



Authors: Lynette Ferrara, Dan Foltz and Fran Turisco

Table of Contents

Page 1

Industry Challenges

Page 2

Enterprise Health Intelligence: Using Data and Analytics to Drive the Next Generation Pharmaceutical Business

Page 3

Enterprise Health Program

Page 4

How Health Intelligence Enables the Next Generation Operating Model

Page 5

Success Story

Page 7

Collaboration is the Future for the Pharmaceutical Industry

Page 8

Getting Started

Page 9

References

Industry Challenges

“Uncertain” is the word often used to describe the future of the pharmaceutical industry. The pharmaceutical business — research, discovery and development of drugs — is inherently risky. When new regulatory requirements, additional market expectations and competitive pressures are added to the picture, it becomes apparent that pharmaceutical companies need to make dramatic changes in all aspects of business operations to thrive. This paper highlights the major industry challenges and describes how some organizations are using information as a strategic asset to work differently — doing and achieving more with less.

Rising Costs for Drug Discovery and Development

Risk and reward for drug development is out of balance. The cost and time to bring a new drug to market continues to escalate. A recent study from the Tufts University Center for the Study of Drug Development puts the average cost of a new medicine at \$1.3 billion, with a R&D process taking as long as 10 to 15 years. For every 5,000 to 10,000 compounds tested, just five make it to clinical trials and only one will eventually receive FDA approval.¹

“The FDA approved 19 new drugs in 2007, the smallest number since 1983 when only 14 drugs were approved.”²

In addition, industry experts agree that the “Era of Blockbusters” is over.³ Specialty and niche, targeted products (personalized medicine) — the new mainstay — are unlikely to have the revenue punch of the blockbusters from prior years. As a result, pharmaceutical companies must find ways to conduct more narrowly-targeted clinical trials at lower costs, while at the same time increasing success rates.

Managing the Influence Chain

Payers, both government and commercial, have wielded a heavy hand in influencing the shift from brand name drugs to generics, motivated by the substantial cost savings that result from steering physicians and patients to the fast-growing pool of very good medications available in generic form. Plan medication coverage is now written to limit access to brand name drugs, and e-prescribing and pharmacy point-of-sales systems enforce the new benefit designs through prescription denials and online reminders for generic substitutions. The revenue impact is substantial. In 2007, there was a \$16 billion patent loss to the pharmaceutical industry, and only a 3.8 percent growth in revenue.⁴ DataMonitor predicts that revenue will actually decline for the first time in 40 years between 2011 and 2012.⁵

This pool of good and inexpensive medications has also raised the bar for new medication market acceptance. New medications need to satisfy the requirements of the decision maker, increasingly the payer, as opposed to the care provider. Payers are demanding evidence that the new medication improves outcomes and/or reduces the total cost of care, before adding it to their formularies. In England, pharmaceutical companies have had to conduct head-to-head trials to “bump” an existing drug from National Health Service (NHS) formularies before they receive market approval. Though the U.S. market is less restrictive, (Centers for Medicare & Medicaid Services (CMS), health plans and provider organizations are beginning to require evidence of health outcomes and economics as a condition for formulary acceptance.

New Regulatory Requirements

Payers and consumers are not the only ones weighing the risk-benefit factors of pharmaceuticals. The FDA has new power to police drug safety, a response to the Vioxx patient safety problems and eventual market withdrawal in 2004.⁶ For drugs that pose potentially serious risks, the FDA can require safety precautions such as special training for physicians, regulated advertising, warning messages on labels and close monitoring of patients.

