

Analytics in Pharma and Life Sciences

Overcoming Challenges in Data Integration, Stakeholder Collaboration, and Talent/Technology Investment to Operationalize Analytics in Pharma and Life Sciences Abhishek Menon, Practice Director Anupam Jain, Practice Director

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Benefits

- Improvement in regulatory compliance / internal reporting
 - Increased timeliness and accuracy of PV regulatory reporting to over 90%
- Better marketing/sales support
 - 300% increase in cross- / up-sell opportunity and also increased customer conversion rates
- Product/service enhancement
 - Drop in readmission rates, especially for critical ailments

Keys to operationalize customer analytics

- Embrace analytics-driven decision making
- Standardization and digitization of data
- Leverage third-party providers
- Increasing Intra-group collaboration

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Executive Summary

The pharma and life sciences industry is faced with increasing regulatory oversight, decreasing Research & Development (R&D) productivity, challenges to growth and profitability, and the impact of digitization in the value chain. The regulatory changes led by the far-reaching Patient Protection and Affordable Care Act (PPACA) in the United States are forcing the pharma and life sciences industry to change its status quo. Besides the increasing cost of regulatory compliance, the industry is facing rising R&D costs, even though the health outcomes are deteriorating. Led by the regulatory changes, the customer demographics are also changing. The growth is being driven by emerging geographies of Asia Pacific (APAC) and Latin America (LATAM). As a result, the pharma and life sciences industry is compelled to focus on these relatively nascent and evolving markets. Concepts of cloud, mobility, and social media are enabling organizations to rationalize internal costs, facilitate integration of information and processes across departments, and focus on better profiling and targeting of clients and medical practitioners.

The industry is viewing the increased regulatory supervision as a burden. However, the regulatory requirements are putting in place a foundation for data requirements that can be used to drive pharma and life sciences analytics. Organizations can extract additional value in a challenging market, and create competitive differentiation by utilizing this opportunity.

Application of pharma and life sciences analytics ranges from basic reporting and internal dashboard creation to high-end predictive and prescriptive analytics. The key applications of analytics in pharma and life sciences include regulatory compliance reporting, marketing/sales support, and product/service enablement. The third-party analytics services market for healthcare is expected to increase by over five times its current size by 2020.

Today, however, the market is still in a fairly nascent stage and there are significant challenges, such as poor data integration, lack of investment in talent and technology, and limited stakeholder alignment, impacting this industry. However, the best practices are emerging to help overcome these challenges and push pharma and life sciences analytics further on the path of rapid growth.

This paper describes the "art of the possible" in analytics, specifically within the context of how it adds value to the pharma and life sciences industry. The paper focuses on:

- Pharma and life sciences industry challenges and opportunities, where analytics plays a role
- Range of analytics leveraged in pharma and life sciences industry and examples of how it creates value for the business
- Critical challenges and the emerging best practices in operationalizing analytics in the pharma and life sciences industry

Drivers of Analytics in Pharma and Life Sciences

The pharma and life sciences industry is undergoing tectonic shifts. Introduction of the far-reaching PPACA in the United States and other similar regulations across the globe are not only changing the regulatory framework, but are also impacting the cost and revenue potential of the healthcare payers, providers, and pharmaceutical firms, specifically around R&D productivity and the ability to drive growth and profitability. Additionally, the impact of digitization on the value chain is adding an additional twist to an already complex and tough industry (see Exhibit 1).

EXHIBIT 1

Drivers of analytics in pharma and life sciences

R&D productivity Compliance Evolving stringent Rising R&D expenditures regulatory environment Falling FDA approvals Rising cost of compliance Significant risk of non-**Drivers of** and life sciences Value chain digitization Profitable growth Increasing cloud-based Need for globalization New customer demographics Proliferation of social media

Cost of regulatory compliance

The Center for Medicare & Medicaid Services (CMS) estimates that the cost of compliance for the Sunshine Act (introduced under the aegis of PPACA) would be US\$269 million, with subsequent years costing US\$180 million to the broader pharma and life sciences industry

Cost of non-compliance

Timely and accurate reporting is critical for the Sunshine Act, as non-compliance penalties range from US\$10,000 for each payment not reported (subject to a maximum of US\$150,000) to US\$100,000 for knowingly withholding information (capped at US\$1 million)

1. Compliance

The regulatory framework of the pharma and life sciences industry is undergoing significant changes. The introduction of the PPACA and other similar regulations across the globe are leading to increased scrutiny of the industry.

