

# HEALTHCARE & LIFE SCIENCES COMMUNIQUÉ

WIPRO INSIGHTS & PERSPECTIVES | Edition 1





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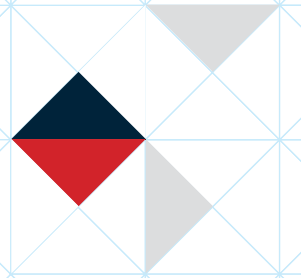
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# From the Editor's Desk



It gives me great pleasure to bring you the first edition of the **Healthcare & Life Sciences Communiqué**. This journal aims at publishing relevant news and insights from the healthcare and life sciences world. We have chosen to open with the three big trends that we see as all-encompassing and indeed all-important – Care, Compliance and Collaboration. Any serious player in the industry must understand and address the rapid shifts that are happening in these areas. We hope the articles we have put together for you will help you do this.

If you have any feedback on this issue or on what you would like us to cover in the upcoming editions, do write to me at [meenu.bagla@wipro.com](mailto:meenu.bagla@wipro.com). We welcome your opinion.

**Meenu Bagla, Head of Marketing  
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# Accountability in Health Care: Collaboration and Analytics are Key

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## ACCOUNTABILITY AND PATIENT-CENTRICITY

The healthcare industry continues to face demands for cost control, even as it needs to demonstrate improvements in the quality and patient-centricity of care. Policy makers are taking a lead in changing the system to achieve these goals – the Accountable Care Act (ACA), signed into law on March 23, 2010 identifies these as its core goals. While there seems to be an equal split between enthusiasts of the ACA regulations and those that prefer to take a wait-and-watch approach, the trend towards accountability in healthcare is irreversible. All industry players will be guided by two principles: accountability and patient-centricity.

## ACCOUNTABLE CARE AND ANALYTICS

The concept of accountable care is popular and very well-documented. It is achieved through documented, transparent performance measures for those who provide care and those who pay for it.

The current methodology of measuring cost and quality is to aggregate claims, financial and clinical data. This, however, does not help the decision making required to deliver high-quality care. The delivery of patient-centric care requires predictive analytics and modeling, where historical data is used to exploit patterns to identify risks and opportunities. This may mean a blurring of the traditionally separate, and often adversarial, positions of those who provide care and those who pay for it. Payers typically have access to analytics for patient identification and stratification. However, most of this information is retrospective and has low ability to affect point-of-care decisions. Hospitals and large provider groups have access to real-time clinical data that can improve point-of-care decision making, but have limited historical data for patients.

There is a need to integrate data from payers and providers to improve outcomes and quality. As options run thin for all players, collaboration between providers and payers is occurring on an unprecedented scale. These collaborations help with the all-important goals of cost-cutting, improving care and creating better reimbursement models based on outcomes. Knowledge of a patient's history can help providers to make better clinical decisions. It is classic 'B-to-C' consumerization. Of help, also, are technologies such as cloud platforms (where data sits on remote servers and is accessible to multiple users) that seamlessly connect hospitals, physicians and patients.

## HEALTHCARE'S HUNT FOR EQUILIBRIUM

Given that accountability will be the chief driver for healthcare organizations as policy makers globally seek to rein in costs it is expected that physicians, hospitals and insurers will seek equilibrium between the lowest-cost treatments and expanding access to patients. That equilibrium most likely will rest somewhere between the U.K's taxpayer-funded National Health Service, which provides almost free services for all residents, and the more expensive, private, insurance U.S. health-care model.

Billions of healthcare dollars could be saved if people could be persuaded to lead healthier lifestyles.

One big organizational issue facing healthcare providers is the likelihood that payers will soon move towards more bundled forms of payment. Those 'bundles' will cover payments for pre-hospital diagnosis, hospitalization, post-hospital care and possibly all drugs used in the treatment. This approach will also incentivize providers to be more cost conscious. The basic idea is to move away from the fee-for-service approach to outcome-based services. The transition will not be easy. In the short run, it could mean pain for some providers as they struggle to think and act in completely new ways.

With the pressure to contain costs, hospitals are pushing for home care, outpatient treatments that avoid hospitalization, parceling out of specialist services to ambulatory care centers and remote patient monitoring and wellness programs. Moving some hospital services out of the inpatient sector into more ambulatory care settings is good news for both patients and payers. Billions of healthcare dollars could be saved if people could be persuaded to lead healthier lifestyles. Sadly, there is no overwhelming evidence yet to suggest that these wellness programs actually have wide results.



## MIXED FORTUNES FOR INSURERS

For insurers, ACA may herald new gains, but not without some pain. The focus on coverage for just about everyone means insurers could enroll millions of potential additional 'lives', or customers but there are obstacles.

The good news for insurance companies is that the rules apply to all. That will make it easier for them to adjust premiums to accommodate additional costs. Premiums, however, will tend to rise and that is a big concern. Payers will have to pay for additional services, and that will add to costs and premiums. There is not much in the ACA that will help control the fees of providers, the prices of drugs or the prices paid to hospitals. Insurers will have to develop new strategies to control reimbursements.

Insurers have been eagerly awaiting electronic health records to bring new efficiencies. Despite more than a decade of talk, progress is slow. Electronic records will inform providers about a patient's conditions and previous treatments, and potentially eliminate duplicated services. The issue, of course, is that providers will adopt new technologies only if they save both costs and time.

## THE CHALLENGE AND THE OPPORTUNITY

The quest for accountability in care is forcing the healthcare industry to introspect. Medical management is 'the next big thing', with a focus on prevention before cure. There is a shift from treatment to wellness and everybody in the food chain will be involved. The biggest challenge and the biggest opportunity is going to be the complexity, heterogeneity and volume of data. The ability to combine, normalize and harmonize this information from multiple stakeholders is going to be the key to success.

# Analyst Insight: Collaborative Strategies Will Drive Significant Value Creation for Healthcare

Eric Newmark  
Program Director, IDC

Eric Newmark directs the Business Systems Strategies program at IDC. In this position, he provides research-based advisory and consulting services, as well as market analysis on key topics within the commercial life science industry. Eric's research expertise includes sales and marketing, channel management, supply chain related technologies and emerging market trends.

What role does collaboration play in today's healthcare and life sciences markets, and how should companies be utilizing collaborative efforts to drive enhanced value for their organizations and end consumers?

Both healthcare and life sciences companies have been increasingly challenged by rising costs, shrinking margins, and growing regulatory oversight. As a result, the industry is seeking opportunities to reduce overhead, increase operational efficiencies and maximize business opportunity for revenue generation. One thematic approach to counter these issues that needs to be progressively explored by organizations across the healthcare value chain is further utilization of collaboration, from both a business process and technology perspective.

Collaboration amongst payers, providers, pharmaceutical companies and physicians will be central to both creation of business value and driving improved patient outcomes over the coming years ahead. For example, connected health care is an emerging space that holds great promise for enabling improved care collaboration by making health information securely available across the enterprise at the point of care and clinical decision making. Recent healthcare reforms in the United States are also driving a fundamental change in both healthcare delivery and financing. On one hand, this has created growing concern over compliance and regulatory risk for healthcare organizations, which has translated into increased investment in GRC (Government, Risk and Compliance) solutions, both internally and through outside partnerships and alliances.



On the other hand, for organizations to appropriately respond, adapt and deliver high quality care going forward, health plans and providers need to significantly expand the collaborative aspects of their relationships to ensure they can meet the objectives of accountable care and The Triple Aim, which includes enriching population health, improving the patient experience and better managing costs.

With physicians and hospitals now taking on more financial risk, they need to adopt many traditional health plan processes such as risk identification, stratification, transition (post discharge), chronic disease management, and health and wellness. To do this, providers and health plans need to increase collaboration to successfully integrate these health plan capabilities into the provider environment. Thankfully, this collaboration appears to already be occurring naturally, as IDC Health Insights Accountable Care Survey 2012 recently found that the dominant governance model emerging for accountable care is health plan and provider joint partnership.

The consumerization of technology, within the context of health care collaboration, will also permit the industry to strive toward achievement of the Triple Aim. Mobile, medical, personal health, and even fitness devices should all be integral components in helping organization's drive consumer engagement strategies, which are a critical component of connected health and enabling enhanced care delivery.

## IDC Health Insights Accountable Care Survey 2012 recently found that the dominant governance model emerging for accountable care is health plan and provider joint partnership.

For example, using wired or wirelessly connected devices, consumers can send their biometric data (e.g., heart rate, blood pressure, blood glucose readings) through a gateway to be aggregated and analyzed for monitoring health status and alerting clinicians (and caregivers) when more immediate intervention might be required. We hope to see U.S. health plans and providers continue expanding availability of connected health technology for consumers by covering all or some of the costs associated with the device and monitoring services to help consumers better manage their chronic conditions. This will also help consumers reduce the risk of readmissions within 30 days of discharge and improve compliance with therapeutic regimens, thus improving patient outcomes.

Increased collaboration holds significant benefits for the life sciences as well. For example, within the R&D space, the industry has already embraced external partnerships as a core approach to improving the efficiency of R&D, and industry transformation has driven leading companies to abandon the traditional 'do it all yourself' approach to drug discovery and development. While the industry has somewhat lessened patent-cliff challenges by exploiting M&A to back-fill weakened drug pipelines, these transactions can be extremely costly and challenging to the fluidity of the business. Outsourcing of IT and expanded use of strategic partnerships in coordination with M&A can help facilitate quicker melding of business processes and easier integration of IT during these business transformations.

## Within the R&D space, the industry has already embraced external partnerships as a core approach to improving the efficiency of R&D, and industry transformation has driven leading companies to abandon the traditional "do it all yourself" approach to drug discovery and development.

This allows companies to focus on more strategically important topics such as synergizing the resulting companies from a business and strategy standpoint. Similar in fashion, on the commercial side of the industry, life science companies need to continue working to increase their collaborative efforts with providers and payers in strides to increase visibility to patient needs, deepen clinical insight, provide better medication education to patients, and help ensure proper formulary coverage of their products for end consumers.

The success of collaborative initiatives in health care will be highly dependent on the ability of all stakeholders across the health spectrum to effectively and efficiently work across organizational boundaries in a transparent fashion.

Ultimately, payers, providers, pharmaceutical companies and physicians all need to bring together their respective domain expertise, technology and data to synthesize additional insight and value from a care perspective, while simultaneously removing overlap and inefficiency in the current healthcare delivery system.



# CARE

Caring can be learned by all human beings, can be worked into the design of every life, meeting an individual need as well as a pervasive need in society.

– Mary Catherine Bateson  
(Cultural Anthropologist)

# Integrated Care Management

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This article is based on UBM Tech's conversation with Sangita Bhattacharya, and SasiKanth RVN. UBM Tech is part of UBM plc, a global live media and B2B communications, marketing services and data provider.

Integrated care management promises great benefits for patients, providers and payers, but requires disciplined planning and execution.

Healthcare is on the minds of everyone in the United States – a result perhaps of the controversy surrounding The Patient Protection and Affordable Care Act, which promises to expand the population of the healthcare system by a sizable 32 million Americans. The hyper-awareness around healthcare is compounded by the country's demographics, especially an aging population bubble – known collectively as the baby boomers – that threatens to overwhelm healthcare providers and payers with increasing and prolonged demands.

