Life Sciences

Approval is Nothing without Reimbursement:
Why Pharmaceutical Companies Need a Value Management Operating Model
Are some pharmaceutical, biopharmaceutical or other Life Sciences companies stuck in the past, using outdated approaches to determine which products to develop? It appears that many companies are, because they continue to emphasize clinical efficacy and safety criteria to determine which therapies to develop rather than criteria such as total product value and real-world, quality of life outcomes. Meeting efficacy and safety thresholds is no longer a guarantee that a new therapy will succeed in, or even reach, the market. Rather, patients, providers, payers and regulators frequently require companies to demonstrate that new therapies deliver distinctive value in order to gain support of providers and justify reimbursement by payers.

The divergent receptions given to two new products illustrate how profound the change in standards is for pharmaceutical companies, and the dangers of not using a value-based approach to guide new product development from the outset. The lukewarm reception and reimbursement that initially created Benlysta, a lupus therapy developed by GlaxoSmithKline and Human Genome Sciences, is a case in point. Benlysta gained Food & Drug Administration (FDA) approval in the US and European Medicines Agency (EMA) approval in 2011. Despite an annual cost of $35,000, Benlysta was eagerly anticipated by patients and investors alike. Benlysta was expected to reach peak sales of $2-$3 billion within 4-5 years. However, Benlysta sales have yet to take off and Human Genome Sciences saw its market value drop by 70 percent as a consequence. Simply put, the companies didn’t achieve reimbursement support and missed months, and even years, in certain markets as a consequence.

In the US, Medicare did not add a reimbursement code for the product for the first nine months it was in the market, which resulted in complications and skepticism among doctors as to whether they would be reimbursed (some doctors were also wary that Benlysta’s benefits were modest in clinical trials). In the EU, despite EMA approval, individual countries decided not to pay for it, which is becoming a common occurrence (see sidebar). The UK’s National Institute for Clinical Excellence (NICE) recommended against coverage because it was not convinced it worked better than an existing product being used off-label for lupus. NICE pointed to a lack of comparative efficacy data and determined that Benlysta did not represent “good value for money.” Germany’s peer agency followed suit, finding “no additional benefit documented.” Benlysta may yet gain the market traction expected, but its developers have a much tougher road to travel given its perceived value profile. GSK, Lupus UK and Primary Care Rheumatology Society all submitted independent appeals to NICE challenging the organization’s appraisal of Benlysta’s benefits relative to standard care. This past September, NICE upheld the appeals and agreed to review additional data from GSK to reassess Benlysta.

Contrast this experience with that of Incyte’s Jakafi (Jakavi in Europe). In November 2011 it became the first pill approved for myelofibrosis, a rare and life-threatening disease that causes a build-up of unhealthy blood cells in the bone marrow and organs, leading to abnormally sized spleens. Most patients also experience anemia, fatigue and chronic pain. Clinical trials cited in the FDA approval noted that Jakafi did reduce spleen size, the primary goal of the trials. Moreover, Incyte and its partner Novartis also detailed quality of life and symptom improvements identified through a validated survey of patient-reported outcomes (PRO).

In fact, Incyte worked closely with the FDA beginning in 2008 to develop the quality of life assessment tool once Phase I/II trial results suggested a marked improvement in symptoms. In the US, the FDA cited both the primary endpoint of spleen reduction and the secondary endpoint of symptom improvement in the clinical evidence supporting the drug’s approval, allowing Incyte to discuss all benefits in promotional efforts. Without the PRO, Incyte leaders believe the drug would have faced a longer and more complex regulatory pathway to gain full approval.
Regulators Increasingly Apply Value-Based Criteria to Reimbursement Decisions

Across the globe regulations are being tightened to require biopharmaceutical companies to demonstrate both initial and long-term product value. Risk monitoring programs don’t just monitor risk but also track outcomes. Beyond the long-term safety and efficacy of the typical Phase IV program, many regulators and payers insist on a “Phase V” to document long-term economic, social and quality of life impact after product launch. Both the FDA and EMA are challenging the Value Dossier in a more aggressive way and are more sensitive to the holistic effects of a drug. In Europe, companies face a proliferation of regulations, with some of the biggest markets imposing their own set of value standards that biopharmaceutical companies must meet in order to gain access (see Figure 1).

