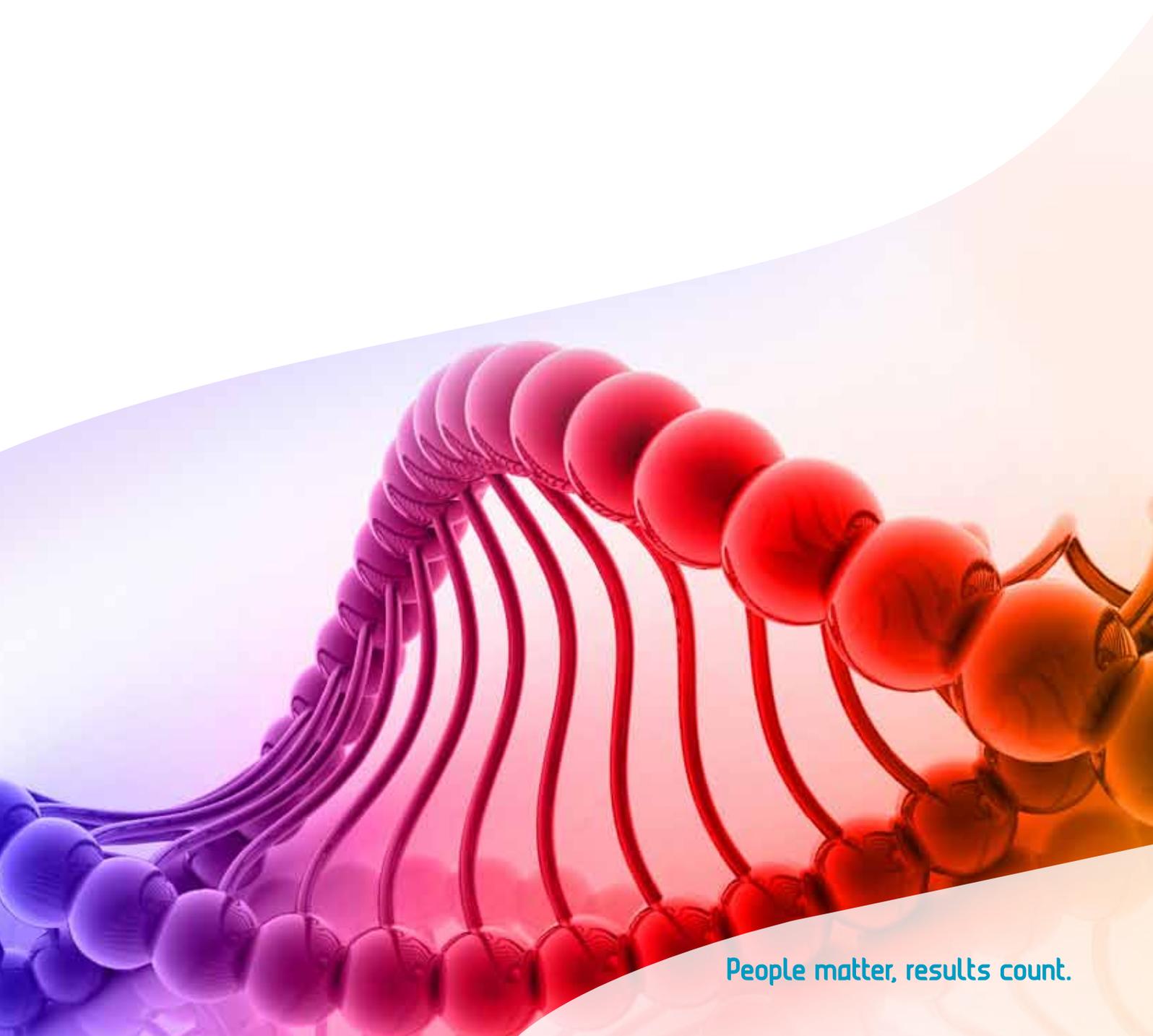


Perspectives on Life Sciences

Spring 2011



People matter, results count.

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Foreword



The new year has brought an exceptional number of questions and challenges for the life sciences sector. This Spring 2011 edition of Perspectives on Life Sciences describes Capgemini's latest thinking and leading-edge research on several of those issues.

As always, our aim is to help you position your company to respond to change swiftly and in ways that will secure competitive advantage.

For example, one of the questions that clients most often ask at the moment is "What impact will the NHS reforms have on pharmaceutical companies?" We are delighted to include an article in which Mike Sobanja, Chief Executive of the NHS Alliance, shares his stimulating views on this topic.

The shrinking revenue contribution from the primary care market is another headache for many clients, and so we suggest some strategies for turning the situation to advantage. We also investigate how the procurement function can start making a real contribution to life science companies' strategic objectives: our 2011 global Chief Procurement Officer survey provides valuable insights into best practice from other sectors that are further along this road.

The Autumn 2010 edition prompted a number of readers to ask us for a better understanding of what Capgemini can do for their companies, so in this issue we're providing an overview of our market-leading services to life sciences. We also provide an in-depth look at specific techniques like closed loop marketing and business model innovation – the latter illustrated with case studies from Apple and the Terrence Higgins Trust. In addition, we take a look at the uses and abuses of the business case: a topic that isn't yet quite as dear to some companies' hearts as we feel it should be.

We have some exciting announcements on the partnership front, too. A new alliance between Novo Oncology Associates (NOA) and Capgemini Consulting will help clients succeed in the high-risk, high-reward area of oncology clinical development. We preview the results of a collaborative research project by Capgemini Consultancy and the MIT's Centre for Digital Business. This path-breaking study should shortly tell us a lot more about the question of how "bricks and mortar" companies can manage and benefit from digital technologies.

We are confident you'll find this edition of Perspectives an informative and thought-provoking read. As always, we look forward to hearing any feedback that you would like to share, and will use it to shape future editions.

Tim Dulle
 Head of Life Sciences
 Capgemini Consulting UK

Synopsis of articles

NHS reforms

By Mike Sobanja, Chief Executive, NHS Alliance, and Mark Holliday

At the end of the consultation period, it is clear that the government's NHS reforms are going ahead. Prescribing will be more tightly controlled than ever as a result. Other changes impacting the pharma industry will include the fact that responsibility for public health is increasingly with local government, so pharma needs to work with new stakeholders; the introduction of commissioning consortia which will further alter the stakeholder landscape; and the boost to "patient power". To get ready for implementation, the industry needs to adjust its commercial model (doing more and better Key Account Management) and to review its talent management.

Primary care

By Suday Karkera

The past decade has seen a substantial slowdown in the primary care drug market because of patent expiries, the advent of generics, a reduction in launches and changes in reimbursement. Companies have adopted various measures to protect the important revenue from primary care: life cycle management, expansion/diversification into new geographies and populations, organisational restructuring and targeting of patients. These have succeeded to a degree, but with increasing commoditisation of products and an emphasis on rewarding outcomes, companies urgently need to move towards a collaborative, outcome-focused model that supports healthcare delivery and health management from diagnosis to long-term care.

Transforming oncology clinical development

By Carmen Allegra, MD, Novo Oncology Associates, and Keith Morris

There is intensive drug development activity in oncology, and the potential rewards are high. However, the already substantial costs and risks are increasing as a result of factors including the trend towards targeted therapies, complexity of establishing acceptable endpoints, use of combination therapies and pressures from payers and patients. To manage costs and risks better, companies can take steps like improving the way they make strategic decisions and use intermediate endpoints. Above all, they need to collaborate with stakeholders such as regulators, payers and patient groups. Novo Oncology Associates (NOA) and Capgemini Consulting have set up an alliance to facilitate these initiatives.

Chief Procurement Officer survey

By Hamish McKechnie-Sharma and Matthew Whitson

The financial challenges faced by pharma over the past two to three years have been well documented. Until now the reaction of the industry's procurement professionals has been to focus on managing indirect costs through price negotiations. We believe that pharma should follow the lead from industries with more mature procurement functions which (as our recent survey shows) are already shifting procurement towards a more strategic role, building value-creating partnerships with suppliers (as opposed to simply driving down price), and thinking about commodities in new ways.

Closed Loop Marketing

By Mark Holliday

True Closed Loop Marketing is an ideal way to achieve customer centricity, and by doing so overcome some of the challenges faced by the pharma industry such as reduced access. It uses information from customer interactions to derive insights that ensure the right messages are delivered to the right customers via the right channels. Some industries have achieved this ideal, but not, as yet, most life sciences companies, which have (for example) rolled out tablet PCs to the sales force, but for e-detailing purposes only. To close the loop, companies need to undertake several interlinked steps that will bring their whole organisation, and all its channels and customer groups, into the loop.

Business cases

By Matthew Whitson and Tim Dulle

A business case should form the objective basis on which decisions are made. However, many companies just use it to rubber-stamp a decision that has already been taken, an approach that has no value. It is important not to take a “one size fits all” approach, but to recognise the different tools that sit under the heading of business case (from a benefits case to a high-level business case to a detailed business case), and to select the appropriate tool for the specific situation or decision. Rational adding up of numbers is only one aspect: attention to the emotional and political dimensions of change and decision-making will ensure success for both the business case and the ensuing initiative.

Business model innovation

By Mark Preston and Tim Dulle

A difficult and increasingly complex business environment makes regular review and redefinition of the business model vital. Companies fail to reinvent their business models for three main reasons: they underestimate the relevance of doing so, they try but fail to execute a change, or they focus on the wrong objectives for the new model. A range of approaches to evolving the model are proving successful; most involve working more closely with customers and partners, for example through crowdsourcing.

Case study: Terrence Higgins Trust

By Vishali Jivan

Capgemini’s Accelerated Solutions Environment (ASE) has helped the Trust to validate a new business model and build a robust implementation plan.

Case study: Apple Inc

By Oliver Schoen

The recent history of Apple is an object lesson in successful business model innovation.

Preview: digital transformation study

By Mark Holliday

Capgemini Consulting and Massachusetts Institute of Technology (MIT)’s Center for Digital Business are investigating how companies are achieving radical improvements with digital technologies.

NHS reforms

What next for the pharmaceutical industry? Mike Sobanja, Chief Executive, NHS Alliance shares his views with Capgemini's Mark Holliday.

With the consultation at an end, it is evident that this train isn't stopping.

In July 2010 Andrew Lansley announced the government's ambitious plans to reform the NHS in England in the white paper Equity and excellence: Liberating the NHS. Since then there has been vigorous debate, with numerous groups and interested bodies having their say through the consultation process. With the consultation at an end, it is evident that this train isn't stopping: with the Bill's introduction into parliament on 19th January 2011 the government's plans are well on their way to being fully implemented.

In this article we examine some of the more significant aspects of the reforms, and the potential impact on the pharma industry.

Individual or guideline-driven prescribing?

Shall we see a return to the "good old days", with individual prescribers making the decisions, or will it still be a case of group decision-making in the form of guidelines, protocols and formularies?

Alas for GPs and the pharma industry, the "good old days" are just that. It is likely that prescribing will be more guideline- and formulary-driven, with a greater emphasis on decision-making at a national level and through the GP Commissioning Consortia (GPCC) at a local level. In fact, the freedom of the individual to prescribe will decrease overall, though this will vary by therapy area, with primary care diseases, such as hypertension, being more tightly controlled compared to more specialist disease areas.

Key elements of the reforms

The broad initiatives are designed to meet the financial challenges faced by the NHS, and specifically to save the required £20bn. They can be divided into three main groups:

- More focus on patient-centred care, and moving commissioning and (especially) clinical decision-making closer to the patient. As the white paper puts it, "no decision about me without me". For example, patients needing hospital treatment will no longer have to go to their local NHS facility: they are free to choose a different one in consultation with their GP.
- Big focus on outcomes and quality standards, not process. The government's objectives are to reduce mortality and morbidity, increase safety, and improve patient experience and outcomes for all. The Labour government had reducing waiting times as a key target, whereas the coalition government is focusing on the outcome, irrespective of how long you have to wait. As a result, we have already seen a small increase in waiting times from 18 to 21 weeks.
- Better services to patients in both outcomes and the overall patient experience.

Efficiency must also be increased, as the NHS has to cope with greater demand with little extra money. Opening the health service to market competition is a key strategy to help achieve this efficiency improvement.

