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Life Sciences | the way we see it

Global research report

Vision & Reality 6th Edition

From Market to Discovery and back...
The Value of Early Commercialization

Contents

Executive Summary

In the traditional "hand-off" model, a medical product moves from a company's R&D division to its commercial division. Since that model's inception, both the research and commercial environments have shifted, making it more difficult for companies to bring profitable products to market. To solve this problem, most pharmaceutical companies have turned to a new model, "early commercialization", in which a company's commercial groups become involved earlier in the development process.

Capgemini surveyed 200 life sciences executives to assess how, and how well, early commercialization is working. We also conducted 45 in-depth interviews to investigate the following:

- the efficacy of early commercialization efforts to date
- the benefits of collaboration between Commercial and R&D functions
- the limitations and challenges of this collaboration
- the risks of an overly commercial focus on the long-term viability of the R&D portfolio

Nearly two-fifths of executives thought the lifetime value of a drug could be boosted by 50% with the proper commercial input, and they thought this input should come early in development. However, current practices are far from ideal. These include establishing cross-functional project teams, organizing groups around therapeutic areas, and creating multi-functional decision-making bodies to manage product portfolios. These efforts have been less than successful because development and commercial teams do not have common goals and incentives and because the organizational structures of the drug development and commercialization have not been optimized for early commercialization.

Though commercial teams already provide input into development at most companies, this input at times takes a backseat to R&D-driven product development. Today, R&D and Commercial are not always speaking the same language; hence, input is not often fully understood or valued from either side. This lack of cooperation can put the product at risk by not fully aligning the product with the market and vice versa. This can result in products that are not prepared for the market and in markets that are not prepared for products.

Rather than emphasizing product approval, early commercialization encourages gathering clinical data to fulfill specific objectives for patients and payers. Early commercialization is also a tricky balancing act; too heavy an emphasis on commercialization can hamper innovation and foster an overly short-term focus, particularly in new therapeutic areas or first-in-class molecules where commercial may not have much experience.

However, appropriate corporate governance structures, goal-setting, tools for portfolio management, and decision making processes can help ensure that the best products are developed. These structures will not only expand collaboration between Commercial and R&D teams but also encourage life science companies to collaborate more effectively with customers: health care providers, payers, and patients. And this supports a shift from an overly product-driven mindset to one that is more customer-centric in its product development, one that ultimately underlies companies' ability to become truly innovative by unlocking untapped potential.

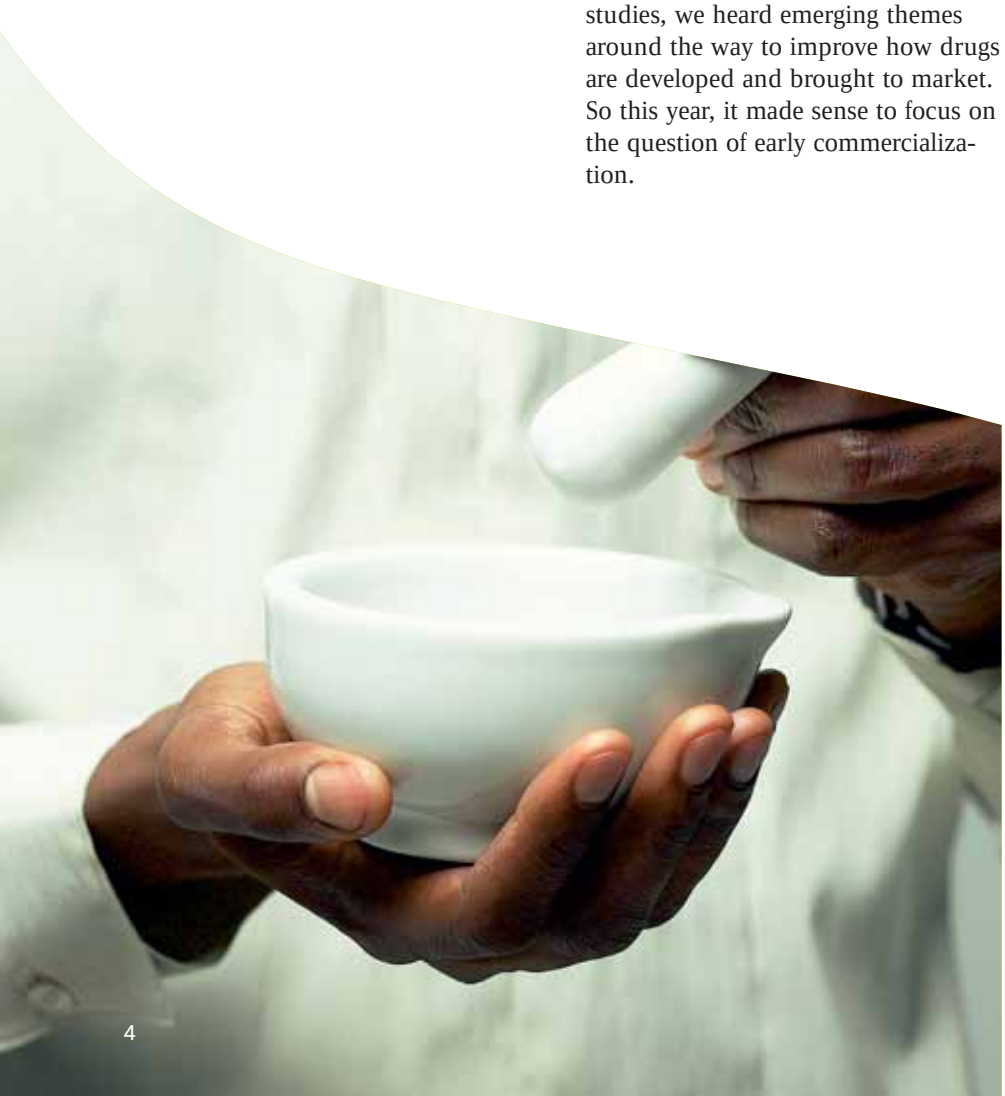
1. Study Overview

Why Do Companies Need to Get Better at Early Commercialization?

V&R series overview: Early commercialization is crucial to success in an increasingly difficult industry.

Every year, the Life Sciences Sector of Capgemini selects a research topic that is both timely and pressing for the life sciences industry. We conduct a global study on this topic and publish this thought leadership piece as part of our annual Vision and Reality series.

Our past two Vision & Reality studies focused on Lifecycle Management and the growing importance of Health Outcomes research. In both of those studies, we heard emerging themes around the way to improve how drugs are developed and brought to market. So this year, it made sense to focus on the question of early commercialization.



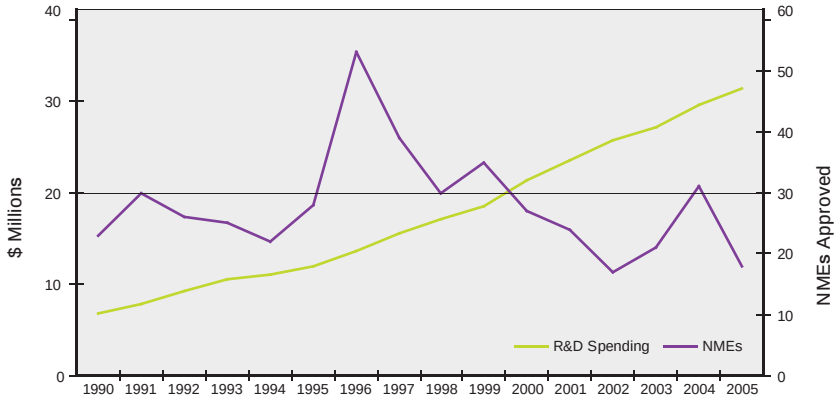
Over the past 15 years, the industry has faced both increased competition and increased difficulties bringing innovative products to market. Health care payers are demanding more from products than regulatory approval. The number of new molecular entities approved in the US each year has been dropping, even as R&D expenditure continues to rise. More significantly, new molecular entities (NMEs) make up a decreasing fraction of approved new drug applications (NDAs), a sign of a decline in innovation. With the cost of drug development climbing, the need to align R&D and Commercial functions has never been more acute.

Drug companies must make sure that both R&D and commercial resources are invested on commercially viable targets. So far, efforts to do so include establishing cross-functional project teams, organizing groups around therapeutic areas, and creating multi-functional decision-making bodies to manage product portfolios. Such efforts have had mixed results. Here, we analyze attempts across multiple companies and therapeutic areas to identify the elements for success in early commercialization.

Definitions of early commercialization: Early commercialization means re-engineering how R&D and Commercial work together, which ultimately means innovative product development.

Faced with increasingly tough customers and competition, drug companies must be sure that their products – fruits of their investments in a decade-plus development process – will be worth the return. Early commercialization is a means of doing so.

Figure 01 NMEs and Total U.S. Pharmaceutical Industry R&D Spending, 1990-2005



Source: Parexel's Bio/Pharmaceutical R&D Statistical Sourcebook 2006/2007; Outlook 2006, Tufts Center for the Study of Drug Development; Table 1 and Table 2, Profile 2006, Pharmaceutical Research and Manufacturers of America (PhRMA), 2006

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Though most frequently seen as the process of adding commercial input at the earliest stages of product development, early commercialization is really about creating a development process that balances the perspectives from the discovery, development, and commercial organizations within a company. Ideally, it blends analyses of market-driven innovation with innovation coming from scientific research efforts.

