



## Life Sciences Take Note: Five Really Cool Observations From the DIA

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The 44th Annual Meeting of the Drug Information Association (DIA), recently held at the Boston Convention Center, was just plain impressive. The event was comprised of keynote speeches, over 300 concurrent sessions, and more than 500 exhibits. While the speakers and sessions were insightful, there was a palpable excitement on the exhibit floor that went far beyond the sheer size of the convention hall.

This article will highlight the observations from the 2008 DIA meeting that all life sciences companies should consider for their new product development strategies.

### Why are external resources important to R&D?

Between now and 2010, the number of companies conducting more than 15 Phase 2 or Phase 3 clinical trials annually will increase by 40% or more, according to a recent AMR Research study. Increasingly, these trials will be conducted thousands of miles away from their traditional locations, with the percentage of clinical trials conducted in North America and Western Europe dropping from 55% to 38% as more clinical trials are conducted in India, China, the Middle East, Africa, and Eastern Europe.

As a result of this increase in R&D spending and clinical trial complexity, life sciences companies will look to external resources for assistance. They will outsource to increase capacity and supply chain agility, decrease costs, and manage more complex regulatory challenges. Companies will also invest in information technologies to improve data visibility, decision making, and regulatory submissions processes.

### DIA exhibitors are prepared to help

The magnitude and technological sophistication of the DIA exhibitors underscored the increasing importance of external resources to R&D. The ones we talked to understand the pain points in life sciences and were prepared to provide the assistance companies require, from lab to clinic. Clinical research organizations (CROs) from around the world were in attendance, including a number of companies specializing in clinical trials in India, China, and Eastern Europe (see "Clinical Trials Are Moving Out"). Contract manufacturers specializing in supply of clinical materials, a wide variety of information brokers, and medical services providers were also well represented.

### Five really cool DIA observations

Listing all companies with cool technologies would read like the DIA's index of exhibitors. However, below are five examples of technologies and business processes that life sciences companies should consider for their new product development processes.

#### *No. 1—Oracle forms Healthcare GBU*

**Oracle** announced the formation of a global business unit dedicated to health sciences. As indicated in its press release, the company formed this new business unit in response to continued growth in clinical trials and the associated interactions between life sciences manufacturers and healthcare providers. Its clinical trial software applications, which can be deployed individually or as a suite, help companies integrate the critical aspects of clinical development, safety, and pharmacovigilance processes into a single, open platform.

Two of Oracle's clients presented case studies of successful clinical trial management application deployments at the company's life sciences conference in May 2008. These deployments were prime examples of creating end-to-end clinical trial supply chain visibility across a complicated network of investigator sites and orchestrating an efficient supply response.

#### *No. 2—Microsoft's InfoMesa*

**Microsoft's** life sciences division worked with over 200 R&D scientists to build a technology demonstrator for storing and collaborating on research discoveries. Building on the Windows Presentation Foundation (WPF) framework that is a part of the Microsoft Vista operating system, the team built an application that uses an enormous whiteboard metaphor to facilitate sharing, visualization, explanation, and discovery timeline development.

A key distinction here is that this application captures not only what was discovered, but also the steps that led to discovery, embedding important annotations along with the data artifacts that come from instruments, images, and three dimensional models. The whiteboard concept allows a wide array of diverse visual

representations to live side by side, allowing scientists to share whiteboards for similarity, differing points of view, or different interpretations of data. This technology demonstrator has broad appeal for enabling collaboration and visibility, from basic discovery to preclinical research, and may also prove valuable in more regulated ends of the new product development lifecycle.

### *No. 3—Advancements in electronic regulatory submissions*

This year's DIA event highlighted several advancements in electronic submission of new product regulatory filings. Vendor capabilities in this area have progressed beyond paperless filings and electronic submissions to integrated suites of electronic data capture, content management, publishing, and tracking. Along with life sciences companies, AMR Research believes it's time for regulatory authorities around the globe to follow the Food and Drug Administration's (FDA) lead in accepting electronic filings as the standard submission.

A good example of progress in electronic regulatory submissions is **Octagon Research Solutions**, which used its exhibit at DIA to preview ViewPoint Quantum. According to Octagon, this is the company's next version of enterprise process management applications to help companies manage the drug development lifecycle, from data collection to submission.

ViewPoint Quantum synchronizes robust publishing capabilities with enterprise process management, allowing users to pull cross-functional content toward finalization and submission, replacing the traditional "throw it over the wall" approach to submission management. ViewPoint allows users to manage processes such as data standards governance, data lifecycles, document management, and e-CTD compilation and submission management. Octagon also uses ViewPoint to manage its submission outsourcing services and as a delivery mechanism for its integrated sourcing model.

### *No. 4—Using technology in clinical trial execution*

Some new drugs and devices rely on medical images such as x-rays, ultrasound, and CT scans as successful proof of efficacy and endpoint. These scans are often transferred to and read by third-party radiologists to provide an independent therapeutic-specific clinical assessment. Today, there are technology providers that help life sciences companies transfer these scans electronically to reduce errors, expedite the review process, and integrate key scan data with regulatory submissions.

As an example, **Bio-Imaging Technologies, Inc.** recently acquired **Phoenix Data Systems** to integrate its medical imaging and clinical trial management technologies. According to Bio-Imaging, the combined companies offer technical resources and imaging capabilities to help life sciences companies with statistical analysis of medical image data, meeting clinical trial timelines and budgets, and facilitating the regulatory submission and approval process.

The company has processed over a million images from thousands of sites across five continents in all imaging modalities. Its computer-assisted masked reading (CAMR) system allows radiologists to concentrate on evaluating images, while a Bio-Imaging technologist records the reader's interpretations directly into a client's customized database. It even provides a means to monitor inter- and intra-reader variability and consistency by randomly inserting images for a second comparative reevaluation. This is a great example of how a combination of technology and business process represents a step change improvement for assessing clinical trial outcomes.

### *No. 5—Information brokers*

As we expected, there were several exhibits from well-known clinical trial management system providers and ERP software companies. However, one information broker stood out for the information provided and its role in clinical trial, new product development, and post-approval surveillance processes.

The National Death Index (NDI) is part of the National Center for Health Statistics (NCHS). The NDI is a central index of death record information on file with state vital statistics offices, beginning with deaths from 1979. NCHS established the NDI as a resource to aid epidemiologists and medical investigators with mortality assessments.

NDI is available to investigators solely for statistical purposes in medical and health research, and is not accessible for legal, administrative, or genealogy purposes. Death statistics assist investigators in determining whether study participants have died and provide a crucial link to participant data, such as dates of death, death certificate numbers, and specific statistical information, including cause of death.

## **The landscape of clinical trial service providers**

These observations are examples of the advancements life sciences vendors have made in R&D processes and supporting technologies. To help guide life sciences companies with their new product development strategies, AMR Research is preparing a landscape of technologies and processes—look for it in a future Industry Value Chain Bulletin. In the meantime, please let us know your thoughts on the state of new product development processes and supporting technologies by contacting us at [wmcdonnell@amrresearch.com](mailto:wmcdonnell@amrresearch.com) or [hmooraj@amrresearch.com](mailto:hmooraj@amrresearch.com).

## **Related research**

- "Clinical Trial Supply Chains: A Look Ahead"

