

Secondary uses of
Electronic Health Record(EHR)
data in Life Sciences



Executive summary

Most Life Sciences (LS) Research & Development functions are under increasing pressure to improve innovation, reduce development inefficiencies and advance product safety. Patient-level data, collected through Electronic Health Record (EHR) systems, offers one promising avenue for redefining Research & Development (R&D) and revolutionizing the LS value chain. Globally-aggregated, patient-level data could support the identification of disease mechanisms and new discovery areas, accelerate the termination of unsuccessful compounds, decrease patient recruitment cycle times for clinical trials, and improve drug safety surveillance through continuous monitoring. Although it has potential for the entire enterprise, this paper focuses specifically on how EHR data can improve Research, Development and Post-marketing Surveillance.

- We need to have more proactive drug safety surveillance—how can we detect drug safety issues earlier to protect our patients?”
- Our trial recruitment cycle time is too long—how can we improve it?
- Our discovery and validation programs are no longer delivering—how can we change our methods?
- We need to find new sources of competitive advantage—how can we collaborate more effectively with hospitals and other payor organizations?

This article will help you think through ways to effectively apply externally-sourced, patient-level data to inform decisions along the product lifecycle.

LS companies struggle to contain costs, fuel innovation and advance safety

R&D costs have increased sevenfold in the last 25 years without a corresponding increase in New Chemical Entities (NCEs). A widely accepted estimate for R&D cost per new compound was \$802 million,¹ however this estimate has been re-assessed at \$1.7 billion² with the expectation that it will only continue to increase in the future. As the industry seeks to lower costs, executives must find ways to support innovation and collaborate more effectively to facilitate the shift toward personalized medicine. At the same time, regulators and payors are demanding better safety and surveillance mechanisms.

Lengthy clinical trials and delays exacerbate development costs

The skyrocketing development costs are partly attributable to the slow pace of discovery and validation. Efforts to find better biomarkers and to terminate ineffective compounds more quickly are hampered by the complex analysis required. Most LS researchers do not have access to the large, comprehensive patient data sets necessary to readily compare disease behavior to associated genetic alterations.

The increasing rigor of clinical trials also drives up R&D costs. The average duration of the clinical phase increased from 3.1 years in the 1960s to 8.6 years in the 1990s.

Inefficient patient recruitment and subsequent delays are another source of increasing R&D spend. In 1998 only 40,000 of the 778,000 physicians in the US participated in clinical trials. Trials miss patient enrollment deadlines almost 80% of the time because of the large number of participants required and the inability to track patients that meet prescreening criteria. The average delay from missing enrollment deadlines is about 90 days for which each day of delay costs an estimated \$1.3 million³ in lost sales.

Current methods do not support the demand for safety and surveillance

Increased media attention has piqued public concern over drug safety at the same time as federal regulations have become more stringent, mandating risk mitigation plans and improved visibility into clinical trials. Since 1998, more than 70% of New Molecular Entities (NMEs) were approved with post-marketing commitments.

Despite the increased focus on safety, most LS companies currently measure safety and efficacy through the limited information reported by physicians. Not only is this reactive surveillance unsatisfactory for improving safety, it provides limited insight into a drug's overall risk/benefit profile.

To compound the problem, payors increasingly demand "medical evidence" on the safety and effectiveness of a drug as a prerequisite for reimbursement decisions and challenge the cost of drugs that lack this evidence.

¹ DiMasi et al. (2003) – in FY 2000 dollars.

² Has the Pharmaceutical Blockbuster Model Gone Bust? A Bain & Company Study; Ashish Singh

³ 3rd Annual Merging Electronic Health Records and eClinical Technologies: Leveraging EHRs for Clinical Research—Considerations for tomorrow's technology, Sept 24-25, Annapolis, Somesh Nigam, PhD, Director of Enterprise Architecture, J&J Pharmaceutical R&D.

Secondary EHR data could provide new insights into patient health and transform the value chain

The EHR Effect—A Vision for the Future

Imagine if your research scientists could query a large database of patient information for quantitative polymerase chain reaction (PCR) results in relation to a variety of treatments. Instead of performing lengthy and expensive pre-clinical experiments to uncover toxic compounds, your scientists would be able to draw correlations between gene expression, disease progression, and treatment efficacy for similar classes of drugs within minutes.

