Denise Myshko

R&D's Technology EVOLUTION

Integration of clinical development technologies is considered a critical element — and the biggest challenge — for efficient drug development.

Technology tools are the cornerstones for achieving a drug development process that is faster, cheaper, and easier. Over the last 10 years, there has been increasing use of EDC, ePRO, CTMS, dashboards, and other tools to streamline the drug development process. Now a changing R&D paradigm is leading to systems integration and a convergence of tools to accelerate clinical trials, reduce costs, and improve efficiencies.

"Over the years systems have become more integrated and provide a more seamless support of processes, which also have become more integrated," says Neil de Crescenzo, senior VP and general manager at Oracle Health Sciences.

The industry's focus is moving from implementing individual applications that were based on features and functionality to realizing the value of being a comprehensive, integrated eClinical suite that provides additional benefits, says Mark Goldberg, M.D., chief operating officer at Parexel International.

"There is a growing level of convergence in e-clinical suites, where there is a level of interoperability that allows the functionality of one application to be accessed through another seamlessly," he says. "The goal is to streamline workflow, facilitate more effective trial management, and support real-time data interchange for better and faster decision making."

Integration needs to maximize the value of the different systems, says Rick Piazza, VP of product management at Medidata.

FAST FACT

THE LIFE-SCIENCES TOOLS AND SERVICES MARKET IS EXPECTED TO GROW AT A CAGR OF 10.1%, WITH THE AMERICAS HAVING THE LARGEST MARKET SHARE OF 59.6%.

Source: Technavio Insights

"Sponsors should be looking for integrations that allow them to take advantage of both clinical and operational data that exist in any of those applications," he says. "It's about passing data through and across systems so that the information can be consumed in multiple places. This is an important part of getting integration right."

One of the greatest advances in technology is the ability to access technology from anywhere around the globe, says Jennifer Goldsmith, VP of strategy at Veeva Systems.

"The advent of technologies, such as cloud computing and mobile devices, as well as a better infrastructure, allows people to participate more thoroughly in these processes to exchange information more quickly," she says. "People are readily able to access information, upload it, and share it and then collaborate in a discussion about what that information means."

She points out that the ability to collaborate has become a critical goal for life-sciences organizations, and globalization of these processes has changed the way in which people do business.

"When I first started in this business, collaboration meant you walked down the hall to a meeting room," she says. "Today collaboration can occur with your global affiliates, it can occur across regions, and across countries. It can occur with an extended ecosystem of external vendors and partners as this type of relationship continues to grow."

Still, Ms. Goldsmith says there is a need for better collaboration at an operational level, especially in the area of content or document management associated with clinical trials.

"One example is the trial master file, which is developed by a number of different people participating in a process, and it's oftentimes still managed manually or managed through a series of disparate technologies," she says.

Enabling Process Improvement

Sheila Rocchio, VP of marketing at PHT, says making integration happen is a combination of people, process, and technology.

"All of these have to be aligned," she says. "There are many different players. Typically, in a clinical trial there are seven or so different providers in addition to an online EKG system, a lab system, an EPRO system, and an EDC system, etc."

Dr. Goldberg says one mistake often made is not seeing technology as part of a change

management methodology. The focus often is on the technology itself as opposed to having a focus on how process change affects people in the organization.

"It's important to ensure that the organization is ready to adopt a change in the way that its conducts business and manages workflow processes," he says. "Such change may even require that companies have to redefine their SOPs, jobs, and competency models."

Because of the myriad moving parts, Dr. Goldberg says a successful technology implementation often has profound change implications for an organization.

"The successful technology service providers are those that think about things from a process standpoint, understand what clients are trying to accomplish, and use the technology as a tool to enable process improvement as opposed to simply implementing a technology with the expectation that there will be efficency gains because a technology was put into place," he says.

At the same time, the IT department is becoming an ever more important part of the mix in solving business challenges, Mr. de Crescenzo says.

"Companies are looking at their strategic imperatives and are now having the IT organization, the CIO, and other technology players sit at the table as they look at their top priorities for the year," he says. "More than ever, IT is becoming an integral part of solving business problems. Now companies addressing a challenge may include an IT-enabled solution."

Dr. Goldberg points out that about 70% of major change management initiatives fail because of the disconnect that occurs between what the top of the company is trying to accomplish and how people experience the change on the front lines.

A survey last year by Cegedim Relationship

Integrating Electronic Medical Records with Clinical Research

EHR has the potential to transform drug development, improve cycle times, and assist with patient recruitment.

Experts say data held in electronic medical records have the potential to shorten development cycle times by identifying patients faster and helping to identify disease patterns.

A 2008 report from Datamonitor predicts North American and European spending on EHRs will grow to almost $13 billion by 2012, a CAGR of 23.8%.

