

i3

i3 delivers breakthrough pharmaceutical clinical trial solution with help from Adobe® Professional Services, the Adobe Flash® Platform, and Adobe LiveCycle® ES solutions

i3

www.i3global.com



Industry

Life Sciences

Challenges

- Help pharmaceutical companies deliver drugs to market faster
- Automate clinical trials from end to end
- Create a competitive advantage for i3 and its customers
- Meet FDA regulations

Solution

- Rich Internet application
 - Clinical trials management
- i3 used Adobe LiveCycle ES solutions and the Adobe Flash Platform to develop a RIA supporting a fully integrated trial management solution.

Results

- Reduced patient enrollment from two months to one day
- Accelerated the clinical trial process by 75% through automating all aspects of the clinical trial process
- Generated competitive edge for i3 and its customers
- Accelerated time to market with easy integration across enterprise platforms
- Delivered an intuitive, rich experience
- Complied with HIPAA and other regulations

A make or break proposition

One FDA-approved drug can earn a pharmaceutical company upwards of \$1 million dollars a day. Therefore, building speed and efficiency into the clinical trial process is key. While clinical trials are mission-critical, industry experts say 69% of all trials miss their timelines, largely due to the difficulties of managing trial processes such as selecting trial sites and finding the right patients.

Recognizing the opportunity to deliver value to companies looking to improve the clinical trial process, leading global pharmaceutical services company, i3, set out to enable pharmaceutical companies to meet their timelines and complete trials more efficiently. Working with Adobe Professional Services, i3 developed i3Cube™, an innovative new clinical trial and data management system that automates the entire clinical trial process to accelerate timelines, decrease costs, enhance collaboration, and increase team efficiencies. The Adobe Flash Platform and Adobe LiveCycle ES (Enterprise Suite) solutions are at the heart of the integrated system.

“We chose Adobe technologies as the basis for i3Cube because we wanted to deliver exceptional ease of use and a rich, engaging user experience,” says Patti Ward, director of product development at i3. “i3Cube is designed squarely with end users in mind—something that’s rare among applications in the clinical trials space. Adobe technologies were key to our ability to provide an innovative, intuitive solution that would drive adoption among pharmaceutical companies and offer them real value.”

A strategic product for i3

i3, a business unit of Ingenix and part of UnitedHealth Group, works hand-in-hand with some of the world’s largest pharmaceutical companies to help them throughout the pharmaceutical product lifecycle.

Clinical trials are highly complex and heavily regulated, involving identifying and recruiting trial sites, gathering extensive documentation and data, and collaborating among multiple parties—from investigators and coordinators to physicians, sponsors, and contract research organizations supporting the trials.

Among the most challenging activities of every trial is identifying the right trial sites, finding patient participants, and managing the documentation required for regulatory compliance. Typically, if pharmaceutical companies want to recruit sites for a trial, they must purchase and validate a site list, then deliver it to an outsourced services company that distributes faxes inviting sites to participate. The site list information must then be entered manually into a Clinical Trial Management System (CTMS), dramatically increasing the potential for data entry errors.

Once the information is keyed into the CTMS, the pharmaceutical company must begin sending each site a comprehensive set of regulatory documents to complete and return. This process typically takes about two months. Furthermore, after patients are enrolled, it can take up to 12 weeks to set up an Electronic Data Capture (EDC) database to begin receiving clinical data.

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From site selection to submission

A rich Internet application (RIA), i3Cube enables pharmaceutical companies to identify investigators and sites, recruit and contract with them, enroll patients, conduct clinical data capture, conduct safety surveillance, analyze and report on data, close out a study, and submit it electronically to the Food and Drug Administration (FDA).

The solution is built using Adobe Flex® Builder™ and based on a full complement of Adobe LiveCycle ES solutions. The Adobe components of the solution are fully integrated with an EMC Documentum content management system, as well as other enterprise software such as Siebel eClinical CRM and financial software from Oracle. The Adobe solution enables companies to rapidly deploy rich, intuitive applications that leverage the existing data and infrastructure.

