Future Breakthroughs

The PharmaVOICE 100 discuss what's on the research and commercialization horizons.

The PharmaVOICE 100 honorees had much to say about where they thought future breakthroughs will be. On the development side, personalized medicine and advances in cancer immunology will create new breakthrough treatments for patients. Additionally, technology in general and mHealth, EMR, and cloud-based systems in particular are expected to make continued contributions to healthcare and the pharmaceutical industry.

On the commercial side, changes in agency-industry relationships will enable companies to better reach patients.

The Data Revolution

Many of the PharmaVOICE 100 honorees talked about how technology is changing our ability to manage and analyze data.

In fact, understanding technology change is no longer the realm of the IT team, say executives from Accenture in a report last year. Organizations that adapt a digital mindset will be the ones best prepared to anticipate and respond to technology-driven disruption.

Half of biopharma companies now have a metadata management project under way, according to a survey conducted by SOA Software. This finding shows that metadata management is emerging as a compelling solution for many biopharma businesses. The top drivers are data quality, regulatory compliance, and business process efficiency improvements. Biopharma companies are seeking metadata management technology solutions more than ever. But only 10% of companies actually have a technology solution in place.

In healthcare data, we're going to start seeing companies trying to centralize patient records, where patient data, medical history, lab and doctor visits are not isolated by hospitals or clinical trials anymore, but rather in a central database where hospitals can access and update the data, says Will Cheung, director of customer solutions, Comprehend Systems.

"This will significantly increase patient safety and reduce costs of each party storing and maintaining data in isolation," he says. "If these data are accessed anonymously, researchers can start spotting trends and outcomes of certain diseases."

Chris Trizna, president of CSSi, says there is already a tremendous amount of information available, but it's not organized in a way that can used effectively for our industry.

"Once we are able to pull this information together, we can bring patients and studies together more effectively," he says.

Neil Gleghorn, CEO of Kallik, says a breakthrough will happen in terms of adoption of technologies that enable data connectivity used in many other industries.

"I see much more connected working practices across multiple departments," he says.

Technology will be a critical enabler, says Dan Goldsmith, general manager, Europe, at Veeva Systems.

"The biggest breakthrough will be interactive, accessible, cloud-based hubs that make it easy for pharma to gather data, orchestrate processes, and reach a wide base of customers effectively, bring safe and effective drugs to market faster, and produce products that are aligned to a targeted treatment approach," he says.

Mr. Goldsmith points out that today's consumers have new tools and information available to them, including access to reliable data and studies.

"This is a dynamic that's in play across multiple industries now," he says. "It will only grow over the next five years, and I think this trend will contribute to the complexity of determining who the customer really is. It will be more important than ever for pharma to create a dialogue with the larger healthcare community, and respond quickly to change."

Julie Ross, executive VP at Advanced Clinical, says a breakthrough in the industry will be business process automation.

"It is prevalent in most industries, even regulated industries such as banking, and it is one of the few ways we will be able to make a profound impact on lowering the cost infrastructure of clinical trials," she says.

The better use of data and information and conversion of that into knowledge will lead to smarter and more insightful drug development, says Badhri Srinivasan, senior VP and head, global data and safety monitoring at Quintiles.

Data standards will become important, several PharmaVOICE 100 say.

Mark Wheeldon, CEO of Formedix, says wholesale adoption of clinical data standards due to regulatory pressures will lead to use of standards earlier in the clinical trial process.

Kenneth VanLuvanee, president and CEO, Virtual Regulatory Solutions, says the implementation of eCTD V4 will become a global standard.

"The new eCTD standard, based on the HL7's RPS effort, will allow sponsor organizations to deliver easier-to-review submissions to health authorities in a much more flexible environment," he says "eCTD V3 was a great start, but was fairly rigid, especially when compared with paper processes, giving a reason at times for continuing to submit in paper. eCTD V4 returns flexibility to the process, while keeping things fully electronic. It should result in better communication between industry and regulators, which means better reviews and safer therapies to market faster."

One of the worst things in science — or any systematic enterprise — is to gather data without a sharply defined question, says Jeffrey Berg, Ph.D., senior VP, director of client services at AbelsonTaylor.

"To a certain extent, many of those who are hawking big data are proposing doing just that," he says. "I believe that breakthroughs in advertising and beyond will come from people who can carefully craft those questions and use big data to provide the answers."

Tracy Foster, president of the Lash Group, says the deployment and adoption rates of technology such as e-prescribing, e-prior authorization, and EMR integration will significantly increase the time providers can spend on patient care and reduce the industry's reliance on manual and time-consuming processes.

