WIPRO
Applying Thought

HEALTHCARE & LIFE SCIENCES COMMUNIQUÉ
WIPRO INSIGHTS & PERSPECTIVES │ Edition 2

DO BUSINESS BETTER

CONTENTS

FROM THE
EDITOR'S DESK

The last few years have seen an explosion of data in the Healthcare and Life Sciences industries. What should organizations do with this data? How can they transform it into insights that can deliver business results? Those are the 'big' questions before us – and we have attempted to address them in this second edition of the Healthcare and Life Sciences Communique.

We believe that analytics done right can help organizations **foster innovation, secure the present** and **accelerate growth.** We do hope you enjoy the articles that explore these business imperatives.

If you have any feedback on this issue or on what you would like us to cover in upcoming editions, do write to me at **meenu.bagla@wipro.com**

We welcome your feedback.

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TRANSFORMING PHARMA THROUGH **BIG DATA AND ANALYTICS**

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THE CHALLENGE & THE OPPORTUNITY

The global Pharmaceutical and Biotech industries are in turmoil. While top blockbusters are going off-patent, the decades-long decline in R&D productivity continues and peak sales of launched products are declining. In parallel, healthcare authorities and payers, troubled by unsustainable increases in healthcare costs relative to GDP, continue to drive relentless focus on reduced prices and enhanced value.

The availability of new (big) data sources and technologies holds the promise to fundamentally transform the Pharma industry – making it more innovative, agile and productive across the value chain.

In this article, we explore key analytics-driven themes that could enable companies to create competitive advantages at each step of the value chain – across R&D, Supply Chain, Marketing and Sales.

FIXING R&D PRODUCTIVITY

R&D is at the root of value-creation in the pharmaceutical industry. It should therefore, be no surprise that the continuing evidence of declining R&D productivity has left the industry with a deep sense of crisis.

Here we outline 5 analytics-driven trends that could enable technology-leading players to establish more innovative and efficient R&D organizations:

- **Predictive modeling ('in silico experiments')** of biological systems is becoming increasingly sophisticated and wide-spread. The nature and focus of models vary widely, from bioinformatics to the modeling of entire organs. Collectively, they hold the promise of identifying new drug candidates and increasing the likelihood of success for drugs entering clinical trials.

- **Genome-scale data sets,** notably gene sequencing data, are becoming increasingly available and affordable. Already used extensively in research today to understand potential disease targets, their biggest benefit may be delivered when companies make collections of genome-scale data sets, a standard part of data collection for late-stage clinical trials. This would enable testing of causal relations between patient genome data (or similar large data sets) with basic patient information, including diagnoses and risk factors, along with treatment response.

- **Risk-based monitoring** is a shift away from the traditional model for clinical trial monitoring. The traditional approach, which still prevails today, involves frequent site visits and 100% 'source data verification'. In recognition of the limited efficacy and high costs that this approach entails, both the FDA and EMA have published revised guidance in recent years recommending risk-based monitoring[i]. The basic thought is that advances in technology provide a foundation for ongoing remote monitoring and risk-assessment, allowing a de-averaged level of monitoring across sites and reduction in trial costs as dramatic as 15-20%[ii].

- **'Social' clinical trials** are a nascent concept, and use social channels both as a tool for subject recruitment and as a lever for patients to interact and receive feedback on progress during trials. Given the increasing competition for patients in some indications – and the fact that 80% of all trials are delayed at least one month due to enrollment issues[iii] – this approach has the potential to improve enrollment and decrease drop-out rates. It could also help provide a valuable understanding of how patients think and behave in a post-marketing setting.

- **Real-world studies** are increasingly coming into focus as regulators and payers push to understand how drugs work outside a controlled trial setting. To proactively engage with real-world data, Pharma companies must integrate with, and be able to analyze a variety of data sources – from disease registries to Electronic Medical Records (EMRs) – while respecting patient privacy. A recent, innovative example of this is a GSK study for Breo/Relvar, a blockbuster hopeful for COPD. GSK initiated this study, although it was not directly required for regulatory submissions. The objective was to send a clear message to payers about the product value delivered, not just in trials but in the real world[iv].

Pharma R&D in general may well be challenged, but organizations that master smart approaches to new technologies will be well placed to continue creating value through innovation.

BRINGING THE PHARMA SUPPLY CHAIN UP TO SPEED

The early IT architecture for pharma supply chains was built to help analyze shipments and order histories in a world where it was impossible to accurately measure or reflect real-time market supply and demand. This is no longer the case.

Consequently, forward-looking companies are implementing cutting-edge solutions to increase visibility, understand risk, enhance demand planning capabilities and improve go-to-market effectiveness. There are tangible opportunities for IT departments to help improve transparency, de-bottleneck and improve end-to-end integration and collaboration. Some key capabilities needed to advance supply chain capabilities include the following:

- **Mobility:** The most innovative enterprise mobility strategies are enabling companies to incorporate data from all points of the supply chain – from the factory to the customer. 'Pull-based' or 'demand-driven' supply chains are able to incorporate real-time data from CRM to point-of-sale, to deliver dramatically increased efficiency and transparency.

- **Cloud and the Internet of things:** The advent of cloud is making it possible to connect the extended supply chain. For example, data from Laboratory Information Management Systems (LIMS) and Manufacturing Execution Systems (MES) can link with each other and with the CRM system for a truly holistic view and thus, optimal demand management.

- **Big data:** This is becoming a significant factor in supply chain management. Pharma companies manage increasingly complex supply chains with a shift in end-market focus towards emerging economies. Regulatory scrutiny is increasing and integration with 3rd parties (and acquired companies) is accelerating. Both structured data (e.g. serialization data) as well as unstructured data (e.g. from call centers) have the potential to enable new insights, often in real-time, into the supply chain.

Not surprisingly, the biggest challenges remain with integrating capabilities into existing systems, and creating a plan for what data to collect and how to analyze it.

In one survey, 75% of supply chain executives responded that the critical element in their analytics strategy was internal data, with challenges focused on integration of big data, updating legacy systems, understanding which data to focus on and having the right talent.

CREATING DIGITAL ADVANTAGE IN MARKETING & SALES

The healthcare industry is becoming increasingly consumerized. Patients (consumers) are empowered by access to data and peers and they are rapidly adopting web and mobile technologies. The underlying cause is the creation of a powerful digital economy[vi]:

~3bn Internet users by 2016, with social networks reaching ~80% of Internet users.

~2bn mobile phones (500mn smart phones) shipped globally per year, with 6.5bn mobile connections and a 90% global mobile penetration rate by 2015.

In moving towards more 'patient-centric' business models, the industry must internalize learnings from leading consumer-oriented companies like Apple, Google and Tesco. This requires them to:

- build a seamless customer experience across channels – a single customer-facing view

- create new engagement models that align with customer segments

- evolve digital strategy from information sharing to active stakeholder engagement

These success factors can inspire pharma companies as they aspire to create services and solutions 'around or beyond the pill'. In doing so, pharma companies should invest in building scalable technology platforms and invest in key capabilities, including:

- **Web platforms and social media** to engage stakeholders, increase brand stickiness and influence patient behavior (e.g. improve adherence/compliance).

- **Cloud solutions (e.g. CRM)** to reduce cost of doing business, improve sales force effectiveness and enable more seamless data sharing between stakeholder networks.

- **Mobility** to connect with stakeholders using medium of choice, offer new location-based services and enable advanced functionalities (e.g. remote monitoring, patient-reported outcomes, etc.)
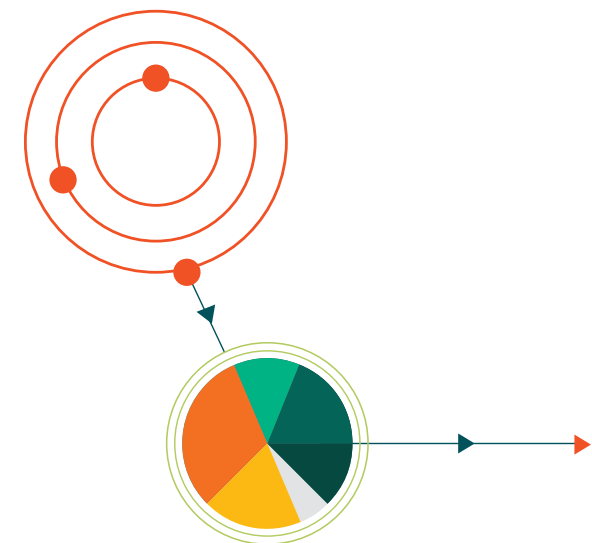
There are many potential entry points for creating new digital commercial models. The key challenge is creating a strategic plan and ensuring that technology platforms are utilized across the business.
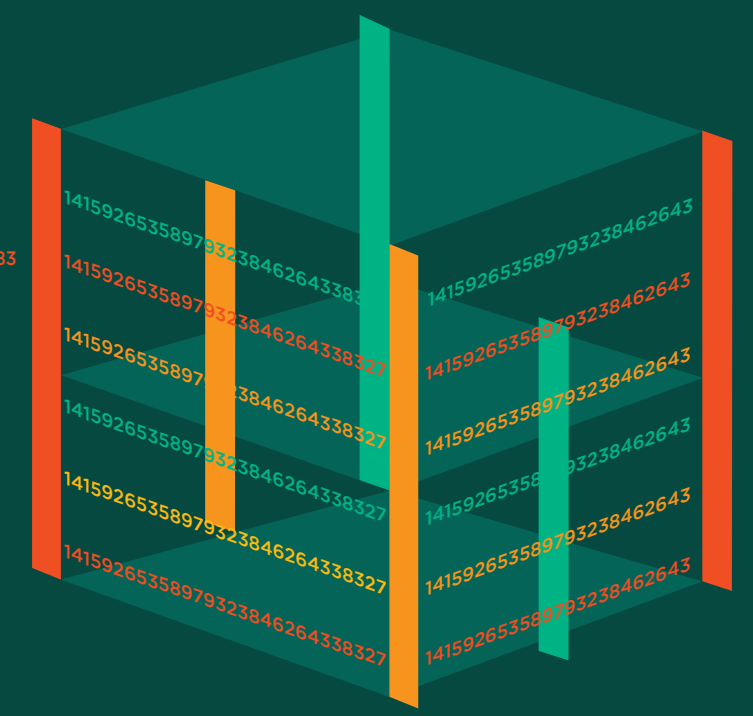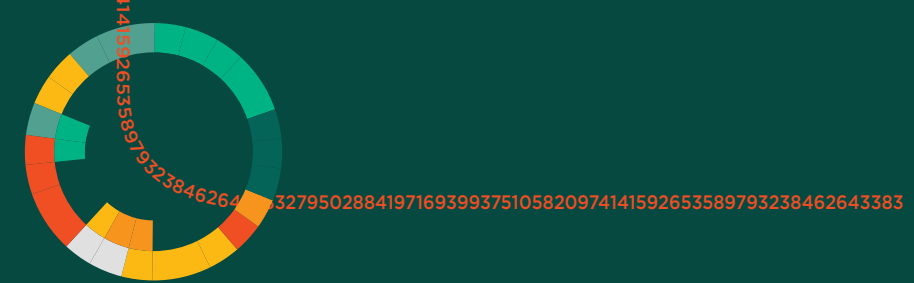
THE WAY FORWARD

