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goBalto: Simplifying the Clinical Study Startup Process


Sujay Jadhav, CEO

Historically, the clinical trial process has been marked by high expenditure, time-consuming often manual processes and over-reliance on archaic technology. Around $150 billion is spent annually by pharmaceutical companies on trials, with only 1 in 10 drugs ultimately obtaining regulatory approval.

The status of clinical trials continues to stymie industry stakeholders anxious to rein in the cost of product development and adhere to tighter timelines. Despite intense pressure to speed development, mounting evidence documents ongoing inefficiencies tied to complicated protocols, globalization, and old-school paper-based processes, driving clinical stakeholders to embrace technologies that are finally moving the needle.

Disrupting the industry trends by leveraging industry-proven experience and innovative big data techniques, goBalto aims to improve the overall clinical product development process. "We are laser-focused on study startup from an end-to-end perspective," asserts Sujay Jadhav, CEO, goBalto. San Francisco-based goBalto is used by 18 of the top 25 pharmas and by 4 of the top 5 CROs (Contract Research Organizations.) This impressive feat is achieved through a three-set SaaS product offering, which includes the operational tools, Select and Activate, and the business intelligence Analyze tool.

goBalto Select is "the Yelp for site selection," as Jadhav labels it. Close to 40 percent of sites under-enroll because they only reiterate the manual selection process from past studies, with little to no regard to the study protocol, recent site performance, and patient data.

Select provides a data-driven approach to weighing selection and performance variables to aid in the identification of sites and patient populations ideally suited to studies. According to Jadhav, "This proactive approach reduces the number of Non-Active, Non-Enrolling (NANE) sites. Top-performing sites are key to quality study execution, and using transparent data analytics to present studies to the right sites is essential to the goal of greater efficiency in site selection."

Upon completion of site selection, the process moves to Activate, a business oriented workflow management tool, which Jadhav labels as the "TurboTax for clinical trials." Activate automates the overall process to get the selected sites ready to enroll subjects for the clinical trial, providing clients with 30+ percent reductions in cycle times—allowing patients access to drugs months ahead of schedule, "which can be life-saving," connotes Jadhav. From a pharmaceutical company's perspective, Activate can save tens of millions of dollars in key process areas throughout the course of the clinical product development and speed the time to market entry.

Rounding up the entire process is Analyze, the company's business intelligence offering, which provides stakeholders with real-time status reporting at the site, country and study level for any on-going clinical trial. As the trial unfolds, alerts notify stakeholders of issues affecting milestone dates. This aids in risk identification and mitigation, benchmarking and forecasting performance and optimization of processes by pragmatically implementing machine learning concepts utilized in Analyze's analytics model.

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goBalto provides a rich and easy-to-use user experience in all their offerings, with minimal clicks, "which is very uncommon to find in healthcare," comments Jadhav.

A growing trend currently present in the healthcare space involves accessing patient data, in such a way that meets HIPAA compliance regulations—something goBalto is heavily involved in, as well. "By leveraging innovative big data technologies, it is much easier to make decisions in a de-identified way," states Jadhav. "It allows you to see what locations and sites you should focus on from a clinical trial perspective and improve the overall efficiency around selection."

goBalto addresses the security challenges in the entire clinical trial process with simplicity, due to constant FDA scrutiny, with regular audits, validation processes, and penetration testing, more frequent than in any other industry. "Companies like us dedicate our lives to security," Jadhav extols. From a security perspective, it allows goBalto to provide their clients with top-notch compliance with country specific regulations and organizational SOPs, ensuring that the clinical trial process is robust. Moreover, operating on a best-of-breed approach allows goBalto to integrate with other systems, "possibly in a better way than a lot of IT security companies out there," comments Jadhav.

goBalto's success stories are showcased through a variety of case studies, which highlight the company's prowess in helping their clients with document workflow collaboration, streamlined communications amongst all stakeholders, progress transparency, adherence to regulatory/SOP compliance and risk identification. This allows for significant time and cost savings and the highest level of efficiency in the clinical study startup process.

With an IPO being almost certain in the upcoming years, goBalto plans to continue its growth into the foreseeable future. The company intends to keep their laser focus on the clinical trial startup process while extending their product offerings. "If you can start a clinical trial well, you reduce overall risks and can eliminate unnecessary costs from being incurred," concludes Jadhav. "We want to find the best ways to assess the opportunity and impact you can make from a financial perspective and to people's lives." CR