BY ROBIN ROBINSON

ELECTRONIC RECORDS:

Beneficial to All, But at a *Price*

{ The future of electronic health exchange has a rosy glow, but the road from here to there will be rocky. }

Benefits for Pharma

Our experts discuss the benefits that pharma companies might realize from a systemswide, interoperable electronic system, such as better trial data, better measurement of drug safety and efficacy, and the potential for reduced costs.

STEEL. PA CONSULTING GROUP. The drive toward EMR implementation is part of a wider revolution taking place in healthcare to improve outcomes and address unsustainable increases in cost. EMRs are important enablers of both and ultimately will support the collation and analysis of data. The availability of these data will drive therapy selection and reimbursement, as is already being seen in other countries, for example, in the United Kingdom with the National Institute of Health and Clinical Excellence. Whether this is a benefit or a risk to pharmaceutical companies depends on how early and how effectively they engage as a key player in shaping the change.

REID. UNITHINK. The benefits to pharma are overwhelming in terms of using accurate and timely EHR data to revolutionize the clinical-development process and deliver drugs and devices faster and cheaper to patients. This impact is widespread and encompasses using these data to identify diseases faster, plan and fund new therapies faster, design more agile clinical programs, recruit patients and sites more effectively, and ultimately save time and the lives of patients around the world.

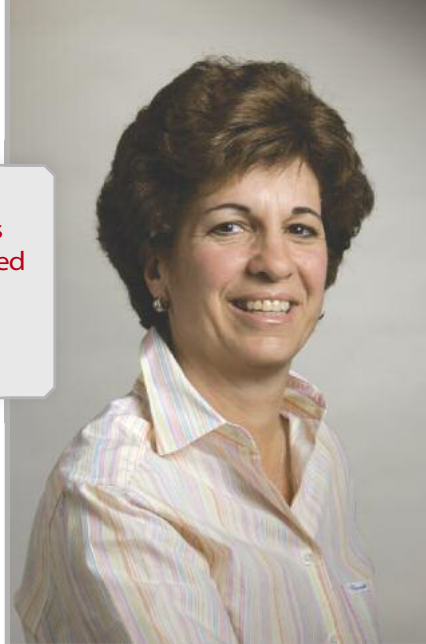**CEVERHA.** PRICEWATERHOUSECOOPERS. One of

The next five years will represent significant growth toward the implementation of electronic medical records (EMRs) in both hospitals and physician offices. Several factors are driving this new momentum, including the recent release of Notice for Proposed Rulemaking on the electronic health record certification process, an increased level of optimism by physicians to implement EMR as represented in several studies, and the approaching deadlines for hospitals to be collecting electronic health records data by Oct. 1, 2010, and physicians by Jan. 1, 2011. This forum explores what this next phase will mean to the pharma industry. EMRs provide real-time, continuous access to patient-related health information, saving time both in the doctor's office and in the clinical trial process. EMR data can provide the industry with a better view of a trial subject's health status, the potential patient population for a new product, and even the probability of successfully conducting a given clinical trial.

the early benefits for pharma is going to be around clinical trials. Today, only a few health systems organizations are active in participating with various pharma companies in conducting clinical trials. As the capture of data becomes automated and there is more standardization around clinical protocols, there will be opportunities for any health system organization — assuming it has fully implemented the clinical systems and developed its protocols for clinical staff — to participate in clinical trials. So the environments and opportunities for clinical trial participation will expand and create a richer data source for the pharma industry to mine. This might make it cheaper to do R&D, and it will most definitely be quicker. There are plenty of clinical trials that never go beyond the first steps because sponsors can't identify patients. The EMR can benefit pharma by making it easier to bring a brand to market. Companies will be able to get a targeted look at underserved populations and be able to market to that population specifically. It is expected that the FDA will require more controlled launches in the future, and through EMR data, pharma will have very specific populations for the launch.

CROWN. I3 INNOVUS. The availability of EMR data will greatly facilitate the analysis of real-world patient outcomes with respect to both treatment effectiveness and safety. It is currently very expensive and time-consuming to collect these data because medical records are still predominantly stored in paper format and medical record abstractors often have to physically travel to sites to obtain the records. For the same reasons, widespread availability of

EMR data may help to speed the conduct of clinical trials and reduce their costs. EMR could reduce the need to capture the data for a clinical trial that are routinely captured anyway: medical history, medications, vital signs, for example. EMR could improve the quality of data because it would involve less manual rewriting and reduced fraud through false patient records. Finally, it could reduce the cost of a trial because the data from the EMR would already be clean and thus reduce monitoring time and queries.