Impact on the pharmaceutical industry

It's fair to say that not all 143 clauses within the white paper will have an impact on the industry. However, where there is an impact it will be significant and will be felt across the whole industry. Here we look at three areas of impact: the shift of accountability for public health, the emergence of GPCC, and the increasing influence of the patient.

The shift of accountability for public health from the NHS to local government will see the introduction of a whole new set of customers and stakeholders. If we didn't think the stakeholder landscape was changing enough through traditional clinical developments, the white paper introduces a whole new set of customers in local government. Thus politicians, locally-elected councillors, chief executives and directors of social services amongst others will become pharma industry customers. Therefore, the industry will need to identify, understand and map this new local government customer base, in the same way it does with other key stakeholder groups.

This area of public health is increasingly important, as several studies and reports on health improvement illustrate. It has been widely reported that over the last 60 years around 50% of health improvement gain is attributable to health care and 50% to the wider determinants of health, including environment, education, housing and personal lifestyle choices.

Asthma/ COPD (Chronic Obstructive Pulmonary Disease) is just one therapy area which illustrates this point. An example of numerous public health initiatives in this area is CHARISMA (Children's Health in Asthma from the Wrexham Public Health Team), which conducted research with the aim of improving health status through modifying accommodation (i.e. housing). On this project the Betsi Cadwaladr NHS Trust collaborated with Wrexham Public Health Team, Wrexham

County Borough Council and colleagues from academia. This illustrates the range of stakeholders with whom pharma companies will increasingly need to engage.

The development of GP commissioning consortia will undoubtedly have a significant impact on the industry. As with new local government customers, there is a need to understand a whole new customer group and landscape. With an estimated 200-500 GPCC replacing 151 PCTs, there will not only be more individuals with different roles, but also more organisations and therefore more accounts to manage. Furthermore, these organisations and individuals will have more freedom than PCTs ever had.

The NHS in England is being opened up to market competition with the likely result that there will be more players from the private sector, voluntary organisations and social enterprise. This will mean a growth in private providers running both hospitals and primary care – do we understand these players, their drivers and methods?

In addition to the GPCC, it is important to understand the new system and superstructure. There are new bodies such as the National Commissioning Board (NCB), as well as existing bodies whose remit is changing. For example, NICE's role in recommending and assessing drugs/ treatments will be downgraded and will move towards offering advice on treatment effectiveness, where it will have responsibility for constructing 150 quality standards by July 2015; these standards will be used by the NCB to performance-manage GPCC. The overall theme is a move from a health service to a health system, and one that will operate less as a state-run monopoly than in the past.

The patient-centric nature of the reforms will strengthen an existing trend: **the rise of "patient power"**, both on an individual level and through patient groups, charities and



so on. Engaging with these groups has always been difficult, especially with direct-to-consumer regulation.

However, it is becoming more important for pharma companies to understand these groups of stakeholders and find ways to collaborate effectively with them.

Is pharma's current commercial model fit for purpose?

In response to the impact of the NHS reforms and the evolving healthcare landscape, the pharma industry yet again needs to review and restructure its commercial and business model fundamentally. In particular, they should consider how they should behave towards the “new” NHS system: it is arguable that they should adopt a business-to-business model rather than a supplier-to-customer one. As discussed above, this is as a direct result of the ever-increasing numbers of stakeholders (now operating at a variety of levels) and the changing organisational environment.

In light of the reforms many companies have already undertaken significant transformation projects and many more are in the process of reviewing what to do next. The concept of Key Account Management (KAM) is of central importance here.

With the lack of new blockbusters, the well-documented patent cliff and pressure from generics, we have already seen a dramatic shift away from primary care to KAM over the last few years. With the healthcare environment changing to reward products that generate superior outcomes, companies will need to transform their business models to a collaborative model that supports healthcare delivery and health management from diagnosis to long-term care. It could also be argued if clinicians have less individual discretion, then less resource is required and therefore fewer salespeople.

KAM remains the best approach to overcoming the challenges and maximising the opportunities of the NHS reforms. Pharma companies should

increase their emphasis on KAM and improve the way they do it, in terms of both structural organisation and the skills sets available.

The new key account manager needs to be a resource investigator, able to gather intelligence on a local level which is then turned into corporate knowledge. An integral part of this intelligence gathering is to have an excellent understanding of key drivers at a local level. Thereafter, this information must be transformed into insight and a key account team deployed to work with, and ultimately influence, the key stakeholders, including commissioning consortia, providers, regulators (such as the Care Quality Commission (CQC) and Monitor) and NCB.

With an increased focus on local needs, it is evident the skills and capabilities of the key account manager and team will differ across different parts of the country to suit the different demographics and healthcare requirements of different areas.

Talent management

Over the years, we have seen a natural progression of the sales rep from primary care rep to hospital specialist to healthcare development executive to market access and key account manager. In general the skills and capabilities of these people haven't significantly changed; it wasn't uncommon for the same rep to progress through each of these roles.

There is no doubt that the skills and capabilities of sales representatives (irrespective of what title they are given) need to undergo a full review in the light of the current reforms.

The skills required as part of a key account team today vary dramatically. There is a need for a multi-skilled “super rep” with in-depth local knowledge and a good network. In addition the key account team must be able to draw upon specialist skills, for example commercial, Key Opinion Leader management, clinical, economic, medical and so on.

This will represent a significant challenge for many pharmaceutical companies as the skills required are in limited supply, not only within their own organisation but across the whole industry.

Conclusion

The reforms will not be fully implemented for a couple of years, but pharma companies cannot afford to wait until then to prepare. They need to overhaul their commercial model and talent management now, using what they already know about the basic structures of the reformed system and the output from the pilots that are now underway.

Primary care

Drug companies need to adopt a more collaborative and outcome-focused business model to ensure sustainable long-term revenue.

By 2013, primary care is expected to contribute less than half of revenue growth in the global pharmaceutical drug market.

On average, the primary care drug portfolio accounts for over 60% of the annual revenues of leading pharmaceutical companies¹. However, trends over the past decade indicate a substantial slowdown in the annual growth rate of this market, with global revenues declining steadily during the past decade.

By 2013, primary care is expected to contribute less than half of revenue growth in the global pharmaceutical drug market. (Specialty market sales, by contrast, are expected to grow at twice the rate of primary care products for the next five years and gain a share of 25% in the global pharmaceutical market².)

Leading companies are worried about the effect of slow growth in the primary care market on their overall growth, as well as about the threat to the revenues. They have started adopting various measures to combat the slowdown, including expansion into new geographies and patient groups, reformulated products, and even organisational restructuring.

These strategies have to some extent mitigated the effects of slowing growth, but this article will argue that, if they are to ensure sustainable long-term revenue growth from this portfolio, companies will need to transform their business models.

Causes of slowdown

There are three main causes for the slowdown in the primary care market.

1. Most of the successful blockbuster drugs that have fuelled revenue growth in leading companies are now in their maturity or declining (patent expiry) phase, and revenues

from them are stagnating. Additionally, a large number of generic companies are now challenging the patents of protected brands via Paragraph IV of the U.S.'s "Hatch-Waxman" Act. The challenge from generics is particularly worrying for companies with large stakes in the market.

2. New launches of primary care drugs have dwindled over the past few years on account of increased developmental, safety and regulatory hurdles. The few launches that have occurred in recent years have not been as successful as their predecessors.
3. Rising health care expenses worldwide have led governments and payers to adopt various pricing and reimbursement tools to contain treatment costs. Generic substitution, reference pricing and prescriptions that come with reimbursement restrictions have all affected primary care revenues.

Current responses

Faced with this slowdown in the primary care market, companies have adopted a range of strategies to address revenue growth. Figure 1 summarises these strategies under four main headings: life cycle management strategies, expansion/diversification strategies, organisational restructuring strategies and strategies targeting patients. We will review each of these in turn below.

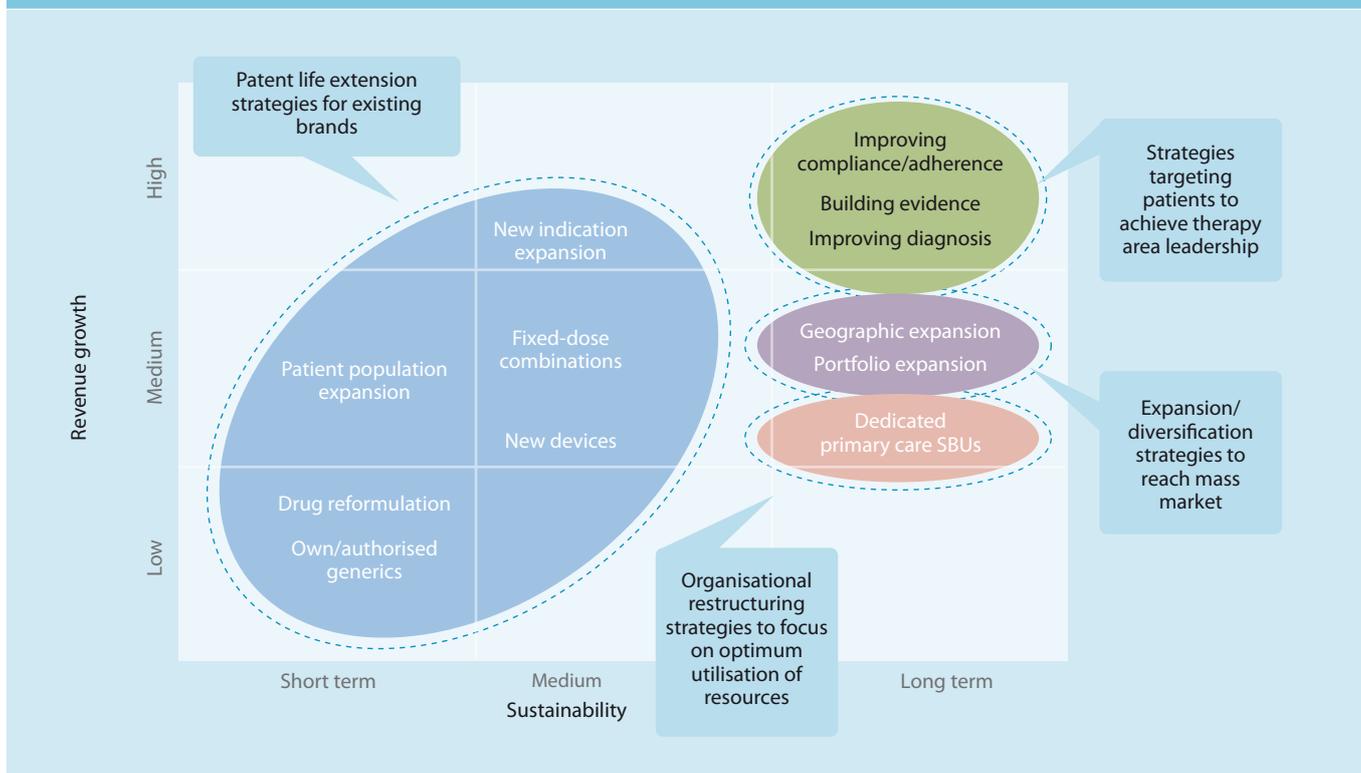
¹ Capgemini analysis of the primary care portfolios of the leading seven primary care drug companies

² IMS Health, "Changing the Channel: Developments in US Specialty Pharmaceutical Distribution", September 2009.



Figure 1 summarises these strategies under four main headings: life cycle management strategies, expansion/diversification strategies, organisational restructuring strategies and strategies targeting patients. We will review each of these in turn.

Figure 1. Four groups of revenue growth strategies in the primary care drug market



The first group of strategies, lifecycle management, represents companies' traditional focus. A summary of the various strategies that fall under this heading is shown in Figure 2.

