A Swiss multinational healthcare company operating in pharmaceuticals and diagnostics was facing multiple challenges in its clinical trial processes. They noticed that their pharma research and development (R&D) productivity had been reduced by half every 9 years for the last 50 years. They were also not effective in handling operational data, and this led to poor participant experience, with a high rate of study participant dropouts. TechM developed a unified cloud-based clinical platform that supported multiple channels using Pega Platform™ with feature driven development (FDD) approach using Agile practices to develop a robust, scalable platform.
Client Background and Challenges

The client is a pioneer in healthcare in Switzerland. Clinical trials are an integral part of the client’s drug and diagnostics discovery and development process, and with improved customer experience across all other aspects of patients’ lives, ease of clinical trial participation for client’s patients was now an imperative. Before a new medicine or diagnostic test can be made available, evidence of its safety and effectiveness must be provided by well-designed, well-controlled, and carefully monitored clinical studies in patients consenting to participate.

However, when the client approached Tech Mahindra, they were facing several challenges in their clinical trial processes. They noticed that their pharma R&D productivity had been reducing by half every 9 years for the last 50 years. Patient satisfaction in early research and drug development trials was not measured. They were using multiple technologies and applications across different platforms for the patient’s journey. Patients needed to remember what to do to prepare for visits due to a lack of digital reminders. The client also faced challenges with the accuracy of operational data, it was estimated to be less than 80% and therefore required manual reviews. This led to data processing time being quite high as it required extensive review and data cleaning. Furthermore, a high number of site visits, improper or incomplete communication, lack of transparency, and complex paperwork led to poor participant experience and increasing costs due to a high rate of study participant dropouts.

With complex long-running study schedules and several legal and regulatory compliance requirements, and ad-hoc updates to in-progress studies based on emerging findings from ongoing research, the client saw a decline in patients to stay committed and adhere to all study engagements. The client wanted to change these and make their clinical trials patient centric.

Our Approach and Solution

The Solution: As their digital partner, Tech Mahindra enabled them in their goal for patient centricity through -

1. **Patient Journey:** We designed and implemented an end-to-end patient trial experience. The Platform was created to track, and measure participant engagement levels and study adherence and help deliver key features such as reimbursement, chat messaging, eDiaries, study progress tracker, and surveys.

2. **CODH - Clinical Operations Digital Hub Platform** to help set up a single point of access for study information and automation

We developed a unified platform that was supported on multiple channels using Pega Platform™ with feature driven development (FDD) approach using Agile practices to develop a robust, scalable platform. Process / workflow automation and out of the box solutions were utilized to improve transparency, efficiency, and standardization.

The solution is built on a unified clinical platform, which is built on the established client cloud-based GIS DPA Pega Platform™ (with dedicated early research drug development trials). It is a private cloud solution hosted by Amazon Web Services (AWS). There are integrations to other client systems and third-party systems.
Partner Center of Excellence (CoE):

Pega CoE was leveraged for design review and quality assurance. Out-of-the-box, custom, and user-built reports were enabled for report generation. Data analysis was performed to measure participant engagement levels and study adherence. The system developed, supports onboarding studies in any language- only translations for dynamic content need to be loaded prior to deployment. In simpler terms, localization comes as a default with this kind of implementation, unless there are complex changes. It would also support multilingual support for study participants across the globe.

The Approach:

A feature-based approach was followed for quick delivery and flexibility for subsequent enhancements with periodic customer feedback. Low-code application development with guardrail scores exceeding 90% was consistently maintained throughout the project. Development was expedited using design/implementation team concept. The mobile app developed for study participants followed a patient centric approach with features like scheduling, reimbursements, real time communication with sites enhancing engagement, reducing burden for patients, and improved treatment compliance. We had a roadmap created to implement the solution.

- We prioritized streamlined information flow with an onshore-offshore delivery model, expedited requirement gathering, and backlog development using vision/scrum team model
- We carried out business analysis activities to identify gaps and improvements by performing assessments on existing projects
- We created and followed a transformation roadmap to implement Agile process and standards
- The unified platform was implemented and supported on multiple channels with robust Agile development and delivery
- We implemented regression test automation using Selenium which reduced regression test execution efforts up to 85%
- Through process / workflow automation and transparent, efficient, and standardized governance

Business Impact

- 10% increase in profitability and a 15% reduction in operating costs, and improved productivity/efficiency in the first year after implementation.
- Improved compliance with Google Cloud Platform (GCP) regulatory norms.
- Increase in patient engagement and compliance, through better communication and information exchange between patients and sites.
- Providing support during the patient journey and improving the patient experience by making it more convenient and less burdensome.

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