

Electronic Health Record (EHR) Data: Modernizing the Pharmaceutical Research Process



Creating new value for life sciences shareholders will increasingly hinge on companies' readiness and competency in accessing and exploiting massive and disparate data sets to drive new paradigms in research, development, marketing and surveillance.

While electronic health record (EHR)¹ systems are far from universal, the potential held within this vast repository of data has the ability to revolutionize and help drive efficiencies in traditional pharmaceutical research. Research organizations can leverage patient data to improve target identification and validation, lead identification and optimization, and biomarker identification and validation. Though market constraints limit the immediate potential, by making the appropriate investments, pharmaceutical companies should position themselves for future success and can reap incremental near-term benefits.

Pharmaceutical Industry Challenges

The pharmaceutical industry is currently facing challenges on multiple fronts. Ongoing expiry of blockbuster patents and increasing price pressure from payers are resulting in an increasing market share for generic pharmaceuticals. To combat these pressures, the industry has allocated more funding to research and development (R&D). Despite this increase in spending, pipelines remain weak and many of the major firms will be unable to replace the revenue from expiring patents.

Existing strategies to maintain the pipeline through increased in-licensing are no longer proving viable in the long-term as the cost to in-license is steadily growing more expensive. The increasing cost of late stage drug failures places more pressure on research to improve the probability of success for compounds across the R&D value chain and to kill unviable compounds sooner to prevent unnecessary spending. The FDA is increasingly hesitant to approve "me too" drugs, an indicator of the increased market demand for novel therapeutics. These unprecedented drugs are more difficult to identify and develop, placing the organization's primary objectives at odds with one another. Faced with added cost pressures and the demand for novel therapeutics, research strategy is increasingly geared towards improving the probability of success in later R&D stages and enabling better decision-making throughout the process.

Secondary Uses of Electronic Health Record (EHR) Data

Electronic health record (EHR) data is captured at the point of care when patients visit their physician for medical treatment. Though EHR systems have been around for decades, until very recently their penetration was very limited as a result of industry fragmentation, capital costs, and cultural challenges. Recently, technological advances, national and regional initiatives, and clearly demonstrated value propositions have increased adoption rates; despite this, only 28% of primary care physicians have electronic records systems in their practices.³ As more medical practices switch from traditional paper-based records to electronic systems, the medical community will be able to build a more complete picture of a given patient's overall health status which should help them better understand the general health of the population. To achieve these goals, EHR data from various sources must be coordinated and compatible to support effective disease profile and patient demographic search capabilities.

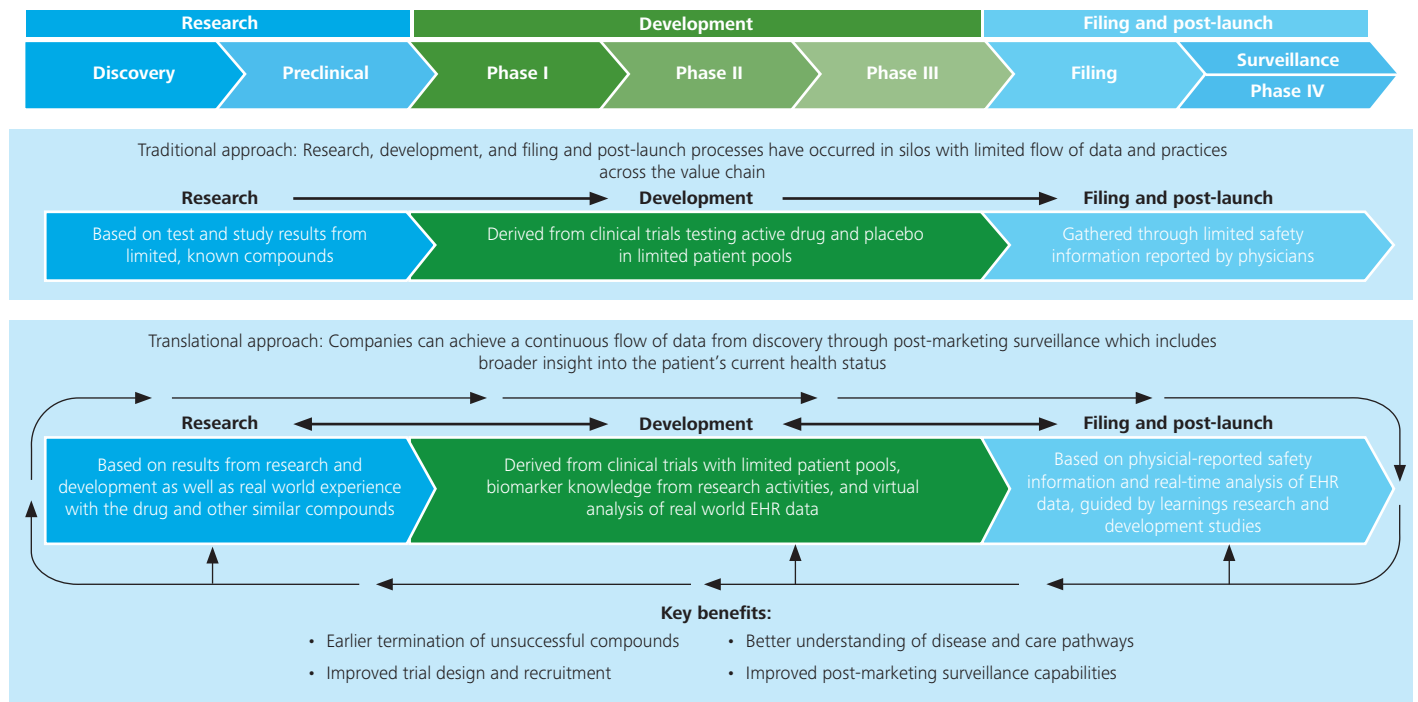
In 2008, more than 1 in 4 primary care physicians in the United States used EHRs in their clinical practice, and close to 1 in 5 have advanced IT capacity.²