Figure 2. Lifecycle management strategies

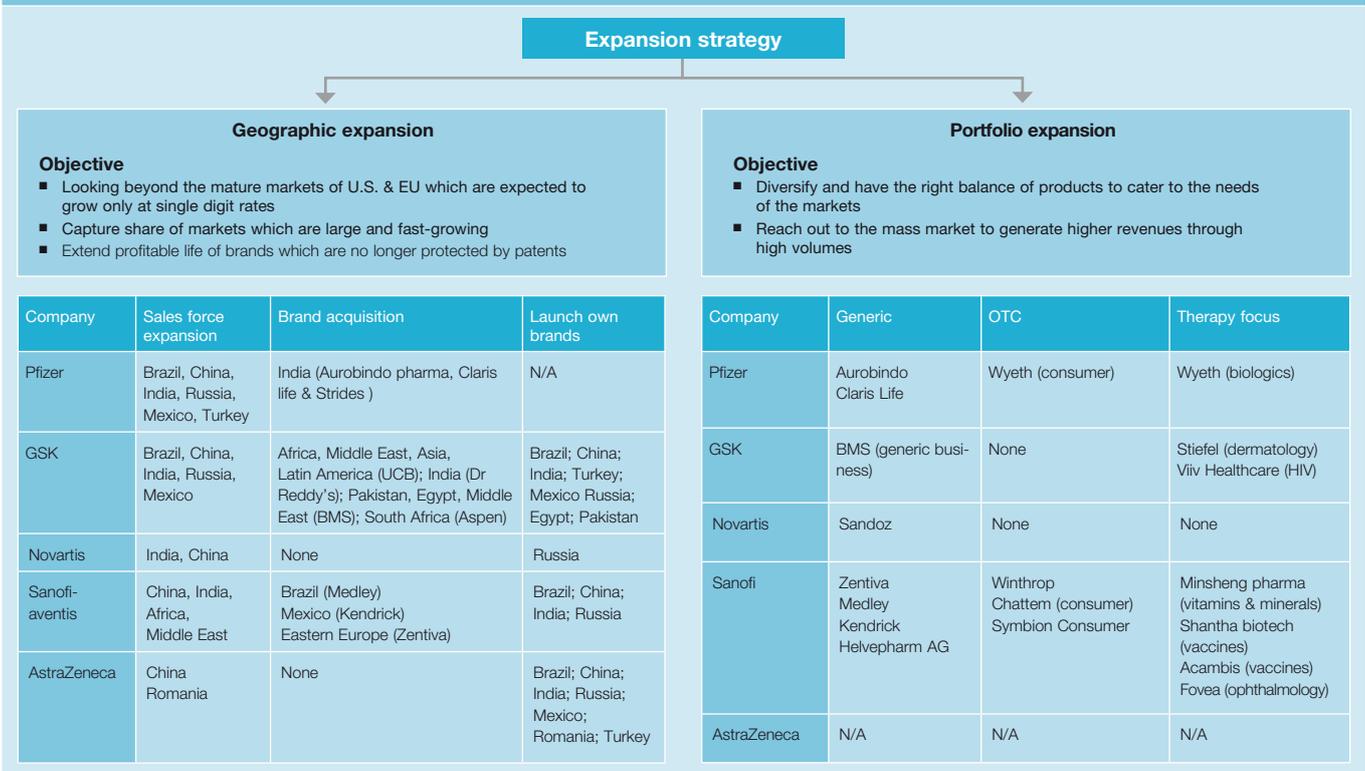
Strategy	Benefits	Limitations	Examples	Revenue impact ¹
Fixed dose combination (FDC)	<ul style="list-style-type: none"> Can be a huge success if achieves improved efficacy or compliance or meets unmet needs 	<ul style="list-style-type: none"> Needs to be backed by strong evidence otherwise may result in a failure 	<ul style="list-style-type: none"> Successful – Seretide (GSK) Failure – Caduet (Pfizer) 	
Patient population expansion	Indication expansion	<ul style="list-style-type: none"> High level of investment in developing strong evidence 	<ul style="list-style-type: none"> Singular (Merck) Lyrice (Pfizer) 	
	Paediatric/geriatric population	<ul style="list-style-type: none"> Needs to be backed by strong evidence 	<ul style="list-style-type: none"> Singular (Merck) Claritin (Schering Plough) 	
	Rx to OTC expansion	<ul style="list-style-type: none"> Not applicable to all drugs Requires increased marketing expenditure May result in removal of reimbursement 	<ul style="list-style-type: none"> Claritin (Schering Plough) 	
New devices	<ul style="list-style-type: none"> Additional brand differentiation Gain patent protection for the device and help maintain revenues after patent expiry of drug 	<ul style="list-style-type: none"> Not applicable to all therapy areas Requires investment into device development 	<ul style="list-style-type: none"> Lantus pen devices for diabetes (Sanofi) Symbicort nebuliser for asthma (Astra) 	
Reformulation	<ul style="list-style-type: none"> Helps in maintaining revenues post patent expiry 	<ul style="list-style-type: none"> Achieving high uptake & desired reimbursement status is difficult 		
Authorised generics	<ul style="list-style-type: none"> Compete with the generic companies Gain share from the new, cost driven patients 	<ul style="list-style-type: none"> Erosion of higher value branded sales Limited viability in markets with generic substitution 	<ul style="list-style-type: none"> Zoloft (Pfizer) 	

Key: Maximum impact Minimum impact

Source: Generic Series: Optimizing Brand Lifecycle Management – Datamonitor, June 2008
 Note: Revenue impact is a function of revenue growth and sustainability

The second group of strategies, expansion/diversification, involves moving into new geographies and portfolios in a bid to grow primary care revenues. Figure 3 lists the objectives of companies adopting this strategy, with examples.

Figure 3. Expansion/diversification strategies



Source: (a) Company annual reports; (b) Company websites

In the third group of strategies, organisational restructuring, leading pharmaceutical companies have created specific business units to focus on the mature primary care products, as shown in Figure 4.

Figure 4. Organisational restructuring strategies

Company	Strategic Business Unit	Objective	Focus of SBU
Pfizer	Primary Care Business Unit	To focus on development and commercial operations of its primary care portfolio	<ul style="list-style-type: none"> ■ Bringing greater value to customers through local and tailored strategies ■ Using consumer insights as the foundation for brand strategies, including pipeline products and marketed assets ■ Delivering comprehensive healthcare solutions that go beyond medicines, and include knowledge and services that are valuable to physicians, payers, patients and caregivers
	Established Products Business Unit	To enhance sales of medicines that have lost patent or are losing exclusivity	<ul style="list-style-type: none"> ■ Increasing access to affordable medicines ■ Stabilising the shrinking business of established brands due to loss of exclusivity and countering intense generics competition ■ Transforming the business by adopting portfolio expansion, reformulation and product enhancement strategies ■ Before loss of exclusivity, launching products in high growth markets and to manage product lifecycle
GSK	Classic Brands Business	To reinforce GSK's core brands	<ul style="list-style-type: none"> ■ Acquired mature products business of BMS in Pakistan, Middle East and North Africa ■ Broadening its branded portfolio business in emerging markets
Novartis	Mature Products Global Business Unit	To support branded older products in various therapeutic areas	<ul style="list-style-type: none"> ■ Increasing pharmaceutical sales for mature products (launched > 10 years) facing competition from generics
AstraZeneca	Established products in Emerging Markets	To drive growth for core brands in emerging markets	<ul style="list-style-type: none"> ■ Launching selected in-licensed local branded generics ■ Transfer of production facility of mature pharmaceuticals to Asia

Source: (a) Established products fact sheet, Pfizer Website accessed 09 April 2010; (b) Middle East North Africa Business Briefing presentation, Fouad Benghalem, SVP-MENA, GSK; (c) Company websites

The fourth group, strategies targeting patients, aims at improving adherence and compliance and ensuring greater patient involvement. Examples include Pfizer's GETQUIT® plan for smoking cessation with Chantix, and Novartis's BP Success Zone for controlling hypertension.

Companies have also engaged with pharmacists in this fourth area. An example is GSK's collaboration in the "Diabetes Ten City Challenge" programme, sponsored by the American Pharmacists Association (APhA) Foundation. This programme provides customised education and counselling for diabetes at the point of dispensing, in addition to waiving co-pays. Companies have also got into risk-sharing agreements with payers, such as MSD's deal with CIGNA to offer discounts and rebates on diabetes drugs to reward improved patient adherence.

Rethinking the business model

While efforts like those described above will create value in the short term, companies will need to do more if they are to drive sustainable revenue growth in the long run. All the leading companies in the past have adopted a business model where blockbuster accounted for a major portion of their revenues. However, primary care companies cannot expect high returns from this model in a future where primary care drugs are likely to become increasingly commoditised with competition from me-too competitor drugs and generic drugs. The fact that governments and payers increasingly want to pay for outcomes rather than products or services compounds the problem.

To guarantee sustainable long term revenue in the future, companies will need to move towards a collaborative model that supports healthcare delivery and health management from diagnosis to long-term care. The focal point of this new model will be comprehensive solutions that will help generate evidence-based and demonstrable health and economic outcomes. The model will enable

companies to provide a suite of complementary offerings around the drug to differentiate their products from competition.

To achieve these comprehensive solutions, companies will need to join forces with a wide range of organisations, both inside and outside the healthcare space. They may for example collaborate:

- With academic institutions to "in-license" innovation
- With diagnostic and medical device companies to bundle companion diagnostic kits and drug delivery devices with their core product
- With providers and wellness companies to provide patient screening and disease education programmes, nutritional advice, fitness regimens and other such comprehensive patient-centred and physician management programmes
- With technology companies to offer adherence programmes and technologies to monitor patients on a real-time basis outside clinical settings

More importantly still, companies will need to build key customer relationships with the stakeholders who influence and measure health outcomes, such as regulatory bodies, healthcare professionals, care providers, payers and patients. They will need to create the infrastructure to ensure they can access the outcomes data generated, create feedback loops and close the currently existing gap between treatment and outcomes.

Conclusion

Already there are signs that forward-looking companies are moving towards the collaborative model recommended above. We have already mentioned GSK's involvement in the Diabetes Ten City Challenge and MSD's adherence-based deal with CIGNA. Another example is provided by AstraZeneca and Janssen-Cilag which have collaborated with Bolton Primary Care Trust on the creation of practice-based registers to ensure that

patients with severe mental illness receive regular checkups in accordance with national guidelines³.

We believe that by focusing on a model that revolves around generating positive health and economic outcomes, companies will be able to convince governments and payers to pay premium prices for their products and services. This transition will not be easy and will require major changes in how companies operate. Given that time is running out for the blockbuster model, companies need to act fast.

³ "Doubled-up, joined-up working", *Pharma Field*, December 2007

Transforming oncology clinical development

A new alliance between Capgemini and Novo Oncology Associates will facilitate collaboration, the key to innovation in oncology.

Given the staggering statistics on cancer rates, there is a renewed emphasis on cancer research and development. More than 1,000 oncology compounds are currently in development and a significant share of the overall industry R&D spend is dedicated to oncology. Historically, the rewards have been big. Blockbuster drugs Avastin, Rituxan, Herceptin and at least seven others each generate more than \$1bn in annual global sales.

Growing risks and costs for developers

However, the development risks and costs are substantial, and growing. It is clear that the more we understand the scientific basis of cancer, the more complex it becomes. Two patients with a similar diagnosis and the same treatment may show very different responses and outcomes. A cancer diagnosis – be it lung, breast, colorectal or others – requires an understanding of how that specific disease originates and how it progresses and spreads in the human body.

The trend toward targeted therapies and companion diagnostic tests means that identifying representative clinical trial patients will be even more challenging than it is now, as only a fraction will meet the traditional inclusion/exclusion criteria. That factor will increase development costs, slow time-to-market, and potentially lead to a limited label.

Acceptable oncology clinical trial endpoints appear to be a moving target, often influenced by the varying positions taken by regulatory authorities, medical academics, and patient advocacy organisations. This uncertainty

adds a considerable amount of risk and instils a defensive (and costly) posture by the innovator company. Tumour response, progression-free survival, and overall survival are among the intermediate and final endpoints that must be measured, but often they are given different weightings by different authorities.

