On *the* Horizon

The PharmaVOICE 100 honorees discuss where future breakthroughs will occur in research and on the commercial side.

The PharmaVOICE 100 have much to say about where they believe industry breakthroughs will be. Many of the PharmaVOICE 100 hope and believe there will be breakthrough discoveries that lead to new therapies in many areas, including HIV, cancer, Alzheimer's, as well as neglected diseases such as malaria and other life-threatening diseases.

Other honorees point to advances in stem cell research, biomarkers, and epigenetics as leading to tremendous advances in the future. On the commercial side, many believe there will be continued emphasis on physicians and patients in healthcare.

> "With the ability to collaborate and share data in the cloud, the industry is now coming together in a number of very interesting ways."
>
> **BRIAN LONGO** / Veeva Systems

A Call for Industrywide Collaboration

Brian Longo, general manager of commercial products, Veeva Systems, says collaboration, both internally within a pharmaceutical organization and across the industry, will be the driver behind significant breakthroughs over the next five years.

"By eliminating internal barriers across research and development and commercial, the industry will be better able to predict and understand the impact and root cause of pipeline failures, adverse reactions, and product withdrawals," he says. "Through improved collaboration, companies can realize more efficient pipeline development, better time-to-market, and faster commercialization."

Mr. Longo says external partnerships through industrywide cooperation in nonproprietary, nonstrategic areas additionally will lead to breakthroughs.

"With the ability to collaborate and share data in the cloud, the industry is now coming together in a number of very interesting ways," Mr. Longo says. "Harnessing the power of crowdsourcing, collectively, companies are able to build a more holistic view of the customer than would have ever been possible alone and the aggregation of data to uncover trends is providing far-reaching insights that are unprecedented."

Graham Simpson, Ph.D., head, chemistry performance unit (CPU), GlaxoSmithKline, agrees that collaboration is imperative for discovering and creating access to medicines for those in the least developed countries.

"There is a need to change business models, for disruptive innovation, and understanding the real challenges on the ground," he says. "These issues must be tackled by collaboration between companies, charities, governments, and global institutions."

Adrienne Robinson, director, business affairs and alliance management, at Merck, says because of the extraordinary challenges that put tremendous pressure on delivering innovative medicines to the patient, companies need to bring all their forces together across what may seem like disparate purposes or industries to find ways to deliver better healthcare to people.

"This means that collaboration, more than ever, is important and it will have to happen inside individual companies as well as externally," she says. "Collaboration will have to span multiple industries, academic institutions, nonprofit organizations, and governments to put together never-thought-of-before solutions and approaches."

FAST FACT

BY 2020, PHARMA COULD BE INVESTING AS MUCH AS 20% OF ITS R&D BUDGET IN GENETICS AND GENOMICS FOR DISCOVERING AND COMMERCIALIZING NEW DRUGS.

Source: PwC

Personalizing Medicine

Personalized medicine was identified by more than a few honorees as an area that holds tremendous breakthrough potential.

In fact, Accenture consultants say a future in which personalized, or precision, medicine becomes a reality, new sources of information, including genetic profiling, will enable biopharma companies to target participants more effectively for clinical trials and treatment.

Mark Curran, Ph.D., VP, systems pharmacology and biomarkers at Janssen Research & Development, part of the Janssen Pharmaceutical Companies of Johnson & Johnson, says

personalized medicine will become a reality for more patients and as a result will drive higher remission rates, reduce side effects, and demonstrate what is achievable for disease eradication.

"The value of the human genome will become increasingly apparent over the coming decade," says David Rear, president and founder of Advanced Clinical Concepts. "In the same way that structure-activity relationships drove the design and development of drugs in the past, the human genome holds a key to the next phase of our industry's evolution."

John Mendlein, Ph.D., executive chairman and CEO of aTyr Pharma, says with very large databases related to the genetic composition of people, researchers will be able to understand human health, as well as human disease.

"That will allow us as a society to direct better nutrition, better utilization of therapeutics, better treatment regimes for many, many different types of people," he says.

The area of genetics is taking off, industry experts say, because the ability to sequence individual genomes and the genomes of diseases is providing new avenues of research and new ways to target patients.

