

# Winds of Change: Implications for the Life Sciences Sector

**Life Sciences Insights, 1st Edition - A Capgemini  
Research Report**



**People matter, results count.**

# Contents

1 Executive Summary	03
2 Survey Results	04
3 Technology Trends That Matter	09
3.1 The Network Effect Leveraged	10
3.2 Intelligence: Inside and Outside	13
3.3 Integrated Multiple Marketing Channels	17
3.4 Technologies for Better Science	20
3.5 Transparency through Technology	24
3.6 From Software to Services	30
3.7 The Journey to the Cloud - An Overview	35
4 Glossary	39
5 Team	42



# 1. Executive Summary

"Winds of Change: Implications for the Life Sciences Sector" is the first edition of Capgemini's annual report "Life Sciences Insights". The report highlights business issues and technology trends that will dominate and impact the Life Sciences industry over the next five years.

Increased competition, shorter product lifecycles, greater customer expectations, changing business models and financial constraints are creating unprecedented demands on our industry's ability to deliver value to shareholders and innovative healthcare to patients. The rapidly changing needs of compliance and regulation have put further pressure and introduced additional operating dimensions to contend with.

Information technology has long shifted from being just a service function to an asset that can drive significant industrialization and innovation in the business. Over the last few years, the intense focus on cost control and spend optimization has not only put significant pressure on business operations, but also on how budgets are allocated across technology initiatives and their adoption. Every organization is looking to shift technology spend from pure operational programs to ones that can support new business imperatives and fuel innovation. Our focus in this report is to highlight the technology trends that are being closely monitored, explored and adopted across the industry.

The findings and views expressed in this report were developed from the results of a survey conducted by Capgemini, interviews with industry

leaders and the insights of our specialists. In our online survey and one-on-one interviews, Capgemini asked senior Life Science Executives 18 questions pertaining to their strategic and operational needs and how their respective organizations are dealing with industry challenges.

Our report has identified several technology trends that are driving change and expected to impact the way technology is perceived within the industry:

**Social Media** – proliferation of social media and its potential to enhance quality of outreach to the extended social network, including regulatory implications

**Compliance & Reporting** – increasing pressure stemming from public and governmental reporting requirements and how the industry is addressing these demands

**R&D Transformation** – cost constraints, regulation and competition driving changes within R&D for reduced time-to-market and drugs that are safer and more customized to population subsets

**Business Intelligence and Data Warehouse** – extracting more leverage from existing investments in information architecture programs and data assets

**Integrated Market Channels** – adopting multi-channel programs that supplement — already shrinking — sales force through new technology solutions combined and business models

**Outsourcing Service Models** – new generation models that utilize innovation as the key driver rather than traditional cost and productivity improvement measures

**Cloud Computing** – potential of cloud computing, limitations and its application within the industry

Capgemini's Life Sciences practice has been recognized as #1 for thought leadership by IDC Research for the last two consecutive years (2009 and 2010) and is the sponsor and author of this comprehensive study.

Our sincere thanks and appreciation to all the respondents and interviewees who took time to participate in our survey. As we bring this report to you, we hope you enjoy reading it and find it useful.

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Shakthi Kumar  
North America Life Sciences Leader

# 2. Survey Results

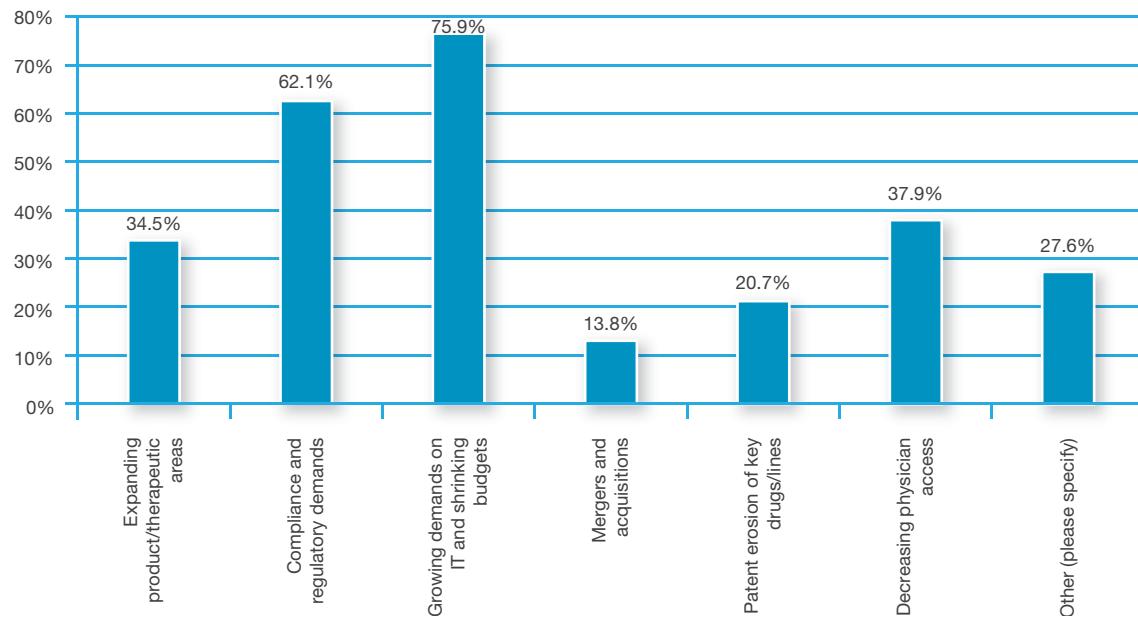
## A Survey for the Life Sciences Industry — Business Insights & Technology Trends

Our “Winds of Change” Report was driven by the input and direction of our clients and key outputs of the online survey. The following pages outline responses provided by our survey participants to questions posed by the Capgemini team in four key areas.

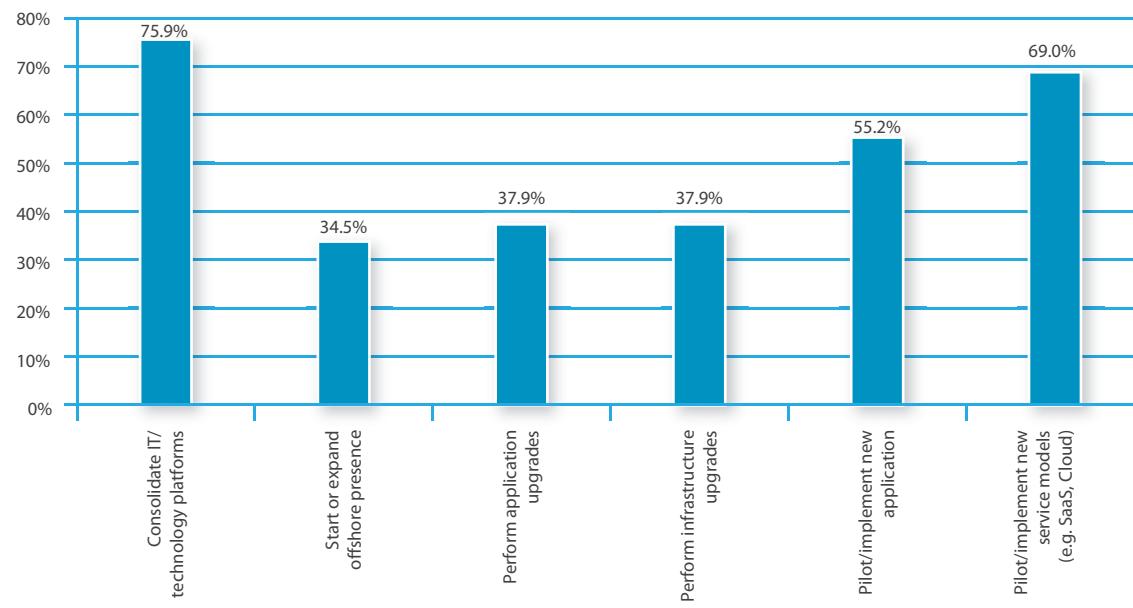
They are:

- Top Business Challenges and Future Investments
- IT Organizational Perception
- Technology Shifts & Business Critical Issues
- Ranking of Your Peer Companies in Regarding to Various Initiatives

Figure A: What are the top business challenges that are forcing you to rethink your organization's IT portfolio?



**Figure B: What are the key areas you plan to invest in over the next 1-3 years to support the business and to improve efficiencies within IT?**



**Figure C: How does your organization perceive the benefits provided by technology?**

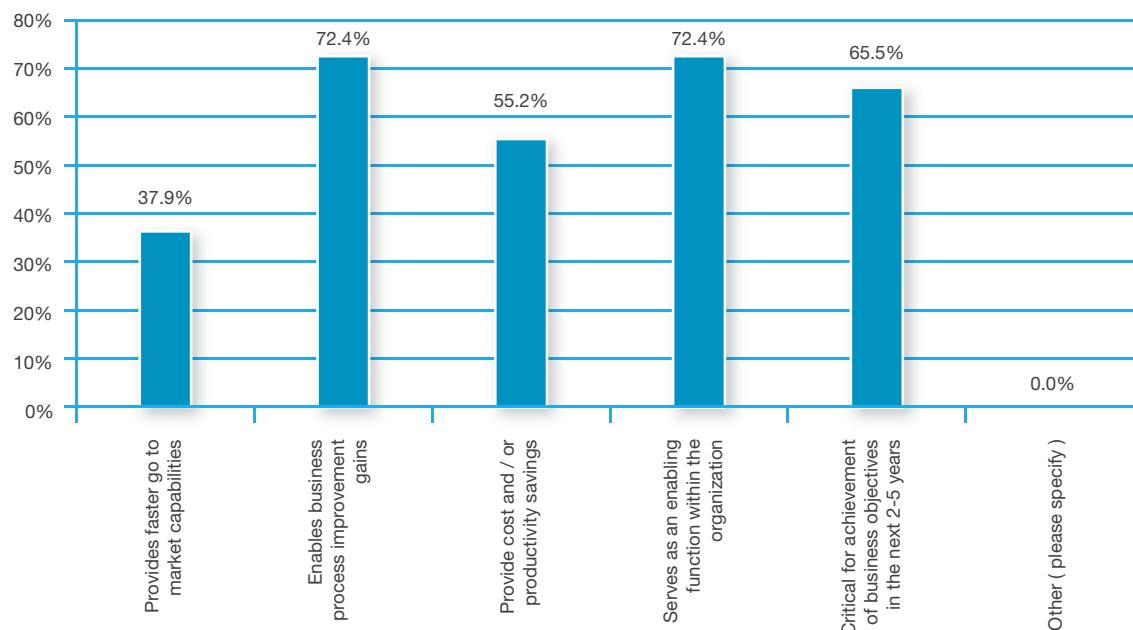


Figure D: Where do you see the technology shifts occurring within the Life Sciences industry?

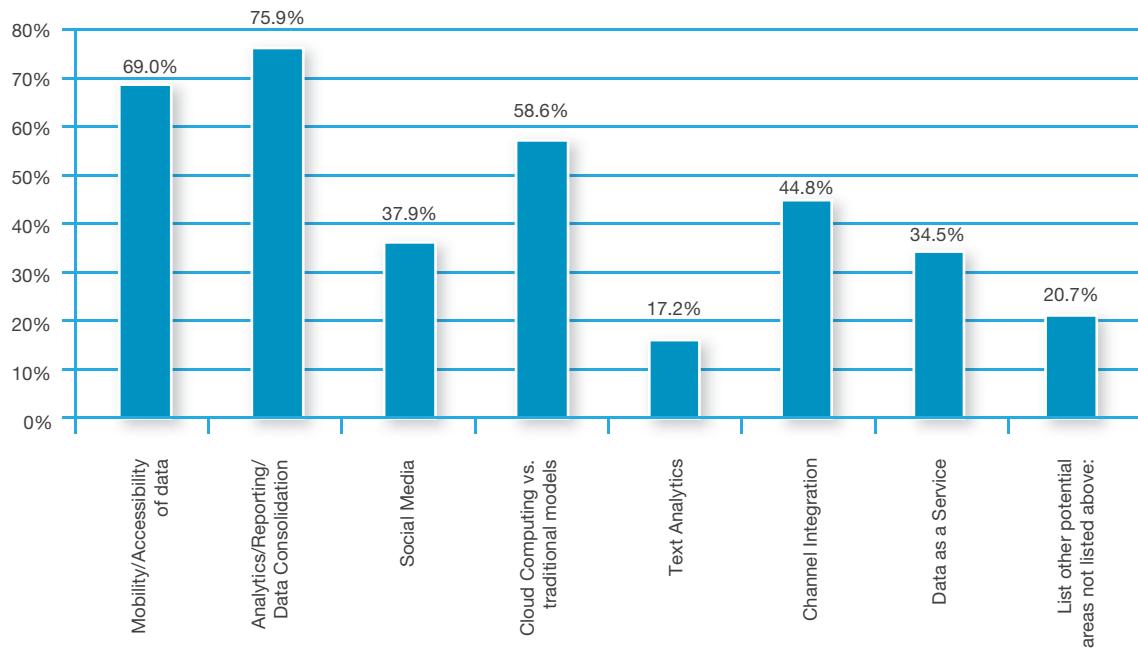
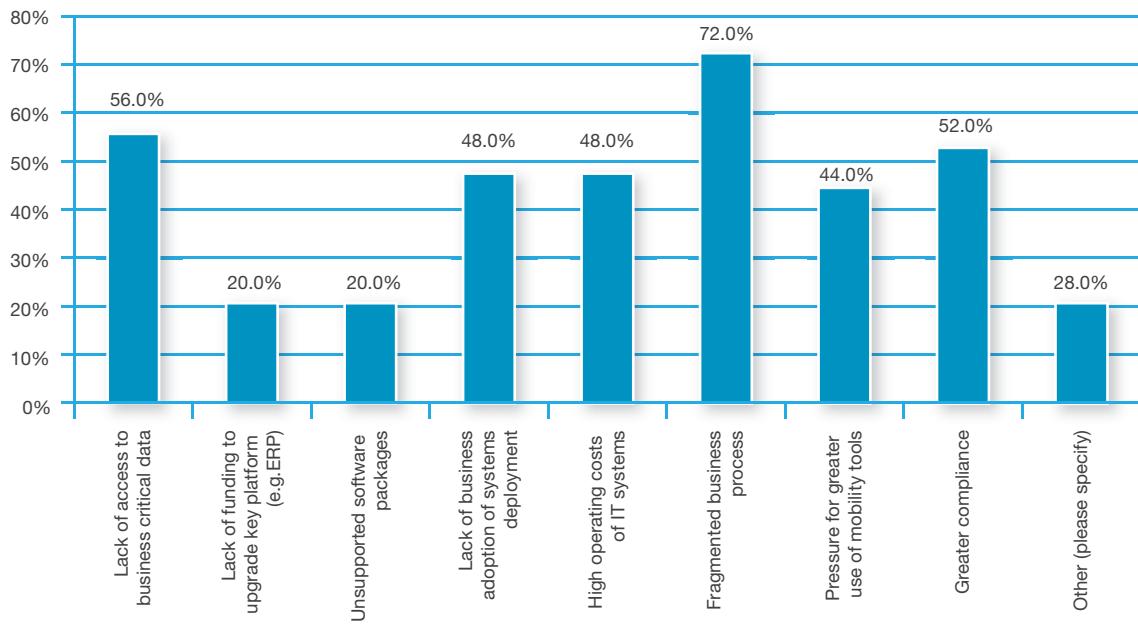
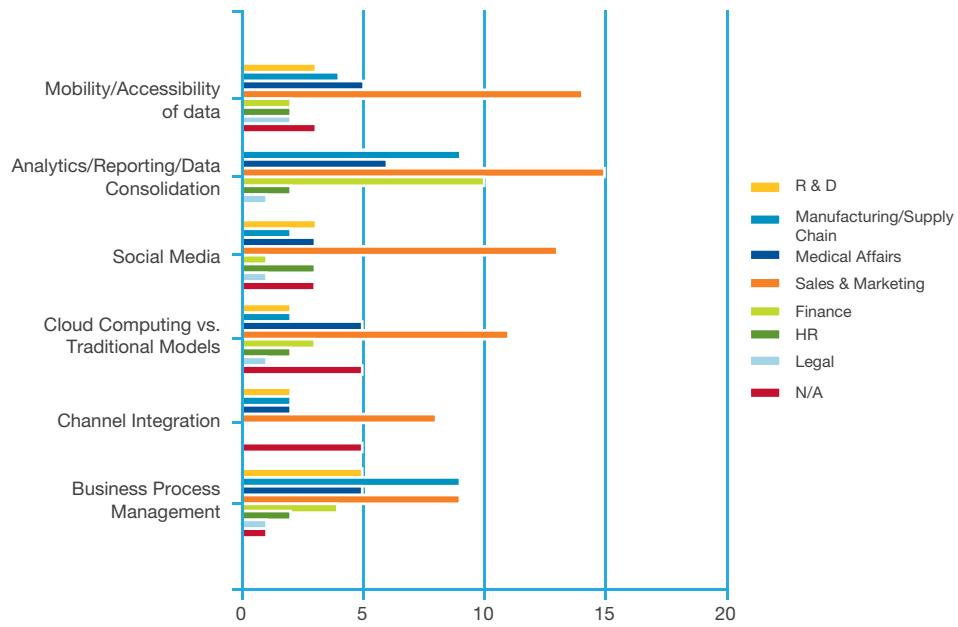
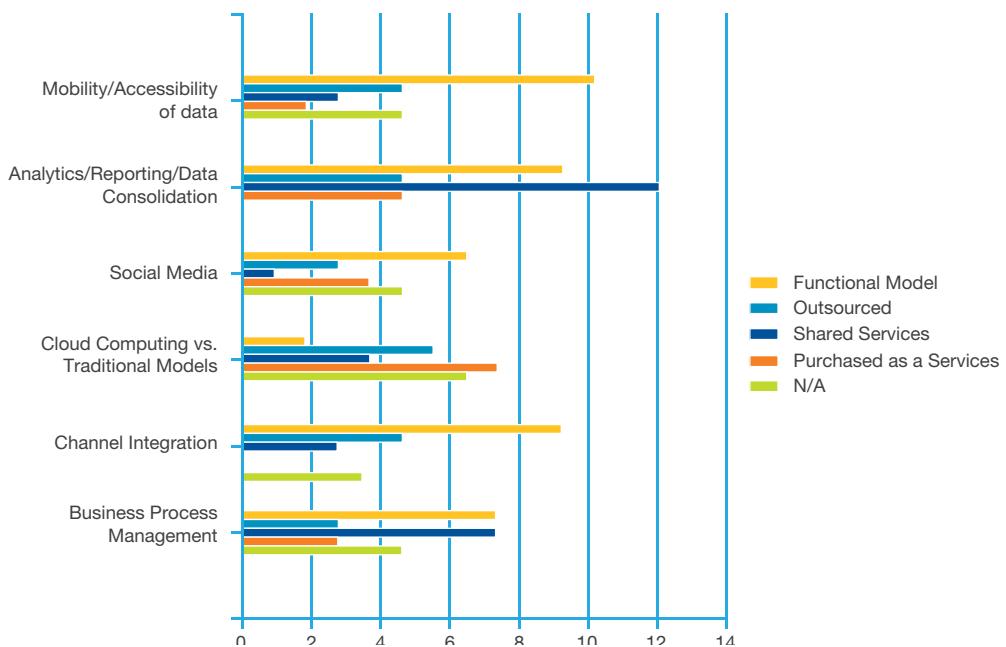