The technologies outlined in this article pose tremendous potential for the global pharmaceutical and life sciences industry. Indeed, we firmly believe that the challenges facing the industry calls for rapid adoption of the analytics-driven technologies outlined.

However, organizations are often hesitant in proactively pursuing these levers of advantage. This is primarily due to the changes required in internal organization and processes, as well as the unique challenges posed in interacting with regulators, physicians and patients using new technologies. *More often than not, the efforts we see in the industry represent 'islands of innovation', e.g. experiments within one therapeutic area, rather than a coordinated effort.*

This is changing but we believe that it is time for the change to accelerate.

i. FDA: Guidance for Industry Oversight of Clinical Investigations: A Risk-Based Approach to Monitoring (2011); EMA: "Reflection paper on risk based quality management in clinical trials (2011)

ii. PWC: Risk Based Monitoring – Reduce clinical trial costs while protecting safety and quality (2013)

iii. http://www.ciscrp.org citing Lamberti, "State of Clinical Trials Industry", 292

iv. GSK jumps new IT hurdles in 'real-world' test of blockbuster hopeful, FiercebiotechIT, 2013

v. Sarah Reynolds, eyefortransport: Supply Chain Big Data Report, 2013

vi. BCG Perspective: "The Connected World: The Digital Manifesto: How Companies and Countries Can Win in the Digital Economy", 2012

SECURE
THE PRESENT

Optimize costs and drive productivity by streamlining and standardizing

DIGITAL DOSE
HOW SOCIAL SHOULD PHARMA BE?

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Social media and the pharmaceutical industry have a complex relationship that has attracted a fair amount of interest lately. On the one hand there are pharma's well-known regulatory shackles and on the other, the undisputed but hitherto unexplored advantages that social media can deliver to the industry.

Pharma companies worldwide have already started to reach out to healthcare value chain participants like physicians, patients and payors through social media channels like Facebook, Twitter, online communities, portals, even gamification. Gleaning insights from big data generated by social media has also become an important focus area for the technology firms that these pharma giants partner with.

The truth however, is that the current situation is a job half done. It is like giving a cow state-of-the-art feed but stopping short of milking it. Pharma companies need to close the loop, i.e. analyze the big data generated by social media, and then put these insights to work through an action plan. As they do this, they will be able to fine-tune their social strategy so that it delivers information that is truly relevant. A continuously improving feedback process must be put in place.

Phase I of embracing social media has begun. Phase II of reaping benefits through action and continuous improvement must follow fast.
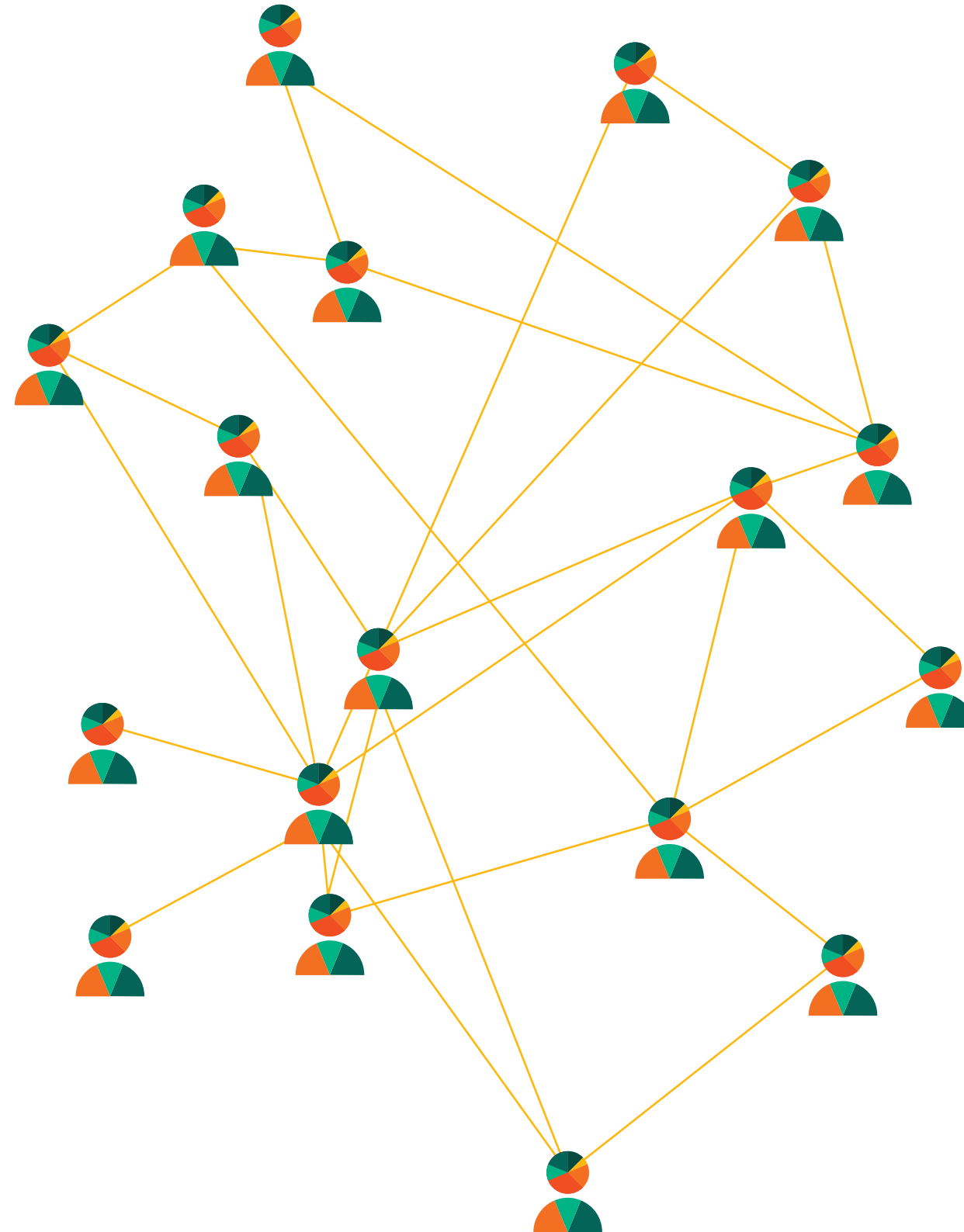
Pharma companies have focused on using social media for creating brand/product awareness, managing communities and reaching out to stakeholders like patients and physicians. This must evolve. Companies need to keep tabs on emerging trends as well as the competitive landscape, and then identify the internal capabilities and responses needed to address these. In order to do this, *they need a well-defined, management-approved social media strategy that allows for continuous feedback and iteration.*

A very important aspect of the pharma-social media relationship is research and development (R&D). Social media is fast becoming an integral part of clinical research and playing a critical role in patient recruitment and retention, as well as reducing time-to-market. Social media is also playing an important role in influencing physician communities via interactions with key opinion leaders. This will continue to be a core area of focus for pharma as they develop a finer understanding of how these direct interactions can help in raising the productivity of clinical research.

Pharma communication has always been limited by stringent regulations. Therefore, the industry's slow adoption of social media vis-a-vis others like financial services, telecom and high-tech, should come as no surprise. However, it is time that pharma overcame the traditional marketing mentality and found innovative ways to use social media while staying compliant.

This discussion would be incomplete without a careful consideration of the FDA perspective. The draft article published in December 2011 generated significant expectations (and speculation). The article focused on unsolicited requests about off-label products, 'including both requests made directly and privately to firms and requests made in public forums, including through emerging electronic media'. Concepts like solicited vs. unsolicited, public vs. private, etc. were described and keywords like adverse event reporting found their way into the draft. FDA also disallowed the participations of sales and marketing personnel in designing responses to unsolicited requests for off-label information. Since this is only one aspect of social media employment, much is still to be clarified. Rules of the game for FDA approved/regulated as well as products pending approval, did not feature in this guidance. FDA has two years to develop a comprehensive, detailed, accurate rule book for the pharma-social media relationship.