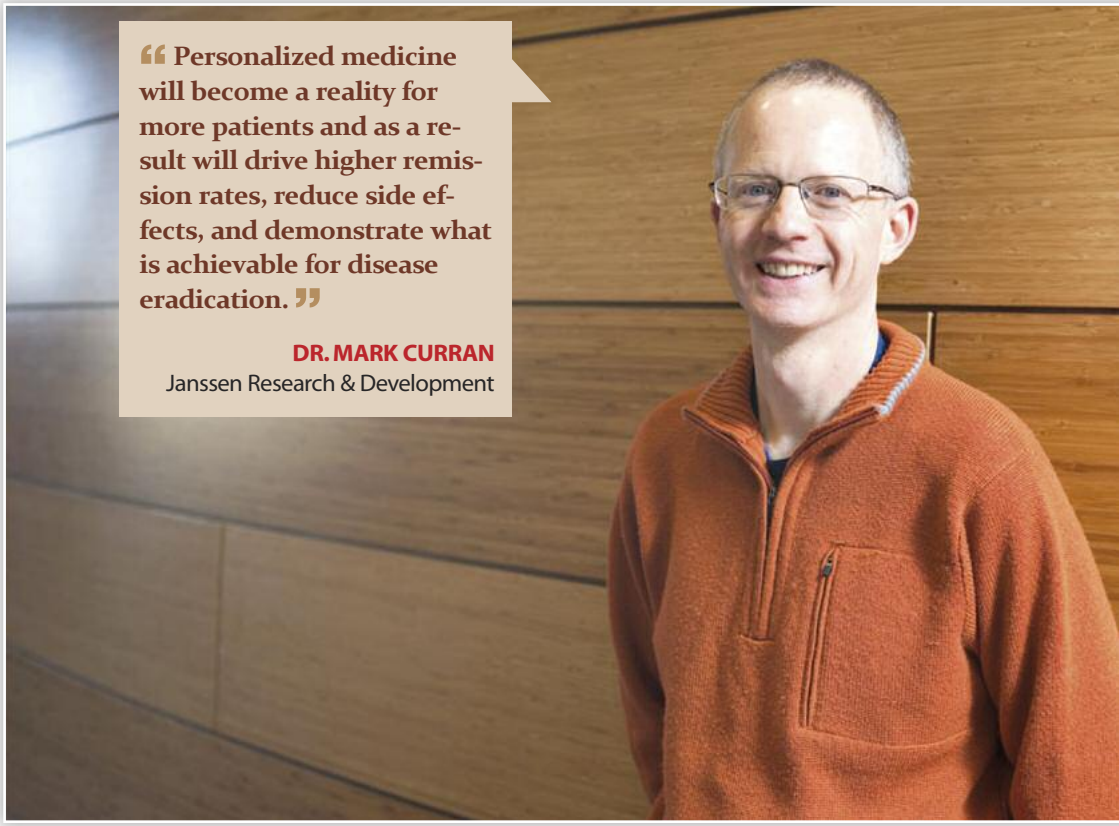
These advances will impact pharma companies in a number of ways. The first is the ability to accurately determine the cause of disease and genes that might be involved and this can help companies find targets to develop drugs.

The second is around selective biomarkers to provide information about those patients likely to benefit from treatments. These data can then be used for selection in clinical studies.

"The more we get into personalized medicine, the more we are using markers to decide who gets treated in the trial," says Kent Thoelke, executive VP for scientific and medical affairs at PRA. "We can artificially create a whole new subset of orphan-like indications and then develop drugs for those indications in a model that is efficient and financially acceptable. It is critical that we start to rethink our current process. There has to be a financial incentives; there has to be a return on investment."

Analysts from PwC estimate the industry spent just $6 billion a year — less than 7% of its total R&D investment in 2011 on genomic research. PwC researchers predict that by 2020, pharma could be investing as much as 20% of its R&D budget in genetics and genomics for discovering and commercializing new drugs.

According to BCC research, the global market for personalized medicine technology is projected to reach $29.2 billion in 2014. Pharmacogenomics is a major revenue generating market, contributing about 28.7% to the total personalized medicine market in 2009, at $4.1 billion; this should reach $9.5 billion in 2014, for a CAGR of 18%.



"One of the areas that I see as a breakthrough in healthcare is personalized medicine at a whole new level," says Andrea McGonigle, managing director, life sciences, Microsoft. "Today, tests can be done to know what diseases people may have, how they might react to one statin versus another, and how weight can affect health, but they are not widely available as a commodity. I see these tests becoming a check box in an individual's annual physical and this information becomes available to be shared. This will change the way scripts are written, drugs are taken, payments are reimbursement, and what is on formulary."

