DDNEWS
PHARMA, BIOTECH & LIFE SCIENCE

Q&A: Mush, you huskies!

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By Lloyd Dunlap

Back in 1925, there was an outbreak of diphtheria in the then-small village of Nome, Alaska. It was a harsh winter, and the only way to get the antitoxin to the sick was by a sled dog team. The lead sled dog on the last leg of the serum run that transported the antitoxin from Anchorage to Nome, saving the entire village, was a Siberian Husky named Balto.

DDNews: Please tell us a bit about goBalto, its origins and corporate successes to date.

Sujay Jadhav: goBalto develops next-generation solutions that simplify how clinical trials are started in the pharmaceutical, biotechnology and medical device industries. Our flagship product, goBalto Activate, is a purpose-built software-as-a-service (SaaS) clinical research platform. It enables clinical trial sponsors and clinical research organizations (CROs) to track milestones on the critical path, and it provides document workflow management capabilities in a transparent, regulatory-compliant and user-friendly way.

The life-sciences industry has recognized study startup as one of the worst performing areas in clinical trials—80 percent of trials fail to meet enrollment timelines, and up to 50 percent of research trial sites enroll one or no patients. According to Cutting Edge Information, 72 percent of studies run more than one month behind schedule, with sponsors standing to lose up to $10 million for each day that the trial delays a product's development and launch. Given these indisputable facts, the "status quo" is not good enough.

Many organizations struggle to control costs and resources associated with ramping up clinical trials. It is generally a manually intensive and highly inefficient process. The multistep process of collecting, reviewing and approving regulatory documentation is cumbersome, resulting in millions of dollars of waste per client, and can lead to delays in findings and, ultimately, approvals.

The processes involved in study startup are complex and rarely performed via a single function, with the sponsor/CRO organization typically requiring the interaction of multiple people at the individual sites, such as contracts, regulatory and finance, in addition to the coordinator and principal investigator.

Existing systems (CTMS, TMF, Study/Investigator Portals, Excel, etc.) support each of these functions in silos. The ability to bring together the collective institutional memory and the facilitation between systems and team members is critical, representing an unmet need. A study startup solution is the missing piece of the eClinical jigsaw that guides sponsors and CROs through clinical study startup and serves as the repository for in-progress documents. The selection of an industry-proven study startup solution with a robust integration framework is critical.

goBalto saw an incredible increase in usage and customer adoption in 2015 with more than 18,000 sites in over 60 countries now using Activate and, with recent multiple enterprise expansions, goBalto now services three of the top five CROs and more than two-thirds of the top 20 pharmas, managing their clinical trial documents globally, representing more than 70 percent of clinical trial sites in Phase 2 and 3 of the top 25 pharma companies.

Earlier this year, goBalto closed a $12-million funding from Mitsui Global Investment and Dolby Family Ventures. These new backers join goBalto's roster of leading strategic partners, which includes Aberdare Ventures, EDBI, Qualcomm Life and West Health Investment Fund. goBalto was recently featured in the Cool Vendors in Life Sciences, 2015 report, published by Gartner Inc.

DDNews: What impact will recently passed congressional action have on goBalto's progress toward its goals?

Sujay Jadhav: At goBalto we bring significant technological disruptions to the historically inefficient and error prone startup stages in clinical trials. Our customers have been able to cut 30 percent-plus of the time required to activate sites for clinical studies, which translates into millions of dollars in savings, as well as enabling medicines to get to those in need faster.

We support expedited programs, like the recent 21st Century Cures Act, which aims to improve medical innovation and reform the FDA's approval process for drug and medical devices. Our primary focus is on site selection and activation—a cumbersome and very inefficient process. Study startup focuses on the faster route to first patient in.

Expedited programs are a manifestation of the public's dissatisfaction with the clinical trials process, which has been slow to adopt new innovative technologies, technologies which have the ability to significantly reduce cycle times in clinical trials and get much-needed medicines to those in need faster.

The impact from recent Congressional action on goBalto is therefore a renewed interest in speeding clinical trials.

DDNews: Is your company working with Johnson & Johnson toward potentially life-saving medicines to desperately sick people? If so, how?

Jadhav: Again, we support experimental drug availability or compassionate use. We now service three of the top five CROs and more than two-thirds of the top 20 pharmas ... The clinical trials undertaken by our customers are typically coded with a proprietary label so we don't know what drug is undergoing study, nor which sponsors are utilizing which CRO.

DDNews: How does cloud-based Activate accelerate the clinical trial process?.

Sujay Jadhav: Current startup processes are cumbersome—Excel trackers don't support collaboration, documents must be faxed or sent by courier, reporting is manual and teams don't have visibility into real-time study status.

With goBalto, these organizations will know exactly how long it takes team members and partners to complete tasks so they can identify bottlenecks and also how much time each party spends completing activities.

Other competitive solutions are not immediately available "out of the box," and they lack key features, such as configurable workflows, submission support, study metrics and updated data. Furthermore, the information is not available to the full team and reports are often generated manually.

goBalto offers:

- A curated collection of workflows that track the requirements and automate the work to ensure compliance in over 60 countries;
- An intelligent workflow-driven approach that guides the work and helps organizations standardize on the most efficient processes and effectively manage resources, even during periods of high turnover;
- The ability to define and track the work at a low level of granularity to enable real-time metrics, cycle time analysis and predictive analytics to drive process improvements.

At the end of the day, goBalto helps get life-saving drugs and therapies to patients faster when days and weeks really matter.

DDNews: What is meant by an "end-to-end" process?

Jadhav: Drug protocol communication to site selection, patient recruitment to activation and conduct to close-out of the trial.

DDNews: What capabilities will Select add to goBalto's tool kit?

Jadhav: goBalto Select is focused on site selection and feasibility, which will streamline the approach to finding sites with the right subjects. Select will offer advanced site profiling combining disparate data sources, unique metrics to improve the site selection process and workflows to facilitate feasibility and screening.

Jae Chung
CEO | goBalto

Sujay Jadhav, *CEO of goBalto, has more than 20 years of experience at leading Silicon Valley software providers, with a life-sciences focus. Jadhav was most recently senior vice president of global corporate strategy and development at Model N, where he filled multiple roles, from corporate development to overseeing their life-sciences analytics and SaaS business unit. His career has also included strategic consulting at Booz Allen Hamilton, product strategy at CommerceOne and general management roles at Singapore Telecom. He received his undergraduate degree from the University of South Australia and an MBA from Harvard University.*