Carolyn Gretton

Building a Better E-MACHINE

Technological innovation remains essential to ensuring companies' success in the data-driven Pharma 3.0 environment.

According to Ernst & Young's Progressions 2011 report, the next-generation pharma ecosystem continues to gain complexity, with initiatives expanding across a broader array of technologies, including a boom in health-related smartphone apps.

IDC Health Insights' biannual Leading Indicators in Life Science IT Spending Survey, released earlier this year, found that sales and marketing ranked first in terms of company IT spending focus, with 40.5% of respondents stating that sales and marketing was currently their company's top area of focus.

In a June blog post on the study results, Eric Newmark, program director, business systems strategies, IDC Health Insights, said the results come as companies look to upgrade and enhance their salesforce automation tools, CRM, closed-loop marketing, e-detailing functionality, and related analytics capabilities.

According to Ingo Elfering, VP, core business services, business transformation at Glaxo-SmithKline, one burgeoning investment area is "big data" solutions that generate analytical insights and responses using data collected from a broad, diverse variety of sources.

"These systems provide a significant upgrade to what we used to do with spreadsheets and pen and paper," Mr. Elfering says, adding that GSK recently made a large investment in this space in its consumer goods area.

Greg Barrett, VP, marketing, for Daiichi Sankyo, says efficient use of technology will continue to be required to accelerate effective implementation of sales and marketing tactics.

"Keeping marketing and sales connected in real time will be a vital part of this new model," Mr. Barrett adds.

With physicians and their staffs able to find so much information and tools online, Mr. Barrett notes it's important that sales reps bring specificity and speed to the table when they do get into the doctor's office.

"Physicians need accurate answers to specific questions and they need them quickly," he says. "Some issues can be addressed via online tools, but companies that offer comprehensive answers quickly will bring real value to the partnership with healthcare providers."

Dr. Michael Ackermann, senior VP, global commercial solutions, at Quintiles, cautions that in a rush to achieve resource efficiencies, biopharma companies may be tempted to let the promise of new technology drive their multichannel sales efforts.

"Technology-based solutions are often viewed as a magic bullet — a cost-effective way to reach audiences with a tailored message," he says. "This can be a mistake. Strategy must always come first, and then the most cost-effective solution can be identified." (To read more about how a multichannel option can support a the conversation with multiple stakeholders, please turn to the thought piece Multi-Channel Sales Solutions: The Evolving Sales Model.)

Elliott Berger, VP, global marketing and strategy at Catalent Pharma Solutions, says marketers have to build on their classic skills of understanding the needs of their audience and developing optimal messaging to motivate the desired action in two key areas.

"One area is to develop an understanding of the new media options and customer behavior across these options, including interactions, context, and different goals for different media consumption," Mr. Berger explains. "This is important in new online and social platforms.

"The other area involves building proficiency and partner networks to supply an ongoing stream of interesting content to place in front of customers at the right time, in the right

INGO ELFERING *GlaxoSmithKline*

"While the already-vast number of health-related applications for mobile devices continues to grow true innovation in the space is only now beginning to emerge."

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channel, with the right message for that context and time in the buying funnel," he adds.

Gaining Mobility

Mobile technology continues to be a strong driver of e-solutions innovation in the healthcare space on both the consumer and physician sides. According to Manhattan Research's Cybercitizen Health U.S. 2011 study, 26% of U.S. adults have used their mobile phones for health information or tools in the past 12 months, more than double the 12% cited in the 2010 survey.

Information-gathering, whether by searching for health information or consuming health news, remains the most common mobile health behavior; however, there has been an increase in consumers using their mobile phones to manage their care or treatment in the past year. The Cybercitizen survey found 8% of consumers used prescription drug refill or reminder services on their mobile phones in 2011, compared with 3% in 2010.

Harry Greenspun, M.D., senior advisor for health care transformation and technology at the Deloitte Center for Health Solutions, says mobile health will become an important factor in issues spanning medication compliance, postmarket surveillance, DTC marketing, and recruiting and conducting clinical trials.