Walter Capone, chief operating officer of the Multiple Myeloma Research Foundation, believes advanced and inexpensive molecular profiling, including patient as well as tissue-specific genetic sequencing at the point of care, will enable precision therapies to be used in the proper sequence for the best and most durable responses in patients.

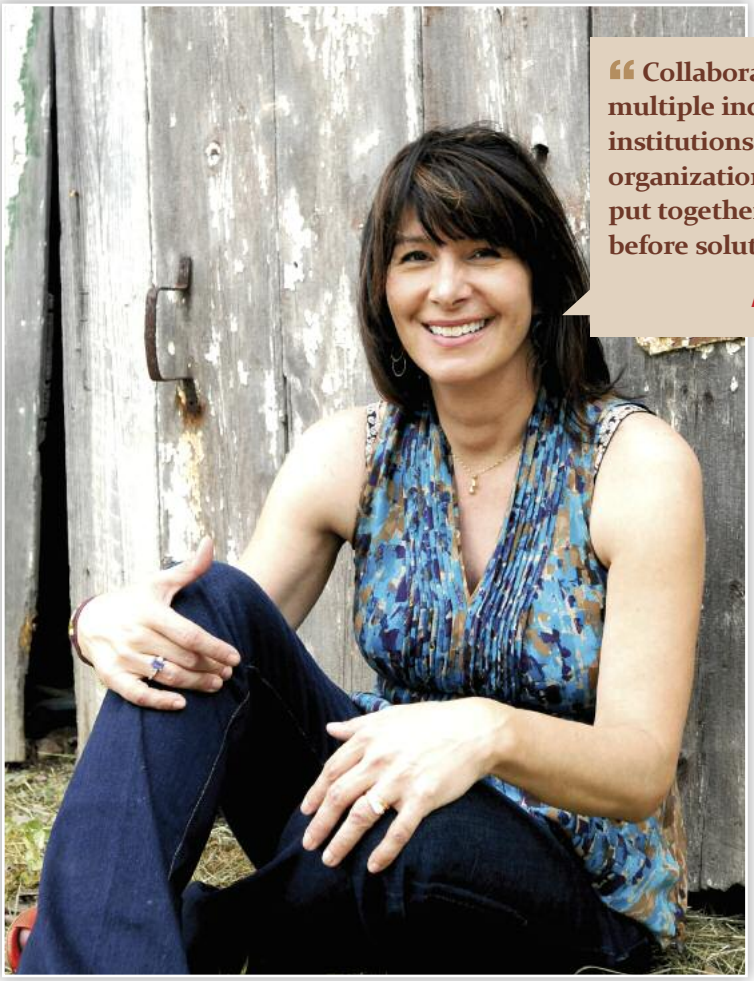
"A systems-biology approach to assessing and managing diseases, using molecular and 'omics' data, will target not just a particular symptom or abnormality but the entire network of pathways contributing to and perpetuating them revealing approaches to mitigate disease development and progression," he says.

Christian Behrenbruch, CEO of ImaginAb, prefers the term "precision medicine" instead of personalized medicine.

"I never liked the term personalized medicine because I always felt that medicine was personal," he says. "But the idea of precision medicine is a great one. We're going to get smarter, more targeted, and more precise about the way in which we develop new drugs and the way in which we deploy new therapies across all fields of medicine. Diagnostics and therapeutics will be fundamentally entwined with each other, and regulators and reimbursement agencies will have to begin to look at medicine with a holistic view. We need to make robust investments and provide a realistic reimbursement environment for both diagnosing and treating patients' conditions."

Daniel Kraft, M.D., chair of medicine at Singularity University, executive director of FutureMed, and founder of IntelliMedicine, says the convergence of big data in genomics and beyond with big analytics, connected to mobile technologies and diagnostics in the hands of empowered patients, will lead to better outcomes, lower costs, and a healthier society.

On a clinical level, Mr. Capone says effectively harnessing the immune system through the advancement of immuno-therapeutics — mAb, gene, miRNA-based, etc. — combined with targeted therapeutics, may lead to the cure of certain types of cancer, and will certainly render many cancer types as chronically



> **"Collaboration will have to span multiple industries, academic institutions, nonprofit organizations, and governments to put together never-thought-of-before solutions and approaches."**
>
> **ADRIENNE ROBINSON** / Merck

managed disease through intermittent and/or sequential therapy.