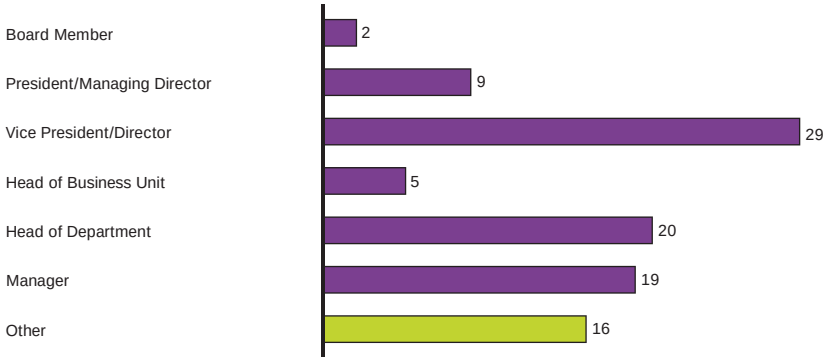
But this shift does not happen simply because industry leaders want it to. Early commercialization requires a different approach to developing products. This means new ways to prioritize potential projects and new ways to allocate resources to them. Additionally, management needs to create both mechanisms and incentives for disparate organizational functions (often functional silos) to collaborate.

Study methodology: This report builds on the views of nearly 200 senior executives from drug companies around the world.
We used input from nearly 200 drug company executives to explore the following:

- the efficacy of early commercialization efforts to date
- the benefits of collaboration between Commercial and R&D functions
- the limitations and challenges of this collaboration
- the risks of an overly commercial focus on the long-term viability of the R&D portfolio

Figure 02 Respondent information

Which of the following best describes your title?



N = 89, Percentages

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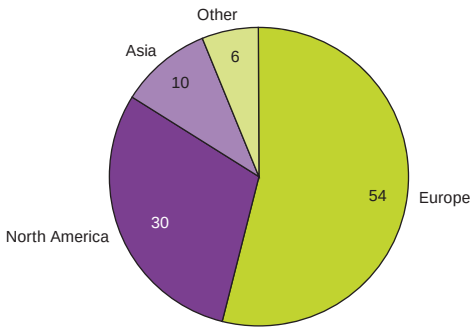
Figure 03 Respondent information

In which region are you personally based?



N = 82, Percentages

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Note: Executives surveyed were not required to provide contact or other personal information to participate

We conducted 45 one-on-one interviews with senior executives in R&D, strategic marketing, managed care, medical affairs and marketing and sales. They came from large pharma, biotech, and medical device companies. Executives shared global and regional perspectives across the US and Europe. Additionally, we solicited opinions from nearly 150 senior executives through an online questionnaire.

We analyzed quantitative and qualitative data to learn how the reality of early commercialization differs from the vision. We evaluated what works and what doesn't in early commercialization and drug development today. Our research answers the following questions.

- What forces are perpetuating changes in the drug development and commercialization process?
- What forces work against change? Do barriers to change reside primarily within organizations, company or professional cultures, processes, or elsewhere?
- How will early commercialization work in the future?
- How will drug development and customer solutions evolve over the future?

We want to express our sincere appreciation to everyone who participated in this year's Vision and Reality Study. There was enormous interest and energy expressed around the topic and we hope you all find our report thought-provoking.

2. The Early Imperative

More-Demanding Payers, Less-Certain Science and the Urgency of Early Development

Nearly half of respondents in our survey felt that early commercialization was driven by a tougher environment (decline of blockbusters, increased R&D costs) and mechanisms to cope with it (importance of portfolio management and product lifecycle management). New technologies have expanded the number of candidates that drug and device companies can pursue. At the same time, extracting revenues from the marketplace has gotten tougher, with more-demanding payers and greater competition.

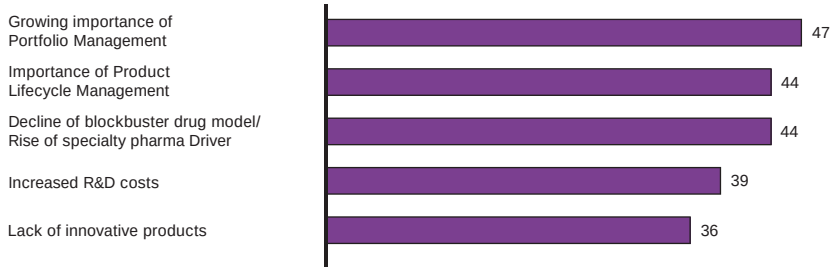
Development faces pressure from both of these trends, but rather than working out systems to resist this pressure, too many development teams keep a narrow focus on getting products through registration. Though commercial teams have input into development today, this input tends to take a backseat if R&D can argue that incorporating commercial input could complicate or delay regulatory approval. Such priorities do not maximize products' uptake and value.

Successful drug companies can no longer feel sure that a product will have a market once it gains approval, they must do everything possible to make sure the market will be there.

Threats to Company Revenues: What used to work no longer does

The market is moving away from blockbusters toward smaller products that face greater competition. Six blockbuster drugs came off patent in 2006, twice as many as the year before. The era of blockbusters is coming to an end. With plenty of effective generics around, health care payers are increasingly reluctant to pay a premium for new products. Even for products that are still on patent, competing drugs exert pricing pressures.

Figure 04 Top 5 drivers for earlier commercial input



N = 87, Percentages

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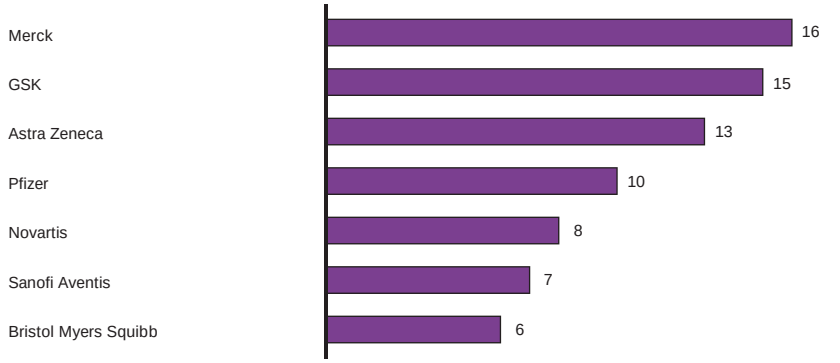
Figure 05 Big pharmas are too vulnerable to patent loss



% Sales vulnerable to patent expirations through 2009

"Pharmaceutical Industry Pulse", SG Cowen & Co, 2006, p 13

New products seem likely to follow the personalized medicine trend and so have smaller markets. Even innovative products increasingly have only short periods of exclusivity. Pharma companies must learn to maximize market penetration and reach peak sales quickly.

Reimbursement and pricing are getting tougher.
Simply registering a compound is insufficient. Currently, decisions about drug development focus on regulatory approval and tend to overlook the need to win payers' support, but managed care organizations are playing a bigger role in health care delivery, and drug costs are under heavy scrutiny. Payers have responded to skyrocketing health care costs by making reimbursement more challenging and by shifting costs to patients. Pharmaceutical companies need to have clinical data to convince health care payers to set favorable reimbursement policies.

The U.S. federal government pays for nearly two-fifths of the health care in America, when Medicare, Medicaid, the Department of Defense, Veterans Administration, and the Office of Personnel Management are taken together. They may not be able to do so in the future. Traditionally, pharmaceutical companies have used higher profits in the U.S. to offset lower profits in the rest of the world. With the recent changes brought about by the Medicare Modernization Act and recent changes in the political environment, US government payers are likely to try to drive drug costs down. Thus, companies will need to find ways to rebuff pricing concessions in Europe and the rest of the world.

Costs of sales and marketing are skyrocketing.
While the rising costs of drug development are well-known, the costs to market and sell drugs are rising as well. Thus, revenues from increased sales may not be worth the cost of increasing sales. As a testament to this, Pfizer laid off a huge fraction of its drug sales force at the end of 2006. To escape this trap, life sciences companies must create products that are less costly to sell.

Threats to Development Resources: Costs of R&D continue to rise

Regulatory authorities are increasing requirements, making trials more expensive.
Regulatory agencies seem more willing to force product recalls and are becoming more likely to require extensive safety data before approval. The number of black-box warnings placed on drugs in the first two months of 2005 was 2.5 times that of the number of drugs approved over the entire year, according to Nature Reviews Drug Discovery. The FDA is on the defensive in the wake of the Vioxx trials and other accusations of lax safety requirements. Thus, the FDA is likely to require evidence from more and more kinds of patients and to require longer-term monitoring with more stringent assessments for toxicity. These new demands will no doubt accelerate the rise in development costs.

New technologies are increasing the number of potential compounds and ways to test them.
Assessing compounds is more complicated because technology has expanded the playing field for R&D. Genomics, molecular diagnostics, and other technology platforms are bringing forth unprecedented numbers of ideas for new products. High-throughput screening and target identification technologies now proceed at a blistering pace, and the pace continues to accelerate. The ability to analyze pathways and expose interactions between proteins gives researchers

many ideas about how to make a drug, or combinations of drugs, work. While these abilities could lead to innovative products to command price premiums, the process of working out new discovery technologies is still risky and expensive.

The Best Protection: Early Commercialization

Development must adapt to pressures from new technologies and a shifting market.

The tougher marketplace and broader research field are squeezing drug development, making the traditional model of developing drugs unsustainable. The drug development process is already facing higher development costs, longer development periods, and more complex trials. Clearly, it cannot afford to waste money on developing drugs that will not recoup development costs.

To adapt to these pressures, companies must know what products have markets worth pursuing (portfolio management) and how to make these products competitive within these markets (product lifecycle management).

Development plans must consider more than regulators' requirements. They must be able to provide payers, providers, and patients with reliable information about health outcomes. The medical and economic benefits of the drug must be clear, and the trials that assess these benefits must be transparent.

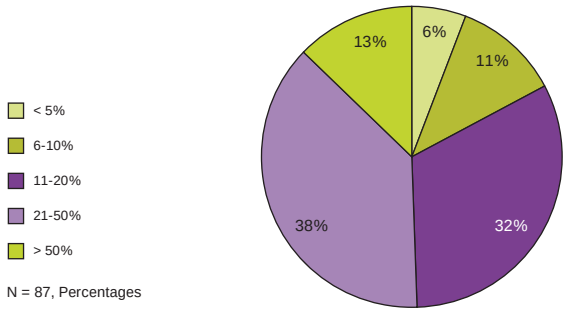
Commercial concerns are often discounted early in development.