But to identify risks, new methods of monitoring drug risks are needed. Clinical trials don't always catch safety risks, and the current voluntary process for spontaneous adverse event reporting probably catches less than 10% of adverse events that actually occur.⁷

The FDA Sentinel Initiative is one effort to build a wider safety net by allowing the agency to monitor usage and assess the risks of drugs already on the market by using information on Medicare claims. Section 905 of the Food and Drug Administration Amendments Act of 2007 calls for the Health & Human Services (HHS) Secretary to develop methods to obtain access to disparate data sources. The goal is to establish a post-market risk identification and analysis system to link and analyze healthcare data. The expectation is to have data from 25 million patients by July 1, 2010 and 100 million by July 1, 2012.⁸ The law also requires the FDA to work closely with partners from public, academic and private entities.⁹

Enterprise Health Intelligence: Using Data and Analytics to Drive the Next Generation Pharmaceutical Business

Escalating costs, more stringent requirements for approval and adoption, and revenue pressures from generics and consumers will require major changes in the pharmaceutical operating model. The challenge to do more with less will require doing it differently.

The ability of the pharmaceutical industry to improve its value chain is based, at least in part, on managing information as a strategic asset to create value. Timely access to rich internal and external sources of scientific, real world patient care, and healthcare cost information is increasingly critical. Pharmaceutical organizations are certainly masters at collecting and analyzing vast and complex data required for clinical trials, while complying with the detailed regulations at many levels. The result, unfortunately, is robust data management at the study level — creating silos of data, most in different data formats and using different coding schema.

Escalating costs, more stringent requirements for approval and adoption, and revenue pressures from generics and consumers will require major changes in the pharmaceutical operating model. The challenge to do more with less will require doing it differently.

Adding observational data collected and maintained by providers, health plans and the government, from diverse electronic medical records and public and privately maintained patient registries, not to mention financial data collected from medical and pharmaceutical claims, exponentially increases the complexity of solving the data integration challenge.

Despite these barriers, pharmaceutical organizations will have to overcome the challenge to answer regulators questions that involve both research and observational data, to re-use valuable clinical trials data for other studies, and to work collaboratively with health plans, providers and government agencies.

Enterprise Health Intelligence Program

To move beyond silo'd research data and study-focused analysis, an organization needs to start at the top to implement an approach to enterprise-wide management of clinical and research information that addresses the lifecycle of the data during the lifecycle of the product. This requires new processes, governance, data management and technology architecture to create an enterprise health intelligence program. Figure 1 depicts the major health intelligence components that are briefly described below.