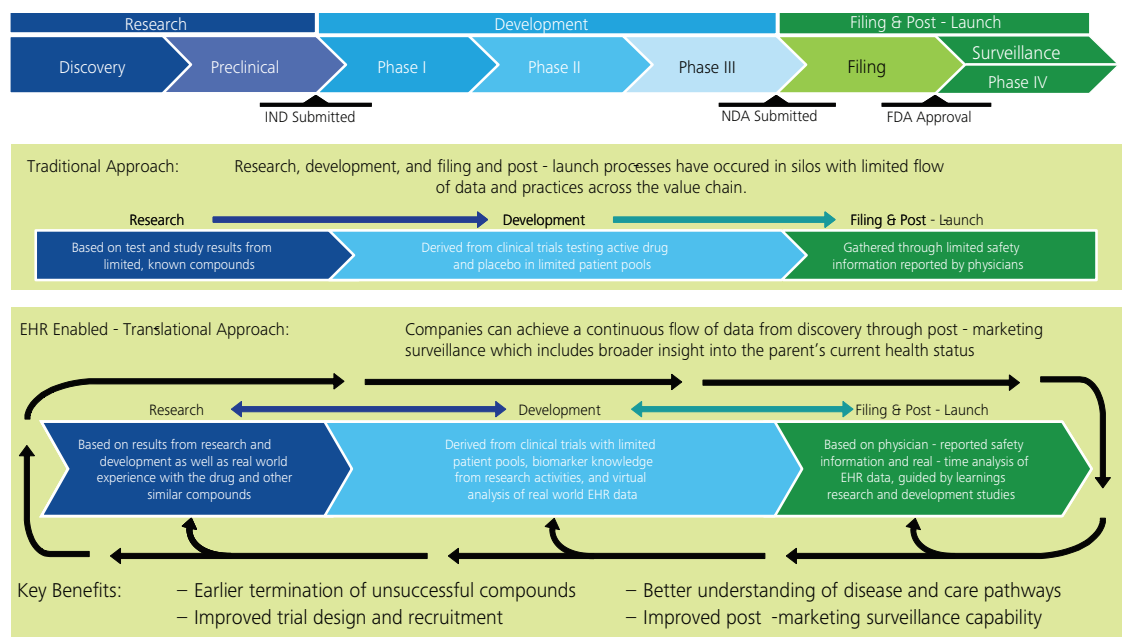
Imagine being directly plugged in to any disease demographic, being able to find locations with the largest target patient populations, and recruiting those patients during routine clinic visits. Instead of relying on investigators to recruit patients as they trickle in, you could know every patient in your trial before the investigator

does, dramatically reducing the cycle-time for clinical trials. Imagine being able to track the safety and efficacy of a treatment through automated adverse event reporting generated by an EHR system. Instead of waiting for a class-action suit, you could stop a potentially damaging treatment or trial before exposing any more patients.

An EHR strategy is a long-term enabler for LS companies

EHR-derived data has the potential to transform the industry's approach to research, development, and post-market surveillance as depicted in Figure 1. While some of these capabilities are already within reach, others will require further development. Early adopters can improve efficiency, reduce costs and gain a competitive advantage in post-marketing surveillance and clinical trial cycle time.

Figure 1: Mining of EHR and patient-level data could drive a new approach for the LS value chain.



Research: As EHR integration becomes more sophisticated, companies will be able to use patient-level data within the discovery process. This data should facilitate biomarker discovery and validation, earlier termination of unsuccessful or toxic compounds, and advances toward personalized medicine.

Development: Access to longitudinal patient records should help reduce clinical trial cycle times by enabling search capabilities that track specific disease demographics, and by identifying investigators and trial-ready sites. By using EHR data, patient populations that meet the inclusion / exclusion criteria can be quickly identified, which could help reduce patient recruitment times. Going one step further, slightly altering the inclusion / exclusion criteria could dramatically increase the patient population and in turn help further reduce recruitment cycle times. Figure 2 quantifies these potential benefits. In addition, prior clinical and diagnostic data could help improve clinical trial design through a more comprehensive understanding of disease progression and care pathways.

Post-marketing Surveillance: There is an immediate opportunity to use EHR data within post-marketing surveillance to measure drug safety. In the near future, large, anonymized longitudinal patient data sets will help to identify emerging health problems and populations at high-risk for disease, support outcome studies on the effectiveness of treatment(s) and evaluate the usefulness of diagnostic tests. As EHR data becomes more widely available and accessible, pharmaceutical companies are at risk from other healthcare organizations, such as regulators or payors, who will compete to master EHR information to measure drug efficacy and outcome statistics. It is imperative that life science companies adopt an EHR strategy early to overcome the growing pains of leveraging a new technology and develop means to elucidate sophisticated, comprehensive data sets from EHR systems.

Figure 2: Potential benefits of integrating EHR data within drug development (Illustrative).

Trial Design (Refining Inclusion / Exclusion Criteria)	Patient & Investigator Recruitment (Patient Recruitment)	Execution Analysis (Patient Compliance Tracking)
<ul style="list-style-type: none"> EHR alerts increased enrollment rates from 2.4% to 22% of recruited patients (Prior knowledge of health status could drive further improvement) Total cost savings for screening 40,000 patients with a 5% "hit" rate is approximately \$3.2 million 	<ul style="list-style-type: none"> Studies show EHR data can drive: <ul style="list-style-type: none"> A 28% increase in eligible patient identification A doubling of monthly patient enrollment rate A near ten-fold increase in the enrolled to referred ratio 	<ul style="list-style-type: none"> Journaling compliance increased from 11% with paper-based methods to 94% electronically EHR-based monitoring enables intervention before patient must be excluded from data set Use of EHR data and patient alerts reduces attrition rate by 50%, reducing overall trial size
Potential Savings: \$3.2 Million	Potential Revenue Estimate: \$125 Million	Potential Savings: \$1.8 Million
Assumptions for Calculating Savings & Additional Revenue	<ul style="list-style-type: none"> Phase III clinical trial 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 	