The considerations of non-regulatory stakeholders cannot be addressed adequately in late-stage trials or when a product is about to launch. Commercial and R&D teams must begin a dialogue early to make sure that 1) a product under development will meet customers' needs and 2) the market potential justifies the investment in development.

Four out of five of the executives surveyed believed that the lifetime value of drugs could be boosted by at least 10%, if only they had sufficient support from company's commercialization teams. In fact, nearly half thought the lifetime value could be boosted by 20% or more.

And these executives thought that the input needed to come early in development.

Figure 06 Predicted increased product value from effective commercial input



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"We need a paradigm shift in our thinking in Phase I and II. ....The only results that would stop us from continuing development is if study results are producing issues around safety and efficacy. We don't ask – early on – whether the patient would feel a difference."

But companies are not yet collecting the necessary information to make these decisions. Here's how one executive described it:

"We would need to have comparative studies much earlier in order to prove the clinically relevant outcome of a new product. If we had that, we could stop projects earlier and decide to out-license such developments."

Competing products are not considered during early clinical development.

Pharmaceutical companies are used to showing regulatory authorities that a drug is safe and more effective than a placebo. Now, they must show payers that it is differentiated and cost-effective. Health care payers want to know how a drug is likely to compare with its competitors and to have pharmacoeconomic data demonstrating that its use could bring down overall medical costs. In addition, governments have shown themselves increasingly willing to sponsor studies that compare generics to brand-name drugs and brand-name drugs to each other.

Drug companies should not be blindsided by outside studies, but plan clinical trials to find the formulations, doses, etc that show their drugs at their most efficacious.

"Being a late entrant to the market requires more data," one interviewee told us. Me-too products need head-to-head studies and outcome-based information to flourish. Now that payers want to see outcome data, companies need to be more rigorous about making sure a compound will be, and will be seen to be, best-in-class.

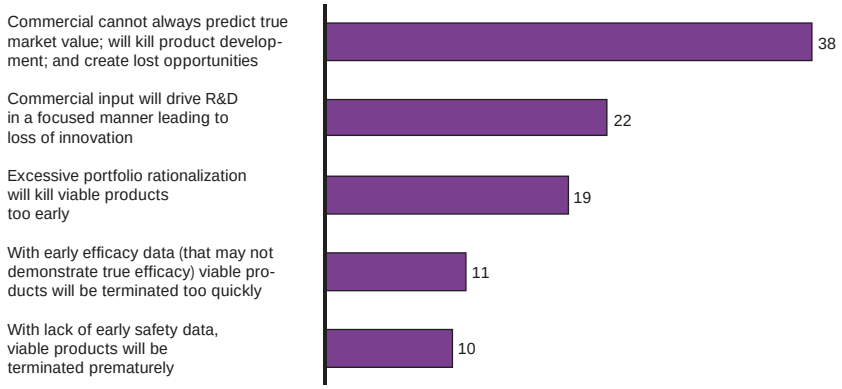
Here's how one executive described a missed opportunity:

"We had to prepare for a product that was less than ideal. If we had known about [the drug earlier in development], we could have shared knowledge we had about our competitor's product, which had been developed with a stronger target product profile and was going to launch first. Instead...it was too late to do anything."

3. The Paradox of Early Commercialization

Companies can ill afford to make costly development mistakes. As the industry struggles to adjust to a more-demanding market, any honest discussion of drug development must acknowledge that commercial input can hobble products' potential as well as expand it. Interaction between commercial and R&D teams can sometimes be more confrontation than collaboration. But addressing these differences in opinion early is the best way to find innovative solutions for products.

Figure 07 The greatest risks of commercial functions providing early input into drug development are



N = 86, Percentages

Capgemini 2006

Too much management can spoil the medicine: the risks of early commercialization.

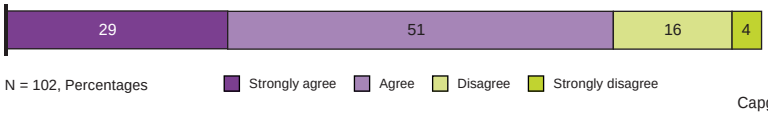
Detractors of early commercialization usually focus on the risk of increased commercial input into R&D. They have a point. Early commercialization doesn't just ask executives to plan for the future. It asks them to predict it. Of course, predictions of future market potential are unreliable, particularly for products that are early in development. Thus, decisions about how or whether to continue a program can easily turn out to be wrong. In particular, companies are likely to kill programs too early because they do not perceive its full commercial potential.

Then, there is a very real risk of bogging a project down with bureaucracy. Commercial input into clinical development complicates an already complex process. In addition to evidence of efficacy, commercial teams want to know about health outcomes, patient preferences, and pharmacoeconomic measures. Heaping additional requirements on clinical candidates can increase the risk of failure, lengthen development times, and delay product launch.

Finally, there is a hazard of stifling innovation. Scientists believe in serendipity; they want to see where the science will lead them rather than follow a planned path. Too much commercial focus can lead to short-term strategies that jeopardize the long-term viability of a company's pipeline and enervate innovation. Indeed, near missteps form a kind of "comeback kid" lore in the pharmaceutical industry. R&D executives like to tell of products that were almost killed for lack of a potential market, and then went on to become blockbusters. These anecdotes follow a familiar arc: a commercial department forecasts a tiny market and moves to kill a project; strong-willed project managers fight to keep the program alive. Years later, they are vindicated by billions of dollars in sales.

Those in the industry will learn, and repeat, these tales. But another story is far more common: only about one in three drugs that make it to market ever recoup a company's R&D investment.

Figure 08 In our current state, I believe we have not achieved the full market potential of our products (or those we could have developed)



Too little planning shrinks markets. Proponents of early commercialization have their own stories of success and failure. Many stories shared with Capgemini do not feature comeback kids, but untapped potential. These tales begin when products reach Phase III trials and executives realize they have lost a treasure through trial designs that lack foresight. The product moving to market is hobbled with a sub-optimal regimen and dosage form, uncompetitive formulation, a higher than expected cost of goods, or other problems.

These stories from executives at different companies are typical.

"All the studies have been designed for the US market only. ...to file for the same indications in Europe we would have needed different study designs. Now we only launched for severe causes of [confidential indication] and thus lost €400m peak sales in Europe – half of the total potential for [confidential product]."

"With [confidential product], it took us ten years to reach $1 billion, and we could have done it in 2-3 years. If [the team] had been able to incorporate commercial input earlier, this would have changed not just ramp-up for [confidential product] revenue, but the total revenue [the team] could have generated and changed the entire company."

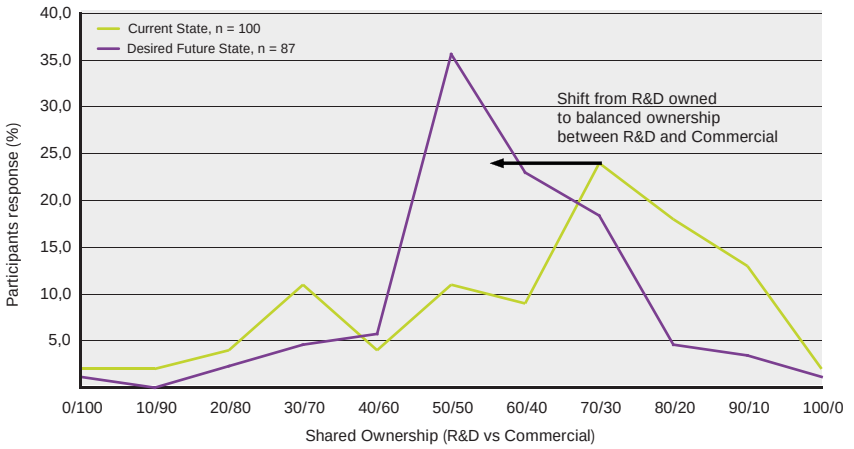
An ounce of early insight can be worth pounds (and dollars and Euros and yen) in sales. The success stories usually involve planning and plodding, and behind-the-scenes details are more likely to be kept confidential. Still, successful "making of" stories share common themes.

- Clinical development processes reflect market requirements. Trial designs anticipate country-specific demands for both regulatory approval and managed care reimbursement
- Lifecycle strategies are identified early. Companies assess priorities for different lifecycle strategies early, and regularly reassess them throughout the product lifecycle
- The product can make claims competitors can't. If a competitor project is set to launch just a few months behind a company's product, early commercial input can craft differentiators that can keep a competitor from gnawing away at market share

Proper processes enable innovation. Of course, both the tales of comeback kids and squandered treasures are true. Early commercialization provides tangible benefits (and success stories) only when done well. Done poorly, early commercialization hinders innovation and obstructs the R&D pipe with a short-term focus – spurring strong-willed project managers to confrontation and derring-do.