Secondary uses of EHR data have the ability to revolutionize and streamline processes across the R&D value chain. Traditionally, processes within the pharmaceutical value chain – research, development, filing, and post-launch activities – have occurred in silos with a limited flow of data and effective practices from one to the next. As companies begin to adopt a translational view of the value chain, that is as they begin to think of components as interconnected processes rather than discrete steps, they can achieve a continuous flow of data from research through to post-marketing surveillance.

This translational view, in conjunction with the increasing availability of EHR data, can enhance the predictive power of current pharmaceutical research methods by giving researchers the ability to make higher quality decisions earlier in the process. Effective use of this information during the research process can allow companies to:

- Better understand disease and response biomarkers
- Identify and validate new targets
- Terminate unsafe or unsuccessful compounds earlier in the research process to increase probability of success in subsequent R&D phases

Figure 1. Traditional versus Translational view of the pharmaceutical value chain



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Key research challenges can be effectively addressed through tools designed to integrate and analyze research, epidemiology data, and EHR data. For example:

- **Target Identification and Validation:** Current in vitro and animal model systems are limited in their ability to fully replicate the influence of a target in the human body. By using EHR data to build a “virtual patient,” pharmaceutical companies can supplement current in silico techniques to better support the identification and validation of novel targets. Linking this information with previous preclinical and clinical trials could enhance the predictive power of current models and prioritize targets based on existing health data.
- **Lead Identification and Optimization:** High-throughput techniques have expanded the industry’s ability to screen potential lead compounds; however, the expanded hit rate has not necessarily led to a higher success rate for converting leads to development programs and marketed products. Additionally, with more hits, scientists must analyze a greater volume of data to reduce the pool of hits to a group of promising leads. By using EHR data to cross reference hits with chemical attributes linked to known safety concerns, researchers can focus on the most attractive leads earlier in the process to reduce safety-related attrition in subsequent R&D.
- **Biomarker Identification and Validation:** Biomarkers have the power to greatly improve quality and probability of success within the pharmaceutical R&D process. By serving as indicators for patient response or safety concerns, biomarkers allow companies to make better decisions about which targets and compounds to pursue. Unfortunately, biomarkers are challenging to identify and, due a lack of industry standards, even more difficult to validate. The wealth of information contained in EHR systems and clinical trial databases can expand a company’s ability to identify new biomarkers and can provide the data needed to validate new and existing biomarkers.

Making a Case for EHR Data Use in Research

Though the pharmaceutical industry has limited experience with employing EHR data to improve its processes, the academic research community and niche biotechnology firms are pursuing paths which demonstrate clear opportunities for the use of EHR data.⁴

Building a Virtual Mouse

A virtual mouse model has been created to study cures for Type I diabetes

ADA – ENTELOS Partnership Strategy

- Preparing for future development of a “virtual patient” to improve research and trials

Ongoing Activities

- Entelos has developed additional virtual environments for rheumatoid arthritis and cardiovascular disease
- HER systems could provide some of the data needed to link the virtual systems in to a virtual human patient

Source: ADA News Release

Because safety is a predominant cause of attrition during costly preclinical and clinical trials, opportunities to eliminate unsafe compounds during research can allow companies to avoid significant costs and improve the probability of success during development. In order to avoid some of the costs associated with pursuing unsuccessful drugs, Iconix has built a database which enables early detection of toxicity in hopes of ensuring that only suitable drugs are put into clinical trials.⁵ The proprietary chemogenomics database incorporates information from animal studies, gene expression profiles, in vitro assays, and literature sources. Through this technology, Iconix has successfully identified and used kidney biomarkers as early indicators of nephrotoxicity. This database, which lacks a broad view of patient data, clearly has the power to significantly impact Iconix’s drug research process. If the dataset was augmented with real world EHR data, its predictive power would increase further.

