

# Modernizing the Pharmaceutical Development Process with EHRs





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

While electronic health record (EHR<sup>1</sup>) systems are far from universal, the potential held within this vast repository of data has the ability to revolutionize traditional pharmaceutical development. Development organizations can leverage patient data to improve clinical trial design, speed patient and investigator recruitment, and improve the efficiency of trial execution and data analysis. Though market limitations reduce the immediate potential, the appropriate investments can position pharmaceutical companies for future success and can return 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.

Increasing regulatory scrutiny compounds the challenges presented by weak pipelines as it now costs more and takes longer to bring a product to market. In order to provide the level of data demanded by the FDA and other regulatory bodies, clinical trials are becoming more complex and are taking longer to complete. Faced with declining revenues, companies are being forced to cut costs across functions. Within development, they are investigating solutions to shorten trial cycle times and decrease costs while still satisfying the stringent regulatory requirements. As a result, there is a greater focus on improvements within trial design, patient and investigator recruitment, and trial execution and data analysis.

#### Secondary Uses of Electronic Health Record (EHR) Data

Electronic health record (EHR<sup>1</sup>) 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. In recent years, technological advances, national and regional initiatives, and clearly demonstrated value propositions have increased adoption rates. 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 it 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.

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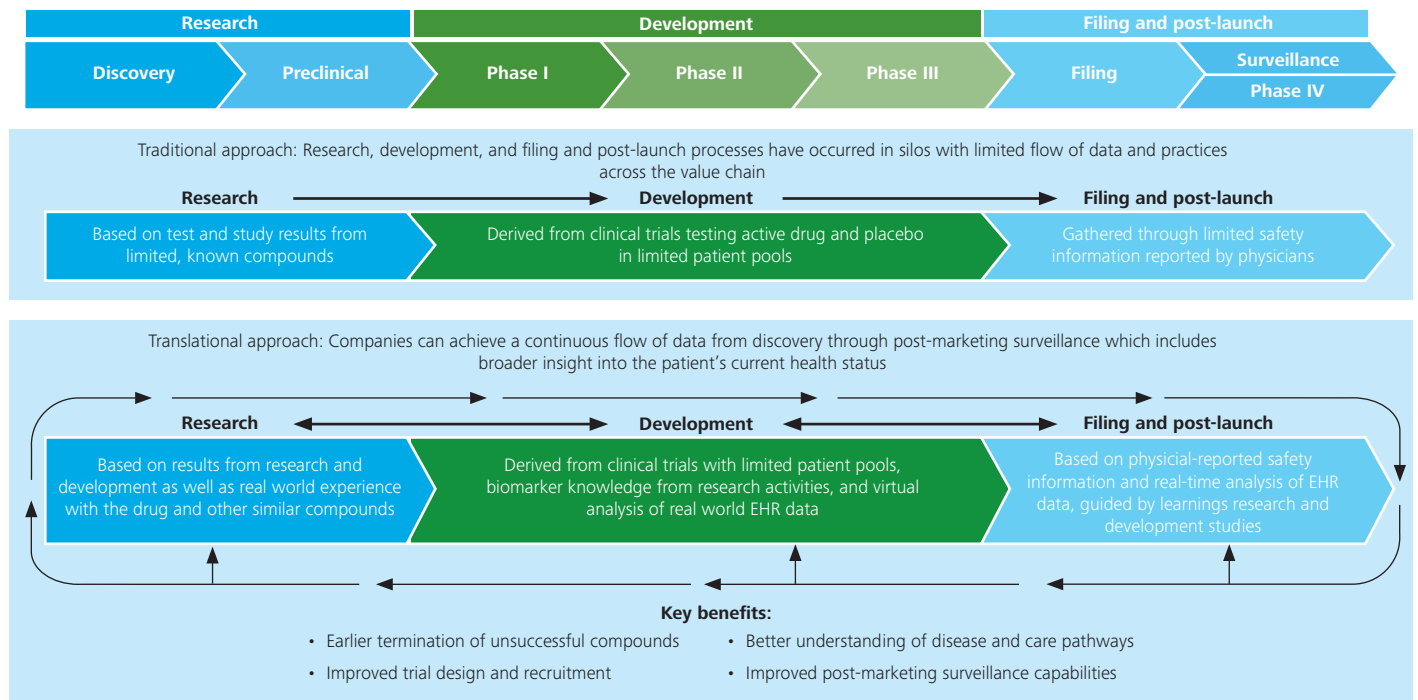
In 2005, approximately 1 in 4 physicians in the United States used EHRs in their clinical practice, a 33% increase from numbers reported in 2001.