Besides the obvious cost of compliance to regulations and the penalties for non-compliance, the regulatory requirements are bringing about far reaching changes in the industry. For example, the PPACA is forcing the industry to become outcome-based rather than input-oriented. PPACA is, over time, moving the industry to a model of reimbursement, based on health outcomes. Drug effectiveness (performance in uncontrolled everyday practice) is becoming more important than drug efficacy (measured in a trial environment).

The regulatory regime also differs significantly across geographies, forcing global companies to adhere to multiple regulatory regimes. For example, the Physician Payments Sunshine Act (PPSA) makes it mandatory for drug companies to report all transfers of value to medical practitioners. It has equivalent and more stringent provisions in European countries. Pharmacovigilance (PV)¹ reporting is governed by global, regional, and country-specific regulations that must be adhered to, in order to operate across the world.

¹ PV is the science of collection, detection, assessment, monitoring, and prevention of adverse effects with pharmaceutical products

Worsening health outcomes in spite of increasing healthcare costs

- Adverse event reports to the FDA increased at 4% CAGR from 2003 to 2011, while serious/death outcomes increased at 16% CAGR in the same time frame
- The cost of drug development has skyrocketed by more than 400% in less than 20 years

New customer demographic

There are an estimated 30 million Americans without health insurance, who need to get enrolled by March 2014 to avoid a penalty in their 2014 tax return

2. R&D productivity

The increased regulatory oversight is leading to a rise in the cost of R&D for drug development. The increasingly stringent U.S. Food and Drug Administration (FDA) guidelines are also leading to a lower rate of approval for new drugs. In spite of this increased supervision, health outcomes are at best static or deteriorating, forcing healthcare payers to move towards an outcome-oriented reimbursement regime. Affordable Care Organizations (ACO) created under the aegis of PPACA have started to focus more on health outcomes and will, in fact, be reimbursed based on the outcomes and feedback from patients. Over time, all healthcare providers and pharmaceutical firms are expected to gradually move towards an outcome-oriented regime. Healthcare providers and pharmaceutical firms are also, then, forced to identify cost optimization measures to reduce costs while delivering better health outcomes.

3. Profitable growth

The patent protection on many of the blockbuster drugs introduced over previous years has expired, leading to increased competition from generics.

The new healthcare reform is creating a large opportunity by opening up the market to a new demographic of customers that has traditionally been underserved by the pharma and life sciences industry. The traditional and mature markets of North America and Europe are getting saturated, and the new growth is being driven by emerging geographies in APAC and LATAM. The industry needs to globalize in order to fulfill this new demand and meet its growth objectives.

Pharmaceutical firms are increasingly looking to acquisitions to manage the increased competition, enter new markets, and combat the threat from generics. This is leading to a wave of consolidation in the pharmaceutical industry.

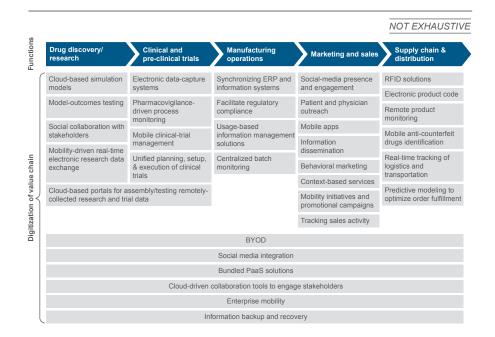
4. Value chain digitization

The advent of cloud-based services and mobility solutions offer pharmaceutical firms the ability to rationalize internal costs, increase agility in responding to client needs, and facilitate an integration of information and processes across R&D, regulatory compliance, marketing/sales, and customer service.