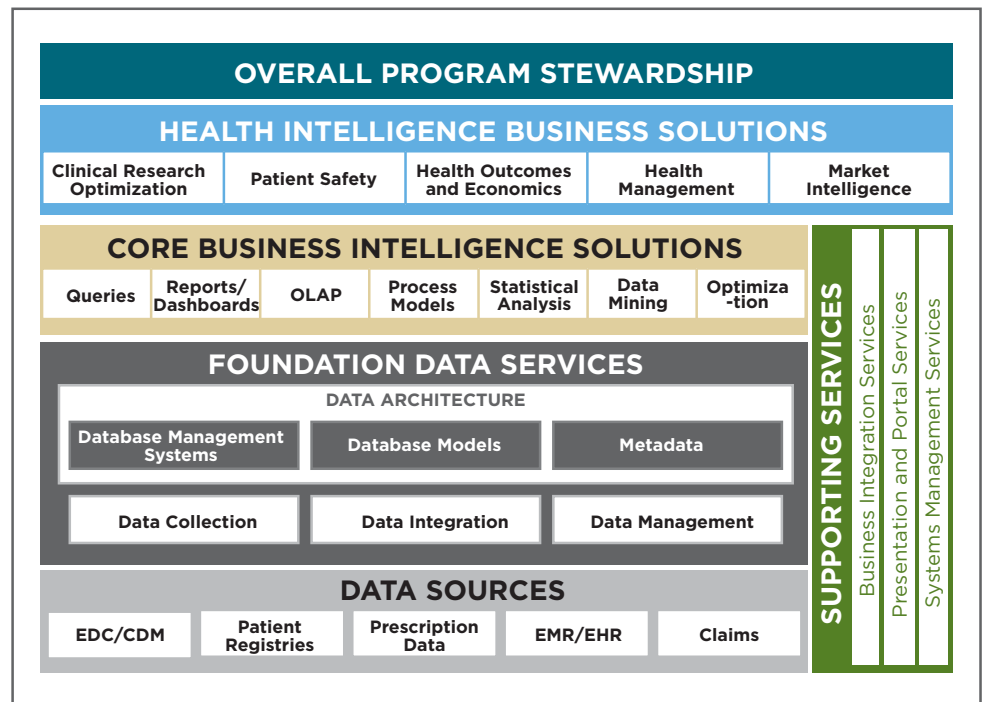


Figure 1: Health Intelligence Program

Data Services — Data from disparate providers (both within the organization and externally) undergoes a transformational process that not only maps them into a consistent data model using standardized code sets, but progressively increases their quality and utility for reuse with sophisticated tools and industry-recognized vocabularies. Robust management and security functionality, integrated into the solution, monitor and audit changes applied to source data, and ensure that data confidentiality and privacy policies are enforced.

Core Business Intelligence Services — Data across studies are now available to researchers who may use a variety of specialized statistical tools to query, mine and analyze the data. These can include both third-party products such as SAS and SPSS, and custom-developed applications.

Supporting Services — Infrastructure services support application management, data management, end-user presentations, business process integration and overall systems management.

Business Solutions — Health Intelligence business solutions combine core business and support services to address specific initiatives including clinical research, patient safety, health economics, health management and market intelligence. When implementing a Health Intelligence solution, organizations typically start in one area such as internal clinical trials data integration and then extend the solution by adding clinical data from provider organizations for health outcomes analysis or to meet FDA post approval surveillance monitoring requirements.

Overall Program Stewardship — The success of the program depends on a top-down approach to clinical information planning, monitoring and coordination. Stewardship starts the process for health intelligence by defining the organization's clinical information management strategies, documenting a plan for building the technology solution, and establishing the processes and governance for ongoing support and development. Moving beyond the boundaries of the organization, stewardship takes on a larger role of creating the processes and policies to guide the development of rich data partnerships with providers, health plans, the government and other life sciences companies.

How Health Intelligence Enables the Next Generation Operating Model

Health Intelligence offers the breadth of data aggregation and analysis capabilities to support the necessary changes to business operations and new partnerships for research, surveillance and regulatory compliance:

- **Clinical Research** — To optimize the design and operation of clinical trials, health intelligence is used to support a new R&D model, with distinguishing features including more targeted studies, rapid recruitment and data capture, faster approvals and controlled launches. Health intelligence provides the foundation for connecting the patients, providers and investigators and supports data standardization so data is useable across all settings. One of the biggest benefits of the aggregated data source is the ability to accelerate patient identification and recruitment for clinical trials. By optimizing the criteria, more and better-qualified candidates are identified, resulting in shorter overall clinical trials timeframe. In the case of multiple clinical trials, health intelligence solutions can aggregate the data from those study datasets to conduct new analyses not possible in any individual dataset.

Health intelligence also lays the foundation for personalized medicine by enabling the capture and integration of both clinical and genetic patient data that can be used through standardized, automated and compliant processes to drive the entire R&D cycle.

Using health intelligence applications frees up the research team from time spent on data collection and integration to devote more time on creating new knowledge, products and services.

- **Patient Safety** — To fully understand and address patient safety issues requires increasing the boundaries for data collection and analysis beyond clinical trials to include data from Electronic Health Records (EHR) and claims. This approach to drug safety provides pharmaceutical companies and regulatory agencies near real-time information that can be used to identify and respond to safety signals. When information from thousands of patients exposed to a new drug can be analyzed, safety issues are identified more quickly, reducing both health risks to patients and financial risk for pharmaceutical companies. Ultimately it will be possible to deliver safety alerts to point-of-care tools that help clinicians manage drug risks and alert them to potential safety issues.
- **Health Outcomes and Economics** — Health intelligence provides the platform and the data to further the “art and science” of determining actual health outcomes and economic value from medications. These analyses can be used to reduce the barriers to market entry and uptake by demonstrating the ability of new and existing products to improve outcomes and/or reduce the cost of care — including head-to-head comparative analyses.
- **Market Intelligence** — Health intelligence provides the data to explore population characteristics that support rapid discovery of new opportunities for drug development. This information helps firms to target research on truly innovative products tailored to the unmet needs of special populations and disease states, and focus on current product usage analysis and provider prescribing trends to identify new uses for current products.
- **Health Management** — According to the 2008 Roland Berger study, industry executives believe their future will include providing integrated healthcare solutions, rather than just selling products.¹⁰ Leading organizations are already heading down this path. For example, one large pharmaceutical provides support services to hospitals attempting to improve surveillance of sepsis patients. Integrated data are critical to making the transition from product-only to product and services.