BAILEY. GE HEALTHCARE. The pharmaceutical industry will benefit significantly when there is more widespread uptake of EMR and HIE (health information exchange). The increased access to electronic clinical data will bring improvements to drug discovery and development in addition to improved measurement of efficacy and safety. For example, we have been able to analyze de-identified clinical data to aid researchers in optimizing clinical trial protocol design by helping them to understand the impact of adjusting various criteria on the size of the eligible population for a trial. Furthermore, EMR data can be used to identify qualified research sites with a sufficient population of eligible patients, and EMR tools can be used to assist sites in identifying and engaging potentially eligible patients. Case report forms could act as middleware, extracting data from the source document — the EMR — so that data re-entry errors are eliminated, thus streamlining the investigator's capture of clinical research data. EMRs can enable data extrapolation to create computer simulations that mimic patient results and identify needs for possible new products, as well as potential new indications for existing products.

In addition to using passively collected, de-identified data for measuring drug safety and efficacy, the EMR can be used to set up and house drug registries to collect more specific data elements, contribute to increased information on disease progression, and support patient adherence programs.

DEVINE. PATNI LIFE SCIENCES. The primary benefit to the pharma industry of a total uptake of EMR is the potential to conduct research based on a fully rationalized medical history of the U.S. population, assuming a universal access

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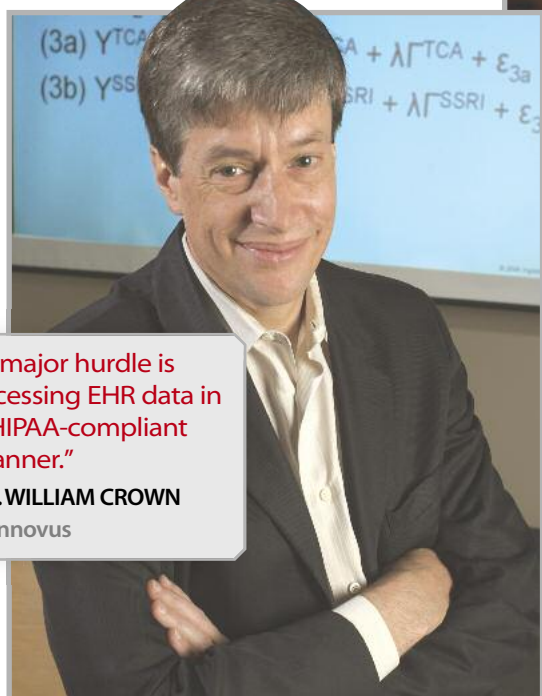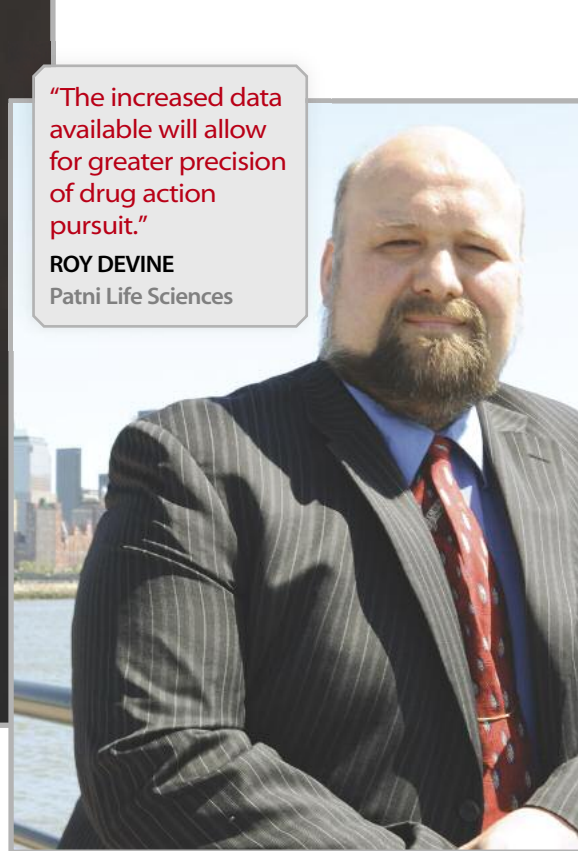
> "A major hurdle is accessing EHR data in a HIPAA-compliant manner."
>
> **DR. WILLIAM CROWN**
> i3 Innovus

> "The increased data available will allow for greater precision of drug action pursuit."
>
> **ROY DEVINE**
> Patni Life Sciences