**Figure 1: EU and Other Country-Specific Updates Will Weigh on Future Products**

<table>
<thead>
<tr>
<th>Country</th>
<th>Key Regulatory Updates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>UK</strong></td>
<td>• The Health and Social Care Bill under consideration is expected to impose significant changes on reimbursement criteria, which is creating uncertainty for many companies</td>
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| **GE**  | • AMNOG Regulations appear to have greater requirements than UK’s NICE to demonstrate comparative efficacy and develop the value dossier  
• AMNOG is expected to parse out indications and carve out clinical trial populations |
| **FR**  | • Economic pressure has forced constraints on healthcare budgets, increased patient cost-sharing, spending caps per patient, and elimination of tax exemptions for orphan drugs above a certain size  
• Increased scrutiny of efficacy and safety claims and pharmacovigilance activities arose from recent scandals |
| **SP**  | • 2011 reforms focus on reducing the drug bill even further than the past  
• Regions are implementing their own cost-controls such as centralized drug purchasing, drug dispensing and formularies |
| **IT**  | • Austerity focus expected via rebates, risk-sharing arrangements, regional bids or buying groups  
• Expected to proactively promote generics and biosimilars  
• Expected increasingly restrictive, appropriate use monitoring of high-priced drugs, medical devices, and diagnostics |
| **Japan** | • Drug prices and reimbursement rates are refined every two years allowing the government system to capture cost savings as patent protection lapses and generics become available. Innovativeness of therapy is among several criteria used to define prices. |
| **US**  | **Landscape for reimbursement to be reshaped and risk and value management will be more prominent:**  
• Medicare, the major government reimbursement agency for specialty therapeutics, poised to implement episode-based reimbursement in major categories  
• Consolidating provider systems continues to emphasize risk management in care delivery for specific populations of patients  
• Large private payers are moving into provision of care with acquisitions of primary care physician practices.” |

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The very different regulatory and reimbursement experiences of Benlysta and Jakafi illustrate the importance of companies demonstrating distinctive and overall value in order to secure reimbursement for new therapies, rather than just meeting efficacy and safety criteria. What is driving the shift in focus to value? There are several factors, and the dominant one is simple economics. National health services and insurers are still dealing with the after effects of the global financial crisis and health care reform legislation, both of which have squeezed funds and profit margins.

In addition, it is now possible to demonstrate and calculate drug value more accurately given scientific and structural evolutions in the industry. First, genomic science enables a higher level of new product scrutiny, and has raised expectations that the efficacy and safety of new treatments be demonstrated for individual patients, not broad classes of people. Second, payers around the world are consolidating, and larger payers can exert more pricing pressure on biopharmaceutical companies to contain costs and more buying power to demand demonstration of value-for-money and proof of positive, real-world outcomes to justify reimbursement.

Most organizations have not adapted to these changes, and are using an increasingly obsolete clinical trial plan and short-lived product commercialization strategy that does not emphasize value. The results: more conditional approvals, more requests for risk evaluation and mitigation strategies and risk management plans, limited reimbursement, and poor market performance.

Yet the advent of personalized medicine and payer focus on value suggests that equally profound change is needed at pharmaceutical companies. Companies need to retool their operating models so that processes and capabilities emphasize value management as early as possible in the product development cycle to meet these new standards and expectations, including how clinical trials are shaped and conducted and the duration and content of post-launch monitoring required.

The changes suggested here can help biopharmaceutical companies adopt a value management operating model where R&D and commercial functions, as well as other organizational units, expand their current focus on efficacy and safety to consider and document the economic, social and quality of life impact products have on patients’ lives.

We propose five tenets to help companies evolve from using a phase-based, sequential approach to securing regulatory and reimbursement approvals to a value management-focused capability (see Figure 2).