The use of EHR in drug development is gaining momentum, says Jason Colquitt, executive director research services, Greenway Medical Technologies.

"EHR has the ability to look across 8 million to 9 million patients to determine how many patients might meet the criteria of a study," he says.

To make this a reality, he says, EDC and EHR vendors have to adhere to standards.

"I sit on the CDISC advisory board and we developed a standard for interoperation of data between EDC and EHRs," Mr. Colquitt says. "It is called Retrieve Form for Data Capture. In our case, we can have case report forms for a study listed on patient charts. The user can click on that link within our software for an initial CRF and the case report form would pop up on the screen. It would have all the data prefilled for medications and demographics, for instance. Whatever is on the case report form that can be prepopulated will be."

> **"We have the ability to look across 8 million to 9 million patients and determine how many patients might meet the criteria of a study."**
>
> **JASON COLQUITT** / Greenway Medical Technologies

Mr. Colquitt says data quality can be improved by linking EHR and EDC systems.

"It's not necessary to make sure the data were entered correctly because the information is already there," he says. "The EHRs are also linked with PBMs to pull in information about a patient."

Source: Greenway Medical Technologies.
For more information, visit greenwaymedical.com.

Benefits of EHR in Drug Development

Trial Design	Patient & Investigator Recruitment	Execution Analysis
» EHR alerts increased enrollment rates from 2.4% to 22% of recruited patients (Prior knowledge of health status could drive further improvement)	» A 28% increase in eligible patient identification	» Journaling compliance increased from 11% with paper-based methods to 94% electronically
» Total cost savings for screening 40,000 patients with a 5% "hit" rate is about $3.2 million	» A doubling of monthly patient enrollment rate	» EHR-based monitoring enables intervention before patient must be excluded from data set
	» A near 10-fold increase in the enrolled to referred ratio	» Use of EHR data and patient alerts reduces attrition rate by 50%, reducing overall trial size

Source: Deloitte. For more information, visit deloitte.com.

SOUND BITES FROM THE FIELD

Experts discuss the tools needed to move clinical development forward as well as the medical advances being made to change the current drug development landscape.

JAE CHUNG is Founder and CEO of goBalto, which is dedicated to improving the clinical study start-up process. For more information, visit gobalto.com.

"One of the biggest challenges in one word is usability, or lack thereof. The tech landscape is littered with tools that scream clunky and complex. This means users waste a lot of time in training and figuring out how to use and integrate systems. Anybody can slap together a bunch of tabs, charts, and statistics and call it a solution. To paraphrase Steve Jobs, 'the challenge isn't trying to figure out which features to include, but rather what not to include.' This is something the most successful consumer apps figured out a long time ago. Until the drug tech industry figures out what not to include, we're stuck with confusing Web spreadsheets."

EDWARD FRITSCH is Principal, Clinical Operations, at Cognizant Business Consulting, a global services partner for the life-sciences industry. For more information, visit cognizant.com.

"Interoperability between systems and presentation of information to stakeholders is the biggest challenge. While a CDR solution is a good first step in collating and harmonizing data, turning data into actionable information for the end users is still a major challenge. Taking the example of EDC alone. There are many different solutions on the market today and yet very few standards for them. Capturing all of this information and feeding it into the CTMS requires standard inputs to effectively capture the data on an almost real-time basis, requiring conformity by CROs. And the distribution of that information to the end user through dashboards is limited. Many sponsors are looking at how they can manage inputs from various sources and providers, collect that information, and provide reports and displays of the information so that the clinical teams can make effective decisions."

MARY C. GAWLICKI is President of Corporate Translations, which fulfills the demand for high-quality translation services in the life-sciences industry. For more information, visit corptransinc.com.

"One of the biggest challenges we face is helping firms understand and prepare for the process of adapting translated documents for use on EDC devices used in clinical trials. Patient reported outcomes (PRO) instruments that were previously validated in paper format cannot be simply put on an ePRO device without significant linguistic adaptation, and the device may not support certain characters or fonts of the target language. Overcoming these obstacles efficiently can only be done with early and effective planning between vendors and sponsors."

MICHAEL HARTE is Founder and President of The Harte Group, a functional services management organization (FSMO). For more information, visit hartegroup.com.

"The greatest advance of technology has been the maturity of EDC systems. These systems facilitate the collection of quality data, and more importantly provide transparency and real-time information on study status throughout the clinical trial, supporting a higher level of management. Timely reconciliation processess have been minimized or eliminated by importing third-party data. Going forward, a more aggressive use of these systems will allow for virtual service models to begin to take shape and lessen the reliance on full-service models for trial execution."