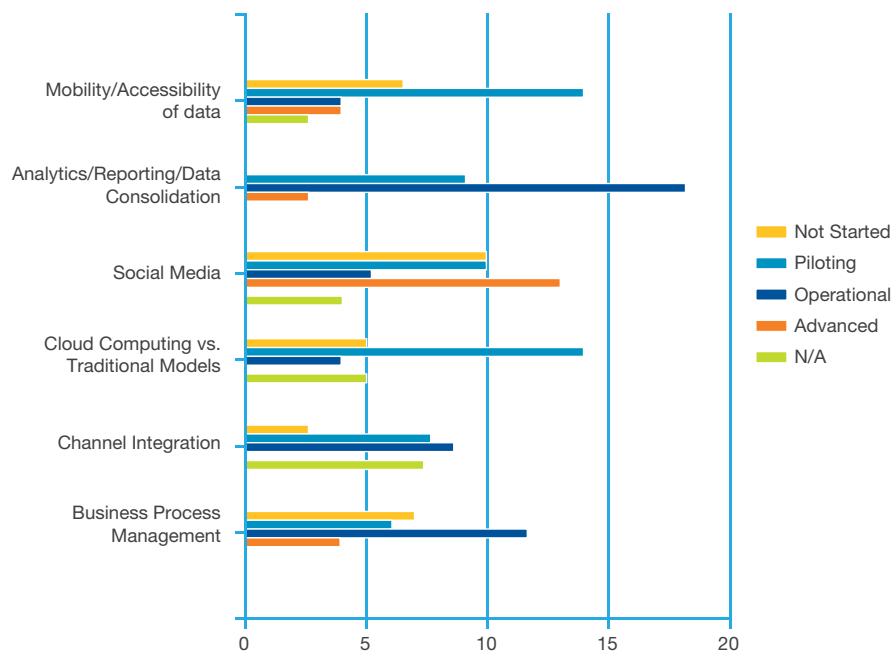
Figure E: What are the top critical business and IT issues that you are currently facing?



**Figure F: Is your company contemplating IT initiatives for any of the following?****Figure G: How are these initiatives being delivered in your organization?**

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Figure H: What is your current level of operational maturity with respect to these trends?



### 3. Technology Trends That Matter



It is not very often that technology shifts result in a wide impact to a variety of industries. Such a transformational shift is now occurring, driving Life Sciences companies to change the way they do business, and indeed, even develop new business models. This report highlights these key trends and business impacts.

For example, the rapid advances in, and adoption of social media, collaboration and multiple device capabilities (sometimes collectively referred to as Web 2.0) is causing a transformational shift in today's businesses. The topic of how social media trends impact the Life Sciences industry and how companies can leverage these is covered in the report under the topic *The Network Effect Leveraged*.

Other trends that will have a major impact are Cloud computing, covered in *The Journey to the Cloud — An Overview*, and the increasing trend to outsource 'non-core' functions using evolving using evolving models. These are covered in the *From Software to Services* topic.

Meanwhile, advances are also being made in the science of medicine. The promise of developing targeted, safer and more effective medicines is appearing closer to realization by the day. While integrated Personalized Medicine technologies and fully developed supporting health care and regulatory environments are a few years away, many companies are putting the building blocks in place. As an example, companies are starting to look at real world patient data and putting systems in place to enable better collaboration among the different stakeholders — Life Sciences companies, CROs, clinical trial sites,

universities, academic medical research centers and other stakeholders. The *Technologies for Better Science* topic covers key trends in this area.

Sustaining innovation is also occurring within technology being used by Life Sciences companies. Customer Relationship Management and Business Intelligence continue to evolve, with the extension of new capabilities such as business activity monitoring, Cloud and SaaS models, and the integration of new devices, new channels and new digital content formats. *Integrated Multiple Marketing Channels and Intelligence — Inside and Outside* covers how these trends can be leveraged by Life Sciences companies.

All the changes impacting Life Sciences companies today are not driven by transformations in science and technology alone. There is increasing social and regulatory scrutiny on healthcare and medicine. *Transparency through Technology* covers topics regarding state and federal regulatory stakeholders, especially in the area of life sciences product marketing — whether they be drugs or medical devices.

In order to be successful in the future, companies need to fully understand the impact of these forces on their business and be adequately prepared for them. In today's world, not acting on time is being left behind.

# 3.1 The Network Effect Leveraged

Social Media is now emerging as a major driver for Life Sciences companies both in how they go market and how they respond to the market. Life Sciences companies are now discovering that if they use social media

correctly, they will be able to expedite their time to market, increase the relevance and safety of their products, increase the likelihood of a positive response by the market (company, brands, initiatives, messaging), and via

competitive intelligence present initiatives and products that are ahead of their competitors.

Figure 1: Business Drivers for Social Media Program Adoption by Life Sciences Companies



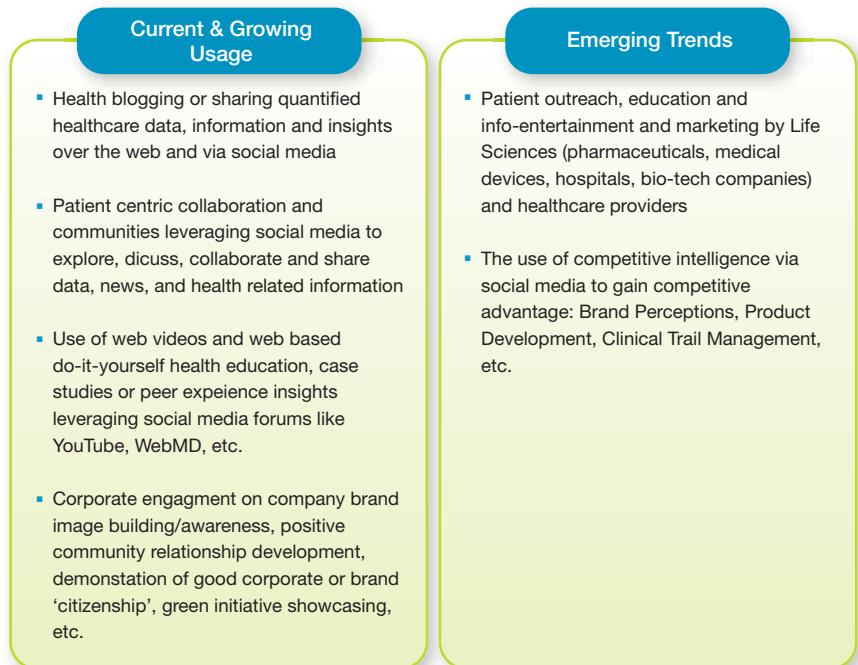
## Network and Collaborate

A huge driver in the increase in social media spending is the changing influence of stakeholders as payors and consumers are becoming more powerful, and commercial influence models need to evolve accordingly. Also, changing regulations are driving increased requirements for access to social data, messaging and promotional investments for marketers, brand managers, and corporate communications functions. As a result, Life Sciences companies are currently building the following types of Social Media programs:

- R&D Social Collaboration programs to drive increased productivity & time to market
- Clinical Trial Patient Recruitment using Social Media
- Brand & Company Perception Enhancement programs
- Health Care Professional (HCP) Social Relations & Influence programs — CROs, Payors, Investors, etc.
- Community Awareness & Outreach programs
- Corporate Social Responsibility & Green Awareness programs
- Direct to Consumer (DTC) Awareness and Brand Perception Enhancement programs
- Product and Service Market Relevance programs for demand
- Enhanced non-R&D internal productivity via social net applications
- Enhanced market intelligence and insights efforts: Key opinion leaders, competitive intelligence, HCPs, payors, regulators, product issues and adverse events, market demand and needs, next waves of innovation, etc.

Figure 2 provides a snapshot of these drivers as well as the programs companies are developing to capitalize on the various opportunities.

**Figure 2: Successful & Emerging Trends**



## Trends in Social Media

The market for social media is large and growing at an amazing rate. Consider some of these social media statistics and market insights, both from an overall market perspective and from a Life Sciences industry perspective:

- 3 out of 4 Americans use social technology<sup>1</sup>
- 2/3 of the global Internet population visits<sup>2</sup>
- Visiting social network sites is the 4th most popular online activity — ahead of personal e-mail<sup>2</sup>
- Time spent on social networks is growing at 3x the overall internet activity rate, accounting for ~10% of all internet time<sup>2</sup>
- Spending on Social media is expected to grow to \$3.1B by 2014, up from \$716MM in 2009<sup>2</sup>
- Virtually all Life Sciences companies have started on some sort of basic

social media program and are expected to grow their investment by 2-10x over the next several years

- Social media is increasingly being adopted and leveraged in a Life Sciences context (especially from a patient centric perspective)
- Patients and caregivers have increased access to medical and product information — Oncology, Diabetes and STDs/HIV are now the three most active healthcare communities in social media

Figure 2 depicts both successful and growing trends within Life Sciences from a market perspective as well as the emerging trends. These trends are centered on the following themes of patient centricity:

<sup>1</sup> Forrester – The growth of Social Technology Adoption, 2008

<sup>2</sup> Nielsen, Global Face and Networked Places, 2009

**Figure 3: Near Term & Longer Terms Trends**



- Patient Self Education
- Collaboration between patients, caregivers and Life Sciences companies involving topics/stakeholders including medical products, pharmaceuticals, hospitals, payors, HCPs, etc.
- HCP collaboration and insight sharing
- Brand and company awareness and relations

The emerging market trends are centered on the following themes of market and patient centricity:

- Patient outreach & education by Life Sciences companies
- Market Social & Competitive Monitoring: Social media sentiment analysis, competitive analysis, professional community analysis
- Brand, product and company image enhancement communications programs

Figure 3 depicts both near and longer term trends within Life Sciences from a market perspective as well as emerging trends. They are centered on the following themes of patient centricity:

- Patient Relationship Management (PRM)
- Tele-medicine delivery
- Patient education
- Patient healthcare access improvement

The longer-term market trends are centered on the following themes of patient centricity:

- Mobile access
- Medical profile transportability and enhanced access
- 24x7 collaboration and information delivery via preferred social or mobile networks

These charts indicate that social media is being driven by a market that is continually seeking to increase social access and influence through an ever increasing set of social media communication and collaboration tools. The pace at which tools are available and utilized for these purposes in Life Sciences is expected to grow at an incredible rate in 2011 and for many more years to come.



## 3.2 Intelligence: Inside and Outside

The economic downturn continues to increase the pressure on organizations to focus on better decision making using Business Intelligence (BI) initiatives to reduce costs and run more targeted campaigns through better customer segmentation. Business users want BI systems to tell them what to do next. They want social software to diagnose problems in their relationships with partners and customers. They want their websites to provide the right content and messaging to customers they haven't encountered before. Also, fueling the need for more intelligent Business Intelligence are government regulatory & compliance reporting regulations. Governments are requiring organizations to share with the public the relationships with and financial investments made to Healthcare Professionals (HCPs) and institutions. A

more intelligent Business Intelligence operational model will act as a key enabler helping organizations dominate and inform every aspect of their information lifecycle, from data

management, through information infrastructure, to actionable insight and performance intelligence.