By employing EHR data during research, companies can build an expanded understanding of safety and effectiveness earlier in the R&D process. With this knowledge, researchers will be able to make well-informed decisions to terminate the pursuit of ineffective targets and unsafe leads before progressing to the next phase in the R&D process. As a result, we believe unnecessary costs could be eliminated and the overall probability of success will increase.

Avoiding Unnecessary Lead ID and Optimization

By understanding the quality of a target before a program enters Lead ID and Optimization, companies can avoid years of effort which translates to significant cost avoidance from staff alone.

Average Cost of Resources for Lead ID and Optimization

Average Duration	3 years
Average Staff Requirement per Year	25 FTEs
Average Salary	\$150,000
Value of Resource Redeployment	\$11M

Assuming a given program is predestined to either fail or succeed based on inherent qualities of the target or molecule, the earlier this fate is understood, the more resources can be reallocated to programs with higher probabilities of success. A hypothetical example terminating a single research program before lead identification and optimization begins clearly demonstrates the potential cost avoidance associated with terminating programs earlier in the R&D process.^{6,7} Similar logic can be applied to decision making processes associated with the stage gates for entry into preclinical and clinical testing.

Use of EHR data during research can also yield benefits later in the R&D process. While the example above illustrates the benefits of understanding whether a target is destined to succeed, EHR data can also be used to assess whether a compound is likely to be safe for human use. If this data is used to augment the current research and preclinical research models, unsafe compounds can be terminated before preclinical or Phase I trials begins. Given that the average Phase I clinical program costs \$15.2M, improving the quality of decision making during research can significantly drive cost reductions for the development organization.

When combined, these benefits can help build the foundations of the business case for using clinical trial and EHR data to guide the research process. Joseph DiMasi of the Tufts Center for the Study of Drug Development has concluded that if increases in research productivity and better clinical screens could improve clinical success rates from about one in five to one in three, capitalized clinical costs per approved drug would decline by about \$230 M, a savings of approximately 30%. Because the use of clinical and EHR data will allow researchers to make better decisions regarding product safety and efficacy, it has the potential to increase the overall probability of success and allow companies to realize the savings DiMasi describes and to allocate those funds to other efforts.

The EHR Data Market

Early experience demonstrates clear, tangible benefits from the secondary use of EHR data in the pharmaceutical research process. However, there are clear hurdles to achieving the full benefit of EHR data use within pharmaceutical organizations.

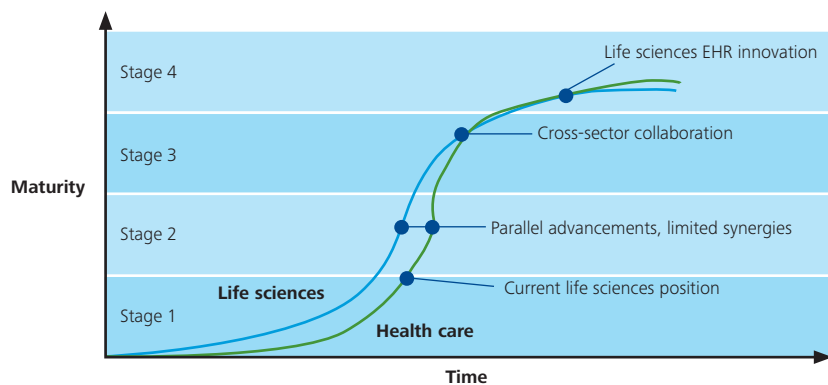
The EHR field is relatively nascent. On the maturity scale, the Life Sciences industry is at stage 2, where by some companies are exploring tactical uses of EHR. Also, it is worth noting that industry standards have not been fully developed or vetted so data and systems interoperability challenges remain. While this is not a significant concern for healthcare providers who deal with only one EHR system, it presents a challenge for other industry players who seek to access data and understand disease characteristics, treatment effects, and other trends across systems.