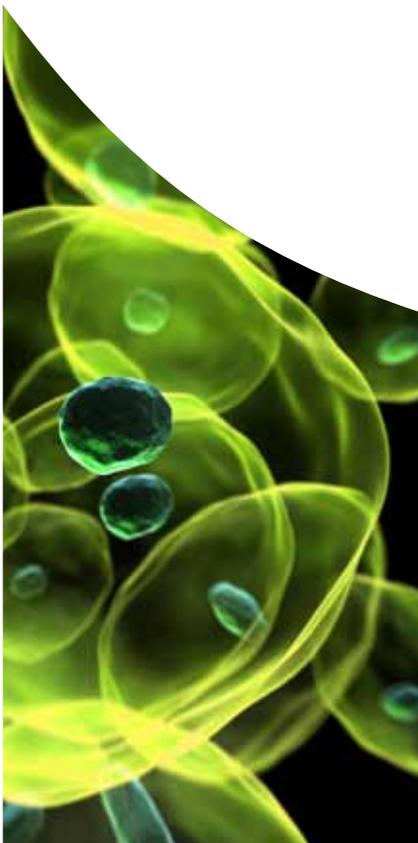
The recent FDA interest in, and emergence of, combination therapies during clinical trials, similar to the “cocktails” use to treat HIV, also leads to more complex trials, requiring multiple companies to work together in a unique situation. At the same time, a more active, educated, and engaged cancer patient population expects more manageable side effects with cancer treatments of the future.

To complicate matters even further, financial pressures related to private and public payers are challenging reimbursement levels for cancer drugs and treatments. Companies must evaluate the payer perspective, and how they define the value of oncology drugs.

The industry is facing a genuine dilemma as costs skyrocket and reimbursement challenges multiply. Are clinical development programmes designed to deliver incremental improvement in cancer care a thing of the past?

Transformation of oncology clinical development

If they are to achieve continued progress towards a cure for cancer, pharmaceutical and biotechnology companies need to address a central issue: how should oncology clinical development be transformed to manage the risks and costs better?



The right treatment for the right patient

The use of biomarkers to match the most effective treatment with each individual patient will remain the focus in the industry. This remains true despite the reality that having a smaller initial patient population makes it harder to recover development costs. The investment in biomarkers will be justified by the higher price that a more effective drug commands, and by additional product lifecycle opportunities that will boost the revenue potential.

Early decisions on product strategy

Given the significant risks and associated costs of oncology clinical development, key product strategy and go/no-go decisions need to be made early in development. Doing so requires a deep understanding of a compound's mechanism of action and of future standards of cancer care.

In particular, critical product positioning decisions (such as whether the treatment is first- or second-line, stand-alone or combination) must be made early, and must be based on scientific and commercial insights. Access, reimbursement and other payer issues are key factors in these decisions.

When there are major uncertainties, parallel development of agents within organ-defined patient populations (for example, colon, breast, lung, prostate) may be required to maximise the scope of eligibility for individual patients. More precise targeting of specific agents for individual patients may help minimise clinical trial costs and greatly accelerate the development timeline for these agents.

Redefined endpoints

To accelerate speed to market, companies urgently need intermediate endpoints that accurately reflect global clinical benefit and are acceptable to the regulatory agencies. Developing such early metrics is challenging, in part because of the complexities and variability of the patient care pathways. Further complexity results from the

fact that multiple interventions may occur during a given patient's care, as each intervention used may confound the "gold standard" endpoint of survival. Identification of new, valid short-term endpoints that are widely accepted across the industry by investigators, payers and regulators remains a vital, but as yet unmet, need.

An eye on the competition

Understanding competitors' pipelines and critical areas of clinical need are important in developing a clear and certain direction and timeline for product approval. Successful trials will change the standard of care and set a higher bar for efficacy and tolerability.

Speed to market

Once a strategy is set, patient enrolment, trials execution, data analysis and dossier preparation must be managed as a process to be continually optimised. Early involvement of the regulators, and in some situations of payers, will make it possible to prepare for rapid decisions and to determine acceptable data points for approval and reimbursement.

Collaboration for better cancer care

The upcoming wave of product innovation in oncology and the advent of personalised medicine holds an exciting promise: a world with improved cancer care that far exceeds the tedious, incremental progress that has characterised cancer developments until now.

However, rapid improvement of outcomes will require collaboration between stakeholders, including pharmaceutical companies, patient groups, regulators, investigators and payers. This collaboration is the only way to maintain a reasonable balance between accelerating safe access to innovative care and managing the cost of care to a level within societal tolerance.

With this need in mind, Novo Oncology Associates (NOA) and Capgemini Consulting have set up an alliance under which we will jointly

help life sciences companies to seize opportunities within the oncology therapeutic area. The alliance will benefit clients by enabling direct and immediate access to academic, government and community practice research.

Life science companies will be able to gain from creative, oncology-specific approaches to solving complex challenges in research, development and commercialisation. Companies will also have access to guidance and direction about oncology drug discovery, early and late stage clinical development and all aspects of the commercialisation of oncology products.

Together, Capgemini Consulting and NOA will help provide practical, specific recommendations and implementation support to help companies succeed in the evolving and complex market that is global oncology.

Chief Procurement Officer survey

Life sciences companies would do well to emulate some other sectors where procurement functions are being repositioned for sustained value.

In the past, pharma - along with a few other industries that had equally deep coffers, such as oil and banking - was said to suffer from “marble hall” syndrome, where high margins meant that they did not have to worry too much about indirect costs. As a result, pharma companies devoted the majority of attention to direct procurement – that relating to manufacturing inputs – and have achieved mature processes in these areas. Until recently, they felt less pressure to improve the indirect side of the business.

However, the last two to three years have presented huge cost challenges for the industry. That means the “marble hall” has now well and truly gone. Pharma now needs to find all the additional value that it can, and has quite rightly begun to do this via indirect procurement: however, as other industries that have gone before have found out, squeezing suppliers on price is not enough.

In the industries that are further along this journey, procurement has seen a shift in focus away from being viewed as a pure cost driver. Increasingly, these industries are recognising that the procurement function needs to play a leading role not only in cost reduction but also in supporting growth.

For our global CPO survey we have interviewed more than 150 senior procurement executives. Most place a strong emphasis on delivering growth and innovation, with procurement generally recognised by the CEO’s agenda as driving a leadership position.

Therefore, the results provide several useful lessons for pharma companies that see themselves as being behind the curve in this area, and that want to adopt a more strategic approach to procurement.

This fourth Chief Procurement Officer (CPO) survey continues Capgemini Consulting’s exploration of the trends and issues affecting procurement executives across the globe. We have conducted 750+ interviews over the past four years, and this edition continues to provide peer-based insights for executives on macroeconomic issues and trends across the procurement profession. This article draws on the full survey report titled “Global Chief Procurement Officer Survey 2010 - Achieving sustained business value through procurement”.

The full report can be downloaded from <http://www.capgemini.com/insights-and-resources/by-publication/global-chief-procurement-officer-survey-2010/>



Preparing for a strategic role

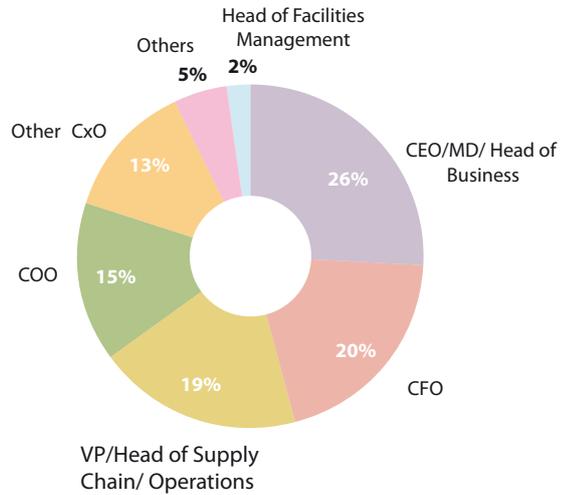
Our findings show that, in many companies, procurement is better positioned than it was in the past to play a strategic role. From the reporting structure perspective, around 70% of respondents said that they now report to the board room within their organisations, and one out of four respondents reported directly to the CEO or head of their business (see Figure 1). The last few years have seen a subtle trend where procurement is maintaining its support of the CFO’s objectives, while shifting its alignment to the CEO. This trend signals a focus on more strategic objectives.

Procurement functions also show awareness that the expectations of their organisation may be changing. Asked about their current strategies (Figure 2), almost 80% of our participants responded that top management expected them to improve the overall value contribution of procurement.

Moving the focus from cost to value

To do so, we envisage that procurement will need to shift the focus from short-term cost cutting to long-term

Figure 1: Who does procurement report to?



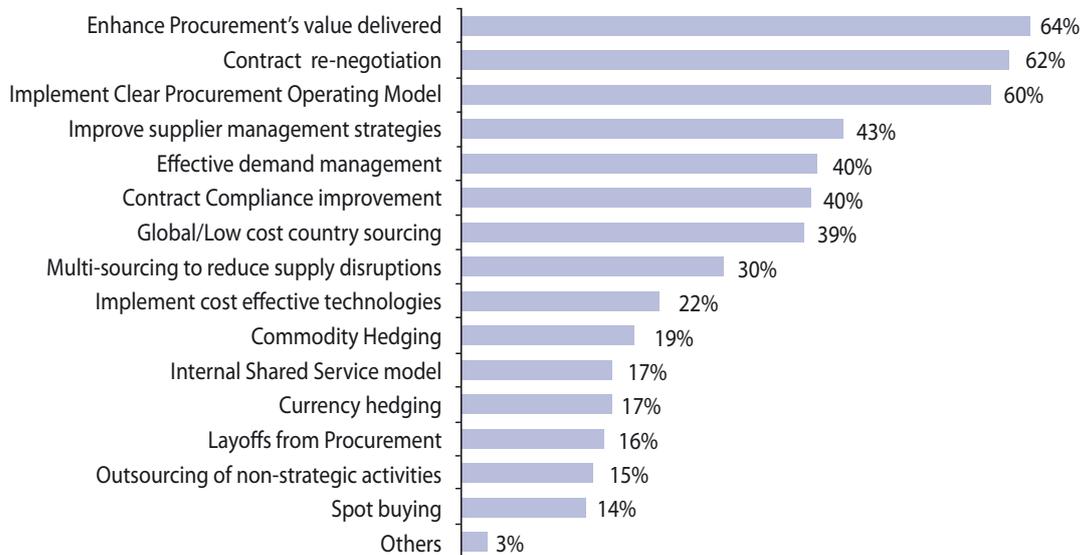
value-based relationships with suppliers. In this way, it can drive deeper savings throughout the supply chain and bring true innovation into the company, as well as maintaining bottom-line reduction.

This change will require new skill sets, such as the ability to understand market mechanisms and the macro- and microeconomic influences in the

end-to-end product supply chain. Procurement can then translate this understanding into opportunities to reduce risks and to contribute to other corporate objectives, such as growth and corporate responsibility.

For now, however, too many procurement organisations remain primarily focused on cost reduction through negotiations on price (and our obser-

Figure 2. Procurement strategies during tough economic conditions



vations suggest that this is particularly true of indirect procurement in pharma). In reality, we would argue, the most important KPIs are related to control and savings, e.g. spend under control, supplier performance, procurement ROI and compliance.

The need for a shift from cost to value is particularly pressing if (as a majority of our respondents believe) the market is on an upward trajectory. If so, procurement must ready itself for two key changes. One is that prices will not be so easy to slash, and simple negotiations will not yield the quick savings of last year. The other change is that procurement organisations will not find every business stakeholder clamouring for procurement's services. When budgets are healthier, cost savings are less of an issue for the business stakeholders that procurement serves.

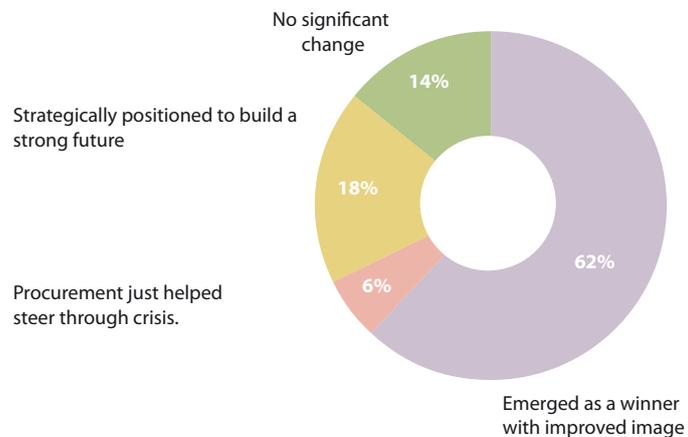
A new way of looking at commodities

More innovative solutions are required, therefore. The impact of changing commodity prices on the sourced product needs to be assessed early in the sourcing cycle in order to get ahead of the volatility and use it to procurement's advantage.

