

Xcyte Therapies Streamlines Clinical Treatment Logistics and Scheduling with TranSenda Clinical Trial Process Manager

Realizing that their existing systems and processes would not be sufficient to handle the volumes brought on by late stage clinical development, Xcyte Therapies teamed with TranSenda to deploy a tailored Treatment Scheduling solution to replace tedious paper-based processes and increase real-time communication between their Clinical, Manufacturing, Quality Assurance, Quality Control, and Material Control departments.

Background

Xcyte Therapies is a biotechnology company developing novel therapies that harness the power of the immune system to treat cancer and other serious illnesses. Xcyte derives its therapeutic products from a patient's own T cells, which are cells of the immune system that orchestrate immune responses and can detect and eliminate cancer cells and infected cells in the body. Xcyte is currently conducting several phase II clinical trials of Xcellerated T Cells™.

The Challenge

Xcyte's therapeutic treatment solutions involve a complex series of interrelated tasks, treatment events, and email notifications. A great deal of coordination is required to ensure clinical sites, participating subjects, and Xcyte employees are all kept up-to-date regarding schedule changes and/or treatment logistics. Previously, Xcyte relied on a variety of tools including MS Project calendars, spreadsheets, paper files, weekly meetings, and manually initiated email notifications to coordinate and track these mission-critical activities. "Our old methods required multiple schedules, coordination of calendars between clinical and manufacturing planners, three weekly coordination meetings, frequent face-to-face communication and a tedious process for scheduling changes," explained Larry Romel, Vice-President of Clinical Operations for Xcyte. "We were working on streamlining a scheduling/coordination system heavily reliant on paper- and fax-based communication methods. We were not aware of anyone with a technology that offered a fast, reliable system to be built to fit our needs."

Based on the go-live date of a new off-site manufacturing facility, Xcyte was faced with the daunting challenge of designing, building, testing, and deploying a solution that would streamline their clinical operations to handle additional volumes in under two months. Xcyte knew there was not enough time to build a solution internally, use a traditional application development vendor, or customize and integrate an off-the-shelf clinical trial management system.

They required a solution that mirrored their own internal processes and could be adapted to handle several disparate clinical trial protocols. They needed a system that could start small by addressing their most urgent needs and expand as new requirements emerged. In addition, the application should have the potential to support integration into safety and regulatory systems using compliant links and standards.

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The Solution

The two companies collaborated to define a “calendar like” graphical user interface that would plug into TranSenda’s configurable Clinical Trial Process Manager (CTPM) platform. Within 2 weeks TranSenda was able to present a prototype that outlined system functionality based on Xcyte’s requirements. This prototype was reviewed and refined over the course of 2 more weeks until it represented the exact functionality Xcyte needed. Leveraging its CTMS platform, TranSenda applied the logic and functionality outlined in the prototype and within 5 weeks delivered a fully functioning and tested production solution that mirrored the prototype’s functionality.

The end result is a scheduling application that allows Xcyte’s Clinical, Manufacturing, QA, QC, and Material Control departments to dynamically manage and coordinate a complex series of interrelated treatment events. It leverages a business rules engine that recommends the best treatment schedule for each of the participants involved in the trial based on protocol-specific event parameters including available manufacturing resources and user-specific permission levels. This functionality automates much of the ad-hoc decisions and “look-ups” that were performed manually in the past and vastly reduces the time Xcyte’s employees spend meeting, calling, and emailing one another confirming dates and tasks. “Timing was everything,” said Romel, “TranSenda’s unique offer and technology entered the scene just as Xcyte was underway with an intensive series of planning activities. The availability of this CTPM platform allowed for a customized solution to our scheduling problem.”

The Results

Prior to the deployment of this solution, Xcyte’s Clinical and Manufacturing teams spent approximately 45 minutes entering and scheduling the various events needed for a new subject. This same process now takes less than 10 minutes – a 75% gain in productivity. Additionally, updates to site, subject or schedule information require only a fraction of the time they used to take. For example, updating and recalculating a subject’s treatment schedule has been reduced from approximately 15 minutes to less than 5.

Automatic event status notifications have greatly reduced the time Xcyte’s Clinical, Manufacturing and QA teams spend creating and circulating email updates among themselves and upper management. What used to be a manual process has now been completely automated saving up to 30 minutes per subject.

“We have just started to use the scheduling solution,” explained Romel. “The initial runs indicate that the scheduling solution will become a valuable tool. TranSenda has been an excellent business partner during the collaboration. The staff is bright, attentive and detail oriented. They deliver on their development schedule.”

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