The proliferation of media in general, and social media in particular, is increasing the public scrutiny on the industry. Drug recalls / adverse reactions are receiving significant attention. The pharmaceutical-medical practitioner relationship is under extreme public scrutiny due to the information being in the public domain as mandated by PPSA. Customers are also leveraging the digital media to take healthcare-related decisions. As a result, it has become imperative for the industry to have a well-thought out digital media strategy (see Exhibit 2).

EXHIBIT 2

Need for digitization across the pharma and life sciences value chain



The increased use of technology and the requirement to gather data as mandated by regulations, such as the PPSA, provide pharmaceutical firms the ability to better profile and segment medical practitioners, allowing for a more targeted sales approach. Sales representatives can be enabled with specific promotional material and approaches, based on the practitioner profile. Similarly, on the customer side, a larger volume of data is available through digital media. This allows for more targeted marketing efforts based on customer segmentation and profiling.

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Using analytics can reduce U.S. healthcare expenditure by US\$200 billion.

 The big data revolution in healthcare: Accelerating value and innovation. McKinsey & Company. January 2013

The Role and Impact of Analytics in Pharma and Life Sciences

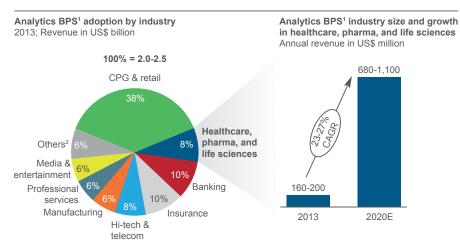
Analytics is playing a key role in helping the pharma and life sciences industry manage the rapidly changing environment and better manage the challenges. While adoption of analytics is still at a fairly nascent stage, third-party analytics business services is growing rapidly and is expected to increase by over five times its current size by 2020 (see Exhibit 3).

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EXHIBIT 3

Size and growth of analytics BPS in healthcare, pharma, and life sciences

Source: Everest Group



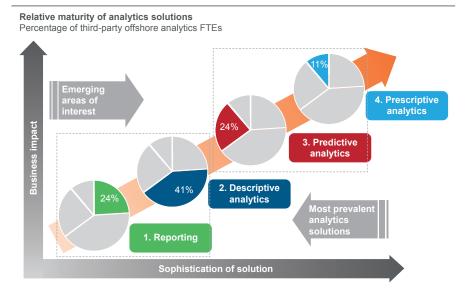
- 1 Analytics Business Process Services (BPS) represents third-party services of the analytics industry and does not include size of internal analytics initiatives and/or revenue of analytics products from companies such as SAS, Orgale, SAD, and Micropath.
- 2 Include public sector, travel & logistics, and energy & utilities

Analytical solutions have grown tremendously over the last decade, specifically, in terms of their sophistication and the resulting business impact they create. There is a wide range of analytics solutions being deployed in the pharma and life sciences industry (see **Exhibit 4**). While basic reporting continues to be a must-have, advanced predictive and prescriptive analytics are now starting to generate powerful insights.

EXHIBIT 4

Range of analytics leveraged in pharma and life sciences

Source: Everest Group



- 1. Reporting. The most basic version of analytics solution that focuses on building data repositories and reporting the current situation using simple and uni- or bi-variate data. Typical examples in pharma and life sciences include adverse event reporting and PPSA-based reporting
- 2. Descriptive analytics. Generating actionable insights on the current situation using complex and multi-variate data. Typical examples in pharma and life sciences include marketing, Return on Investment (RoI) measurement, customer journey analysis, and customer satisfaction analysis
- 3. Predictive analytics. Predicting the likely future outcome of events often leveraging structured and unstructured data from a variety of sources. Typical examples in pharma and life sciences include customer lifetime value analysis, revenue forecasting based on health outcomes, and prediction of adverse event occurrence
- 4. Prescriptive analytics. Prescribing action items required to deal with predicted future events using data from a variety of sources. Often associated with simulations in various business scenarios. Typical examples in pharma and life sciences include Electronic Health Records (EHR) analysis for insights into early-stage drug development, marketing strategy planning, and guidance to medical practitioners on the best medical procedure/approach

The application of pharma and life sciences analytics falls into three key areas:

- 1. Regulatory compliance / internal reporting
- 2. Marketing/sales support
- 3. Product/service enhancement

Typical analytics in each of these areas is summarized in Exhibit 5.

