



CRIX TRUSTS RED HAT, ALFRESCO, AND JBOSS TO QUICKLY AND SAFELY SPEED NEW DRUGS TO MARKET

FAST FACTS

Industry	Pharmaceuticals
Geography	US
Opportunity	Create an electronic information exchange for all stakeholders involved in getting new drugs to market from research and development, to clinical trials, to government approval
Software	Red Hat Enterprise Linux, JBoss Enterprise Portal Platform, JBoss Enterprise Application Platform, JBoss jBPM Framework, Alfresco Enterprise Content Management (ECM), and TriCipher
Benefits	Will enable previously unmatched levels of collaboration among pharmaceutical companies, government agencies, academic institutions, and health care providers to make the drug development, testing, and approval process more secure and efficient while reducing costs and safeguarding the safety of the end consumer



BACKGROUND

Clinical Research Information Exchange (CRIX) International is a not-for-profit collaborative consortium that includes government agencies, members of the bio-pharmaceutical industry, academic researchers, healthcare providers, and other stakeholders in development of new drug therapies. CRIX has created a secure and standards-based electronic information exchange for everyone involved in clinical drug research that facilitates faster, less-expensive, and secure alternatives to exchanging clinical research information. Open to everyone involved in clinical drug research and development, the CRIX community currently includes more than 20 companies ranging from smaller clinical research organizations to pharmaceutical giants like Merck & Co. Inc. and Pfizer Inc.

OPPORTUNITY

Getting new drugs to market has always been a complex, costly, and labor-intensive process. One of the most painful aspects of this procedure has been the vast amount of paperwork involved in collecting, processing, and distributing documentation of clinical trials to submit to the U.S. Food and Drug Administration (FDA). As it currently works, all the various parties involved in clinical research - the bio-pharma companies themselves, the doctors and hospitals performing the trials, and the FDA, as well as numerous other organizations - communicate with one another on a one-on-one basis: The bio-pharma organizations exchange data with the healthcare providers and academic institutions performing the trials; the bio-pharma groups interact with the FDA and other government entities, and the organizations involved in the marketing and distribution of the approved drugs have to establish independent connections with all parties.

Although most of the large bio-pharma businesses have implemented proprietary IT systems that attempt to automate most or all of the process, frequently, this information is still collected, processed, and exchanged manually. In either case, the result has been "siloes" data as well as investments in technology by different organizations that overlap and even outright conflict with each other.

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Mark Vermette, product manager for CRIX International.

SOLUTION

Initially created under the auspices of the National Cancer Institute in 2005, CRIX's first pilot deliverable, called Firebird (for the Federal Investigator Registry of Biomedical Information Research Data), automated the FDA's Form 1572 submission process. Form 1572 is the FDA-required document in which clinical investigators agree to conduct investigational new drug clinical trials according to federal regulations. The much-needed Firebird applications enabled the electronic completion, signing, and submission of the copious amount of paperwork that the doctors and other health-care providers have to complete during a clinical trial.

But although useful, Firebird was limited in scope, as it automated just a fraction of the clinical trials process. So in 2007 CRIX International was formed, and the CRIX project was placed under its jurisdiction.

The first decision that Vermette and his team made was to use open source to build what would be called the CRIX Collaborative Platform. To that end, CRIX International worked with Rivet Logic, the Reston, Virginia-based, open source systems integrator.

“This would ensure the end result would be based upon established standards, and also that it would be easier for participants to contribute their efforts to the general innovation and contribution we were making to the industry,” said Vermette. Once he started looking at actual products, “it was clear we wanted Red Hat Enterprise Linux, Alfresco Enterprise Content Management and JBoss Enterprise Middleware to support our efforts,” he said.

The CRIX Collaborative Platform was developed using Red

Hat Enterprise Linux, JBoss Enterprise Portal Platform and JBoss Enterprise Application Platform, including JBoss Hibernate for database access. It also utilized TriCipher as a unified authentication infrastructure.

BENEFITS

Launched in June 2008, the CRIX Collaborative Platform will create a shared knowledge base, enable increased opportunities for collaboration, and facilitate economies of scale unprecedented in the pharmaceuticals industry. Lower transactional costs will free up more funds for research; human errors will be reduced because manual data entry will be minimized or outright eliminated; and patients will reap the benefits of new therapies much faster. Perhaps more importantly, the fact that the entire clinical trial process will be easier will motivate project participants, which in turn will improve quality of health and life for people around the globe.

Because Red Hat technologies promote a modular approach to development, one of the biggest benefits of the CRIX Collaborative Platform will be that independent software developers will be able to create and own modules that reside on top of it. Bio-pharmaceuticals stakeholders will thus have an entire menu of open source functionality from which they can choose. “They will have a choice of implementing content management functionality, clinical analysis tools, or the document publication capabilities - there will be an entire laundry list of options they will have based upon their needs,” said Vermette.

Red Hat products were an integral part of the CRIX effort, said Vermette. “Although this would have been possible without Red Hat products, it would have been substantially more difficult,” said Vermette. “The biggest reason we went the Red Hat route, in addition to the technical excellence of its products, was its legendary support. And its reputation for it is well deserved.”

Alfresco ECM was also a critical part of the solution. “Alfresco provides us with an enterprise-scale content management solution, based entirely on open standards, enabling consortium members to accelerate collaboration and information flows for clinical research,” said Vermette.

Looking ahead, Vermette is anticipating implementing JBoss jBPM and Alfresco ECM to bring process automation capabilities to the CRIX Collaborative Platform.



“The pharmaceutical industry has some very complex regulatory requirements, and - historically - binders and binders of paper documents with complicated rules on who gets to author them, how they are edited, and how the content is controlled,” said Vermette. “The JBoss jBPM Framework and Alfresco ECM are very sophisticated technologies that will provide these capabilities, and should be the ‘tipping point’ for getting organizations to adopt the CRIX Collaborative Platform.”



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