Figure 4: Issues Driving More Advanced Business Intelligence

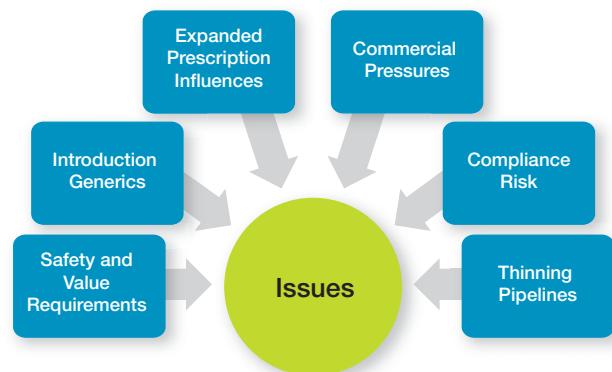
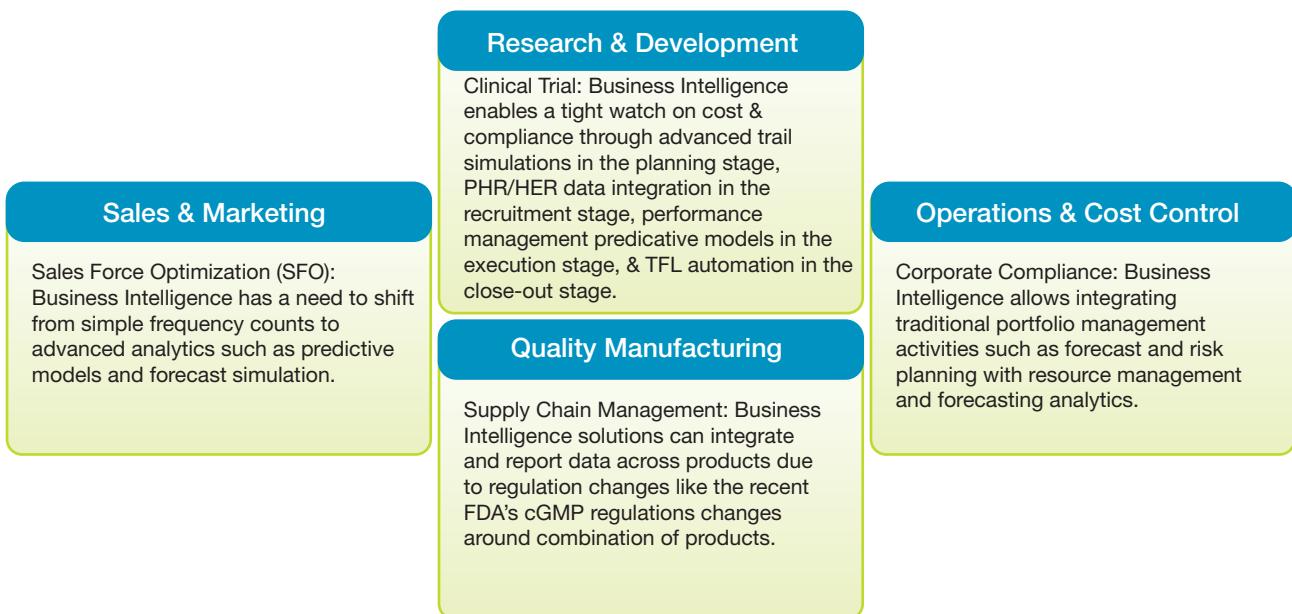


Figure 5: Business Intelligence Shifts



## Major Business Intelligence Trends

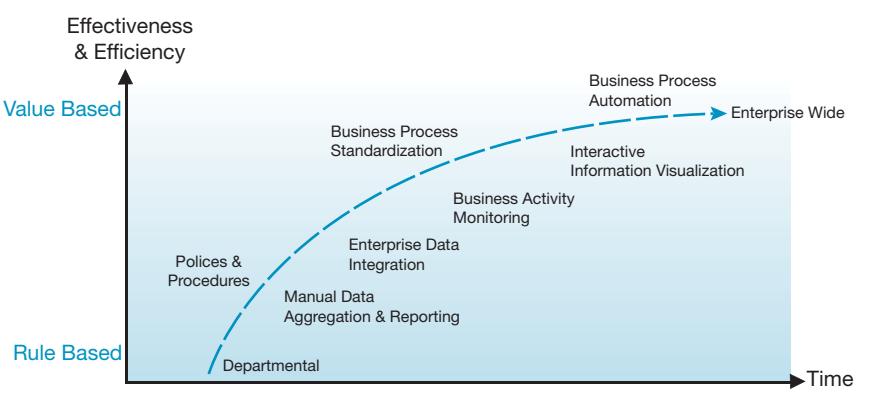
To help organizations achieve better decision making and compliance reporting, Business Intelligence technology continues to evolve in the areas of enterprise wide data integration, data quality, analytics, mobile reporting, data governance, and master data management. More importantly, many emerging innovative technologies not only provide technology innovation, but also represent innovations to delivery or deployment models, including Software as a Service (SaaS), Cloud-based offerings, and mobile Business Intelligence technology. These new delivery models, such as Software as a Service (SaaS) and Cloud-based offerings, can provide organizations with Business Intelligence technology that can integrate data silos, improve data quality and provide compliance reporting more quickly or even instantly, with a scalable cost model. These offerings free organizations to focus on things that really matter, such as knowing their customers better and enterprise compliance reporting through improved methods of data collection, integration and reporting.

## Data Integration Generating Compliance Transparency

Accurate spend reporting requires an understanding and management of the interrelationships between policies, business processes, data capture and integration. Moreover, to ensure that they are capturing all areas of spend, organizations need to aim for complete enterprise-wide transparency of their spend data enabling access to enterprise-wide information to meet the dynamic reporting needs of internal and external stakeholders.

One key Business Information Management trend with the potential to greatly facilitate transparent compliance reporting is Business Activity Monitoring (BAM). BAM can provide real-time situation awareness and detect anomalies in the processes of compliance activities (HCP spend) along with orchestrated business processes and workflow. Employing a BAM application can provide the transparency of the time-sensitive HCP spend processes to better understand status and identify problems along with raising alerts.

Figure 6: Pathway to Enterprise-Wide Business Intelligence



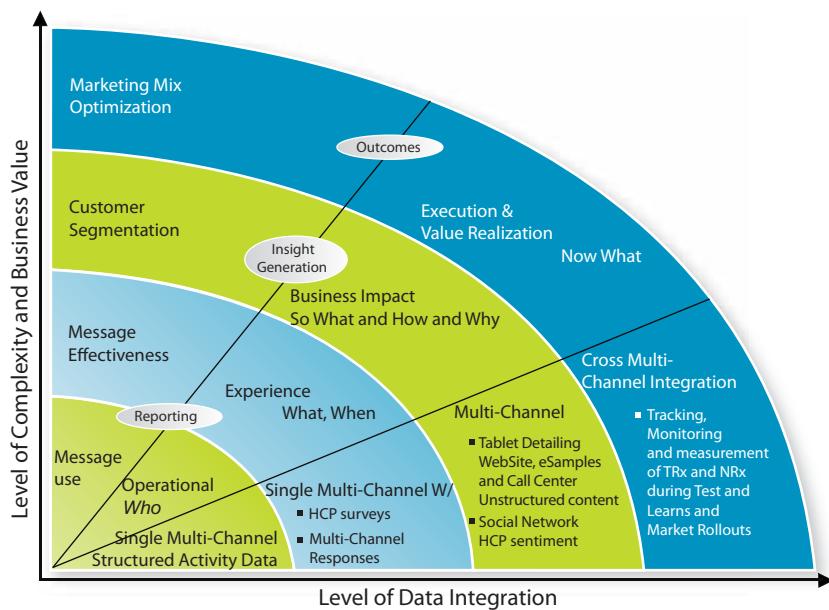
## Innovative Reporting Technologies Enabling Greater HCP Intimacy

Reporting and analyzing all interactions between Life Sciences companies and their customers, collectively referred to as Health Care Professionals (HCPs), requires canvassing a multitude of data sources. A major trend occurring is that face-to-face access, by sales representatives, to HCPs continues to decline. One of the core reasons creating this trend is that HCPs are seeing more patients and simply do not have the time for direct interactions with sales representatives. Thus, HCPs are increasingly using the Internet and other technologies, to get the information they need when and where they want it. The marketing of content to HCPs is therefore transforming into a variety of electronic channels.

Several key Business Information Management trends can be leveraged to effectively and efficiently collect this new data and provide insightful actionable information to marketing and sales organizations. The following trends are anticipated to reduce the delivery time and cost of providing HCP operational reporting to the end users and thus greatly contribute to earlier adoption of the data into core business processes.

- The use of semantic technologies, like search tools, allowing structured queries over unstructured data can provide greater precision, better speed of delivery, and reduction of information overload when analyzing activity data and content usage.
- Insights about HCPs social media interactions can be achieved through technologies such as social mining and social intelligence which utilize sophisticated data mining and text analytics to understand the implicit meaning of unstructured data.

Figure 7: Multi-Channel Business Intelligence Maturity Model



- Delivering early views of HCP activity across can be accomplished by employing data virtualization technology, pulling together data from a variety of source systems and applying business rules without physically creating tables.

With all this new data, it is more important than ever to get accurate data in order to make the most of the Business Intelligence and analytics the data provides. This means establishing a data governance discipline, achieving and maintaining a level of data quality that is appropriate for the applications and developing a corporate standard for data terms and usage.

### Smart & Advanced Analytics

Predictive analytics can play a pivotal role in day-to-day business operations. If available to information workers — not just to statisticians and professional data miners — predictive modeling

tools can help the business users continually tweak their plans based on flexible what-if analyses and forecasts that leverage both deep historical data and fresh streams of current event data.

### In Memory Analytics

Just as significant, in-memory Business Intelligence clients provide an important alternative to traditional data mining tools for subject matter experts who wish to explore a multivariate data set from all angles without having to do heavy-hitting data preparation, clustering and classification beforehand.

### Green Business Intelligence

While most executives agree that a green strategy is a good idea, few know how to value or prioritize their initiatives. “They struggle with the business case, waiting to implement strategies until outcomes can be predicted more reliably.” — IDC

## **Standardization Into Fewer Platforms**

Multiple products in the landscape simply high cost of high cost of maintenance as well as reduced user satisfaction due to multiple windows for information. Additionally, it is difficult to ensure single version of truth and trust on the data is reduced. Reducing the number of platforms reduces the TCO, which is an important benefit in these tough economic times.

## **Application Rationalization**

Over the years, enterprises have many applications built in silos and many enterprises are now embarking on rationalization of these applications to provide higher value out of the data. This also means enterprises are looking at enterprise class platforms and software to support the enterprise information and reporting requirements.

## **Regulatory Requirements**

Data has become the critical asset especially for decision making and the regulatory requirements also necessitate the importance of trust on the data. Not just the data is important, but the ability to analyze the source and root of the data are equally critical.

## **User Self Service**

There is a strong focus on enabling self service for the users whether it is for ad hoc analysis or intuitive dashboards.

The move is towards reducing the dependency on IT to create the reports & analyses, by using best of breed technologies that are simple to use and scalable for the enterprise.

## **Summary**

Exponentially growing data sources resulting from multi-channel HCP messaging and tighter more complicated regulatory compliance reporting represent significant Business Information Management challenges.

These growing data volumes and reporting complexities are increasing business risk and can potentially reduce agility. Compounding these challenges, Business Intelligence professionals are faced with financial constraints necessitating cost-effective IT solutions that meet business objectives and not simply "technology for technology's sake." Traditional data integration and reporting approaches, such as data consolidation and replication have not kept pace with the demanding Business Intelligence capabilities that organizations require to make decisions on both a day-to-day and a long-term strategic basis. A more intelligent Business Intelligence operational model will act as a key enabler helping organizations dominate and inform every aspect of their information lifecycle, from data management, through information infrastructure, to actionable insight and performance intelligence.



## 3.3 Integrated Multiple Marketing Channels

Life Sciences companies are looking at different approaches and different channels to engage Health Care Professionals (HCPs) and get their message across to their key customers.

- Physicians have less time and willingness to see sales reps, resulting in a decline in reach and frequency of face-to-face selling time
- Increased regulations require limiting marketing spend and reporting spend information to state and federal authorities
- Cost pressures are forcing Life Sciences companies to reassess sales and marketing efforts with a goal of making them more efficient, effective and targeted

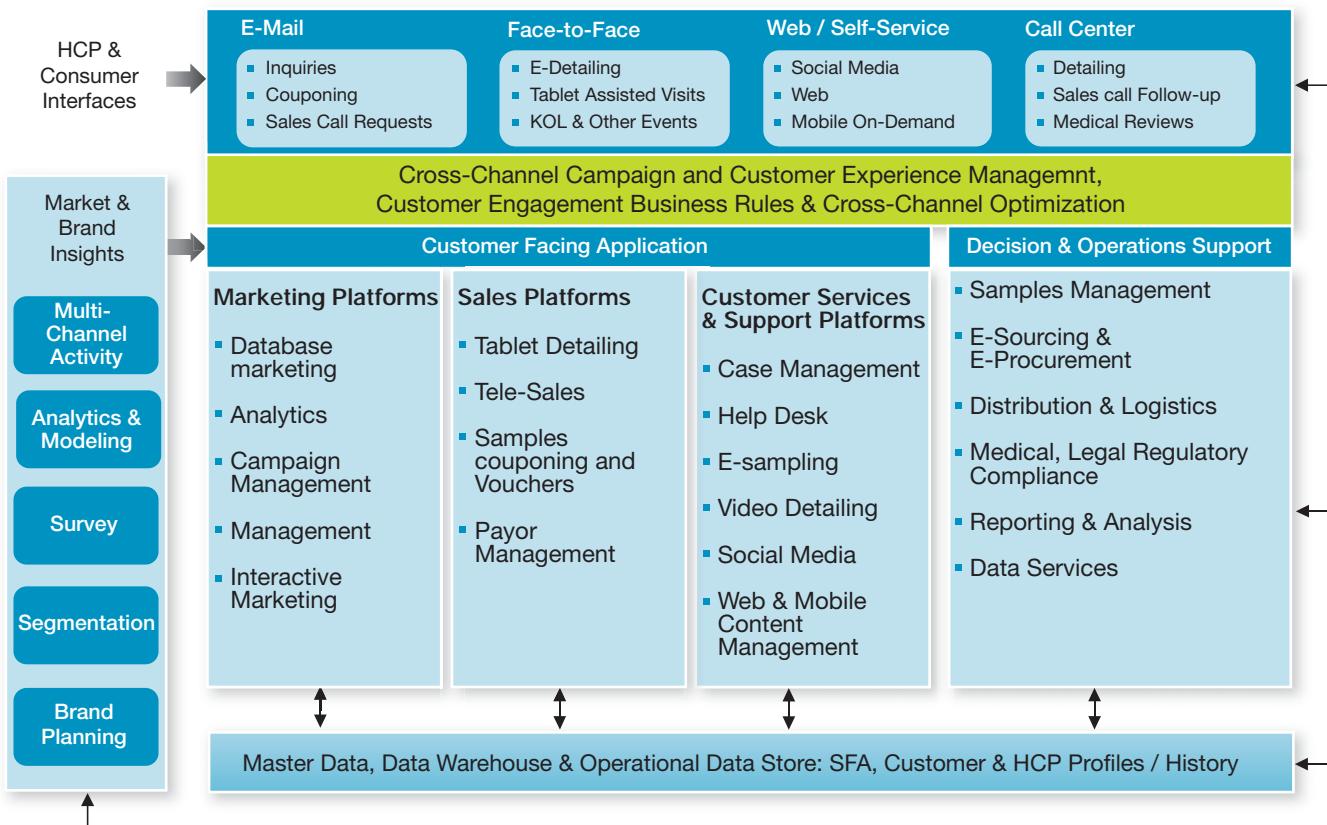
In addition, studies have indicated that HCPs would like Life Sciences companies to develop differentiated and personalized information delivery mechanisms for the following reasons:

- HCPs still need access to information to keep themselves up to date on medical trends and product information
- HCPs are struggling to balance patient, practice and learning needs
- HCPs are increasingly using internet-based information sources as part of their regular practice activities and continuous learning

### The New Channels

Life Sciences companies are opting to supplement the traditional Sales Force face-to-face model with a multi-channel integrated campaign approach. In doing so, they are mixing traditional channels such as call center, web portal and speaker events with new channels such as web based sampling, web publishers and social media.

