

→ Technology at the Speed of **LIGHT**

The Internet's potential 10 years ago was just a glint in Web entrepreneurs' eye. Today, its power and reach are creating new markets, revolutionizing business practices, and seamlessly connecting the world's life-sciences community.

The impact that the Internet and follow-on technologies have had on all areas of the life-sciences is well-documented throughout this special section, and the majority of our thought leaders have identified this as the biggest game changer in the last 10 years. Going even further, these same thought leaders believe technology — in all its forms — will continue to revolutionize the industry at an ever-increasing pace for the next decade.

"The biggest paradigm shift in the industry has been technology," says John Racik, president and CEO of Stonefly Communications Group, a healthcare communications company. "In particular, there has been a tremendous change in how technology has emerged and evolved across all channels and socioeconomic segments. It has brought forth the ability for all patients, consumers, caregivers, and payers to share and understand the same information that used to be the sole scope of the healthcare professional. As communicators, we now can have two-way conversations instead of being influenced solely by big business that has historically tried to drown out competition. Technology has evened the playing field so big, small, and emerging companies can have the same shot at winning the hearts and minds of their target audiences."

Technology has had such a significant impact on the industry — from the way products are developed to how companies interface with physicians to the way everyone communicates in the workplace, says Kim Huggins, owner and president of K HR Solutions, a human resources consulting firm.

"Technology has changed the way all busi-



"As more technology is deployed to solve major healthcare problems, new ways of getting product information into the hands of those who need it will also be developed."

SHARON CALLAHAN / LLNS

"As businesses continue to become even more global, technology will be a driver for success and a competitive advantage within the life-sciences industry."

KIM HUGGINS / K HR Solutions

ness is conducted," she says. "I am constantly amazed at the pace at which technology changes and how it is being leveraged in the industry. As businesses continue to become even more global, technology will be a driver for success and a competitive advantage within the life-sciences industry."

Jim DeSanti, CEO of PharmaVigilant, a clinical trial service provider, agrees that technology will continue to be a catalyst, shaping the market for the next 10 years.

"Regulatory agencies will increase their need for transparency into data and the processes needed to collect and analyze it," Mr. DeSanti says. "The industry, with significantly reduced headcount, will have to in-



crease its reliance on technology to close the gap, which it has successfully done in other sectors of its businesses. Furthermore, as the call for internal and external transparency grows, the need for sponsors to have ultimate control over their data increases in parallel, as they are ultimately responsible."

Looking forward, experts say there will be a further convergence between healthcare and technology.

"The Internet, social media, tablets, mobile apps, etc., are only the tip of the iceberg,"

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JOHN RACIK / Stonefly Communications



“Healthcare information technology connectivity will prove to be one of the most substantive market shaping aspects to healthcare in the next 10 years.”

KEITH RUARK / Avos Consulting



tailored to the individual, says Kristie Zinselmeier, director of marketing, BioPharma Solutions, a business unit of Baxter that partners with pharmaceutical companies to support their commercialization objectives.

“Health monitoring applications and personalized health history information can be integrated with communication devices and provide the next advancement in information technology,” she says. “The demands on the life-sciences industry to maintain its information stewardship responsibility

will increase in complexity and importance. This information advancement may facilitate the evolution of further alternate site healthcare settings, such as retail pharmacies as sites of delivered care. Furthermore, the portability of information and the increased level of available information and knowledge enhance the possibility that access to care may be increased in underserved populations and geographies.”

In the E-Clinic

“As I reflect on the last 10 years, the expanded and more effective use of technology within clinical trials has been the biggest game changer, bringing clinical research professionals more closely together,” Mr. Andrus says. “Expectations for these personnel have required game plan changes. Data managers and monitors need to work more closely together and systems need to be up and running with a full complement of features and functionality ready for the entry of site data. Roles and responsibilities around query management and data review require close coordination. The silos have started to come down and groups have started to work more closely together and bring their expertise to the table to affect overall study quality.”

At the time of this writing, the iPad and other tablets are less than a year old and are already changing the way clinicians operate because of its ease of operation and portability, says Colin Miller, Ph.D., senior VP of medical affairs at BioClinica.

says Sharon Callahan, CEO of LLNS, a healthcare advertising communications agency. “As more technology is deployed to solve major healthcare problems, new ways of getting product information into the hands of those who need it will also be developed.”

Filling in the Gaps: EMR

Beyond social-media applications, Ms. Callahan says for example, EMR technology will lead to new ways that bridge the communication gap between physicians and patients, and play a role in improving patient adherence.

Deborah Schnell, president of sales and strategic planning at the healthcare information company Healthy Advice Network, believes the universal implementation of EMR and e-prescribing will drive healthcare decisions in the future.

“Automated health records will enable us to determine the actual cost of using a generic over a branded drug — if indeed there is one — and patient outcomes will be infinitely trackable, increasing the ability to affect change,” she says. “Increasing adherence, lowering the abandonment rate, and encouraging compliance will have a greater likelihood of success. Yet, it is also ultimately conceivable that physicians who are compensated on health outcomes and armed with such readily available information will choose to de-select those patients who do not comply with their

recommendations or even be forced to choose treating only the healthiest patients.”

From a clinical standpoint, the use of EHR will continue to change the way clinical research data are collected.