The global market for electronic health records (EHR) is estimated to reach $22.3 bil-

HOPE FOR A BETTER FUTURE

The PharmaVOICE 100 honorees discuss the breakthroughs they believe will impact the future of healthcare.

LISA ADLER
Takeda Pharmaceuticals
(At press time, Ms. Adler is now with Ironwood Pharmaceuticals)

My hope is that we can solve the problems that are inherent in today's system that stymie innovation and prevent people in need from getting the healthcare they deserve.

ANN AERTS, M.D.
Novartis Foundation for Sustainable Development

My hope is that more challenges arising from unequal access to healthcare can be addressed on a large scale.

MATTHEW D'AMBROSIO
Sunovion Pharmaceuticals

My hope for the future of healthcare is that many of the unmet medical needs of patients are addressed. There are still some devastating illnesses without effective therapies; stroke and Alzheimer's are two that come to mind.

ROBERT FORRESTER
Verastem

My greatest hope for the future of healthcare is that we truly can convert cancer into a chronic condition for many patients, so that it becomes a manageable, chronic disease and not an all-consuming death sentence.

RICHARD ALAN GAMS, M.D.
Novella Clinical

I hope to see the day when no one in the world is denied quality medical care.

JOHN GLASSPOOL
Baxter BioScience

I hope that we can eventually reach a state in which this industry is recognized as a critical partner to improve the health and quality of lives of the people we serve, rather than as a cost to the system.

DIANE ILER-SMITH
Ogilvy Healthworld

My hope for the future of healthcare is that the promise of gene therapy is realized and results in cures for serious and debilitating diseases such as ALS and Alzheimer's disease.

BOAZ MENDZELEVSK
BioClinica

I wish that all people, wherever they live, will have access to effective healthcare systems and programs, and will benefit from a better quality of life, including end-of-life.

JAN NIELSEN
Sonexus Health

My hope is that we appropriately align incentives for payment based on quality and outcomes. I would like to see more collaboration across all the stakeholders — manufacturers, specialty pharmacies, providers, and payers.

YVONNE PATERSON, PH.D.
Advaxis

My hope is that we will be able to offer quality healthcare to all in our society and not just those who can afford to pay for it. I strongly believe that health is not a commodity that should be bought and sold in the market place.

MIRANDA POTHIAWALA
Samarind

I hope we find ways to prevent disease and disability or deal with them naturally rather than just curing them or managing the symptoms with medication.

KEN RIBOTSKY
Brandkarma

My dream for healthcare is to create a functional system that can balance the need between providing access to care for everyone with the ability to create innovation without the limitations that we are currently seeing.

MICHELLE ROHRER, PH.D.
Genentech

My hope is that the advances we've had in science to understand disease biology will translate into meaningful benefit to patients.

DINAH SAH, PH.D.
Voyager Therapeutics

My hope is for better drugs that can be accessed by more people worldwide.

KENNETH VANLUVANEE
Virtual Regulatory Solutions

I'm hopeful for a closer relationship between providers, patients, and therapy developers. I see this emerging as part of our industry conversation now and I'm hopeful that this will lead to development of therapies with value to the patient communities.

lion by the end of 2015, with the North American market projected to account for $10.1 billion or 47%, according to research released by Accenture.

A recent report from Kalorama Information finds there is still no one clear leader in the EMR market and there is opportunity for entrants, particularly in Web offerings. Due to the fragmented industry, there seems to be room for additional mergers and acquisitions and new players.

Daniel Ghinn, CEO of Creation Healthcare, also sees EMR as a breakthrough.

"Electronic medical records that are patient-owned and truly portable between health systems and providers internationally is likely," he says. "It's a dream to think we could see this within five years, but one day it will happen, I hope in my lifetime. The possibilities then will be endless. I want to learn from conversations among healthcare professionals how these technologies play a part in identifying new practices or ideas that bring about better healthcare."

More than half (51%) of U.S. consumers with chronic conditions believe the benefits of being able to access medical information through electronic medical records (EMR) outweigh the perceived risk of privacy invasion, according to the Accenture 2014 Patient Engagement Survey of more than 2,000 U.S. consumers.

Michelle Marlborough, VP, product strategy at Medidata Solutions, says real-time data will play a larger role in the broader healthcare environment.