Secondary uses of EHR data have the potential 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 discovery through to post-marketing surveillance.

This translational view, in conjunction with the increasing availability of EHR data, can provide pharmaceutical firms 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. Effective use of this information can allow companies to:

- Better understand disease and care pathways
- Improve trial design and recruitment
- Terminate unsuccessful compounds earlier in the development process
- Improve understanding of the drug benefit risk ratio through expanded post-marketing surveillance activities

Figure 1.



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

- **Trial Design:** When drafting a clinical trial protocol, access to results from previous trials and real-world diagnostic data can promote efficient and effective trial design. When designing a clinical trial, analysis of the overall patient population allows a researcher to test and modify proposed inclusion and exclusion criteria prior to protocol approval.
- **Patient and Investigator Recruitment:** In addition to testing the ability to recruit prior to initiating a trial, EHR data allows trial sponsors to rapidly identify eligible patients and investigators who treat large numbers of these patients. Because patient recruitment is becoming increasingly difficult, effective recruitment strategies can significantly reduce clinical trial cycle times.
- **Trial Execution and Data Analysis:** Trial challenges do not end once patients are enrolled; patient attrition during trial execution presents significant costs to trial sponsors. By tracking patient compliance with EHR data and other electronic means, an investigator can intervene before a patient must be excluded for non-compliance. If effectively employed, this compliance monitoring can reduce attrition and provide a significant cost savings compared with traditional paper-based monitoring mechanisms.

### Making a Case for EHR Data Use in Development

Though the pharmaceutical industry has limited experience with employing EHR data to improve its processes and decision making, provider groups have published successful development-specific applications of EHR data that could easily be applied within the industry.<sup>2</sup>

At least 30% of all sites in a given trial fail to enroll even a single patient, a clear indicator of the challenges associated with patient recruitment.<sup>3</sup> The Mayo Clinic realized its EHR data could help to address this challenge. Using the system, trial physicians were able to search patient data and identify those eligible for participation in a heart failure trial.

### Patient recruitment in physician groups<sup>2</sup>

Since 1996, Holsten Medical Group has used an EHR system to enroll thousands of patients in clinical trials

#### Case study

- HMG's EHR database includes nearly 200,000 patient records
- A pharmaceutical company contacted HMG to ask if the group could identify 25 patients for a rheumatoid arthritis trial
- Within 30 minutes, a search of the EHR database identified 430 patients eligible for participation in the trial

#### Impact

- HMG has a highly successful, self-sustaining clinical research unit, revenues from which cover the cost of the EHR system for the entire practice

Going one step further, EHR systems at some academic medical systems are now equipped to alert physicians when a patient is eligible for participation in an ongoing trial. Doctors at the Cleveland Clinic have quantified the effects of one such EHR-based clinical trial alert system on physician participation in clinical trials. Specifically, the study showed that the number of physicians participating increased nearly nine-fold and those physicians referred nearly ten times more patients and doubled their rate of enrollment.<sup>4</sup> Given that 80% of trials are delayed by over a month as a result of recruitment challenges, this application of EHR data can significantly improve the development process.<sup>2</sup>

In addition to increasing physician willingness to participate in trials and refer patients, EHR data can improve the quality of patients referred. Researchers at the University of Pittsburgh have provided convincing results which demonstrate that EHR data increases specificity in patient referral and increases the diversity of trial populations.<sup>5</sup>

### Improving quality of recruitment and enrollment<sup>5</sup>

	Enrollment rate	Enrolled population:	
		Male	Non-white
Without EHR	2.4%	18%	5%
With EHR	22%	28%	23%

Patient attrition also continues to be a significant challenge during clinical trials; attrition rates are 25% on average but can be higher depending upon therapeutic area.<sup>6</sup> Though other factors have a significant impact, non-compliance remains a key driver of attrition. Research published in the British Medical Journal indicates that use of electronic journals increased patient compliance with journaling requirements to 94% compared with the 11% seen when using paper journals.<sup>7</sup> Combining an electronic journal with EHR monitoring could enable investigators to intervene before a patient must be excluded from the dataset. In turn, this could reduce overall trial populations as fewer subjects would be needed to buffer the anticipated attrition.