> "Creating connectivity is only part of the challenge; the other component is semantic interoperability."
>
> **DR. RICHARD GLIKLICH**
> Outcome

control model can be implemented to deal with data privacy and security issues. One of the primary cost drivers for pharma is clinical research. The wealth of information that we can glean from in-silico research could dramatically change the way Phase IV trials are conducted and could decrease the overall cost of research because of the increased availability of exposure and outcome data for the patient population. We can power the adaptive, personalized medicine of tomorrow using the detailed information on patient demographics, even including genotype information. As we know from the development of orphan drugs, the development of tailored therapies for smaller patient populations is extremely costly. The ability to mine data for safety trends and relative efficacy will provide the information required to make better use of early-stage products, drive research direction, and make the study of smaller targeted solutions for more esoteric diseases commercially feasible. As you know, today's average cost to bring a product to market is about $800 million, therefore, the target therapies have, by necessity, been restricted to diseases that affect extremely large patient populations. The increased data available will allow us to increase the precision of our drug action pursuit, enabling the development of therapies for smaller patient populations. In my estimation, we can reduce the overall cost of bringing a new drug to market by 15% to 20% using the data available from EMR, if we use it correctly.

BAILEY. GE HEALTHCARE. Once a medication is approved and released, completely confidential patient databases can measure the actual efficacy of the medication in real-world usage through careful analysis of aggregated, de-identified EMR data. These types of studies will be critical in helping influence formulary decisions and can be used to better understand the safety profile of medications.

EASTAUGH. GEORGE WASHINGTON UNIVERSITY. EMR can help assist pharma and the government in doing comparative effectiveness research. One can compare treatment X with treatment Y to see what works best. Often comparative effectiveness research leads to more medications and higher revenue for pharma, but not always. Consider the case of diabetes. In looking at diabetes prevention, a public health faculty observed that if a patient is prediabetic, that person is better off with diet and exercise as an alternative to medication.

GLIKLICH. OUTCOME. The rapid implementation of EMR systems creates the possibility of new, clinically rich data sources to use for a range of activities from better understanding clinical practice to modeling clinical trials. The digitization of health records also offers opportunities to change the safety reporting paradigm, such as have been performed in programs such as ASTER, a pilot program sponsored by Pfizer and launched at Partners HealthCare/Brigham and Women's Hospital and now being expanded with our organization to include other health systems. This model uses an automated approach for reporting adverse events directly to the FDA from

the patient's electronic health record. The digitization of health records may also potentially improve the ability of a much broader and representative group of practices to participate in clinical, safety, and effectiveness research.

HISEY. DELOITTE. The benefits of EMR implementation include increasingly complete information with more of a focus on a comprehensive health history view, as opposed to individual transactional elements, and a better informed clinical development strategy, which will support a generation of evidence for efficacy, effectiveness, and ultimately value and use. Portfolio and product strategies will also benefit as they will be able to evolve based on ongoing monitoring and data mining. There are inherent risks in the increased transparency, however, such as access to the same information for all, including exposure to adverse event signals, not all of which prove to be true. In this data-driven environment, facts will overshadow messaging. Companies will need to provide strong clinical and economic data to support their products.

EASTAUGH. GEORGE WASHINGTON UNIVERSITY. Shifts in reimbursement policies caused by the introduction of insurance exchanges will change the landscape for pharma and may help enhance the landscape for personalized medicine. We need to do what is best for our patients so that we pick the right drug for the right person at the right dose for the right time. The field of pharmacogenomics is in for a great growth spurt.

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> "The biggest challenge will be evolving the processes, systems, and governance."
> **TERRY HISEY**
> Deloitte

> "The implications for drug development and manufacturing are profound."
> **CHRIS STEEL**
> **PA Consulting Group**

> "EMR can help assist pharma and the government in doing comparative effectiveness research."
> **DR. STEVEN EASTAUGH**
> **George Washington University**

LAKE. CIRCLE SQUARE. Surescripts reports that 170,000 prescribers are using the service with around 70% using EMRs. Utilization, however, remains relatively low and mitigates much of the potential impact. Another dynamic is increased patient health engagement through physician-patient portals, driven by specific requirements of the ARRA HITECH legislation. This will close gaps in care over time and increase medication adherence. It will likely improve physician-patient relationships, and better relationships are linked to better health outcomes.

CRANE. EPOCRATES. Everyone — even pharma — wins when technology is added to medical practice. We've heard the new U.S. Chief Technology Officer, Aneesh Chopra, say he has confidence that if the industry builds better products, doctors will use them. Entering the market with an EHR solution can deepen our relationship with physicians and can provide greater knowledge of their workflow, which will support everyone's activities. The bottom line is that EHR adoption will provide more timely data outcomes and encourage more consistent physician/patient communications.