- **Tenet #1**: Nurture a highly collaborative, inter-connected value team
- **Tenet #2**: Evolve traditional commercial roles to focus on value
- **Tenet #3**: Invest in infrastructure to help drive value
- **Tenet #4**: Embed value management as a continuous process
- **Tenet #5**: Expand and redefine relationships with stakeholders

Most biopharmaceutical organizations have not yet adapted to regulators’ and payers’ pronounced shift to using value-based reimbursement criteria when evaluating new therapies, or are doing so too slowly and incrementally. Instead companies continue to use increasingly obsolete clinical trial plans and short-term product commercialization strategies that will fall short of meeting the higher standards of value now required to verify maximum reimbursement.
The benefits of adopting a value management-centric operating model and related capabilities are significant—and the necessity of doing so is becoming clear as regulators, payers and providers across the globe place more emphasis on value. In the US, specialty therapeutics payers, PBMs, and specialty distributors increasingly deploy clinical pathways and other tools to limit use of innovative therapeutics to only high responder patient populations to control reimbursement costs. Similarly, Japan is seeking to control the costs of treating its rapidly aging population by resetting drug prices every two years, and making innovativeness the top criteria in setting prices. These global healthcare dynamics underscore that pharmaceutical companies must be willing and able to refine and conduct appropriate clinical trials. These trials must generate the information needed to demonstrate distinctive value in order to attain faster regulatory approval and meet the demands of public and private payers to maximize reimbursement.
Tenet #1: Nurture a global, cross-functional focus on value

Value management is an operating model grounded in cross-functional collaboration and incorporating the input of outside stakeholders to pro-actively identify and demonstrate the different value drivers of a pharmaceutical drug. Essential to successful implementation of the value management model is global adoption of such a model across all levels of R&D and Commercial senior leadership, as well as the managed markets and payer relations teams.

Standard Operating Approach

Today, such collaboration between functions is sporadic and inconsistent at best, and non-existent at worst, while communication with payers and regulators is frequently a case of too little, too late.

This lack of communication is most prevalent between R&D and Commercial functions and it has dire consequences in an era of personalized therapy and outcomes-based reimbursement. In many companies R&D does not generally include or seek feedback from other functions or regions until well into Phase III trials. This limits the R&D teams understanding of market and competitive dynamics, inhibits R&D’s ability to develop high potential personalized or personalizable therapies, and can lead to a trial focus and business case that demonstrates maximum clinical benefits, but not overall value.

Some or all of these outcomes could be avoided with tighter collaboration between R&D, Market Access and Commercial functions (including Sales and Marketing), all of which have close relationships with providers and customers who can provide feedback on which disease states warrant investment and why. Increasingly, the therapies delivering the highest value are ‘personalized’ or specific to the disease state, life style, age, etc. of the individual patients. The value of personalization increases as functions including Commercial, Health Economics and Medical Affairs gain respective knowledge and then provide that back to R&D to help identify the greatest needs and areas in which to focus.

Needed Evolution and Expected Impact

While functional silos will always exist, companies can mitigate the effects of them by emphasizing that value management is everyone’s responsibility. Meeting objectives is more likely if all functional and team leaders collaborate to ensure they are:

- Identifying scientific and clinical opportunities to apply biological or disease insights to specific populations of patients
- Capturing and synthesizing any new data that can demonstrate value (e.g., real-world EMR-derived clinical information) or that can provide insights into current therapeutic approaches and their value, not just data developed in-house to support specific therapies
- Developing and refreshing business cases for all future therapies so that the current probability of success is monitored and understood, thus preventing late-stage surprises

Value management is everyone’s responsibility.
The objective is to have R&D, Market Access, Health Economics and Commercial work together to focus on value earlier and bring a value-based perspective to relationships with healthcare professionals.

- Committing to working across key groups, knowledge bases, and talent (e.g., research, translational medicine, clinical development, managed markets, medical affairs/evidence-based medicine/HEOR) to develop a more holistic perspective on the value of proposed new products.