Using health intelligence applications frees up the research team from time spent on data collection and integration to devote more time on creating new knowledge, products and services.

Success Story:

Early experience with health intelligence applications is very promising. Organizations are proving through pilots and large-scale operational programs that both internal and externally available information can be combined and leveraged in new ways to create value. The following case summary highlights one pharmaceutical company's experience implementing health intelligence that leverages internal data from numerous clinical studies.

Large Multinational Pharmaceutical Firm

Goal: Create a new core competency that manages data as a primary asset to defend competitive threats, support marketing activities and identify new scientific leads and research opportunities.

Program: Comprehensive approach involving people, process and technology and driven by business leaders

- New organizational roles and responsibilities, new policies and procedures
- Health Intelligence Steering Committee and governance process
- Single data repository and sophisticated data mining and reporting tools for conducting exploratory analysis on large quantities of clinical data
- Standardized process and format for importing post-approval trial data to the health intelligence data repository

Examples of Health Intelligence Studies:

- Refuted a competitor's claim about medication reduction-episodes and acute rejections for a transplant medication by re-analyzing data already collected as part of the registration trials using more sophisticated tools.
- Determined dose rates to achieve optimal dose concentration for a new drug by integrating blood sample data that looked at troughs and areas under the curve (AUCs) for that drug from another study; eliminating the time and expense to collect and analyze blood from the clinical study patients.

Benefits Summary: Very successful program now expanded to all therapeutic areas world-wide

Pilot Program Metrics:

Research Studies	Pre-Health Intelligence	Post-Health Intelligence
Number of Studies	3	9
Number of Analytical Projects	5	7
Total Duration of All Projects (Days)	110	80
Resources (FTEs)	2.0	2.5

Other: Last year, 60 percent of US publications were based on analysis studies from the health intelligence data repository

Collaboration is the Future for the Pharmaceutical Industry

The above case summary is not singular data point; rather it is part of a growing trend of collaborations and effective data aggregation initiatives to increase the body of knowledge about medication safety, effectiveness and their impact on healthcare outcomes. Figure 2 depicts some of the leading healthcare collaborative efforts and expected timeframes for data availability, including several pharma-related initiatives. For example, the Pharmaceutical Research and Manufacturers of America (PhRMA), the Foundation for the National Institutes of Health, the NIH, and the FDA have formed a public-private partnership to search for and validate new biomarkers. Some initial projects for the collaborative will identify genomic biomarkers for treatment response in major depressive disorder and look for new biomarkers for Type II diabetes that could lead to a more reliable and faster diabetes test.¹¹



Figure 2: Healthcare Data Iceberg

In another Foundation for the National Institutes of Health partnership, the aim is to actively and systematically assess the risks and benefits of marketed drugs and devices, using a technology solution that captures data from many research and observational data sources. As technology and the science of pharmacoepidemiology continue to mature, this initiative could provide enhanced capabilities to detect adverse events and other outcomes along with the potential of faster, better-informed decision making and communications to the public.¹² The results from the pilot will inform the FDA Sentinel Initiative about long-term technology requirements.

M2Gen is an example of a partnership between health delivery and the pharmaceutical industry. Jointly, H. Lee Moffitt Cancer Center and Merck & Co. will develop personalized cancer treatments for patients. Researchers will use genetic profiles from tissue samples to identify genetic biomarkers for diagnosis and prognosis and to identify targets for drug development. They are building a database that combines a patient's phenotype data with genotype data. By analyzing patients' responses to specific treatments, researchers expect to more quickly match patients to clinical trials and to develop medications and personalized treatment protocols that improve outcomes with fewer side effects. To date, tissue samples from nearly 6,000 patients have been collected and thousands more have signed consents.^{13, 14}

Information technology is at the heart of these programs — aggregating data from a wide number of sources, using sophisticated analysis and reporting tools in support of the care and health management initiatives.