"In just the last three years, we have seen the first generation of such agents capable of this approach, with many more to come," he says.

One of the biggest breakthroughs in the laboratory area in the next five years will be the transfer of technology from the social side of the world to the science side, says Ken Rapp, senior VP and managing director analytical, development, quality, and manufacturing segment, at Accelrys.

"You can easily Google a topic and get instant results, but if you want to know the history of a medicine's life cycle, you can't find it with a simple search," he says. "If I'm in research and want to know when a product was manufactured or which company contributed to its development, there isn't an intranet or database that connects the dots between research, development, and manufacturing. If we really want to learn from the history of a cancer medicine and bring that knowledge up and downstream, it can't be done today electronically. Bringing technology models like Facebook and Google into science will be game changing."

The McKinsey Global Institute recently estimated that applying big-data strategies to better inform decision making could generate up to $100 billion in value annually across the U.S. healthcare system, by optimizing innovation, improving the efficiency of research and clinical trials, and building new tools for physicians, consumers, insurers, and regulators to meet the promise of more individualized approaches.

Honorees also mention that genomics will enable new therapies for hard-to-treat diseases.

There will be an evolution that leads the industry away from traditional drug discovery to the discovery of therapies that are more curative than palliative, says Sharon Presnell, chief technology officer at Organovo.

"This means that companies will need to shift focus away from single target drugs, and onto strategies that interfere with multiple pathways at the same time to get to the root of what causes a particular disease in a particular individual," she says. "In the next five years, I would like to see a curative regenerative medicine product, either a drug or tissue, reach clinical trials."

Antony Loebel, M.D., executive VP and chief medical officer at Sunovion Pharmaceuticals Inc., says there will be more focus in CNS on understanding the genetic basis of major mental illnesses and neurological conditions such as bipolar disorder and Alzheimer's disease. This new knowledge will likely lead to the discovery of novel treatment options for patients who are resistant or unresponsive to current treatments.

Another area related to gene expression is epigenetics. Epigenetics — the study of changes in gene expression — is rapidly emerging as a field that presents tremendous opportunity for drug discovery. This area of research looks at environmental impacts when genes are turned on or off.

"Epigenetics can influence how proteins are up-regulated or silenced through lifestyle, diet, and exercise, impacting our response to disease," says David Ormesher, CEO of closer-look. "This is more than just 'living right.' There is a growing body of scientific evidence that suggests that we can alter not only our own gene expression but also that of our offspring. This has potential significant impact on public health."

With the aging population increasing in numbers and the rising incidence of oncology and non-oncology disorders, such as Alzheimer's and arthritis, the demand for epigenetic diagnosis and drugs is also expected to increase.

The global epigenetics drugs and diagnostic technologies market was valued at $1.6 billion in 2011 and is expected to grow at a CAGR of 19.4% from 2012 to 2018 to reach an estimated value of $5.7 billion in 2018, according to a recent study by Transparency Market Research.

Fatima Scipione, associate director, Velcade patient and nurse marketing, Millennium, says one thing is for sure, novel, ground-breaking medicine will be necessary to improve the quality of care for future generations.

"New medicines will hold a significant place in the prevention, treatment, and management of many diseases that the baby-boomer generation will be living with," she says. "In 2000, there were about 35.6 million Americans who were 65 or older. By 2030, that number is projected to double to an estimated 71.5 million. Diseases such as Alzheimer's and diabetes represent a growing risk for patients and systems' ability to afford appropriate healthcare. We know that we have to do better in our lifestyles as do our healthcare organizations to avoid a colossal disease burden and financial burden to patients, families, employers, and governments."

The Technology Component

In the clinical trial arena, David Bruggeman, president and chief operating officer at Clinical Research Advantage, says technology will be key to future innovations.

"Technology has streamlined the clinical trial process and the transfer of information," he says. "I expect that we will integrate more technological solutions over the next five years. We will find new ways to incorporate technology in recruitment, data collection, and patient monitoring."

Abbe Steel, VP, patient and physician services, at UBC, says one of the biggest breakthroughs in clinical development will be the increase in patient-centric studies.

