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Managing Pathways to Convergence in the Life Sciences Industry

A Deloitte Research Study

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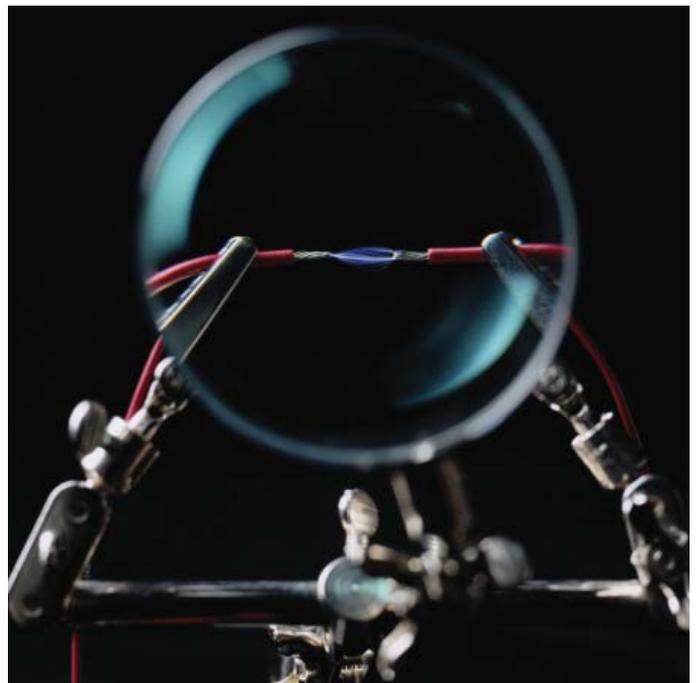
Executive Summary

The convergence of drugs, devices, and diagnostics is leading to innovative health care solutions and new opportunities for business growth and product differentiation in the life sciences industry.

Motivated by scientific advances, consumer demand, and market pressures, firms in all sectors of the life sciences industry have already created a full spectrum of combination products. Examples include diagnostics that help target drug therapies, devices that can monitor patients and precisely deliver drugs, and devices that are coated, filled, or packaged with drugs. Many of the early examples involve combining diagnostics or devices with drugs, but this is shifting as new opportunities emerge to integrate diagnostics and devices with sophisticated instrumentation and information technologies. Innovations through convergence are resulting in earlier diagnosis, more patient-centered care, and safer, more effective treatment for many conditions.

Convergence is occurring at all stages of the value chain and through various approaches. Defining a successful pathway to convergence depends on a company's assessments of its position and priorities, opportunities for partnership, and associated risks. Investment orientations will differ, given the technological uncertainties surrounding the product components or interfaces.

Developing a combination product requires more than the integration of disparate technologies. Most companies look outside their walls and across sector lines to access additional capabilities. Although partnerships are common in the life sciences industry, partnering to create convergent solutions is especially challenging. Synchronizing the goals, knowledge, capabilities, and expectations of fundamentally different companies can be critical to the success of such innovations. Companies that view convergence as an opportunity for mutual transformation—one that allows firms to work symbiotically with each other—may achieve greater success than those that see convergence only as a transaction involving the exchange of ideas, resources, and capabilities. As companies pursue new convergent opportunities, alliance networks are likely to evolve in scale and scope, further changing the landscape of the life sciences industry.

