

A spoonful of sugar

R&D costs for life sciences have been on the increase for many years, but at last the pill may be sweetened by EHR data, which can cut the time and cost of clinical trials and pretrials, as Deloitte Life Sciences Division's **Terri Cooper** and **Glenn Carroll** explain.

Most life sciences (LS) research & development (R&D) functions are under increasing pressure to improve innovation, reduce development inefficiencies and improve product safety. Patient-level data, collected through electronic health record (EHR) systems, offers one promising avenue for redefining R&D and revolutionising the LS value chain. Globally-aggregated, patient-level data could support identification of disease mechanisms and new discovery areas, quick termination of unsuccessful compounds, rapid recruitment of patients for trials, and continuous drug safety surveillance. Although it has potential for the entire enterprise, this article focuses specifically on how EHR data can improve research, development and post-marketing surveillance.

R&D costs have increased sevenfold in the past 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, however this estimate has been re-assessed at \$1.7 billion with the expectation that it will only continue to increase in the future. As they seek to lower costs, industry leaders must find ways to support innovation and collaborate more effectively as the industry moves toward personalised medicine. At the same time, regulators and payors are demanding better safety and surveillance mechanisms.

Lengthy trials and delays raise costs

Skyrocketing development costs are partly attributable to the slow pace of discovery and validation. Efforts to find better biomarkers and 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 behaviour to associated genetic alterations.

The increasing rigour of clinical trials also drives up R&D costs: average durations of the clinical phase have increased from 3.1 years in the 1960s to 8.6 years in the 2000s.

Inefficient patient recruitment and subsequent delays are another source of R&D cost increases. In 1998 only 40,000 of the 778,000 physicians in the US participated in clinical trials. Trials miss patient enrolment 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 enrolment deadlines is about 90 days; each day of delay costs an estimated \$1.3 million in lost sales.

Current methods don't 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 want "medical evidence" on the safety and effectiveness of a drug as a prerequisite for reimbursement decisions and are challenging the cost of drugs that lack this evidence.

The EHR effect

Access to secondary EHR data could provide scientists with 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, within minutes they would be able to draw correlations between gene expression, disease progression, and treatment efficacy for similar classes of drugs.

Also, access to any disease demographic, locating the largest target patient populations, and recruiting those patients during routine clinic visits will cut not only reliance on investigators to recruit patients but will also dramatically reduce the cycletime for clinical trials.

Automated adverse event reporting through the EHR system would also allow tracking of the safety and efficacy of a treatment and could stop a potentially damaging treatment or trial before exposing any more patients.

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 (Figure 1). Some of the capabilities are already within reach while others require further development. Early adopters can improve efficiency, reduce costs and gain a competitive advantage in post-marketing surveillance and clinical trial cycle time.

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 personalised medicine.

Figure 1: Potential benefits of integrating EHR data within drug development.

Trial design (refining inclusion/exclusion criteria)	Patient and investigator recruitment (patient recruitment)	Execution and analysis (patient compliance tracking)
<ul style="list-style-type: none"> EHR alerts increased enrolment 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 	Studies show EHF 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 dataset Use of EHR data and patient alerts reduces attrition rate by 50%, reducing overall trial size
Savings: \$3.2 million	Additional revenue: \$125 million	Savings: \$1.8 million
Assumption for calculating savings and 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 	<ul style="list-style-type: none"> Per patient screening cost: \$100 Cost per enrolled patient: \$6,000 Anticipated product revenue: \$1m/day

Source: Deloitte

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. In addition, prior clinical and diagnostic data could help improve clinical trial design as a result of better understanding 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, anonymised longitudinal patient data sets will be available to help 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 organisations who will compete to master EHR information to measure drug effectiveness and outcome statistics. It is imperative that LS companies adopt an EHR strategy early to overcome the growing pains of leveraging a new technology and develop a means to elucidate sophisticated, comprehensive data sets from EHR systems.

The limitations of a nascent field

Although there are many benefits from an EHR strategy, LS organisations will face several challenges. Conceptually, using this data effectively depends upon integrating multiple EHR systems in a way that maximises 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. They'll 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 the LS company's ability to develop relationships with provider institutions.

Building a foundation for long-term EHR success

Early adopters of an EHR strategy 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.

Industry leaders are paving the way to an EHR strategy

Companies such as Pfizer have already recognised the significant potential for integrating patient-level data across multiple areas of drug discovery, development and commercialisation. Life Sciences companies have dedicated resources to health informatics and is in the process of evaluating applications for EHR data use.

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. ■