So far, pharma's usage of social media has been in the context of past data – a sort of lagging indicator. The need of the hour is a leading indicator. Pharma companies have been investing in expensive and time consuming methods like personal interviews, opinion polls, etc., to gain insights into the minds of the healthcare value chain stakeholder. By the time they receive the analysis, the information is probably outdated.

Social media analytics allow marketers to get a quick glimpse into consumers and make adjustments to their traditional market research strategy. In addition, there have been efforts in creating internal social media channels across regions and functions. Methods like crowd sourcing have found relevance in this space. Examples like Roche disclosing internal social media principles speaks volumes about the mind-set change that is on its way in the industry.

The sheer volume of users and therefore the information that they generate has become a real-time data source, too significant to ignore. Pharma companies must collect this data, apply regulatory filters, and then parse this resulting data using advanced analytical techniques to generate meaningful insights. Areas like R&D clinical trials recruitment, closed loop marketing and segmentation-targeting-positioning are areas where this can be applied for immediate benefit.

Patients, caregivers, healthcare companies and physicians will only increase their use of social media in the future. Given the fact that timely and high-quality information is key for pharma companies, they must put social media at the center of their strategy proactively and devise strategies to mine the structured and unstructured information that this provides. Adverse unregulated comments are a risk, but pharma needs to think about finding a path. through this. Instead of waiting for regulations,

Pharma companies should use this period to start putting their own social media initiatives to work to identify those that deliver the maximum benefit.

THE COST, QUALITY AND COMPLIANCE CHALLENGES FACING PHARMACEUTICAL COMPANIES

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The need for pharmaceutical companies to lower the manufacturing costs of drugs has never been greater. The traditional model of patent-protected, blockbuster drugs generating huge sales at very high margins is quickly fading away as the industry experiences the so-called 'patent cliff'. According to The Economist, drugs that account for $170 billion in annual revenues will be off-patent protection by 2015 and will be open to competition from generic versions. Generic drugs are chemically equivalent to the original branded versions and are often sold for a small fraction of the price. The portion of prescriptions being filled by generic drugs, rather than the original branded version, is rapidly approaching 80% in the U.S. and Europe.

An obvious response to the need for reduced manufacturing costs is to move production to lower-cost, emerging economies. Achieving savings from such a manufacturing move is not necessarily as easy as it may appear on the surface. Regardless of the location of manufacturing, the same product quality requirements must be met. Investments to build and maintain this quality infrastructure can sometimes outweigh the benefits of reduced direct-labor costs. In a highly-publicized decision, GSK actually moved a significant bio-manufacturing capacity out of India, sending it to an existing site in Montrose, Scotland.[i]

Should a manufacturing location fail to meet the required manufacturing compliance and product quality standards, the cost of product recalls, regulatory fines, lost sales and market share can be enormous. One large pharmaceutical company reported that lost sales due to product recalls cost them $900 million in a single year![ii]

The high costs associated with product recalls are not unusual. The graph below shows the number of FDA quality and compliance recalls per month over a one year period.

The total of four hundred and nineteen recalls means that there was more than one product recall per day in that twelve month timeframe!

Number of FDA Quality Recall Events Per Month

NUMBER

FISCAL YEAR 2011

TOTAL = 419

Reducing manufacturing costs in the face of generic competition and avoiding costly product recalls, are not the only challenges facing pharmaceutical companies. Meeting new requirements from global regulatory agencies is also bringing big changes to the pharmaceutical manufacturing floor. Providing patients with a safe, effective and uninterrupted supply of drugs has always been a top priority for regulatory bodies and pharmaceutical companies.

Before a prescription drug can be marketed, it must undergo a rigorous series of clinical trials designed to ensure safety and efficacy. Upon completing this process and receiving approval from the U.S. Food and Drug Administration (FDA), the European Medicines Agency (EMA), and other global regulatory bodies, the drug product is ready to be put into production.

Similar to the clinical trial testing that is required for drug approval, there are regulations governing manufacturing that are designed to ensure that the manufacturing process will consistently produce a safe and effective product. The protocol that must be followed before specific manufacturing procedures can be implemented to produce a drug for patient use is known as **process validation.**

The specific requirements for process validation were first clearly defined in a guidance released by FDA in 1987. The guidance largely focused on the need to operate the manufacturing process in a very consistent fashion, with the requirement that certain operating parameters be precisely maintained at 'validated' setpoints. While this approach to process validation was fairly effective at ensuring drug safety, it did not foster process understanding or process improvement. The result was that many drug manufacturing processes remained stagnant for years, even as process knowledge and manufacturing IT solutions were rapidly evolving. This resulted in high costs and low manufacturing innovation. There were also risks to the integrity of the drug supply chain because, without a fundamental understanding

of production processes, manufacturers were not well equipped to respond to process upsets, often resulting in scrapped products, missed deliveries and finally, patients without the drugs they needed.

The guidelines for pharmaceutical process validation changed dramatically in January 2011 when FDA issued its first new guidance on the topic since 1987. The new requirements stress process understanding and continuous process improvement. When process understanding is demonstrated, an operating **design space** can be validated rather than a set of fixed operating setpoints. This design space can evolve over time as process understanding improves. For process validation, FDA now requires that 'an ongoing program to collect and analyze product and process data that relate to product quality must be established'. The guidance also specifies that 'the data should be statistically trended and reviewed by trained personnel. The information collected should verify that the quality attributes are being appropriately controlled throughout the process.' [iii]

The traditional status-quo in the pharmaceutical industry is a thing of the past. Blockbuster drugs are losing patent protection, low-cost generic drugs are flooding the market while, at the same time, regulatory requirements and scrutiny are increasing. How can pharmaceutical manufactures cost-effectively meet today's complex challenges? Ironically, in many cases, it is simply a matter of making better use of the information they already have.
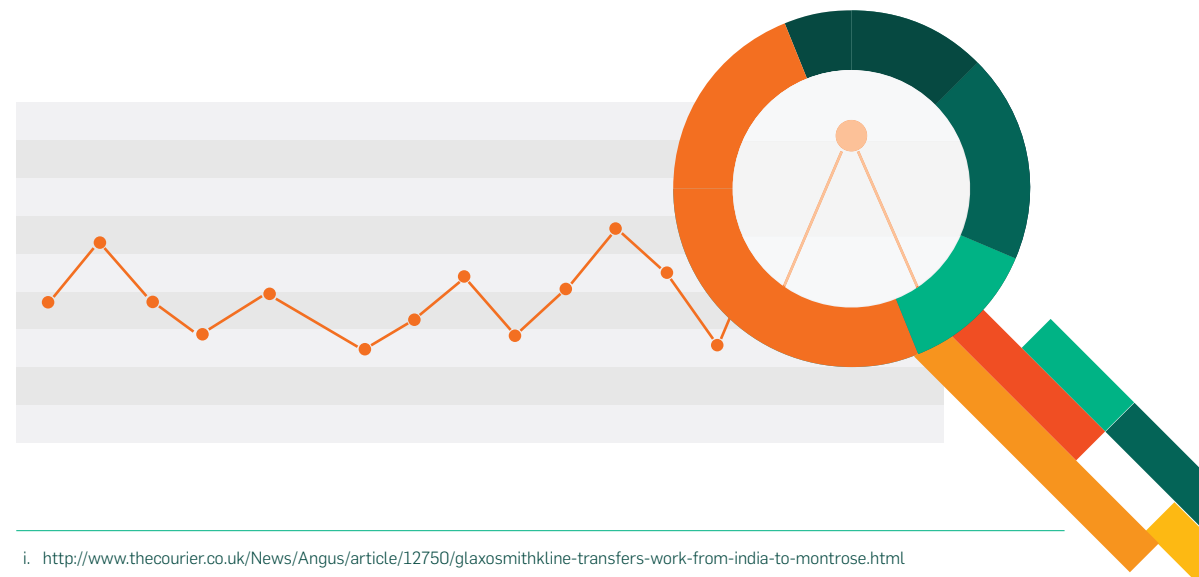
THE SOLUTION & THE ROLE OF MANUFACTURING ANALYTICS

Pharmaceutical companies, for years, have been collecting manufacturing, product quality and yield data as well as tracking adverse patient events related to the drugs they produce. The challenge has been that all of this information is often spread across numerous data silos that are maintained by different organizations within the company. Raw materials information is often managed by procurement and resides in the ERP system. Specific batch manufacturing execution details are in the Manufacturing Execution System (MES). Operating parameters are captured in the data historian, product quality in the Laboratory Information Management System (LIMS) and adverse patient events in the Incident Management System, which is maintained by the quality organization. When all of this data can be consolidated in a single location and raw materials specs, execution steps, operating parameters, product quality and patient events can be viewed in the context of a specific manufacturing batch, it is possible to drive process improvement, increase production yield, improve product quality AND comply with the new regulatory guidelines that require improved process understanding.

Important regulatory initiatives such as Quality by Design (QbD) require pharmaceutical companies to identify the Critical Quality Attributes (CQAs) that make their drugs safe and effective. When manufacturing execution data, process details and product quality are readily available and can be viewed together, offline analysis can be performed to identify Critical Process Parameters (CPPs) that directly impact product CQAs. Basic statistical analysis or more advanced techniques such as Multivariate Analysis (MVA), can be employed to identify the CPPs and the acceptable range of these parameters throughout the course of a production process. These parameters are used to build the design space as required by the new process validation guidance and other regulatory initiatives such as QbD. This improved process understanding enables continuous process improvement, manufacturing cost reduction and continuous process verification to assure product quality.