R&D and Commercial must find a way to balance power and collaborate for the greater good of the company. A third of our interviewees felt that portfolio management should become more patient-centric and less product-centric. When R&D has too much control, companies risk developing products that are misaligned to market needs. When commercial takes control of the decision process, it has too short a focus and too much

Figure 09 Ownership of drug development



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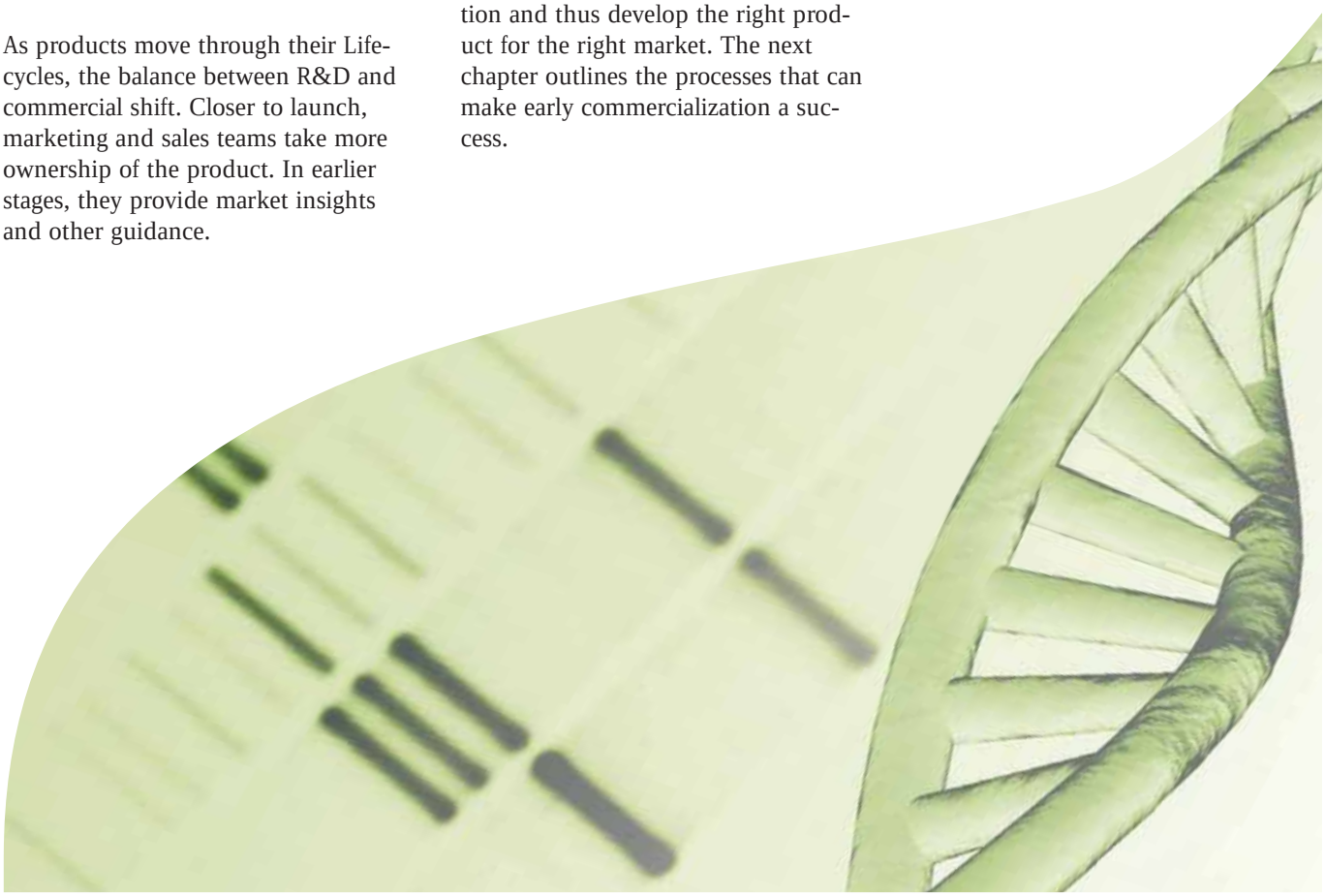
emphasis on products' lifecycle. Executives sense this. Most respondents in our survey thought that the ownership of drug development should be split 50/50 between the R&D and Commercial organizations.

As products move through their Lifecycles, the balance between R&D and commercial shift. Closer to launch, marketing and sales teams take more ownership of the product. In earlier stages, they provide market insights and other guidance.

The question is not whether to change the current model in order to incorporate commercial input earlier. The question is how to do this well – to bring in the appropriate input at the appropriate time to optimizes innovation and thus develop the right product for the right market. The next chapter outlines the processes that can make early commercialization a success.



4. Components of Early Commercialization

What It Takes to Develop the Right Products for Tomorrow

Today's Snapshot

Many commercial functions provide some input into product development, with market research and new product marketing departments most closely involved. The timing of commercial involvement varied significantly from company to company in our survey. About half of respondents said commercial began to provide input in Phase II or later stages. Our results might be somewhat biased toward the later stages, since some of our respondents would be more likely to become involved later in a products' lifecycle. For example, executives working in a regional division of the company would likely participate later than executives in headquarters do.

Still, people are likely to overstate how early commercial input comes into the drug development process. As one executive put it, "Everyone likes to say they get involved at Phase II, but we all get involved in Phase III." Given that 82% of our respondents said that commercial input should happen by Phase I or earlier, Phase III is clearly too late to help shape a product's launch and development. In fact, nearly a third of our respondents thought commercial input should occur even before a product moved into animal testing.

Transforming organizations to foster better innovation will require significant change. In the current model, organizations are NDA-centric prior to launch. Their core objective is to bring the product to market as soon as possible. In the new model, mindsets will need to change. Having the right product and the right evidence to ensure market access and penetration will go side-by-side with speed to market.

This new model will require the transformation of several activities conducted during the development and market preparation stages (see Figure 10). These include, but are not limited to, the following:

- Therapeutic area / technology platform strategy
- Portfolio management
- Corporate development
- Commercial input into clinical development, TPP, and labeling
- Pricing, reimbursement and health economics
- Lifecycle management
- Market shaping
- Messaging

The point is to evolve from a drug development process that sees an NDA as the end point toward one that sees meeting customers' needs as the end point. The rest of this section exposes how each one of these activities should evolve if companies are to

really benefit from early commercialization.

Therapeutic Area (TA) Strategy

Companies should define the strategic framework that will guide the search and development of new products.

The most researched disease areas (cardiovascular, diabetes, etc) are the most competitive. No company can afford to develop even a fraction of the compounds pursued through research, so companies must make these investments strategically.

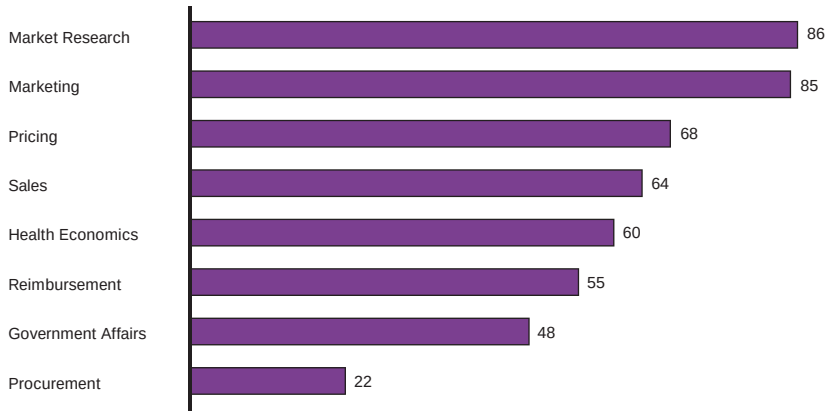
Therapeutic areas typically refer to a cluster of products in a similar category. The designation should go far beyond that: TAs should be viewed as business entities with their own TA strategies. In addition to conducting all the necessary market research, companies should develop concrete vision for each TA. These should include overall goals, a strategy for which spaces the company will compete in, and a pipeline plan to support the TA strategy.

Crucial first steps are taking a thorough inventory of the therapies now available and forecasting likely developments. Companies must also take stock of their own assets and capabilities. The assessment can be broken down along the different functions of the company.

- Understanding the disease. What is its prevalence and prevalence of diagnosis? What are the approaches to treating it? What population is afflicted or at risk?
- Understanding the technologies: What established or promising technologies can provide ways to address unmet needs?
- Understanding stakeholders' needs and the competitive environment: What kinds of patients need treatments? What are attitudes toward treatment? What do competitors have in their pipelines? What is the reimbursement potential?

Based on such analyses, companies can choose what therapeutic areas to pursue. These will provide the guiding principles to manage the overall portfolio. From there, the company can select the targets and compounds to test, look for treatment mechanisms, delivery mechanisms, and any relevant devices. They can even look for companies or compounds to acquire.

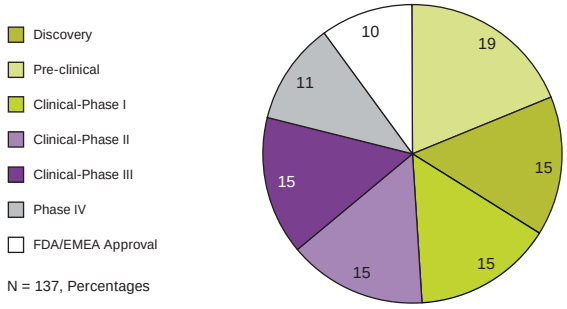
Figure 10 Involvement from commercial functions includes participation from the following areas



N = 148, Percentages

Capgemini 2006

Figure 11 Commercial functions begin to provide input in drug development during…



N = 137, Percentages

Capgemini 2006

Figure 12 When should commercial involvement begin in drug development?

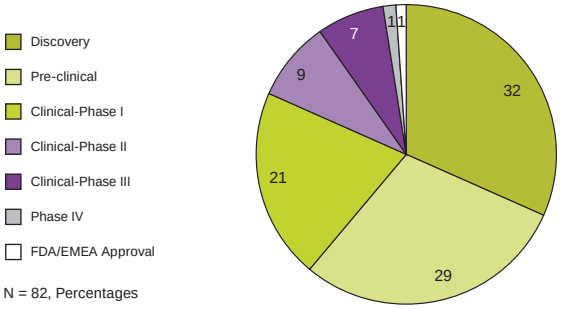


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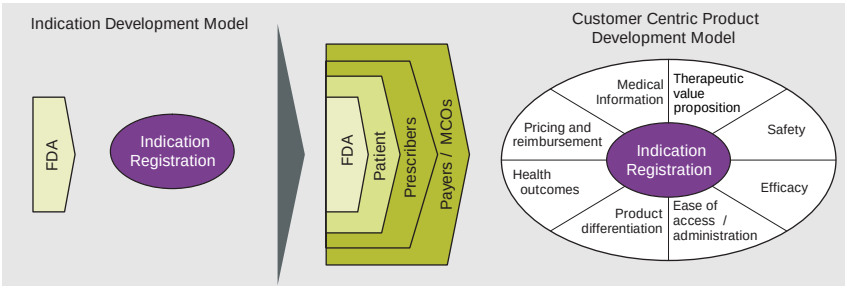
Figure 13 Life Sciences companies need to reconsider their indication development model and expand it to a „Customer Centric Product Development Model“



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Portfolio Management

Optimal portfolio management flows from overall corporate development strategies.