That threat is exacerbated by the fact that medical care in the United States today suffers from problems related to cost, quality, fragmented delivery and compliance with new models/reforms. Other significant challenges include a lack of coordination among physicians, lack of concern for patients' positive experiences in the healthcare system, and accessibility to widely dispersed medical records

## HEALTHCARE TODAY

Providing healthcare in today's fast-paced global environment is a challenge. That is particularly true among the elderly and the chronically ill population, where the bulk of the cost of healthcare is generated. Based on industry estimates, payers and providers could spend between \$15 billion and \$20 billion over the next decade on advanced care management.

Currently health care delivery with its set of limitations is not able to support personalized care goals and outcomes that are important to a patient. Since the system is reactive, it cannot reduce the need for expensive medical services and hospitalizations. There is a need for a next generation model for care management that is proactive, integrated, patient-centric and outcome-based. Only such a system will succeed in providing best effective management of chronic diseases, post-acute care and other complex health and social care needs.

Problem areas for payers and providers include, controlling costs as well as improving quality and the coordination of care delivery. The potential for dramatic change brought on by regulatory reforms also needs to be realized.

## IMPACT OF REFORMS: EVALUATION OF NEW DELIVERY MODELS

The Patient Protection and Affordable Care Act calls for the creation of an Accountable Care Organization (ACO) program administered by CMS by January 1, 2012. Qualifying providers, including hospitals, physician group practices, networks of individual practices, and partnerships between hospitals and other health care professionals will be eligible to form ACOs. ACOs will be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to them. They will also be expected to meet specific organizational and quality performance standards in order to be eligible to receive payments for shared savings.

National Committee for Quality Assurance (NCQA) recently announced the technical specifications that any healthcare organization looking to show ACO readiness must meet. "Releasing these measure specifications is also an important step in making ACOs a functioning, vibrant part of American healthcare," NCQA Vice President of Performance Measurement Mary Barton said in a statement.

## INTEGRATED CARE MANAGEMENT

This new ACO accreditation measure adds to the already established criteria – patient-centered primary care, access to needed providers and patient rights and responsibilities. By using information technology, ACO's are looking to meet this accreditation measure, which will also dovetail with the outcomes available through its sophisticated use.

On the other hand, CMS's star ratings provide an opportunity for health plans to earn huge bonuses by improving the scores in the 53 performance measures specified by CMS. By implementing new IT systems, health plans can track their performance in the specified measures.

Efficiency and integration are inherent in the use of sophisticated and meaningful IT. It offers healthcare providers and payers capabilities that contribute to lower costs and higher quality of service, while giving patients the control of their care and access to easy physician interaction.

Integrated care management is a process where an individual's needs are assessed and evaluated, eligibility for service is determined, care plans are implemented, services are provided and needs are monitored and re-assessed.

Next generation technologies enable care delivery that is fast, secure, and affordable. Integration with analytics, CRM, remote patient monitoring, online collaboration tools and mobility ensures the right care for the right person at the right time. It seeks to change the nature of healthcare from reactive to proactive, from fragmented to coordinated, and from static to dynamic. Integrated care will be key to improving quality outcomes for the frequent, expensive care that the elderly and patients with chronic conditions need.

Key to success of ACO's lies in incentivizing both patients and providers

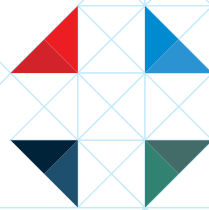
## Integrated care management works on 5 major building blocks



1

### Analytics

This involves simplifying the process of integrating information from diverse sources and systems including claims, eligibility, lab results, health risk assessments, personal health records, and care management. It helps organizations to stratify members using predictive modeling and classifying them under different categories based on the level of criticality of the care needed.



2

### Collaboration

Online collaboration between constituents – the patient, the physician and the care coordinators using sms, chat, voice, video for patient health assessment, clinical report diagnosis, e-appointment, e-consultations and e-prescriptions, enables anywhere, anytime care for patients.

3

### Interoperability

Because care management approaches the patient from a whole person perspective, it demands that disparate, distributed systems are able to work together to share information and data. Therefore, technology interoperability is a key element of these strategies.



4

### Portability

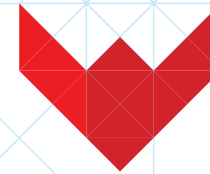
The ability for the patient and his or her physicians to interact quickly, easily, and on a 24/7 basis requires technology that is portable among differing systems and able to interact with varied end-user devices. Mobility enables on-the-move access to health records and availability throughout the encounter.



5

### Security

Privacy and security are two of the most critical and compelling concerns within the healthcare community today. Due to its multiple parties and various input and access points, these are even more important in the integrated care management environment.



As with any process or project that incorporates IT as an integral element, these approaches can be challenging and need focus and direction. They demand an outlook that recognizes the big picture as well the nuances.

## THE TECHNOLOGY FOR INTEGRATED CARE MANAGEMENT

Integrated care management requires technology that addresses the requirements detailed in the previous section and is tailored to these specialized approaches. There are such systems on the market, some of which address certain aspects of these requirements, while others attempt to encompass the entire spectrum of requirements. Specific aspects to these systems should be considered essential.

For instance, an integrated care management system should incorporate technology for performance analytics to help in developing an outcome-driven and quality-focused healthcare environment. It should have a built-in collaboration platform that uses tools such as alerts, chat, reminders, SMS, and activity workflows to help in avoiding treatment overlaps, multiple clinical tests, and unnecessary or redundant hospitalizations. The solution should be compatible with devices such as smartphones, tablet PCs, and support integration with remote patient monitoring devices, which to ensure access to patient medical records at the point of care, for proactive and preventive care delivery.

A key factor in terms of a sophisticated integrated care management solution would be to leverage the benefits of software as a service (SaaS) which provide advantages in terms of flexibility, scalability, and cost control. Leveraging a SaaS-based platform provides quick implementation and deployment of the application and also ensures no maintenance and hardware cost.

Next-generation technology solutions can now propel healthcare in a direction that is proactive, integrated and patient-centric.

# Data and Analytics in the Pharmaceutical Value Chain

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Nitin is responsible for technology consulting for leading Pharmaceutical organization on their important initiative around Data and Analytics. For over 13 years in IT industry, he has been exposed to various technology management roles. His current portfolio also includes building domain capability in D&A space across commercials, R&D, manufacturing and supply chain for Wipro's pharmaceutical business.

## THE DRIVE FOR INNOVATION

The challenges facing the pharmaceutical industry like the demand for value by payers and patients, growing awareness of healthcare among consumers, new economies, newer technologies, efficiencies demanded by financial stakeholders, diminishing pipelines, generics and compliance are the drivers for a more efficient and innovative environment.

The pharmaceutical industry is no longer the mysterious ecosystem it used to be. The early 2000's saw pharmaceutical companies collaborating with external vendors and reaping the benefits of cost rationalization. The drastic changes in the technology landscape over the last few years have spurred a further opening of the industry, with new CXOs crossing borders from other industries.

Pharmaceutical companies are today focusing on innovation across the value chain as well as on operations. Emerging markets, diminishing pipelines and patent cliffs have become a given. The imperative now is to grow a biologics portfolio pipeline and create an efficient strategy to compete in the face of generics, consumerization, industry standardization and compliance.

Diversification of portfolios into products that sit on the border of pharma and OTC (dermatology, eye care) and acquisitions are also important trends. The recession has played its part in fueling innovation. The healthcare and pharmaceutical industries – hitherto thought to be recession-proof – are feeling the pain. The fact that not many pharmaceutical companies can boast of a very strong pipeline of potential blockbuster drugs has only amplified the impact.

The industry has responded positively to these challenges but there is room for more. Innovation is leading the way for predictive analysis in place of traditional analytics in order to forecast probability of success more accurately and minimize loss. Payers/ customers have become the central cog in the pharma wheel, a place traditionally held by products. Outcome analysis is driving payer and regulatory decisions and the emerging value drivers are health outcomes for patients and health systems.

## BIG DATA IS HERE TO STAY

The Life Sciences sector today is inundated with data – from the large volume of data generated internally to other sources like public databases, data from market research companies and other payers and providers. Worldwide healthcare data is expected to grow to 25,000 petabytes by 2020, a mind boggling 50 times of the current 500 petabytes<sup>1</sup>.

Big data is of course here to stay; the need is to harness it. Pharmaceutical firms are increasingly focusing on analytics as a way of ensuring they are able to transform this data into valuable insights. Insights could mean an early warning of success that allows the development of optimal pricing strategy for a new product launch or predicting manufacturing process deviations to avoid loss or worse, recall of products from the market. According to McKinsey & Company, the potential annual value to US health care of 'big data' is approximately US\$300 billion. The four attributes of 'big data and analytics' are identified as *volume, variety, velocity and value*.

## LEVERAGE THE EXISTING ECOSYSTEM

There are several areas that require sharpened focus by the industry. Improvement in business solutions can address only part of the problem.

It is important to recognize the fact that no organization is currently in a position to adopt a green field approach. Not only are there significant investments in current systems, there is also a very high dependency on them for current operations. Optimal solutions will find ways of leveraging the existing ecosystem and not disregard it. Many of the challenges that these systems address are still valid. However, the generation of data-driven insights is now an imperative and has moved from being viewed as a competitive advantage to becoming the lifeline of the industry.

## GETTING GRANULAR

The impact of analytics for a pharmaceutical organization is best viewed through the patient lens.

**According to Gartner, the next generation of analytics must have a social dimension to include social network, sentiment and contextual analysis.**

The revolution of the last decade is social media. Use of social media has seen an unprecedented rise over the past few years by all stakeholders in the healthcare value chain, most importantly the patient. The data generated by the advent of social networking and media, use of mobile devices, Internet transactions, etc., need more than traditional ways of data processing and analytics. Online social networks and health records today offer a huge repository of real-world patient data. The granularity of data in the US is significantly different to the data available in Europe and other emerging markets. In the US, the sales data from third party sources like IMS, Dendrite, Verispan, Wolters Kluwer et al., is granular enough to generate reasonably rich insights.

In the EU, sales data granularity is limited to zip codes. Given the low regulation of purchase of prescription drugs, this is even thinner in emerging markets. In this scenario, the data from social media could be a true insight generator on a global level.

With the right data input, analytics in this space provide valuable information for improving and customizing drug development and services, identifying undiagnosed patients, predicting hospital re-admissions and other medical forecasting. It can also zone in on health outcomes and comparative effectiveness.

Referral patterns, drug switches, off-label use, as well as disease trends and locations can be understood better through efficient harnessing of data from social media. Pharmaceutical and healthcare systems can monitor public sentiment, receive customer/patient feedback, ratings and reviews and then deliver targeted, relevant content and improved services<sup>2</sup>. According to Gartner (2011), the next generation of analytics must have a social dimension to include social network, sentiment and contextual analysis. Gartner also suggests that companies will have to build a social analytics plan and integrate it with business intelligence and social communication and collaboration strategies.





## CONSUMERIZATION IS KING

The growing trend of consumerization (and yes, let's add the word to standard dictionaries) is, according to Gartner, a force that requires healthcare organizations to focus on the direct, individual user of the healthcare service, not just the data of a generalized audience. Consumerization develops and distributes information specific to a given user's needs. A consumer's individual experiences are aggregated, used for evaluation and then to respond to her/his specific needs. Individuals whose needs are not met in this way will eventually leave and favor competitors. To succeed in this new consumer-oriented society, healthcare organizations must identify consumer segments critical to their product offerings<sup>3</sup>. These consumer segments must also be individualized, so that needs and individual goals are aligned. An emerging trend points to organizations looking to leverage this data for Health Economics and Outcomes Research (HEOR). Even governments have recognized this trend and are bringing in amendments and legislations to empower patients with access to information and bring about greater transparency in healthcare operations. This includes the breakdown of overall healthcare costs to a set of standard attributes, and measuring the success of healthcare industry participants based upon ultimate health outcomes.