REID. UNITHINK. The pharmaceutical industry is in the midst of a true paradigm shift with the large mergers and limits of access to funding reflective of the fact that the old expensive and timely R&D model has failed. The perfect storm has been created for innovative companies to take advantage of this shift and meet the requirement of robust drug and device pipelines with long patent lives with the availability of electronic patient data. The timing of this upheaval within the pharma-

ceutical industry, with the potential access over the coming years of this information, could very well change not only the pharmaceutical industry but also healthcare as we know it.

Risks for Pharma

Preparing for the future and being ready to use the data available from the EMR system will be challenging for the pharmaceutical industry, as well as the healthcare industry as a whole.

CEVERHA. PRICEWATERHOUSECOOPERS. There are definite risks to the industry. There will be clearer visibility into product efficacy and more transparency on product effectiveness and on defining the correct population for a drug. These factors can lead to variability in pricing based upon outcomes information. The general projected market size for future and current medications will be smaller than it would be without EMR data available.

DEVINE. PATNI LIFE SCIENCES. I believe the relative risk of EMR to the pharma industry falls into two categories: risks associated with implementation of a system and risk associated with the data that are discovered by that system. Risks associated with system implementation include the following: security or privacy breaches, the costs associated with aggregating data or getting metadata wrong, and the need for new high-performance computing to leverage the data. I think it is clear that the data risk category includes such things as newly uncovered safety concerns, security of

e-discovery, data, additional REMS requirements imposed on more prescription classes, the massive amount of data to process, and the possibility of unseen comparative efficacy data that would make second-in-class, and me-too drugs will become harder to get approved.

BAILEY. GE HEALTHCARE. The main challenge associated with the use of clinical data for research will lie in developing the skills to properly use the generated information. GE Healthcare has discovered that data collected during routine medical care are fundamentally different from data collected specifically for research or administrative data. Most current industry research techniques have been developed using the latter types of data. At GE Healthcare, we have been using our deep understanding of clinical data to develop techniques to account for the variables in real-world clinical information so that researchers can still derive meaningful conclusions from studies depending on it.

REID. UNITHINK. The challenges will be many. As with any government-driven initiative, progress in the overall implementation and standardization of EHR and EHR vendors, suppliers, and systems will continue to be slow and costly. The real and phantom security and privacy risks will need to be thoroughly addressed. What this means is that innovative organizations that can quickly simplify and assimilate to this changing environment will reap significant returns while organizations not as agile will incur significant costs in an attempt to only adapt without truly embracing this new, spontaneous access and use of information.

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> "The benefits to pharma are overwhelming in terms of using accurate and timely EHR data to revolutionize the clinical-development process and deliver drugs and devices faster and cheaper to patients."
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> **HOWARD REID JR.**
> Unithink

> "Standardization is a major challenge the medical industry faces."
>
> **BOB LORSCH**
> MyMedicalRecords

> "A new breed of independent solutions is now appearing with a Web-based architecture that can operate in real time."
>
> **MICHAEL LAKE**
> Circle Square

CROWN. I3 INNOVUS. EMRs by themselves provide a limited perspective on patient outcomes. Although they tend to have more clinical richness than other electronic forms of health information, such as medical claims, they are usually confined to specific sites. Thus, the EMRs in a diabetes clinic will tend to provide deep clinical information about the patient's diabetes but may not contain information about their co-morbid heart disease or depression. Major health events such as hospitalizations may also not be present in the EMR for a particular setting. Thus, there are major potential benefits from linking EMRs to other forms of data, such as claims data, in order to obtain both clinical depth and a broader perspective on patients' healthcare utilization. Currently, there are no standards for the many EMR systems. Similar to early EDC, there is a need to develop a common set of data standards that can link data. Also, we need to take into account the lack of EMR systems globally. There is a variety of patient regulatory standards around the world. EMR will also necessitate completely retraining investigators, site personnel, CRAs, data managers, and statisticians on the use of this information.

CEVERHA. PRICEWATERHOUSECOOPERS. The biggest hurdle for pharma, and the entire healthcare universe, is becoming comfortable with changing the current data mining process. There are things companies can do right now to make the process faster and cheaper simply by changing the source of their information. Becoming comfortable with EMR analytics is strictly a cultural thing. There are other hurdles such as finding the right partner and making sure data are collected correctly and aggregated in large enough numbers. The first thing most people are worried about is the enormity of the undertaking and the time frame in which it needs to be accomplished. Pharma can start getting advantages from HEI almost immediately. Pharma companies should not be passive; they should start to think now about ways in which this impacts them with regard to modifying clinical trial programs or access to information. It's a downstream impact but a sea change is likely to occur.

LORSCH. MMR. Another challenge is creating standardization. The healthcare industry is talking about standardization and pushing HIT but unfortunately I don't see companies talking about creating this standardization. Further, that type of collaboration is quite possibly illegal. Additionally, creating standards may mean that those companies might have to throw away their current infrastructures and start over. These things are not going to happen easily.