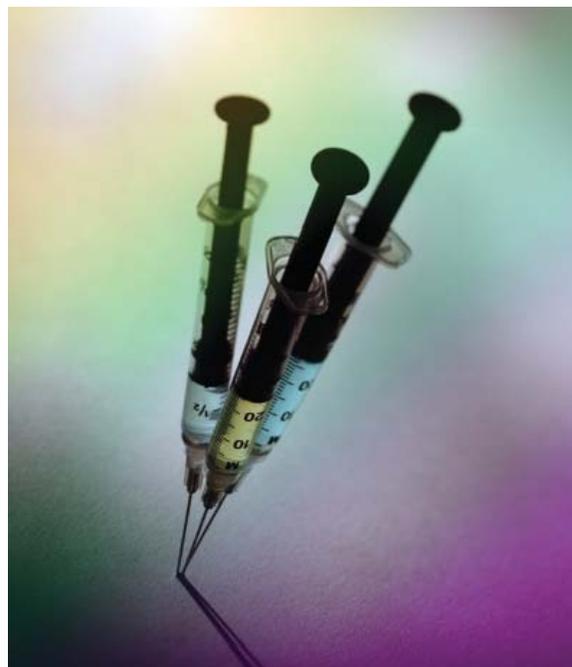


Introduction

Life sciences firms are moving beyond traditional industry boundaries to create new health care solutions for patients and providers. By combining life sciences' core technologies (diagnostics, devices, and drugs^a) in innovative ways, firms are creating new technology platforms and products that offer improvements in safety, effectiveness, convenience, and value. These convergent solutions are also providing life sciences companies with new avenues for innovation, growth, and differentiation in markets characterized by increasing competition, R&D stagnation, expanding consumer demand, and pressure from payers to reduce health care costs.

Life sciences leaders considering convergence must make several strategic decisions in choosing and managing the convergence pathway. In this paper, we highlight various examples of convergence in the life sciences industry, identify the driving forces behind the convergence trend, and discuss the pathways to convergence that are seen in the marketplace today. We propose alternatives for investing in convergence under different scenarios of technological uncertainty, as well as strategies for choosing a specific convergence pathway, managing successful cross-sector partnerships and alliance networks, and addressing regulatory challenges.

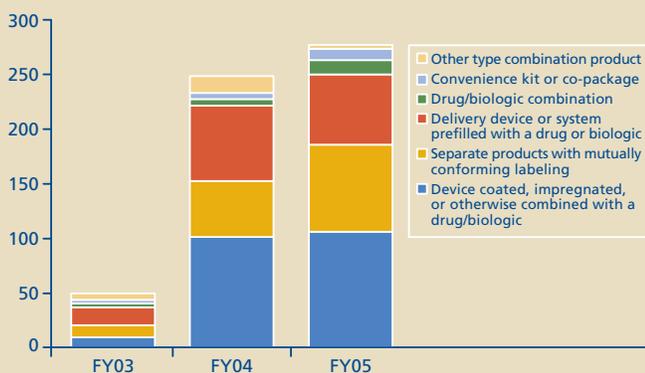
^aIn this report, the term "drug" is used to refer to any chemically- or biologically-based substance that is used for medicinal purposes. Both pharmaceuticals and biologics are implied by the term.



Examples of Convergence

In the life sciences industry, convergence is defined as the integration of two or more core technologies (diagnostics, devices, and/or drugs) to create an improved health care product^b. The number of combination products under development is rising quickly (Figure 1) as developers seek to enhance existing products and introduce fundamentally new health care solutions to the market. The promise of enhanced therapeutic efficacy has prompted investment in a wide variety of convergent solutions (Figure 2). Convergence is transforming cardiovascular care, orthopedic treatment, tissue-wound management, and other clinical areas.

Figure 1. Number of applications submitted to the FDA's Office of Combination Products



Sources: U.S. Food and Drug Administration, Office of Combination Products, *FY2003 Performance Report to the Congress for the Office of Combination Products and FY004 Performance Report to the Congress for the Office of Combination Products*. Mark D. Kramer, *Regulation of Combination Products: ACRP 2006*, accessed April 23, 2007 <<http://www.fda.gov/oc/combination/presentations/>>.

^b The FDA's definition of a combination product is as follows:

1. A product comprised of two or more regulated components, i.e., drug/device, biologic/device, drug/biologic, or drug/device/biologic, that are physically, chemically, or otherwise combined or mixed and produced as a single entity;
2. Two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products;
3. A drug, device, or biological product packaged separately that according to its investigational plan or proposed labeling is intended for use only with an approved individually specified drug, device, or biological product where both are required to achieve the intended use, indication, or effect and where upon approval of the proposed product the labeling of the approved product would need to be changed, e.g., to reflect a change in intended use, dosage form, strength, route of administration, or significant change in dose; or
4. Any investigational drug, device, or biological product packaged separately that according to its proposed labeling is for use only with another individually specified investigational drug, device, or biological product where both are required to achieve the intended use, indication, or effect.