## BIG DATA IN CLINICAL OPERATIONS

Another area where analytics is playing a big role currently is in drug development, specifically on the clinical side. There is a clear focus on data analysis from Last Patient Last Visit (LPLV) through to the New Drug Application (NDA). This area, loosely called Drug Development, involves supply and demand management between investigators and subjects. Pharmaceutical companies have been struggling with challenges related to recruitment of doctors and patients for clinical trials. The numbers of doctors/patients at the end of a successful clinical trial is about 75-80% lower than initial recruits at the beginning of the cycle. Attrition takes place at various stages of the process. This makes effective segmentation and targeting critical. Important data generated at various stages of the process goes waste and is not acted upon to derive meaningful information. The use of data analytics can provide predictive analytics on key indicators like subject enrollment, dropouts, data quality and utilization of study medicine. Study managers/sites/CRAs can monitor site performance and effectiveness, and identify high and low performing sites and vendors. Role-based, pre-built dashboards to access information on clinical operations and improved discrepancy management, together with high-quality, clean data can lead early insights into a study helping to lower overall duration and therefore costs of the clinical trial.

## BIG DATA IN THE MANUFACTURING AND SUPPLY CHAIN

Another area that pharmaceutical companies are focusing on is the manufacturing and supply chain. Regulation compliance has emerged as one of the biggest concerns in pharmaceutical manufacturing. As an indicator, the number of warning letters from the FDA has almost tripled between 2010 and 2011. The number of seizures has grown 50% in the same period. Numerous challenges exist in the manufacturing space. There is no consolidated view on plant performance. A large volume of data still exists in paper form and proactive alerts are limited.

Government regulations like FDA's Prescription Drug Marketing Act (E Pedigree track-and-trace) pose fresh challenges. These challenges demand a two-pronged approach that includes enhancement of business solutions as well as smarter data analytics. Manufacturing operations generate a massive amount of data that is used by multiple processes around their periphery. Seamless data integration with these processes, collaborative analytics that share process models and predictive analytics can help improve product quality and enable cross-functional analysis across the supply chain.

The use of data analytics can provide predictive analytics on key indicators like subject enrollment, dropouts, data quality and utilization of study medicine.

In a recent cost containment and innovation promotion effort, a group of 10 big pharmaceutical companies (J&J, Pfizer, GSK, Bristol Myers Squibb, Eli Lilly, AstraZeneca, Abbott, Sanofi, Boehringer Ingelheim and Genentech) are collaborating in a move that could change the way clinical trials are done<sup>4</sup>. One goal of the nonprofit organization will be to provide better information on the risks and benefits of drugs and therapeutics. The organization will work with regulators like the U.S. Food and Drug Administration, the European Medicines Agency, the Clinical Data Interchange Standards Consortium, Critical-Path Institute, Clinical Trials Transformation Initiative, the Innovative Medicines Initiative and contract research organizations. Big data is expected to be generated from this exercise and the insights will play a crucial role in the clinical trial process.

## IN SUMMARY

The benefits of this are manifested in improved factory yield, reduced rate of annual returns, compressed cycle times and lower costs of diagnosis and repair. The application of analytic techniques generates metadata on regulatory compliance, which can be further analyzed and processed to generate deeper, meaningful information.

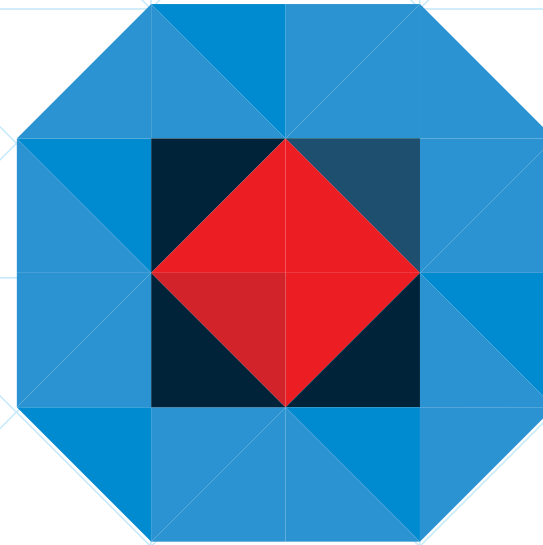
The supply chain which is closely integrated with the manufacturing is another area of focus. Different pharmaceutical organizations have different levels of integration between the factory and warehouse. There is typically a gap in data from the commercial entities that own the product after it leaves the manufacturing unit. To add to the complexity, big logistics players have their own inventory systems which may or may not be integrated with the parent organization. Many pharmaceutical organizations are now restricting their logistics partners to control parallel trade. This can also be an opportunity to simplify data environments and data integration with third parties. Most importantly it has the potential to deliver an understanding of inventory levels at different stages for different products. This insight can deliver the big savings that will accompany the more efficient usage of inventory, including reduction of expired goods.

The areas highlighted in this article demonstrate some opportunities for pharmaceutical companies but there are many more. One size does not fit all. There is no dearth of data in the system and outside it. The need is to transform this data into meaningful insights to be consumed appropriately. A true rate of return on technological investments requires a careful evaluation of individual needs.

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# CASE STUDY



HELPING DELIVER  
**FASTER**  
MEDICAID SERVICES

Wipro enabled comprehensive transformation for a Medicaid claims process, helping to achieve 99.5% of paperless claims submission.



## INDUSTRY LANDSCAPE

The healthcare industry in the US is in the midst of seismic changes. Healthcare reforms have spurred public health agencies to use technology innovation to address Medicaid expansion. The prime focus is to support proactive outreach, facilitate Medicaid enrollments through community initiatives, and modernize business processes to support growth in membership.

## THE OPPORTUNITY

The client wanted to upgrade their Medicaid Management Information System (MMIS) that processed Medicaid claims. The objective was to achieve a paperless and automated environment for improved services.

The existing complex IT architecture was unable to scale to business demands and lacked operational flexibility. Some key challenges for the client included:

- ▶ High claims processing time (2 days)
- ▶ Ineffective self-service channels, leading to lower electronic submission of claims and higher call center volumes
- ▶ Addressing the strategic priority of moving towards a digital environment by laying the groundwork for a universal system for electronic patient records.

## CLIENT BACKGROUND

The client is responsible for the Medicaid program in a state that has 890,000 Medicaid participants and 38,000 Medicaid providers covering hospitals, physicians, pharmacies, clinics and nursing homes.

## THE SOLUTION

Wipro upgraded the client's entire application landscape with Service-Oriented-Architecture ensuring regulatory compliance. This spanned enrollment, verification, point of sale and claims payment. The team automated processing by mapping the entire business logic into a Commercially-Available Off-The-Shelf (COTS) system's rules engine. This led to reduction in time for claims processing from 2 days to 0.69 days and enabled 421,000+ member enrollments.

The new architecture now manages the 95 million claims paid annually by client. The team overhauled the client network capabilities to handle 775,000+ customer service calls, along with HIPAA privacy and security provisions.

The project also enabled the processing of 27 million claims annually, with the development and maintenance of a pharmacy point-of-sale system.

The client's MIS and Medicaid Internet site, eMomed was upgraded along with related online applications to address paper-filing gaps and provide a full set of e-submission services. This has enabled self-servicing for over 41000 registered users.

## BUSINESS IMPACT

- ▶ The auto adjudication rate (a measure of claim process efficiency), improved from 60% to 82.35%
- ▶ 99.5% of paperless claims submission achieved, covering 95+ million claims annually
- ▶ The average time for claims processing decreased from 2 days to 0.69 days
- ▶ Annual savings of \$2.9 million achieved by automating provider claims submission
- ▶ Process performance and reliability improved
- ▶ Transaction management made more secure



# COLLABORATION

In the long history of humankind,  
those who learned to collaborate  
and improvise most effectively  
have prevailed.

– Charles Darwin

# Remote Healthcare Device Monitoring and Analytics Boost Manufacturers' Bottom Line

Jyotirmay Datta  
Vice President & Head,  
Medical Devices, Wipro Technologies

Jyotirmay has more than 20 years of experience in the IT industry that includes business management and sales. In his current role, he is responsible for Wipro's offerings across service lines including R&D, Infrastructure, BPO and IT services for medical devices customers.

This article has been written in collaboration with Outsourcing Centre, an Alsbridge company.

The recent U.S. Supreme Court decision on Obamacare is just one business change buffeting the manufacturers of healthcare devices (which includes everything from MRI machines to cardiac pacemakers). Like most manufacturers, their markets are flattening and so are their profits – developments that are squeezing their bottom lines.

Manufacturers typically have to devote a significant portion of their resources to post-market services to insure that devices perform as intended and with maximum uptime. A large segment of the post-market service cash outlay goes to deploying field service engineers to provide services on-site. This is how manufacturers have serviced their devices for years. Many manufacturers also believe that on-site service actually enhances customer satisfaction.

However, that is no longer true in today's wired world. Now the most efficient way to stay profitable is to turn to the Internet to achieve better outcomes at a lower cost. This means that manufacturer must:

- ▶ Maximize the device's up time
- ▶ Reduce the cost of servicing the instrument either in the hospital or on the patient. This is key to solving this business challenge because sending repair crews to fix devices on site is expensive.
- ▶ Make services a reliable revenue stream
- ▶ Use the data the devices that are already collecting to maximize performance and reduce service costs

Manufacturers of healthcare devices find that their markets are flattening and so are their profits – developments that are squeezing their bottom lines.