Commodities like oil have always been subject to external factors. The price of a barrel has fluctuated significantly owing to the increased demand over the last years, not to mention the impact of the recession, the growing economies in China and India, and several conflicts in the world. Bad weather has caused the price of soybeans and potatoes to rise, causing the price of beef and chips to increase. Simple as these examples are, they demonstrate that fluctuation can present both opportunity and risk.

These external drivers demand a completely different way of looking at a commodity. The procurement professional should look all the way down the supply chain to understand which commodities are part of the "bill of material" of the product to be

Figure 3. Position of procurement after managing the crisis



sourced, to understand how the external factors affect the price, and how procurement can be pro-active to mitigate the financial consequences. This requires different skills and in-depth market knowledge. For example, a change in the price of oil will have an effect on the cost and therefore price of downstream products such as plastic and energy. Understanding of these commodity inter-linkages and mechanisms can not only reduce the risk of volatility but also provide opportunities since benefits can be obtained when commodity prices fluctuate in either direction.

Conclusion

Facing a difficult economic environment and challenging targets, nearly 65% of the CPOs utilised management's attention, plus the targets, to initiate a review of the procurement operating model and the way of working with functional interface partners. Consequently, the move to central procurement functions has continued, with more than 70% of our participants managing their spend centrally. Looking back on the past two years, most CPOs have stated that it has been a tough environment consisting of increased pressure on procurement, but as a positive result, over 60% confirm that economic crisis has left procurement a winner on balance.

A newfound position at the boardroom table and the need for immediate action has changed the role and recognition of procurement and its performance capability in most companies. At the same time, a substantially high number of procurement managers exploited the given opportunity and initiated the improvement of organisational set-up to manage their spend efficiently.

Now that recent shifts in the pharma industry have forced cost reduction and control on to the agenda, its need for an effective approach to procurement is as pressing as any other sector's: perhaps more so, given the continued downward pressure on pharma's margins in contrast to a potential upturn in the rest of the market. All pharma companies would do well to learn from other industries' pioneering work in adopting a more rounded, and more strategic, approach to procurement, indirect as well as direct.

Closed Loop Marketing

“Closing the loop” can unlock the benefits of customer centricity within life sciences, but so far few pharma companies have succeeded in doing so fully.

There is a considerable advantage to being one of the first companies in life sciences to close the loop successfully.

Today, life sciences companies are being challenged to increase both efficiency and effectiveness across marketing and sales activities, while also enhancing their customer focus. One approach to meeting this challenge lies in the successful application of Closed Loop Marketing (CLM). CLM uses cutting-edge business capabilities and detailed customer data to optimise marketing and sales efforts across channels, creating value for both customers and company (see Figure 1).

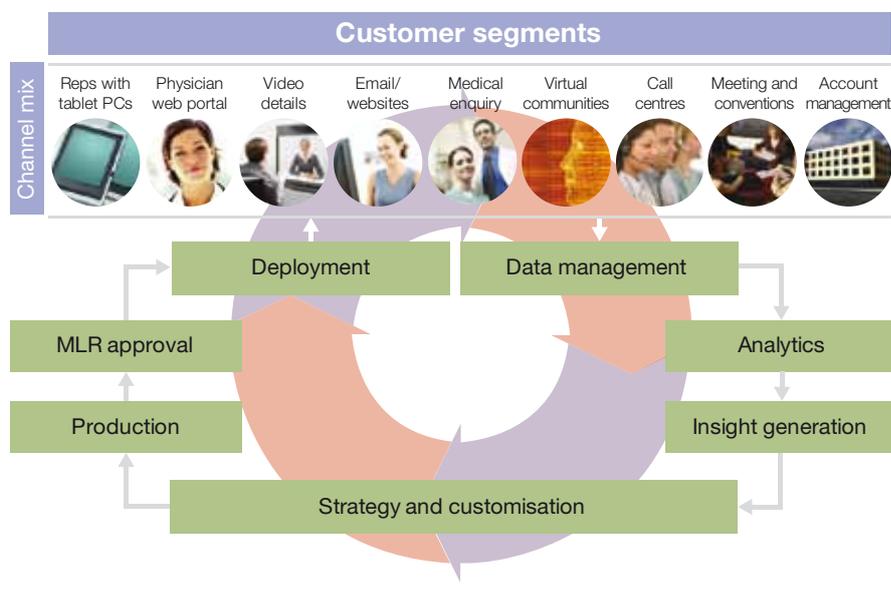
Many companies outside pharma have successfully applied closed loop approaches where the analysis of customer data delivers practical insights. These enable the company to drive value for customers while maximising channel effectiveness and efficiency by delivering the most relevant message,

content or offering to the right customer in the format they prefer.

However, implementing integrated multi-channel CLM has proved difficult for many in our industry, and arguably, the industry has yet to make the most of this opportunity. There is a considerable advantage to being one of the first companies in life sciences to close the loop successfully: it will pave the way to a new commercial model that puts the customer first.

In this article, we examine the current state of CLM implementation in pharma and the benefits of fully closing the loop. We look at the steps involved in doing so and assess what the future of CLM may look like as organisations seek to apply the concept across more customers and channels.

Figure 1. CLM in a multi-channel model



The current state of CLM in pharma

Over the last few years, most of the industry’s main players have implemented CLM-type programmes. However, evidence indicates that these initiatives fall short of full CLM, and most focus on rolling out new technology to the sales force.

This should not be surprising given the drive within the industry to re-tool and re-model the sales force. While there is an upward trend in the use of technology to transform the sales force, we estimate that only a quarter of the pharma companies implementing such programmes are doing so as part of a true CLM strategy. In spite of the fact that many companies label such programmes as CLM, their efforts are more comparable to basic electronic detailing.

These programmes aside, the primary reason CLM initiatives fall short is that companies are not able to apply the data they collect from customer interactions to close the loop fully (see Figure 2). For this reason, many businesses have found themselves “drowning in data and thirsting for knowledge” – and, as a result, unable to make progress in becoming more customer-centric.

True CLM enables customer centricity

There is a strong consensus within the industry that customer centricity (or customer focus) will be a key feature of the new commercial model. The product-centric approach that characterised pharma in the past is outdated in today’s environment of decreased access.

Customer centricity can be defined as the application of customer knowledge in all aspects of business to drive strategic and tactical decisions. This delivers increased value to the customer with the expectation that doing so will, in turn, also drive value for the organisation where customer and

company objectives are aligned (for example treatment compliance or reducing barriers to prescription medication access).

As other industries have shown, CLM enables customer centricity by supplying customer knowledge and insights. It does this by collecting unprecedented amounts of data directly from customer interactions through marketing channels.

However, as mentioned above, turning data into insights is not straightforward. We will now examine some of the processes and functional elements involved in doing so.

Data collection and management

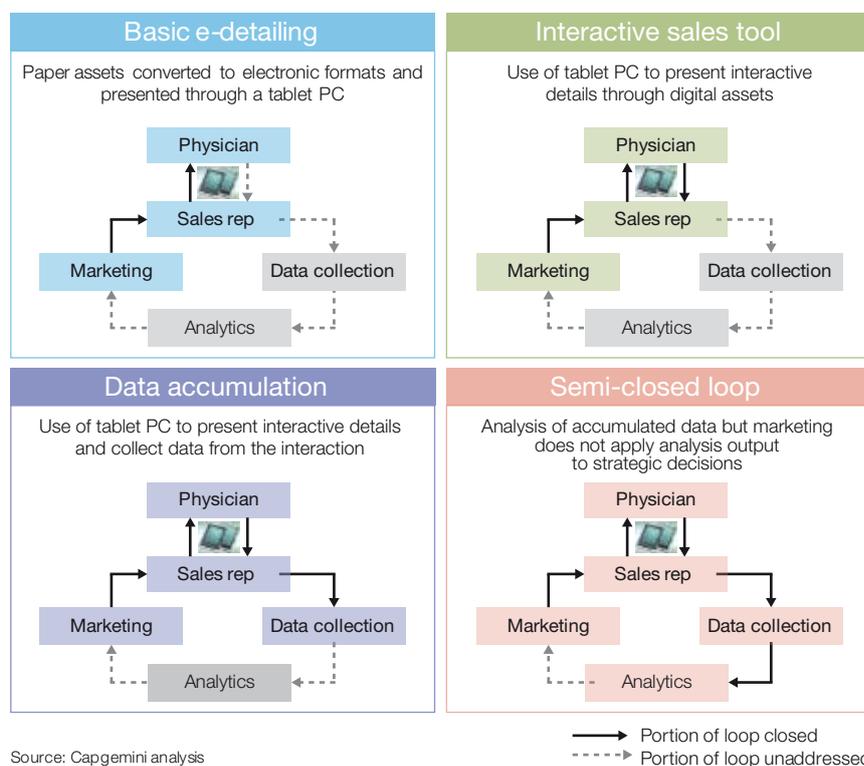
CLM creates considerable volumes of data from each channel. From the sales force alone, it might capture every item viewed during a sales call, who saw it, how long it was viewed

for, how the customer reacted to it, and many other possible data points. Companies need to address how all this data can be sorted, cleaned and summarised into usable formats for subsequent analysis.

Data management is a challenging enough task with the data from just one channel. Coordinating the huge volume of data available under multi-channel CLM is far more so, and the critical question of how to tie all sources together at the customer level must be addressed.

The organisation will probably have to consider integration with customer relationship management (CRM) and sales force automation (SFA) systems. A review of the overall business information management strategy may therefore be necessary in order to achieve effective implementation across processes and channels.

Figure 2. Not all current “CLM” initiatives close the loop fully



Source: Capgemini analysis

Analytics and insight generation

An important consideration is the balance between reporting and insight generation. CLM data reports contain key metrics that are essential to monitoring performance and are important components of the broader analysis. However, where CLM programmes can fall short is in not considering how to progress from basic metrics to insights that guide business decisions.

To avoid this pitfall, an organisation should consider the following questions:

- What process is needed to complete a comprehensive analysis of message effectiveness based on CLM data?
- What role will existing market research capabilities and data play?
- What frequency of insight generation is realistic?
- If a higher frequency is required, what is needed to obtain it?

With analytics processes in place, data from customer interactions can be analysed to form new strategic insights. The organisation will need to decide how it will act on initial findings and how it will prove they are meaningful and reliable. For example, it can test such findings over time, seek direct field feedback as to their validity, or look to corroborate them with other sources.

When a finding holds true, it can be used to inform the development of new, tailored messages for specific customers. Within a multi-channel approach, an additional layer of analysis can look at channel response to discern new sub-segments. In this way, the new message can be targeted to the customers within a sub-segment through the channels they engage with most.

Production

CLM entails the rapid production of new and tailored content by customer type and channel as new insights are developed. The pharma organisation will need to take stock of the preparedness and capabilities of its marketing teams and agency partners, and

assess the roles of each under a CLM model. Agencies are ramping up to supply the capabilities required for CLM, but pharma companies should be cautious in the early stages of their CLM initiatives, assessing the readiness of current partners and if necessary examining alternatives.

The organisation can also consider Digital Asset Management (DAM) as an option for managing the development, cataloguing and utilisation of assets across channels. DAM may be able to address inefficiencies created when content is developed in silos for different channels.

Deployment and channel mix

Once approved, tailored or new content can be rolled out to channels to execute the strategic decisions of the marketing team. In a complete CLM model this would occur across highly integrated channels running parallel content and targeted only to the customers predicted to engage or respond.

To reach this state, the organisation will again have several implementation factors to consider:

- To what degree do channels currently operate in silos, and are they ready to execute frequent simultaneous deployments?
- How dependent is execution on the actions and outputs of external agencies? Can those agencies meet CLM requirements?
- How will the development of new sales training materials for new messages and directions be coordinated with the content development process?
- How can new market resource management systems be employed to facilitate multi-channel management?
- To what extent are CLM and CRM strategies aligned to enable execution across customer touch points?

For many companies, CLM can act as an enabler of alignment around customer focus because of the number of functional areas potentially involved.