Source: U.S. Food and Drug Administration, Office of Combination Products. "Guidance for Industry and FDA staff," September 2006.

Figure 2. Examples of convergence

Device – Drug

- Drug-eluting stent that opens and prevents restenosis in coronary and peripheral arteries
- Bone grafting scaffold/sponge coated with a growth protein that promotes bone regeneration
- Implantable, programmable pump that delivers a drug or biologic in small, timely doses
- Implantable polymer wafer that releases a chemotherapy agent to a specific site
- Implantable neuromodulator that enables the targeted, regulated delivery of a drug or electrical stimulation
- Transdermal patch that transports drugs locally and systematically through the skin
- Pre-filled, metered dose syringe, injector pen, or inhaler

Diagnostic – Drug

- Screening test for the presence of a specific gene or protein coupled with targeted drug therapy
- Use of passive pharmaceuticals and radiopharmaceutical tracers as contrast agents for positron emission tomography (PET) scanners

Diagnostic – Device – Drug

- Glucose monitor with an insulin pump

Source: Deloitte Research

Device-Drug Convergence

Combinations involving a device and a drug include a diverse array of products, such as drug-coated devices, drug delivery devices, drugs packaged with devices, and drugs labeled to be used with specific devices. Some combinations—syringes pre-filled with a specific drug, for example—offer benefits related to convenience. Others provide significant therapeutic benefits over conventional approaches. For instance, some device implants can deliver a drug directly to the site of its action within the body, as well as control the dosage with need- or time-based release, providing greater efficiency and better therapeutic effect than oral forms of the therapy.

One of the most salient examples of convergence between a device and a drug is the drug-eluting stent (DES), a tiny, bare metal stent coated with a drug that helps prevent restenosis (the narrowing and relogging of arteries) after heart surgery. Johnson & Johnson's device division, Cordis Corporation, launched the first DES (*CYPHER*[®]) in 2003, quickly achieving world-wide sales of \$1.9 billion^c in 2004 and \$2.6 billion in 2005¹. Boston Scientific launched its version of a DES (*TAXUS*[™]) soon after in early 2004, reaching sales of over \$2.5 billion by the end of 2005². To date, J&J and Boston Scientific are the only two firms approved by the FDA to market their stents in the United States. However, the prospect of growth in international markets such as the European Union and Japan, coupled with strong product margins, has fueled competition. Companies like Abbott and Medtronic are currently engaged in clinical trials for their own state-of-art drug-eluting stents for coronary arteries^{3,4}.

The success of coronary stents prompted many firms to venture into creating convergent solutions for peripheral arteries that carry blood to parts of the body other than the heart and brain. Cook Medical, the early leader in this area, launched a clinical trial of its peripheral drug-eluting stent (*ZILVER*[®] *PTX*[™]) in 2005, targeting the prevention of restenosis in the arteries that supply blood to vital organs like the kidney and the liver^{5,6}. In total, the U.S. peripheral vascular stent and stent graft sector had sales of nearly \$856 million in 2005 and is projected to achieve over \$1.1 billion in sales in 2012⁷.

Examples of drug delivery devices are numerous. Medtronic's spinal cage fusion solution (*INFUSE*[®]), for instance, involves implanting a metal cage that is pre-packed with a bone growth-promoting protein (rh-BMP-2) discovered by Wyeth. This converged product is designed to replace painful bone grafting procedures with a natural bone regeneration process. Launched in 2002 for spinal applications, *INFUSE*[®] has since been approved for certain tibia fractures and additional uses are under investigation⁸. Revenues for Medtronic's biologic-based spinal products topped \$570 million in 2006 due to strong global acceptance of *INFUSE*[®]. Strong product growth and margins have attracted competition in the spine segment from DePuy Spine (J&J) and others¹⁰. Additionally, dental bone grafting solutions have recently been developed and approved by the FDA¹¹.