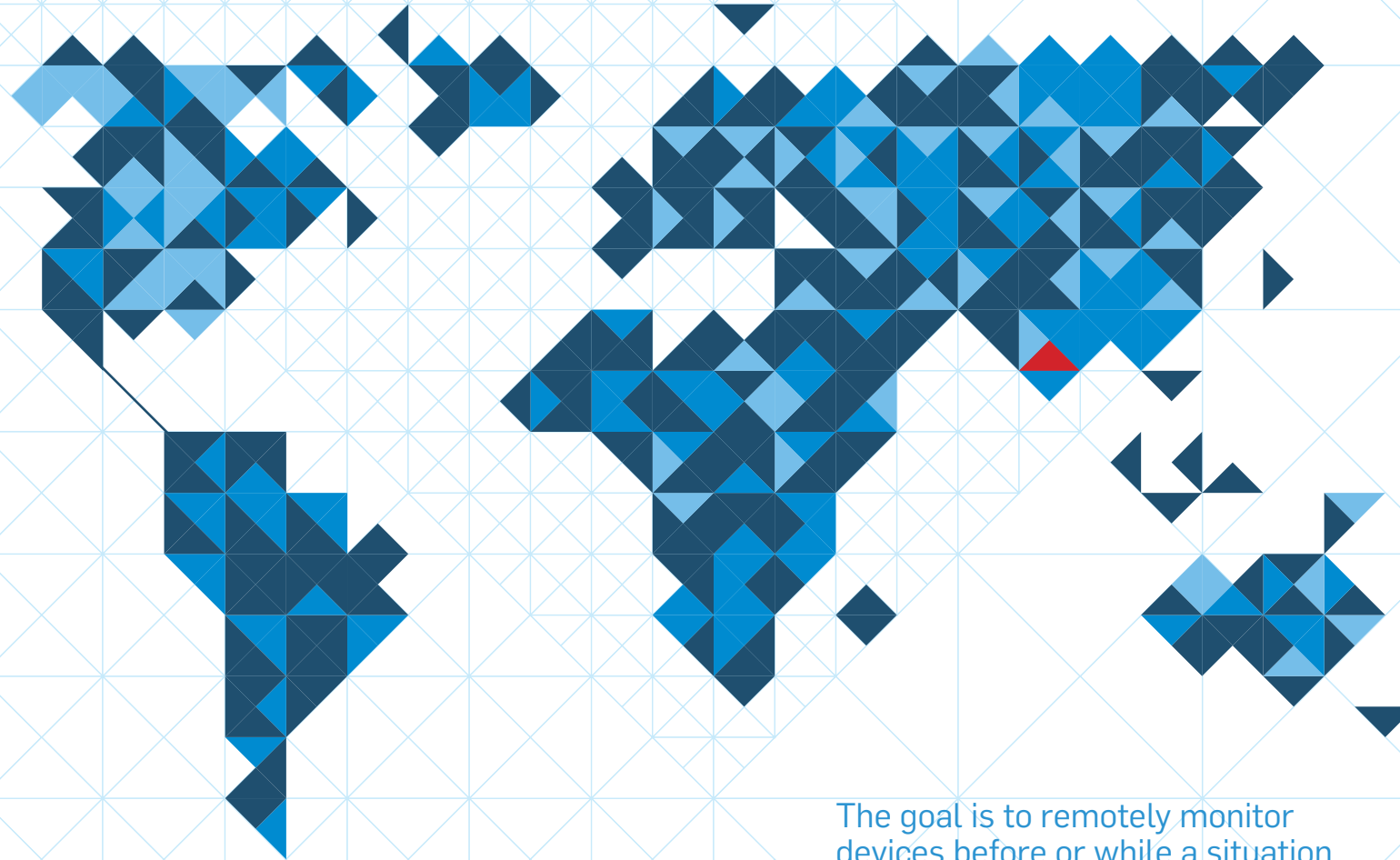


## MANAGING DEVICES REMOTELY

Companies have been managing their IT infrastructure remotely for many years. Today, it is possible – indeed beneficial – to monitor healthcare devices from remote global command centers. The goal is to remotely monitor devices before or while a situation is developing that could lead to device problems or failure and then immediately fix it. This ability takes field service effectiveness to the next level.

Remote device management (RDM) includes the following remote services:

- ▶ Monitoring devices
- ▶ Diagnostics for devices
- ▶ Resolution of problems or failures
- ▶ Preventative maintenance
- ▶ Product upgrades



The goal is to remotely monitor devices before or while a situation is developing that could lead to device problems or failure and then immediately fix it. This ability takes field service effectiveness to the next level.

Remote device management can:

- ▶ Reduce on-site field visits by up to 30%
- ▶ Achieve a first time fix rate of up to 20% (a plus for customer satisfaction)
- ▶ Improve field service engineer productivity by up to 25%

Machine to Machine (M2M) communication plays a key role in RDM enabling the device to communicate with a central server in real time. For example, software can monitor battery, parts and performance and analyze real time data to predict possible device malfunction. A surveillance tool can fix problems proactively or send a technician, if the job needs to be done on site. RDM also helps with service scheduling based on parts availability. All of the above reduce field service visits.

The resulting analytics can also improve productivity of engineers. Since the data details the failure, the company knows which expert to send to fix it. They know who is best suited to handle the repairs. This optimizes their logistics.

## THE IMPORTANCE OF ANALYTICS

Analytics has become a big piece in healthcare device monitoring, given that data collection has happened over a decade. For example, predictive analytics identify patterns that lead to device failure. The service provider then monitors the familiar failure patterns. If they occur, the software immediately alerts the remote service command center. There, experts initiate actions to prevent the device's failure before it happens. The outcome is increased availability and reliability.

Analyzing data from devices accomplishes the following:

- ▶ Helps the manufacturer understand the user's experience better
- ▶ Improves product reliability through engineering changes
- ▶ Boosts customer satisfaction

By looking at data proactively, manufacturers can leverage a strategic asset in their quest for profitability. Insights driven out of analytics will help manufactures accelerate product turnaround time and drive bottom line improvements.

## HOW TO INCREASE REVENUE

Difficult economic times have caused many healthcare providers to defer new purchases or replacements. One way manufacturers can make up some of this lost sales revenue is to increase their service revenue.

First, they can deploy variable cost structures for service based on the device's age. In addition, they can use RDM to cut costs. RDM allows manufacturers to migrate from an SLA-based approach to performance-based contracts. Service providers today can manage service fulfilment, supply chain needs and revenue-cycle management to deliver business-linked KPIs instead of traditional SLAs.

This change typically increases sales of these services in addition to enhancing customer satisfaction and delivering cost savings.

## SELECTING THE RIGHT PARTNER

Service providers today can manage service fulfilment, supply chain needs and revenue-cycle management to deliver business-linked KPIs instead of traditional SLAs.

There are a few essentials that medical devices manufacturers should consider while partnering with an organization for RDM solutions.

### PREDICTIVE DEVICE ANALYTICS

RDM solution providers must possess the ability and experience to decode multi-year longitudinal data to identify causes of device failure or define scope for product improvement. They must be able to improve the reliability of the device and either add features that improve ROI, or remove ones that do not contribute. The goal of these additions or subtractions is to provide inputs for the R&D department that help improve product reliability.

### ENGINEERING SUPPORT

Details of provisioning, monitoring, administering and troubleshooting should be articulated clearly. These help drive operational excellence in the long run. The maturity of details is in fact, a reflection of the capabilities of the delivery model used by the solution provider

### SERVICE LIFECYCLE MANAGEMENT

Apart from regular warranty and post warranty support, manufacturers should discuss service fulfilment, supply chain and revenue cycle management with their solution provider. These are important value-adds to the engagement.

Wipro has partnered with Axeda, which pioneered Internet-based remote monitoring systems in 2000, to deliver RDM solutions. The partnership has successfully implemented M2M communications and management of connected products over cloud.

Using the Axeda platform, Wipro has set up remote device command centers that mirror its IT infrastructure monitoring units across multiple geographies.

Concepts like RDM have short turnaround time from being best practices to becoming necessity. Medical devices manufacturers have started to realize that RDM is helping in driving cost out of the healthcare ecosystem in more ways than one.

Rapid adoptions of RDM, bundled with proven analytics will boost bottom lines sooner than anticipated and play a significant part in making the world a healthier place.

**Rapid adoptions of RDM, bundled with proven analytics will boost bottom lines sooner than anticipated and play a significant part in making the world a healthier place.**



# Consumerization and Collaboration

Dr. Sujith Kumar Krishnan  
Senior Manager, Pre-Sales and Domain,  
Healthcare Business Unit, Wipro Technologies

Sujith has worked in the National Health Service, UK as a surgeon and neurosurgeon. He has consulted for pharmaceutical majors like Glaxo SmithKline, Pfizer and Novartis and has experience with conceptualizing end-to-end IT systems for healthcare clients in the US, UK and APAC market. Sujith is also an MBA graduate from the London Business School.

## HEALTH LET IT SLIDE TILL IT HURTS

Traditionally health is something most of us ignore till it hits us where it hurts – our wallets. To-be patients usually do everything possible to make their health worse, but leave all of the mending to doctors. Fast food consumption, long working hours, smoking, drinking and lack of exercise have all contributed to the epidemic proportions of chronic diseases today. This is compounded by the fact that the majority of developed-world citizens suffer from obesity.

This has meant that healthcare costs have been rising in most countries and indeed have been a step above inflation. Medical advances, the use of cutting edge technology and new medications have all contributed to this. Nowhere is this effect as pronounced as in the United States where healthcare costs now account for almost 20% of GDP.

Healthcare is changing for the better because of collaboration between different healthcare entities and the fact that consumers are willing to take a bigger stake in their own health.

A large part of this increase in healthcare costs can be attributed to the increase in the incidence of lifestyle diseases like diabetes and hypertension, which now have an urban prevalence of almost 15% in the new growth centres of the world. In addition to diagnosed cases, a large number stay undiagnosed and present to hospitals only after complications of the disease have set in. These facts tell their own story:

- ▶ By 2020, chronic diseases will account for almost three-fourths of all deaths in most big countries in the world.
- ▶ One in four (25%) individuals will suffer from at least one chronic disease in their lifetime.
- ▶ The prevalence of hypertension in the over 50 population is projected to reach 90% by the end of the decade in big population countries like India.
- ▶ Tobacco-related mortality will grow to 13% of all deaths in 2020, as more people in developing countries fall prey to smoking-related cancer.
- ▶ Obesity is now the single biggest factor behind the increasing incidence of diabetes and hypertension. By 2025, the proportion of overweight people in the world will reach 24% of the population.

## CONSUMERIZATION THE CONSUMER STARTS TO TAKE CHARGE

In the past, the health knowledge pyramid was firmly in favor of the clinician. The doctor told you what was wrong with you, what the diagnosis was, what your treatment options were and what was best for you and your condition. The consumer allowed the doctor to take all treatment decisions. After being an uninterested bystander for so long, consumers are now starting to take charge. The healthcare knowledge pyramid is tilting. The consumer is becoming more knowledgeable and starting to become an active stakeholder in this process.

A large part of this is due to the availability of information and knowledge. The near ubiquitous availability of the Internet in many countries including social media sites and mobile health portals, have all contributed to make the consumer more knowledgeable about their health. Healthcare is becoming more interactive and the consumer is becoming an active collaborator in all decisions concerning their health.

## MOBILE, SOCIAL AND PERSONALIZED HEALTHCARE THE EFFECT OF CONSUMERIZATION

The intersection of the Internet, social media, and mobile has created a new dynamic in healthcare. More and more information is being made available online, even on clinical treatments. Now most people know enough to make some basic diagnoses themselves, and understand what their options are before they even visit a doctor. There are any number of health portals that offer symptom checkers that help them make a diagnosis sitting at home. There are online health profile assessments that provide health scores and risk profile calculations based on questionnaires. Social media is fast becoming a favored channel for accessing health information. Some studies show that as many as 50% of social media users turn to their favourite online hangout to search for details on health and diseases.

An increasing number of healthcare providers now offer Personal Health Records (PHR) to their customers. Hospitals are now making available to their consumers all clinical information that was traditionally in the hands of doctors. This brings personalized healthcare to the forefront and delivers better patient

care and enhanced experiences during a visit. Healthcare technologies that seek to know each patient, remember preferences and engage with them effectively to identify the right treatment option for each individual.

Mobile as a channel has also become increasingly important. Most mobile users in developed countries use smartphones that offer the same health information that was earlier available on a computer. Start-ups that promise to bring your clinician to your mobile have proliferated and they have found takers. The number of healthcare apps available on the iStore and the Android market place increases by the day. In 2011, the area of mobile health applications was worth \$718 M – an indication of their zooming popularity. It is not inconceivable that soon smart phone users will carry their basic health records and their test results on apps on their phones. When they visit their doctor next, they can themselves present him/her with all the information needed to inform a treatment decision.

## THE FLIP SIDE OF CONSUMERIZATION

The downside of consumerization is the danger that the consumer, with incomplete information, and no training, starts taking potentially harmful decisions. The rise of antibiotic-resistant strains of infections and bacteria is evidence of this trend that can be attributed to self-prescription of strong antibiotics. Consumers may also ignore serious conditions that need the attention of a medical practitioner.