GLIKLICH. OUTCOME. Convincing EMR providers to adopt open interoperability standards that will allow drug development firms to collect data across different EMRs from providers without significant customization by the providers or requiring the permission of the EMR is a big challenge ahead. But creating connectivity is only part of the challenge. The other component is developing semantic interoperability such that the data conveyed between systems carries the same meaning. This ultimately will come down to the development of common core data elements and definitions across different conditions. That is a big effort that requires multi-stakeholder involvement.

HISEY. DELOITTE. The biggest challenge in the coming years will be evolving the processes, systems, and governance so that the right people are making the right decisions with the right information. This will be an organizational change and it will have a strong technology dimension. These focused clinical R&D programs will accelerate the adoption of products in the marketplace.

LAKE. CIRCLE SQUARE. Two key challenges stand out as EMRs begin to impact the drug development process. The first is access to patient data and the second is sophisticated clinical data management and real-time analysis of those clinical data. As the industry moves toward demonstrating efficacy in addition to safety, it's likely that smaller trials with smaller, narrower patient segments will become advantageous. Provider EMR data will be key, particularly as genomic data becomes more widely available and more personalized therapies become possible. Pharma will be challenged to put processes in place to establish channels for access to these new rich data sets and then to manage these in the context of a rigorous research process. Additionally, once the drug is approved for a narrow segment and gets into the market, continuous research will enable broadening segments over time.

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DEVINE. PATNI LIFE SCIENCES. Managing immense data volumes will be a major challenge in EMR integration. The existing metadata models in our industry have not been built to allow this volume of data to be used effectively, nor have enough universal standards been defined to assist in the use of such a wealth of data. The early adopters can help drive the standards, but the cost of picking the wrong standard would be significant to all of our industry. The increased use of e-discovery will increase the privacy and data security concerns. We have all seen the results of the changes in the rules of disclosure of information in court, which now includes all electronic stores. The additional information people can explore is growing exponentially. I can easily imagine whole new cottage industries growing from the litigation related to the managing of information and the knowledge required to index, archive, analyze, and retire data. This will be a big challenge for us. The impact of EMR on information security and privacy is accentuated by the data volume and the need for portability. Because electronic health records are the personal property of the patient, not the intellectual property of the company, a distributed data ownership model will pose even greater challenges to this industry. Our additional data stewardship concerns will increase the cost and complexity of e-discovery programs. We will have to address the challenges of identification, authentication, and authorization as well. With all of this information available, we will need a mechanism to verify the identity of all persons involved so that particular sets of personal information can be accessed only by those specifically authorized. Managing access control may be the single greatest challenge within our industry in the foreseeable future. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

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Sound Bites from the Field

IN 2005, DR. DAVID BRAILER, FORMER U.S. PUBLIC HEALTH OFFICIAL, CALLED INTEROPERABILITY THE KEY TO THE FUTURE HEALTHCARE SYSTEM. INTEROPERABILITY IS THOUGHT TO BE THE ONLY WAY TO BIND TOGETHER A WIDE DATA NETWORK, ALTHOUGH SOME HAVE THEIR DOUBTS ABOUT ITS FEASIBILITY. WE HAVE ASKED OUR EXPERTS IN THE FIELD WHETHER INTEROPERABILITY IS A GOAL TOO HUGE TO BE DOABLE.

JASON BURKE is Worldwide Director of Health and Life Sciences R&D at SAS, a provider of business analytics, software, and services in the business intelligence market. For more information, visit sas.com.

"EMR interoperability is a realistic goal, but it may not give us what we want. Whenever EMR interoperability is discussed, two issues — data standards and the infrastructure connectivity to allow standardized data to be shared — seem to hold the center of attention. But if one goal of sharing EMR data is to improve patient outcomes, much more attention needs to be placed on how the data will be used. Nontechnical issues such as medical context and semantic interpretation must become focal points, as they are critical to successfully applying retrospective and predictive analytics to patient outcomes. If we don't address these issues, it is unlikely any EMR interoperability solution will deliver on the promise."

BRIAN O'NEILL is President and CEO of Office Ally, a claims clearinghouse that offers a Web-based integrated system that connects patients, providers, and payers. For more information, visit officeally.com.

"Interoperability between electronic health record (EMR) systems is not only realistic, but mandatory. HL7 is the standard for communicating data between EMRs, registries, labs, and external devices; technology is not the obstacle to the widespread adoption of EMR. What is stopping us from fulfilling the promise of EMR is cost to providers and vendors that won't enable the use of their technology with competitive EMR products.

