Data-Driven Transformation in the Pharmaceutical Industry

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Executive Summary

Pharmaceutical companies continue to face disruption in their market and traditional business processes. Although the peak of the patent cliff has passed and R&D productivity is increasing, the industry must still navigate major changes related to the following trends:

- **Increased collaboration** with other pharmaceutical companies, academics, outsourcing partners, and other parts of the healthcare community
- Global **increases in regulation** and oversight
- Shift to **value-based pricing** for pharmaceutical products

The pharmaceutical industry is not immune to the global trend toward a data-driven world. As the volume and complexity of pharmaceutical data expands, the available technologies to analyze this data become increasingly sophisticated. Unsurprisingly, this shift also sharply raises expectations of these tools' ability to deliver detailed, accurate reports to support new business models and increased regulatory oversight.

As success becomes ever more dependent on the ability to transform data into information, the pharmaceutical companies that outpace the competition will be those that manage their data most effectively and efficiently. This paper explains how Informatica provides the key differentiator: Great Data—clean, safe, and connected —that's ready to use throughout the company.

Delivering Great Data to the Pharmaceutical Industry

As science, manufacturing, and marketing become increasingly digital, pharmaceutical companies must develop strategies and infrastructure to derive value from huge volumes and variety of data. Many pharmaceutical companies turn to Informatica to deliver Great Data to a wide variety of employees who make frequent decisions on a daily basis.

Informatica's technology can deliver business value across all of a pharmaceutical company's operational areas. Our technology directly addresses common challenges faced within the pharmaceutical industry.

1. Research and Development

Pharmaceutical companies are adopting a number of different approaches to the key focus of improving R&D efficiency, including partnerships, acquisitions, and increasing use of contract research organizations. However, data volume, variety, and velocity often hamper efficiency. So does the highly fragmented data management environment created by cross-organizational collaboration, mergers and acquisitions (M&A), and a historic lack of comprehensive data management strategy.

At one major pharmaceutical company, Informatica helps deliver Great Data to improve decisions in drug discovery by drawing data from 400 Oracle databases comprising 700 million rows of data covering 12 million compounds. Data, including high-throughput screening data, is loaded by Informatica tools into four data marts for analysis, reporting, and discovery of new treatments.

Our technology also contributes to life life-changing medicine within the extended health carehealthcare community, including a focus on outcomes analysis. A leading American health care provider relies on Informatica to support a sophisticated enterprise analytics initiative that brings together clinical, financial, administrative, genomic, and other information. The initial project combined clinical and genomic information on cancer patients—the first time this data had been integrated electronically. Eventually, the company will manage more than 1,200 applications with data integration, master data management, and complex event processing capabilities from Informatica.

> "Companies should focus on improvements in R&D returns by maximizing the value of science, preserving and developing talent in R&D, and harnessing the power of analytics to enhance R&D decision-making."
>
> – Deloitte 2015 Global Life Sciences Outlook

Informatica's ability to deliver high-quality data is well recognized by contract research organizations (CROs) such as Quintiles. Quintiles supports quality and efficiency, by speeding promising trials toward patent approval. To meet the challenges of fragmented and delayed data, Quintiles launched Infosario, an end-to-end suite of foundational technologies that power the pharmaceutical product development process. Quintiles considers Informatica the leading enterprise data integration provider with an integrated platform that addresses key requirements of the Infosario vision.

ICON uses Informatica's Master Data Management (MDM) solution to create a consolidated and reliable view of clinical trial master data, delivering 360-degree insights into study- and site-related program activities. The solution is a key element of ICON's information platform, ICONIK, which enables more informed, data-driven decisions regarding the clinical trial process, including the effective use of monitoring resources, patient treatment, and safety and site performance.

Use of Informatica technology in the clinical trial domain is not limited to CROs. For example, a British multinational pharmaceutical company also uses Informatica's MDM solution to manage clinical trial data. The solution contributes to improving efficiency, controlling costs, and ultimately enabling the company to deliver quality medicines to patients more efficiently.