In the hypothetical trial described below, the hit rate of patients meeting the enrollment criteria increases 5-fold, dramatically reducing the number of patients to be screened and the associated costs. As the patient attrition rate is halved, fewer patients need to be enrolled resulting in cost savings. Finally, and most importantly, using EHR data, patient recruitment durations can be significantly reduced; in this hypothetical example, 125 days are eliminated from the trial timeline resulting in the potential for significant additional revenue. Overall EHR data use generated approximate cost savings of \$5 M and incremental revenue of \$125 M.

**Figure 2. By describing a hypothetical phase III clinical trial, we demonstrate that the use of EHR data can provide substantial, quantifiable benefits**

- 40,000 patients screened given 5% “hit” rate
- 2,000 patients enrolled in anticipation of 25% attrition rate
- Recruitment expected to last 250 days
- Per patient screening cost: \$100
- Cost per enrolled patient: \$6,000
- Anticipated product revenue: \$1 M/day

**Improvements and impacts**

Trial design		Patient and investigator recruitment		Execution and analysis	
<ul style="list-style-type: none"> <li>• Use of EHR data to define enrollment criteria improves enrollment “hit” rate 5-fold</li> </ul>		<ul style="list-style-type: none"> <li>• Use of EHR data doubles patient recruitment rate cutting recruitment period in half</li> </ul>		<ul style="list-style-type: none"> <li>• Use of EHR data patient alerts reduces attrition rate by 50% thus reducing overall trial size</li> </ul>	
Typical patients screened	40,000 pts.	Typical recruitment period	250 days	Typical patients enrolled	2,000 pts.
Patients screened with EHR	8,000 pts.	Recruitment period with EHR	125 days	Patients enrolled with EHR	1,700 pts.
Reduction in screening	32,000 pts.	Reduction in trial duration	125 days	# of patients saved	300 pts.
Cost to screen	\$100	Average value of one day	\$1M	Cost per patient	\$6,000
Total cost savings	\$3.2M	Additional revenue	\$125M	Total cost savings	\$1.8M

### The EHR Data Market

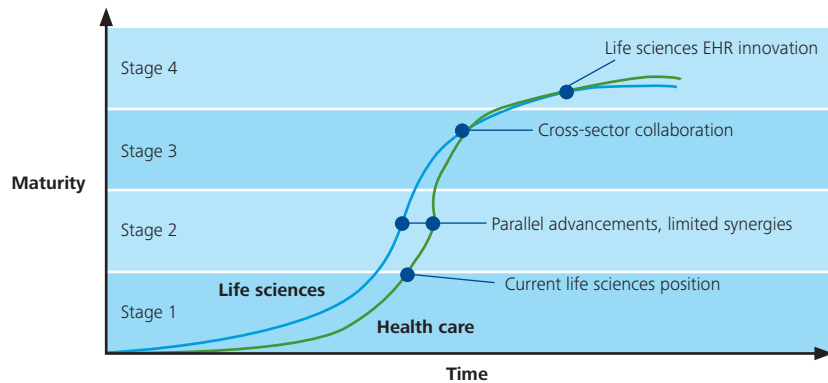
Early experience demonstrates clear, tangible benefits from the secondary use of EHR data in the pharmaceutical development process. However, there are clear hurdles to achieving the full benefit of EHR data use within pharmaceutical organizations.

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 data. 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 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 benefits to using EHR data for patient recruitment, expanded physician participation, and adverse event reporting.