Keys to a successful CLM programme

- Embrace transformation, as CLM enables a new way of doing business
- Insist on data quality, the first step in CLM success
- Prepare for analytics – understand data to be collected and how it will be modelled
- Rethink Medical, Legal and Regulatory (MLR) processes and adapt them to suit digital content better
- Assess vendor and agency readiness and evaluate required capabilities

The future of CLM in pharma

As we have seen, the majority of CLM programmes today concentrate on the sales force, and on data collected from the physician customer via tablet PCs. However, the full potential lies in multi-channel CLM, and, in addition, there is a growing interest in applying CLM concepts to other types of customer.

Two main approaches to the expansion of CLM programmes appear to be emerging in the industry (see Figure 3). One sees CLM continuing to be concentrated on the physician customer, integrating all customer-facing channels to drive insights and actions. The second approach aims to take the CLM capability beyond the physician, utilising all relevant channels across

all relevant customer groups. (Figure 3 shows only a representative sample of channels and customer groups)

It is by addressing the entire customer network of influence, as in the second of these two approaches, that companies can probably obtain the most insight. Although it is important to close the loop with each customer in the pharma landscape of influence, truly innovative value capture comes from leveraging each customer loop to gain insights that will shape interactions with other customers.

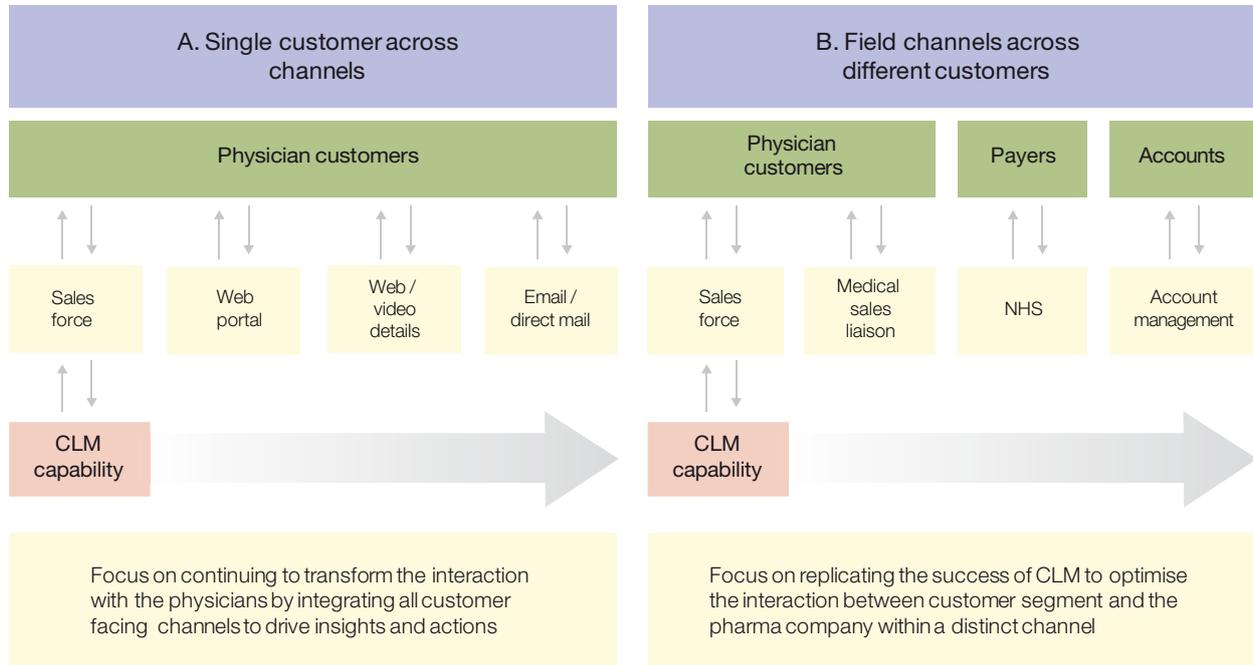
Conclusion

Is CLM the answer to all of the industry's challenges in marketing and sales? Of course not. However, it does represent an opportunity for life sci-

ences companies to put in place a new approach that can truly enable customer centricity.

To do so requires the acknowledgment of the transformational power of CLM, together with a commitment to the implied change. This change is not small or easy, but the challenges faced by the industry today will not be effectively addressed by minor improvements.

Figure 3. Two emerging approaches to expanding CLM in pharma



Source: Capgemini analysis

Business model innovation

When it comes to evolving the business model in line with a rapidly-changing environment, “innovate or die” is no exaggeration.

“The business model is broken.” This sentiment has been expressed with increasing frequency in recent years, in life sciences and many other sectors.

A failure to adjust the business model to reflect the future likely market and competitive positions has been the downfall of many non-pharma companies during the recent economic downturn. As our industry approaches the “patent cliff” (pharma’s own equivalent of economic recession), we believe there are important lessons to be learned by pharmaceutical companies from other sectors.

The economic crisis has underlined to managers how critical a well-structured business model is, so that the topic is now on the agenda of many CxOs. As well as identifying the elements critical to success, they also need to understand the significant chance of failure in business model restructuring. In this article, we review the imperative to restructure, and then outline both the risks that need to be avoided and the fundamentals required to succeed.

Why change the business model?

General Motors, Circuit City, Nortel and TrekStor are just some of the well-known companies that filed for bankruptcy, or came close, during the recent downturn. Commentators continue to claim that these events arose purely as a result of the economic crisis, but we believe this is a misjudgement. Certainly, slumps in demand and financing difficulties contributed to the failures.

However, many companies omitted, over the years, to adjust their business models to the altered market conditions and competitive environment – an environment that is becoming increasingly complex and fast-moving, requiring changes that are ever more extensive and difficult to achieve and sustain. In this instance, “innovate or die” is no exaggeration.

Previously, many industries were characterised by a single dominant business model. In effect, therefore, competitiveness was a question of better execution of that one business model. Today, many business models exist simultaneously in each industry, and their evolution is rapid and constant.

Consider the airline industry, for example, where a wide array of players co-exist and compete: traditional, globally operating passenger and freight carriers, locally operating low-cost airlines, as well as companies renting out private jets on a time-sharing basis. In pharmaceutical terms this could be equivalent to three separate businesses: ethical pharma in the major markets, ethical pharma in the emerging markets and generics globally. In addition we are seeing the emergence of more niche models, such as the “orphan” drug market.

Companies that want to be successful in this environment have to scrutinise their business model fundamentally on a regular basis, and redefine it if necessary. The factors driving the requirement for change vary. Customer requirements evolve, and new technologies enable different ways of providing services. In



addition, regulatory changes alter the playing field. Barriers to competition change or are suddenly obsolete, whilst new competitive advantages become possible. New, better or more convenient ways of addressing customers' wishes open up as a result.

The challenge lies in developing suitable business models and actively driving the change required. Takeda has demonstrated how this can be done with its Regional Account Director (RAD) programme.

Reasons for failure

Many of the companies that disappeared from the S&P index over the past 40 years failed to survive because of outdated business models. Why didn't these organisations succeed in reinventing their models? Our observations point towards three main reasons.

1. Underestimated relevance.

Management does not realise that the rules of the industry game have changed. Declines in turnover are not attributed to fundamental market changes. Early signs of the arrival of new competitors are regarded as irrelevant. Instead of business model innovation, isolated product and service innovations are pursued. The "more, faster, cheaper" approach does not work when you are confronting radically changed customer needs, a different market environment and completely new competitors.

2. Poor execution. Business model innovation is not addressed consistently, and adequate resources are not made available even when the need for action has been recognised. Executives often hesitate for a number of reasons, such as impending cannibalisation of existing income sources; tough, short-term performance expectations; and internal resistance to radical reconstruction.

3. Wrong focus. Once the pressure to act has intensified, management often concentrates on re-establishing profitability as quickly as possible, and on adapting the cost base to a declining income. There is little time for strategic thinking, and not enough attention is paid to the seismic changes that caused the decrease in income.

It is possible to do things differently, as Warner Music has shown. One of the world's biggest music labels, it was hit hard by the "digital revolution" and the move to downloading music via the internet. Turnover shrank dramatically because of the unstoppable fall in CD sales.

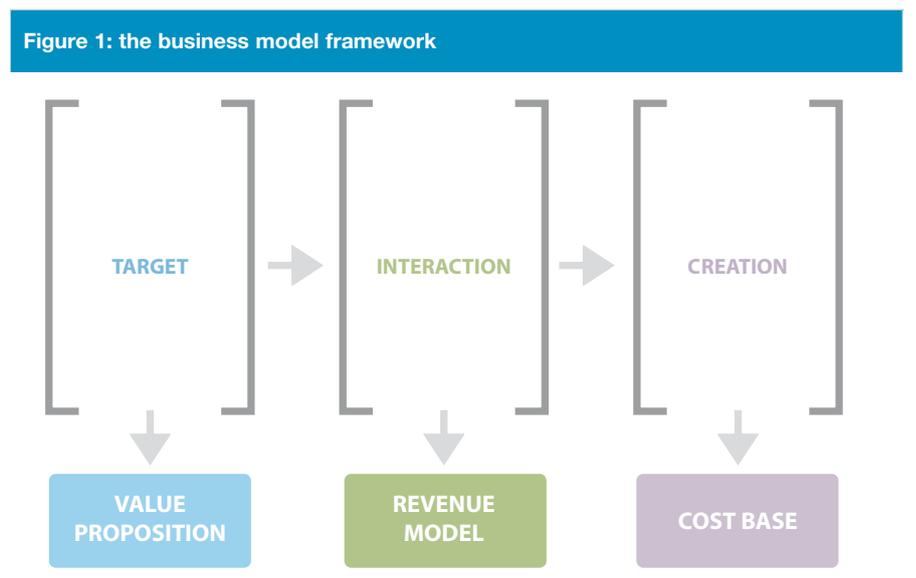
Chairman and CEO Edgar Bronfman Jr. made some fundamental changes to reverse the decline. He adapted the business model, aligning it to the digital era. The value proposition for artists was updated, new digital distribution channels developed, and new cooperation models established. The numbers speak for themselves. Warner Music secured a 21% share in the U.S. market in 2008, the highest for ten years. Yet Warner knows that

this model will need to continue to evolve as the market around it changes.

The structure of business models

The goal of a business model is to address a business opportunity in such a way that value is created for customers, as well as for the company. It consists of three strongly interlinked dimensions, shown in Figure 1.

- 1. Target:** The revenue potential needs to be defined first. It has three elements: the geographical markets aimed at, the customer segments and requirements to be addressed, and the product/service range offered.
- 2. Interaction:** The second dimension defines the manner in which the company interacts with customers to meet their requirements. It consists of the customer relationship (its nature, intensity, duration, content and typical/ ideal sequence of events); channels of distribution for marketing and other interactions; and payment structure (including mode, timing, and frequency of payments.)



New technologies are constantly forcing the pace of disintermediation as service providers and consumers come into direct contact.

3. Creation: This defines how a company can profitably fulfil its value proposition, including the assets and special capabilities it brings to value creation, such as production facilities, brand, technologies and processes. It identifies which service components have to be delivered in-house and which should be ordered from a network of partners. The approach to value creation characterises the cost basis and determines the competitive capacity and sustainability of the business model.

Approaches to business model innovation

Based on our project experience and analysis of numerous business model innovations, we have identified five essential approaches, all of which are capable of transforming today's business models to take advantage of new opportunities.

Peer-to-peer

The stages of value creation between service providers and consumers are increasingly disappearing. New technologies are constantly forcing the pace of disintermediation as service providers and consumers come into direct contact. In extreme cases, the customer even takes over tasks originally performed by producers. Prominent examples of peer-to-peer models are Wikipedia and Yahoo Answers.

Another interesting example is peer-to-peer bank concepts like ZOPA, Prosper or Smava, which connect lenders and borrowers directly. Everyone can become a lender or borrower in Smava and can freely select the rate of interest as well as the credit amount. The advantages of Smava are low interest rates, no penalty for premature settlement, and convenient terms of credit even for smaller amounts. The volume of Smava credits is increasing rapidly, totalling €15m in 2009.

Push-to-pull

We see a move towards decentralised, and more customer-centric, business models. Customer centricity is starting to be extensively adopted by pharma companies as they recognise that their traditional model is no longer working.