Many of the larger EMR vendors charge a substantial fee (up to $5,000 per link) for every connection between the providers' EMR and their system. Until we make it affordable for physicians and other healthcare providers to send and receive information contained in the EMR, it simply won't happen on a wide-scale basis. We see tremendous clinical, operational, and economic value in sharing EMR data, within HIPAA guidelines, among key healthcare providers. Once vendors move beyond a silo mentality, we can all begin to fulfill the promise of EMR."

F. RANDY VOGENBERG, PH.D., is the Principal of the Institute for Integrated Healthcare, as well as a senior scholar at Jefferson School of Population Health. The Institute for Integrated Healthcare provides integrated pharmaceutical benefits consulting and education to self-insured employers and business coalitions. For more information, e-mail randy@iihonline.net.

"The EMR remains mired in controversy and turf battles over information content due to the perspectives among stakeholders who use that patient information.

Another challenge includes the hardware or software upgrades that cost significant sums of money, owing to the standardization of information under HL7 through its members representing all aspects of the healthcare system. Interoperability is a concern to third parties, such as a manufacturer engaged in clinical or market research, but for most users there is a relative lack of urgency and willingness to stay with the status quo.

This reluctance to change comes from the concern over fully transparent access to such detailed personal medical information, worry of how such personal medical information may effect insurance coverage or costs, the real possibility of regulatory or legal exposure to a law suit, and the general nature of human decision making to go slow with change. If there was a true issue with identifying and collecting data today, then most health management organizations or employers managing healthcare budgets would be in far worse shape than they are in working with EMR related information.

The solution to interoperability issues lies in a willingness in this country to address the key human nature or behavioral aspects around EMR by most stakeholders, including fear of litigation, and determining how financing of improved EMR systems can be accomplished in a systematic and large-scale manner. This may not be what researchers in pharma firms want to hear."

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BY ROBIN ROBINSON

Preparing for the
EHR ENVIRONMENT

A survey by Athenahealth and Sermo recently reviewed physicians' sentiment on electronic health records at the HIMSS10 conference in Atlanta. Findings show a level of optimism and enthusiasm around EHRs, but also reveal a physician community in need of better solutions than are currently available. In the meantime, pharma can use this time to prepare for the new world of EHR data.

> "Companies will have to get much more closely involved in working with payers and providers to understand what treatment approaches they would like to be able to use over the next five years."
>
> **CHRIS STEEL**
> **PA Consulting Group**

2010 Physician Sentiment Index on EHR

Athenahealth and Sermo teamed up to survey 1,000 physicians to gauge their sentiment on electronic health records. Most respondents say they have a somewhat or very favorable opinion of EMR/EHR.

Physicians also say EHR:

- Improves access to clinical data (85%)
- Improves bill collections (77%)
- Helps with integrating clinical data with practice management systems (71%)
- Reduces medical errors (71%)
- Improves compliances with clinical guidelines (69%)
- Improves efficiency (47%)
- Reduces costs (41%)

Source: Athenahealth.
For more information, visit athenahealth.com.

The promise of government incentives and meaningful use has stimulated and will continue to stimulate the EHR discussion, says Rose Crane, CEO of Epocrates.

"But full-scale deployment is still dependent on practice-based physicians," she says. "Beyond the pending stimulus money for healthcare providers, the move to broader acceptance is dependent on the development of more physician-centric, affordable solutions for smaller practices, which accounts for more than 50% of office-based physicians in this country."

Despite the disparity between physicians' enthusiasm and the actual implementation of EHRs in hospitals and physician offices, the healthcare industry is at the point of no return. Pharmaceutical companies such as Glaxo-SmithKline, Merck, Millennium, Pfizer, and Roche are weighing the pros and cons of EHR in relation to drug development programs and clinical trials. Many are facilitating pilot programs to test the waters. PhRMA and the eClinical Forum have establish an EHRCR Profile outlining suitable criteria to certify EHR systems as suitable for use in a clinical research environment.

EHR will become a reality, says Steven Eastaugh, Sc.D., professor in the Department of Health Services Management and Leadership at The George Washington University School of Public Health and Health Service.

"The major change in the evaluation of processes for pharma research is to realize that we are all in Bayesian theory now," Dr. Eastaugh says. "With more uncertainty in the marketplace, Bayesian inference can better discriminate between conflicting hypotheses."

Bayesian inference is statistical inference in which evidence or observations are used to update what is known about underlying parameters or hypotheses.

Pharma cannot sit by the sidelines and wait it out, our experts say. According to Chris Steel, leader of PA Consulting Group's Healthcare IT business in the United States, pharma companies will have to get much more closely involved in working with payers and providers to understand what treatment approaches they would like to be able to use over the next five years.