Pharmaceutical companies that work with CROs must enable data exchange and collaboration tools. A large European pharmaceutical company uses Informatica to enable efficient data exchange with its CRO partners. Data profiling and quality checks during the data exchange highlight poor data and trial non-compliance immediately, enabling fast resolution and improved analysis. Most importantly, this data monitoring gives fast feedback on trial progress and patient compliance, reducing the overall elapsed time and cost of clinical trials.

Increasingly, pharmaceutical companies are expected to publish trial data externally, but that also raises the stakes for data accuracy and confidentiality. Public trial data, electronic health records, and an increase in the types of medical data generated (e.g., genomic data), combined with increasing data privacy legislation around the globe, make the safety of patient data in large-scale trial publication a significant concern. Informatica addresses this concern with data masking technologies and data security intelligence that identifies data risks and helps organizations mitigate them.

Finally, Great Data in R&D must be stored for future reference—but the cost of storing vast volumes of data can easily spiral out of control without comprehensive information lifecycle management strategies and tools. Informatica's market-leading capabilities in information lifecycle management help control IT infrastructure costs while ensuring continued access to valuable data. A global healthcare leader has used this technology to retire hundreds of applications and archive hundreds of terabytes of data, reducing its expected IT spend by millions of dollars.

2. Manufacturing and Supply Chain

Pharmaceutical companies squeezed by healthcare providers and governments on pricing must pursue greater efficiency by eliminating bloat in the supply chain. One popular approach is to use contract manufacturing organizations (CMOs), but supporting the necessary collaboration across organizational boundaries requires pharmaceutical companies to provide high-quality data that enables analysis of current processes and their associated cost levers.

Great Data is also key to meeting more stringent regulatory requirements, such as the game-changing March 2015 EU guidelines governing traceability requirements on Active Primary Ingredients.

The new guidance increases the regulatory oversight started by Mass Serialization and ePedigree initiatives. It creates a greater need for supply chain data to be collected, shared, and made available to multiple interested parties within the healthcare community. Quality by Design or Continuous Process Verification extends the need for data collection and analysis into the heart of pharmaceutical manufacturing, forcing increased investment in

[1] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2015:095:FULL&from=EN

monitoring and sensor equipment, as well as advanced data management capabilities to deal with the expected data volumes once implemented.

The value of Great Data that is readily available throughout the supply chain should not be underestimated. For example, better data management enabled by Informatica allowed an American manufacturer of medical devices and pharmaceutical and consumer packaged goods to save more than $15M through increased efficiencies in the contracting and supply chain, more accurate transaction processing, better compliance with GxP regulation, and faster adaptation to new market requirements.

A U.S. research-based pharmaceutical company achieved a multimillion-dollar ROI by using Informatica technology to reduce inventory levels and understand total purchasing from each vendor globally. Smith & Nephew capitalized on Informatica technology to access and to improve master data quality to help streamline manufacturing production and improve sales order management and product logistics. The data quality and governance project has been viewed as a huge success and is getting visibility by the senior executives all the way up to the company's Senior VP of Supply Chain and CFO.

According to Deloitte, information sharing between agencies is a growing trend, leading to cascading inspections around the world once an issue has been identified [2]. As the pharmaceutical industry comes under increased regulatory pressure across organizational boundaries, it needs to control its data better in the face of increasing complexity and collaborate with entities beyond manufacturing partners. Informatica can ensure Great Data is delivered where and when it is needed to support patient safety through greater traceability and to increase collaboration, communication, and coordination across all organizations involved in the manufacture of medicines and medical devices.

3. Sales and Marketing

The pharmaceutical industry currently suffers from a serious reputation problem. Far from being embraced for delivering life-saving medicines, the industry as a whole is treated with suspicion, damaging individual companies' ability to maintain a trusted advisor role with the public, doctors, and patients alike. This poor public perception is backed up by regular doses of bad news: large fines for poor pricing, sales, and marketing practices that are directly linked to increased regulation.

An increase in regulatory oversight has had a profound effect on the way medicines are marketed and sold across all regions globally. This oversight may be legislated, as it is in the United States, or adopted through industry guidelines such as the EFPIA HCP/HCO Disclosure Code. Marketing spend on individual prescribers must now be closely monitored and capped, in principle reducing the influence manufacturers have over healthcare decision-makers.