The aggregate objective of changes such as these would be to break down traditional organizational barriers and have R&D, Market Access, Health Economics and Commercial work together to focus on value earlier rather than later, and bring a value-based perspective to relationships with healthcare professionals. Specific actions to meet this goal include:

- R&D incorporates cross functional and local market input to validate primary, secondary and exploratory end points across Phase III, IV and V trials to verify that clinical and value measures actually matter to a global audience
- R&D, Market Access and Health Economics continuously share and update the expectations of leading medical experts and healthcare authorities
- Commercial (i.e., Sales and Marketing) and Market Access continuously share and update the expectations of payers and the broader healthcare community
- Sales can develop a comprehensive strategy to identify and recruit locations to act as patient registries after gaining an understanding of the scope and objectives of trials
- The Evidence-based Medicine or HEOR groups in Medical Affairs or Market Access should be part of the assessment of current therapeutics, their value, and value targets for new approaches at registration
- Medical Affairs’ role in post-registration for personalized and more ‘niche’ therapeutics can build on knowledge of the research teams and translational medicine experts in ways that are practical in community care contexts
- Market Access can work with Health Economics to build value models and use external real-world clinical data sets to summarize new therapeutic approaches and how health systems and patients can be real therapeutic and economics beneficiaries.

The impact of this collaborative, value-based environment across the global organization is to allow proactive shaping of trials that can generate data related to total value, and enable functions like Sales and IT to plan ahead to best support the value profile. All these factors together will give the brand the best chance of being successful. The downside of failing to collaborate is that regulators and payers will be in a stronger position to dictate the structure and objectives of Phase IV & V trials, which in turn increases trial costs and limits a product’s ability to fully demonstrate value across the criteria that matter most to individual stakeholders.
Tenet #2: Evolve traditional commercial roles to focus on value

Apart from the global evolution to instill a value-based culture, companies will need to invest more in commercial functions at the market level to evolve them to have a value-based mindset.

Standard Operating Approach

Today, most commercial functions focus almost exclusively on the results of Phase III trials to generate messages, secure regulatory approval, gain market access, generate demand and drive sales. Indeed, employees in core commercial functions critical to product success are hired, trained and rewarded for having this clinical orientation and for communicating to the market a strictly clinical message. Examples include:

- **Marketing**: Usually develops and communicates a brand position based on clinical results to generate demand across healthcare professionals and consumers
- **Market Access**: Focuses on clinical results to secure the best possible formulary position at the lowest possible cost
- **Sales**: Emphasizes clinical messages when calling on physicians, developing patient/physician resources and re-stocking sample closet (where applicable)
- **Health Economics**: Develops a limited, opportunistic set of Phase IV and/or Phase V studies to support and improve brand standing in the medical, regulatory and payer communities

While a valuable source of information, Phase III results are too narrow to serve as the basis for real insights regarding total value. Further, this restrictive approach limits the product’s ability to drive sales, improve outcomes and lower overall healthcare costs. Yet, companies rarely make use of head-to-head studies or outcomes data to demonstrate value. If it is done at all it is done on an opportunistic basis.

Needed Evolution and Expected Impact

The evolution of science and the emphasis on value by payers requires a different approach. Companies and functions leaders need to evolve key commercial roles to emphasize value not only when dealing with internal colleagues, but also when collaborating with external stakeholders.

For example, a few US pharmaceutical companies have run early phase, collaborative pilots where payers and providers are recognized as thought partners with broad disease state knowledge relevant to Phase I and II activities. The collaborative approach can refine product development, and confirm that more patients within a specific disease category benefit from new therapies. Companies are working with leading provider systems to verify that the individual patients (potentially beneficiaries of their new medicines) are clearly identified, placed on therapy, and then offered compliance support during treatment. Implementing this requires coding and translating evidence-based information on patient treatment (protocols or care management plans), agreeing on selection criteria for patients to use different treatments, identifying specific therapeutics as most efficacious within those treatment approaches, and knowing the practical and behavioral aspects of care management that can help confirm better overall performance. The difficulty is not in knowing what to do and for whom a therapy might work, but rather in integrating all the elements into a ‘system’ that results in better than average adherence and patient outcomes. This is crucial as the latest research indicates that as many as one-third of prescriptions are never filled, and patients with chronic conditions are noncompliant about half the time. A successful transformation of commercial roles to broaden their perspective would most likely require the following refinements:

- **Marketing**: The Brand Manager role could be recast to be more of a ‘Value Manager’, focused on orchestrating value management for the product. In addition to coordinating a cross-functional value strategy with R&D, Health Economics and others, Marketing also feeds ongoing input into the clinical plan based on local regulation and market conditions. Finally, in conjunction with other functions, Marketing develops and communicates a brand position based on the value profile to generate demand across healthcare professionals and patients.