Medtronic has also developed an implantable, programmable pump for baclofen, a drug that relieves muscle spasticity in patients with multiple sclerosis, cerebral palsy, or brain or spinal cord injuries^{12,13}. By delivering minute doses of a special formulation of the drug directly into the spinal fluid, the convergent solution has significantly improved treatment for spasticity. The pump's reservoir is refilled every one to three months, also making it more convenient than the oral form of baclofen.

Another example of an implantable drug delivery device is *GLIADEL*[®] developed by Guilford Pharmaceuticals and now marketed by MGI Pharma^{14,15}. *GLIADEL*[®] is a dime-sized, implanted polymer wafer that provides controlled and timely release of a chemotherapy agent in the treatment of malignant brain tumors. The drug is delivered only to the site of the tumor, which minimizes systemic toxicity.

A non-implanted example of a drug delivery system is ALZA's programmable *E-TRANS*[®] patch that can transport drugs through the skin using low-level electrical energy^{16,17}. *E-TRANS*[®] works well when precise, localized, systematic delivery of the therapeutic drug is required. Convergence here has created a non-invasive, cost-effective delivery platform that can be customized for use with a broad range of drugs.

Diagnostic-Drug Convergence

The integration of diagnostics with drugs, and more recently with instrumentation and information technologies, is helping to improve both diagnosis and treatment. Some diseases can be detected at very early stages now with diagnostic technologies that involve the use of drugs. Consider the example of positron emission tomography (PET) scanners that are used in combination with pharmaceutical contrast agents and radiopharmaceutical tracers. By comparing the biological reactions of healthy and potentially cancerous cells to the radioactive agent that is injected into the patient, the scanner is able to diagnose cancers at earlier stages and less invasively than is possible through surgery. Recent sales estimates for the top producers of PET scanners and the radiolabeling agents exceeded \$28 billion and \$2 billion, respectively¹⁸.

^c Monetary figures are specified in U.S. dollars for consistency throughout the report.

The discovery of new biomarkers (anatomic, physiologic, biochemical, molecular parameters and indicators of disease¹⁹) is also improving the ability of researchers and clinicians to detect the presence and severity of disease, as well as enhancing the therapeutic design and target specificity of various drugs. Drug companies are using molecular diagnostics to measure the treatment effects of various therapeutic approaches and to study patient responsiveness at different dosage levels. Through advances in target identification and gene expression profiling, it is becoming possible to direct treatment to the patients for whom therapy is most likely to be effective. In these ways, diagnostic-drug convergence is improving treatment as well as diagnosis.

The most prominent example of this type of convergence involves prescribing Herceptin® (a genetically engineered humanized monoclonal antibody) only for breast cancer patients for whom a diagnostic test, such as PathVysion™, has detected the presence of a specific protein, human epidermal growth factor receptor-2 (HER2). The FDA reviewed Genentech's Herceptin® and Abbott's PathVysion™ jointly, approving the drug and test within the same week in 1998.²⁰ After Genentech received FDA approval to include PathVysion™ on Herceptin®'s label in 2002, sales jumped by 18 percent to \$406 million the following year.²¹

While a screening test reduces the number of patients for whom a particular drug therapy will be prescribed, and therefore shrinks the market, there are strong incentives for drug and test developers to co-develop and co-launch their associated products. Drug developers stand to lose if a predictive test is discovered after their drug has been introduced to the market, and diagnostic developers will be motivated to develop a test for a drug that is already on the market only to the extent that they are able to share the revenues created by combining the products²². Consider the case of the lung cancer drug, Iressa®, which was developed by AstraZeneca and approved for use without a diagnostic test. Following evidence that Iressa® was effective only in specific patient subgroups, sales dropped 31 percent in 2005, mainly due to a 63 percent decline in the US drug sales, and continued to decline in 2006^{23, 24}. Genzyme recently developed a diagnostic test, but whether Iressa® sales will recover remains to be seen^{25, 26}.