In addition, institutional prescription decisions are reducing the direct influence of individual healthcare practitioners on what medicines are prescribed. Leaders in the field base their treatment decisions on analytics that support value-based pricing determined by patient outcomes. Others are expected to follow as data and the technology to analyze patient outcomes become increasingly available.

"The term Big Pharma has come to represent many negative things: questionable sales and marketing practices, the ways in which research is commissioned, undertaken and published, regulatory capture through lobbying and the revolving door and monopolistic behaviour."

– Dr. Robert Barrington
Executive Director, Transparency International UK Speech to the EFPIA, Beijing, September 25th 2014

[2] Deloitte 2015 Global Life Sciences Outlook

> "In short, pharmaceutical companies need a data strategy that reflects the shift in how data are shared and analyzed, as well as a plan to manage all types of data that affect product sales, pricing, and reimbursement."
>
> – McKinsey, A digital prescription for pharma companies, November 2014

The digitization of the healthcare community means that in many mature markets, the patient is more involved in decision-making. In 2013, Accenture found that 80 percent of patients surveyed proactively researched medicines online, and 75 percent were proactive in their search for information on chronic conditions. Patients' choices are increasingly influenced by online information and forums; key influencers of healthcare providers are surfacing via the Internet and social media.

As in other industries, a one-size-fits-all approach to sales is no longer appropriate, nor is marketing based on large segments. Deloitte encourages a shift from brand-centric to personalized, customer-centric marketing across multiple communication channels[4].

Informatica has seen a large adoption of customer data management technologies in U.S.-based sales and marketing organizations, primarily to achieve compliance with Sunshine Act reporting requirements. However, many of these customers have gone on to realize benefits across sales and marketing functions. Companies report a variety of benefits from customer data management:

- IT cost reduction

- Increased sales and marketing employee productivity

- Improved insight into and performance of sales teams and territories, in some cases leading to sales uplift of 5-7 percent of revenue

- Enhanced customer segmentation, resulting in reduced communication costs of up to 30 percent, and increased marketing ROI

- Better customer service

A Massachusetts-based pharmaceutical company relies on Informatica to enable a new business model in sales and marketing. By visualizing the relationships among prescribers, research organizations, teaching institutions, and internal staff, they can now effectively identify, track, and manage key opinion leaders, who in turn influence other customers.

4. Regulatory Compliance

In its 2015 industry overview, Deloitte[5] recognizes increased regulatory requirements and expectations as a key driver for the need to transform business models. Although costs of compliance are not necessarily published, Elias Zerhouni, President, Global R&D at Sanofi, provided some insight when he mentioned that 20 percent of the R&D budget is spent on managing requirements from different regulatory agencies.[6]

With improved data management and governance, pharmaceutical companies could reduce the cost of compliance by having Great Data ready for all regulatory requirements, from submissions to inquiries and inspections.

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[4] Deloitte 2015 Global Life Sciences Outlook

[5] Deloitte, 2015 Global Life Sciences Outlook

[6] http://www.in-pharmatechnologist.com/Regulatory-Safety/Sanofi-80-of-population-ignored-as-pharma-cash-focuses-on-orphan-R-D

The adoption of the Identification of Medicinal Products (IDMP) ISO standard by the European Medicines Agency is causing a number of pharmaceutical companies to consider the usefulness of Great product Data beyond compliance. Informatica has been promoting a Master Data Management (MDM) approach to IDMP compliance, and the benefits of this approach are increasingly being recognized. Many of the supporters of the MDM approach to IDMP compliance already have mature Informatica MDM implementations within R&D and realize the value of readily available, trusted data. For example, Janssen Pharmaceutical uses Informatica technology to help create a single, trusted record for all its substances.

A March 2015 IRISS Forum survey[7] showed that more than 80 percent of respondents counted improved data management and data quality as a benefit of IDMP compliance. Although the sample size was small, it highlights two trends:

• The desire for Great Data within pharmaceutical companies

• Compliance as a driver to identify and fund data governance projects

This trend can also been seen in the USA where medical device manufacturers are rethinking the way they manage their manufacturing data to comply to the Unique Device Identifier (UDI) regulation. Like IMDP, the process is simple in theory, but not easy in practice due to the diverse data required to comply. Managing 100's or even 1000's of products with spreadsheets or existing PLM systems will expose these companies to delays which will directly affect their ability to market and sell the products in the USA.