Figure 8: Multi Channel & Closed Loop Marketing Conceptual Architecture



Despite the diversity this approach implies, there are common denominators:

- The promotional model is moving from a “push” to a “pull” model
  - Enabling feedback from customers on channel/content preferences and activity
  - Driving interactions with customers and learning from these interactions
- Providing revised value added services based on customer interaction feedback
- Creating a robust analytics engine that drives promotional decision making

### Technology Trends That Matter

A portfolio of integrated Multi-Channel services needs to be coupled with Closed Loop Marketing to deliver a true customer and HCP personalized experience based on needs and preferences.

Consider the following data regarding the use of three separate marketing channels

as it relates to marketing to HCPs<sup>3</sup>:

- 70% of smart phone/PDA users say it is essential to professional practice, and 34% use it during patient consultations. Physicians have indicated they prefer to use a PDA for prescription dosage, formulary status, and drug reference compared to a computer
- 75% of physicians show interest in ordering samples online
- 63% of the physicians in a survey indicate a preference for electronic detailing. Over 2/3 of physicians found sales representatives to be more credible when a tablet computer was used during the sales call.

The underlying reason for these positive results is that these new approaches enable the use of richer, more compelling content that contains rich graphics, more data, videos of KOL and patient case studies and more. The bottom line is that Multi-Channel and Closed Loop Marketing offers venues to send more

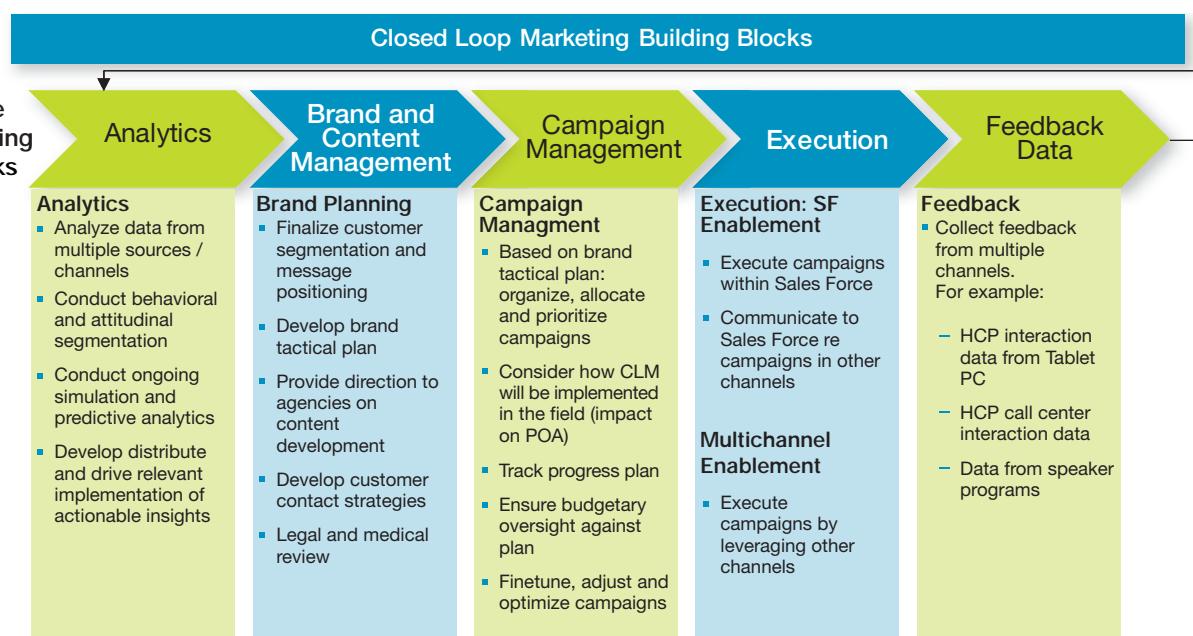
compelling content and messaging in such a way as to increase customer reach, brand awareness and brand equity with efficiency and effectiveness.

### The Implications

In a way, the concepts of Closed Loop Marketing have parallels with TQM's Plan-Act-Measure cycle. The path to building Multi-Channel Capabilities and implementing Closed Loop Marketing requires comprehensive planning, focused project management and implementation effort and organizational investment. This has wide ranging implications for sales and marketing in terms of resource investments and organizational change management.

There are several basic building blocks that make up the “central nervous system” of typical Multi-Channel and Closed Loop Marketing environments. These building blocks are illustrated in figure 9 below.

Figure 9: Closed Loop Marketing Building Blocks



<sup>3</sup> Manhattan Research; Steven Niles, “Feedback loop” PharmaLive; “Optimizing the e-Channel Significant case studies from UK Pharma”, PM Society and Capgemini analysis

These building blocks need to be enabled by designing and implementing a “techno-functional” architecture that integrates HCP/Customer Interfaces, Applications, Decisions and Operations Support Tools, Reporting and Analytics Infrastructure along with new business processes and organizational design. The technology aspects of Multi-Channel Closed Loop Marketing include several dimensions, all of which need to be managed in an integrated manner. These technology dimensions include:

- Customer facing applications (tablet detailing, contact center, web applications, social media applications etc.)
- Technology to manage the flow of data from central sales and marketing to/from channels (HCP/customer targeting and content out to the channels; activity tracking back)
- Content Management process and systems to manage Create, Review, Measure and Optimization of Multi Channel messaging
- Data repositories for HCP transactional activity and as part of enterprise data warehouse
- Customer Master Data management (including Customer & HCP Profiles/ History and change governance)
- Integration with other key systems (including SFA, CRM, ERP and others)

For companies to be successful in achieving Multi Channel Closed Loop Marketing, the technical infrastructure needs to be coupled with the vision of how the people and process aspects of the business will change with the implementation of the technology. This requires thinking through ways to achieve a consistent customer experience for a go to market approach across channels.

### The Road Ahead

Many Life Sciences companies have been successful in implementing multiple channels for their sales and marketing efforts. However, few companies have achieved complete closed loop analytics and marketing potential. The true test of a successful multichannel implementation is the extent to which information and intelligence from each channel can be leveraged by itself and across channels to achieve a complete view of HCP preferences and behaviors, and having the ability to continually adjust the channel mix as well as the messages and the campaigns within each channel to achieve optimum results.

We anticipate additional multichannel analytics technologies to be available in the marketplace over the next couple of years. Vendors that currently offer some of these capabilities will enhance their product suite to enable Multichannel / Closed Loop Marketing. Newer devices (such as the iPhone, iPad, etc.) and newer technologies (e.g., touchscreen) will give rise to newer channels and newer ways of marketing. The availability of new technology will continue to drive changes in the industry.

### Summary

Life Sciences companies are opting to supplement the traditional Sales Force face to face model with a multi-channel integrated campaign approach. In doing so, they are mixing traditional channels such as call center, web portal and speaker events with new channels such as web based sampling, web publishers and social media. This is facilitating HCPs’ “pulling” information based on their preferences and needs as opposed to previous “push” programs.

New channels not only offer HCPs innovative services but also enable HCP-specific activity tracking that delineates their preferences. Many Life Sciences companies are using Closed Loop Marketing to “mine” this information to improve marketing activities, segmentation and targeting. Closed Loop Marketing provides Life Sciences firms an organized process of program planning, execution, feedback/ tracking and analysis. These activities form a continuous improvement process in which the resulting analysis informs subsequent program planning. The Closed Loop collaborative process provides a systematic way to opening up communication channels for collaborative discussions and using quantitative feedback to improve decisions. Ultimately, this approach keeps stakeholders focused on improving effectiveness, increasing ROI and making programs a positive influence on growth.

While a number of companies have made Multi-Channel and Closed Loop Marketing investments, the opportunity still exists to use these functions in an integrated way to establish differentiated marketing services to establish sustainable competitive advantage.



## 3.4 Technologies for Better Science

One of the key issues facing Life Sciences is, "How to bring more effective and safer drugs into the market in less time while reducing the overall cost of the overall cost of translating bench-side innovations into important medical products?"

Currently, of all medicines in the market, 90% are effective in only 30-50% of individuals.<sup>4</sup> Furthermore, studies on drug safety indicate that drug related adverse events are the third leading cause of death.<sup>5</sup> Today's drugs are studied and marketed to treat general disease populations, despite the fact that there is significant patient variance within each population, resulting in lower than optimal effectiveness and safety.

Personalized Medicines, targeted for subgroups of patients based upon their genetic makeup, can help increase effectiveness and safety. According to a recent study by the Tufts Center for the Study of Drug Development, 94% of biopharmaceutical companies are investing in personalized medicine research. These companies report that up to 50% of their pipeline compounds are potential personalized medicine treatments. Over the last five years, their research investments in personalized medicine have increased by 75% and they anticipate another 53% increase by 2015. Information technology plays a key role in personalized medicine programs by providing collaborative platforms for research and by helping to develop innovative ways to integrate and analyze real world patient and research data to translate bench-side science into bed-side medicines efficiently.

The key drivers that Life Sciences R&D companies deal with include:

Key R&D Drivers
<ul style="list-style-type: none"><li>▪ Enriching pipelines and increasing revenues from existing drugs</li><li>▪ Shortening time from target identification to candidate validation and optimization</li><li>▪ Shortening time for clinical trials and drug approvals</li><li>▪ Addressing increasing regulatory pressures to make drugs more effective and safe</li><li>▪ Recruiting clinical study subjects globally on a timely basis</li><li>▪ Enabling more effective internal and external collaboration</li><li>▪ Integrating real world data and providing feedback mechanism from post marketing observational data</li><li>▪ Driving increased innovation while decreasing costs</li></ul>

### The R&D Imperatives

As Life Sciences companies simultaneously address these drivers, an increasing number of companies are looking to emerging countries to help lower R&D expenses through collaborations, expansions and outsourcing. The large patient populations available in countries such as China and India provide additional reasons for this shift. Trends in R&D Key technology trends impacting R&D include:

- Providing a platform for more effective integration and analysis of real world and research data containing genomics/proteomics data, using a semantic integration approach
- Enabling a greater degree of both internal and external collaboration through innovative technologies
- Implementing pattern recognition technologies for biomarker analysis for personalized medicine and companion diagnostics

### Personalized Medicine Platform

Figure 10 shows a high level framework showing the spectrum of services needed to realize Personalized Medicine. A clinical decision support system will support the administration

of personalized therapy by providing appropriate recommendations to the clinician at the point of care.

### Enabling Collaboration and Partnerships

Due to the highly complex and diverse information needed for personalized medicine R&D, no single player can undertake such an ambitious endeavor and succeed in isolation. It is collaboration in itself that will become a key accelerator in the development of personalized drugs. Vast libraries of molecular, genomic, and disease networks and EMR/EHR data are just beginning to become networked together. Biopharmaceuticals are forming partnerships with entities that own these data repositories to integrate them into their R&D initiative.

Different types of stakeholders (pharmaceuticals, biotechs, diagnostic companies, hospitals, universities, payors and data providers) are starting to come together in symbiotic relationships and collaborate through the drug development lifecycle and beyond with a goal of reducing drug development costs, outsourcing non-core functions and generating new business opportunities.

<sup>4</sup> Harvard Business Review – "REALIZING THE PROMISE OF PERSONALIZED MEDICINE" Mara G. Aspinall, Richard G. Hamermesh OCT 01, 2007. PROD. #: R0710F-PDF-ENG

<sup>5</sup> The JOURNAL of the AMERICAN MEDICAL ASSOCIATION (JAMA) Vol 284, No 4

## Pattern Recognition Technologies for Biomarker Analysis

Development of robust biomarkers (genes, proteins, pathways) is of utmost importance for targeted therapy and companion diagnostics development. Biomarkers can be used to measure and evaluate biological processes associated with normal and disease states much earlier than analysis based on external symptoms. Biomarkers can also give an earlier indication of response to a therapy and can be substituted for conventional clinical trial endpoints, resulting in cutting expenses and time of clinical trials.

Identifying biomarkers requires integration and mining of complex data

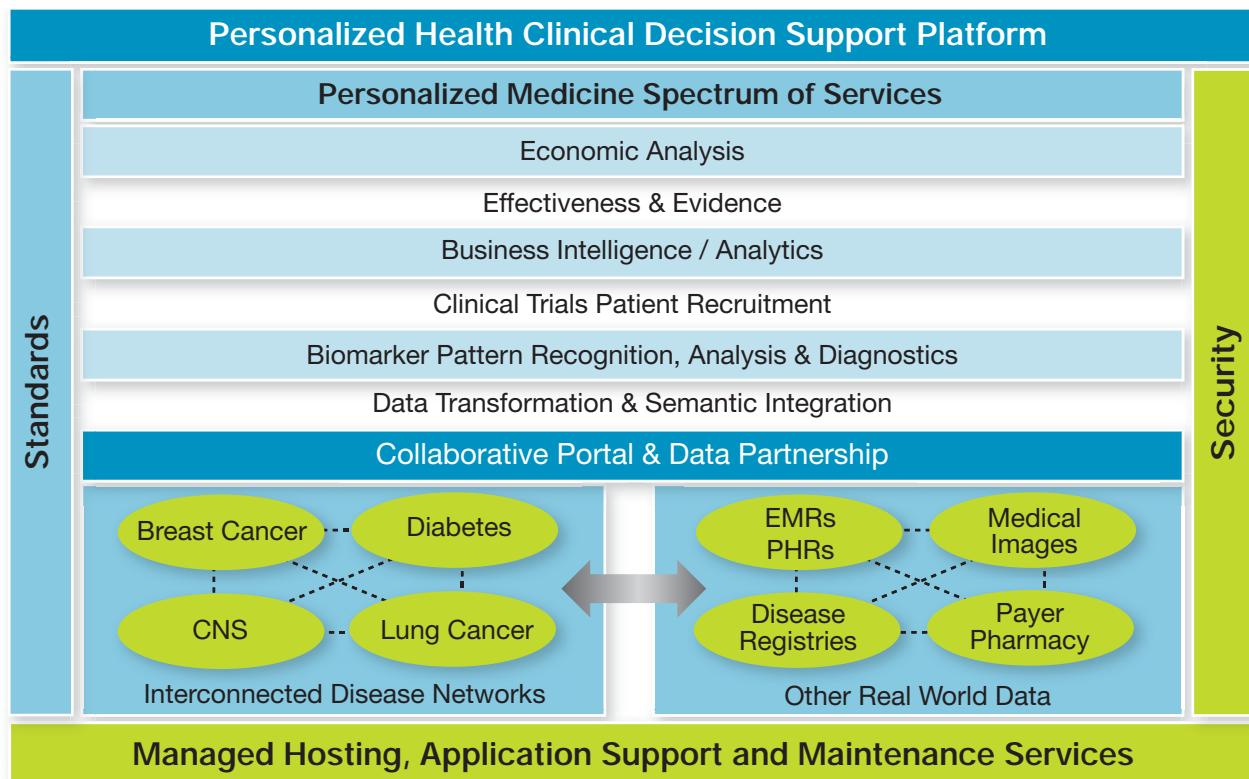
from diverse sources such as NextGen sequencing machines, liquid chromatography and mass spectrometry.

Support Vector Machines (SVM) technology is now replacing neural networks as the leading approach to pattern recognition and is being utilized for biomarker analysis. Using advanced mathematical techniques such as Fractal Genomics Modeling (FGM), scientists are able to study complex networks of genes inside a living organism. These pattern recognition techniques are elucidating genes implicated in several cancers, HIV infection and many other diseases. This technique has also been found effective for pharmacogenetic profiling of patients for adaptive trials.

Using this technique, scientists have been able to access information in micro-array datasets and improve the mapping of genetic pathways involved in the diagnosis and prevention of certain diseases.