Real-time measurements of CPPs allow pharmaceutical manufacturers to leverage statistical analytical methods to monitor process consistency and proactively raise alarms indicating potential failures. This provides opportunities to correct manufacturing conditions before a product quality failure occurs. This also helps in achieving a predictable product supply, reliable quality, improved operational excellence and patient safety. Even basic operating KPIs such as asset utilization are improved because yield improves, scrap is reduced and the need to use manufacturing equipment for product rework is minimized or eliminated. More importantly, the quality teams charged with regulatory compliance benefit greatly through improved process

understanding established through statistical process analysis, resulting in reduced site inspections and quality audits. Visibility into key operational quality metrics in the form of dashboards, when made available to plant personnel on mobile devices and large touchscreen displays, empower the production teams by making critical, actionable information available when and where they need it. Given the benefits, it is no surprise that pharmaceutical companies are turning to end-to-end solutions that provide a holistic view of manufacturing, quality and patient event data enabling process improvement and cost reduction while simultaneously maintaining manufacturing compliance and product quality.

i.   http://www.thecourier.co.uk/News/Angus/article/12750/glaxosmithkline-transfers-work-from-india-to-montrose.html
ii. http://www.bloomberg.com/news/2011-01-25/j-j-profit-declines-12-on-product-recalls-2011-outlook-trails-forecast.html
iii. "Process Validation: General Principles and Practices", U.S. Department of Health and Human Services, Food and Drug Administration, January 2011

ACCELERATE GROWTH

Focus on pockets of growth – new segments, new geographies or even new business models

ANALYZING THE ROLE OF **ANALYTICS**

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Shalini has incubated and set up several pharma knowledge centers at Wipro, including the Glaxo Smithkline Knowledge Centre. She provides consulting around business and commercial solutions to the top 10 pharmaceutical companies across the US, EU and Middle East. Shalini has deep experience with understanding and conceptualizing end-to-end outsourcing models and analytics solutions in global markets.

Early detection of patterns and the strategic intent to get to real-world results is the key for effective business strategies

Most decision-makers have felt the need to respond to the unprecedented change in the life sciences world. This change has been compounded by developments like transitioning sales and marketing models, greater collaboration among regulators across the globe, evolving physician-patient dynamics and the all-important growth avenue of emerging markets. Life sciences companies are moving from treatment to preventive scenarios and management of the patient's health outcomes.

To effect this transformation successfully, life sciences companies must deploy controls and levers like insights from data and analysis. They must leverage the right information and analytics and then deploy these insights strategically. This is happening, but there are leakages in key channels that must be addressed.

THE ROLE OF ANALYTICS

The benefits of analytics in life sciences are manifested in significant areas such as early detection of prescription and treatment patterns, strategizing the intent of the patient to real world results and most importantly achieving the operational excellence to drive through the intellectual journey of patient centricity.

The need for early detection of prescription patterns and quick adoption of tactics to address these is becoming key, both for patient-centricity and competitive advantage. Insights around early detection can be used in a range of activities now that paper-based interaction models are moving to multi-channel, digital ones. Organizations can make predictions about the development of optimal strategies as well as track deviation in existing ones.

Analytical assaying needs elevation to the next strategic level through a focus on two levels of imperatives – prescriptive and predictive. The prescriptive analysis will include sales and marketing competitiveness while predictive imperatives will include physician behavioral analysis across channels, promotion response modeling and customized sales and marketing content.

This will drive ROI-based outcomes as well as provide near real-time feedback about developments on emerging patterns.

Organizations can also quantitatively analyze the hypotheses or strategies that they wish to pursue. So far, the focus of these strategies has been legal and regulatory compliance. By ignoring data and the real world effectiveness of the strategies, there is a significant potential loss. The stakes for these losses are also higher than ever before. To ensure effective implementation of business strategy, a collaborated effort from conceptualization to implementation is required. A well-crafted strategy combined and implemented through defined and tested assessments and other innovative ways of execution, including areas such as digitization of sales and marketing models, and access to emerging markets will help businesses reap long term success. The key to achieving this is collaboration across multiple stakeholders to drive growth.

LEARNING FROM OTHER INDUSTRIES

Pharma companies can learn from telecom, consumer and financial services industries when it comes to leveraging analytics. In fact, there is an enormous lag that will take time to close. Understanding and adapting their talent acquisition models will also enhance 'people assetization' – an important requirement of a changing context where selling has become harder.
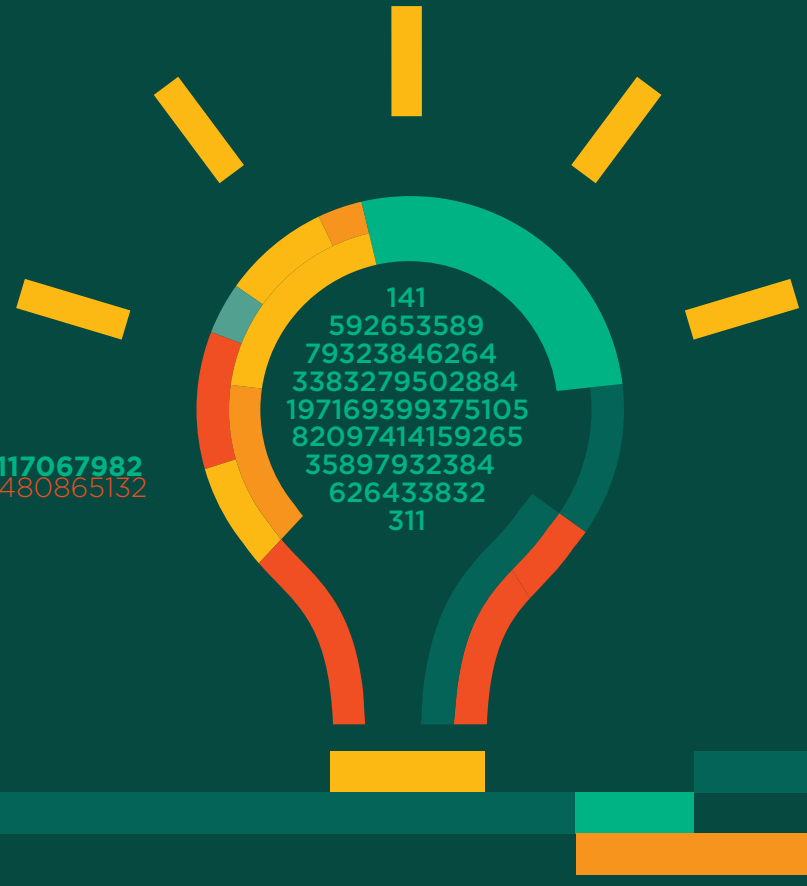
One issue is the life sciences industry has always considered analytics to be descriptive and not predictive. By definition, predictive analytics involves uncertainty. We need to focus on understanding those boundaries of uncertainty and take corrective actions. The role of analytics must undertake a journey from 'descriptive' to 'predictive' and 'prescriptive'. Predictive analytics helps to forecast and design models. Prescriptive analytics uses stochastic optimization and factors in uncertainty. It is all about finding an optimal solution from the best alternatives.

There is also a need for change from linear analysis to non-linear analysis. The switch to real-world events provides an opportunity to assess status quo without artificialities. Continuous analysis of pattern detection and strategies allows insights into performance and responses to external and internal drivers, through implementation of forward thinking approaches.

Finally, organizations must internalize the insights generated from analytics into their basic operating model and track execution against strategy.

The pharma world needs to transform today's health system to reduce healthcare costs, improve patient outcomes and enable access to health information. This requires that organizations transform from being traditional 'pharma players' to 'health players'. The smallest change in one area has a cascading effect through the entire health system. Therefore organizations must embrace the potential of signal, detection and prediction enabled by technology.

FOSTER INNOVATION

Use technology to address the next decade of emerging needs, demographics and geographies

ANALYTICS
OPPORTUNITIES AND CAPABILITIES FOR ACCOUNTABLE CARE ORGANIZATIONS (ACO)