"Studies must be designed with the patient in mind," she says. "Today, there are a tremendous number of channels with which to com-

> **"There will be a transformation of healthcare marketing from selling features and benefits to helping people make more confident healthcare decisions and experience greater levels of health and well being."**
>
> **ALEXANDRA VON PLATO**
> Publicis Healthcare Communications Group

municate with patients. The Internet has not only facilitated increased patients' access to information, but it has also enabled new pathways for patients to find and access research. And while social network sites, blogs, online communities, email groups, and other tools allow people to share information, they are still largely underutilized in clinical research today."

Ms. Steel says these communication mechanisms are truly transforming traditional care models and could be used even more in clinical research.

"Companies, now more than ever, must incorporate the technology and trends of today into clinical trials," she says. "People connect and communicate online, or through their smartphones, so our study designs must accommodate this. It is my hope that the research models of tomorrow will incorporate patient-centered designs and leverage technology to facilitate better research, less expensive research, and bring drugs to market faster."

One of the single biggest opportunities changing the paradigm in clinical trials is patient recruitment, says Bob Klein, chief strategy officer at Blue Chip Marketing Worldwide.

"The most progressive pharma and biotech companies are partnering with us much earlier in the development process to unearth insights and identify clinical study candidates who are not only most likely to participate, but remain committed and compliant once they enroll in the study," he says.

Technology will also have an impact on regulatory affairs, says Mauricha Marcussen, CEO of Auditgraph and Agano Solutions

"I envision new technology that will allow life-sciences companies to harness intelligence from their big data sources in a way that we have never seen before," she says "Imagine if we could connect our product lifecycle data — from the laboratory to research and development to clinical research to regulatory affairs to manufacturing — in a way that adds valuable insights and ensures accuracy of key safety parameters. The breakthroughs will come when we begin to connect our data sources and systems to one another in a way that benefits not only the end user and senior management, but also accounts for health authority interactions and keeps pace with evolving regulatory guidelines."

Breakthroughs in Marketing

David Zaritsky, president at Roska Healthcare, says creating configurable experiences based on preference, disease state, and where the patient is in his or her journey will be the basis of experiential marketing.

"This will make the shot-gun approach of traditional marketing look antiquated and insufficient," he says.

Experiential marketing focuses on delivering a personal, positive experience for customers throughout their relationship with a brand, product, or service.

This approach allows customers to engage and interact with brands in a narrative that goes far beyond providing information, Mr. Zaritsky says.

Personal experiences help people connect to a brand and make intelligent and informed purchasing decisions.

Other honorees on this year's PV 100 list echo that there will be continued emphasize on physicians and patients in healthcare. Ms. McGonigle says there is no one patient strategy driving the industry across the board.

"Yet, we are all focused on the same patient population," she says. "Patients are demanding to take control of their health through technology for both themselves, their children, and their parents. I believe the leaders in the space will emerge through partnerships of cross-vertical collaboration that includes a technology partner to deliver a broader patient strategy that will drive real results and better care at a lower costs for patients."

Calvin Butts Jr., VP of strategic services at CMI/Compas, says patients and insurers are no longer settling for a low-value healthcare experience.

"Our biggest challenge in the next five years is to deliver value to patients and payers," he says. "They will expect high-quality care and a satisfactory customer experience delivered at a sustainable price. Additionally, doctoring is becoming a lot less about 'laying on of hands' and more about information management. This will mean there will be less of a push of information and more of a relationship built with prescribers. And I say prescribers because this relationship will extend beyond physicians to include NPs, PAs, and providers. Data will allow this shift, as we better understand what makes prescribers tick and the information of value that we can provide to them. Once they see pharmaceutical companies as true resources, they will regard our industry as part of their essential diagnostic toolkit."

There will be a more robust understanding of comparative effectiveness and more aggressive approaches to messaging, says John Guarino, executive VP, managed markets and global payer access, Palio+Ignite Managed Markets.

"We have amazing information available but manufacturers sometimes struggle with their understanding of the legislation that allows them to inform payers," he says. "The industry is so conservative and risk averse, a lot of the best opportunities are being lost. As the ACA moves the definition of value from cost to outcomes, it will be up to us to ensure we have the technologies and smarts to create programs that effectively communicate that effectiveness."

Alexandra von Plato, president and global chief creative officer at Publicis Healthcare Communications Group, says there will be a transformation of healthcare marketing from selling features and benefits to helping people make more confident healthcare decisions and experience greater levels of health and well being.