Pharmaceutical companies are now collaborating with molecular diagnostics companies to develop companion diagnostics for personalized medicine, based on biomarker analysis from various GeneChip platforms. "Theranostics," the use of diagnostic products, developed in parallel with drugs, can identify favorable responders to a personalized medicine.

Figure 10: Personalized Medicine/Personalized Health Framework



## The Implications

### Stakeholder Impact:

Various stakeholders will benefit as follows:

- **Physicians:** Will have more robust evidence of new product's effectiveness
- **Patients:** Will receive more assurance regarding a drug's safety
- **Payors:** Will get demonstrable proof of a therapy's value-add
- **Policy-makers:** Will be more confident that a product's real-world benefit outweighs risk in large patient populations

Biopharmaceuticals and Diagnostic companies need business models that result in sustainable revenues for both entities, as they support one another in playing an essential role for personalized medicine — drugs for treatment and

companion diagnostics for helping accelerate drug approval and adoption by consumers.

Figure 11 shows the effects on various parameters of the model in moving from blockbuster to the personalized model.

### Key Challenges:

- Developing new business models to capitalize on the value of data
- Developing/embracing new technologies for measurement and visualization
- Creating new partnerships
- Developing common data standards
- Accelerating medicine / IT convergence
- Understanding and influencing emerging regulatory standards
- Protecting privacy and preventing genetic discrimination

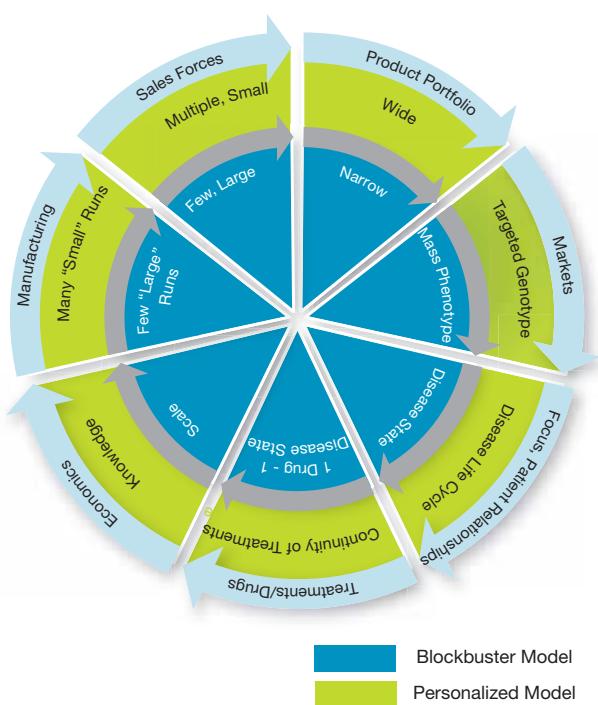
## The Road Ahead

To sustain growth and bring into the marketplace more effective drugs targeted at specific sub-population groups, Pharmaceutical and Biotech companies will need to enhance their strategy to segment disease categories and patient groups in drug discovery and development. The availability of new tools, technologies, and new knowledge will make it possible to practice these strategies more effectively.

Within the personalized medicine model, although the individual tailored drugs may bring in smaller revenues than the "blockbuster" drugs shall, overall revenues from the aggregated groups will be larger since tailored drugs can command premium prices and are likely to be used by the consumers for longer time because they are more effective. In addition, the development timeline is compressed due to smaller, more focused clinical adaptive trials. This will result in less money spent on non-promising drugs and better ROI for Biopharmaceutical Companies in bringing new effective drugs into the market. Pursuing this model will also make more resources available for innovation than going after blockbuster for the sake of blockbuster. Moreover, success from personalized drugs may reduce the need to depend for revenues on product line extensions and less expensive "me too" versions of drugs with little or no therapeutic advantage over existing drugs.

The blockbuster model has traditionally been supported by small-molecule drugs. As the industry moves toward the personalized medicine model, greater emphasis is expected to be placed on biologics comprising of therapeutic proteins, monoclonal antibodies and vaccines. In 2009, FDA approved 26

Figure 11: Impact of Personalized Medicine on Stakeholders



new drugs of which 7 were biologics. According to Datamonitor, the sales of the top 50 Pharmaceutical companies from small molecule drugs will decrease from \$414 B in 2010 to \$394 B in 2014, while during the same time sales of biologics will increase from \$124 B to \$166 B, a notable increase of nearly 34%.<sup>6</sup>

In between biologics and small molecules is a new class of therapeutic chemical compounds, in the range of molecular weight from approximately 500 Daltons to 2000 Daltons, known as Ensemblins, that are providing new leads against a variety of targets including protein-protein interactions. Unlike the small molecule drugs that do not have enough size to prevent the protein-protein interactions, Ensemblins have enough binding energy to disrupt this interaction and can be useful in the development of targeted therapy. Ensemblins have the oral availability and other advantages of small molecules together with the biochemical power of biologics.

An additional focus area for personalized medicine will be Ribonucleic acid interference (RNAi) based drugs. These innovative drugs are an emerging type of drug that involve stopping RNA in target viruses from being transcribed and thus preventing virus genes from being expressed in the body. RNAi breaks up the unwanted target RNA into pieces that can no longer be translated into protein, thus preventing emergence of disease.

The emphasis moving forward will be on predicting disease onset, providing personalized and preventive diagnosis and treatment and on comparative effectiveness of drugs.

### Summary

Personalized medicine is becoming a reality with an accelerated pace foreseen in the upcoming years. All stakeholders stand to gain from personalized medicine. Patients in particular will benefit from products and services in the form of more effective and safer drugs. Biopharmaceuticals will experience increased overall sales.

Companies that bring combination of companion diagnostics and tailored targeted therapeutics into the marketplace faster are likely to be rewarded with the greatest benefits and sustained growth.



## 3.5 Transparency through Technology

In the last decade, the Life Sciences sector has experienced significant changes to the traditional business model. Decreasing blockbuster drugs, the downturn in the general economy, heavily increasing scrutiny into business practices by both the public and state & federal agencies, and huge mergers have resulted in turbulent times for the Life Science industry. These impacts have affected all parts of the value chain and have resulted in major changes throughout companies. The downstream effect has been an evolution of overall business processes, which have in turn created significant changes and trends in the compliance landscape. These changes have resulted in a need for greater transparency through the business.

### Changes in the Life Science Business Model

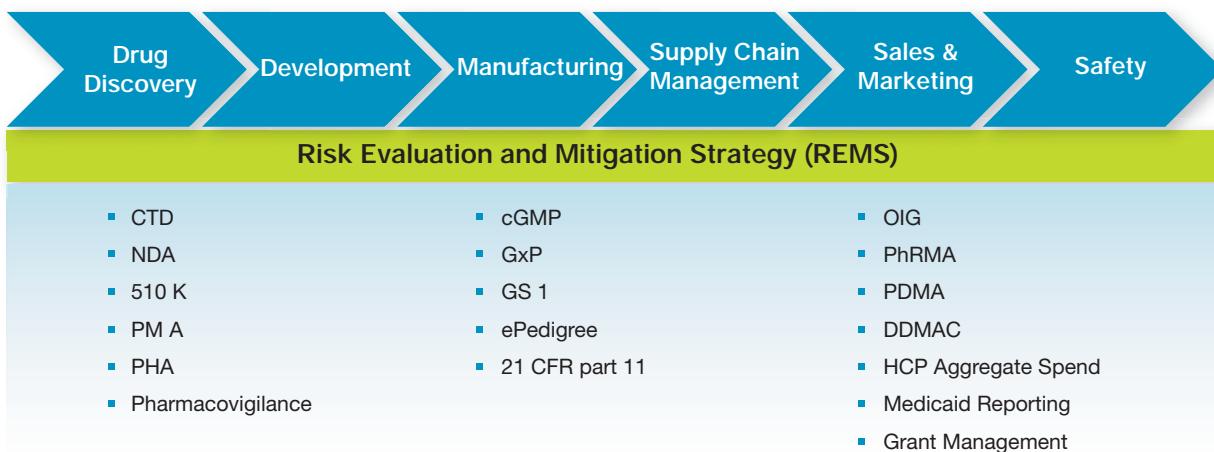
The decline in the blockbuster drug and the pressure brought about by this downturn has required the Life Science business model to make some radical changes. Among those changes are:

- Commercial strategy has taken a page out of the retail industry and is working on Customer Relationship Management in full force. This has led to an increased focus on multi-channel communications, an increase in direct contact with various consumers of product beyond the physician, and a move to new avenues such as social media and data gathering for personalized medicine
- Manufacturing has increased its leveraging of third party vendors and outsourcing to drive down costs and attempt to drive more demand planning. This has resulted in requiring more information to be available to the manufacturing arm than ever before. In addition, new regulatory requirements focused on attempting to control counterfeiting of drugs and devices have increased the need for information transparency through the supply chain
- In the R&D area, the pressure is to drive down the overall costs and time to get drugs/devices through the approval process. Processes are being reengineered and/or eliminated in

order to accelerate the time taken within and between each phase. In response, a major trend is the integration of third party service providers such as Clinical Research Organizations (CROs) into a more tightly integrated information sharing platform. The move is to decrease the amount of effort and time to manage studies between organizations through higher transparency of data. In addition, companies are attempting to consolidate clinical studies in order to more accurately detect potential problems by mining clinical studies data for “signals” that might identify a study that may not successfully complete the protocols or some potential adverse events that would indicate problems with the treatments

Each of these significant business changes represents radical changes from the traditional way of doing business in the Life Science industry. Beyond the impact at the business level, the impact has also been felt in the Compliance Area.

Figure 12: Major Focus Areas of Compliance Across the Value Chain



## Major Trends in Regulatory Compliance

If the last decade has brought radical change to the business approach, a similar and almost equal change has been brought to the compliance aspect of the Life Science industry. Prior to this last decade, compliance and regulatory support was viewed as an auxiliary function to the business. Compliance support was primarily performed outside the mainstream and always viewed as a necessary evil. Each requirement was typically taken in a silo approach and completed as necessary to meet the specific requirement need. The net result was the creation of a series of stand-alone, sporadic, and disjointed compliance activities that would start and stop seemingly randomly with the generation of documents that would either be shipped to the FDA for review and approval or simply be put on a shelf until some audit body needed to inspect it. This changed radically in the early part of this decade with the advent of the Office of the Inspector General (OIG) and the PhRMA guidelines. These two major

compliance requirements radically changed the role of compliance and how it would be supported. Figure 13 shows the major focus areas of compliance mapped across the value chain.

The advent of several major regulatory and compliance requirements has created a challenge for Life Science companies attempting to stay within the rules and regulation of compliance. Approaching each of these compliance needs in the traditional fashion of "one-off" was no longer an option. In addition, compliance dictates such as OIG now required executive level involvement in ensuring that compliance was top of mind with Life Science companies. Of the major compliance requirements, there are several that have put an exceptional strain on processes, technology, and data. These are:

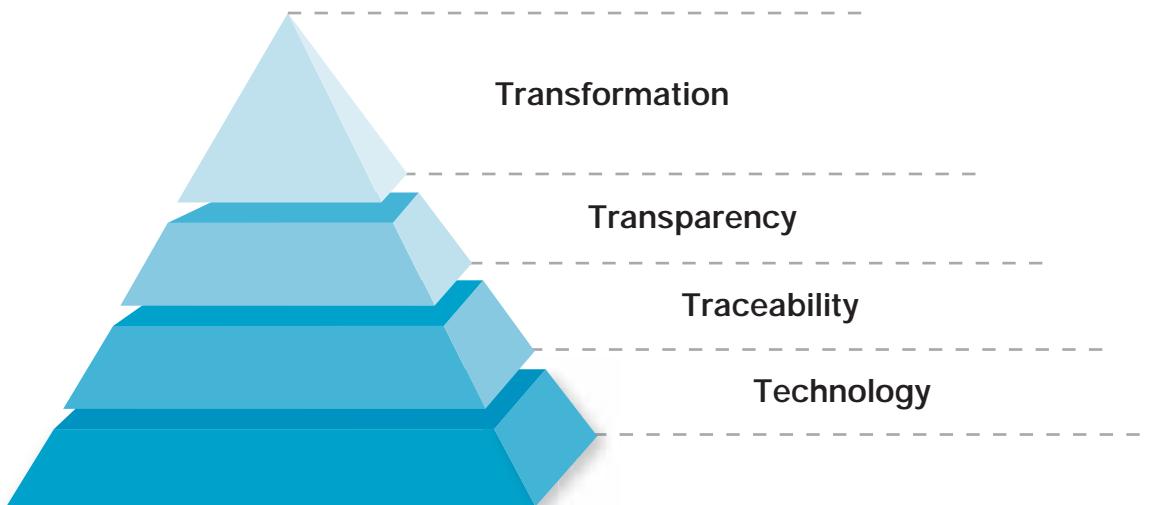
- Risk Evaluation and Mitigation Strategy (REMS) requires companies to identify all potential areas of risk and develop a strategy to decrease and manage the risk

- cGMP requires the accurate and detailed validation of processes and system support.
- Healthcare Professional (HCP) Aggregated Spend is a relatively new requirement that requires the tracking, capture, processing, and timely reporting of expenditures with "covered entities"

As a result of these types of far reaching requirements, compliance organizations began to see compliance in a four prong approach that covered Transformation, Transparency, Traceability, and Technology. The four T's are stages that represent a maturity model of the evolution of the Compliance functions in the Life Science industry. In Figure 14, they are represented as a set of capabilities that build upon the following services and capabilities.

The first stage of the pyramid is Transformation. Transformation represents the change in the approach to compliance by companies. Due to the nature of the compliance requirements

Figure 13: The Four Pronged Approach to Compliance





and the need for them to be embedded into the business strategy, the compliance group has transformed into a strategic group. OIG required that an executive position be created and the position to have direct access to the CEO and Board. As a result, companies have been moving towards integrating the compliance requirements into the business strategy. This has resulted in the need to provide a more closely linked and automated relationship between business processes and the supporting technology. Previously, this lack of integration resulted in “blind spots” in the compliance adherence program. Activities such as off-label or violations against DDMAC could potentially go unmanaged because there was insufficient integration of process activity with technology that would support the transparency of results. As the risk exposure increases due to the innovative approaches to business, there is a greater need for compliance transparency.