Sangita Bhattacharyya

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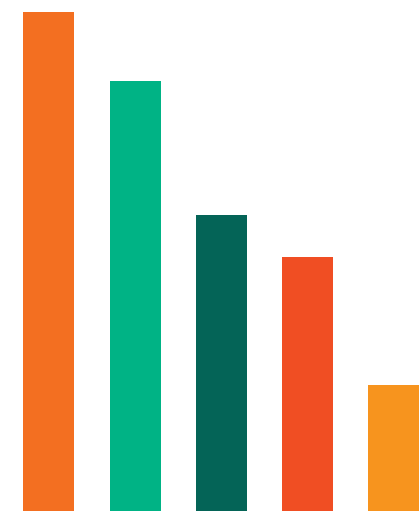
Accountable Care Organizations (ACOs) have been pioneered as a promising model for transforming the way care is organized and delivered across the continuum. An ACO is a group of providers who are jointly responsible for improving care outcome and controlling increase in cost of care for a targeted population of patients. The providers participating in ACOs coordinate and collaborate to treat an individual patient across care settings, including doctors' offices, hospitals and long-term care facilities. The group also shares the risk and financial incentives received when care and cost outcome goals are met.
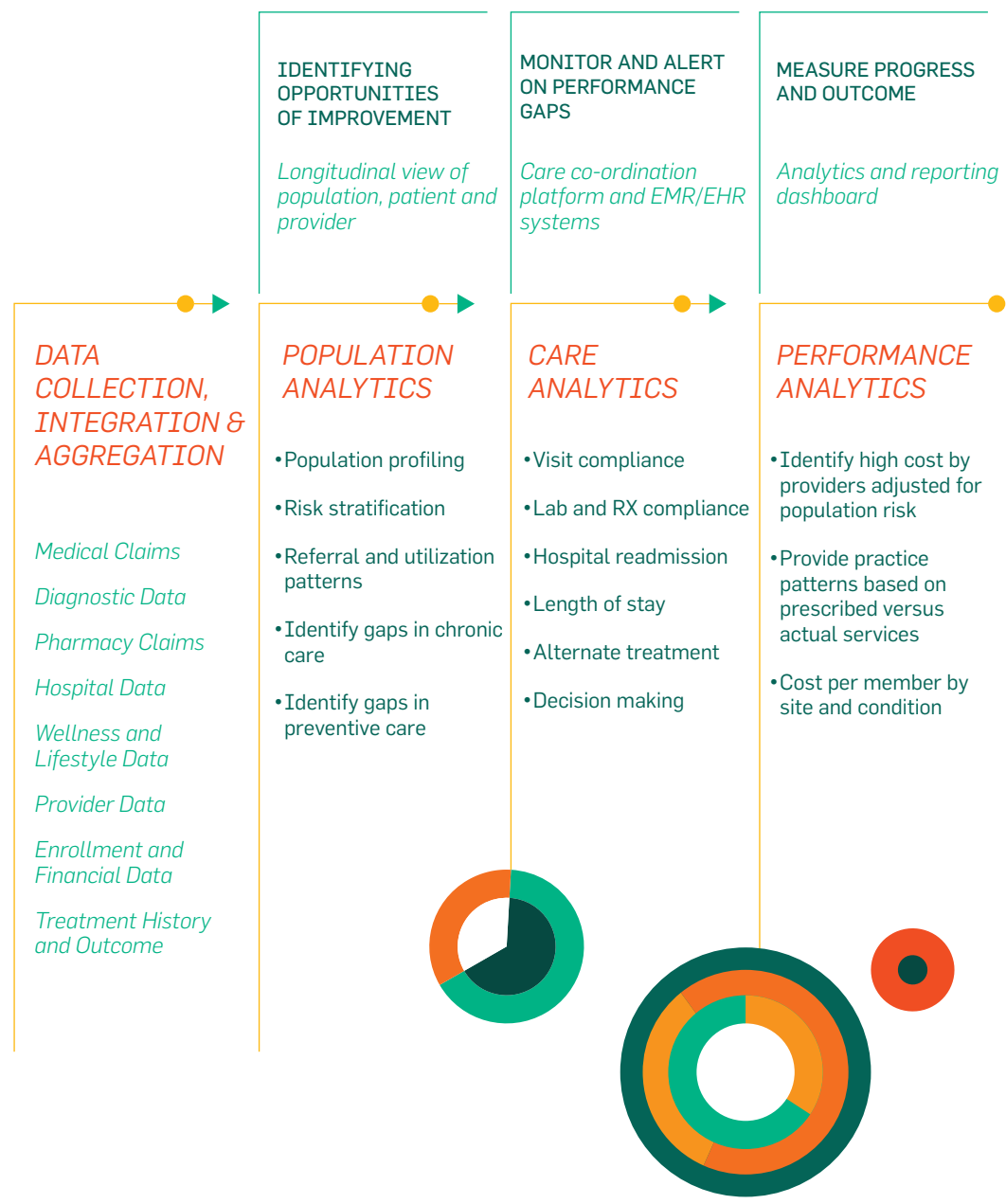
The success of an Accountable Care Organization is determined by its ability to deliver outcomes – both financial and clinical. To obtain the promised financial incentive, ACOs need to factually demonstrate 'how much' value has been created and meet the 34 quality performance measures set up by CMS across four key categories:

- Patient and caregiver experience

- Care coordination and patient safety

- Preventive health

- Caring for at-risk populations

To accomplish these critical quality requirements, ACOs need to recognize the immense amount of valuable data they are sitting atop across various hospital, physician and facility systems. ACOs must first integrate the consumable data of patients, providers, treatment outcomes and clinical best practices and then analyze the data to reveal the exact areas that are most likely to improve care and reduce cost. Accordingly plans of action for care coordination activities can be charted, tracked, measured and reported.

Population analytics, care analytics and performance analytics will play a key role in helping ACOs achieve their goals.

IDENTIFYING OPPORTUNITIES OF IMPROVEMENT

Longitudinal view of population, patient and provider

MONITOR AND ALERT ON PERFORMANCE GAPS

Care co-ordination platform and EMR/EHR systems

MEASURE PROGRESS AND OUTCOME

Analytics and reporting dashboard

DATA COLLECTION, INTEGRATION & AGGREGATION

Medical Claims

Diagnostic Data

Pharmacy Claims

Hospital Data

Wellness and Lifestyle Data

Provider Data

Enrollment and Financial Data

Treatment History and Outcome

POPULATION ANALYTICS

- Population profiling
- Risk stratification
- Referral and utilization patterns
- Identify gaps in chronic care
- Identify gaps in preventive care

CARE ANALYTICS

- Visit compliance
- Lab and RX compliance
- Hospital readmission
- Length of stay
- Alternate treatment
- Decision making

PERFORMANCE ANALYTICS

- Identify high cost by providers adjusted for population risk
- Provide practice patterns based on prescribed versus actual services
- Cost per member by site and condition

DATA COLLECTION, INTEGRATION & AGGREGATION

Objectives

The creation of benchmark data is one of the most important steps in creating transparency and predictability across the care continuum for greater clinical and financial effectiveness. Based on this benchmarked data, the plan of action for a proactive care delivery can be defined and effectiveness measured.

- For a composite health record, substantial amounts of data is collected from claim, payment, billing and reporting systems. This cannot be handled or inferred by traditional analytics tools and strategies. Only an advanced data aggregation and normalization technology can rapidly combine clinical and demographic information from multiple sources.

- Quality of data must be improved to deliver more accurate patient's information to providers, drive workflow integration with timely alerts and notifications.

Required Analytics Capabilities

ACOs need to develop capabilities in 'Big Data Analytics' to continuously collect, aggregate and normalize data, be it structured data or unstructured data, such as radiology reports and physician notes. The collected data has to be analyzed and presented in an understandable format, to extract meaningful information such as symptoms, diagnoses and tests to facilitate informed decision-making by the care giver.

Long implementation times and the high cost of implementing a big data analytics strategy does prove challenging for most providers. Emerging technologies offer viable alternatives that must be evaluated carefully. For example, cloud-based big data systems that could potentially reduce the cost of operations and accelerate speed of deployment.
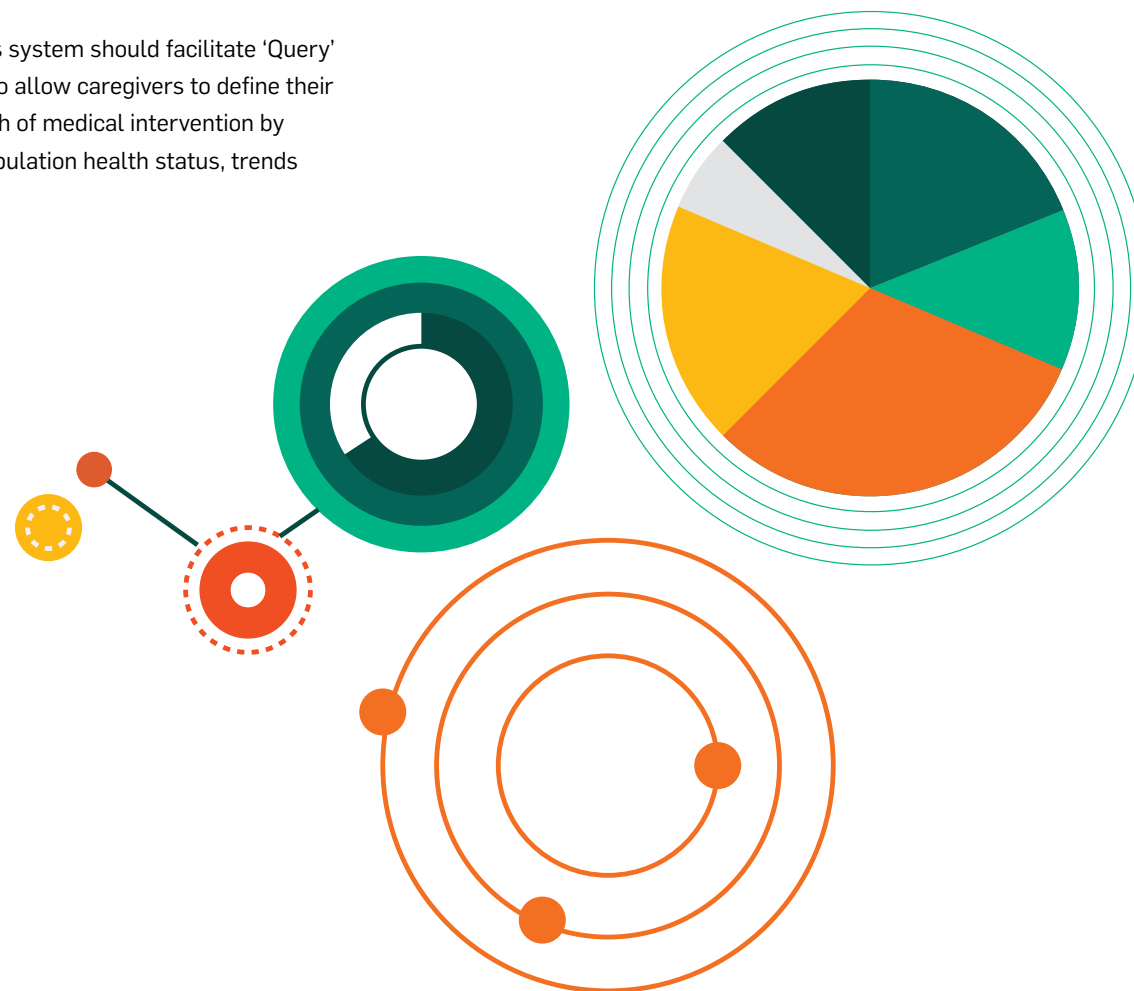
POPULATION ANALYTICS

Objectives

In the risk-based reimbursement and incentive model followed by ACO's, getting insights into population and medical utilization is the key to defining success criteria. Population data can be approached from both clinical and cost perspectives:

- Identify high risk members and predict who are likely to need care in the future or get readmitted for same condition. Accordingly, providers can intervene to modify risk factors.