## CONSUMERIZATION MARCHES ON THERE LIES THE OPPORTUNITY

These dangers will not really have significant impact on the spread of consumerization. Consumers will continue to demand greater say in decisions that affect their health. A large proportion of medical technology advances in the past few years have been in the area of personal health. Companies have taken note of rising consumerism and have started targeting patients directly, allowing them access to information, providing them with the right devices and helping them take charge of their own health.

New healthcare companies are taking health directly to the consumer. The rise of preventive health management programs and personalized disease management plans are all steps in this direction. Healthcare communication and interactions rely on patient data to target the relevant group with customized messaging. The opportunity in this area is becoming bigger by the day.

## COLLABORATION

Consumerism has led to the other big trend in the healthcare industry – collaboration. Collaboration is a theme that doctors are familiar with. The basic physician referral is a typical example of collaboration. Inter-speciality collaboration has always been a feature of big hospitals. Similarly informal collaboration between primary, secondary and tertiary care is the way that healthcare is delivered in most parts of the world.

Gone are the days when one family doctor provided medical care from cradle to grave. Today, a cataract surgeon may need pre-operative information from a refractive surgeon. A retina specialist may need to exchange information with a patient's internist or nephrologist. Neuro-ophthalmologists work closely with neurologists, and they may collaborate with endocrinologists for patients with thyroid and pituitary disease.

There is now a move from the informal way collaboration happened to a more structured framework of collaboration.

There is now a move from the informal way collaboration happened to a more structured framework of collaboration.

Collaboration between dissimilar institutions is changing the way healthcare is delivered. Technology has played the biggest role in this. Medical devices and sensors can gather patient vitals from his/ her home and transfer them over the Internet to the physician location. Tele-radiology allows radiological patient images, such as x-rays, CTs and MRIs to be transmitted. The physician is now able to consult remotely through audio-video/mobile devices. Telemedicine has changed the face of healthcare for remote locations and has helped rural doctors collaborate with the specialist sitting in a tertiary facility.

## LEAPFROG CONSORTIUM AND THE SEEDS OF COLLABORATION

One of the earliest examples of collaboration between different institutions in the healthcare arena was the setting up of the 'Leapfrog Consortium'. This group was set up by Fortune 500 companies spurred by increasing health insurance costs. They formed what was essentially a lobbying group to pressure health maintenance organizations and other providers to institute disease management programs for their covered populations.

These measures kick-started collaboration between insurance companies and providers and laid the foundation for a move towards better patient care.

## ACCOUNTABLE CARE ORGANIZATIONS THE ESSENCE OF MULTI-INSTITUTION COLLABORATION

The next step in the continuum is the move towards making organizations accountable for the care they provide. Accountable Care Organizations (ACOs) bring together providers and reward them for controlling costs and improving quality. This critical platform for delivery system reform is enshrined in the Patient Protection and Affordable Care Act. It necessarily involves a great degree of collaboration and cooperation between different care groups and provider organizations as well as insurance companies, since they must all agree on outcome-based payments.

Many countries are investing in developing National Electronic Healthcare Records (NEHR) to maintain a single patient record for each patient. Encompassing all levels of detail of care, including health issues, diagnoses, medications and allergies, these records will be made available to all providers across the country. The United Kingdom has created a national spine which is a 'cradle to grave' record for each individual in the country. Singapore has implemented the first step of the NEHR by providing access to relevant medical records of to concerned clinicians anywhere in the city state.

## OPTIMIZING THE USE OF AVAILABLE RESOURCES

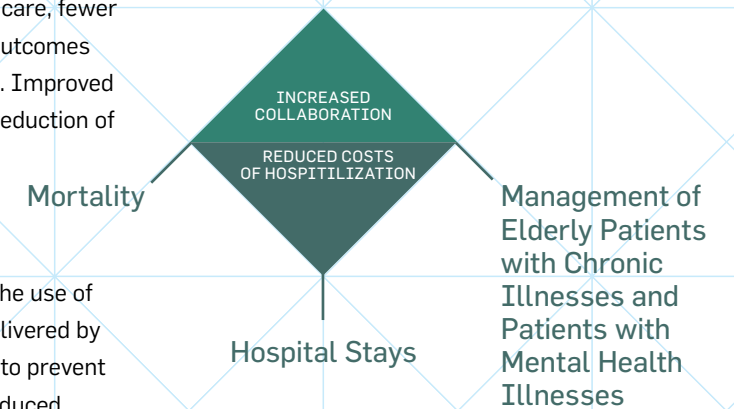
While collaborative practices do not address the current and forecast shortage of physicians, nurses and other health professionals, they do lead to the best use of the human resources available.

By optimizing the use of existing resources, collaborative care can, therefore, be an important element of a more comprehensive solution to improving patient access to care. Patients have reported higher levels of satisfaction, better acceptance of care, fewer clinic visits and improved health outcomes from the use of collaborative care. Improved communication has also led to a reduction of medical errors.

In addition, studies indicate that the use of evidence-based care pathways delivered by inter-professional hospital teams to prevent complications, have resulted in reduced mortality, hospital stays and ultimately lower costs.

Studies with primary health care teams have also suggested that they can reduce the frequency and costs of hospitalization for elderly patients with chronic illnesses and mentally ill patients.

The relentless march of consumerization along and the collaborative model of delivery health are two of the biggest trends in healthcare delivery in the last few years. In spite of some obvious downsides, the rise of consumerism is definitely good news for consumers as also for providers. The collaborative model of working ensures the right information is available at the right time and greatly increases the chance of the right diagnosis and treatment.



These measures will in the longer term, eliminate inefficiencies, ensure optimization of resources and ultimately lead to more affordable and better health for all.



Partnering  
for Patient  
Centricity,  
Compliance  
and Innovation  
for a Global  
Pharmaceutical  
Major

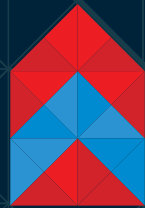


**A WIPRO  
PARTNERSHIP  
FOOTPRINT**

**2005**

**The start of  
an enduring  
relationship**

Formation of the first  
off-shore development  
centre



**2007**

**Foray into  
commercialization**

eMarketing Development  
factory established

Support and testing  
engagements initiated  
for sales and marketing  
platforms



**2006**

**Partnering  
for web and  
infrastructure**

Establishment of Web  
factory for Web Services

Packaging factory for  
Global Infrastructure  
Services started

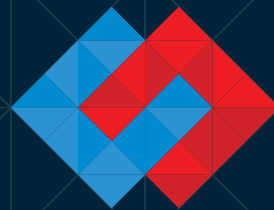
Application Hosting  
Support initiated



**2008**

**Strengthening  
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Formation of the second  
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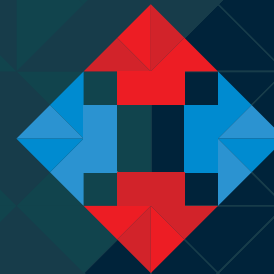
**2009**

**Expanding  
horizons**

Support services  
undertaken for lab  
automation applications  
in R&D

Cross-divisional  
document management  
and regulatory  
submissions support

Europe chapter of web  
factory inaugurated  
— rechristened Web  
Services



**2010**

**Web Services go  
global**

Engaged in a large legacy  
modernization program

Web Services portfolio goes global

Engaged in core domain  
applications in Research IT



**2011**

**Ready to take  
a giant leap –  
Transformation  
initiatives**

Engaged in Procurement  
Transformation Program

Partnered for pioneering  
eHealth Platform  
Development

Program Management  
of Global Infrastructure  
Services

Engaged in  
implementation of  
eLabNotebook as part  
of Paperless Lab initiative



**2012**

**Enabling  
business through  
emerging  
technologies**

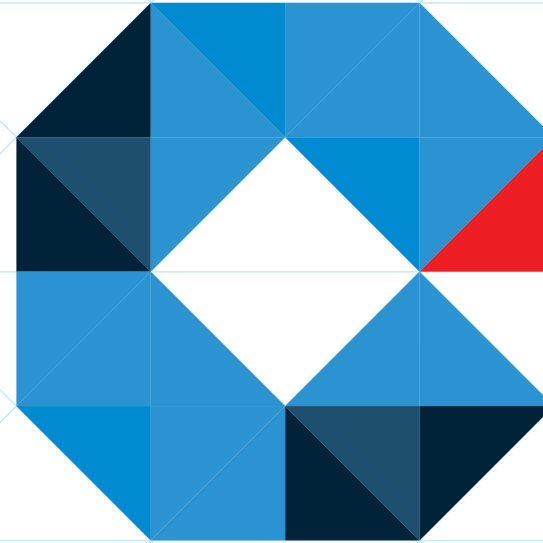
Partnered in Large  
Transformational  
Migration Programs

Cloud, Mobility and  
Analytics Initiatives in  
Sales and Marketing

Engaged in Global  
implementation of a  
Product Lifecycle  
Management solution



CASE STUDY



SUCCESS  
THE  
**360 WAY**



## INDUSTRY LANDSCAPE

The current Medicare Advantage environment demands dynamic adjustments and changes. Under the Centers for Medicare and Medicaid Services (CMS) Star Rating System, health plans are under pressure to attain high customer satisfaction to remain competitive in the market.

Success can be attained by having an exceptional system, expert staff, standardized processes and advanced policies and procedures. By developing and maintaining a relationship with vendors, health plans have the ability to create an alliance that promotes superior services, knowledge, planning and results.

## THE OPPORTUNITY

Enrolment of new members is a key focus for insurance providers. When this large US health plan provider needed to overhaul their member enrolment system, they turned to Wipro – their trusted technology partner of over 10 years.

A critical challenge was to enable the system to handle the ever-growing number of letters to be sent to members, as required by CMS, the healthcare regulatory body. The rapid pace of reforms had also expanded the membership base and there was the need for a more user-friendly interface and a future-proofed system that could scale with increased computing demand.

**Wipro helped us to automate 60% of our processes, and reduce our staff by 50%. Overall, it has been a huge success for us.**

**Director for Medicare Enrolment, Billing and Reconciliation, large US Healthcare Payer**

## CLIENT BACKGROUND

The client is a large, health insurance products and services provider for employer groups and members in Central Pennsylvania and the Lehigh Valley, USA. It offers medical insurance, Medicare and dental insurance products as well as health coverage; health maintenance organization products and accidental death and dismemberment coverage.

## SOLUTION

Wipro teams streamlined the entire enrolment process, including verification and member management, by automating validation and documentation at all input and processing points. This was achieved by implementing Member360 – Wipro's comprehensive membership management solution for healthcare payers.

Member 360 is a web-based solution delivered over a SaaS platform with subscription-based costing. This is in complete alignment with the client's IT road map for scalable applications and infrastructure with reduced total cost of ownership. Member360's in-built record keeping module allows client teams to easily access all letters generated for members, solving a long-standing challenge. The user-friendly interface has been received well by the client workforce dealing with enrolment.

## BUSINESS IMPACT

Key features of the solution included improving CMS Star rating, enrolment reconciliation, billing, verification using the CMS Medicare database and a regulation-compliant appeals and grievances module.

Wipro's deep involvement through the design and implementation process reduced the turnaround time for the client and contributed to the overall success of the engagement.

The Wipro and client teams worked together to quantify business impact with a time study. Previously it took 15 to 17 minutes to process an enrolment. It now takes 1.5 to 3 minutes to accomplish the same task.