WHITE PAPER

A UNIQUE SERVICES MODEL TO SUPPORT PHARMA'S CHANGING NEEDS

Presented by: The Harte Group

bit.ly/Harte-ServicesModel

JOSEPH F. RENZULLI II, M.D. is Chairman of the Medical Advisory Board, American Medical Alert Corp., a provider of call center solutions. For more information, visit amac.com.

"Molecular targeted therapies are one of the biggest advances in drug development. These medications attempt to derail tumor cell growth and progression and/or induce cell death. These molecules differ from tradition chemotherapeutics in that they are selective for the tumor cells and spare injury to the patient's normal surrounding cells. The biggest challenge with targeted therapies is the cost to deliver these therapies. In this current cost-conscious healthcare environment, society will continue to be faced with the difficult question of whether a particular patient should receive a successful therapy regardless of the cost."

"Advancements in technology infrastructure have allowed the tools used for drug development to become very effective at real-time information gathering, review, and analysis."

RICK PIAZZA / Medidata

Key E-Clinical Attributes

More than half (53%) of respondents to a survey by Perceptive Informatics view integration to be the most important attribute of an e-clinical suite. These respondents indicate that the data exchange between applications to prevent duplication of activities and the need for database reconciliation are critical. Another 29% believe that the functionality of an e-clinical suite should simplify workflow for various users and 18% say an e-clinical suite should be able to consolidate data.

Source: Perceptive Informatics.
For more information, visit perceptive.com.

Management found that executive management is the primary driver of technological decisions, followed by IT.

Dr. Goldberg says buy in from upper level management is critical but insufficient.

"It is relatively easy to get a management team aligned around certain changes for process improvements, but it's the people on the front line whose jobs are going to be impacted who are critical to the success of any change," he says.

There also is a tendency to stop at the point of implementation, Dr. Goldberg says.

"In the technology world, just getting the system up and running is a starting point, not an end point," he adds. "Success is not achieved when a big switch is thrown to turn on the system. Success is achieved when a company reaches predefined metrics, which are representative of the productivity enhancements that result from refining processes and having them enabled by technology."

The Value of IT

Dr. Goldberg says many companies don't maintain the effort required to take an organization from the point of implementation to the full realization of the benefits.

"Value is shown mainly in two ways: cost savings, which include direct savings such as the need for fewer people or facilities through more efficient and effective capacity use, and cycle time reduction, which has huge value because of the focus on getting a product to market ahead of the competition," he says.

Ms. Goldsmith says a step that is often missed is determining what the objectives are for any new technology.

"From the outset, metrics need to be created to understand the value of the technology," she says. "It's important to establish the metrics before the implementation stage to make sure that the technology is configured in such a way to capture those metrics. Oftentimes, people want to capture metrics only to realize that because they didn't define these at the outset, the systems won't match to the milestones."

Darlene Panzitta, president of DSP Clinical Research, agrees that metrics are critical for assessing the value of IT.

"Time is a big issue because of the competitive nature of contract research," she says. "We have to be able to find ways to do studies faster. Study start up, for example, is usually a three-month process. We look at whether using a completely electronic system will get that down to one month."

In terms of IT partners, Ms. Panzitta says a system provider needs to be flexible and has to provide a customized system.

"We often are given a system and told that it can do certain things, but ultimately it is one system sold to different groups of companies, which then have to adapt," she says. "I'm always looking for flexibility. In addition, I'm looking for an IT provider that is always evolving and making the system better."

Ms. Rocchio points out that because so many legacy systems still exist there is reluctance by some companies to take on an additional integration projects.

"Integration is not easy and it's not clear necessarily what the best option is for return on investment," she says. "There is certainly a user benefit to having the front-end systems working together. A lot of investigator portals have been introduced lately to help with that consistent look and feel from the site perspective."

Experts say more widespread adoption of standards could help with the integration of back-end systems.

"In the IT industry, there have been a number of initiatives over the years to create more standardized ways of linking different systems," Mr. de Crescenzo says. "This is important because it makes these systems more robust and less expensive to manage for our customers and for us. We can have standards that allow data to be communicated or transfered between applications without having to write specialized code that makes the integrations more brittle, more expensive, and more challenging to maintain."

> "Integration that creates an end-to-end clinical trials process in which data and documents and information in general flow freely from one activity to the next is the Holy Grail of the clinical trial process."
>
> **JENNIFER GOLDSMITH** / Veeva Systems

Also important, he says, is that IT partners have to understand the vision of the industry and their sponsor partners.

"Integration is about creating a whole new set of solutions and processes that will make a company more efficient for the long run and on a global basis," Mr. de Crescenzo says. PV

> "There is a distinction between implementing technology and changing process. The focus should be on defining and demonstrating how key benefits are going to be achieved to create value for the business."
>
> **DR. MARK GOLDBERG** / Parexel

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