- Segment patients into care management groups by chronic conditions, such as high-risk asthmatics or diabetics. Accordingly perform individualized analysis to design patient-specific care protocols and care coordination mechanisms.

- Analyze the referral and utilization patterns to identify physicians who have opportunities to practice more efficiently.

- Highlight correlations and patterns among data. For example, detect patterns among patients with type 2 diabetes by analyzing various attributes such as type of patient visits, charges, admission locations, diagnoses, and procedures. Based on that analysis, in a similar sub-population, a patient's risk of developing Type 2 diabetes in a predefined future timeframe can be predicted. Physicians can utilize this data to prioritize intervention strategy.

Required Analytics Capabilities

A sophisticated data mining, or 'Predictive Analytics', is key to identify care practices that result in better outcomes, such as reduced readmissions. Such analytics engine should have access to enough historical data (worth of 5 to 7 years) both structured and non-structured that can be mined to estimate patients' risk of developing certain chronic condition based on recent encounters.

The analytics system should facilitate 'Query' capabilities to allow caregivers to define their own approach of medical intervention by analyzing population health status, trends and costs.

CARE ANALYTICS

Objectives

Care analytics can help in evaluating performance gaps by condition, site, provider and other parameters during care coordination.

- Care coordination performance can be constantly monitored and modified by analyzing actual medical or clinical workflow against benchmarked data. For example, in the case of a patient readmitted to the hospital, the care plan, patient compliance with treatment plans and readmission rates against benchmarks, can all be measured and analyzed, to derive a modified clinical workflow and better decision-making.

- Analytics can help to evaluate alternative treatments. The outcomes of such analysis may reveal disease patterns and patients at high risk. They may also help to evaluate performance of individual physicians as well as determine which treatment works best.

Required Analytics Capabilities

Care coordination activity needs an analytics system that can generate actionable alerts to providers and care managers based on a patient's vital data, such as blood glucose level crossing a threshold value or a prescription medication not refilled.

'Real-time analytics' can be performed to mine active data from care coordination and EHR/EMR systems, discard unnecessary details and deliver relevant data in a dashboard or message to the care giver team. Real-time analytics using in-memory capabilities can support rapid turnaround in decision making.
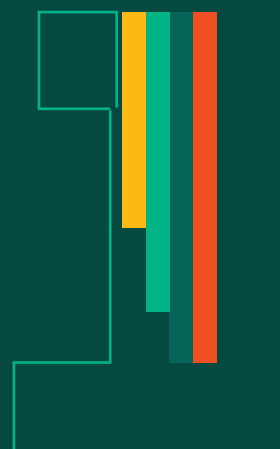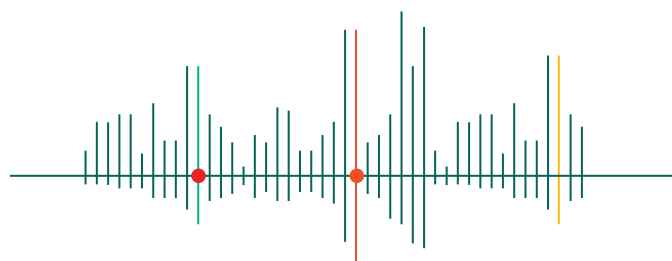
PERFORMANCE ANALYTICS

Objectives

ACOs must manage risk to achieve clinical, business and financial goals, so reporting key performance indicators is essential. For example, profitability of the ACO or physician practice to healthcare executives, medical directors and quality leaders must be easily available, preferably in a management dashboard format. Performance analytics can be categorized into 3 main segments:

- **Care outcome:** Process and outcomes metrics must be measured by ACOs internally to determine how well the organization is performing care processes. For example,, helping to ensure that patients with diabetes receive HbA1c tests and eye exams at specified intervals.

- **Provider performance**: The performance of individual providers, care sites, quality improvement initiatives and the organization as a whole must be tracked. This performance data includes not only quality indicators, but also shows how resource utilization varies across the ACO.

- **Financial reporting:** ACOs must be able to do financial reporting of a very different kind – most healthcare organizations are not accustomed to this. Since ACOs aim to bend the cost curve while improving quality, they need analytics to compare their cost trends to industry benchmarks, measure their enrollment changes, monitor average costs per member, compare costs by site, and break down costs by condition.

Required Analytics Capabilities

To analyze performance, the analytics solution should have capabilities to adjust nuances like physicians treating higher-risk patients, incorporating case mix and measuring concurrent risk measurement by illness burden for the patient set of a specialty or provider. This produces a balanced efficiency rating and fair comparison across entities or clinicians. The system should also consider various published standards such as Physician Quality and Reporting System (PQRS), Healthcare Effectiveness Data and Information Set (HEDIS) to establish portable reporting that can be shared with CMS and Payer organizations.

***Information** is the single most valuable currency an ACO can leverage to create value and competitive differentiation. While ACOs do recognize the untapped value in data and analytics, determining what data should be collected, what analytics to run on it and how to reward physicians for improved patient health, are still 'work-in-progress' areas. ACOs should carefully evaluate their information strategy and integrate it rightly with enterprise IT strategy. An ACO should find an IT partner that offers strategic consulting and implementation services in healthcare informatics across different analytics technology. The role of the IT partner will cut across strategy definition, product selection, implementation and business-as-usual services. The remuneration for the IT partner should also be tied to the achievement of the ACO's quality and financial outcomes.*

WHY IT IS TIME TO STOP BEING AVERSE TO **SOCIAL MEDIA**

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Impact of FDA guidance on social media strategies for Life Sciences companies

While most industries are rapidly adopting social media to listen to and engage with customers, the Life Sciences industry has remained largely cautious in its social endeavors. Owing to the lack of clarity on social media guidelines Life Sciences companies baulk at extending their social presence in the current, highly regulated environment.

On Dec 27, 2011, the FDA released guidelines on responding to unsolicited requests for off-label information. These guidelines have defined the regulator's stance on social media, where it has for the first time, acknowledged "emerging electronic media" such as Twitter and YouTube.

Life Sciences companies considering an entry into the social media space have naturally been wary about discussion of adverse events. Are consumers sharing information online that would indicate an adverse experience? Does monitoring social media trigger the adverse event reporting requirement? Will Life Sciences companies be drowned in a deluge of adverse events on social platforms?

In the view of these FDA guidelines, this article aims to shed light on the realities of adverse event reporting in social media. Our objective is to assist Life Sciences companies in determining the scope and potential impact of creating a social media engagement program.

LIFE SCIENCES COMPANIES – SHYING AWAY FROM SOCIAL MEDIA

According to guidelines, when a Life Sciences company has knowledge of any adverse event, it has an obligation to file a report with the FDA through the Form 3500A-Mandatory Reporting.

Considering the nature of social media, Life Sciences companies are naturally concerned about consumer discussions that would indicate an adverse experience. The guidance is not clear if monitoring these discussions would trigger the AE reporting requirement. At this time, there is no FDA guideline or regulation that specifically covers the content of online discussion in a way that is different from reporting AE information derived from any other source.

Current FDA guidelines give four parameters for submitting information about adverse experiences. These include:

An adverse event (AE) is defined as any unfavorable and unintended sign including abnormal laboratory finding, symptom or disease associated with the use of a medical treatment or procedure, regardless of whether it is considered related to the medical treatment or procedure.

• An identifiable patient

• An identifiable reporter

• A specific drug or biologic involved in the event

• An adverse event or fatal outcome

According to the guideline, "If any of these basic elements remain unknown after being actively sought by the applicant, manufacturer, or licensed manufacturer, a report on the incident should not be submitted to the FDA because reports without such information make interpretation of their significance difficult, at best, and impossible, in most instances".

To make a case for Life Sciences companies to adopt social media, we need to look at two key questions:

1. When adverse experiences are mentioned within consumer-generated media, do they meet the FDA's criteria for reporting?

2. If companies are monitoring social media, are they obligated to respond to any unsolicited requests on such consumer-generated media?

To answer the first question we did an analysis of two thousand, one hundred messages related to pharma and medical device products posted online across various online forums.

