key stakeholders

Trained dozens of pharmaceutical executives and leaders on how to successfully and compliantly use the new digital tool to streamline workflows and key processes

Digital tool has been in place for >12 months and successfully used daily by a variety of stakeholders (HCPs, PIs, MSLs, clinical operations, others)

CONTACT US

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