- **Market Access**: Works more closely with payers to anticipate barriers and communicate with medical directors to integrate key clinical and value-based measures into trial designs. Communicates value results to secure the best possible formulary position at the lowest possible cost.

- **Sales**: Delivers a value profile message to target physicians, acts as a key channel in establishing Phase IV & V patient registries, offers patient/physician resources and re-stocks sample closet (where applicable)

- **Health Economics**: Works with key internal and external stakeholders to develop a robust set of Phase IV and V studies to support systemic tracking of economic, social and quality of life outcomes, and to improve brand standing in the medical, regulatory and payer communities
Commercial functions not only need to transform themselves but to also ‘re-train’ external stakeholders to expect something different. The impact of this transformation in commercial functions is a much broader perspective of and positioning about a product, and a re-education of stakeholders about what to consider when evaluating a product. Enrolling core functions in this value mindset and transforming roles to reflect this value mindset will help confirm the organization is moving in a common direction.

Tenet #3: Invest in information technology to help drive value

Like the commercial functions, the traditional role of IT will need to be expanded for companies to successfully compete in a value-based environment.

Standard Operating Approach

Usually the primary focus of IT (in addition to supporting enterprise operations) is supporting clinical trials; the IT team has limited budget for much else in the commercial area and minimal experience in supporting Phase IV and V trials or collecting trial data on a country or regional basis. This focus has led to an IT function built on two core capabilities: clinical data management for Phases I – III and pharmacovigilance to track adverse events. While the latter certainly provides critical in-market performance data, extending the clinical data management process can help build a value management mindset as it directly relates to the ability to develop personalized therapies or target the most promising and needy customer segments.

Yet, the IT role and infrastructure in most organizations is not designed to support a wide range of value measures spanning Phases III thru V. Despite the increasing availability of health care and clinical data analytics, for example, many companies still do not have a data and analytics environment that can contribute to the robust set of value measures and studies soon to be required by regulators and payers.

Needed Evolution and Expected Impact

While value-based reimbursement has been piloted by health systems such as NICE in the UK, these approaches are receiving more consideration in Germany and other markets as well because of the increasing accessibility of in-depth, patient specific, clinical data collected in electronic medical records (EMRs). The growing use of EMR systems in the US and in Europe provides unprecedented amounts of data to pharmaceutical companies. The challenge for companies is developing the data management and analytical capabilities needed to make cost efficient use of this data to improve outcomes. IT can play a critical role in delivering needed tools and capabilities.

Using High-Quality, Consistent Data to Improve Therapies and Sales

The availability of such high-quality and consistent patient data offers the potential to model, plan and direct therapies with greater accuracy, giving Life Sciences companies the vehicle to improve therapies more quickly so that they provide the greatest value for a specific patient population. Data from EMRs can help generate sales insight as well. In the past, Life Sciences companies used sales data to model market share and growth. The number of new prescriptions written usually equated to the number of new patients placed on a treatment, and the total prescriptions indicated the current size of the market. Now, Life Sciences companies are finding value in such EMR-derived data as individual patient medical histories and clinical interventions including prescription history, outcomes and costs. Because these data are generally organized around the patient, collected in the context of a care management process and are in-depth in nature, they give Life Sciences companies a more granular perspective on process and outcomes previously unavailable except through expensive customized studies.
Leveraging the Clinical Digital Revolution to Demonstrate Value

Several forces are accelerating this clinical digital information revolution. Health systems are developing the ability to use data to improve operations in a number of ways such as:

- Making tradeoffs as to where to place their services and facilities
- Allocating expenses more accurately in delivering services to patients
- Driving productivity
- Achieving service cost levels to reach targeted profit margins.