EXHIBIT 5

Types of analytics in pharma and life sciences

Key application of analytics pharma and life Regulatory compliance / Product/service Marketing/sales support internal reporting Adverse event reporting Marketing spend tracking Drug effectiveness PV master data Marketing Rol reporting Patient health outcomes management measurement • Customer account activity Regulatory reporting tracking based on Sunshine Act tracking Rating of providers based requirements First Call Resolution (FCR) on health outcomes analytics Reimbursement calculations based on · Customer iourney analysis · Brand reputation analysis health outcomes Forecasting PV Forecasting sales based · Signal analysis to predict workload based on past on past marketing Rol data potential occurrence of Marketing budget serious adverse events estimation for new drugs . EHR and health outcome Revenue forecasting based analysis to develop on health outcomes for insights in the early stages providers of drug development · Revenue forecasting for Guidance to medical pharmaceutical firms practitioners on the best medical based on drug effectiveness procedure/approach · Customer lifetime value analysis/customer retention Customer segmentation Up- / cross-sell opportunity analysis

Examples of regulatory compliance / internal reporting impact

- Increased timeliness and accuracy of PV regulatory reporting to over 90%
- Replacement of multitude of reports with a few more insightful dashboards

Examples of marketing/sales support analytics impact

- 300% increase in cross- / upsell opportunity and also increased customer conversion rates
- 80% reduction in customer churn
- Increase customer satisfaction scores by 25 to 30%

Examples of product/service enhancement analytics impact

Drop in readmission rates especially for critical ailments

- 1. Regulatory compliance / internal reporting. The use of analytics helps organizations ensure regulatory compliance, while minimizing the cost of ensuring compliance and mitigating the risk of non-compliance. The people, process, and technology being put in place to manage regulatory reporting requirements is also helping organizations do better internal reporting and tracking, as well as use this foundation for complex, high-impact analytics. As a result, the burden of regulatory compliance can be converted into an opportunity for high value-adding analytics impacting the marketing/sales and product/service delivery. For example, the reporting requirements under PPSA have created an opportunity to better track and predict marketing Rol, which was hitherto a fuzzy and relatively difficult metric to measure
- 2. Marketing/sales support. The vast amount of data collected and classified as part of regulatory requirements has created opportunities for enhancing the sales and marketing functions. For example, the marketing expense data collected, as required under the PPSA, is helping pharmaceutical firms measure the Rol from marketing initiatives across channels, products, and locations. Also, learning from the reported information of competitors can help refine and optimize the marketing strategy based on the medical practitioners being targeted.

The vast amount of information available from medical claims, health assessments, health screenings, wellness activities, pharmacy claims, and general customer information from online/social media sources, can be brought together to generate significant insights into customers, and hence, aid the sales process. Up- / cross-sell, customer lifetime value, and customer retention metrics can be enhanced with the aid of pharma and life sciences analytics on customer data

3. Product/service enhancement. Adverse event reporting requirement, as part of PV, and the mandate to drive health outcomes is leading to the integration of clinical trial data, hospital records, physician notes, research papers, and patient demographic and characteristics data (including digital/social media information). This rich source of data can be used to create insights to aid the early stages of drug development and testing for potential adverse events. Also, the health outcome analytics can help guide medical practitioners on the best medical process/approach based on analyzing the past data, giving practical insights relevant to patient demographic, location, etc., to drive the best outcomes

Operationalizing Analytics in Pharma and Life Sciences – Challenges and the Emerging Best Practices