As a result, much of the early progress in EHR data use has been made outside of the life sciences space. Provider organizations, academic medical centers, and regulatory bodies have demonstrated real – but self-contained – benefits to using EHR data for patient recruitment, expanded physician participation, and adverse event reporting.

Recent changes in federal policy are expected to lead to an accelerated uptake of EHR systems at hospitals and medical practices across the country. Newly enacted policies create an incentive for providers to purchase and implement EHR systems and federal funds have been allocated to back up the policy. Some estimates indicate that as many as 90% of U.S. medical practices could be automated by 2015. Further, the Office of the National Coordinator for Health Information Technology (ONCHIT) has articulated the goal of developing national interoperability standards and standardization of patient data fields by 2010. These developments, in conjunction with continued support for regional health information organizations (RHIOs) and HIPPA amendments to enable data sharing among authorized users, are paving the way for a more connected and accessible EHR network.

In the near term, pharmaceutical companies must not only consider the availability and interoperability challenges but must also address internal challenges. The traditional pharmaceutical value chain with the R&D silos as previously described presents a significant barrier to achieving these benefits. Within the R&D organization, the silos often lead to an antiquated technology infrastructure with incompatible data sources which use different language standards. In order to be ready for the future of the EHR market, an R&D organization must align its capabilities and invest in dedicated resources to better understand the specific benefits it can hope to achieve through secondary use of EHR data.

Figure 2. Future vision of EHR data market



Stage	Market	Life sciences
4	Cross-sector synergies fully realized	Sector brings innovation EHR data uses to market
3	Cross-sector collaboration with increasing synergies	Cross-sector collaboration to maximize use EHR data
2	Various players test capabilities but see limited synergies	Initial tactical exploration EHR data uses
1	Interest mainly in provider sector, federal funding to encourage innovation	Growing interest in the EHR data market

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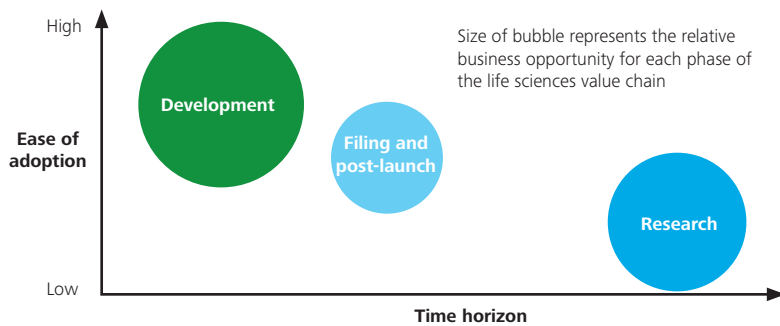
EHR data use and the ability to realize its full potential in the near term differs by both degree and definition across the life sciences value chain.

- EHR data usage is most limited in research organizations, most likely because these groups are most separated from real world patient interaction. Because of the benefits expanded use of clinical trial and EHR data offers, its application will drive changes in research strategy. For example, virtual models could eliminate preclinical animal tests or costly trial failures or well-informed databases could alert researchers to safety signals earlier in the research process.
- Within the R&D process, EHR data can most easily be applied to the development process. Use of electronic data capture systems is becoming more commonplace within the industry and development organizations can also benefit from the EHR systems currently in place at clinical trial sites. Because of the practical benefits it offers, EHR data will bring about tactical changes in

the development process. Access to EHR data at the population level could help companies understand whether enrollment will be feasible and, at an individual trial site, the same information could help to alert investigators of a patient’s eligibility to enroll.

- The opportunities to use EHR data during filing and post-launch are more apparent than those for research and development: scanning patient data can allow firms to monitor real-world use and proactively identify safety concerns. While the benefits associated with reducing the burden of post-marketing surveillance and mitigating future risks are clear, achieving those benefits does present a challenge. In the current environment, the EHR market is fragmented, data formats are inconsistent, and pharmaceutical companies do not have access to current information. In this arena, access to EHR data is likely to change the tactical attributes of post-marketing surveillance as well as the strategy for Phase IV trials.