The limitations of a nascent field

Although there are many benefits of an EHR strategy, LS organizations will face several challenges. Conceptually, using this data effectively depends upon integrating multiple EHR systems in a way that maximizes query and search capabilities. The lack of a common language for patient information may prevent effective interoperability between EHRs and the IT systems used by LS companies. Other hurdles include confidentiality issues, intellectual property concerns, ownership/governance regarding EHR data, and other legal and ethical considerations related to using patient data. These issues will require the collaboration of relevant stakeholders to establish standards and develop innovative solutions.

An EHR strategy requires proactive communication and relationship building

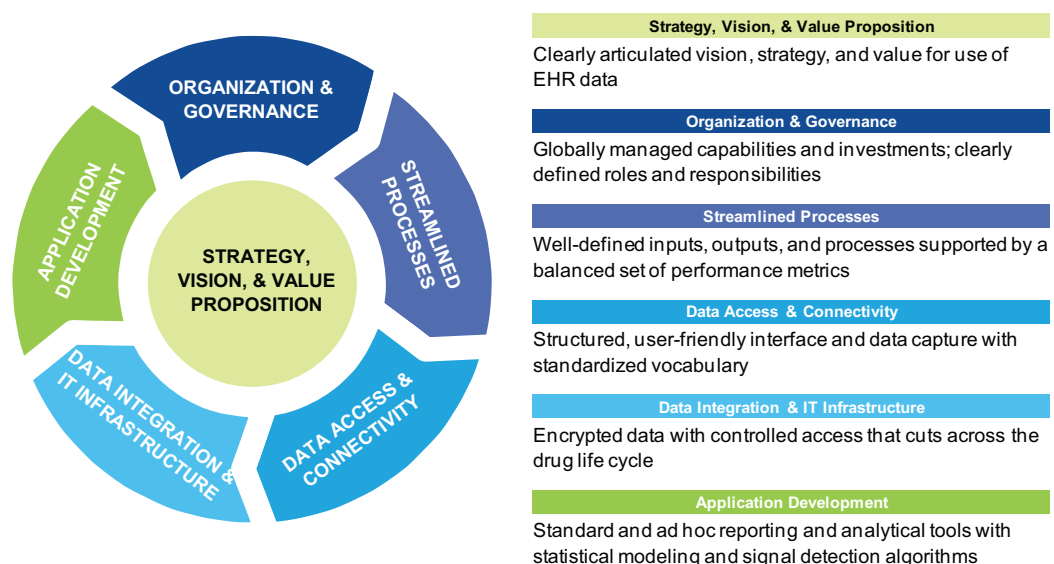
In an environment focused on short-term success, communicating the value of a long-term EHR strategy may be difficult. Executives must first create believers and enable the industry collaborations that will demystify the value of applying EHR data. Industry leaders will need to:

- **Gain internal buy-in:** Resolve varied and conflicting perspectives on the relevance of patient-level data and alleviate skepticism regarding how use of that data will impact research innovation and decision-making.
- **Establish cross-functional linkages:** Promote effective internal and external collaboration. Because EHR data resides in hospitals and health systems, gaining access to patient-level information hinges on a LS company's ability to develop relationships with provider institutions.

Early adopters will be positioned to build a foundation for long-term EHR success

A successful EHR strategy is not an event but a journey. Early adopters will focus on developing the processes that will be positioned to accelerate their ability to use patient-level data to drive cost reduction and operational efficiencies. The first step is to develop a comprehensive approach that is aligned with Corporate Strategy and drives measurable business value. The model shown in Figure 3 provides an overview of the areas that must be addressed early in the journey.

Figure 3: An initial approach to develop an effective EHR strategy



Industry leaders are paving the way to an EHR strategy

Companies like Pfizer and Johnson & Johnson have already recognized the potential for integrating patient-level data across areas of drug discovery, development and commercialization. Pfizer has dedicated resources to health informatics and is in the process of evaluating applications for EHR data use. Similarly, Johnson & Johnson has begun exploring the strongest applications for EHR data, including the integration of EHR data in areas of safety surveillance, clinical trials and outcomes research. A variety of other healthcare companies are currently assessing opportunities to apply external EHR data using methodologies and governance models for future-state, EHR-based operations. Using secondary EHR data is a long-term strategic play with the potential to transform the value chain.

- **Research:** EHR data can help accelerate research processes by facilitating biomarker validation efforts and supporting the termination of unsuccessful compounds earlier in the process.
- **Development:** Patient-level data can help improve clinical trial design and protocol feasibility as well as reduce cycle times for recruiting investigators and patients.
- **Post-marketing Surveillance:** Aggregate patient data from longitudinal medical records can yield improved insight into a drug's efficacy and risk-benefit profile.

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