Centralised business models aim to optimise the supply chain, but do so at the expense of flexibility at various levels, from production to customer interaction. In an increasingly intensive competitive environment with shorter lifecycles, more complex distribution channels and an ever more powerful and better-informed customer, this approach is destined to fail. In particular, organisations can be running a product range that is at best static and at worst irrelevant to the customer.

Decentralised models take the opposite approach, putting the customer centre stage. To ensure that customer-centricity is not just an empty phrase, the entire value chain has to have the flexibility to react quickly and to cope with varying customer requirements. Often, the entire supply chain and production methods must adapt to manufacturing specific (existing or new) products faster, more flexibly and economically. Communication channels, organisation and decision-making structures have to be synchronised so that customer requirements can be recognised and met quickly and accurately.

Examples of the effective set-up of decentralised systems are provided by Expedia, Apple, the fashion retailer Zara, and Dell, one of the pioneers of this trend in the technology sector. By switching to direct sales and the proximity this gave to customers, Dell was able to shift to demand-oriented production. Using modular just-in-time production, and eliminating forecasting errors in the value chain, the company significantly reduced inventory holding costs and above all capital

lockup costs, which carry a lot of weight given the short lifecycles of computer hardware. Dell revolutionised the computer industry in the nineties, rose to become the one of the top five companies worldwide in 1997, and became the market leader for the first time in 2001. (The fact that Dell has since forfeited this position perhaps shows the limited lifespan of business models and the ever-present need to continue to reinvent yourself.)

Crowdsourcing

Companies increasingly source goods and services via open networks of external service providers, extending from open source software to product design to research and development. New forms of organisation, collaboration and financial participation broaden access to critical resources while simultaneously reducing procurement costs and time to market. Specialist networks such as Innocentive are emerging, able to process the highly specific demands of niche companies. This gives small companies access to a pool of experts on a scale that they could never finance themselves.

“Crowdsourcing” – getting the public to provide opinion or expertise – is a logical extension of this trend. Lego provides a successful example. It faced major financial difficulties in 2003 and 2004 owing to increasing competition from new competitors, a heightened price war due with producers from low-cost countries, and the digitalisation of the toy environment and products.

On the lookout for new themes, topics and stimuli, Lego was among the first companies to discover the potential of online communities. Some particularly expensive and high-risk projects, such as “Star Destroyer” (an unusually large construction kit), were developed in close collaboration with the Lego community. Since 2005 Lego has offered its “Ambassador Programme”: a community-based programme for adult Lego hobbyists who

are willing to share their experiences with the worldwide community and the company itself in exchange for benefits and privileges.

Fragment and mash

This approach involves modularisation of the entire business model, simplifying integration of individual modules by means of standardised interfaces. The result is the break-up of the classical sequential value chain into a value chain network, with new possibilities for involving suppliers and customers, who can supply competencies, perform tasks, and provide services in any part of the network. Instead of company-specific value chains, function-, product- or service-related value chains emerge, and the “mashable” company comes into existence.

Competitive advantage can be realised on at least three levels:

- The module. Where producing it internally provides no benefit from specialisation or economies of scale, the module is sourced from the partner network.
- The bundling of modules. Once you have broken your company down into value models you can sequence and assemble them in innovative ways (as Amazon has demonstrated by putting together a range of cohesive services to customers and partners from basic building blocks).
- The organisation of the value creation network. Modularity allows companies and their partners to work together in new ways.

Amazon provides an example of this trend. The huge growth of its online store meant it had to establish special technological competencies, especially the operation of highly scalable server structures for the operation of the electronic trade platform. Amazon recognised that it could use this emerging core competency to meet the growing demand for computing and storage capacities, and in particular for flexible delivery costs.



It therefore built a new business area for leasing the same structures and services it used internally to other businesses – an arrangement which we know now as cloud computing. In addition, Amazon developed a complete business model to support this area, comprising everything from product development to accounting and administration processes to new marketing channels. Amazon Web Services (AWS) is now, of course, a major provider of cloud infrastructure.

Summing up

We have summarised what can go wrong when companies fail to recognise the need to change their business model, or prove unable to do so. We have also put forward some successful approaches to change. We'll leave you with three pieces of advice.

1. Scrutinise your company's business model regularly. Don't let yourself be blinded by current success: today's successful models can quickly become dated. Examine whether "megatrends" are relevant to your industry, and pay careful attention to changes in the market environment and any emerging business models. Small fluctuations in the performance of your own company – or robust growth from new niche competitors – are early warning signs that need to be heeded.

2. Business models are not abstract; they can be described and analysed in a very concrete manner. They form the bridge between strategy and organisation, and significantly influence the continued success of your company. Approach the analysis in a structured manner: pay attention to the entire group of companies to make sure that, when you move to a new business model, all entities can adopt the business model if appropriate, with no one left behind.

3. For business model innovation to succeed, a number of prerequisites must be in place, from the right culture to the right organisation. Promote creative and radical thinking, and break open your silos. Decisive leadership from top management, as well as the readiness to adapt existing structures radically, are needed for innovation to be successful.



Case study: Terrence Higgins Trust

The Terrence Higgins Trust faces growing demand at a time of constrained funding. Capgemini's Accelerated Solutions Environment (ASE) has helped it to validate a new business model and build a robust implementation plan.

The Terrence Higgins Trust (THT) is a leading HIV and sexual health charity in the UK, and the largest in Europe. It was one of the first charities to respond to the HIV epidemic in the early 1980s. THT provides advisory and support services in the sexual health domain, campaigns for sexual health awareness and raises public and political support for HIV and sexual health policy.

THT faces increasing demand for its services particularly as more people are being diagnosed with HIV than ever before; other sexually transmitted diseases are also spreading rapidly. At the same time, both voluntary and statutory funding are affected by public spending cuts. Following October's Comprehensive Spending Review, THT realised its funding would decrease to an unpredictable but significant extent.

THT management therefore set out to define pre-emptively how it could deliver services more effectively in a constrained funding environment. Among other things, this would mean transferring certain services from face-to-face delivery to other channels (telephony and internet). THT was able to define, at a high level, what its strategy for doing so ought to be – for example, which services could be moved online – but it needed to develop a delivery model and a detailed implementation plan.

From strategy to action

It was with this challenge that the Deputy Chief Executive approached Capgemini. The Accelerated Solutions Environment (ASE) was deployed as an ideal vehicle for putting THT's high-level strategy into action.

Capgemini consultants and the ASE team worked with a core team from THT for about six weeks on a pro bono basis to define the framework for an implementation plan as well as the streams of work that would be required to support its delivery. The team also spent time identifying the information THT would need to build the plan.

This activity culminated in a one-day ASE event, attended by almost 30 THT staff from all levels and functions. First the Deputy Chief Executive explained the need to change and why the current model was no longer viable. The group stress-tested the strategy to ensure that it was an implementable business model. The core component of the ASE event was the building of a plan to implement the new business model. Capgemini subject matter experts (SMEs) shared best practice relating to key implementation considerations such as customer (beneficiary) segmentation, change management and appropriate technology use, to provide THT with more context within which to build the implementation plan.

The ASE allowed THT to define and agree a common aspiration that everyone could work towards. A key outcome was the joint development of the detailed 18-month implementation plan, including milestones, activities and sponsors across the areas of integrated customer (beneficiary) management across channels, technology, staff capability and beneficiary engagement. More importantly, the event helped to build consensus and buy-in for the new business model – a prerequisite for success, given that

moving certain counselling services online would represent a considerable cultural shift.

The ASE approach resulted in a robust, achievable plan, plus a commitment to change on the part of THT managers and staff at every level.

For more information on the Accelerated Solutions Environment, please go to <http://www.uk.capgemini.com/ase/>

Case study: Apple Inc

The recent history of Apple is an object lesson in successful business model innovation.

Apple Inc.'s company history reached rock bottom in 1997. Revenues fell by over 35% over two successive years. Management was being replaced almost every year. The company suffered a loss in the region of \$1bn plus on a 1997 turnover of \$7bn. Market share in the PC sector fell to 2% and the share price hit an all-time low of just \$13.

Fast forward 12 years, and we find a completely different picture. In 2009 turnover rose by about 35% compared to the previous year and stood at over \$43bn. Profit for the year rose to \$8bn in 2009 and the share price rose to over \$185 in the same year. What had happened?

The old model: PCs and software

Apple's mid-1990s business model was based on the production and sale of PCs and related software. It targeted a number of groups but built up a particularly faithful following among software developers, designers and creative professionals, who bought into a brand positioning that had more of an emotional resonance than IBM's mass-produced goods.

Apple focused heavily on closed platforms, from hardware components to its own operating system, which gave the company maximum control of the supply chain as well as of the usability of its products. Furthermore, Apple developed specific capabilities in design and simplification of user interfaces of its products. Sales were run through distribution partners, and revenues were obtained almost exclusively through the sale of PCs and software.

However, the company's ability to innovate declined significantly after the departure of Steve Jobs. Instead of satisfying its demanding customers with a pipeline of creative and innovative products, existing products were milked to the end of the product life cycle. The downfall had started.



The new model: digital entertainment

The return of Steve Jobs in the mid-nineties was the turning point. As well as many specific measures, such as the strict optimisation of the supply chain (which soon bettered even Dell's), he re-activated the company's ability to innovate. Essentially, Apple moved from being a hardware and software producer to a supplier of "digital entertainment". Instead of earning money from the production of PCs, it would now focus on lifestyle products and content.

The starting point was the development of new lifestyle products like the iPod and iPhone. In Apple's former core area of PCs, it created products like the MacBook Air, oriented towards mobility and entertainment. The software required for the new entertainment business model-iLife, iTunes, QuickTime or MobileMe-was variously developed or purchased.

At the same time, the company built up new capabilities in digital content such as music and films, which complemented the entertainment products it was developing. In order to have better control over customer interaction and market positioning, Apple established its own flagship stores, where products are showcased and customers educated and advised.

Capitalising on existing strengths

Despite the radical transformation to a new business model, Apple built on some of its existing strengths in the creation of this new world: its design competence, loyal customer base, and skill in managing proprietary systems.

The design competence, in particular, is in the genes of the company. Since its inception, Apple has systematically built up capabilities in design and specifically interface design, and these award-winning competences later helped it design attractive entertainment products. Be it the iPod, iPhone or iPad, each product's success can be traced to the

improvement it offers in usability compared to existing solutions. Apple has consistently retained its design competence in-house, whereas many other producers have outsourced design.

This approach has secured an almost irrationally loyal customer base, particularly with designers and programmers. This loyalty helped Apple during the launch of the App Stores, where it was able to gain a fast growing portfolio of interesting applications for the iPhone, for example. This group, as brand ambassadors, were also one of the main reasons for the jump from early adopters to the mass market.

Another success factor has been Apple's expertise in the set-up and consistent management of closed, proprietary systems, which permit complete control over the product and the customer process. This has enabled the development of simple, customer-oriented, smoothly operating platforms like iTunes (the first really unified development platform in the mobile market), as well as the creation of attractive incentive systems for application developers. At the same time, this absolute control ensures a uniform customer experience and brand perception across all sales platforms.

Innovation culture

Strong synergies between various business models (for example iTunes/App Store and iPod/iPad/iPhone) help Apple considerably. These micropayment-enabled marketing platforms also offer Apple customers a simple and convenient way to personalise entertainment products for greater usability and usefulness. Further synergies exist between hardware and entertainment products. Taking these two areas together, Apple has enormous purchasing power and a strong position in sales channels.

The effect of the change in the Apple business model is clear. With the iTunes music store, Apple hit 6bn

downloads and a market share of 70% of the worldwide digital music sales in early 2009. The iPhone applications were even more successful with over 1bn downloads in the first nine months. And Apple is achieving significant revenues in the new areas. iPod and music-related services contributed almost 30% of turnover; the iPhone and related services almost 20% in the second quarter of 2009.

A final, crucial factor for success was and is the innovation culture that is enshrined in Apple's processes and structures. The foresight to recognise and embed these in the company came from Steve Jobs.

Business cases

Properly used, a business case is a valuable tool for decision-making, not just a way to justify decisions that have already been made.