"This does not replace the current push model of drug development that starts with finding the molecule, but complements it with a more patient-oriented pull model that could result, for example, in known molecules being delivered as part of different treatment

approaches through different devices in different formulations," Mr. Steel says.

Pharma companies will also need to take an active role in determining how and what standards will develop and how the data will be managed and secured in order to maintain their competitive advantage.

Shaping how the data will be shared, who will have access, and where it will be stored will allow companies to be in the best position to leverage the data as they become available, says Roy Devine, associate VP of Patni Life Sciences.

"The most critical strategy required for the pharma industry's use of EHR data is early rationalization of its present research and production data systems and the attendant data loading processes," Mr. Devine says. "Unless we rationalize and harmonize the existing data, the additional data, especially from external sources such as EHR, will cripple our data management efforts."

Harmonized metadata along with a data warehouse/datamart infrastructure will provide the industry with the ability to manage large volumes of data and unleash the analytical power required to generate new, effective tactical and strategic objectives. Ensuring that the internal information can be incorporated with external data, such as from virtual clinical trials and research outcomes analysis, will provide the most fertile environment for research growth, Mr. Devine says.

Standardization may be a stumbling block for the implementation of large, complex systems, but there is an alternative, says Robert Lorsch, president, MMR Information Systems.

"In a perfect world you need standardization but I'm not sure standardization is attainable," Mr. Lorsch says. "There are all kinds of governing bodies out there that require hundreds of various elements, but there is no standard solution on how to do that. My answer is keep it simple and create a process that will enable you to start collecting data sooner by faxing information that can be digitized into an electronic record."

He says there are user-friendly products that enable any doctor in any hospital regardless of type or level of technology to deposit any form of information into an EMR.

"With this application, any patient or doctor can scribble a handwritten note and put it on fax machine or scanner and have it end up in the pages of an EMR," he says. "There is no solution to reduce cost of clinical trial management other than an EMR, and how a company approaches it determines whether it will start using it six months from now or years from now," Mr. Lorsch adds.

Pharma should also be focusing efforts on defining the elements of data collected.

"To the extent that pharma can push or fund

PhRMA has made available a checklist to help EMR suppliers and clinical trial technology vendors determine if their combined systems can legally supply source data for clinical trials. Each item in the checklist has an associated U.S. or European regulation requiring it.

For more information, visit http://www.clinpage.com/images/photos/EMRCR_Apr09.pdf

specialties toward developing common, core data elements and definitions that can be adopted in the EHRs, this could have a very positive impact on the ability to use the data collected in the EHR, says Richard Gliklich, M.D., president of Outcome.

Most critical for success is to get access to a clinical analytics engine that's flexible, fast, and can operate in real time, says Michael Lake, president of Circle Square.

"This resource also needs to include a medical thesaurus to help normalize data from different provider organizations and EMRs," he says. "The large healthcare payer organizations have gobbled up the first commercial engines, for example, Aetna and ActiveHealth, HCSC and MEDecision, United and Ingenix, WellPoint and Resolution Health. A new breed of independent solutions is now appearing with a Web-based architecture that can operate in real-time."

Mr. Lake says also required are data partnerships with providers for translational medicine and clinical research. These partnerships can also be used by pharma companies to use their clinical analytics resources to work with providers and their data on medication adherence and gaps-in-care programs. On the commercial side, over time, pharma will be advantaged by wrapping services around its pills.

GE Healthcare executives suggest pharma should continue to be involved in championing the development of provider recognition and pay-for-performance programs to both improve care and drive appropriate use of medications.

"With regard to using EHR data, pharma should take the opportunity to better understand the characteristics of data source: what is available, what are its strengths and weaknesses, what types of studies is it best suited for and so on," says Peter Bailey, general manager of GE Healthcare IT Clinical Data Services unit.

"One of the main reasons for the relatively slow guideline adoption rate is the difficulty

Electronic Records Terminology Defined by HIMSS Analytics

Electronic Medical Record: An application environment composed of the clinical data repository, clinical decision support, controlled medical vocabulary, order entry, computerized provider order entry, pharmacy, and clinical documentation applications.

This environment supports the patients' electronic medical records across an inpatient and outpatient environment and is used by healthcare practitioners to document, monitor, and manage healthcare delivery within a care delivery organization. The data in the EMR is the legal record of what happened to the patient during their encounter and is owned by the care delivery organization.

Electronic Health Record: A subset of each care delivery organization's EMR, presently assumed to be summaries like ASTMs Continuity of Care Record (CCR) or HL7s Continuity of Care Document (CCD), is owned by the patient and has patient input and access that spans episodes of care across multiple care delivery organizations within a community, region, or state (or in some countries, the entire country). The EHR in the United States will ride on the proposed National Health Information Network (NHIN).