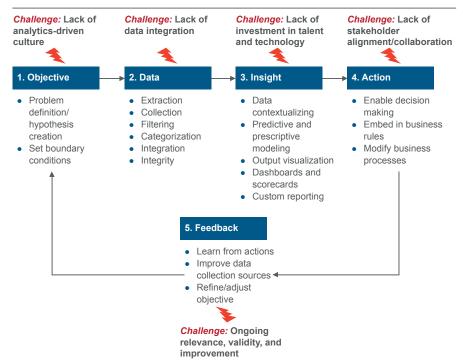
Analytics in pharma and life sciences promises significant value creation potential, if it is operationalized keeping the following three success factors in mind:

- 1. Business insights are created using data
- 2. Insights are used to take decisive action
- 3. Results from business decisions are fed back to improve data and analytics further

This "data-to-insight-to-action" loop is summarized in Exhibit 6 below.

EXHIBIT 6

Typical challenges across the "data-to-insight-to-action" loop in pharma and life sciences



Operationalizing analytics in pharma and life sciences requires significant investments of time and money across people, process, organization, and technology. This section summarizes key challenges that healthcare payer/providers and pharmaceutical firms face across each element of the "data-to-insight-to-action" loop, as well as identifies some of the emerging best practices.

Need to look at regulatory requirements as an opportunity

Unexpectedly, PPSA has created an opportunity for competitive intelligence.

-The COO of global pharmaceutical major

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Phase of "Data-Insight-Action" loop

1. Objective

Critical challenge in operationalizing analytics

Lack of analytics-driven culture

The key enabler for analytics in the pharma and life sciences industry is the increasing regulatory requirement. The need for regulatory compliance has driven the collation and standardization of data, which can then be used for analytics. While the organizations currently consider regulatory requirements as a necessary evil, they are missing out on the opportunity to derive insightful analytics basis the foundation provided by these requirements.

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The emerging best practice: Pharma and life sciences organizations are beginning to realize the benefits of the stringent regulatory regime. They are also realizing that the foundation of data, people, and technology created by the need to meet regulatory requirements is a boon to derive insights through analytics. Organizations need to overcome the initial skepticism and embrace the culture of making decisions based on analytics.

Phase of "Data-Insight-Action" loop

2. Data

Critical challenge in operationalizing analytics

Lack of data integration

The challenge of data sources

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The key is to bring together the data from many different sources into one integrated data mart.

-The CIO of a U.S.headquartered pharmaceutical

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Availability of credible data is still a major issue. We are still not sure how clean our internal data is, let alone linking it with external data.

-The CIO of a large healthcare company across various sources. Data from clinical trials, hospital records, physician notes, sales/marketing data, claims, research papers, and patient demographic and characteristics needs to come together to drive pharma and life sciences analytics. The data also ranges in format from structured EHR to voice recording by physicians. Even within an organization, the technology systems across functions (clinical data management, PV, CRM, and marketing/sales) are not integrated.

The data required to drive pharma and life sciences analytics is distributed

Beyond traditional data sources, organizations also need to tap into the vast reserve of information on digital and social media, which is especially helpful in building customer demographics, characteristics, and behaviors. This data, then, needs to be integrated with traditional data sources to drive enhanced analytics solutions.

The emerging best practices

- Most pharma and life sciences organizations are migrating to digital records, leading to higher standardization and ease of integration. For example, healthcare providers are moving to EHR, which has a standard format. The PPSA regulation allows pharmaceutical firms to analyze marketing spend and competitor data to derive insights with relative ease, because the data is being collated in a standard format across organizations. Advancement in text and voice analytics is helping convert notes and recordings made by medical practitioners into structured digital
- Organizations have also started integrating data across different technology systems. For example, pharmaceutical firms have started integrating their clinical trial data with PV data to drive better analytics
- The need to leverage data from common sources is driving pharma and life sciences organizations to collaborate and share information to reduce duplication of effort

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Lack of investment in talent and technology

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To do high-end PV analytics you need to find talent with a unique mix of medical and statistical skills, which is difficult to come by.

-The PV Lead in a European pharmaceutical company

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There is not a lot of high-end health outcome analytics happening due to a lack of data and talent.