"It can be tricky to incorporate real-time data into the day-to-day operations of healthcare service and clinical research, but as buy-in increases from patients, doctors, industry, and regulators, real-time data has the ability to greatly improve health outcomes and research outcomes," she says. "Regulators are looking for tightly controlled data, and new technology in mHealth can help generate strong data, as well as generate data at a lower cost. Mobile health can lower the burden on patients, make excessive visits to clinics unnecessary, all while

providing timely and relevant information to the sponsors, doctors, nurses and researchers collaborating on a study. It gets back to access. We're entering an age where we can not only access more information than ever before, but we can access the right kind of information that has a real impact on health."

Jim Curtis, chief revenue officer and chief advertising officer at Remedy Health Media, says mobile and wearable trackers are a fast growing sector that will provide breakthroughs for patients.

"With major industry movers such as Apple getting into health I think there are interesting times ahead at the intersection of life science and technology," he says.

The global mHealth monitoring and diagnostic medical devices market was valued at $65 million in 2012 but is expected to grow at a CAGR of 43.3% from 2013 to 2019, to reach an estimated value of $8.03 billion in 2019, according to a recent report from Transparency Market Research.

Mobile health is super exciting, says Joe Doyle, director of digital strategy, at HCB Health.

"I enjoy wearables and fund startups that hit the crowdsourcing market," he says. "The notion that will soon get diagnostics from ingestibles is fascinating as well. I truly think we'll see more entrepreneurs building their own device models using digital printing and finding unique ways to fund their adventurous ideas."

Researchers at Deloitte say the promise of mobile health and the use of mobile devices to support the practice of medicine and public health is profound but, as yet, unrealized. mHealth strategies are not a one-size-fits-all.

Deloitte suggests that healthcare organizations — providers, payers, and life-sciences companies — should consider each of the four dimensions of mHealth as they weigh market entry: demographics; local infrastructure; reimbursement and regulatory issues; and disease dynamics.

Life-sciences companies, according to Deloitte, should focus on building better relationships with consumers through population health and medical compliance initiatives; understanding how stakeholders — governments, health plans, providers, patients — define, determine, and value mHealth; and leveraging gamification and approaches based on behavioral economics to increase adherence, brand awareness, and user preferences.

Stephan de la Motte, M.D., chief medical advisor at SynteractHCR, says while computers are part of daily life and have brought huge advancements in diagnostics, but for therapeutic purposes, in my opinion, computers are still under-utilized today.

"Bio-sensors, parallel computing, and modern genetic or neuronal algorithms will facilitate the construction of devices unprecedented in history," he says. "Retinal or cochleal chips to make the blind see or the deaf hear are already being tested, and this is only the beginning."

Personalizing Medicine

The development of personalized medicine continues to be an area that the PharmaVOICE 100 say is going to change healthcare. Biopharmaceutical companies have increased R&D investment in personalized medicine by 75% between 2005 and 2010, according to the Pharmaceutical and Research and Manufacturers of America.

Ten years after the Human Genome Project began, there were 104 drugs with pharmacogenomic information on the label, according to the National Human Genome Institute. The genotyping of drug-metabolizing enzymes has produced improved dosing of drugs for conditions as wide-ranging as depression and anxiety, coronary and peripheral artery disease, inflammatory bowel disease, and cancer. This has helped patients avoid harmful side effects, adverse drug interactions, or ineffective treatment. Yet much remains to be done to realize the promise of personalized medicine, say leaders at the Personalized Medicine Coalition.

James Powers, CEO of HemoShear, says our understanding of genetic differences among patients will lead to better, lower-cost diagnostics so that treatments can be tailored for patients.

Raman Singh, president, Asia Pacific, Latin America, Middle East, Africa, at Mundipharma, says truly accessible personalized medicine will increase efficacy and reduce cost to the payer.

"Targeted therapies will lead to remissions, if not cures of some diseases, and justify the cost of innovation," he says.

Boaz Mendzelevski, M.D., VP of cardiology at BioClinica, says personalized medicine has great potential, but in the near term it will also likely increase costs, which may slow development and uptake.

Dr. Berg says the combination of genetic mapping and diagnostics will help us begin to realize the promise of personalized medicine.

Much more widespread use of biomarkers and the molecular profiling of many more cancer types are going to radically change oncology in coming years, predicts Jonathan de Pass, founder and chief executive of Evaluate.