In addition to considering these broad market challenges, pharmaceutical companies 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 3. Future vision of EHR data market

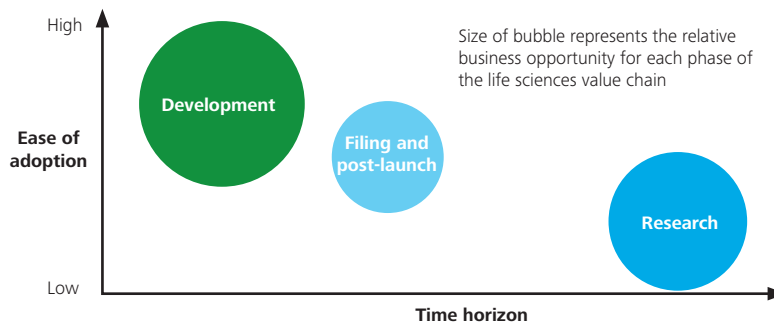


Stage	Market	Life sciences
4	Cross-sector synergies fully realized	Sector brings innovation EHR data uses to market
3	Cross-sector collaboration with increasing synergies	Cross-sector collaboration to maximize use EHR data
2	Various players test capabilities but see limited synergies	Initial tactical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

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 of expanded use of clinical trial and EHR data offers, its application will drive changes in research strategy.
- 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.
- The opportunities to use EHR data during filing and post-launch are more apparent than those for R&D: 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 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.
- In the current environment, the EHR market is fragmented, the business model for obtaining EHR data has not been defined (e.g., will Life Sciences companies purchase discrete data sets or will they purchase subscriptions to data streams?). It is also not clear who will provide access to the EHR data. Finally, the EHR data formats are inconsistent, and some data sets are incomplete, thus companies will need to be wary of conclusions drawn from mining the data.

**Figure 4. Business opportunity for EHR use in life sciences**



	Current EHR data uses	Near-term opportunities
<b>Research</b>	Very limited, exploring some treatment associated biomarkers to understand potential	Expanded use of internal data from clinical trial populations
<b>Development</b>	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
<b>Filing and Post-Launch</b>	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

### Deloitte's Model for Success<sup>®</sup>

We help our clients in their efforts to the potential value of using EHR data to support their processes. This understanding is the key dimension of our Model for Success which, in turn, 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 5. 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 trail

#### 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

### 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 development 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 development 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. 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 development 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 development 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 clinical trials while reducing cycle times and cost. As pharmaceutical companies better understand the power of EHR data and build the capability to apply it to the development process, they will be better armed to compete in the pharmaceutical landscape of the future.

## Endnotes

- <sup>1</sup> EHRs are defined as records that contain an individual patient's medical record in digital format and are managed by healthcare providers; they are distinct from personal health records.
- <sup>2</sup> Miller, Caldwell, Childress: The EHR Solution to Clinical Trial Recruitment in Physician Groups. 2005.
- <sup>3</sup> Li: Site Activation: The Key to More Efficient Clinical Trials, *Pharmaceutical Executive*, 12 Dec 2008.
- <sup>4</sup> Embi, Jain, Clark, Bizjack, Hornung, and Harris: Effect of a Clinical Trial Alert System on Physician Participation in Trial Recruitment. *Archives of Internal Medicine*, Vol. 165, 24 Oct 2005.
- <sup>5</sup> Rollman, Fischer, Zhu, and Belnap: Comparison of Electronic Physician Prompts versus Waitroom Case-Finding on Clinical Trial Enrollment. *Journal of General Internal Medicine*, Vol. 23, No. 4, 2007.
- <sup>6</sup> Avitabile: Marketing Strategies for Clinical Trial Recruitment and Patient Retention, *Product Management Today*, 01 Dec 2006.
- <sup>7</sup> Stone, Schiffman, Schwartz, Broderick, and Hufford: Patient Non-Compliance with Paper Diaries, *British Medical Journal*, Vol. 324, 18 May 2002.
- <sup>8</sup> As used in this document, "Deloitte" means Deloitte Consulting LLP, a subsidiary of Deloitte LLP. Please see [www.deloitte.com/us/about](http://www.deloitte.com/us/about) for a detailed description of the legal structure of Deloitte LLP and its subsidiaries.

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