Getting Started

A health intelligence program is the new core competency for any pharmaceutical business that will thrive. Future success will require dramatic changes in how a business acquires, manages and analyzes data — supporting new data types, new research methods and technologies. Health intelligence provides the platform.

The first step in getting started is to build a compelling business case for the health intelligence applications that address the most urgent business priorities. This process not only produces an action plan, but it also quantitatively declares the gains to the organization and builds executive awareness and sponsorship needed to sustain the development of this new competency.¹⁵

References

- 1 "Pharmaceutical Research and Manufacturers of America." *Pharmaceutical Industry Profile 2008*. (Washington, DC, PhRMA, March 2008).
- 2 "Bloomberg News" via the *Arizona Daily Star* (January 10, 2008).
- 3 "2008 Trends Brief: 2008 Trends to Watch: Pharmaceutical Technology." *Data Monitor* (January 2008).
- 4 "US Prescription Drug Sales Growth Slows." *Houston Chronicle* (March 12, 2008).
- 5 "Big Pharma Faces Grim Prognosis.) *WSJ*(December 6, 2007).
- 6 R. Pear. Senate Approves New Power for F.D.A. on Drugs. *NY Times* (May 9, 2007).
- 7 "Adverse Events: Surveillance Systems for Adverse Events and Medical Errors: GAO Testimony." (February 9, 2000).
- 8 "FDA to Expand Scrutiny of Risks from Drugs After They Are Approved." *NY Times* (May 23, 2008).
- 9 Title. <http://www.fda.gov/oc/initiatives/advance/reports/report0508.html>. Date accessed (October 3, 2008).
- 10 Press Release. Roland Berger Strategy Consultants. "Pharma at the Crossroads" Study. (July 7, 2008).
- 11 "Pharmaceutical Research and Manufacturers of America." *Pharmaceutical Industry Profile 2008*. (Washington, DC, PhRMA, March 2008).
- 12 Foundation for the National Institutes of Health Website: http://www.fnih.org/index.php?option=com_content&task=view&id=583&Itemid=730. Date accessed (September 24, 2008).
- 13 C. Gentry, "Have Merck, Moffitt Found Cure?" *Tampa Tribune* (December 24, 2006).
- 14 M2Gen, Moffitt Cancer Center's new research initiative and collaboration with Merck,& Co. Moffitt Cancer Center Website. www.moffitt.org. Date accessed (March 24, 2009).
- 15 "Thriving on Disruption". CSC White Paper (2007).

Worldwide CSC Headquarters

The Americas

3170 Fairview Park Drive
Falls Church, Virginia 22042
United States
+1.703.876.1000

Europe, Middle East, Africa

Royal Pavilion
Wellesley Road
Aldershot, Hampshire GU11 1PZ
United Kingdom
+44(0)1252.534000

Australia

26 Talavera Road
Macquarie Park, NSW 2113
Australia
+61(0)29034.3000

Asia

139 Cecil Street
#08-00 Cecil House
Singapore 069539
Republic of Singapore
+65.6221.9095

About CSC

The mission of CSC is to be a global leader in providing technology enabled business solutions and services.

With the broadest range of capabilities, CSC offers clients the solutions they need to manage complexity, focus on core businesses, collaborate with partners and clients, and improve operations.

CSC makes a special point of understanding its clients and provides experts with real-world experience to work with them. CSC is vendor-independent, delivering solutions that best meet each client's unique requirements.

For 50 years, clients in industries and governments worldwide have trusted CSC with their business process and information systems outsourcing, systems integration and consulting needs.

The company trades on the New York Stock Exchange under the symbol "CSC."

Copyright © 2009 Computer Sciences Corporation. All rights reserved.

DS08_0718
March 2009