“With Adobe technologies, we were able to take a staggeringly complex process that involves many diverse participants and countless critical documents and transform it into one elegant, unified user experience,” says Jawad Zaka, technical architect of i3. “While we considered other solutions, Adobe tools offered exceptional flexibility in creating a robust, enterprise-ready system capable of supporting hundreds of concurrent users. Flex provided exceptional cross-platform and cross-browser portability and accelerated development by providing reusable components such as data grids, text fields, and other common elements out of the box.”

Integration between the Flex front end and LiveCycle Data Services ES accelerates data exchange between the front- and back-end portions of the application, while the object-oriented nature of the Adobe solutions keeps code related to the system tight and clean and streamlines development.

“The integration between Flex and LiveCycle Data Services ES is especially beneficial because we can retrieve, store, and exchange information in an object-oriented manner instead of dealing with textual information,” says Zaka. “It greatly improves performance and makes the application more responsive for our end users.”

A unified, real-time view with automated workflows

Intuitive dashboards in i3Cube deliver real-time reporting, study-specific automated workflows driven by LiveCycle Process Management ES software, as well as access to study information for the sponsor, research team, and site staff. Adobe LiveCycle Process Management ES enables users to customize the system based on their roles—users can even create their own workflow tasks to stay on track during a study. LiveCycle Process Management ES also kicks off business processes automatically and tracks the status of each “to do” item, from in-progress through to completion.

All documents, e-mails, and faxes related to the trial are saved as Adobe Portable Document Format (PDF) forms created in Adobe LiveCycle Forms ES in a study library within the EMC Documentum content management platform. Instead of relying solely on developers, business specialists who are most familiar with the clinical trials process can design forms in Adobe LiveCycle Forms ES and upload them seamlessly into the system for data capture and initiation of business processes.

Data and documents flow automatically into the study library—without error-prone rekeying—and are updated in real time so that everyone can see at a glance how a trial is progressing. Users can analyze and interact with the data by sorting or filtering it based on an array of criteria. As information is updated, it is synchronized via a secure channel between the database and the client side using Adobe LiveCycle Data Services ES.

Delivering value to pharmaceutical companies

The advantages for i3’s customers are substantial. For instance, i3Cube condenses what was a two-month patient enrollment process into a single day. The system also accelerates the process of setting up EDC databases to collect trial data from 10 to 12 weeks to just 2 to 4 weeks, accelerating trials by months.

The system maps to regulatory processes and is fully compliant with the Health Insurance Portability and Accountability Act (HIPAA), 21 CFR Part 11, and other electronic system guidelines required by the FDA. It is also integrated with Microsoft® Active Directory for user authentication and single sign-on.

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“i3Cube automatically selects investigators, communicates with sites by their preferred method—e-mail or fax—sends the letter, and captures their responses and documentation,” says Ward. “By leveraging our proprietary data, the system also can pinpoint the most feasible sites with the best patient population to accelerate recruitment. This translates into a huge advantage for our customers in hitting their timelines for trials.”

With i3Cube, i3 has created a substantial competitive advantage for itself as well. “Working with Adobe, we were able to accelerate development and time to market of i3Cube with software that is flexible and easy to integrate across enterprise platforms,” says Ward. “But what we’re most excited about is the impact i3Cube has on our customers and their end customers. The faster a pharmaceutical company can obtain information about a clinical product’s efficiency, safety, and efficacy, the more it can focus on delivering drugs that work to the people who really need them.”

Systems At A Glance

- Adobe LiveCycle ES. Components used include:
 - Adobe LiveCycle Forms ES
 - Adobe LiveCycle Reader® Extensions ES
 - Adobe LiveCycle Process Management ES
 - Adobe LiveCycle Data Services ES
- Adobe Flex Builder

For More Information

www.adobe.com/products/livecycle/



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