Richard Russell, executive VP and chief commercial officer, Sunovion Pharmaceuticals, says one of the biggest breakthroughs will be the ability to customize interactions with healthcare providers and patients based upon the insights identified on their unmet needs.

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>
> **DR. CHRISTIAN BEHRENBRUCH** / ImaginAb

> **"There will be an evolution that leads the industry away from traditional drug discovery to the discovery of therapies that are more curative than palliative."**
>
> **SHARON PRESNELL** / Organovo

This means marketers will have to harness big data to improve healthcare, says Matthew West, VP, chief talent officer, McCann Regan Campbell Ward, a division of McCann Health.

"Ninety percent of all data in the world was created in the past two years, with a mind-boggling 2.5 quintillion bytes being created every day," he says. "Innovative companies are starting to mine the mother lode of medical data to curb medical mistakes, waste and unnecessary treatments, lower healthcare costs, aid drug development, and facilitate tracking patients' outcomes."

Mr. Ormesher says data will provide increased transparency and integration across sales, marketing, and service efforts.

"Similar to the connected health movement, there will be a growing connected marketing trend that will empower physicians and consumers to access personalized health content and enable marketers to get smarter about how they create and provide health value to the market," he says.

The digital health space is going to have a huge impact to the conventional way of thinking about healthcare, says Punit Dhillon, president, CEO, and co-founder of OncoSec Medical.

"This is going to evolve even further as people are looking at other digital health devices that can share information more readily and be connected to the overall health network," he says. "Over time we hope that the digital health network becomes more knitted so that patients can take a measurement of their own vitals, for example. This can reveal different metrics that may be helpful for a physician when they have discussions with other healthcare providers. The digital health space will be transformative in terms of the industry relying on new tools that makes the network more knitted with one another."

The use of mobile technology in the form of wearable monitoring devices will be a big breakthrough, says Marc Weiner, managing partner, at Ogilvy CommonHealth Worldwide.

"I'm looking forward to wearable devices that use near field communications to monitor important health data," he says. "We know that many patients ignore important symptoms for days to years. If we can get people to see a doctor before an underlying condition causes permanent damage, we can dramatically cut the cost of healthcare and improve health outcomes. And perhaps most importantly, the next generation of patients will be more in tune with proactive health management, since they have tools to reward health-positive behavior."

We are at the start of a breakthrough in access to healthcare and health management, says Tim Davis, co-founder and CEO of Exco InTouch.

"The industry is just starting to recognize the opportunity, and the value, of using patient-centric devices," he says. "Right now, platforms are starting to integrate tools such as data capture applications and medical devices. I think smartphones, in terms of access and integration, will revolutionize clinical trials and healthcare approaches."

David Escalante Jr., senior VP, OneKey and marketing, Cegedim Relationship Management, says the convergence of medical devices with EHRs with consumer mobile applications and their general adoption by the public and primary care physicians could be the key to truly getting more people actively involved in managing their own health on a day-to-day basis.

Michael Kelly, CEO of Kantar Health US, says the growth of electronic medical records will allow physicians and others to longitudinally see how interventions are impacting patient outcomes.

"The transformation to big data as well as our ability to access much more individual patient data will lead to breakthroughs that ultimately will be great for patients," he says.

The continued adoption of electronic medical records across healthcare will help companies locate, screen, and enroll patients for trials much quicker, says Jeff Kueffer, senior VP, global operations management, at INC Research.

"With EMR data, we'll be able to electronically screen patients and identify those who may best benefit from a particular treatment," he says. "Once identified, subjects can be provided information either through contacting them directly or through consultation with their healthcare provider. In addition, access to EMR data will allow researchers to evaluate their protocol's inclusion/exclusion criteria toward ensuring there are sufficient patients in the population who meet the criteria for a study."

Last year's Accenture report predicted that patient-specific longitudinal EMR data will be coming together with genomic and genetic data, financial data, and electronic patient-reported data to deliver real insights into optimizing care management and evaluating which therapies provide the highest overall value to patients and healthcare systems. Being able to combine information from EMRs and e-prescribing will enable tracking of a patient's outcomes over the care continuum and is critical to the provider's ability to demonstrate outcomes that result from care for which they should be reimbursed. The outcome-based reimbursement models of the future will require complete, deep, longitudinal data that clearly illustrates positive patient outcomes. PV

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