"Mobile health will enable innovative capabilities such as remote monitoring for greater patient safety and support for clinical effectiveness," Dr. Greenspun says. "It may also help reduce costs and increase benefits through greater compliance, variable dosing based upon remote monitoring, early interventions, etc."

Mr. Elfering says GSK is exploring potential mobile opportunities in various countries and partnering with external groups and entrepreneurial companies to test different mobile information or delivery methods and where they might best fit with the company's strategies.

"Depending on which country you're in, the opportunities in the mobile space are very different," he observes, citing the different rules governing SMS messaging as one example. While receiving SMS messages is a free service in some countries, in others, mobile companies charge recipients for each SMS message, making useful applications like reminder services a potentially onerous cost burden that could affect acceptance by the user.

"The business case for mobile solutions is something that is very much driven by the country environment, the population, and the types of phones that are out there," Mr. Elfering says. "It's something that has to go down to an individual market level, knowing the cus-

tomer in terms of physicians and patient populations, knowing the capabilities that they have, and really zeroing in on the value-add that will spur the customer to use these services."

VIEWPOINTS

FRANK PIJPERS
CEO
eClinso

Migrating to the Cloud

There should be a well-thought out migration plan identifying the objectives of the project and the responsibilities and timelines for selection and implementation of the applications. Implicit in this is that quality and service are equally important as cost. Next, a risk-management plan should be implemented to minimize security concerns and to identify contingency procedures. Finally, training is critical. This should include an interactive demo to enable users to become proficient with the new systems and business processes.

JOHN BLAKELEY
Executive VP and Chief Commercial Officer
eResearch Technology Inc.

IT Integration

Integration can take several forms from a more simple data integration process using CDISC models such as ODM and SDTM, or xml, or SAS formats for data transfers to more complex integration methods using Web services or application programming interfaces. The key to overcoming integration challenges is to establish an interface control specification that defines how both parties will conduct integration. As part of this, it is important to define file formats and to define the Web service or application interface specifications. It is also important to establish how a system changes and how upgrades will be coordinated to ensure such upgrades will not cause new integration issues. Frequency of interchanges — real time or batch-oriented — and establishing hand shaking between the

integrations are also essential to confirm proper processing.

JOHN WOODS
Senior VP, Business Development
J. Knipper and Company

Integrated Value Network

From our perspective, the main challenge constraining successful integrations is not usually based on technological limitations, but most frequently on the expectations of those participating in the extended (integrated) value network. In order for complex process and system integrations to yield all of their promised value, the business has to first define in exactly what way(s) the value is expected to be generated (i.e. more effective outreach, cost reductions, decreased time to market, etc…) and how the key stakeholder intend to measure that value. Each network participant must then look at their process in terms of contribution to total value which cannot realistically be done in a vacuum. Therefore a cross-organizational leadership team must be established to share strategic purpose, to provide implementation oversight, and to confirm that anticipated value is received.

JIM O'DEA
President and CEO
LeveragePoint Media/Rx EDGE

A Technology Boost

Technology solutions have tremendous potential to support medication therapy and in particular to boost compliance. A challenge in integrating these solutions, and the only way to really unleash their potential, is through measurement. It is critical to evaluate the effectiveness of technology in two key ways: one, impact: did it shape patient behavior and improve out-

In another Manhattan Research study, ePharma Physician v11.0, about 38% of so-called ePharma physicians reported having seen a pharma or biotech sales rep use an iPad or

other tablet during a face-to-face meeting in the 12-month period ending in June 2011. But study findings suggest marketers have significant room for improvement in fully leveraging the interactive features and capabilities of these devices to support a customized, efficient discussion with doctors.

"iPads are all the rage for pharma at the moment, which makes sense given the potential of these devices to support intelligent, nimble sales conversations," says Monique Levy, VP of research at Manhattan Research. "Unfortunately,

comes?; and two, usage and engagement: in what ways did the patient interact with the technology? These questions can ideally be answered by evaluating patient-level data.