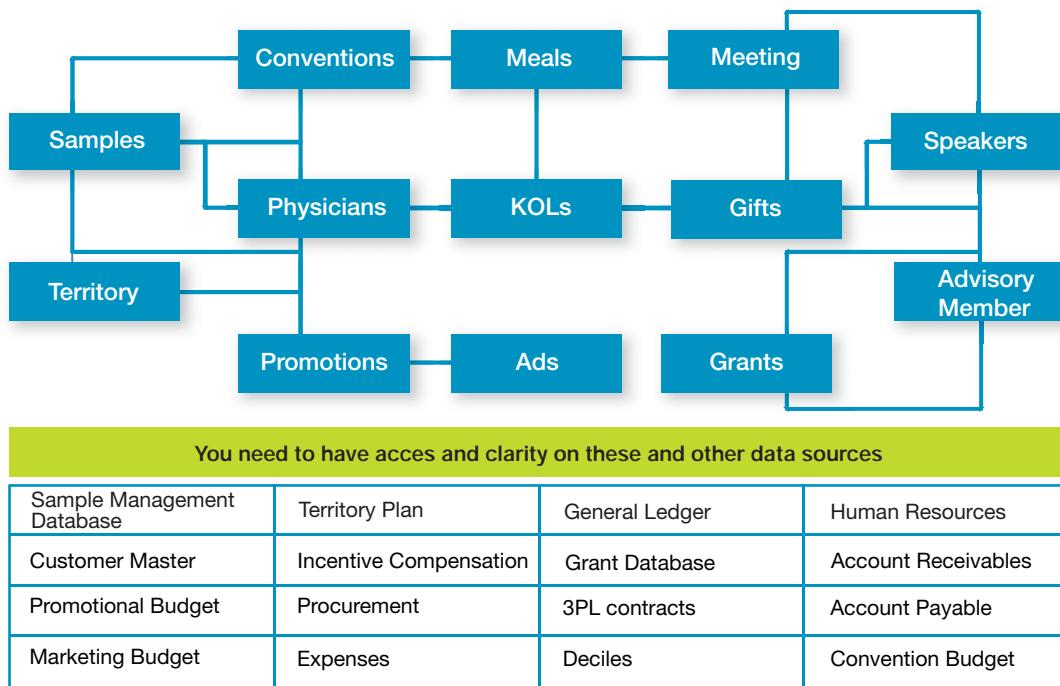
The second stage of the model is Transparency. Transparency is the ability to view and trace the results of compliance activities across the department, divisions, and across companies as these compliance regulations become international in scope. Manufacturing is a prime example of the need for transparency. Counterfeit drugs and sales of drugs on the black market have put the public at risk. In order to counteract the counterfeit market, regulations such as GS 1 and e-Pedigree are being pushed to require companies to be able to track drugs, lots, and shipments as they go through the point of creation through the point of distribution. This has placed

a significant burden on manufacturing processing as well as technology to satisfy these evolving requirements. Similarly, for many years the Pharmaceutical Drug Marketing Act (PDMA) has required that samples provided to licensed physicians be accompanied with a mandatory acceptance signature.

Within the last 5 to 7 years, individual states have required Life Science companies to disclose the amount of spend with each licensed “covered entity” from that state. This requires companies to track the actual dollar amounts and/or in kind transfer of value to a physician or institute that could influence the prescription and/or sale of drugs or devices. This requirement, called HCP Aggregate Spend, has significantly increased the need to establish and provide total transparency to major portions of its financial and budgeting information. The HCP Aggregate Spend and Medicaid/Medicare reporting has resulted in the need to make major investments in IT to be able to adhere to these requirements.

The challenge and inability to easily provide and sustain the compliance transparency has been due to several factors. First, many transactional systems were not designed to support the collection and reporting of the types of data needed for this transparency. Second, for many companies, the functions that support the reporting needs actually reside in separate and disparate systems.

Figure 14: Sample Sources for Aggregate Spend Reporting



The spend associated with the “covered entities” resides in many different systems and at various levels. Being able to provide this level of transparency has created a significant challenge to the companies that must meet this reporting requirement. However, there is a more severe problem with compliance transparency and that is “traceability.”

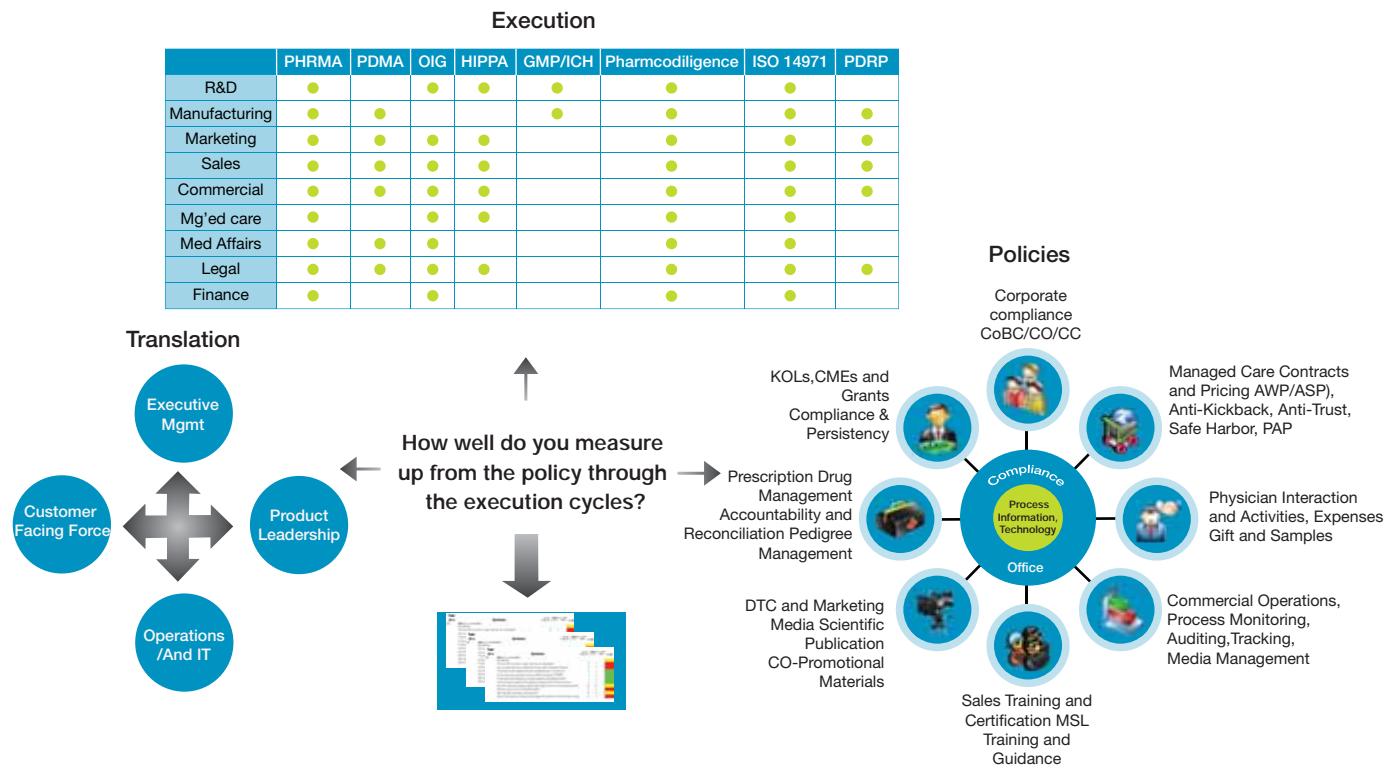
Traceability is the third stage in the pyramid of maturing compliance. Traceability has to do with the ability to consistently and accurately trace every transaction that is a part of satisfying a regulatory need. The challenge of being able to perform this task has been the

inability to intimately tie the business and compliance policies, procedures, and ultimately the Standard Operating Procedures (SOPs) to the supporting underlying technology. As is demonstrated in Figure 14, there is difficulty in accurately tying the interpretation of SOPs to how they are tracked.

There is a challenge in being able to have supporting IT systems accurately track the transactions needed to be recovered to demonstrate an adherence to compliance requirements. Mainstream business systems are not currently designed to support the tracking of many of the compliance requirements.

As a result, there has been a need to create compliance systems and/or applications that are designed and responsible for the tracking of events and transactions related to compliance. The challenge is three-fold — first the compliance requirements need to be accurately translated to ensure proper adherence; second the requirements must be integrated into the business flow and processes otherwise they disrupt the normal course of business; and third the requirements must be accurately modeled in the supporting technology in order to demonstrate on a consistent basis the adherence to the requirements.

Figure 15: Execution Cycle from Policy to Deployment



Technology is the last stage of the maturity pyramid. As stated above, the dilemma has been to either “customize” complex systems such as ERPs to do the bidding of compliance or purchase additional systems to perform the work. Either approach has been traditionally expensive, disruptive to the business, and not very successful. However, in recent years there has been a migration towards a more unified approach to this dilemma. Two key perspectives are emerging in relationship to compliance. First, companies are recognizing that transparency which is a key element for compliance, can also be a competitive advantage as well. Second, much of the data needed to satisfy compliance requirements is similar to what the

business has been seeking for years, consolidated, integrated, and harmonized information about the business and customers. Some of the new technologies that are supporting innovative approaches to compliance are:

- Master Data Management (MDM) Systems – These repositories are designed to create and house the master record as it related to customer, product, vendors, and other critical data that needs to be consistent across the company
- Collaboration Tools – New technology such as MS Sharepoint or IBM Websphere provide the ability to view, access, and leverage structure and unstructured information with the business processes

- Intelligent Search Engine – A new technology that incorporates the ability to control actions of employees while providing some insights to trending behavior. For example, a rules engine can help in cases where marketing materials are being distributed to physicians and/or institutions prior to the minimum 30 day review by DDMAC

These are just some examples of evolving technologies that are not compliance specific but help to satisfy compliance needs while being an integral part of the overall IT architecture. These technologies will continue to play an important role in assisting companies maintain their adherence to compliance.

### Future Considerations

Many studies have shown that it is likely that the need for transparency in compliance will continue to increase.

The European community sees compliance regulations such as HCP Aggregate Spend to be part of the future of regulations.

Informational transparency is going to be a key aspect of the growth of Life Science companies and the partnerships they maintain. A mature compliance function and organization will have to continue to seek ways to integrate the compliance requirements with the business functions and ensure accurate tracking, auditing, and reporting. Many Life Science executives are counting on it.



## 3.6 From Software to Services

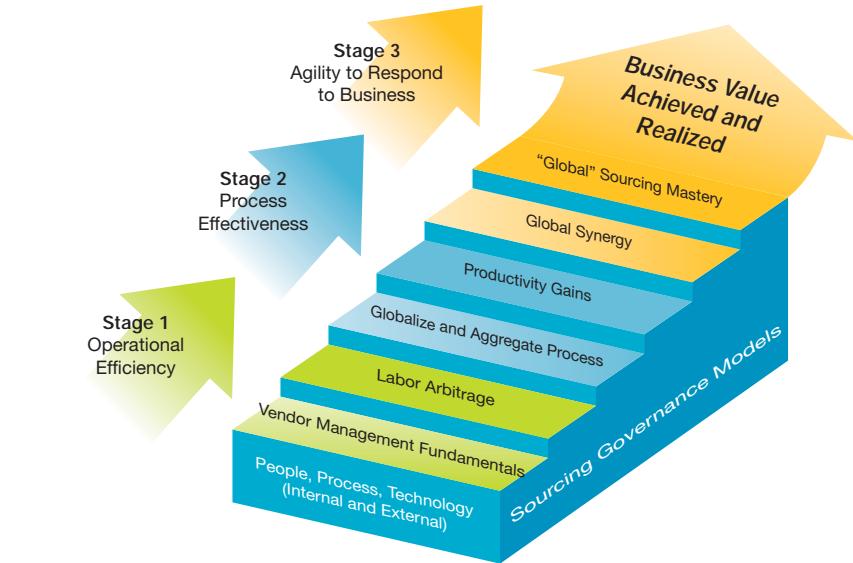


As increasing pressures are being placed on Pharma/Biotech firms due to patent erosion, decreased market share in the US and the global recession, organizations are now faced with moving more work offshore or to outsource new areas to close financial and skills gaps within their global firms.

- Now, newer models of outsourcing are focused on delivery innovation and business value (beyond the traditional cost + process + lean advantages).

In addition to business process outsourcing, Technology outsourcing has taken a turn where organizations are looking at next

Figure 16: Gartner's Global Sourcing Framework: The Journey of Globalization



### Trends in Outsourcing Models

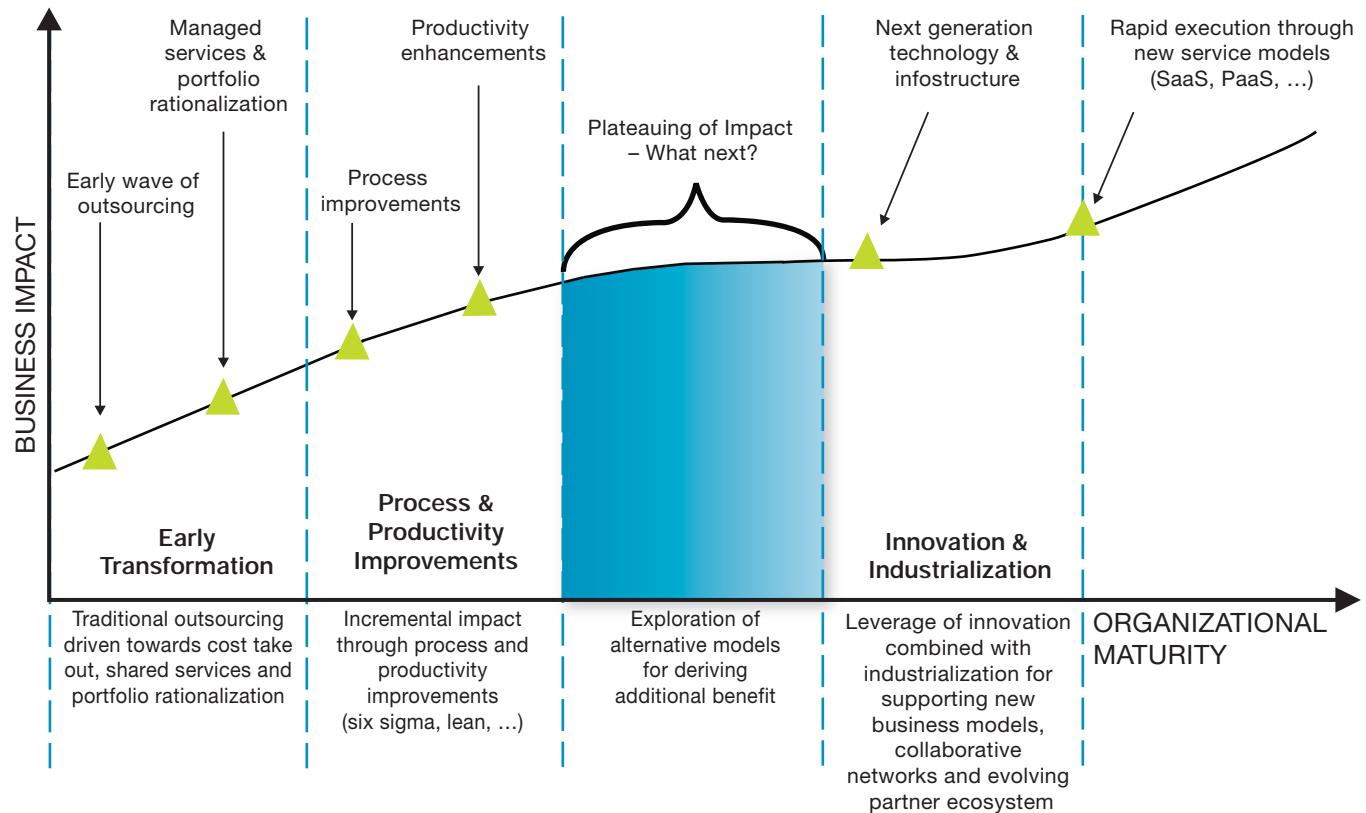
Organizations have gone from traditional outsourcing models to newer ones that are based on business benefits and value delivered.

- The first wave of outsourcing was focused on cost arbitrage to lower overall operating cost and eliminate on-site staff for IT support services.
- The second and subsequent waves of outsourcing focused on productivity improvements. Many organizations have moved to BPO models of the back office financial and transactional services with delivery centers in multiple regions for global organizations.

generation technology infrastructure and business oriented solutions delivered through different services models such as SaaS and PaaS. Key technology enablers for the new wave of outsourcing and underlying trends include:

- Fully connected networks (corporate, WiFi, personal) with an ever increasing array of devices from laptops, mobile devices and personal equipments
- Cloud computing and ability to rapidly create value based networks either in a private, public or hybrid space
- Availability of high end and scalable infrastructure services (for instance, Amazon Web Services,...) without the need to host anything internally

Figure 17: Emerging Outsourcing Model: Journey Towards Leveraging Innovation



### Assessing Stakeholder Impact

As organizations move into the outsourcing world, they will encounter many new challenges that they will need to overcome and address while building their strategy. They are not monumental changes but a different way of looking at how to perform their business. Key to these new initiatives is a rigorous change management effort as the staff's livelihood is impacted when offshoring initiatives begin within a firm.