"If such discoveries manage to translate into other therapy areas — the confirmation of genetic or molecular drivers or targets for cardiovascular and CNS diseases — this would be a huge breakthrough," he says. "It would not only allow more targeted drugs to be developed, it would aid in patient selection. Being able to pre-select the patients most likely to respond has driven a lot of success in oncology studies. I think there is great hope in the CNS and CV fields that such advances will be made in coming years, although work is at a much earlier stage than in oncology."

Many patients do not benefit from the first drug they are offered in treatment. For example, 38% of depression patients, 50% of arthritis patients, 40% of asthma patients, and 43% of diabetic patients will not respond to initial treatment, according to a recent report from the Personalized Medicine Coalition. The majority of patients have at least one DNA-based

FDA Policy and Guidance Documents on Personalized Medicine

- 2013 Guidance on Clinical Pharmacogenomics: Premarket Evaluation in Early-PhaseClinical Studies and Recommendations for Labeling
- 2012 Guidance on Clinical PG: Premarketing Evaluation in Early Phase Clinical Studies Guidance on Clinical Trial Designs Employing Enrichment Designs
- 2011 E16 Guidance on Biomarkers Related to Drug or Biotechnology Product Development: Context, Structure, and Format of Qualification Submissions Guidance on in vitro Companion Diagnostic Devices
- 2010 Guidance on Qualification Process for Drug Development Tools
- 2008 E15 Definitions for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories
- 2007 Guidance on Pharmacogenomic Tests and Genetic Tests for Heritable Markers
- 2005 Guidance on PG Data Submissions Concept Paper on Drug-Diagnostic Co-Development

Source: PwC Health Research Institute

variation in the enzymes that metabolize half of the most commonly prescribed medicines.

Yvonne Paterson, Ph.D., professor and associate dean at the University of Pennsylvania and scientific founder and consultant at Advaxis, says the ability to analyze and diagnose disease on an individual patient level is going to expand.

"In the cancer field this is already a reality and it is now routine at top cancer centers to do GWAS sequencing of tumors to identify drug targets for a particular tumor," Dr. Paterson says. "And this is going to become a reality for many other diseases as well, and, though it may be expensive, it will improve patient care and avoid the costs of treating patients with drugs that they are not likely to respond to and that may have serious side effects."

Andrea McGonigle, managing director, life sciences, at Microsoft, says personalized medcine will be taken to a whole new level.

"There are tests that can be done today to know what diseases you may have, how you might react to one statin versus another, and how your weight can affect your health, but they are not widely available as a commodity," she says. "I see these tests becoming a check box in your annual physical and this information will be made available to you and those you chose to share it with. This will change the way scripts are written, how drugs are taken, and what medicines are reimbursed and put on formulary."

Personalized medical care has the potential to reduce healthcare costs worldwide, an effect particularly salient in the United States, where the cost of healthcare is on an unsustainable upward climb. Incorporating personalized medicine into the fabric of the healthcare system can help resolve many embedded inefficiencies, such as trial-and-error dosing, hospitalizations due to adverse drug reactions, late diagnoses, and reactive treatment. It can also play an important role in the implementation of Accountable Care Organizations (ACOs) set up under the Affordable Care Act (ACA) to coordinate patient care and reduce costs, say those at the PMC.

For example, the Mayo Clinic and the pharmacy benefits manager Medco put the model to the test in a 3,600-subject prospective study. Hospitalization rates for heart patients were reduced by about 30% when genetic information was available to doctors prescribing the drug.

Therapeutic and Development Advances

Several PV100 honorees mentioned the possibility of breakthroughs in the area of immunology.

Jennie Fischette, executive VP, director of

client and strategic planning services, Concentric Health Experience, believes one of the biggest breakthroughs in the next five years will be in immuno-oncology.

"Immuno-oncology is focused on using a patient's own immune system to generate medications," she says. "This new wave of medications will focus on patients with high unmet needs and are pushing us into an entirely new realm of science. It has the promise of true breakthrough science and that is exciting for the category overall."

According to a recent report from IMS Health, innovation in cancer therapies is becoming more targeted. New drug development has yielded significant innovation across cancer types and therapeutic approaches, including preventive vaccines. Pharmaceutical company investments remain high and cancer therapies account for more than 30% of all preclinical and Phase I clinical development products, with 22 new molecular entities being launched and reaching patients in the past two years alone. While much of the pipeline is focused on lung and breast cancer, tumor types with lower prevalence such as ovarian, leukemia, stomach, and liver cancers also are being actively pursued.

Ken Ribotsky, CEO of Brandkarma, believes that scientists will find new ways to either shut down cancer in its early stages or at the cellular level by stopping normal cells from becoming cancerous.