PATRICK CHASSAIGNE
Director, Late Phase Solutions
Medidata Solutions

Planning for Success

The biggest challenges to integrating technology solutions resides in the planning stage, as the different groups involved generally need to reach an agreement regarding data mapping, process workflow, business rules, and various group responsibilities for a given project or study. As an example, integrating EDC with a safety system can lead to a more efficient and accurate process to collecting serious adverse events by minimizing reconciliation of safety and clinical databases and providing an end-to-end safety system.

ERIC PETERSON
VP, Research & Development
MedNet Solutions

Cost Efficiencies and Easy of Use

Traditional challenges to implementing eClinical solutions have included significant upfront costs, long development timelines, and complex system configuration tools that require programming expertise. New solutions now available, however, have eliminated these barriers. Non-technical sponsor and CRO staff can use these new technologies to quickly and easily configure studies using intuitive, drag-and-drop tools. Furthermore, the solutions' lower cost, SaaS-based pricing models make them cost-effective for any type of study, even preclinical and early-phase research.

BUDDY SCALERA
Senior VP, Interactive Content and Market Research
Ogilvy CommonHealth Interactive Marketing, part of Ogilvy CommonHealth Worldwide

Brand Alignment

There is so much great new technology that one of the biggest challenges is to decide which tactics will be best for the brand strategy. New media channels, mobiles devices, and other technologies are so exciting that marketers sometimes fail to align their ideas with their strategy. It's also important to start with the key performance indicators (KPIs), so brand managers know if their media program is generating an acceptable ROI.

MIKE ACKERMANN
Senior VP, Global Commercial Solutions
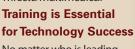*Quintiles*

Setting Strategic Objectives

Designing and implementing commercial solutions requires a strategic approach that factors in not only the commercial objectives for the product but also the biopharma company's desire to maintain personal relationships with its stakeholders and prescribers. For example, call centers may appear to be a promising way to contact many physicians at an attractive price. However, these do nothing to develop and build personal relationships, which is often a high strategic priority for biopharma firms. Similarly, relying heavily on Web-based selling may not be the best approach for a company that wishes to participate actively in multichannel activities. In an era of shrinking sales forces, one new approach is remote live detailing, where healthcare professionals are serviced either virtually or through a combination of online and face-to-face calls via the same
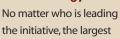
person. This allows cost-effective information sharing on a very personal level. This can increase access to less accessible physicians and territories, and increase sales reps' productivity.

DAVE YOUNG
CEO
Trifecta Multimedical
Training is Essential for Technology Success

No matter who is leading the initiative, the largest challenge of integrating an enterprisewide solution is process training. Training on the technology itself should be simple and straight forward, but having management and the users themselves invest enough time into understanding how the solution will affect one's work flow is often nonexistent. We have witnessed that if teams make this the first point of discussion when training begins, users grasp the "nuts and bolts" of the technology quicker and exhibit more enthusiasm for the solution.

RONALD S. WAIFE
President
Waife & Associates Inc.
Actualizing the Concept

The biggest challenge in integrating multiple clinical IT solutions is rationalizing the diverse reasons for each solution's original creation. They come from different needs, serve different users, on different timelines, with different rigor and criticality. It is not sufficient to rationalize a data dictionary; it is necessary to identify how the disparate data can contribute to actionable knowledge. We must ensure that the resulting information product is truly a synergistic benefit, and is not outweighed by the difficulty to achieve it.

A Certificate of Trust

Mollie Shields-Uehling, president and CEO of the nonprofit SAFE-BioPharma Association, believes a critical best practice for life-sciences and healthcare organizations moving to the cloud is the adoption of a standards-based, secure authenticated interoperable digital identity and digital signature. According to Ms. Shields-Uehling, the standards for such digital identities need to be globally prevalent and recognized, subject to identity-proofing processes, and based on interoperable technical standards.

"A standards-based interoperable digital identity allows an organization to trust the identities of those with which it is conducting business over the Internet," she says. "It also enables the company to engage in legal contracts and sign regulatory-compliant documents, as well as protect the privacy of patients and safeguard sensitive information."