Executives in our study most frequently cited better portfolio management as the strongest reason for bringing commercial input into early development. Many organizations underperform when managing their portfolios because they do not realize that evaluating a portfolio is more than evaluating the current status of products within it. Too often, companies consider products in isolation, without considering the competitive landscape or the rest of the portfolio. Portfolio management should proceed on two fronts: in terms of the therapeutic area as a whole and then in terms of products. Without that framework, companies can maximize the value of one product, but adversely impact the value of the portfolio.

Too often, pharmaceutical decisions come from an inconsistent process that makes no sense even to those within an organization. R&D often feels that its projects or products are misunderstood and undervalued. Often they are right (see previous chapter). For example, at least one product to treat GERD (gastroesophageal reflux disease) was nearly killed because of low estimates of its value, but went on to become a blockbuster. Thus, portfolio managers, whose goal is to maximize the potential of products, are widely viewed simply as project killers.

Go/No-Go decisions, a jumble of political, emotional and rational components, need parameters.

An early strategic analysis creates a structure in which rational portfolio management and go/no-go decisions can be made. More powerfully, it ensures that the R&D team is better equipped to consider the competitive environment when designing trials and deciding what studies should – and should not – be done.

Rather than simply asking if a product is likely to get approved, managers can ask whether it will help the company succeed. They can ask how an opportunity is aligned to the TA strategy, or whether the opportunity is sufficiently attractive that the TA

strategy should be realigned. This has several benefits:

- helps define how an organization should focus its research, development and commercial resources
- creates a context to evaluate potential projects within a given therapeutic area
- builds cross-functional awareness of what a company wants to achieve

These strategies must not be made too rigid (or too flexible), and should be regularly re-assessed. Done well, an early analysis ensures that resources will go toward deliberate progress, and not haphazard, unfocussed exploration.

Use broad evaluation tools to evaluate a portfolio, and take them with a grain of salt.
The current valuation methods provide limited input into an investment's actual value. The cost of failure (having a drug fail at a stage 3 or having scarce specialized resources working on a compound that fails) puts intense economic and emotional pressure on these decisions.

Clear criteria for evaluating elements within the portfolio are difficult to set. Usually, portfolio managers use tools that are too blunt to make crucial decisions. Overwhelmingly, our interviewees tell us that they rely too much on assessments of net present value (NPV), and that this instrument is inadequate for assessing products going through a complicated development process within a complicated industry.

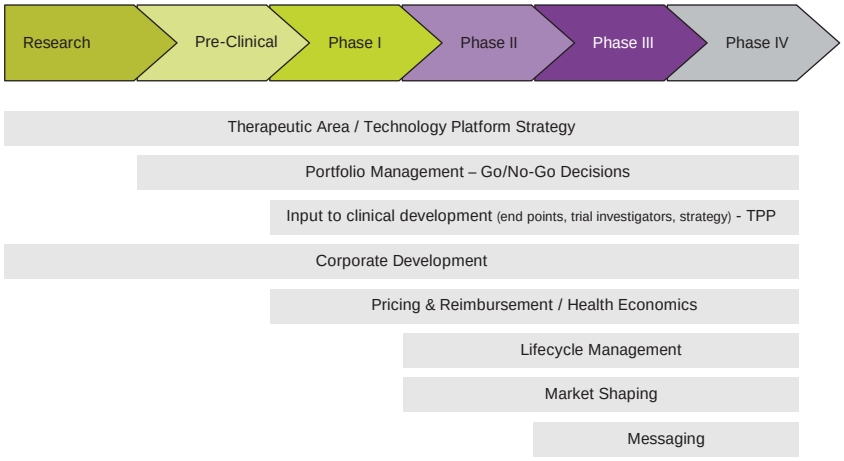
More powerful options; such as Real Options and Monte Carlo analysis exist but are not yet widely used.

Financial tools such as these should be only one component of an evaluation process that includes many other factors. Criteria that are essential to a product's success, such as competitors' products and the attitudes of patients, physicians, payers, are often given too little weight.

Consequently, researchers rightly dismiss some of these tools. One R&D manager questioned whether marketing insights were valuable:

"The key question is what marketing can contribute! They should answer the question whether a product fits into the overall strategy or whether it meets a new medical need. But who defines the medical need? They don't do profound-enough market research [to define the world 15 years from now], and they lack scientific and systematic ways of working."

Figure 14 The components of early commercialization



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Decision-making processes must be clear and inclusive.

What's missing, are not only evaluation tools, but also management practices that support good decisions. Currently, departments work in isolation or even against each other. The situation described below is typical.

"[The] portfolio is either managed by Finance (from a pure NPV approach) or by R&D from a project resource allocation perspective. This is difficult to change because R&D is very protective and territorial, and Marketing is not sufficiently equipped resource-wise to own portfolio management."

Successful portfolio review must be supported by appropriate processes and organizational structures. Though each company will implement their reviews differently, the following characteristics are essential:

- Decision-making criteria should remain consistent between annual portfolio reviews, milestone reviews and reactive reviews (reviews triggered by significant events, like regulatory changes or competitors' activity)
- The same groups of decision makers should be represented across review processes
- All parties, from financial to marketing to R&D, must have clear deliverables
- Senior management should take part in all critical decisions
- All levels and departments within the organization should believe in the process
- The portfolio database and models must be kept up to date (regular reviews, at least once a year)

Once criteria are clear and understood by everyone, resources can be allocated appropriately. Organizations within the company should know how to demonstrate potential worth, so that when they compete for limited resources, the winners are those whose products fit corporate strategy. Such competition should support a culture of innovation without overspending on exploratory research and without overproducing me-too products. Clear, sensible criteria would truly enable an innovative culture incorporating a balanced view from R&D and Commercial.

Commercial Input into Clinical Development, TPP, and Labeling

More than a series of go/no-go checkpoint, a good development strategy shapes products for the market.

Too often, product development strategies are based mainly on a product's toxicology and the desire to minimize development time. Global R&D teams make the strategic decisions about which studies to conduct and when to recommend abandoning a project. Though marketing generally briefs these project teams on products' likely commercial environment, new product marketing teams usually operate separately from R&D and have little influence on clinical decisions. Even if a cross-functional global marketing team exists, its influence rarely extends beyond the definition of an often shaky NPV for the product.

The problems of disjointed approaches are manifold. Too many resources are wasted on low potential products. Product potential is poorly understood or appreciated too late. Not infrequently, potential product advantages are wasted, because the clinical studies do not demonstrate appropriate health outcomes or superiority against competition. The case study below shows that this is not necessarily the case.

To develop products that customers need, the currently isolated teams (R&D, marketing, and health outcomes) must collaborate. They will have to jointly design end points and study protocols based on future competitive dynamics. Questions they should answer together include the following:

- What dosing is best for the product based on unmet medical needs and competitive offerings?
- What is the optimal clinical end point? Should we wait for a true clinical change as the end point? Given that managed care organizations in the US have relatively short-term relationships with their customers, should a quickly assessed and easily monitored surrogate end point be used instead?
- What non-clinical end points can be analyzed during the studies? Patient-reported outcomes are based on a subjective scale of their experience. When can such information be useful?
- Should we conduct head-to-head trials that could demonstrate superior efficacy against existing treatments? When would a cheaper, quicker placebo trial be appropriate?
- Who should be involved in designing the studies? What kind of input from what experts or thought leaders could help us obtain buy-in from the medical community? From patient and payer groups?

TPP and labeling should drive development strategy.

Used well, the target product profile (TPP) can become the roadmap for success that different functional teams navigate by.

"The TPP defines hurdles for the development process. And since the accountability for the TPP lies with Marketing, they provide the frame for the [team] and influence go/no-go decisions. Within the TPP we very early on define planned pricing, estimate patient flows, define the clinical profile and thus set the baseline for the Business Case Model and the ROI and NPV calculations. And we define realization probabilities which in turn are the basis for the decision tree analysis. All these give us data which will be discussed within the Business Committee who then decide about the development portfolio."

To be an effective tool, a good TPP must have the following characteristics:

- Set the direction for the clinical strategy
- Be the standard against which the development team is held accountable
- Be developed jointly by R&D and Commercial
- Incorporate the insights from an in-depth analysis of the current and future market and competitive environment for the new compound
- Be a living document, updated in light of all changes in the internal and external environment

In reality, the TPP is too often a "must do" task that R&D teams complete to comply with a process imposed by Corporate. In some organizations, Commercial has no input into the TPP – it's all R&D driven. In others, Commercial owns the TPP, but it does not impact the clinical strategy.