Informatica is helping three medical device companies as they adopt a MDM approach to UDI compliance. This approach will help them deliver Great Data for compliance, despite production data for medical devices residing in multiple systems, with multiple variations and duplicate records.

All pharmaceutical regulation is largely based on the submission of accurate data. It follows that in order to comply, a pharmaceutical company has to show that it is in control of its data. The higher the degree of internal data control (or governance), the lower the cost and effort of compliance across all regulations. Informatica already manages data for regulatory compliance in a number of pharmaceutical companies (as discussed in "Sales and Marketing" above) and continues to strengthen our offerings for specific pharmaceutical regulations.

Data control is required not only by the pharmaceutical companies but also by the regulators to ensure efficient oversight. Informatica counts major regulators among our customers, including the U.S. Food and Drug Administration, which credits Informatica technology for aiding the protection of public health. Informatica ensures the regulators can access and analyze high-quality, current data.

Non-compliance is not an option when regulators do not hesitate to impose fines in the millions of dollars or withdraw products from the market. With Informatica technology, pharmaceutical companies can actively manage their data subject to regulatory oversight. The resulting Great Data reduces the cost and effort of compliance—and, what's more, can be repurposed internally to deliver business value.

[7] http://www.iriss-forum.org/page-index.html

5. Finance, Mergers & Acquisitions

Pharmaceutical M&A remains active, with the first quarter in 2015 showing the highest deal volume for six years.[8] This trend is likely to continue into the future and not only because the pharmaceutical landscape is fragmented and undergoing transformation. A McKinsey study[9] showed that pharmaceutical mergers tend to result in positive shareholder returns. In particular, the mergers that delivered a higher return aimed to consolidate companies with significant overlaps.

After a merger or acquisition, public companies need to show a unified face to customers and shareholders. They often have only a limited time to integrate their data and applications to publish consolidated financial reports. Informatica provides powerful data profiling tools that quickly discover where data resides across all applications for integration purposes. In addition, because our solutions include features that deliver an effective and efficient communication channel between business and IT users, integration projects can be completed faster at lower risk. Informatica creates a consolidated view rapidly, then delivers long-term value.

When one of the world's premier biopharmaceutical companies made a major acquisition, it turned to Informatica's enterprise data integration platform to integrate critical information assets. The combination of centralization and repeatable processes accelerated the integration for faster time to value. It also realized hundreds of millions of dollars in savings—for example, by consolidating multiple financial reporting systems into a single set of finance and procurement applications.

Benefits to the finance department go beyond M&A. With Great financial Data, organizational decision-making will improve across the board. Johnson & Johnson Finance has embarked on an enterprise initiative to provide people, processes, and technology to create an enterprise platform for global Finance data, leveraging big data and business intelligence capabilities. Some key innovations at Johnson & Johnson include:

- Data integrations across hundreds of operating companies with an approach for sustainable data quality

- Augmented active archival approach to cost effectively store and "data-mine" insights from historical financial data

6. Supporting Connected Practitioners and Patients

The world's population is increasingly embracing digital channels for information, transactions, and community interactions. Patients are not exceptions to this rule. Accenture[10] has found that patients are proactive in their search for health-related services, consuming information from multiple channels. If pharmaceutical companies are unable to fulfill the information needs of their target patient population, they risk losing their influence over patients to other parties.

"Pharmaceutical companies that remain fixated solely on prescription volume, rather than on sustaining relationships between a brand and patients, risk ceding the role of trusted provider to others."