Health care analytics is a new industry onto itself, with new ventures and spinout companies alike providing advanced health data analytic services. Payers are analyzing claims data more closely and forging partnerships with Life Sciences companies and other organizations to reduce costs of care. Many are creating new approaches to care management predicated on use of EMR-derived clinical data to group patients by evidence-based care management pathways which can generate therapeutic value. Government initiatives are aggregating and analyzing data gleaned from regulators to develop new reimbursement models.

Harnessing EMR data effectively can benefit Life Sciences companies across the value chain. Gaining access to EMR derived real-world clinical data in focal disease areas and in specific regions of emphasis will help drug makers better target therapeutics and stratify populations, optimizing value and patient outcomes. Building capabilities for analytics across proprietary data, public data sources, and dynamic real-world clinical data sets may allow companies to generate cutting-edge insights, develop proprietary approaches, and develop unique insights or reinforce existing intellectual property. EMR data can be critical to building partnerships with payers and alliance partners.

The move to in-depth clinical data as the basis for decision making also could bring Life Sciences companies closer to providers. Companies and providers could identify specific opportunities within populations of patients, look for collaborative approaches, and measure the benefits from their unified approach. This brings the expertise and insights of Life Sciences companies more directly to bear on the care of patients, and provides Life Sciences companies with a more practical view of the benefits and constraints of alternative therapeutic and care management approaches.

The head of Phase IV clinical trials at a global firm sees significant value in the data revolution but also the need for future investment in IT (see sidebar). His company as well as others are relying less on traditional transaction data and more on higher-value and insight-rich EMR data to guide them in making more precise decisions and to impose more focus on outcomes, giving value to patients and health systems. These companies intend to use their combined insights to develop novel programs that may be delivered to the individual patient, but which will change the performance and outcomes of an entire patient population. Overall, this trend bodes well for Life Sciences companies looking to deliver more value to patients and health systems.

Embracing the value management concept will act as the catalyst needed by many companies to invest more strategically in IT, particularly in areas such as:

- **Clinical data management:** Core investment needs to be in a clinical data management capability that can support clinical and value measures captured in Phase IV and V trials and can incorporate data globally
- **Cutting-edge data sources:** To support robust collection of value-driven data, organizations should identify and integrate new data sources including pharmacy (both retail and in-hospital), patient advocacy and pre-profiled patient registry data
- **Innovative technologies:** Investigate innovative technologies such as report patient monitoring that could strengthen the quality and quantity of data sources in support of key value measures.

These investments will support and amplify the organizational and process investments made in other functions as the organization transitions to be more value-focused.
Pharma Can Reap Multiple Benefits from Data Revolution

Excerpt from an interview with a leading R&D executive at a global pharmaceutical company

As an executive who leads Phase IV clinical trials for a global pharma company, I believe real-world data are becoming mandatory for several reasons. First, the macro economic situation globally has decision makers looking for ways to reduce costs to National Health Systems. Understanding the performance of new and expensive drugs in every day practice is a way of verifying money is spent on what works. Second, questioning the usefulness of Clinical Trial results in real-world practice is a valid response to the first issue, especially with several high-profile drugs not living up to the promise seen in trials. Third, asking for real-world data buys some time and also puts the responsibility on the drug manufacturer to generate it for continuous reimbursement. Fourth, safety surveillance has been elevated with the recent new EU regulations. Some adverse effects of drugs, especially in cancer with very costly treatments, have not only ethical implications, but potentially significant costs associated with management, adding to the payer burden. Lastly, with the availability of EMRs and related significant data collection and warehousing capabilities, drug manufacturers are almost in a catch-22 situation because they are being forced to verify that they collect this real-world data and analyze/publish/disseminate accordingly.

Companies need to move from viewing real-world data as opportunistic/accidental to making its use automatic and systematic.