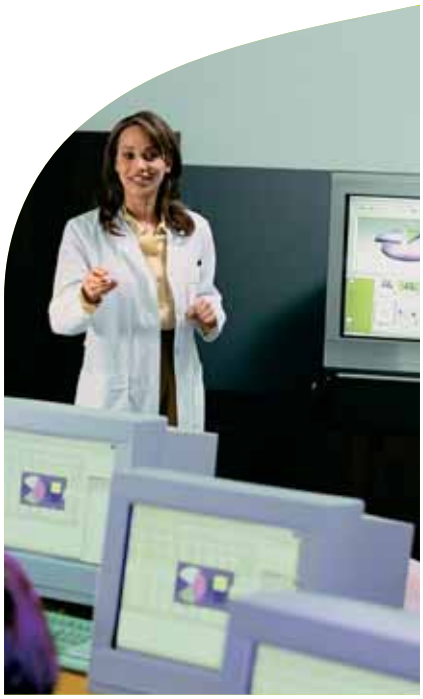
Case Study: Merck's Clinical Trial Differentiates Its Drug

A well-shaped clinical strategy matters. For example, Merck made its anti-cholesterol drug Zocor (simvastin) stand out from a crowded field of statins by opting for an outcome with an impact.

Before Zocor, most statins won approval through measuring the ability to lower cholesterol, a surrogate end point. Merck decided instead to look at real clinical outcomes: deaths from heart disease and heart attacks compared to placebo. It made a significant investment in conducting one of the world's largest outcomes-based trials ever.

In 1994, Merck reported that Zocor could help prevent heart attacks and save lives in people with high cholesterol who have heart disease. Patients taking Zocor had 42 percent fewer deaths from heart disease and 34 percent fewer heart attacks compared to patients on placebo. Such results trumped what other companies could claim; patients and doctors are less inclined to choose drugs shown only to lower cholesterol when they can use one shown to save lives.

Though Merck spent more time and money conducting large outcome trials, these results made Zocor more than a 'me-too' product. Indeed, despite the dominance of Pfizer's Lipitor, the tangible outcomes from the study gave Merck a powerful marketing tool, turning Zocor into a frontline therapy for cardiovascular disease.



To make a difference, the TPP must become a core process even more than a document. It must be a tool that enables Commercial functions to be a part of the creative process that makes a product happen.

Corporate Development

A clear corporate strategy means fewer wasted resources.

Early commercialization only works if a company knows where it's headed. Corporate Development should work with internal product development teams better to recognize good external opportunities. In particular, internal and external programs should complement, not compete with, each other. The role Corporate Development plays in drug development can take many forms, but it must be clearly defined and transparent to all parts of the organization: research, development or commercial.

"So now we're at the Board, trying to make decisions on three different [internal and external] projects that are all going after development of the exact same thing. How did it happen? What a total waste."

Transparency of vision and clearly defined roles mean similar projects against similar targets are less likely to duplicate efforts. Better, teams are more likely to share knowledge with one another. Dialogue across therapeutic areas and between commercial and R&D will increase. Not only will this increase efficiency, it could boost innovation.

Getting the best pipeline will mean both inlicensing and outlicensing.

Corporate development plays a key role in identifying licensing opportunities and negotiating with companies to share the risks and revenues of a product with its originator. Licensing strategies intersect many company functions. Both scientific and business due diligence are required. Lifecycle management teams must weigh in.

Recently, companies have tried to fill dwindling pipelines and increase efficiencies through mega-mergers, biotech acquisitions, development and marketing alliances, and licensing deals. Though some deals have been misaligned with overarching strategies, big pharma for the most part invested in compounds that fit into its pipeline and overall strategy. Big pharma has been less active outlicensing compounds that no longer fit with its strategy. Given the low probability of success for innovative compounds, big pharma must develop contingency plans and other approaches in parallel with its planning to sell and distribute the product.

Deciding which products to invest in and which to divest of within a therapeutic area is impossible without a well-defined corporate strategy. Companies need to clearly set forth what defines them as a business today, what they hope will define them in the future, and how they will bridge that gap.

Pricing & Reimbursement & Health Economics

Early commercialization should anticipate payers' questions of a drug's value.

Large pharma companies attempt to circumvent payers' influence by using sheer commercial muscle to make sure that the provider and patient communities are demanding the drug and then going to the payers for reimbursement. Huge organizations or companies with a very innovative product can still use this tactic. However, for most companies, addressing payers' needs can make the difference between lackluster and booming sales (see case study).

Payers are taking a more central role in defining a drug's market. In

response, pharmaceutical companies and biotechs will have to address payers' needs earlier in their strategies. Price level is often a determining factor in how payers approach drugs. Pharmaceutical companies must be able to argue that their price levels are appropriate. Why should they put a drug on a formulary that is priced 10 times the cost of existing treatments?

Payers also have a very specific perception of value. Valuable drugs must not only have demonstrated their ability to reduce overall treatment costs, they must also be deemed likely to benefit the types of patients that a payer covers. For example, Medicare plans may be reluctant to pay for drugs tested only in younger patients with few comorbidities.

Pricing, reimbursement and health economic strategies are all about meeting payers' expectations. Pricing and reimbursement strategies require a deep understanding of the medical and economic value of competitors' existing and potential treatments. A thorough analysis should be conducted when a company selects which therapeutic areas to pursue. These strategies should start even before the very first patient is dosed. As more is learned about a product's characteristics, manufacturers should make sure they obtain a payer's perspective on them, and adjust their strategy in line with their expectations.

Clearly, the benefits and characteristics most important to payers should be emphasized. Health economics and health outcomes are increasingly being used to set reimbursement and policy decisions. In Europe, central government payers already demand an analysis of health outcomes in reimbursement dossiers. In France, committees plan to look at Amélioration du Service Rendu. In the UK, the National Institute for Health and Clinical Excellence (NICE) has very specific expectations of what data should be included.

Drug companies must appreciate that payers are different and create specialized plans for each main payer. In Europe, central government payers look at the full benefit for society over the long term. After a drug has been approved, its reimbursement status and sales could be drastically revised based on health outcome studies on actual patients. In the US, payers are more interested in showing that drugs can save money by avoiding the need for more costly treatments.

In particular, price differentials across different countries should be considered very early in development to determine the order products should be introduced in different countries and therefore what clinical studies to run first.

The lesson here is to assess what data each payer needs to see today and what data they are likely to need in the future. Then, drug companies should adjust clinical and health economics plans accordingly.

In the near future, drug companies will need to partner with payers as early as the initial development stages. They will have to understand precisely the needs of each payer. Collaboration will go beyond input into pricing and reimbursement approach. Payers may become critical partners in the design of the drug profile and clinical study strategy. Drug companies may even need to establish advisory boards to gather payer input systematically.

Payers can be critical partners in designing drug profiles and clinical study strategies.

Historically, US payers have paid little attention to health economics data. Until recently, health economics was not even part of the information payers requested from pharmaceutical companies for making formulary decisions. This is starting to change. The AMCP successfully imposed a formulary dossier that requires health economics. Though health plans may not make their decisions based on this information now, they are likely to do so in the near future.

The proposed Effective Health Care Program (MMA Section 1013) aims to conduct and support research focused on outcomes, comparative clinical effectiveness, and the appropriateness of pharmaceuticals, devices and health care services. If this initiative succeeds, the effectiveness of competing drugs will be assessed by independent organizations. A similar program initiated by the state of Oregon provided results that favored the use of generic drugs and brought down prices in that market. Medicare Part D is demanding that drugs show their cost-effectiveness, and private payers will certainly follow the governments' lead. In addition, public agencies are increasingly publishing comparative data. As price points become more transparent, pricing concessions made to one entity are likely to be demanded by others.

Lifecycle Management

Product lifecycle management: plans can help aging compounds retain their vigor.

Lifecycle management strategies should be considered routinely during portfolio review. Though it cannot compensate for mistakes during product launch, product lifecycle management is growing in importance. Companies must manage a product as its own entity and consider its various indications and formulations collectively. The product should be managed from a services or solution point of view, focusing on how the product can serve unmet needs of various customers.

Amevive Case Study
Drug Companies that Fail to Anticipate Payer Policy Can Pay a Very High Price

In 2003, Amevive, Biogen's highly anticipated biologic for psoriasis, was poised to be a big hit with patients, physicians, and payers alike. It was the first biologic to win FDA approval for psoriasis, and its immunosuppression represented a unique mechanism of action with the potential for a more durable response to the drug.

Consequently, Biogen priced Amevive at a significant cost premium over Amgen's Enbrel (etanercept), which commanded over three-quarters of the biologic market for psoriasis. But Biogen did not justify the price premium with pharmacoeconomic arguments.

At Amevive's launch, Enbrel had been used by dermatologists for the treatment of psoriatic arthritis for more than a year. Though its prescriptions were off-label, doctors and payers were familiar with Enbrel and confident about its efficacy and safety.

FDA approval gave Amevive a useful message for marketing, but it offered no additional justification for its price. But physicians and payers did not believe that Amevive's unique method of action translated to an improvement in care. In fact, Amevive's onset of action was more than five weeks slower than Enbrel, and payers were not convinced that Amevive even offered a more durable response, let alone one that had clinical or pharmacoeconomic significance.

Reimbursement policy also discouraged physicians from using Amevive. Enbrel can be purchased and self-administered by patients, but Amevive must be purchased and delivered by clinicians, who risked not getting reimbursed for their purchase.

In fact, many payers refused to add Amevive to their preferred formularies, and doctors who did use the drug were not always reimbursed for its use. Patients also balked at the often 20–30 percent co-pay required for Amevive.

Because these problems were not addressed proactively, Amevive's launch was stillborn.

Source: Russo, M. and Balekdjian D. Biologics Beware: A new study says biologics are at the top of payers' lists for cost containment. Pharmaceutical Executive (June 1, 2004)

Companies that are successful at lifecycle management know how to sequence indications and leverage new delivery mechanisms to maximize a product's lifetime value, through higher peak sales, longer time at peak sales, and extended patent protection. Appropriately planned market exits or switches to OTC are also essential to raise the bottom line.

However, as with other commercial inputs, lifecycle management usually begins far too late for maximum success. Some executives reported that lifecycle management starts four years after launch. The planning process for lifecycle management could begin much earlier, as early as phase II development.