Taking a step back and looking at the bigger picture of the effort will allow organizations to be much more successful in building a partnership with the provider and gaining the confidence of their employees as the initiative rolls out.

Figure 18: Key Challenges to Offshoring/Outsourcing Strategies

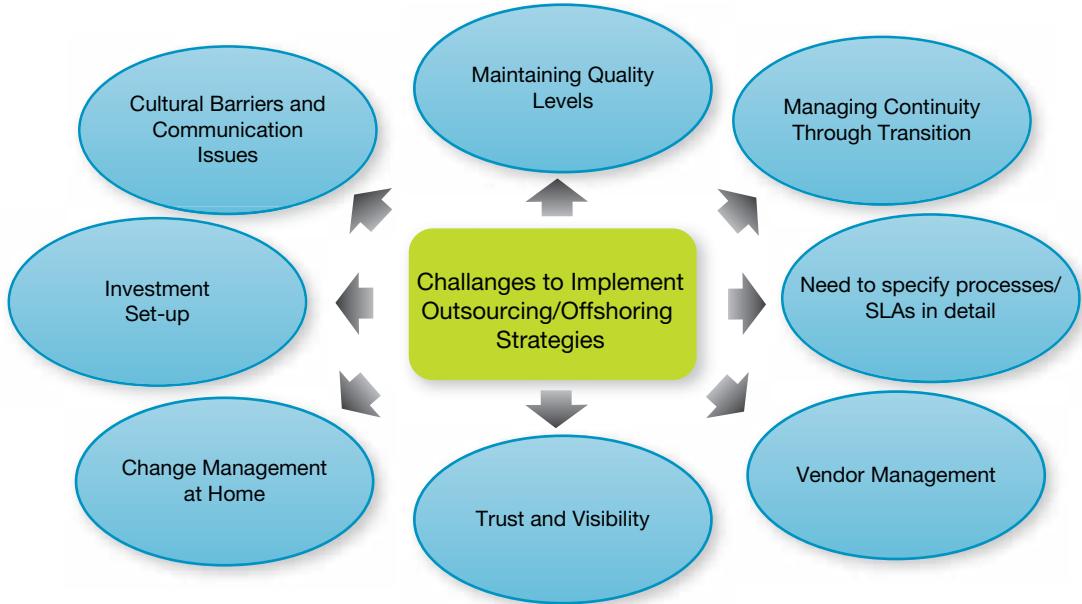


Figure 19: Key Areas to be Considered During the Process

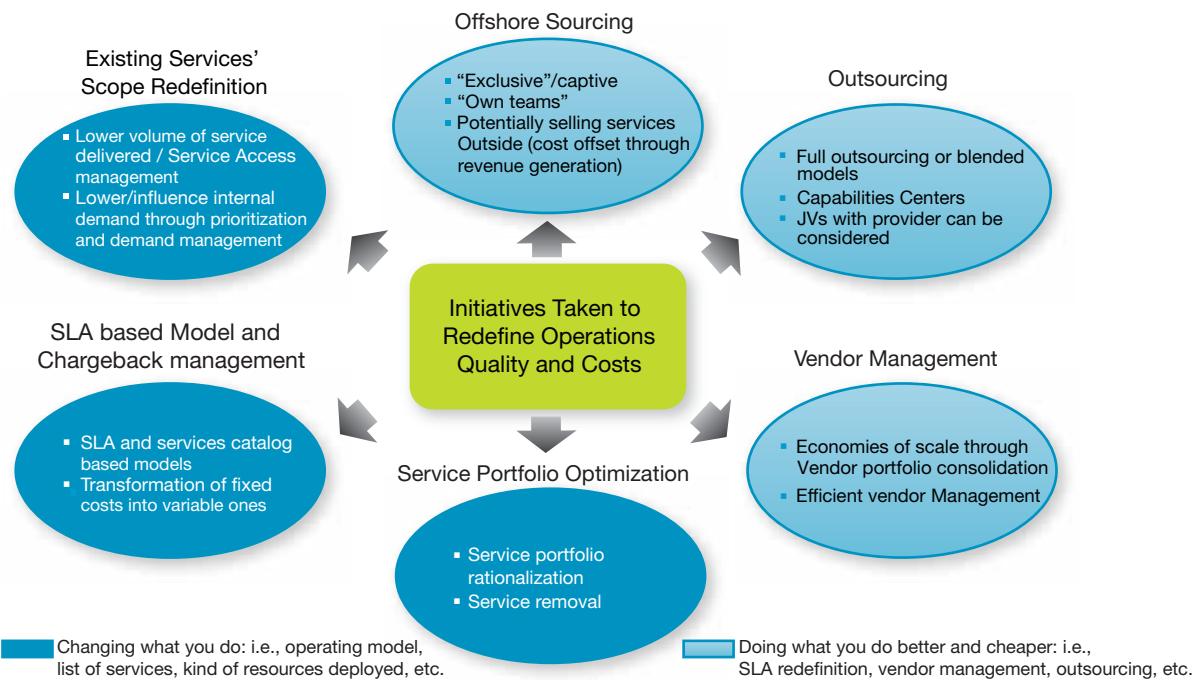
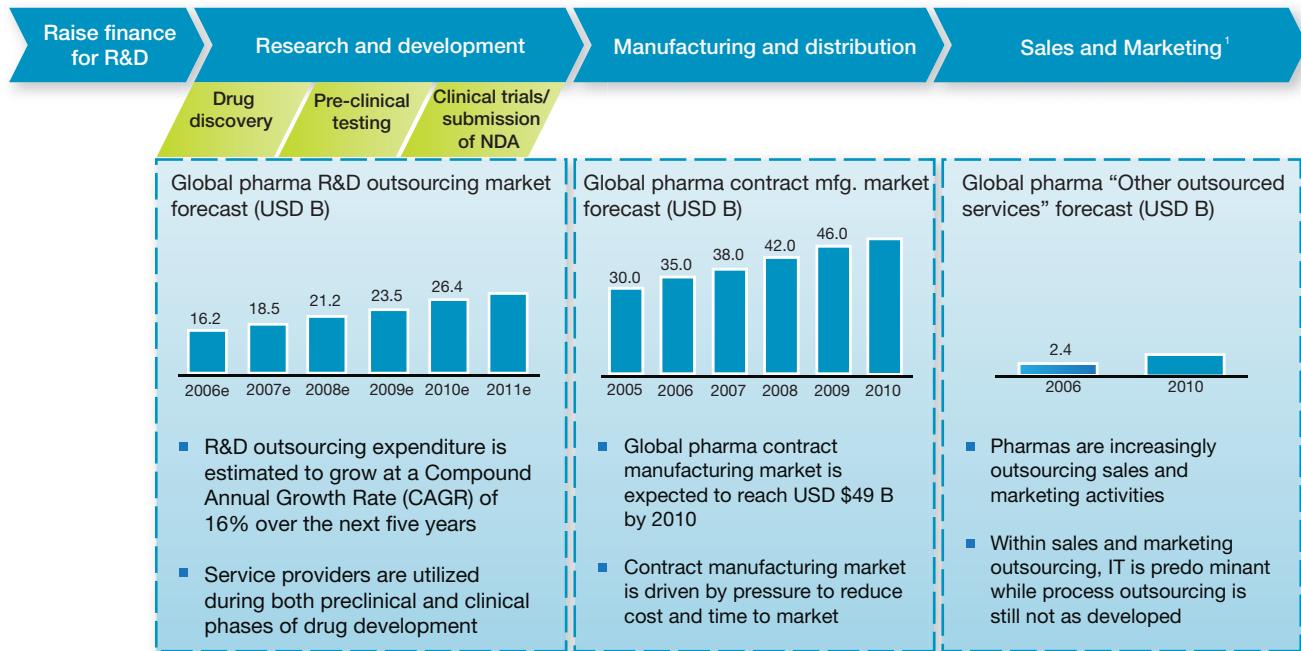


Figure 20: Outsourcing Opportunities Across the Value Chain



1. Other services can be broadly classified into finance and accounting, information technology, and various support services including sales and marketing, customer relationship management, human resources, and procurement.

#### Source:

Penn Pharma, 2009: "Trends in Pharmaceutical R&D Outsourcing"; Applied Clinical Trials Online, 2008: "Outsourcing's Evolution from Commodity to Partner"; Outsourcing-pharma.com, 2007: "R&D outsourcing set to climb"

In the past, the Life Science industry has been more conservative than other sectors moving into the outsourcing world, but now organizations are seeing the power and competitive advantages of an outsourced model. Research & Development and Manufacturing & Distribution have led the way and now Sales & Marketing is moving into a mainstream outsourced model as noted below:

#### The Road Ahead

With the economy improving, and technology spending expected to rise, organizations are utilizing outsourced models to better position themselves to

have greater flexibility in their core initiatives while allowing them to be ready for the new economical environments ahead.

Among the highlights from Morrison & Foerster's Global Sourcing Trends in 2010 report are the following:

- Rates of outsourcing pricing declines are expected to slow in the year ahead.
- Sourcing Providers are not likely to be as accommodating as they were last year
- Market activity in should be busier, as many outsourcing projects were put on hold

▪ There is likely to be a continuation of shorter deals, shorter procurement processes and an emphasis on "making things work rather than engaging in complex strategies."

- Do-it-yourself sourcing by internal teams will continue, with less reliance on advisory firms while favoring incumbent suppliers
- There will be renewed emphasis on shared services, with competitors cooperating on certain sourcing platforms to reduce costs in shared cost areas

## Summary

As most organizations have learned and new ones learn each year, the outsourcing journey is not a short term effort, but a way of doing business which is refined both on the client and provider's sides as productivity gains and lessons learned chart new direction for them.

The journey is not always easy at first until the two organizations learn the key cultural drivers of their business and how to obtain overall business satisfaction. Many organizations find this settling in period to last up to a year until both sides are comfortable with their new operating models.

As noted in this report, business impact is the greatest when operational model is adopted and the outsourcing effort becomes a part of day to day operations with the outsourcing teams being treated as members of the organizations rather than a 3rd party provider. Many organizations leverage this seamless operational model to gain innovational competitiveness against their peers.



## 3.7 The Journey to the Cloud - An Overview

Cloud Computing is regarded by many as the new revolution in the IT industry. A significant buzz has been generated by analysts and media, reporting multi-billion dollar market developments. The major players of the IT Industry (IBM, Microsoft, Sun, HP, Cisco, etc.) pure Internet players (Google, Yahoo, Amazon, Salesforce, etc.) as well as telecom operators have developed their "Cloud" offering. They also have developed multiple alliances to cover the whole landscape and value chain when required. The hype that continues to surround the Cloud means today's CIO faces a dilemma. To get deployment wrong could be disastrous, but to do nothing may risk becoming non-competitive. The Life Sciences sector, competition dictates IT agility but regulation and risk have to be considered. There are already many documented cases of the use of Cloud computing by major Life Sciences firms.

The majority of corporations are looking closely at Cloud computing with the object of improving the efficiency of their IT operations. Within their IT organizations, the predominant view of Cloud is a technological one – Cloud is simply a set of next generation technologies that promise cheaper and better IT.

At the same time, business users are being sold a fundamentally different view of the business advantages of Cloud by analysts and the trade press, and consequently they expect it to be a magic silver bullet – one that significantly cuts costs whilst simultaneously fixing all their existing issues with their in-house IT organization, all to be completed within the next sixty days and without effort, thus rapidly creating business nirvana as a result.

Successful Cloud adopters are the ones who focus on the business advantage or transformation first. They understand how that advantage is going to translate to top-line growth or bottom-line savings quickly, and they have understood the risks inherent in their adoption. They have looked at their overall business use of Cloud and have decided on the specific approaches and focus. And they have considered the totality of their Cloud usage and determined it is both manageable and consistent

### A large but fragmented market

Cloud computing is known now as the fifth generation of computing models after mainframe, personal computer, client-server, and the web.

Cloud computing market development has reached a first phase where all leading players have positioned themselves on this promising market. The first significant alliances and massive investments in new data centers have emerged to cover the whole scope of services and to create critical mass on a fragmented market. The market is also reaching a first segmentation stage with 3 types of services:

### Public Cloud, Private Cloud or Hybrid Cloud?

We are seeing already that the two accepted models of Cloud service provision, private (dedicated to one organization) and public (shared by many), are only parts of a more complex answer. And organizations will not simply use either Software-as-a-Service or infrastructure services, but each will form part of the solution. Yet another option available today is virtual private Clouds like the VPC offering from Amazon. These offer a

way to segregate resources within a private Cloud from the public Cloud. Local infrastructure within the corporate firewall can be extended into the virtual private Cloud via a secure tunnel. This enables extending internal infrastructure to Cloud infrastructure on demand and tearing it down when the resources are not needed.

It therefore looks likely that a combination or 'Hybrid Cloud' will become the model of choice. By adopting a hybrid strategy, advantages of economies of scale, flexibility and agility of public Cloud offerings can be leveraged while a private Cloud can be used for mission critical and secure environments.

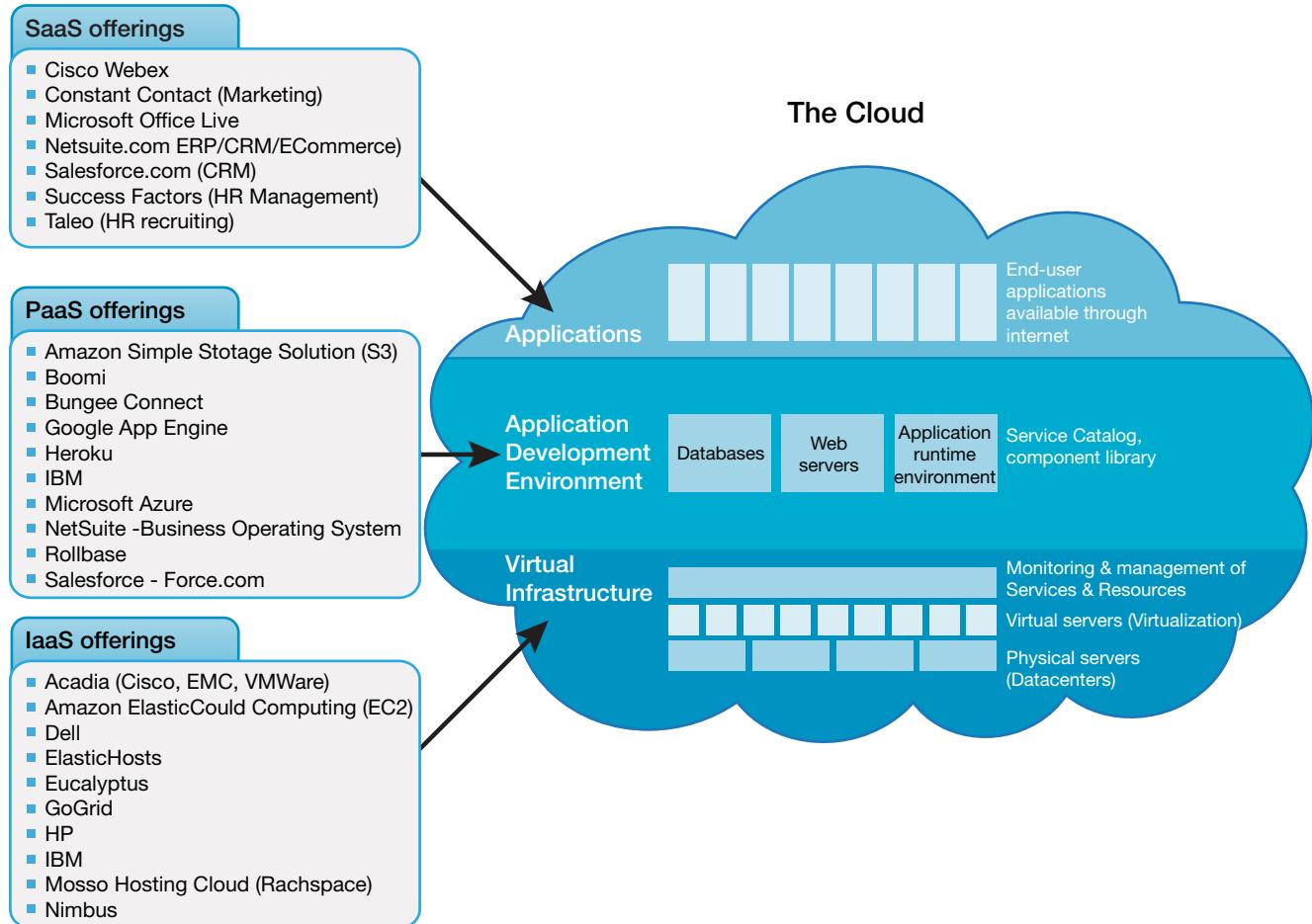
### A new business model for the whole IT value chain

Cloud computing has a major impact on the whole IT ecosystem, from hardware vendors to software publishers, web players, telecom operators and system integrators.