Diagnostic-Device-Drug Convergence

Treating chronic diseases requires regular and long-term monitoring of patients. Device implants can provide patient monitoring systems that offer less invasive, less painful, and more convenient diagnostic and monitoring methods than traditional methods. By integrating diagnostic and device capabilities, this model can improve early- to late-stage diagnosis and disease progression monitoring. Solutions that can also deliver appropriate doses of drug therapy based on routine monitoring provide greater efficiency, convenience, and therapeutic effectiveness for the growing number of patients with chronic illnesses.

Blood glucose monitors combined with implanted insulin pumps are the most visible example of this type of convergence. By integrating convenient, round-the-clock monitoring with timely, controlled release of insulin, this convergent solution provides diabetes patients with a less invasive and more effective treatment alternative. Medtronic was the first to launch its *Paradigm Link*® (512/712 series) glucose monitors in 2004, resulting in 18 percent growth for the company's diabetes division²⁷. Medtronic's diabetes-related sales, which exceeded \$722 million in 2006, continue to be driven by the company's *MiniMed Paradigm*® monitors²⁸.



Forces Driving the Trend Toward Convergence

Scientific advances, shifts in consumer demand, and market pressures and opportunities are driving the trend toward convergence in the life sciences industry.

Scientific Advances Are Enabling Convergence

Recent scientific advances have set the stage for convergence among drugs, diagnostics, and devices. The sequencing of the human genome and advances in areas such as genomics, proteomics, stem cell research, and nanotechnology have opened new diagnostic and therapeutic avenues. The discovery and development of molecular markers continues to improve target identification, genetic-risk profiling, test accuracy, disease detection and monitoring, and treatment selection. Significant advances in implant device technologies, such as better I/O protocols, software/hardware interfaces, and delivery controls, make them ideal technology platforms for delivering drugs in a targeted, controlled manner.

Changing Demographics, Shifting Health Care Needs, and Rising Consumerism Are Increasing Demand

As average life expectancy continues to rise, and the Baby Boom generation grows older, consumer demand for health care is increasing. Consumers are also becoming more knowledgeable about treatment options and more vocal about their preferences. The shift toward an older, more engaged patient (consumer) base is prompting greater focus on and demand for improvements to the diagnosis and treatment of chronic conditions. Effective therapies for chronic conditions typically involve regular monitoring and prolonged medical treatment. Patients, therefore, favor convenient solutions that offer long-term benefits and few side effects. For example, convergent solutions that involve remote monitoring and treatment delivery provide tremendous advantages over traditional therapies that require frequent doctor visits.

Providers also continue to support efforts to develop better ways to detect pre-symptomatic conditions, diagnose diseases more accurately, monitor patient responsiveness, reduce side effects, and measure treatment efficacy. Convergent solutions are responding by offering products that are less invasive, less painful, more patient-specific, more convenient, and sometimes more affordable. Commensurate with increasing demand, however, is the continued rise in health care spending. The high costs associated with hospital procedures and prolonged drug therapies are prompting payers, providers, and consumers to push for more affordable, cost-effective alternatives.

Shifting Industry and Market Conditions Are Creating Pressures and Opportunities

Each of the life sciences sectors—pharmaceuticals, biotech, devices, and diagnostics—faces different industry and market conditions. All, however, are seeking business growth in the midst of diminishing returns from R&D, intensifying cost pressures, and increasing competition²⁹. For many firms, convergence presents a new avenue for product innovation and business growth amidst shifting industry and market conditions.

Pharmaceutical Sector

In a mature sector characterized by slowing revenue growth, declining profit margins, and increasingly expensive R&D, pharmaceutical firms are looking for ways to increase innovation, efficiency, and profitability³⁰. Recent product pipeline shortages and increasing competition from cheaper generic drugs and biologic alternatives are pressuring pharmaceutical companies to create new growth opportunities. Convergence provides opportunities not only to develop entirely new products, but also to extend and expand product portfolios—a useful strategy for pharmaceutical firms striving to get the most out of existing product lines. Moreover, pharmaceutical firms potentially can reduce development costs and increase profitability by partnering with or acquiring other firms with products or platform technologies in advanced stages of development. The significant drug

portfolios and extensive distribution channels of many drug companies position them well to lead the development of convergent solutions. However, the risk remains that a drug will become secondary to the diagnostic or delivery device if those are designed for use with multiple drugs or if the manufacturers of those components take the lead in provider and patient relationships.