Pharma companies should understand the above environmental shift, and make real-world data generation part of the drug development pathway. As more payers and other key players get used to the idea of having RW data available (eventually) for all new drugs, strategic plans will have to include real-world data generation as early as late Phase II, and certainly at the start of Phase III programs. This means that companies will have to create the internal functions that have expertise that can lead the data generation program. They also need to form unique relationships/partnerships with organizations that generate these data, such as EMR software suppliers, Center of Excellence, etc.

Lastly, functions that take the responsibility for generating real-world data have to show that the data enhances the science, and confirms trial results (or, conversely, that a drug does not show as much value as the standard protocol). That is, they have to be very good at communicating the results of real-world studies – otherwise real-world data generation will never be accepted to be automatic.
Tenet #4: Embed value management as a continuous process

Brands typically develop a value dossier between Phase III and Phase IV trials, although the dossier has played a limited role in reimbursement, regulatory, healthcare professional or patient dialogues.

Standard Operating Approach

Today’s version of a value dossier provides little support in securing maximum reimbursement, as payers are generally neither asked to provide input into the development of the dossier, nor do they consider the outputs a major factor in negotiations. Characteristics of a typical Value Dossier include:

- The inclusion of point in time documents developed at the conclusion of Phase III trials and shelved once Phase IV trials have begun
- The uneven influence of regulators and payers which may or may not follow Phase III closely enough to influence the objectives, depth and timing of the dossier
- An orientation favored by Medical Affairs and Health Economics groups, with limited collaboration from nearly all commercial functions.

The upshot is that today’s value dossier is an incomplete version of what it could be. The “point in time” nature of the document, coupled with the meager input from a broad range of internal and external stakeholders limits the ability to demonstrate the brand’s true value across the dimensions that matter most to regulators, payers, healthcare professionals and patients.

Needed Evolution and Expected Impact

Like other processes and tools, the value dossier can be re-tooled and evolve to provide better support in securing maximum reimbursement, as payers work with the brand to help define clinical and value measures with trial results acting as the centerpiece of negotiations. For example, companies can begin evolving the Value Dossier so that it:

- Documents value findings from Phase II and across the product lifecycle through Phase V (see Figure 3)
- Incorporates critical feedback from a broad range of external stakeholders
- Is developed by a cross-functional value team (see Tenet #2)

Evolving the value dossier may require enhanced IT capabilities and external relationships. Yet the investment is worth it, because if executed properly a Value Dossier will position the brand to maximize sales, optimize patient outcomes and rationalize total healthcare costs.

Figure 3: Refining the Product Lifecycle to Integrate Value Management

Successful drug value management

New Phase III endpoints anticipate market access barriers

The new Value Dossier covers multiple value drivers

New pricing & reimbursement strategies secure market access, but...

...post-approval, real-world data is needed to maintain access
Tenet #5: Expand and redefine relationships with stakeholders

Today’s brands have a relatively limited set of transactional relationships with key stakeholders, yet transactional relationships don’t generally lay the foundation needed for the collaborative, integrated exchange of information and insights needed to reach better outcomes and demonstrate clear value.

Standard Operating Approach

Much like the silos that inhibit collaboration within biopharmaceutical companies themselves, the traditional narrow view of stakeholder relationships can undercut companies’ ability to focus on and demonstrate value as quickly as possible. A typical interaction model treats regulators as the recipients of results and playing the critical role of approving therapies. Interactions with physicians and healthcare professionals center on shaping clinical trials and providing access to patients. The relationship with payers is focused on market access and pricing negotiations. This traditional approach reinforces the notion that biopharmaceutical companies are insular organizations not willing to partner with external stakeholders to determine the value a particular product brings to the market.

Needed Evolution and Expected Impact

Yet, when market access and adequate reimbursement hinge on demonstrating value throughout development and post-launch, companies will need to reorient their relationships with stakeholders to maintain ongoing dialogues across every phase (see Figure 4). Rather than point in time communications pegged to Phase milestones, companies need the capabilities and resources to maintain continuous communication with many stakeholders simultaneously.

Many executives, including the head of Market Access at a high-performing pharma company, recognize that relationships with external stakeholders have changed with the expectation being more communication and collaboration is needed (see sidebar).
Changes in Market Access Have Immediate and Long-term Consequences

Why is market access different today? And what are the consequences for R&D, MA and Commercial functions?