Staff satisfaction with the enhanced system has increased noticeably, including a drastically improved training process. In sum, the implementation of Member 360 has delivered multiple success levers, including:

- ▶ Significantly decreased time to process enrollment requests
- ▶ Increased automation
- ▶ Higher staff satisfaction
- ▶ Improvements in staff training
- ▶ Decreased costs due to staff reduction
- ▶ Decreased costs due to paperless transactions

# COMPLIANCE

Compliance in today's complex world is  
an ever-moving goal, not an end-state



# Enterprise Governance, Risk and Compliance

## The Niche to be Explored

Vineet Chaudhary

Head – Risk, Safety & Compliance Practice  
for Pharmaceutical & Life Sciences, Wipro Technologies

He has 17+ years of experience in strategic and business transformation across global health care value chain. As a Registered Pharmacist, over the last decade, he has focused on solving complex problems in Informatics, Manufacturing, Quality, Safety, and Compliance and Governance by improving collaboration and mature execution across global Pharmaceutical clients. He has a MS (Pharmacy), MBA and another Masters in Organization Change from Harvard.

The Enterprise Governance, Risk and Compliance (eGRC) market has evolved exponentially since its inception ten years ago. The key differentiator is the delivery of advanced risk management functionality by establishing a good governance and management. Today's market need is risk and regulatory compliance, combined with analytics to offer solution at an enterprise level. Every industry, due to the growing business demands in security, data privacy, external reporting obligations, stakeholder transparency stringent regulatory norms, are foreseeing unprecedented requirement for Governance, Risk and Compliance management at an enterprise level.

Enterprise GRC frameworks appraise the strategic risks and objectives throughout the business, connect objectives with enterprise risks, augment decision making process and reduce loss. GRC has moved from more than just processes and tools, that span the enterprise, to essential philosophy required to be high on transparency and integrity.

Regulatory requirements continue to grow, making enterprise GRC more and more challenging. The present trend is that the faculty of GRC is to provide enterprise-wide risk assessments and hauling evidence from organizational siloes. Legal and regulatory compliance is a key part of the effective governance of an enterprise while assessing Risks. All enterprise activities include control activities that are designed to ensure compliance not only with externally imposed legislative or regulatory requirements but also with enterprise governance resolute of principles, policies, process and procedures. Exercising governance and management effectively in practice requires using all enablers appropriately.

A GRC program can be established in an organization to focus on any individual area within the enterprise, or bring in a fully integrated mode which can help to work across all areas of the enterprise, using a single framework by linking strategic risks with other governance, risk, and compliance business processes, Enterprise Governance, Risk and Compliance (eGRC) for risk management provides structure, visibility, and transparency to your risk management program. Let us now look into some of the key interrelated components that constitute the Governance, Risk and Compliance program.

## STRATEGY, PERFORMANCE AND OBJECTIVE MANAGEMENT



## ENTERPRISE GOVERNANCE

The enterprise governance is defined as 'the set of responsibilities and practices exercised by the board and executive management with the goal of providing strategic direction, ensuring that objectives are achieved, ascertaining that risks are managed appropriately and verifying that the organization's resources are used responsibly' (Information Systems Audit and Control Foundation, 2001). An effective governance framework warrants Commitment from the senior management, Strategic alignment, Maturity assessments, Value delivery and management, Resource Management, Performance Management, Service Management. The IT capability is threaded into the long term consequences of decisions made by senior management in an organization. An enterprise consists of multiple domains, systems, resources, capabilities, each striving to meet the organization's business goals which are governed by different regulatory affairs and contractual obligations. The Governance body of an enterprise should have the ability to respond rapidly to the market needs, interoperate seamlessly, Well equipped in managing enterprise, risk management, disaster planning, scale in magnitude and be responsive to internal and external changes. The Governance

framework and structure should be defined such that there is a control in every aspect of the business in the organization, regulate performance and comply with regulatory needs. Enterprise Governance also warrants that organization's goals objectives are realized by evaluating and understanding stakeholder requirements, set direction through prioritization and decision making, continuous monitoring and improvement and align to the market needs. The framework encompassing the above said aspects will establish Systemic governance and directed management through interconnected enablers in the system.

## RISK MANAGEMENT AT ENTERPRISE LEVEL

The present outlook of Risks Management is based on the compelling business demands and ever changing market needs which gives us a different perspective that Risks are not hazards to be avoided altogether, but can also be an opportunity to be embraced to do business better. This also helps in efficient use of resources, promotes continual improvements and increased certainty in all aspects of business.

Risk management can also be performed at an enterprise level through interconnected enablers in the system. The Risk Assessment done at enterprise level will be a High Level Risk Assessment and Management (HLRA). The Enterprise Risk Management is an ongoing process and is an integral part of how an organization operates. The risk management framework needs to be a holistic, future based, process oriented approach for risk management for creating true business value. This system measures risk using a combination of qualitative and quantitative methods to set a standard method for analyzing risk across the many functions within the enterprise. Moving from traditional risk mitigation and planning towards risk tolerance to have more business value. Enterprise Risk Management also stresses the management of operational and strategic risks. Compared to the traditional risk management methods, Enterprise Risk Management facilitates

to anticipate problems before they become a threat to business. The mandatory requirements for effective risk management at an enterprise level are Senior management and stakeholder commitment, Risk management Policies, Process and procedures well established for the most prominent risks with specific objectives and parameters, distinctly defined responsibilities for managing and controlling risk, Ongoing awareness training, Tracking, Testing and monitoring of all programs, process and procedures, Reports and score cards including audits. Last but not the least, regardless of what the risk appetite may be, every risk should be assessed and kept under control.



## BUSINESS IMPACT ASSESSMENTS TO ADDRESS ENTERPRISE RISKS

A Business Impact analysis (BIA) predicts the aftereffects of disruption of a business function and process in an uneventful case of disaster. This assessment process musters information needed to develop recovery strategies in case of an occurrence of an event. The business impact assessment warrants that the potential loss scenarios be identified during a risk assessment. BIA is an essential component of an organization's business continuance plan; it includes an exploratory element to expose any vulnerability case of a disastrous event, and a planning component to develop strategies for minimizing risk and impact. The result of this analysis is a BIA report, which describes the potential risks specific to the enterprise, program or a project that is getting evaluated for. Loss of income, Regulatory fines, Contractual realities and obligations, Business SLA's are some of the business vital components which will be assessed.

The BIA process can be done at an enterprise level, project level and for services too. The BIA done at enterprise level will be a High Level BIA (HLBIA),. The Service BIA starts in the operational state of a service in service oriented architecture. Business resilience plan to safeguard critical business processes can be derived out of the business impact assessment.

## BUSINESS CONTINUITY MANAGEMENT (BCM)

A BCM programed at an enterprise level aims at providing integrated responses to multiple risks. The BCM programs typically emphasis on the continuous assessment of business needs, acceptable levels of risk and responding with a set of defined processes and exact infrastructure designed to augment operational availability. The Recovery strategies will be formulated based on the corresponding recovery objectives and the outcome of the BIA. An effective response demands meticulous planning, regular rehearsal/testing and awareness across organization.



## ENTERPRISE TRAINING

Enterprise training comprises of awareness training and training of individuals who will be a part of the Enterprise governance and risk management team. The core members of the team will have to be conversant on the design and implement of an appropriate enterprise governance and risk Management system which encompasses the policies, procedures, practices, and accountability required to establish the right levels of Risk management in compliance with current standards and other requirements for the enterprise. The training should also be focused on creating awareness – Training, Development and Education with every member of the organization on the Enterprise Risk Management Plan. Training is also mandatory on the awareness on the regulatory compliance for the enterprise.

## THE ENTERPRISE GOVERNANCE, RISK AND COMPLIANCE FRAMEWORK

The eGRC framework and solutions integrated with the core business as an enterprise will also help to bridge between audit, risk and compliance groups, increasing business value while decreasing operating costs and minimal risk loss. Enterprise modeling (EM) is a method which can be used to create a logical model or a framework for an organization. Complex organizations with well-established standards provide form and inter-operability to Enterprise Modeling practices.

A Framework that can be referenced for Governance and Risk is COBIT 5. This framework helps enterprises to create optimal value from IT by maintaining a balance between realizing benefits and optimizing risk levels and resource use. The Cobit 5 framework uses a core set of control material, charted to the primary

governance factors in the system. The set-up of governance framework and maintenance in line with the recommendations from COBIT will help to, Ensure benefits delivery, Ensure risk optimization, Warrant resource optimization and Ensure stakeholder transparency.

One other aspect to progress successfully using eGRC frameworks is the Data Integrity, Analytics and metrics. The exactness and integrity of GRC information is a mandate now and the corporates are looking for reassurances that the organization is making all-encompassing risk management rulings based on reliable, information which is more archetypical. There is an immense need for reliable analytics to assist and identify the relationship of risks from various departments of the organization to determine which risks are priorities at the enterprise level. This will help to build a consistent heat map across the entire organization. Analytics and genuine information will help to arrive on an accurate decision at organization level. This will support the businesses to cruise with the minimum loss in case of unavoidable risks that may occur. Business intelligence and data governance will factor more prominently in GRC decisions.

Organizations are now increasingly planning GRC road maps with cross-silo integration between departments. IT GRC is a better choice to start

as a quick win in most of these implementations. It is definite, and it can be used to construct an extensible framework for all other GRC programs in future for other departments in an enterprise. Also, the GRC market today is more akin to the breadth of the IT security market. Another interesting finding is that the Mobile, social, and cloud technologies will begin showing practical value for GRC. The access to huge data will help the businesses to draw in the required information and judgments to run business smoothly.

To conclude, Enterprise GRC frameworks will enable standardization, automation and help manage key aspects of every process at organization level. Risk and Compliance integrated with information and analytics will offer more precise judgments which will help businesses to surge more successfully in the scenario of ever changing Regulatory and Compliance needs. The Governance, Risk and Compliance metrics will be perceived as key indicators of business performance. The Vendors who will address the vast and diverse GRC Needs with capabilities such as workflow flexibility, user interface flexibility, data model, extensibility, and ability to support new and changing market requirements (Ref: Forrester wave) have a Substantial market landscape to source on.

## ACRONYMS

BCM – Business continuity Management

BCP – Business Continuity Planning

BIA – Business Impact Assessments

COBIT – Control Objectives for Information and Related Technology

eGRC – Enterprise Governance, Risk and Compliance

GRC – Governance, Risk and Compliance

HLBIA – High Level Business Impact Assessments

HLRA – High Level Risk Assessment and Management

IT – Information Technology

# Regulatory Compliance and Administrative Simplification

Mohd Ehteshamul Haque  
Vice President & Global Head,  
Healthcare (Payors & Providers), Wipro Technologies

Regulatory and compliance trends in the healthcare market aim to increase quality while lowering costs. Patients and providers are encouraged to enter a collaborative model of care, where decisions are shared and information is widely available. The robust use of interoperable data to improve care at a population level, coupled with administrative and process standardization is necessary to achieve these goals.

## KEY HEALTHCARE TRENDS

### STANDARDIZATION OF DATA COLLECTION AND USAGE OF IT FOR INFORMED DECISION MAKING

Over the last few decades, the US has amassed over 100 billion terabytes of medical data. Pharmacy, laboratory, imaging, physician orders and other clinical documentation have collected data for years, although these systems are not always interoperable and lack the ability to easily exchange information. Current regulatory changes promote the increased collection, standardization and use of data for improved health outcomes and efficiencies.