METHODOLOGY

The research was carried over nine prescription drugs (Hydrocodone, Amoxicillin, Lipitor, Lisinopril, Simvastatin, Plavix, Nexium, Singulair, Lexapro) and four medical devices (Medtronic's Revel, Resolute and Paradigm, Moog's Curlin). These thirteen brands were monitored on online forums such as Twitter, Facebook, Reddit, Deli.cio.us, Digg, Medscape, Blogs, etc. for a period of seven days using a social listening platform and the results were examined. Youtube results were omitted in this research.

This social monitoring was performed using **Wipro's Social Media monitoring platform**. This platform searches user-generated content such as blogs, comments, bookmarks, events, news, and videos across the social media space directly.
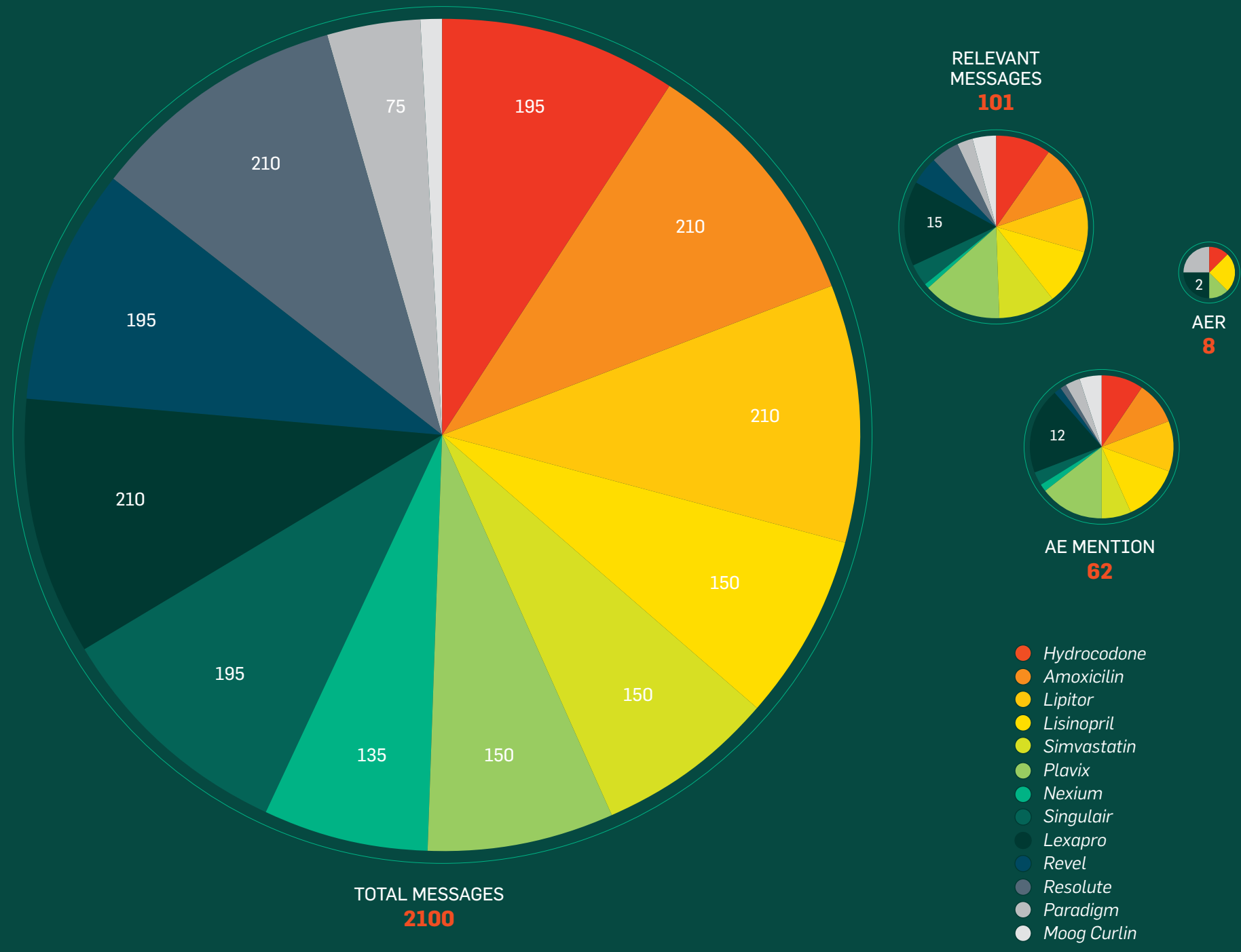
The table on the following page shows the number of messages that were analyzed for each drug /device.

TOTAL MESSAGES
2100

RELEVANT MESSAGES
101

AER
8

AE MENTION
62

KEY FINDINGS

The research revealed that for all posts containing mentions of the brands considered for this study:

- Only 3% of all posts have mention of an adverse reaction

- Only 0.38% messages actually qualify for AE reporting

- The incidence of adverse events is almost the same for pharma drugs and medical devices

- The messages with mention of adverse events are however considerably less for medical devices as compared to pharma drugs.

The figures in this research suggest that a Life Sciences company that aggressively monitors social media may pick up the occasional AE within patient or physician online discussion. However an instance qualifying for AE reporting would be encountered very rarely, with a volume that would be entirely manageable within the company's broader AE monitoring programs.

Legend:
- Hydrocodone
- Amoxicilin
- Lipitor
- Lisinopril
- Simvastatin
- Plavix
- Nexium
- Singulair
- Lexapro
- Revel
- Resolute
- Paradigm
- Moog Curlin

FDA GUIDANCE

To answer the second question, i.e. whether Life Sciences companies that are monitoring social media, are obligated to respond to any unsolicited requests on such consumer-generated media, we analyze the FDA draft guidance addressing how Pharmaceutical and Medical Devices companies may respond to unsolicited requests for off-label information.

Off-label use is the practice of prescribing pharmaceuticals for an unapproved indication or in an unapproved age group, unapproved dose or unapproved form of administration.

The FDA issued draft guidance on Dec. 27, 2011. The guidance addresses how manufacturers should respond to non-public and public requests for off-label information. This guidance for responding to questions posed in public online forums what the FDA calls "emerging electronic media" directly addresses forums such as Twitter, YouTube and discussion boards for first time. Two key points of relevance for the Life Sciences companies are:

1. The company has the choice to respond to unsolicited requests or not.

2. If the company chooses to respond, the actual response can only be provided in a private, one-on-one communication. This applies to questions posed in both a private and public setting.

Though not directly addressing Adverse Event reporting; the guidance does provide some insight into FDA's stance on Social Media.

THE COURSE OF ACTION

From the research it is clear that an overwhelming majority of posts on social media do not meet the FDA criteria for adverse events. In this research only 0.38% of the monitored posts qualified for AE reporting. However the benefits of social listening far outweigh the risks. The companies that actively engage in social listening can:

1. **Understand patients' doubts and concerns**
   Patients, who are new to a treatment often have doubts about when and how to take it. It is increasingly becoming the norm for patients post their queries on online community forums. Manufactures could monitor these concerns and update the product label, website and marketing communication accordingly.

2. **Avert risk of unapproved usage**
   Monitoring and immediately responding to off-label use, and any related conversations can avert the risk of unapproved usage.

3. **Learn about patients' experiences using the product**
   Candid feedback through online queries can be obtained to issues like, 'Is the packaging difficult to open?' 'Is the dropper too short?' 'What are the concerns while using the medical device?' This can significantly help in improving product features.

4. **Conduct competitive analysis**
   In open social forums it is easier for companies to understand what patients and physicians are saying about competitive products. Which attributes are more valued? Which attributes are pain areas?. They can also determine how their product is perceived against other products in the category.

5. **Engage with caregivers**
   An increasing number of care givers are participating in online discussions. A recent survey by Google & Manhattan Research found that 93% of physicians influence treatment decisions based on online clinical and treatment information. This presents a huge opportunity to equip hitherto unreachable caregivers with the right and complete information about the product.

CONCLUSION

Life Sciences companies should set aside over-hyped concerns about a deluge of AE reporting resulting from social media engagement. The benefits of social listening far outweigh the challenges. As patients and physicians increasingly engage online, companies have no choice but to follow. Crafting a comprehensive strategy and using the right tools, is an essential to the success of this move.

Life Sciences companies need to develop their social strategy and employ tools and platforms for social listening and managing social media communication. The social strategy should incorporate people, process and technology.

People: Life sciences companies would need social media consultants who understand the social space and the life sciences domain and can integrate it with their marketing strategy.

Process: Business processes need to be established to ensure that all communication follows an approval process and is communicated to the appropriate stakeholders and compliant with OPDP (Office of Prescription Drug Promotion) regulations.

Technology: For a single view of social media across business units and geographies companies may implement a digital marketing platform that would aggregate data from various sources, implement business processes, help in campaign management and provide analytics & reporting for gaining actionable insights.

The future of Life Sciences marketing is in being part of the conversations in the online space.

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USING M2M DATA ADVANCED ANALYTICS
TO TRANSFORM MEDICAL DEVICE COMPANIES

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Machine-to-Machine or M2M communication is not a new concept in the medical devices industry. However, the recent trend towards accountable healthcare, combined with disruptive technologies like big data, cloud and analytics have spurred a renewed interest in the utilization of M2M data due to its many potential benefits. Unfortunately much of this data exists in silos in disparate systems and applications, or leaks into a black hole where it cannot be effectively harnessed.