Many of the changes in market access are grounded in the tremendous change in communication, knowledge, technology and economics. The world is increasingly interdependent and information flows nearly instantaneously. The ‘world is flat’, going global, going local are concepts we increasingly hear about and live through. Market access naturally evolves with these changes. The ‘bar’ needed to gain market access changes, be it in terms of evidence needed at time of launch or the need to accumulate evidence as experience increases. What society requires in terms of evidence, or efficacy promise/guarantee, tolerance for risk, expectations and legal responsibility evolves and manifests themselves in market access requirements.

Unsurprisingly, this can be far-reaching and have ramifications throughout the organization: From the evidence collected and analyzed at the time compounds are conceived to when they are pursued, to the way they are supported by continuous research and marketed.

Fortunately, the shift toward value management and integrated care presents the opportunity to expand the breadth of relationships with key stakeholders, as well as the necessity to develop a more networked approach that has more stakeholders collaborating to achieve the same end. Pharmaceutical companies can expand their communications and interactions with all of them without running afoul of regulations. The goal for biopharmaceutical companies should be to become part of developing a care management solution; this could involve sharing deep disease state understanding as well as process support. This shift in perspective in each of a company’s primary relationships can enhance both patient care and the bottom line. The evolution will impact:

- **Healthcare Professionals**: Still recruit and partner with the world’s leading experts, but also gather additional input and value measures from a broad network of healthcare professionals ranging from regional and local thought leaders, to pharmacy & therapy (P&T) committee members to nurses and pharmacists.
- **Regulators**: Expand the relationship with regulators to include gathering feedback on key value measures before trials are constructed.
- **Payers**: Shift to a more collaborative relationship in which payers work with the brand to develop value measures most important to them.
- **Patient Advocates**: Develop ties within the patient advocate community to understand what value measures would have the biggest impact on patients and caregivers.
- **Diagnostic companies**: Develop relationships and involve diagnostic partners early in clinical trial development to identify and validate potential biomarkers.

Some companies are already putting more collaborative approaches into practice and emphasizing value management as well. In the UK, an acute disease therapy offered by one company rebates back the therapeutic costs of non-responders to the UK authorities after the first 90 days of initiating therapy. In essence this company has created a ‘performance warranty’ for their product that implies an ability to identify those patients for whom their therapy may be most efficacious and to stand by that ability with an explicit warranty to make the UK health system whole for those not benefitting. This is both ‘personalized’ and ‘value-adding’ in that patients and the health system are guaranteed beneficiaries.

More collaborative relationships with a broader set of stakeholders will make for quicker, smoother reviews with regulators, more constructive, transparent negotiations with payers, and a much higher likelihood of acceptance among the healthcare professional and patient communities.
Conclusion

Many biopharmaceutical companies are burdened with outdated operating models that are ill-suited to demonstrating, verifying and communicating value-based stories to the regulators and payer organizations that control reimbursement rates. These legacy models do an adequate job of demonstrating efficacy and safety, but are often inadequate to meet today’s more stringent requirements of demonstrating distinctive value and improving real-life outcomes. Consequently, there is an urgent need for biopharmaceutical firms to evolve to a new operating model that puts value management at the core of R&D and commercial decisions.

Adoption of the value management focus will require new ways of working as well as new role definitions and responsibilities for personnel at both the global, enterprise level and within individual markets. While the shift would not necessarily involve hiring more employees, it is a significant cultural change that will require process reengineering, a specific training program, investment and a comprehensive effort encompassing commercial and non-commercial functions alike. The shift is challenging but entirely possible. Accenture has supported companies throughout the change process, helping them build needed capabilities and processes in areas such as value management, value vigilance, and value competitive intelligence.

The biopharmaceutical industry has had to contend with seismic shocks in the last few years, from the economic downturn, to the ‘patent cliff’, to health care reform in both mature and emerging markets. The shift to a value management focus is as urgent as any of these changes, but if navigated successfully can result in better products, better patient outcomes, and better reimbursement and returns on investment.
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