Cost consciousness is now a familiar part of the life sciences industry, to an extent that few would have imagined two to three years ago. We see an emphasis across all our clients on better understanding and controlling their cost bases. For most companies this emphasis now extends past the knee-jerk, “non-essential” areas of spend into all aspects of the business and decision-making.

However, what is striking from an outsider’s point of view is to see how many of these businesses misuse, misunderstand or ignore the value of a business case to support decision-making. We see both ends of the spectrum in our client organisations, and everything in between: from companies that make most decisions without any objective analysis to those that won’t consider anything unless it has been through a rigorous process of business case evaluation.

Interestingly, in the vast majority of instances where business cases are used, the exercise is viewed as nothing more than a process that must be gone through on the way to implementing a decision that’s already been made. In other words, the business case is used to justify and rubber-stamp decisions that have been made by some other means, whereas it should be used to ensure that the right decision is made in the first place.

We believe that sound, objective analysis is a precondition for good decision-making, and that the business case should be the vehicle for this analysis. It is a critical tool for the organisation, and should be understood not only in rational terms but also in the context of the broader political and emotional environment

in which decisions are made. This article examines what forms a business case can take and the role that it can, and indeed should, play in your organisation.

What’s in a name?

A benefits case should be distinguished from a business case proper. These are two fundamentally different categories of analyses, designed to answer different levels of questions and support different decision-making situations faced by individuals and organisations. Here are some broad definitions:

- **A benefits case** is typically a short document, most commonly a presentation but perhaps backed up with a high-level spreadsheet, that articulates “why we might be interested in doing something”. The intention here is to look at what is possible and begin to gauge the potential scale of benefit to the business. The case would normally cover the likely projected returns, and is often presented from an “opportunity loss” point of view: “if we don’t do this, we will miss this much of an opportunity...” Benefits cases are normally straightforward to pull together; they contain a few assumptions (sometimes heroic ones) and very limited scenario or sensitivity analysis.
- **A business case** can take two main forms:
 - A high-level business case is about understanding orders of magnitude, assessing options, choosing where to focus and deciding where to spend time calculating detailed figures. In our article on Shared Service Centres (SSC) in the Summer 2010 edition, the high-level business case was recommended as the



vehicle to support the decision about which option (outsourced, in-house, offshore and so on) would be right for your business – or indeed whether there was justification for an SSC at all. This is an excellent example of how high-level business cases should be used.

- A detailed business case (sometimes called an investment case) is where the detailed implementation costs, investment requirements, revenue streams and cost reduction projections are analysed and explained. Often, some sensitivity analysis is performed to understand how sensitive the results are to the key assumptions. Ideally, this detailed business case should be prepared in such a way that it can easily map to either a departmental or a business unit P&L to allow budgets to be agreed and released.

It is worth noting that, as the detailed business case contains a thorough assessment of all the costs, it nearly always looks less financially attractive than a benefits case. In other words, if you have prepared a benefits case and

it doesn't look particularly appealing, it is unlikely that by proceeding to prepare a detailed business case you will make it look more attractive.

We sometimes find that after a detailed business case has been prepared there is a need for further scenario analysis, to examine the likely effects of “what if” factors, such as changes in the market place, changes in customer demand and external pricing pressures.

Choosing the right type of analysis

Where many organisations go wrong is that, where they do use a business case, it is a standard “one size fits all” type document that tries to cover all the situations mentioned above. The effect is that it fails to hit the mark with certain stakeholders or in certain situations.

For example, a detailed business case for a single option is not appropriate right at the beginning of a project or discussion as it offers too much information about the single solution. Later, too, it will be hard to convince stakeholders that enough time was

spent on understanding the reasons for a given action, or on considering a number of options before jumping to a conclusion.

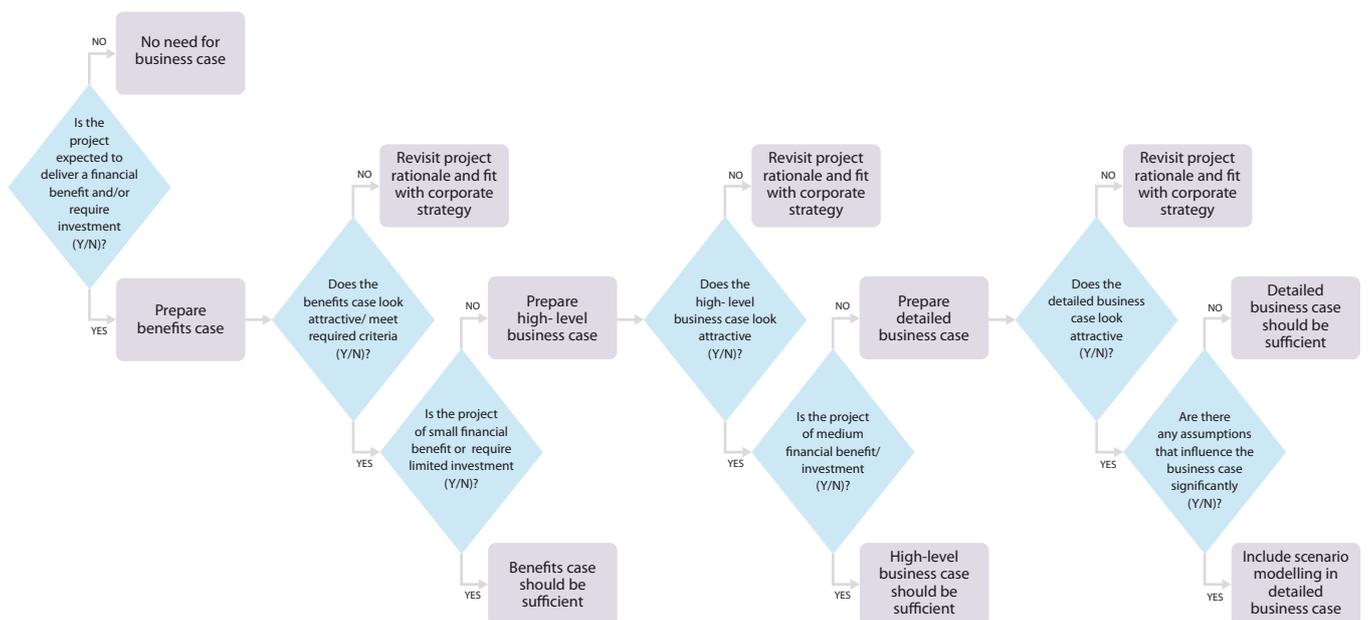
In our experience, organisations that successfully use business cases are those that have a clearly laid out process that explains how to determine which type of business case is needed. Figure 1 shows a possible process.

Important as it is to “add up the numbers”, several other elements need to be considered when creating a business case. More often than not business cases are created when something significant is going to change, and in these situations there are not only rational aspects to consider, but also political and emotional ones. In our view, attending to the following areas drastically improves the execution and success of a business case.

Set up a robust benefits tracking process

A benefits tracking process that kicks in as soon as the business case is prepared is a great way to make the business case stick, yet this is the element that most organisations overlook. It answers the question “did

Figure 1. Decision tree for determining what type of business case is required



we deliver what we said we would?” by measuring and tracking the delivery of benefits from the initiative. If you knew that someone was going to be asking you for a monthly update on how the benefits are flowing versus the stated profile in the business case, wouldn't it keep your mind on what was agreed?

Understand the overall change management approach The business case is a tool to support decision-making, which is often a group event, performed through management teams, steering groups and so on. Therefore, the business case needs to be viewed as (among other things) a stakeholder management tool. A well-executed business case can address various levels of question or potential objection from individuals such as “Why are we doing this?” “Have we considered all the options?” “What about doing X or Y instead?”.

But for the business case to do this, the process by which it is created is as important as what it contains. That process should start at a high level and gradually refine the supporting numbers and arguments. This might mean beginning with a benefits case and working through a high level business case to a detailed business case.

Rapidly get to one version of the truth Those that work with numbers on a daily basis understand that there is an element of subjectivity in all calculations. For the most part these inherent decisions about how to build up a particular figure are programmed into our information sources (Enterprise Resource Planning applications, business information systems, and so on).

Often when creating a business case, numbers are required that are not readily available from the business, and the process of creating and agreeing these numbers can often lead to disagreement. One important principle that should be understood and accepted by all those creating, reviewing and agreeing the content of the business case is that there are no “exact” or “right” answers (or rather, there are a number of potentially “exact” and “right” answers).

Therefore what is important is that the process used to create the case is as rigorous and objective as possible given the need for a timely decision. Sometimes this means a day of desk-based research; at other times it may mean weeks of detailed analysis of the business.

Either way, the business case is a tool to support decision-making that for the most part needs only to be directionally correct rather mathematically perfect. Experience suggests that problems with buy-in to the numbers are for the most part nothing to do with rational considerations regarding the numbers themselves, and more to do with emotional/political aspects that are not being addressed.

Get others to test the business case

Gardeners say you should ask your worst enemy to prune your roses, because the owner is often too delicate with them. Much the same can be said of the creation of business cases: the individuals that are closest to a particular initiative (which in many cases will already have performance objectives associated with its success) are not best placed to make an objective assessment of its potential benefits. For this reason, the assump-

tions and numbers in the business case should be tested not only with supporters but also with cynics and critics, to ensure that the case is balanced and fit for purpose.

Conclusion

Too often, the business case is seen as a hurdle that must be jumped in order to get on with the initiative. In our view there is no value in going through the motions of creating a business case to justify a decision that's already been made.

In the current climate of cost containment and where every dollar invested needs to deliver a clear and demonstrable return, a business case is essential to support effective decision-making at senior executive level. They are not always easy to prepare, but given sensible guidance over what type is needed and when, and with a clear process for tracking delivery of intended benefits, they can be one of the most powerful decision-making tools at your disposal.

Preview: digital transformation study with Massachusetts Institute of Technology Center for Digital Business

Capgemini Consulting has signed a three-year research collaboration agreement with the Center for Digital Business at the Massachusetts Institute of Technology (MIT). Under this significant agreement our two organisations will conduct a joint research programme to find out how companies are managing and benefiting from digital transformation.

Digital transformation is already an area of strategic focus for Capgemini. We define it as the radical improvement of products, services or business processes through the use of digital technologies.

The rationale for the study is that, although mobility, smart products, social media, analytics, and electronic commerce have already had a profound impact on business, the extent to which they have transformed organisations varies across companies and regions, and even within companies. By studying companies as they currently are, we plan to gain a perspective on the state of digital trans-

formation, the process of transformation, and how companies can position themselves to benefit in the future.

Our approach contrasts with existing research, much of which has been focused on the internet and pure “bit-based” businesses. We believe that businesses and organisations oriented towards physical products will be equally dramatically affected by digital technologies, and our research will probe their experiences.

The programme will gather and analyse the views of senior executives from 25-30 major global organisations, together with insights from leading industry experts. The type of questions we will be exploring include:

- How have digital innovations affected your company’s operations?
- What has triggered change?
- What is the best way to manage this type of change?
- What benefits have emerged from digital transformation?
- What are the lessons learned and keys to success?
- What has proved most difficult?

We expect to publish initial findings in Q3 of this year, followed by a full report later.



About Capgemini Life Sciences

Capgemini's Life Sciences Practice

is a leading global provider of management consulting, technology and outsourcing services to the pharmaceutical, biotechnology, and medical devices industries. Established in 1993, the team globally includes 200 strategy and transformation experts who concentrate on this industry, plus an affiliated network of 2,500 consultants with significant experience. Recognised as a thought leader in this sector, Capgemini brings an insider's perspective to the challenges facing life sciences companies and employs a deep industry understanding to provide integrated global solutions for top-tier clients in the sector.

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About Capgemini

Capgemini, one of the world's foremost providers of consulting, technology and outsourcing services, enables its clients to transform and perform through technologies. Capgemini provides its clients with insights and capabilities that boost their freedom to achieve superior results through a unique way of working, the Collaborative Business Experience™. The Group relies on its global delivery model called Rightshore®, which aims

to get the right balance of the best talent from multiple locations, working as one team to create and deliver the optimum solution for clients.

Present in 40 countries, Capgemini reported 2010 global revenues of EUR 8.7 billion and employs around 110,000 people worldwide.

More information is available at

www.capgemini.com

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