Figure 3. Business opportunity for EHR use in life sciences



	Current EHR data uses	Near-term opportunities
Research	Very limited, exploring some treatment associated biomarkers to understand potential	Expanded use of internal data from clinical trial populations
Development	Broader understanding of value proposition, expanded use of electronic format for trial data	Use of past data to inform future trial designs, coordination with investigators for trial recruitment via investigator EHRs
Filing and Post-Launch	Clear understanding of ability to decrease burden of surveillance, broader analysis across trials	Coordination with large health systems and EHR providers to build surveillance capability

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Deloitte's Model for Success⁸

We help our clients in their efforts to understand the potential value of using EHR data to support their processes. This understanding is a key dimension of Deloitte's model for success which we believe drives the vision and strategy for plans to leverage EHR data. Once the value has been clearly established, successful secondary use of EHR data requires organizational buy-in, training, and technological capabilities in addition to advanced data access and hardware systems. When transforming a pharmaceutical company into one which leverages EHR data, success is contingent upon building capabilities within each of the following six dimensions:

Figure 4. Model for success



- Strategy, vision and value proposition**
Clearly articulated vision, strategy, and value for use of EHR data
- Organization and governance**
Globally managed capabilities and investments across therapeutic areas and business units with clearly defined roles and responsibilities around management and usage of EHR data
- Streamlined processes**
Well-defined EHR inputs, outputs, and processes supported by a balanced set of performance metrics on EHR data on clinical trial
- Data access and connectivity**
Structured, user friendly interface and data capture with standardized vocabulary
- Data integration and IT infrastructure**
Encrypted data controlled access that cuts across the drug life cycle
- Application development**
Standard and ad hoc reporting and analytic tools with statistical modeling and signal detection algorithms

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An Approach to Bringing EHR to your Organization

1. Start with a baseline – evaluate current capabilities

The ability to effectively incorporate EHR is predicated upon an organization's ability to understand its current capabilities and deficiencies. There is no substitute for an end-to-end assessment. A research organization should first monitor and document its current uses of EHR data as well as its cross-functional information sharing capabilities. Next, the organization should understand how its current practices measure up against industry leaders and world class goals. Utilizing a maturity matrix to map the organization's current capabilities to end goal can help a company to size the gap and subsequent effort required to incorporate EHR data into research operations.

2. Set a goal for the organization – create a vision and build a strategy

Armed with a clear understanding of its current capabilities, an organization should focus on defining the vision and strategy for EHR data usage and mapping how the EHR data will change the organization and operations. Organizational analysis is needed and should be cross-functional in nature and delve into the classic dimensions of people, process, and technology. To make the most of efforts to bring EHR data into R&D practice, program sponsors should focus on understanding the needs and intended data uses across the research, development, and filing and post-launch functions. The specifics of the EHR vision will be dependent upon specific business issues it aims to address; key inputs for that vision may come from executives ranging from the head of R&D to clinical program leadership to those in the commercial organization seeking to plan Phase IV trials. By taking the time to establish a governance model and align the organization's goals and objectives with the EHR strategy, leaders can help to propel the vision into reality.

3. Articulate the value to the organization and set a pace for achieving it

Often times, a business case is critical for gaining the support of the broader organization. A solid business case will clearly articulate not only the value proposition for use of EHR data within the research organization but should also make the case for the broader organization as well. An effective evaluation of organizational needs and the expected return on investments in people, process, and technology will provide a quantification of the benefits to the organization. In addition, a high-level roadmap deploying EHR data within the research organization should be created to help visualize the plan for realizing future goals. Finally, EHR leaders should document an overall deployment plan for gaining approval for the business case and building organizational support so EHR goals are not overlooked in the face of competing priorities.

Your organization has an opportunity to apply EHR data to combat the challenge of managing the growing complexity of pharmaceutical research. As pharmaceutical companies better understand the power of EHR data and build the capability to apply it to the research process, they will be better armed to compete in the pharmaceutical landscape of the future.

Endnotes

- ¹ EHRs are defined as records that contain an individual patient's medical record in digital format and are managed by healthcare providers. EHRs contain an aggregation of electronic medical records from a patient's multiple providers but are distinct from personal health records.
- ² Evans, Stemple: Electronic Health Records and the Value of Health IT. *Journal of Managed Care Pharmacy*, 14:6, S-c, 2008.
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- ⁵ Burley, Park: Meeting the Challenges of Drug Discovery: A Multi-disciplinary Re-evaluation of Current Practices. *Genome Biology*, 6:330, 2005
- ⁶ DiMasi, Hansen, Grabowski: The Price of Innovation: New Estimates of Drug Development Costs. *Journal of Health Economics*, 22:151–185, 2003
- ⁷ DiMasi: The Value of Improving the Productivity of the Drug Development Process: Faster Times and Better Decisions. *Pharmacoeconomics*, 20 Suppl. 3: 1-10, 2002
- ⁸ As used in this document, "Deloitte" means Deloitte Consulting LLP, a subsidiary of Deloitte LLP. Please see www.deloitte.com/us/about for a detailed description of the legal structure of Deloitte LLP and its subsidiaries.

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