Biotech Sector

The biotech sector will undoubtedly continue to grow, given the significant intellectual property assets many biotech firms hold and the premium prices that unique biologic treatments can command³¹. However, as with pharmaceuticals, the number of new product submissions to the FDA appears to be holding steady rather than increasing³². For an individual company, strained funding, limited development capacity, and relatively weak distribution capabilities can provide the motivation for collaborating or merging with other biotech or pharmaceutical firms to develop, launch, and market a product^{33,34}. Through convergence, some biotech firms are able to secure a stronger position than they might have on their own. Licensing and partnering with device and diagnostics companies are viable options, but the risk (or opportunity) of becoming an acquisition target remains strong.

Device Sector

Relatively low technology entry barriers (compared to what is required for drug development), coupled with recent stagnation in new product discovery, have resulted in competition over medical device products with little or no differentiation. In recent years, many newly approved devices have been incremental or supplemental improvements over existing products, rather than more fundamentally innovative technologies³⁵. Device developers are generating new business opportunities through the integration of devices with other core technologies and seeking higher market value through convergence. Devices are becoming essential components of diagnostic tools and effective platforms for drug delivery. Several large device companies are leading the development of convergent solutions, while smaller firms wishing to avoid acquisition are trying to develop platforms that can be used in multiple solutions.

Diagnostics Sector

The mapping of the human genome and the discovery of gene-based molecular markers for expression profiling and target identification are transforming the diagnostics sector and providing test developers with new opportunities. The

diagnostics sector notched up close to \$28.6 billion in sales in 2005, largely due to the emergence of in-vitro diagnostics (IVDs), in-vivo diagnostics, and molecular medical imaging tools for non-invasive diagnosis³⁶. Opportunities for growth through convergence are likely in the areas of gene-based testing, early and chronic disease detection, and less invasive methods for monitoring chronic conditions. Given the close tie between a diagnostic test and therapeutic efficacy, test developers face the threat (or opportunity) of being acquired by pharmaceutical companies. Evolving licensing agreements, innovative funding models, and new market opportunities, however, are allowing diagnostic companies to remain competitive.

Even more evolutionary is the trend toward convergence between diagnostics and instrumentation companies, as capital intensive requirements position further improvements and labs seek automation efficiencies. Two recent examples include Siemens' acquisition of Bayer Diagnostics³⁷ and General Electric's expected acquisition of some of Abbott's diagnostic units³⁸.

An Avenue of Growth for All

Although motivated by different industry and market circumstances, convergence is proving to be an avenue of growth for firms within each sector. Firms like Johnson & Johnson, Boston Scientific, Abbott, and Medtronic are creating integrated solution pipelines and building portfolios of related products through convergence, a trend that may come to characterize the life sciences industries.

Creating new technology platforms requires the integration of capabilities across core technologies that firms may not have. Companies with existing capabilities in more than one area could have a first mover advantage if they can integrate those technologies quickly and effectively. Collaboration and consolidation across the life sciences sectors are likely to continue as firms seek to acquire new R&D capabilities and/or expand economies of scope and scale in manufacturing and distribution. Because of their greater resources, experience with partnerships and acquisitions, and ability to realize economies of scale and scope, large pharmaceutical and device companies have the opportunity to drive the trend toward bringing multiple, cross-sector capabilities into a single enterprise. However, market pressures and opportunities are motivating life sciences firms of all types and sizes to invest in convergence. Consequently, players from all sectors are entering the competition for R&D assets, setting up new rivalries and changing the life sciences industry landscape.

Addressing the Uncertainties and Risks of Convergence

There are many ways to define a pathway to convergence, and therefore, many opportunities for tailoring the approach. However, there are also many risks given the various considerations and trade-offs in selecting and investing in a particular pathway.