– McKinsey: A digital prescription for pharma companies, November 2014

[8] Reuters: http://www.reuters.com/article/2015/03/05/us-pharmacyclics-m-a-abbvie-deals-idUSKBN0M11HC20150305

[9] Why pharma megamergers work; McKinsey 2014

[10] Great Expectations: Why Pharma Companies Can't Ignore Patient Services 2013 Survey, Accenture

Reaching out directly to patients is a new frontier for pharmaceutical companies, and in many markets direct contact with patients is strictly regulated. However, product information, which is often isolated in silos internally, should be made available to all interested parties through an appropriate channel (call center, web site, government agencies, or healthcare providers). Informatica Product 360 rapidly delivers rich product information across all channels and can fuel provider portals with the most current information, managing across geographies for the information that regulations require. While this solution is not yet in broad use in the pharmaceutical industry, it has great potential.

As pharmaceutical companies become increasingly active in online conversations about diseases, conditions, and treatments, identifying individuals who are part of this conversation is important. Informatica can help deliver a great product and brand experience for both patients and providers by gathering customer data through social media and web sites as well as traditional sales and marketing channels and analyzing the data to make sense of the relationships it reveals. One Informatica customer that combines customer data from internal, external, and non-traditional sources has already reduced its data prep time from two to three weeks to just 17 hours, dramatically accelerating its decision cycle as well as its ability to provide prompt answers to questions.

Informatica can help pharmaceuticals in reaching out to the connected patient and the connected practitioner in three ways:

1. Finding **relationships** that were previously hidden

2. Rapidly **enriching** existing data with new sources of data

3. **Organizing** the data to provide context for big data (and other) analytics

Cloud and Big Data: Delivering on the Promise

Companies are migrating data and applications to the cloud for cost savings and efficiencies that internally hosted applications can't deliver. They're also investing in big data technologies specifically designed to harvest value from large volumes of data. However, these tool sets are only as good as the data that feeds them—and without trusted data, they cannot deliver a clear ROI based on business measurements.

While big data technologies such as Hadoop exponentially increase analytical processing power, they don't always deliver a clear ROI. In fact, only about 30 percent of companies investing in big data have projects deployed[11]. Informatica Big Data products simplify Hadoop complexity by providing a single, scalable platform that works with traditional data warehouses, cloud-based data, and new types of data from social media and sensor devices. As Hadoop resources remain scarce, Informatica-certified developers can easily transition to a Hadoop environment without learning Hadoop.

A stunning 64 percent said they were unable to integrate their cloud apps with other enterprise apps.[12]

Cloud does not have a skills shortage driven by complexity, but it does have challenges of its own. One of the biggest barriers to effective cloud adoption is connecting, synchronizing, and relating data, applications, and processes between cloud and on-

[11] Survey Analysis: Big Data Investment Grows but Deployments Remain Scarce in 2014, 9 September 2014, Gartner

[12] http://www.forbes.com/sites/oracle/2013/05/14/cloud-computing-and-the-integration-quagmire/

premise systems. Without an integration strategy and appropriate tool set, the added complexity of cloud makes it difficult to effectively share and use business data throughout an organization.

Informatica Cloud offers the most complete suite of cloud integration for batch- and real-time patterns, cloud test data management, cloud data quality, and cloud master data management applications—all powered by the market-leading cloud Integration Platform as a Service (iPaaS). Informatica can ensure seamless data transition between cloud-based applications and the contract organizations becoming increasingly important within pharmaceutical businesses.

Summary

The global digital disruption affects the pharmaceutical industry as much as any other industry. The companies that succeed will be the ones that best manage, use, and share data. Companies that enable their employees and business processes with Great Data will gain clear advantages in three areas:

• Significantly reducing the (distributed) cost of data management tasks through re-use of trusted data

• Improving efficiencies for all employees, enabling them to focus on value-generating activities

• Rapidly developing new data-fueled opportunities and processes

Transformation, however, is not necessarily an immediate change. Especially in large companies, new processes and technologies will be implemented over time and potentially a large number of individual projects. Each project will need its own justification, delivering a measurable return on investment. Using Informatica to deliver the Great Data needed for each project's success accelerates ROI on each project by making it easy to rapidly find and reuse the data required for an individual project.

Informatica's large user base includes multiple use cases in the pharmaceutical industry, all proving the value of our technologies and their ability to realize project value faster through Great Data. Given our broad customer base within the pharmaceutical sector, your company may already have Informatica data management tools and skills available to deliver competitive advantage and turn Great Data into measurable business value.

Informatica

Put potential to work.™