Market Shaping

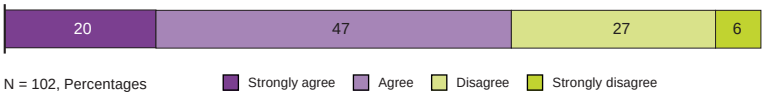
Market Shaping: Soliciting input from diverse opinion leaders can identify, and influence, ideal market conditions.

Even pharmaceutical companies that think carefully about shaping their products do not always work to shape their products' market.

For market shaping to be effective, pharmaceutical companies must get closer to their different customers: patients, providers, payers and the associations and coalitions that represent their interests. Markets shaping generally means working with these stakeholders to help them better express their needs and impact health care systems. Beyond providing them with disease state and product information, pharmaceutical companies can support their activities. Such actions can take the form of prevention campaigns, vaccination clinics, information for patients about the risks of a specific condition (notably in the context of serious co-morbidities, etc.).

Patients benefit because they get better information about their health

Figure 15 Market shaping activities occur typically too late and limit the speed to peak sales



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and can make more educated decisions. Associations benefit by expanding their scope and/or effectiveness. Thought leaders benefit by having their opinions better reflected in treatment design and patterns. And pharmaceutical products benefit from the increased visibility the conditions they treat receive.

As regulations become more stringent, pharmaceutical companies must start thinking of preparing the market for their product much earlier in development. Our interviewees told us that market shaping is done infrequently and done well even less frequently. When market shaping is attempted, it typically occurs too late, especially for first-in-class products. A good time to start market shaping activities is in phase II when the product concept is being finalized.

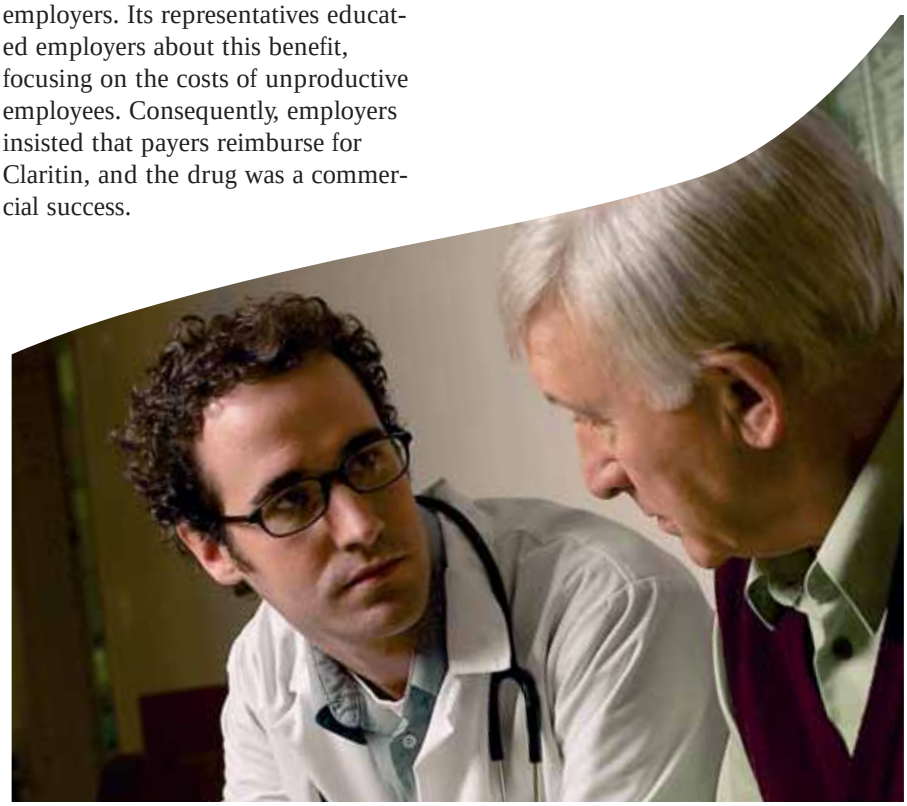
Messaging

A good product is no good unless the right customer appreciates it. In addition to exploring and shaping market opportunities, drug companies must become better at explaining the value proposition of their product to each set of customers.

Today, most new product marketing units research market needs and test potential product positioning, usually starting their activities around phase II (earlier in the best cases). Teams define core marketing messages around each product and often do use feedback from the thought leaders in the medical community to good effect. However, they are less likely to consider the perspective of other customers, such as payers or employers, and so miss opportunities to distinguish themselves from competitors.

The allergy drug Claritin is a powerful example where considering a non-medical customer vastly improved a drug's potential. From an efficacy and safety standpoint, Claritin offered no advantage over the established market lead, Benadryl. However, Claritin had one critical difference: it caused less drowsiness in patients in the two hours after they took the drug.

From a provider or a payer's perspective, this is unimportant, and is certainly not a big enough advantage to justify a higher price point or better formulary placement. However, Claritin's sponsor realized that this difference would be very important to employers. Its representatives educated employers about this benefit, focusing on the costs of unproductive employees. Consequently, employers insisted that payers reimburse for Claritin, and the drug was a commercial success.



5. Toward the Transformation of Early Commercialization

The benefits of successfully implementing early commercialization are clear. The actual means of doing so are not. The transformation requires inventing new processes, redefining the culture of both R&D and Commercial organizations. Each company will ultimately have to define its own model and approach to make it work.

Early commercialization is not just another process for executives to pace through. It is a transformation of the drug development process. To succeed, early commercialization must be less focused on increasing commercial influence over R&D and more focused on integrating inputs across a company. Currently, R&D works to meet the needs of drug approval agencies; commercial departments must essentially repurpose these products toward other customers, particularly health care payers. Early commercialization must bring patient needs and payer expectations into the early development process. R&D and commercial organizations must work collaboratively to develop products that meet these demands.

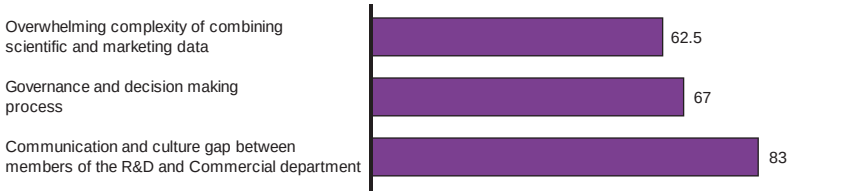
This is a huge shift in the way product lifecycles are managed. Rather than gathering clinical data to get a product approved, early commercialization builds specific objectives for patient and payer needs into development.

In our survey, respondents identified several barriers to effective commercialization. The top three stem from factors that hinder collaborations between commercial and R&D teams. In some cases, corporate structure itself can be problematic.

Drug companies can use several levers to implement early commercialization, but for the effort to succeed, executives must appreciate the scale of the changes they are asking for. Teams must understand and accept that customers' needs must impact the development process while simultaneously protecting the integrity of scientific innovation. This is not only a change in behavior and mindset, it requires organizations to develop new capabilities at the intersection of science and marketing that are still rare in pharmaceutical companies. The transformation will, of course, be difficult.

However, the transformation is not unprecedented. Diverse industry sectors – car and other manufacturers, food packagers – have faced similar challenges successfully. For these industries, product development is both part of R&D and responsive to market specifications. The health care

Figure 16 Top 3 barriers to better drug development



N = 88, Percentages

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market is unusual, however, so pharmaceutical companies will need to invent their own solutions for early commercialization.

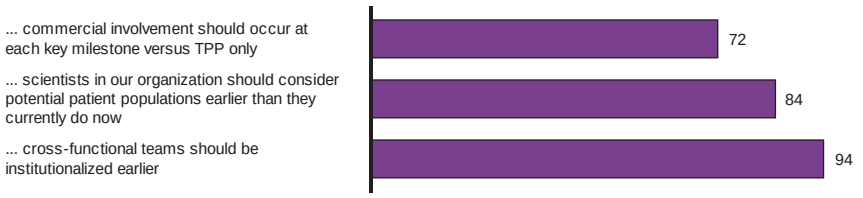
Early commercialization requires balance in corporate governance. Commercial inputs must not impede R&D integrity and creativity.

All pharmaceutical companies interviewed in this survey had set up a governance model that brings commercial functions into early development. However, these models must also protect R&D. Commercial teams want to ensure that products developed will not only have a market but that they can beat competition in that market. However, no one can really know what the future market will be, nor can a product's potential be fully understood until its performance in the market can be gauged. Thus, when commercial teams want to kill projects deemed to have low revenue potential, they must take care to consider whether their forecast is a failure of the product, or of their own imagination.

To make these decisions, companies typically use cross-functional committees that meet regularly to assess the scientific potential of a molecule as well as its commercial viability. It is unclear that each team is willing to hear what the other has to say within the current organization. Here's how one interviewee described the situation:

"It can't just be cross-functional teams. As long as someone in another 'territory' owns the product, the team won't work together and follow the same motivations."

Figure 17 In the future state, ...



N = 87, Percentages

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To be effective, cross-functional teams need to share several characteristics. They need to:

- Be institutionalized early enough to really impact the product concept (i.e. at the beginning of Phase I or earlier)
- Continuously oversee the product's strategy and its implementation (not in an ad hoc fashion at major milestones)
- Be empowered to define product strategies independently from the different functional silos
- Have the leadership required to drive the organization's implementation of these strategies
- Base their decisions on an in-depth analysis of scientific and market facts

Drug companies must reshape their incentive systems to favor collaboration.

When R&D and commercial departments do not share a common goal, collaboration is not likely to work. R&D managers are typically rewarded for reaching key milestones in product development on time. These milestones are geared toward approval by regulatory authority. Commercial teams are rewarded for their efforts on products that have launched. Their milestones are based on short-term sales and P&L targets. Each kind of team tends to feel that the other's goals are a hindrance to its own, if they feel the other team has any influence at all.

To solve this problem, companies should develop shared project incentives. Right now, R&D teams have little reason to focus on market conditions or unmet needs, complained one executive.