Mollie Shields-Uehling

Ms. Shields-Uehling notes that current Internet authentication processes, even in an industry as regulated as healthcare, is generally limited to a user-name and password that can be easily forged or shared, making for an extremely untrustworthy system.

Recently, SAFE-BioPharma introduced a one-time password roaming credential that eliminates the need for a specific software or certificate download, which often interfered with other computer software or applications.ware or applications.

"When a user wants to access the SAFE-BioPharma credential, he or she logs on to a computer and requests that a one-time password be sent to a second preregistered device, such as a mobile phone or tablet computer. The password can even be sent to an office phone via voice message," Ms. Shields-Uehling says. "The user then enters that one-time password, gaining access to the SAFE-BioPharma credential, which is stored in the cloud. It's highly mobile and highly flexible."

Ms. Shields-Uehling says she ultimately envisions a system based on standards facilitating interoperability where people in the life-sciences and healthcare spaces can trust each other's identities and do business in a way that's secure and HIPAA-compliant, and that protects patient privacy and the intellectual property of companies conducting research.

some of the detailing programs that are being rushed out the door are subpar; they are really no better than tactics seen on tablet PCs six years ago. Doctors won't waste their time with these."

Mr. Barrett believes that to effectively access the full potential of mobile technology such as iPads, as well as other technological advances, companies need to treat them as tools to enrich the dialogue between sales rep and healthcare provider.

"Technology will never eliminate the need for human interaction," he says. "Companies that understand how to leverage technology to enhance the value of their engagement with healthcare providers will succeed, while companies that try to replace all human interaction with technology will ultimately fail, or at least fail to reach their full potential."

While the already-vast number of health-related applications for mobile devices continues to grow, Mr. Elfering believes that true innovation in the space is only now beginning to emerge.

"For example, there are hundreds of weight-tracking applications that allow people to enter eating habits and calorie information and so forth into their smartphone," Mr. Elfering explains. "There's even one application that allows the user to take a photo of a meal, and the application uses interesting new technologies to estimate the number of calories that dish contains. It may not be exact or totally accurate as of yet, but it's a very different use case than replicating an activity that could be done with pen or paper.

"It's this type of innovation and entrepreneurial thinking that will start to catch on over the next few years, spinning out new mobile applications that we're not even thinking about currently and that may be of much more value to customers than just translating a current paper-based process or computer-based process to a mobile device," he concludes.

IT in R&D

About 29.7% of respondents to the IDC Health Insights study named research as their top IT spending priority, and 19.8% ranked clinical development as their first priority. Interestingly, while clinical development placed higher than manufacturing and supply chain in terms of company focus, it is actually receiving slightly less IT spend.

Mr. Newmark noted this is most likely due to a stronger need to upgrade older manufacturing and supply chain systems, coupled with the increased difficulty of switching IT

platforms in the middle of existing clinical trials and the already widespread existing use of more modern CTMS and EDC systems.

Patrick Chassaigne, director, late phase solutions, Medidata Solutions, says implementing EDC in Phase IV studies and registries can present unique challenges since it is a departure from the "status-quo" and familiar randomized clinical trials models.

"For these real-world studies — characterized by a large number of research-naive sites and long duration — it is essential to use an EDC solution that is intuitive and flexible to meet specific study requirements, therefore leading to increased satisfaction and retention of site investigators and patients throughout the study," he says. (To read about the opportunities companies have to change the way they interact with patients as they design new studies to capture real-world data, please turn to the thought piece: The Increasing Role of the Patient in Phase IV Studies and Registries.)

Given the overwhelming volume of data now being created for biomarkers at the functional level, Kimberly Ramko, Americas life sciences sector leader for Ernst & Young, predicts more sophisticated methods of data aggregation and semantic search technologies are going to become the norm.

"Simulation modeling techniques will be leveraged to create virtual patients based on the combination of existing provider, payer, and clinical data in specific disease states," Ms. Ramko explains. "Researchers are going to team more with health informatics experts or become an expert themselves to be speed up the discovery timeline."

Dave Young, CEO of Trifecta Multimedical, says one of largest challenges with technology is managing the expectations across a broad range of stakeholders.