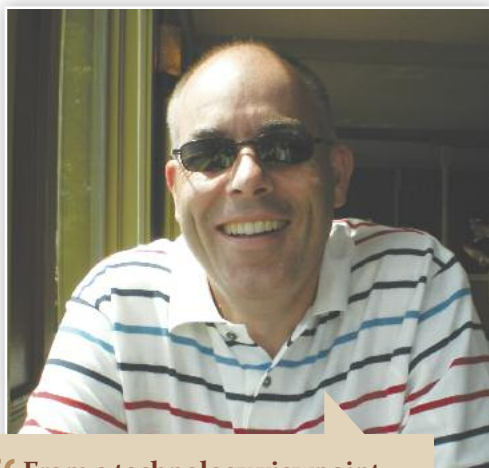
“As a result of the 2009 stimulus package incentives, which included incentives for adopting EHR, medical professionals will continue to increase their use of the technology,” says Jennifer Price, senior director of clinical solutions at BioClinica, a global provider of clinical trial management services.

“Sites will no longer be willing to enter data into an EHR system and then re-enter the data into an EDC platform,” she says. “This process change is forcing technology providers to find a standard way to move these data electronically into clinical research databases in a safe, secure, validated manner that meets all regulatory requirements.”

Jonathan Andrus, VP, data and study operations, at BioClinica, concurs that the expanded use of electronic health records and their impact on clinical trials will continue to change the way the game is played.

“How data are monitored, verified, reviewed, cleaned, and overall managed, is going to change,” he says. “Collaboration will become even more important in the next 10 years.”

With the continued development of technology capabilities and miniaturization, it is logical to see a further advancement of health-related information, although it is likely to be



“From a technology viewpoint, medical imaging has played a major role in the development and acceptance of new therapies.”

DR. COLIN MILLER / BioClinica

“A second-generation version is under development and there are now several new wannabes coming onto the market,” he says. “With such a huge change occurring by one new product in such a short period of time in the clinical arena, the use of this technology and the potential to change the face of medicine because of the interaction with the patient and ease of information cannot be underestimated. This will have a major carry over effect into clinical trials and the way products are marketed to patients.”

Neil Matheson, CEO of Huntsworth Health, a provider of consulting and communications services, believes technological advances, including ongoing development of the Internet, will play a major role in the next 10 years.

“It is now possible to replace a heart valve using a catheter and to perform a coronary artery bypass procedure via intercostal ‘keyhole’ surgery,” he says. “These procedures are the result of major technological advances. Additionally, the speed at which these advances are being made is accelerating. Information is being shared in real time, resulting in immediate knowledge enhancement. The challenge for all of us is to keep up with this rapid pace of change to ensure we are fully using the opportunities that will be generated.”

Dr. Miller says from a technology viewpoint, medical imaging has played a major role in the development and acceptance of new therapies.

“While the FDA is still reliant on clinical

end points for primary efficacy evaluation, there are a number of new biomarkers that are now being used for Phase II and go/no go decisions,” he says.

“For example, molecular imaging is now a term that is almost commonplace compared with 10 years ago,” he explains. “The Radiological Society of North America (RSNA) has launched the Quantitative Imaging Biomarker Assessment (QIBA) under the leadership of Dr. Dan Sullivan with the mission to evaluate and develop new quantitative imaging biomarkers initially for clinical trials but also to take this into clinical practice.”

Furthermore, the FDA has slated to produce its first set of draft guidelines on the use of medical imaging in clinical trials by the end of 2011, Dr. Miller explains.

“Medical imaging has had a significant impact and will continue to do so,” he says.

To the Cloud

Healthcare information technology connectivity will prove to be one of the most substantive market-shaping aspects to healthcare in the next 10 years, says Keith Ruark, VP of Avos Consulting, a division of INC Research and a strategic consulting and research products firm.

“The need for connectivity across the care continuum is increasing given market pressures facing payers, providers, and healthcare product companies,” Mr. Ruark says. “Parks Associates recently estimated 2010 revenue from the digital health market in the United States already exceeding \$1.7 billion. Information technology advances in mobile health coupled with emerging interoperability standards will redefine care boundaries, support more coordinated care pathways, and build the evidence base to underpin more rationalized care. This will certainly impact the current care environment but also open up new avenues for the integration of systems and processes within R&D.”

The need to develop drugs and new products quicker and in a more cost-effective manner will continue to be a driving need for the life-sciences industry, agrees Michael Naimoli, worldwide managing director of Microsoft Life Sciences, a provider of software solutions.

“A big market shaper will lie in collective development, where we’ll see organizations collaborating around, or bidding on, early-

stage products shared by others through an online data market,” Mr. Naimoli says. “The way this will become a reality is through the cloud, as companies continue to grow comfortable with cloud-based solutions and recognize and want to take advantage of the cost and time savings.

“The evolution of cloud computing over the last year or two has been a significant game changer for the industry,” he continues. “Life-sciences executives know they need to move their focus off IT and back on development and discovery, yet at the same time provide researchers and scientists with the tools needed to do their jobs faster and better. As a result, we’ve seen companies outsource traditional IT platforms, including messaging and calendaring, to the cloud, saving up to 30% in operational costs. And, we’ve seen companies use cloud-based computing to give their researchers and scientists access to compute intensive applications, such as 3D, reducing data processing time from hours to minutes.” **PV**

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