–Analytics Lead for a healthcare payer

Phase of "Data-Insight-Action" loop

3. Insight

Critical challenge in operationalizing analytics

Lack of investment in talent and technology

High-end analytics in pharma and life sciences requires people with medical/science background as well as strong analytical/statistical skills, a fairly unique requirement that is difficult to find in the talent market. Also, high-end predictive and prescriptive analytics is relatively new in pharma and life sciences; as a result, there is a limited talent pool available with significant experience in this space, to lead the practice within an organization.

Beyond the talent issue, organizations need to invest in data collection, storage (data warehousing/business intelligence tools), and data analytics tools for pharma and life sciences analytics.

The emerging best practices

- The requirement for very specialized talent to cater to regulatory regimes, globally, related language dependencies, and the need to maintain 24x7 operations, has led organizations to adopt a global sourcing model with delivery locations across the world. Multiple locations also help manage the fluctuating volumes better, by distributing work across delivery centers
- The organizations are employing third-party providers to help expedite the time-to-market for pharma and life sciences analytics, both from a technology and analytics services standpoint. There are multiple BPO service providers and analytics specialists in the market, and their existing experience can help organizations adopt the best practices already prevalent in the industry

Inefficiencies due to functional silos

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Our PV function has traditionally been run independently by the different BUs/geographies with almost no interface.

-The COO of a large global pharmaceutical company

Phase of "Data-Insight-Action" loop

4. Action

Critical challenge in operationalizing

Lack of stakeholder alignment/collaboration

In most organizations the analytics function has not been centralized and, as a result, there are different teams across products and geographies that are sometimes involved in replicating work that has already been done by another group. This also means deriving organization-wide or global trends/insights becomes an uphill task. Putting pharma and life sciences analytics into action requires different Business Units (BUs) to come together. For example, a pharmaceutical firm's stakeholders across sales, operations, marketing, and even R&D need to come together with data and involvement to derive insights from pharma and life sciences analytics.

There are multiple sets of stakeholders in the pharma and life sciences industry, which include healthcare payers, providers, pharmaceutical firms, pharmacies, Health Information Exchanges (HIX), ACOs, research groups, and digital/social media firms. Currently, there is a reluctance to work across stakeholder groups, and even within groups, as they perceive each other as competitors

The emerging best practices

• Organizations are trying to create shared services for pharma and life

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- sciences analytics by standardizing their own internal processes and data capture formats, while allowing for variations to accommodate regional regulatory requirements
- The intra-group collaboration is on the rise. Large healthcare payers are
 creating analytics organizations and providing services to other smaller
 payers. The pharmaceutical firms are coming together by sharing data with
 each other. The healthcare providers have started aligning towards common
 EHR formats and also sharing information among themselves

Phase of "Data-Insight-Action" loop

5. Feedback

Critical challenge in operationalizing analytics

Ongoing relevance, validity, and improvement

Predictive and prescriptive analytics need to be fluid, dynamic, and open to self-learning and improvement. This is not a onetime exercise and needs ongoing updates and refinements. A continuous feedback mechanism is required from frontline systems, which is hard to implement.

Most variables within an analytics model are dynamic and change continuously over time – customer demographics, medical procedures, and economic and regulatory environment. The analytical model, however, needs to stay relevant and stand the test of time. Making sure that the predicted and actual values stay within a zone of acceptable error is a significant challenge.

The emerging best practices

- Analytical and simulation models need to be designed keeping in mind that
 they will be adjusted and refined over time and therefore be self-learning
 and flexible solutions. For instance, revenue predictions based on health
 outcomes are compared against actual results, and the model is then
 tweaked to reduce the prediction error
- Offshore third-party service providers can also be utilized for testing and ongoing maintenance of models. This enables organizations to keep model development and validation separate, as well as improve scalability and speed- to-market

Conclusion

The pharma and life sciences industry is still considering the increased regulatory oversight as a burden and not realizing the opportunity that it presents. Organizations need to utilize the additional information made available as a result of the regulatory requirements and move away from a siloed approach across functions. They should also utilize the full impact of cloud, mobility, and social media to embrace analytics-driven decision making to create differentiation in an extremely competitive, dynamic, and challenging market.

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