"An area that I think will explode is vaccine therapy that generates an immune response so that a person ends up fighting the cancer from within his or her body, rather than traditional treatments like chemotherapy and radiation that cause such devastating side effects," he says. "We're starting to see some promise of it now, and this is just the tip of the iceberg."

Diane Iler-Smith, executive VP, chief creative officer, Ogilvy Healthworld, says immuno-oncology agents will help transform cancer into a chronic disease.

Pablo Umaña, Ph.D., head of oncology research and large molecule research, at Roche Pharma Research and Early Development (pRED), says the industry is working on achieving durable responses in a large number of cancer patients by using combinations of immunotherapies and personalized healthcare approaches.

Robert Kotin, Ph.D., VP of Voyager Therapeutics, says there has been research on the immunogenicity toward the virus vector and transgene product.

"At the current rate of progress, we expect that with a combination of virus vector capsid modifications, routes of administration, and prophylactic treatments, many of the limitations may be ameliorated," he says. "In addition, within five years, we should establish a serological ranking system for predicting which patients will be the best and the worst candidates for gene therapy."

Robert Forrester, president and CEO of Verastem, says a breakthrough will be the development of drugs targeting cancer stem cells, which can be used in combination with existing therapies, including surgery, chemotherapy, molecularly targeted drugs and immunotherapeutics that fundamentally changes the way cancer is treated.

"Patients, and their physicians, deserve an armamentarium of treatments to manage their disease as a chronic condition," he says.

Advances on the Commercial Side

Our PharmaVOICE 100 touched on many issues in the marketing and commercial side of the business.

Ms. Fischette says we are going to see more proactive promotion in the social space.

"We see companies dipping their toe in now," she says. "To form a true brand connection with the patient, there has to be a two-way dialogue. The social connection is a lure for many brands because the patients desire that connection. I think by 2019 we will figure how to go there and be there authentic in our approach."

Ms. McGonigle says patient engagement will become even more important.

"Our industry today looks at patient programs at the drug or therapy level," she says. "Some programs focus on education, have technology as simple as texting to using Kinect and Healthvault to improve physical therapy. There is no one patient strategy driving the industry across the board, yet we are all focused on the same patient population. Patients are demanding to take control of their health through technology for both themselves, their children, and their parents. I believe someone will emerge as a leader in this space and it will be through a partnership of cross vertical collaboration and tied with a technology partner to deliver a broader patient strategy that will drive real results and better care at a lower costs for patients."

Sydney Rubin, chief communications officer at inVentiv Health, says there will be continuing expansion of the role of patients and healthcare consumers, which has only just begun.

"Changes will be vast and we already see hints of what's to come in the empowerment of patients in the physician-patient relationship, in desperate parents setting up their own pharmaceutical companies, in the power of Change.org to force policy changes by government and the private sector," she says. "The breakthrough of the patient will only pick up steam as more and more digitally savvy Baby Boomers reach retirement and begin accessing Medicare. There are dozens of business opportunities to be capitalized on from this changing landscape."

Michelle Keefe, chief operating officer, Publicis Touchpoint Solutions, says within the next five years, we will have solutions that allow for healthcare manufacturers to have an option to deploy field sales teams in some very unique and creative ways.

"I believe it will become the norm to have every communication channel fully integrated and able to inform (via big data) the channel, timing, and message for each physician," she says. "Big data is going to provide us with greater opportunity to impact healthcare at a macro level.

More companies are adopting more customer-centric approaches. More than half (58%) of U.S.-based companies surveyed have implemented a customer-centric sales strategy, according to new sales management research by Cutting Edge Information.

Patient-centric salesforces can leverage real-time claims data and other information to identify opportunities within a physician's patient group. Representatives can then provide relevant information to physicians by targeting specific cases and drawing attention to the company's value-adding initiatives.

Other salesforces focus their customer-centric efforts on physician-specific needs. Commercial teams may leverage field data and segmentation to determine rep-physician communication patterns, including discussion topics and promotional material content and format. Reps may also pay close attention to physicians' schedules and the types of information that most impact doctors' specific patient groups.

Still other life-science salesforces blend patient- and physician-focused efforts in their commercial approaches. During these visits, reps present two important product perspectives: what the product does and how it helps physicians treat patients.

Matt Brown, general manager at ICC Lowe, says a new and much needed agency model is needed, one that recognizes not only the way customers are engaging and communicating about healthcare, but one that also addresses the unique challenges and significant changes within our industry. PV

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