"In many cases, requests come from multiple stake holders who have varying levels of technology knowledge and expertise," he says. "Each has an idea of what they would like the technology to accomplish and what the value proposition is for the service," he says. "This is especially true if the solutions is new to the organization and there is no historical foundation to help guide stakeholders." (To read how to successfully implement online investigator training for clinical research, please turn to the thought piece: Online Investigator Training in Clinical Trials: A Roadmap for Success.)

Floating on a Cloud

Cloud technology, which encompasses software as a service (SaaS) solutions as well as database, storage, and email services, has be-

come an integral part of most pharmaceutical companies' IT strategies.

John Blakeley, executive VP and chief commercial officer, says to ensure cloud best practices, it is vital that a thorough audit of vendors takes place, with the following considerations taken into account: ability to scale, security policies, level of experience, financial stability, and problem resolution practices.

"The ability to scale applications to meet demand is particularly essential," he says. "Characteristics of a truly scalable application include the ability to handle heterogeneity, operational efficiency, a resilient service, the ability to increase resource results in a proportion to the increase in performance, and a service that becomes more cost-effective when it grows. It is also vital that security policies are implemented in every step of the cloud application architecture. Physical security is normally handled by a service provider of the cloud application, while network and application level security are the responsibility of the business. It is vital to ensure that data in transit and data at rest are protected, in addition to ensuring the protection of AWS credentials. (To read about how mulitmode technology options can best capture outcomes assessments, please turn to the thought piece: Health Outcomes Research — An Evolution Towards Personalized Medicine and the Digital Future.)

Mr. Elfering says his company has moved several application areas to the cloud.

"Generally speaking, I think the more hori-zontal a business process is, the more likely it is that there is a good, well-established market-place with a cloud-based solution," he says. "The more vertical the function, the less likely there may be a readily available environment, at least at this point, for cloud-based solutions. The big benefit is that the cost can spread across lots and lots of customers."

Steve Gransden, VP of marketing, at J. Knipper and Co., says aside from the ever-present need for strong ROI, by far the greatest challenges include process fit and flexibility.

"Of the many e-solutions available within the many verticals of pharma, each with its unique attractors and detractors, it is the choice that provides the biggest challenge; few provide either a broad enough baseline usability, or a granular enough set of configuration controls to insure that the solution integrates with the process," he says. (To read more about the fit and flexibility involved in implementing e-solutions, please turn to the thought piece: Not Just Another Pretty Face...)

In terms of best practices for using the cloud, Mr. Elfering stresses the importance of shifting the mindset from the requirements-led mindset typical of most internal IT groups to more of a solutions-led mindset.

"While it's important to understand the goals and what needs to be achieved, it's equally critical to remember that in this particular use the company is not building or customizing its own solution," he says. "The IT team should be using the product that is offered in the cloud as it is preconfigured and designed, then tweak it based on the configu-ration capabilities, rather than trying to change the product itself."

Mr. Elfering adds that shifting to cloud-based solutions also requires a more cross-functional approach by the IT team.

"In the past, there might have been a business analyst front-ending the solution to the business, and then, if necessary, people from infrastructure, networks, and other teams would get involved," he says. "With SaaS, the company really needs to bring in a cross-function team from the legal, performance, IT, and business sides — experienced people from a requirements perspective who know how things work and what the business ultimately can live with."

Buddy Scalera, senior VP, interactive content and market research, at Ogilvy CommonHealth Interactive Marketing, part of Ogilvy CommonHealth Worldwide, agrees that cross-functionality is vitally important when implementing an e-solution.

"As with all digital pharma projects, it is important to connect early with the legal affairs team," he says. "They need to understand the core technology, the security concerns, and the privacy issues. Have a few discussions in the beginning to outline what you want to put on the cloud, so they can give you feedback and direction. If you are developing an application or plan to store personally identifiable information, make sure it is HIPAA-compliant." (To read about new opportunities for health marketers looking to engage patients, please turn to the thought piece: Enter the Age of the E-Reader.) **PV**

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