The digital age is changing the nature of healthcare delivery. In their quest to provide better and more accountable care, healthcare providers are turning to increasingly sophisticated and complex medical devices in procedures and treatment protocols. At the same time, the use of computer-based patient monitoring equipment has expanded exponentially. The overall market for such medical connectivity is expected to increase according to M2M analyst Harbor Research. In 2009, 6.2 million devices were shipped. This includes all modules used for connecting machines and other manufactured products, both wired and wireless This number is expected to increase to 32.7 million devices by 2014.[i]

M2M IN THE MEDICAL DEVICES INDUSTRY

Changing the healthcare ecosystem

Traditionally, medical device companies have focused their attention on their manufacturing processes, supply chains and partner alignment The focus on providing a world-class customer experience has been secondary. Customer service has been typically limited to onboarding customers by providing training in the usage of the product and responding to an agreed service level when product failures were reported. This was similar to the way their own customers operated. Hospitals, for instance, operated within the broad mechanism of diagnosis through trial and error and mostly reactive care of patients. The healthcare ecosystem operated on a long-established, fee-for-service model, where payment was linked to services delivered to the patient and not to improved health outcomes.

As the healthcare industry moves towards accountable care where providers are rewarded for patient health outcomes, all participants in the ecosystem are increasingly trying to provide solutions that empower clinicians and patients to take the right actions at the right time.

As key participants in the ecosystem, medical device companies can play an important role by:

• Seeking to develop ways on how their technology can best be used for better outcomes

• Understanding how their customers (i.e. clinicians) successfully utilize their devices/technology and establish best practices for replication across the board

• Ensuring their devices work seamlessly in an interoperable manner in the overall context of a clinical setting

One way that medical device companies can deliver value is to utilize the data produced by devices. Medical devices and equipment produce data almost continuously and are designed to transmit streams of data, both medical and otherwise, via wire line or wireless connections, to receivers or to a central storage facility. This is known as machine-to-machine communication, or simply M2M. This provides medical device companies with a deep understanding of product behavior, allowing them to respond proactively to a developing undesirable event and thereby improve customer experience.

DRIVERS OF M2M ADOPTION

The use of M2M has long been prevalent in the medical devices industry due to the numerous benefits it provides. However, recent developments such as the push towards accountable healthcare, combined with disruptive technologies like big data, cloud, and analytics have spurred a renewed interest in the utilization of M2M data. In addition, the following technological developments have improved the accessibility of M2M analytics:

• The cost of sensors has come down drastically over the last few years, allowing embedded devices to remotely report on the state and functioning of their critical parts

• A surge in the development of M2M connectivity platforms like Axeda that provide connectivity modules and device agents, making it easy for devices to be connected and transmit the information to central servers on the cloud

• The availability of open source big data platforms like Hadoop and open source statistical analytics tools like R make it economical for device companies to analyze and act on this continuous stream of information related to device usage and device conditions

DERIVING BUSINESS VALUE FROM DATA

In addition to the bounty of data that is being produced by medical devices, there is a lot of service data that includes information about service resolution, spare parts' supply chain, product consumption and usage context. Unfortunately much of this information exists in silos in disparate systems or applications that cannot be easily connected, or is leaking into a black hole where it cannot be effectively harnessed. When integrated and analyzed for decision-making, this information enables proactive service, allows for consumption-based business models and drives recurring revenue and improved customer experience.

Some benefits that organizations can expect when this data is integrated, analyzed holistically and harnessed are as follows:

- **Proactive service at reduced cost of service per device:** Near real-time analytics based on data received from the device can remotely monitor a developing situation and predict failures by leveraging machine learning algorithms. The same data can be used to change the maintenance model from a periodic maintenance model to a condition based one, allowing the device company to utilize resources where they are actually needed and thereby improve uptime of the device.

- **Improving first time fix rate:** Often, service personnel have to make multiple trips to the customer site due to non-availability of the required part at the time of service. By combining

error sequence patterns retrieved from the device and drawing on earlier resolutions applied for similar situations, the device company can predict the resolution as well as the knowledge artifact needed and can have the required part shipped to the target location before the service engineer arrives. This helps reduce the time spent for diagnosis, reduces the number of field trips and significantly improves the first time fix rate and the mean time to repair, besides reducing the overall cost of service.

- **Optimized spares parts inventory:** The high volume of value engineering and redesign needed for medical devices results in high product obsolescence and consequently spare parts obsolescence. At the same time, the criticality of the required parts can lead to longer equipment repair time. Monitoring certain critical parts of the device can help predict need patterns to ensure stocks are maintained depending of the propensity of failure across the installed base.

- **Ability to learn from best customers and develop best practices:** M2M data combined with analytics can lead to an understanding of which customers are most profitable and/or which customers are deriving the maximum benefit from the product or technology. Such insights can help the device company reward its best customers, and also understand device performance and usage patterns to develop best practices.

These proven practices that lead to predictable results can further be evangelized across the customer base as differentiated solutions. This can improve service revenue as well as product differentiation, and lead to consistent equipment performance and satisfaction.
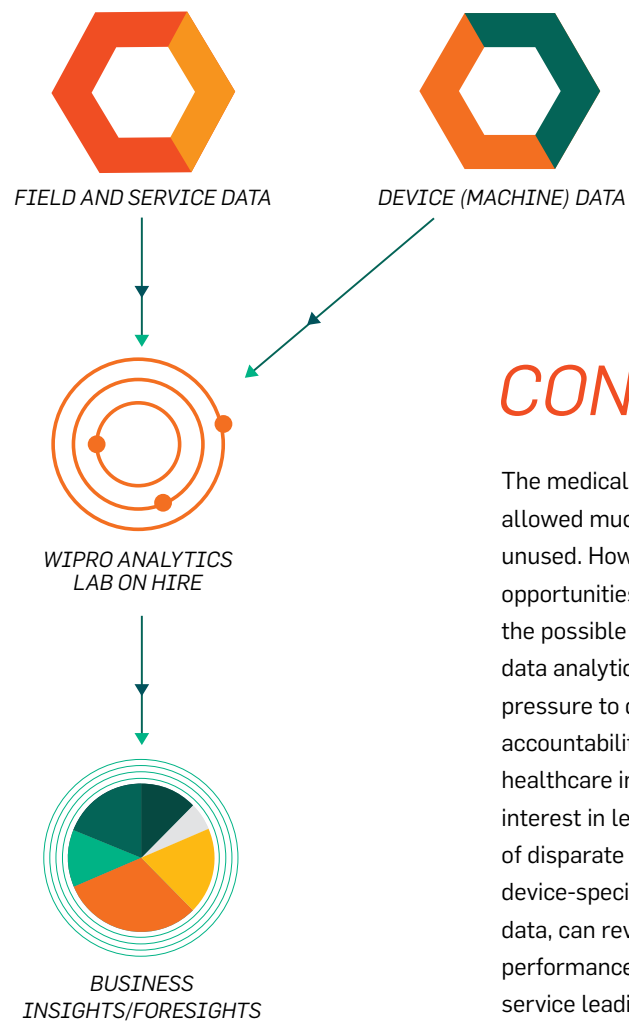
- **Support for consumption-based payment models:** The uncertain economy has given rise to demanding customers who are looking to reduce capital outlays via payment models based on actual consumption of the device. M2M-enabled smart metering can accurately bill customers for the usage of the device and promote consumption-based payment and business models.

- **Improve recurring service revenue:** Consumables form a significant portion of recurring revenue for a medical device company. The company can utilize machine usage data, to estimate, to a very good degree of accuracy, the consumption of consumables and create measures to improve the same.

- **Cross-sell and up-sell opportunities:** As companies get to learn more about the utilization and usage patterns of their devices by customers, they can cross-sell or up-sell to these customers for mutual advantage.

A well designed device with due importance paid to service requirements, can drive the success of the product as well as profitability from service contracts. Adding sensors as required and

transmitting consumption information including the continued capture of alarms and faults can help device companies understand and predict device behavior. This information can then be fed back to R&D to improve product quality. This iterative cycle can lead to significant product quality improvements in a reduced time frame resulting in lower service costs along with the benefits detailed above.

Wipro recommends an integrated data model, combining data from both the device and from the service business processes, followed by the deployment of advanced analytical models in order to enable device companies to realize the benefits detailed above. However, this can be overwhelming for organizations just embarking on their analytics journey, given the investments needed to acquire the new skill sets, capabilities, software platforms and tools.

Wipro's Analytics Lab on Hire provides a wide range of choice of analytical platforms, tools and data scientists. It allows organizations to assess benefits before making investments. With their deep domain expertise, our teams can help initiate an organization's journey towards competitive advantage by harnessing machine and service data. The Lab on Hire model is designed to demonstrate quick wins within a week, provide a first-hand experience of the value of M2M analytics. It can help to draft a roadmap that will help medical devices companies realize the true potential of their M2M initiatives to transform their service business.

FIELD AND SERVICE DATA

DEVICE (MACHINE) DATA

WIPRO ANALYTICS
LAB ON HIRE

BUSINESS
INSIGHTS/FORESIGHTS

CONCLUSION

The medical devices industry has traditionally allowed much of the data it collects to go unused. However, it is now waking up to the opportunities and is beginning to consider the possible benefits of investing in M2M data analytics. In addition, policy incentives, pressure to deliver more with less and fixing accountability for care is transforming the healthcare industry and driving a renewed interest in leveraging M2M data. The integration of disparate data, including service data and device-specific data along with social media data, can reveal key insights to product performance. This, in turn, can enable proactive service leading to superior customer experience, determine opportunities for recurring revenue growth and provide customers with a range of consumption-based business models. Wipro's Lab on Hire model provides the required infrastructure to help companies experience the potential of M2M through quick wins, and develop a strategic roadmap that is perfectly tailored to each company's business model and objectives.

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Applying Thought

DO BUSINESS BETTER