Cloud computing is driving an unprecedented business model change in the IT industry. While most of the industry was built on a Capex model where clients or players were massively investing upfront, the Cloud model is based on an Opex model with faster time-to-benefits. This change in business

Figure 21: Landscape of the Offerings Available on the Market

## Examples of offerings



model will affect all players, but especially the software publishers, hardware vendors and systems integrators that need to adapt.

Cloud service vendors, potentially hardware manufacturers and software firms, are now emerging as significant players in the IT Value Chain. However, companies should consider that shifting

the business case from traditional IT model to a Cloud based model triggers two main changes: nature of costs differ and hidden costs exist. For instance, software costs may no longer be relevant and are replaced by license fees or even transaction fees. (see figure 22)

Transition costs and project costs hide different kinds of new costs, such as

interoperability with legacy system updates, legal and regulatory validation issues, support adjustment and even trainings for the IT resources to cope with their new assignments. A company's net added value depends on how well it will foresee and manage these new costs.

The following points will therefore require careful attention when selecting applications to be migrated to the Clouds:

### Security and Privacy of data

Security and equally important data privacy are paramount for the Health Sciences. In public Cloud computing, data is stored anywhere (certainly not inside the firewall of the client company or institution). Security measures and guarantees are required and Cloud computing service providers should be able to provide them. However, users of Cloud services should not either assume that security is sacrificed by moving into the Cloud, for instance, some Cloud companies are providing a unique level of data security, from logical to physical intrusion, where each data set is split,

encrypted and stored in several data centers throughout the world. These concerns can be mitigated by using a hybrid model to a large extent.

### Regulations

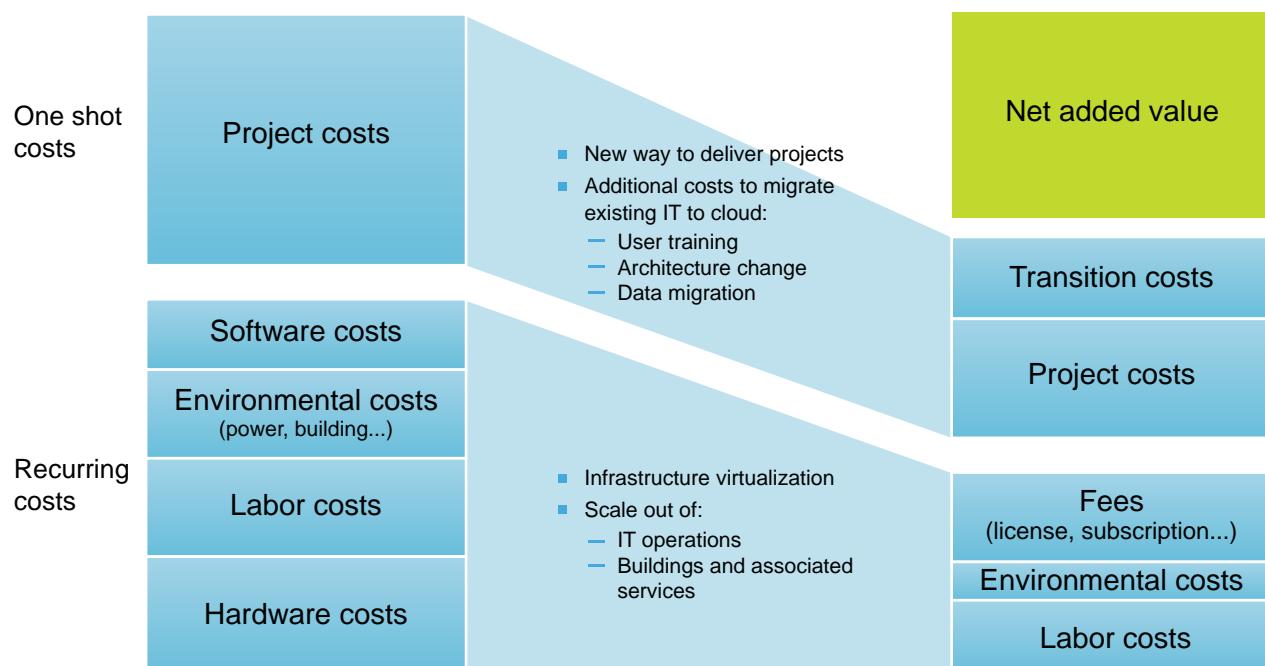
Health Sciences is no stranger to strict regulations. Many workloads and data have to comply with mandated regulations like Part 11, HIPAA, System Validation, etc. Additional regulations prohibit the storage of data abroad or in certain countries. The level of complexity of such issues has significantly increased with the development of national and multi-national constraints. With Cloud computing (at least in its public form) where data can be stored anywhere, Cloud providers and their clients will have to make sure they still are compliant.

Several small Cloud providers have started offering full stack of Cloud services specialized for Health Sciences. Careful design of a Hybrid model can also alleviate security, privacy and regulatory concerns.

### Integration

Cloud computing has a significant impact on IT architecture. Although the adoption and roll-out of Cloud applications is faster, these applications still have to be integrated with the rest of the technology architecture. Besides, Interoperability standards between Clouds are still missing. The availability of application architecture and of middleware solutions can be a strong help in making the right decisions and deploying quickly.

Figure 22: Landscape of Costs



### **Control over changes**

Software as a Service speeds up the roll-out of new systems and versions without a significant and complex administration task; new functionalities can be deployed instantly to all users. However, this can lead to a lack of control over the changes that could impact the user's experience or the interoperability with the rest of the information systems.

### **Performance**

Managing performance on the Cloud with multiple clients and users on the same architecture can be a complex challenge. Cloud Computing providers usually perform according to agreed service levels. Most providers deliver periodical reports, but SLA failure penalties might be insufficiently deterrent. Besides, in the event of ongoing bad performance, the client will have to rely on the supplier's ability to improve performances and operations.

### **Summary**

The Cloud is here to stay. The benefits it can offer business are, quite simply, too compelling. Therefore the important thinking being done in the marketplace now is around mechanisms for adoption. While phrases like 'plug and play' or 'pay as you go' are easy enough to say, they are much harder to deliver in a robust and holistic IT framework. Deciding on a Cloud strategy and putting in place the process and governance to control its use is something that can only be done effectively with the business. But the starting point of that discussion should be very clear: the IT function is there to enable the business to get the benefits of the Cloud.

# 4. Glossary

- **Bioinformatics:** Bioinformatics is the application of statistics and computer science to the field of molecular biology.
- **Biologics:** Complex drugs, vaccines or antitoxins that are made from a living organism, or from products of a living organism.
- **Business Activity Monitoring (BAM):** Enterprise solution primarily intended to provide a real-time summary of business activities to operations managers and upper management. Key processes include, but not limited, to the aggregation, analysis, and presentation of real-time information about activities inside organizations and involving customers and partners.
- **BPO:** Business process outsourcing (BPO) is a subset of outsourcing that involves the contracting of the operations and responsibilities of specific business functions (or processes) to a third-party service provider.
- **CAGR:** Compound Annual Growth Rate.
- **CEO:** A chief executive officer (CEO, American English), managing director (MD, British English), or chief executive is the highest-ranking corporate officer (executive) or administrator in charge of total management of an organization.
- **cGMP:** Current Good Manufacturing Processes.
- **Cheminformatics:** Cheminformatics is the use of computer and informational techniques, applied to a range of problems in the field of chemistry.
- **CIO:** The chief information officer, or information technology (IT) director, is a job title commonly given to the most senior executive in an enterprise responsible for the information technology and computer systems that support enterprise goals.
- **Closed Loop Marketing (CLM):** an organized process of program planning, execution, feedback/ tracking and analysis. These activities form a “loop” so that the resulting analysis informs subsequent program planning, thereby creating a continuous improvement process.
- **Complex Event Processing (CEP):** Consists in processing many events happening across all the layers of an organization, identifying the most meaningful events, analyzing their impact, and taking subsequent action in real time.
- **CRM (Customer Relationship Management):** is a widely implemented strategy for managing a company's interactions with customers, clients and sales prospects. It involves using technology to organize, automate, and synchronize business processes—principally sales activities, but also those for marketing, customer service, and technical support.
- **CROs:** Contract Research Organizations.
- **CTD:** Common Technical Document (pharma to agency transfer of regulatory information.)
- **Datamonitor:** An international company originating in the United Kingdom which publishes market research on a number of different industries.
- **DDMAC:** Division of Drug Marketing, Advertising, and Communication.
- **DTC:** Direct to Consumer.
- **EHR (Electronic Health Records):** The aggregate electronic record of health-related information on an individual that is created and gathered cumulatively across more than one health care organization and is managed and consulted by licensed clinicians and staff involved in the individual's health and care.
- **EMR (Electronic Medical Records):** The electronic record of healthrelated information on an individual that is created, gathered, managed, and consulted by licensed clinicians and staff from a single organization who are involved in the individual's health and care
- **Ensemblins:** Therapeutic chemical compounds, in the range of molecular weight from approximately 500 Daltons to 2000 Daltons
- **ePedigree:** An pedigree (sometimes referred to as e-pedigree or electronic pedigree) is an electronic document which satisfies a pedigree requirement. The primary purpose of an pedigree is to protect consumers from contaminated medicine or counterfeit drugs.
- **ERP (Enterprise resource planning):** Integrates internal and external management information across an entire organization, embracing finance/accounting, manufacturing, sales and service, etc. ERP systems automate this activity with an integrated software application. Its purpose is to facilitate the flow of information between all business functions inside the boundaries of the organization and manage the connections to outside stakeholders.
- **FDA:** The Food and Drug Administration (FDA or USFDA) is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments.
- **FGM (Fractal Genomics Modeling):** It is a technology that is designed to study complex networks, such as genes inside a living organism. FGM uses a new

approach toward modeling network behavior to rapidly generate diagrams and software simulations that facilitate prediction and analysis.

- **GeneChip:** The array of cells makes it possible to carry out a very large number of genetic tests on a sample at one time.
- **GS:** Government Services.
- **GxP:** Is a general term for Good Practice quality guidelines and regulations
- **HCPs:** Health Care Professionals
- **HIPAA:** Health Insurance Portability and Accountability Act.
- **HIV:** Human Immunodeficiency Virus.
- **KOL (Key Opinion Leaders):** Are physicians who influence their peers' medical practice, including but not limited to prescribing behavior. (Source: Terry Nugent, Director of Marketing, Medical Marketing Service, Inc. (MMS)). Pharmaceutical companies generally engage key opinion leaders early in the drug development process to provide advocacy activity and key marketing feedback. Article: "Developing Win-Win Key Opinion Leader Relationships," Pharma Marketing News, Vol. 2, #10; REPRINT #210-01.
- **MDM:** Master Data Management Systems.
- **MMS:** Medical Marketing Service.
- **NDA:** New Drug Application.
- **NIH:** National Institutes of Health: It is an agency of the United States Department of Health and Human Services and is the primary agency of the United States government responsible for biomedical and health-related research.
- **OIG:** Office of the Inspector General.
- **Ontology:** An ontology is a description (like a formal specification of a program) of the

concepts and relationships that can exist for an agent or a community of agents.

- **PAAS:** Platform as a Service (PaaS) is the delivery of a computing platform and solution stack as a service. PaaS offerings facilitate deployment of applications without the cost and complexity of buying and managing the underlying hardware and software and provisioning hosting capabilities, providing all of the facilities required to support the complete lifecycle of building and delivering web applications and services entirely available from the Internet.
- **Patient Relationship Management (PRM):** The practice of developing and maintaining a patient relationship by Healthcare professionals, stakeholders and organizations
- **PDA:** A personal digital assistant (PDA), also known as a palmtop computer, or personal data assistant, is a mobile device that functions as a personal information manager.
- **PDMA:** Pharmaceutical Drug Marketing Act
- **Pharmacovigilance:** (abbreviated PV or PhV) is the pharmacological science relating to the detection, assessment, understanding and prevention of adverse effects, particularly long term and short term side effects of medicines.
- **PHR:** A personal health record or PHR is typically a health record that is initiated and maintained by an individual. An ideal PHR would provide a complete and accurate summary of the health and medical history of an individual by gathering data from many sources and making this information accessible online to anyone who has the necessary electronic credentials to view the information.
- **PhRMA:** The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country's leading pharmaceutical research and biotechnology companies.
- **Pharmacogenetic:** The study of genetic factors that influence an organism's reaction to a drug.
- **PMA:** President Management Agenda.
- **POA:** Plan of Action (Marketing.)
- **PRM:** Patient Relationship Management.
- **TQM (Total quality Management):** Is an integrative philosophy of management for continuously improving the quality of products and processes.
- **REMS:** Risk Evaluation and Mitigation Strategy.
- **RNAi:** RNA (Ribo Nucleic Acid) interference: RNA interference refers to the inhibition of gene expression by small double-stranded RNA molecules.
- **ROI:** Return On Investment.
- **SaaS (Software as a service):** (SaaS, typically pronounced [sæs]), sometimes referred to as "software on demand," is software that is deployed over the internet and/or is deployed to run behind a firewall on a local area network or personal computer.
- **SFA:** Sales Force Automation.
- **SLA:** Service Level Agreement.
- **Social Networks:** Networks like Face Book and LinkedIn that enables social bi-directional conversations and relationships.
- **Social Technology:** Technology that enables social bi-directional conversations and relationships.
- **SOP:** Standard Operating Procedures.
- **STDs:** Sexually transmitted disease.
- **SVM:** Support Vector Machines: These are a set of related supervised learning methods that analyze data and recognize

patterns, used for classification and regression analysis.

- **TCO (Total cost of ownership):** is a financial estimate whose purpose is to help consumers and enterprise managers determine direct and indirect costs of a product or system. It is a management accounting concept that can be used in full cost accounting or even ecological economics where it includes social costs.
- **Theranostics:** The process of diagnostic therapy for individual patients - to test them for possible reaction to taking a new medication and to tailor a treatment for them based on the test results
- **TIBCO:** Headquartered in Palo Alto, California, TIBCO Software Inc. (NASDAQ:TIBX) provides enterprise software that helps companies achieve service-oriented architecture (SOA) and business process management (BPM) success.
- **21 CFR part 11:** Title 21 CFR Part 11 of the Code of Federal Regulations deals with the Food and Drug Administration (FDA) guidelines on electronic records and electronic signatures in the United States.



# 5. Team

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