

# pharma

eCLINICAL TRIAL MANAGEMENT SPECIAL

## TECH OUTLOOK

April - 2018

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## Top 10 eClinical Trial Management Solution Providers - 2018

While research is critical to achieving medical breakthroughs, conducting comprehensive clinical trials is the vital facet of medical research to establish drug efficacy and safety. Today, the term eClinical refers to the complete business process of a digitalized clinical trial system. Development of Clinical Trial Management Software (CTMS) has helped researchers circumvent the cumbersome process of maintaining disparate physical records. The use of CTMS has helped organizations reduce delays and cost and improve standardization, efficiency and the trial integrity.

Organizations are increasingly exploring new ways of leveraging these technologies and are partnering with solution providers to create innovative systems. The increasing adoption of cloud-based services is expected to further change the eClinical landscape. The universal applications of technology

such as big data and blockchain have spilled over into the eClinical trial system. Solution providers are incorporating various data analytics techniques to help deliver the best solutions to their clients. A boom in the number of eClinical management systems has made it a complicated process for business leaders to choose the right partner.

In the last few months, a distinguished selection panel comprising CEOs, CIOs, VCs, industry analysts, and PharmaTech Outlook's editorial board reviewed the most promising solution provider in the market and selected a list of eClinical Trial Management solution providers that have developed innovative solutions that address the dynamic challenges of eClinical trials. The following companies have exhibited extensive business process knowledge, along with integrated and innovative capabilities to handle the unique challenges in the clinical trial space.



**Company:**  
Gobalto

**Description:**  
Workflow-based technology is critical in the clinical trial continuum, encouraging process optimization, facilitating communications, breaking down organizational silos, and enhancing operational performance and quality

**Key Person:**  
Jae Chung  
Founder & President

**Website:**  
gobalto.com

## Gobalto Dismantling Silos by Embracing Business Intelligence

**T**he focus on technology as a driver of performance improvement in clinical trials is intense, but despite years of valiant efforts, study execution remains far from optimal. For study startup, the data are dismal: Contract cycle times have doubled from an industry median of 1.5 months in 2009–2011 to more than three months in 2014–2015, 37 percent of sites under-enroll, and 11 percent fail to enroll a single subject. Overall, poor site selection, the inability of sites to predict the rate of enrollment, and the subsequent need for study rescue may increase cost of trials by 20 percent or more.

The continual reliance on spreadsheets, multiple databases and unsecured email without audit trail is inadequate to manage study startup activities. Overseeing activities from dozens or even hundreds of sites involves tracking and storing country-specific documents, ensuring regulatory and SOP compliance and identifying bottlenecks as the startup process unfolds. The high degree of complexity results in valuable time being wasted trying to find data buried in documents along with subsequent analyses that are not readily available. In this environment, a multitude of status meetings to understand the results and key metrics driving startup performance is routine.

An end-to-end solution with workflows that aggregate data from disparate sources can identify the documents needed to conform to downstream regulatory requirements and can also signal bottlenecks or breakdowns in study execution. This approach helps to avoid rework, delays, and cost overruns; improves cycle times; and facilitates audit readiness. This

approach can break down silos that have long performed in isolation with little understanding of what the next department needs to fulfill its regulatory obligations and achieve targets measured by performance metrics.




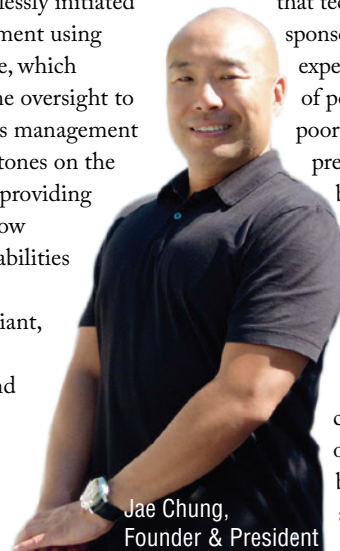
### Workflows that integrate operational data across all functions allow for meaningful insights, which help to break down the inefficiencies of silos

goBalto offers the only complete end-to-end platform for starting clinical trials, from site identification, feasibility assessment and selection through to activation, with comprehensive metrics to track adherence to timelines and budget. goBalto's Select assists with the identification of high-performing investigative sites by providing a data driven approach to weighing selection and performance variables, ensuring recruitment is completed on-time, on-budget and that the data is delivered with excellent quality. Study sites can then be seamlessly initiated for subject enrollment using goBalto's Activate, which enhances real-time oversight to clinical operations management by tracking milestones on the critical path, and providing document workflow management capabilities in a transparent, regulatory-compliant, and user-friendly way. Advanced and comprehensive reporting capabilities are provided by

goBalto's Analyze providing real-time visibility into study startup activities across multiple studies and regions, making it easier to quantify team performance and discover meaningful patterns in study data.

goBalto's technology provides organizations with an opportunity to rethink the inefficiencies of silos and "think horizontally." This method uses automation and workflows to integrate operational data across all functions, making it easier to extract meaningful insights from those data. Bringing interdependent functions together using technology and critical teams will help navigate the highly complicated global regulatory maze.

As the arduous task of dismantling silos begins, there is a growing recognition that technology is critical. Without it, sponsors and CROs will continue to experience the measurable ramifications of poor quality: delays, cost overruns, poor communication, and lack of audit preparedness. These problems can be avoided with the expanded use of workflow-based tools and performance metrics. By embracing this approach, complemented by support from key decision makers, it is possible to move the needle on process change and increase the likelihood of more predictable cycle times, better adherence to study budgets, and audit readiness. 



Jae Chung,  
Founder & President