The EHR can be established only if the electronic medical records of the various care organizations have evolved to a level that can create and support a robust exchange of information between stakeholders within a community or region.

While some forms of early EHRs exist today in limited environments, it will be difficult to establish effective EHRs across the majority of the U.S. market until we have established clinical information transaction standards that can be easily adopted by the different EMR application architectures now available.

Health Information Exchange: The transmission of healthcare-related data among facilities, health information organizations and government agencies according to national standards. HIE is an integral component of the health information technology infrastructure under development in the United States and the associated National Health Information Network.

To meet requirements, HIE technology must enable reliable and secure transfer of data among diverse systems and also facilitate access and retrieval data. The purpose of HIE development is to improve healthcare delivery and information gathering.

Source: HIMSS Analytics. For more information, himssanalytics.org.

ELECTRONIC Records

implementing new guidelines into existing clinician workflows," he says. "A well-implemented EHR can address this issue. By implementing the guideline in the EHR, the information can be presented at the point of care at the appropriate time, making it more likely to be acted upon."

Another major hurdle is accessing EHR data in a HIPAA-compliant manner, says William Crown, Ph.D., president, i3 Innovus.

"This is particularly true for linkages of EHR to other forms of patient information such as medical claims histories," he says. "Assuming that these challenges can be met, there is the additional issue of drawing correct conclusions from observational data. Traditional biostatistical methods used in randomized trials are not adequate for the analysis of observational data."

Here, the methods used in epidemiology and health economics are more appropriate, he adds. Companies will need broader integration of their data to conform with submission standards. EHR, clinical data, labs, etc. must all harmonize. Also, it will be necessary to have the ability, in a HIPAA-compliant manner, to identify patients eligible for a clinical trial.

Comparative effectiveness programs for current or potential products will also get a boost from EHR adoption.

"The comparative effectiveness insights, when appropriately applied, will enhance companies' competitive strategies and actions, resulting in greater competitive effectiveness," says Terry Hisey, vice chairman at Deloitte.

Perhaps the most difficult step of preparation for the industry will be getting its collective head around the idea that things are going to change.

"Pharma will have to be comfortable with a novel process that will replace the current decades-old business process," says Paul Ceverha, director, PricewaterhouseCoopers' Health Industries Group. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

A Case Study: Pfizer

In 2007, Pfizer conducted a series of interviews pertaining to electronic health records. The results were published in the Journal of American Medical Informatics Association in June 2008. The Pfizer Healthcare Informatics team conducted a series of guided interviews with 35 Pfizer senior leaders to elicit their understanding, desires, and expectations of how EMR might be used in the pharmaceutical industry today.

The interviews yielded 14 categories comprising 42 specific use cases. The highest priority use cases were drug safety and surveillance, clinical trial recruitment, and support for regulatory approval. Fifteen EMR companies were surveyed to assess their functionality against the specified use cases. Self-reported responses from the EMR companies were highest for virtual Phase IV trials and document management for clinical trials.

In an effort to access information more efficiently, Pfizer had started to investigate potential opportunities around how electronic health records (EMRs) might be used to augment, supplement, or replace EDC based systems. In addition, other departments (e.g., outcomes research, safety) within Pfizer traditionally relied on claims data for various analyses; they too are attempting to evaluate the value of real-world clinical data available from EMRs.

The report determined that the pharmaceutical industry could more effectively research, develop, and monitor safety of medicines by using such clinical databases that are made possible by the growing adoption of EMRs in healthcare institutions.

An interesting note at that time is that vendors surveyed reported they had little to no intention of offering services that would support regulatory approval, with 33% indicating they fully meet the use case to support regulatory approval and 13% having no intent of developing such functionality. Although in theory the needed data can be captured by EMRs, unless it is actually acquired with the quality and completeness necessary for regulatory bodies, there is limited value for pharmaceutical companies who must adhere strictly to regulatory requirements, e.g., 21CFR Part 11, which pertains to electronic signatures and audit trails.

According to the report, EMRs can provide some support to the pharmaceutical industry for data re-use, but it will take an ongoing dialogue among EMR companies, research-based organizations, and the pharmaceutical industry to ensure that the data being captured, aggregated, and analyzed can produce the value necessary for all stakeholders. The pharmaceutical industry is interested in population health, and EMR vendors can help to better capture and analyze health information. Particularly in the areas of drug safety surveillance, clinical trial recruitment, and in observational studies, the EMR vendors can partner with the pharmaceutical industry to help satisfy regulatory requirements in order to bring life-saving drugs to patients faster.

Source: Jamia. For more information, visit
http://jamia.bmj.com/search?fulltext=pfizer&submit=yes&x=0&y=0

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