#### ICD-10 Adoption

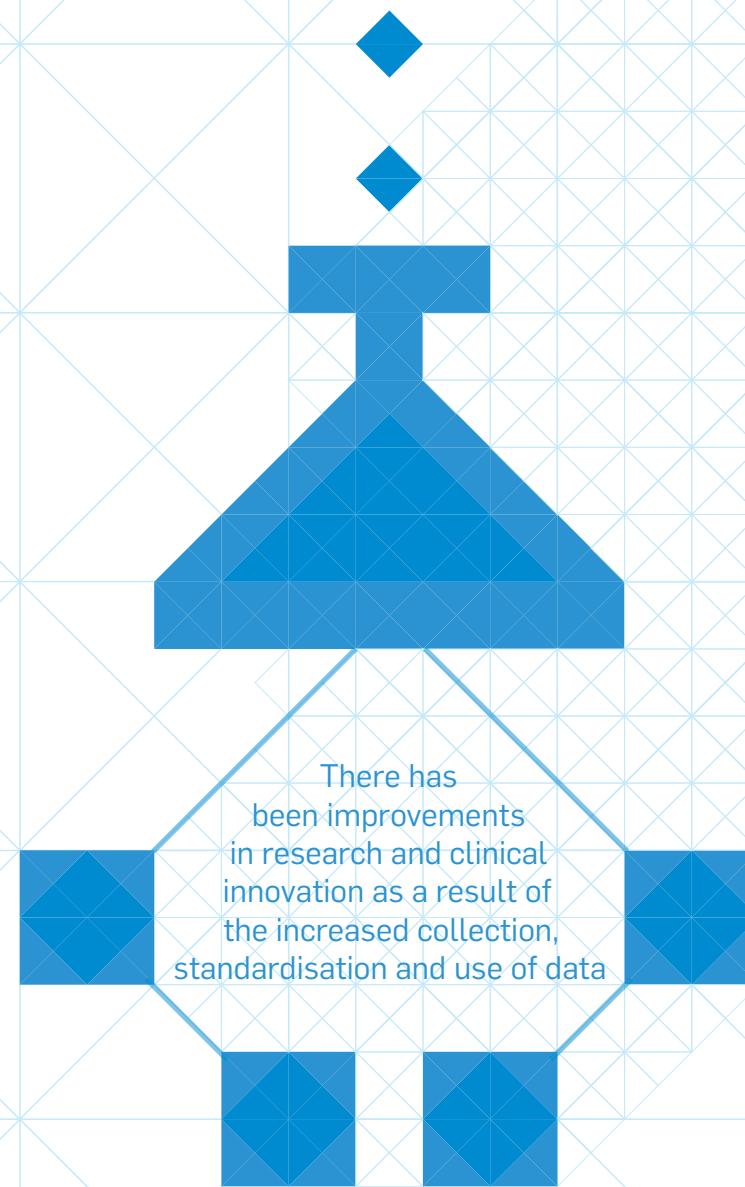
CMS has mandated that the ICD-10 standard is used for the billing and coding of medical procedures and diagnoses. The new standard increases the specificity of codes offering the new potential benefits including<sup>1</sup>:

- ▶ More efficient claims adjudication by requiring less additional documentation
- ▶ Improvements in research and clinical innovation because of more detailed information

#### HITECH Act of 2009

The HITECH Act of 2009 aims to incentivize the widespread adoption of health information technology (HIT) using financial incentives for hospitals and healthcare providers. The majority of the over \$20 Billion are set aside for the adoption of Electronic Health Records (EHR), with a goal of implementation by 2014. In order for healthcare institutions and providers to qualify for incentive payments, they have to implement an EHR system and demonstrate "meaningful use." Meaningful use aims to collect more accurate and complete information, improve data access and empower patients to more actively engage in their health. To maximize benefits, eligible providers must demonstrate meaningful use in three stages<sup>2</sup>:

- ▶ Data capture and sharing
- ▶ Advance clinical processes
- ▶ Improved outcomes

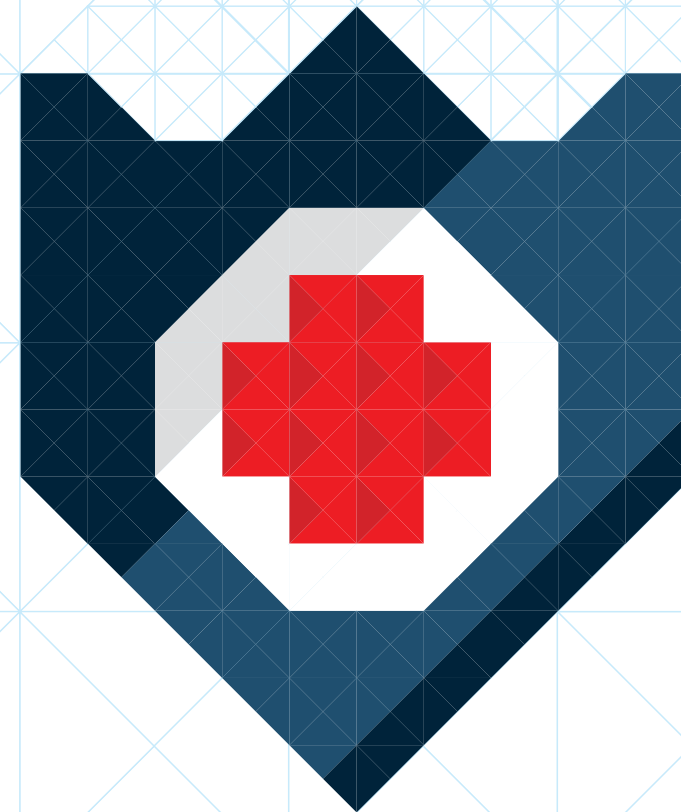


## CONSUMER PROTECTION AND PARTICIPATION

For the last half-century, direct patient/consumer engagement with the healthcare system has been minimal. The heavy involvement of employer-sponsored healthcare does not require consumers to make choices based on cost and the lack of available data makes quality of care difficult to measure. The Patient Protection and Affordable Care Act of 2010 (ACA) requires healthcare organizations to engage with consumers and attempts to bring accountability and transparency to the system.

### Making Healthcare Easy to Buy

The ACA provides funding to build statewide health insurance exchanges. Exchanges provide the ability for individuals to make informed buying decisions based on the uniform information available from health plans. They also require that health plans that participate in the exchange provide 'essential health benefits'. Additionally, exchanges must also allow eligible individuals to choose Children's Health Insurance Program (CHIP) and Medicaid from the same portal as commercial consumers.



### Expanded Access and Protection

The ACA provides expanded access and new coverage to a number of services and populations including: expanded Medicaid programs, dependent coverage to age 26 and zero-deductible preventative care services. The lifetime coverage limits and pre-existing condition clauses are removed to provide protection to citizens.

### Privacy and Security

While the HIPAA act of 1996 established baseline security and privacy rules for a patient's health information, the HITECH act of 2009 significantly expanded the scope of responsibility for healthcare organizations to protect and secure health data. Specifically, the HITECH law added a number of components:

- ▶ Required notification of all security breaches
- ▶ Additional audits
- ▶ Tougher fines and enforcement, up to \$1.5 million per violation
- ▶ Patients must be able to obtain electronic copies of their medical records
- ▶ Health information must meet 'minimum necessary' disclosure tests

## FOCUS ON VALUE IN HEALTHCARE

Healthcare costs have risen astronomically in recent years and now consume 18% of GDP in the USA<sup>3</sup>. However, there is little evidence that demonstrates a commensurate improvement in outcomes. As explained by strategy guru Michael Porter, the competing interests of different healthcare stakeholders make reductions in cost a poor measure for system improvement. Instead, healthcare systems should be measured in terms of value, which can be defined as outcomes relative to cost<sup>4</sup>. New programs and regulations aim to align the interests of various healthcare stakeholders to create a sense of shared value by improving outcomes while controlling costs.

### Accountable Care Organizations (ACO)

In the current payment model providers are reimbursed under a fee for service model (FFS), where they are paid based on the services provided. This model does not incentivize collaboration to provide valuable care and may create competing interests.

The ACOs seeks to align various healthcare stakeholders to encourage collaborative, patient-centered care with improved outcomes and lower costs. In the Pioneer ACO model, participating organizations accept a substantial amount of their reimbursements

under a population-based model. Organizations are given a fixed sum of money based on the relative actuarial risk of the population they serve. This offers the potential for increased profits if costs are lowered while improving quality at the same time. Other forms of ACOs will come in the following years, but all will have the following features and goals:

- ▶ Improved healthcare for populations
- ▶ Patient-centered, collaborative care
- ▶ Lowered costs relative to the healthcare growth rate

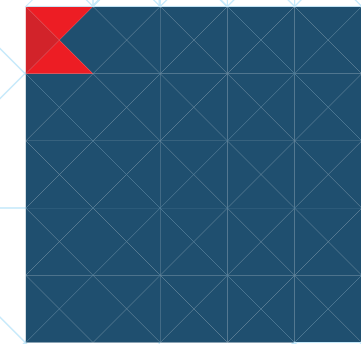
As cost pressures continue to increase, payment models similar to the ACO are likely to emerge. Hybrid payer and provider networks, such as Kaiser, are one of the earliest examples of an ACO-like model. Additional models such as Blue Cross Blue Shield of Massachusetts's Alternative Quality Contract have already been shown to ensure quality healthcare by sharing financial risk with providers.

Healthcare costs have risen astronomically in recent years and now consume **18% of GDP in the USA.**

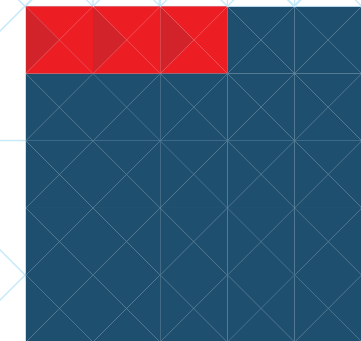
### Dual Eligibles Demonstration Project

Providing high-value healthcare for the most expensive patients presents some of the biggest challenges. Dual Eligibles, defined as individuals that qualify for both Medicare and Medicaid, account for just 3% of the population, yet represent 12% national health expenditures and 34% of public spending<sup>5</sup>.

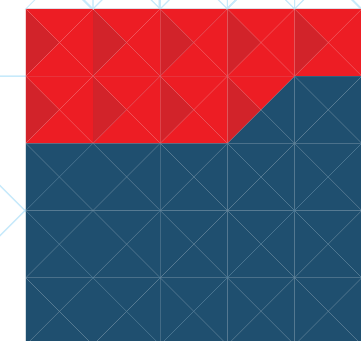
Providing services for the dual eligible is difficult. Over half of them have either cognitive or mental impairments and have three or more chronic conditions<sup>7</sup>. Since Medicare and Medicaid pay for different types of services, care coordination is stifled. At times, providers can offer competing services, resulting in duplicative or unhelpful care. New payment models, such as the Dual Eligible Special Needs Plans, fully integrate funding. This allows health payers to reimburse for services that provide high-value care, rather than just those available under their funding stream.



**3%** OF THE POPULATION QUALIFY FOR MEDICARE AND MEDICAID



THEY ACCOUNT FOR **12%** OF NATIONAL HEALTH EXPENDITURE



THIS IS ABOUT **34%** OF PUBLIC SPENDING

## IMPLICATIONS: DATA INTEGRATION AND SHARING

The rapid adoption of HIT, combined with the proprietary nature of many systems makes integration a challenge. However, to meet regulatory requirements such as the Meaningful Use, integration is necessary. Additionally, in order to support the exchange of information between healthcare providers, both inside and outside of the organizations, data must be interoperable and compliant with information-sharing standards such as HL7.