Convergent solutions, which are relatively new opportunities for many firms, typically entail many uncertainties related to the technological components and interfaces needed for integration, the potential partners the firm may need, and the size and receptiveness of prospective markets. A starting point, then, for determining a convergence pathway is to assess specific opportunities in relation to one another and choose a set of investment strategies that enable the firm to execute toward a convergent solution in a way that balances risks and rewards in the face of these uncertainties over time.

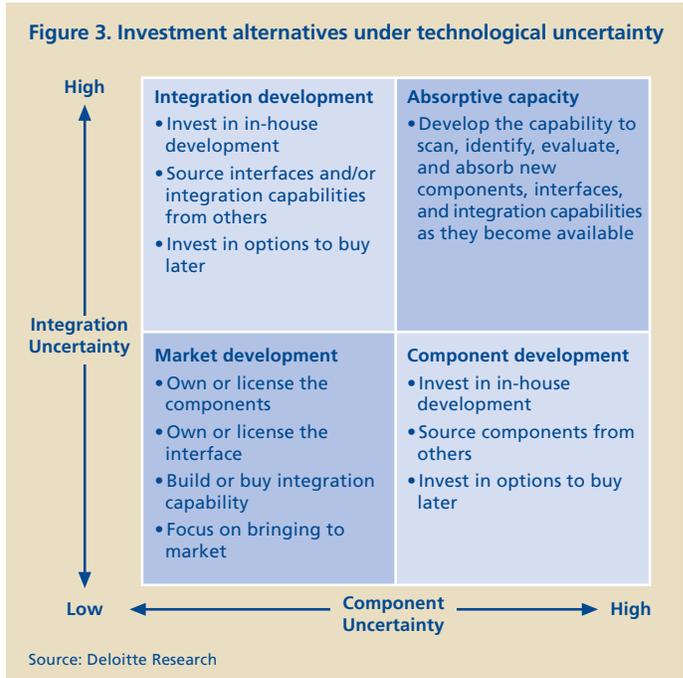
To explore this further, assume there is no uncertainty related to partners and markets (assume these exist), and focus on a firm’s options when facing uncertainties related to technology. There are two major types of technological uncertainty involved in convergence: **component uncertainty** and **integration uncertainty**.

Component uncertainty refers to whether key components are already available for a convergent solution. For example, in combining blood glucose monitors with insulin pumps, both components – the monitor and the insulin – were well-known. The challenge was to integrate these components into an effective combination product. In contrast, targeted drug therapies associated with diagnostic tests for various cancers are still in their infancy, reflecting considerable uncertainty for product developers.

Integration uncertainty refers to whether necessary interfaces exist to integrate the components into an effective combination product. In creating the first drug-eluting stent, a special material was needed to enable the anti-clogging drug to adhere to and be released from the metal stent. J&J partnered with SurModics to adapt its patented drug-delivery coating technology. From the early stage of feasibility testing to the later stages of formulation and process optimization, the two companies worked together to integrate J&J’s stent and Wyeth’s sirolimus drug³⁹.

Differing levels of component and integration uncertainty define different landscapes for action. Depending on the landscape, different investment approaches may be needed to balance risk and reward. Four strategic orientations defined by different levels of technological uncertainty are summarized in Figure 3.

Market Development Orientation: When component and integration technologies are generally understood, the challenge for companies is to focus on developing markets and maximizing the return from the commercialization process. To do this, a company may choose to own or license the suite of component and interface technologies needed to develop the combination product. Ownership will generally be preferred to maximize the profits derived from intellectual property or to preclude others from offering the same technologies in the marketplace.