"They don't understand the business and have no interest in commercial input because they have no incentives to make commercial products. Hence, they feel no benefits or consequences."

Clearly, the solution is to change key performance indicators. Instead of rewarding R&D teams for getting a drug approved, for example, perhaps both commercial and R&D teams should be rewarded based on time to peak uptake.

To support new incentives, the role of the TPP could be expanded to include needs of patients and payers that R&D teams can consider when designing trials. Accordingly, specific commercial objectives for the product could be shared between market and research. No matter what tools are used to align the goals of market and research, shared goals should be based on a company's objectives within a therapeutic area.

Early commercialization will demand new skills from both R&D and commercial organizations.

Early commercialization will transform what executives expect from their core teams. In R&D, managers must expand their knowledge outside science. They must be able to consider patient needs and how these needs may vary across patient segments. Their development plans should consider factors like optimal formulations or delivery devices for different populations. They must understand market potential and pricing and be open to input from commercial representatives – even if these representatives have only a limited understanding of the science underlying this therapeutic area and the product. Finally, R&D professionals must completely revise their idea of success. They must accept that the end game is not submission to regulatory authorities but the timing and height of peak sales, and they must adjust their activities in pursuit of this new, more ambitious, goal.

Commercial teams must also be willing to embrace change. They need to keep an open mind that projects may have commercial potential that is not obvious at early stages. They must be more willing than ever before to get a firm grasp of the science. This is essential both to gain legitimacy and communicate with R&D teams. At the same time, they must find the right language to describe market input and

communicate these data so that researchers can act on that information.

Ultimately, this transformation requires a new breed of executives who are respected by both sides of the organization. Drug companies will need to groom these executives from both the R&D and marketing organizations. Additionally, pharmaceutical companies should train executives from outside these two core functions who can work to bridge cultural differences.

Pharmaceutical companies must prepare for expanded external collaborations.

Multiple departments across a company have a role to play in the development and marketing cycle. Success requires internal collaboration between R&D, regulatory affairs, managed care, reimbursement, strategic marketing, medical affairs, and more. The next level of collaboration is finding ways to elicit input from physicians, external scientists, patients, and payers. This input can be used to design protocols and position the product.

Pharmaceutical companies often resist opening development processes to outside influences such as payers. Though the risks are real, the benefits clearly outweigh them. Developing products with properties that payers value can ensure a better position in the formulary as well as higher reimbursement levels. Drug companies should view such collaboration as just one more approach to secure a product's future.

Finally, enhanced collaborations will redefine the nature of a company's relationships with CROs and other service providers to the industry. Pharmaceutical companies must prepare for this change, and get more comfortable exchanging their traditional secrecy for an ultimately more profitable transparency.

Case Studies

Capgemini has significant experience in helping companies improve how they optimize drug development. The following case studies highlight only a sample of projects where we have helped companies, in different ways, through early commercialization efforts.

A key actor in the biotech business with worldwide presence has, with Capgemini's assistance, formalized when and how to accelerate the preparation of early commercialization activities.

For this biotech, commercial involvement now starts by having a member of corporate marketing on the R&D project team as early as the pre-clinical phase. The TPP is at the center of the dialogue with R&D and is updated on a regular basis. It is then approximately 1 year before moving to Proof of Concept that the number of actors involved in the early commercialization effort is broadened, with the inputs of departments such as Medical Affairs, Governmental Affairs, Health Economics and Regional Marketing. A pre-launch plan will then be formalized around the R&D clinical milestones and will enable building a two-way highway describing the interactions between R&D and early-commercial teams until launch. This plan also details the interactions among the early commercialization teams themselves where individuals accountable for their early-commercialization activity jointly design and describe the required interactions with other team members. The plan will be updated on a regular basis.

The approach to early commercialization that Capgemini designed and tailored for this biotech, has now been implemented and standardized cross the organization and widely accepted by R&D. A system has been developed to capture the various pre-launch activity details thus allowing the extended pre-launch teams to have full and regular visibility on the work needed for commercial success.

With several upcoming launches into a single therapeutic area, a mid-size pharmaceutical client faced serious challenges integrating new product positioning and messages into an existing portfolio. Lacking a unifying portfolio strategy the success of future launches was at risk. Moreover, if patient-physician confusion arose around relative benefits and product choice across the category, these future products could dilute the core franchise.

Capgemini assisted a cross-functional therapeutic area team to look across the current and future competitive environment, and to begin the work of clearly positioning the individual therapies, and the portfolio as a whole, for clear market success. After an internal assessment of the pipeline products and an external market assessment, ten major initiatives were identified. These initiatives spanned the organization – spawning a cross-functional planning team comprised of marketing, managed markets, sales, medical affairs and R&D. This team worked together to reassess the individual strategies and positioning for each product, and to create an overall portfolio strategy. To ensure alignment across the company, Capgemini facilitated a series of checkpoints and workshops in which the combined functions and teams discussed product fit and likely positioning, and overall portfolio plan and path-forward.

As a result of this undertaking, launch sequences, planned clinical trials, cannibalization strategies, and promotional education strategies have been amended and refined to ensure continued overall portfolio success. The organization now has a documented and aligned portfolio strategy which has helped clarify how new products will affect inline brands and how new products will be received in the marketplace.

A top-10 pharma sought to increase the lifetime value of its brands – both in-market and near-term pipeline products – so it could meet current business objectives and bridge an innovation gap while awaiting future high-potential products in development. Additionally the company sought to assess and refresh its go-to-market approach to account for rapid evolution in the healthcare buying markets.

Through a multi-phased process of market and environmental assessment; competitive analysis; and stakeholder identification, requirements, and evolution; this company with Capgemini developed an innovative approach to comprehensive pharmaceutical brand development. Ultimately, the core of this brand development strategy comprised three key ideals to brand optimization –

- Evolutionary shifts in the healthcare buying markets had raised the importance of 'customers' beyond the traditional physician-patient duopoly, and these customers were all keenly intent on demonstrated evidence-based value (EBV) in enabling their healthcare purchase choices
- Long-term, comprehensive planning processes are required, as annual brand planning processes can significantly impair long-term brand development. Imbalanced focus on current year sales and marketing goal achievements can undermine longer-horizon brand development initiatives
- Longer-term brand development required a new degree of collaboration between and among R&D teams, marketing teams, medical affairs, and therapeutic area business units to ensure unity of vision and purpose, resource balancing, and overall agility to respond to market opportunities

Development of the concept was followed by a series of pilots, each building on the learnings of the previous. Through progressive rollouts, the concept extended to mature brands, launch planning, and long-term disease state / therapeutic-area strategies.

Following pilot confirmations, Capgemini and our client developed detailed processes, toolkits and analytical aids. It has rolled this comprehensive planning process out to select co-development and co-promotion partners in important therapeutic categories, and built an organizational capability to envision and develop EBV messages and supporting research.

Like many companies in its peer group, a mid-size pharmaceutical manufacturer had very R&D-centric early commercialization processes. R&D Project Management was ultimately in charge of defining the product and clinical strategy with inputs from New Product Marketing. Reimbursement issues were largely overlooked until the year prior to launch, resulting in sub-par product positioning and market preparation.

Capgemini was brought in by Managed Care to build a new process that would ensure the reimbursement perspective is built into product development and commercialization strategy early in development. After many interviews and workshops with both commercial and R&D stakeholders, it became obvious that the company needed to develop and communicate a long-term reimbursement strategy plan along with its product development plan to ensure payer needs were appropriately addressed and maximize future reimbursement potential. A cross-functional team, including Managed Care, New Product Marketing, and R&D was developed to drive the strategy. More importantly, processes were put in place so that recommendations for reimbursement strategy would be translated into evidence that matters to payers: adequate clinical and health economic end points and studies.

The process is now being implemented. If everything goes according to plans, reimbursement, health economics and pricing considerations will be incorporated into product strategy as early as pre-clinical development. The company will then be equipped to make rationale decisions to fund the potentially larger clinical and/or health economic studies required to demonstrate evidence-based differentiation to payers.

About Us

Who we are

Capgemini's Life Science Practice is a leading global provider of management consulting, technology, and outsourcing services to the pharmaceutical, biotechnology, and medical devices industries. Established in 1993, we are known for the talent and dedication of our people, the value we deliver to our customers, and for how we work collaboratively with our clients. Our clients include the majority of the leading pharmaceuticals, biotechnology, and medical device companies.

What we do

Management Consulting: High-end, issue-based consulting, to enhance the top line or to optimize the bottom line of our customers.

Our expertise covers namely: Strategic and brand planning, product launch, reimbursement strategy, marketing and sales effectiveness, R&D transformation and portfolio management, and operations excellence (includes supply chain and shared services).

Technology Services and Outsourcing Services: Package-based implementation services (SAP, Document Management, Oracle, etc.) as well as custom-based development (on-, or off-shore). We also provide run services (BPO and IT services out of our Rightshore Centers located in: India, China, Canada, and Poland).

Thought leadership: Vision & Reality, our annual thought-provoking research primer zooms in on some of the industry's most pressing topics. The 2006 topic is entitled, "Early Commercialization." Topics from previous years include: Health Outcomes and Lifecycle Management.

We also provide to our customers access to Capgemini's Accelerated Solutions Environment (ASE) to drive senior management teams and large groups of participants (30 to 150) to collaboratively address critical issues and resolve vital challenges.

About the Capgemini Group

Capgemini, one of the world's foremost providers of Consulting, Technology and Outsourcing services, has a unique way of working with its clients, which it calls the Collaborative Business Experience. Through commitment to mutual success and the achievement of tangible value, Capgemini helps businesses implement growth strategies, leverage technology, and thrive through the power of collaboration. Capgemini employs approximately 61.000 people worldwide and reported 2005 global revenues of 6,954 million euros.

More information about individual service lines, offices and research is available at **www.capgemini.com**

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