Systems will need the ability to share information with other providers outside of a hospital or provider network. Health information exchanges must be carefully planned to ensure the patient has given appropriate permissions to share information and only the minimally-necessary amount of data is shared.

For the first time, patients are poised to become consumers of health data. Patients will need to be able to view their health data in a form that they can understand and use to make decisions about their care. Additionally, they will desire two-way interaction with data, such as the ability to message a provider or schedule an appointment.

This will require healthcare organizations to have a system architecture that supports two-way, extranet communication while complying with relevant security protocols.

Next-generation clinical data systems should be patient-centric and adaptable to new technologies. Data in healthcare is now a commodity. Value is not created by summing all parts, but instead by through integration that creates a whole-person view.

## CARE MANAGEMENT

While EHR systems provide important capabilities that improve the quality of care such as decision support, e-prescribing and information sharing, they are not usually built with a patient-centered, system of care focus. For example, few EMRs integrate the numerous social factors that may be affecting a person's health. Providing patient-centered care will require the integration of the individual's unique biological, psychological and social status to create a care plan capable of producing positive, measurable results.

## ANALYTICS

Robust analytic capabilities are important for monitoring compliance and key to providing patient-centered, high value care. At the most basic level, administrators will need dashboards to monitor progress toward meeting new regulatory demands and ensuring compliance across healthcare organizations. At the next level, they must provide the insight necessary for improving population-level care.

Analytics provide a key insight that EHRs cannot: information about people that are not using the healthcare system. Engaging system users and non-users are pivotal to achieving population-level health. As ACOs and other value-based healthcare models become more pervasive, analytic capabilities will be increasingly demanded.

## REPORTING

Almost every new regulation requires a significant amount of both periodic and on-demand reporting. Meaningful Use requires demonstration of compliance with various measures at each stage of EHR adoption. Value-based programs, both regulated and driven by market demands, will require increased reporting of clinical quality targets. Security and privacy rules require a number of new reporting requirements.

Reporting engines will need to support the integration of different types of data, most likely from clinical, financial and administrative systems. Regularly changing requirements will require user-level customization for ad-hoc reports. Systems will need to meet the demands of the business users and be scalable for widespread use.

## SOLUTIONS

The healthcare regulatory and market environments of today demand that organizations leverage data to deliver high-value, accountable care. Standards for securing and collecting data have been established. Choosing a dedicated partner with domain expertise and the scale to deliver enterprise-level solutions may ensure returns on IT investments. Healthcare organizations need to invest in the infrastructure, data management, applications and analytics necessary to provide compliant, high-value care.

## INFRASTRUCTURE PLANNING AND MANAGEMENT

The velocity and volume of data flow will require thoughtful integration and implementation of scalable data management platforms.

### Infrastructure Management

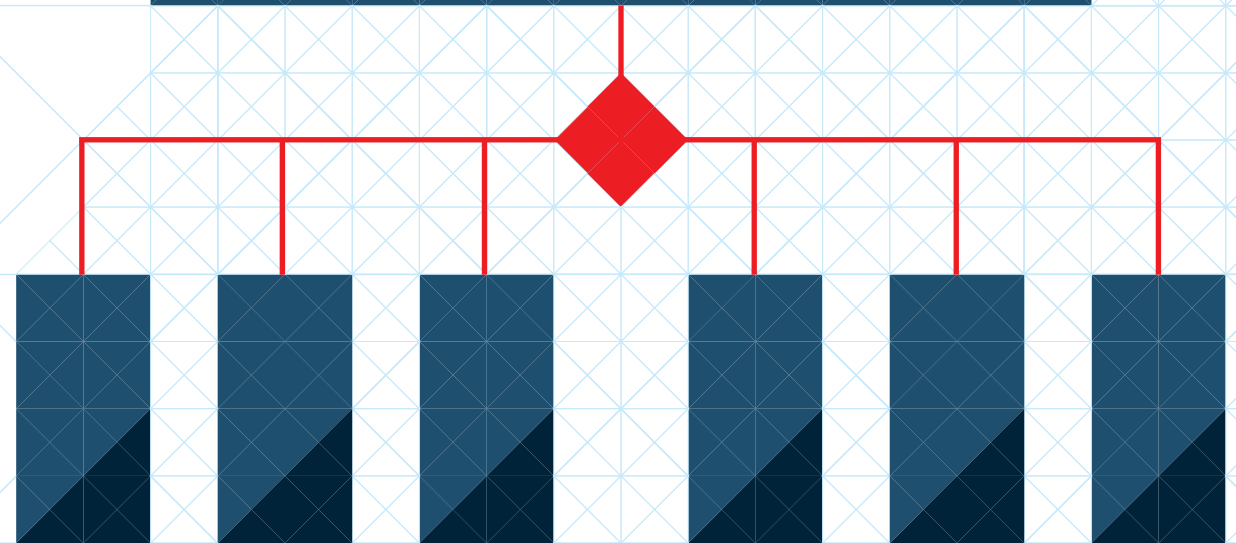
As healthcare organizations receive continued cost pressures, IT leaders will need to demonstrate the value their services provide. Infrastructure Management services reduce the burden of day to day IT needs, allowing organizations to focus on innovation. Some of these services include:

- ▶ Remote infrastructure management
- ▶ Unified communications management
- ▶ Device management
- ▶ Virtualization

### Cloud Migration

The volume and consistent growth of healthcare data makes it an ideal candidate for cloud storage. Whether internal or external, organizations can benefit from a scalable, agile storage architecture that supports secure sharing and integration with analytics platforms. As providers, payers and patients increasingly participate in collaborative care, a cloud-based architecture is often the logical choice for application hosting and management.

Both internal and external organizations can benefit from the scalable, agile architecture of Cloud Storage. It is the most logical choice for application hosting and management.



Services that provide immediate and measurable benefits include:

- ▶ Cloud infrastructure hosting
- ▶ Application migration
- ▶ Security advisory
- ▶ Virtualization

## DATA MANAGEMENT

Value-based healthcare, new regulations and the need to share information with a variety of new consumers requires that information is both standards based, platform independent and secure. While an agile core infrastructure provides the building blocks of good data management, organizations will need to build their own platforms.

Given the current emphasis on privacy, security and compliance, a good data management strategy will include the following capabilities:

- ▶ Standards compliance
  - ▶ ICD-10 Compliance
  - ▶ HL7
- ▶ Application Integration
- ▶ Health Information Exchange services
  - ▶ Management and hosting
- ▶ Data standardization

## CARE MANAGEMENT PLATFORM

Incremental improvements of healthcare outcomes are measured at the population level. To achieve these outcomes, care must be focused on the individual. This requires providers, care managers and consumers to be able to work together. Through a comprehensive care management platform, a patient-centered approach to care can be realized.





## ANALYTICS

The current regulatory environment requires robust reporting and analytics capabilities. Data scientists will continue to be a scarce commodity for the foreseeable future, but will be required to create targeted clinical programs, measure progress and demonstrate outcomes.

- ▶ Population health services
  - ▶ Patient stratification
  - ▶ Case finding
  - ▶ Trend analysis
- ▶ Meaningful use
  - ▶ Adoption monitoring
  - ▶ Demonstration of outcomes
- ▶ Program and therapy effectiveness testing
- ▶ Management dashboarding

## CUSTOM APPLICATION DEVELOPMENT

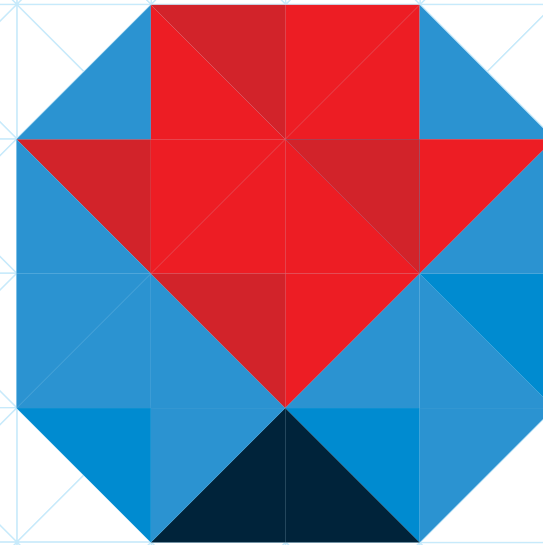
Healthcare organizations may need to both add new capabilities and enhance current offerings using information technology. Additionally, they may need to adapt their current applications to meet current regulatory and market demands by requiring:

- ▶ Systems integration
- ▶ Care management platform development
- ▶ Legacy modernization
- ▶ New application suites – Mobile Health Applications

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# CASE STUDY



## GLOBAL COMPLAINT **LOCAL SERVICE**


Wipro enabled standardization and optimization of processes in product complaint handling that resulted in costs reduction of 15%.

## INDUSTRY LANDSCAPE

Regulatory agencies governing the life sciences industry have been continually increasing monitoring of adverse events and product complaints. It has become critical for companies to efficiently handle product complaints and streamline their reporting processes to avoid costly recalls and warnings from regulatory agencies.

## THE OPPORTUNITY

In response to rapid business growth, competitive pressure and global recession, the client launched an organization-wide transformation initiative focused on driving operational excellence. The client had gaps in standard processes and unstructured complaint handling and medical information fulfillment frameworks. They partnered with Wipro to set up a workflow process that would aggressively pursue greater internal efficiencies, strengthen its financial position and establish a stronger foundation for its future as a leader.



It is truly amazing how far our team has come since beginning this journey a year ago! We would not have been as successful as we are today without Wipro's continued support. A big thank you goes out to the Wipro team for contributing to the success of our call center. I look forward to raising the bar 'even higher' in our second year of operation.

Associate Director, Global Medical Communications

## CLIENT BACKGROUND

The client is a multi-billion, global, medical device and pharmaceutical company, with broad portfolios in injectables, infusion therapy and medication management solutions.

## SOLUTION

Wipro set up an offshore delivery center for the client at Cebu city, Philippines, which has a rich pool of nurses and pharmacists required to manage the process of global product safety, complaints handling, medical information dissemination and fulfillment.

The process assessed events for potential risks and determined regulatory reporting requirements. Intake, registering, tracking and follow-up of all customer complaint reports for manufactured and/or distributed products till closure was also done. The customers included – but were not limited to – pharmacists, doctors, nurses, dentists, researchers, marketing, customer care and sales force.

Medical information fulfillment and dissemination of product-specific information through written

or verbal form for over 3,000 products is now possible. This includes generic drugs, proprietary drugs and devices. The lab set up in Cebu incorporated product models and can be used for training seamless transitions.

This model mitigated any business disruption risks and was implemented across APAC and US and soon to be implemented in EMEA. Wipro partnered with the client in facilitating Kaizen Projects (overall complaint management, devices complaint cycle time reduction, experience code standardization, drug complaint registration and closure) and also participated in the projects as a team member – a unique honor for Wipro.

## BUSINESS IMPACT

▶ Streamlined processes and systems have led to greater internal efficiencies with optimized efforts (average customer call handling time reduced by 36%) and reduction in upfront operational costs by 15%

▶ Process improvements in overall complaint management, devices complaint cycle time, drug complaint registration and closure

The client wanted to extend the scope of the complaints handling and information-disseminating site, set up by Wipro in the Philippines, to serve all its business divisions across the world.

## RESULT

15% reduction in operational costs and overall improvements in all processes





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