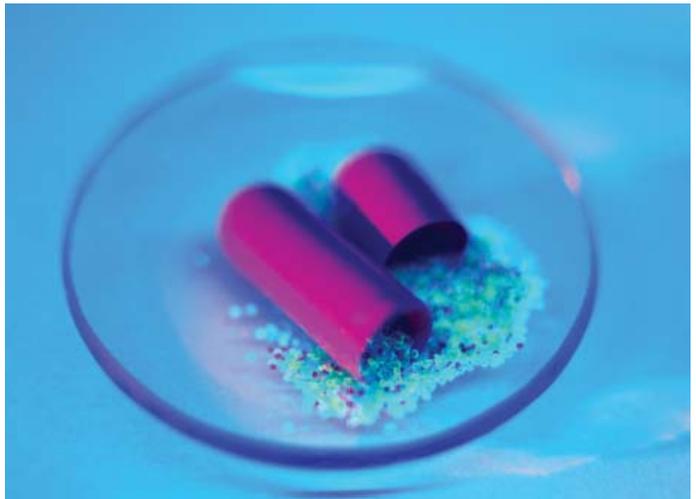


Component Development Orientation: When technological uncertainty about the performance of specific components is high, companies have two choices. First, they can invest internally in R&D to develop or improve a specific component technology. This can lead to proprietary new technologies for future use. The second and often complementary choice is to invest in a series of options to buy externally developed components as new products and technologies emerge and performance issues are tested and resolved⁴⁰. One way of purchasing options is to co-invest or become a limited partner in venture capital firms that are investing in specific component technologies. This gives an established firm the opportunity to scan for new breakthroughs and identify acquisition targets to incorporate into a convergent solution.

Integration Orientation: When component uncertainty is low, the strategic focus should shift to integrating the components into a coherent solution. Companies again confront choices for how to do this. They can increase their in-house efforts to develop unique and proprietary interfaces, or they can source integration capabilities from other firms. A third option is to acquire a series of real options to hedge their risk across different emerging integration alternatives⁴¹. As with components, co-investing or becoming a limited partner in a venture capital firm is a possible approach to investing in interfaces or integration capabilities.

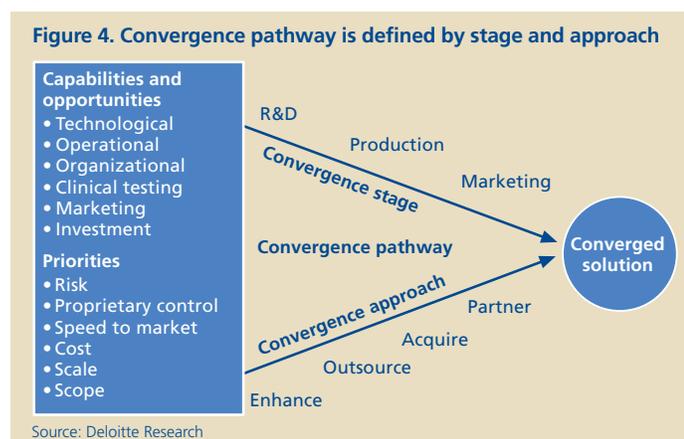
Absorptive Capacity Orientation: When component and interface technologies are highly uncertain, a company is best-off not limiting itself to investing in just one set of technologies. Instead, the company should develop the capability to survey for, identify, evaluate, and absorb new technologies as they become available. This can be done by establishing an emerging technology evaluation group that focuses on evaluating the suitability of emerging components or interface technologies rather than trying to invent new technologies. Such a group can scan for opportunities in product and service development. As progress is made on specific technologies, investments in convergent engineering solutions can be scaled up.

Each of the above strategic orientations helps to balance developmental risk and reward for different levels of technological uncertainty. Translating an orientation into a specific executable convergence strategy requires further choices about the level of investment a company is willing to make, the stage of solution development at which to commit investments (R&D, production, and/or marketing) and the approach that is to be taken to execute the strategy (enhance in-house capabilities, outsource, acquire other firms, or partner with other companies through alliances, joint ventures, and other collaborative agreements).



Pathways to Convergence

To develop a combination product, companies have taken various pathways defined by the *stage* of the value chain at which they integrate the technologies and the *approach* they use to organize the sourcing and integration of capabilities. Determining which pathway to pursue depends on a company's existing capabilities, opportunities, and priorities (Figure 4).



integration of the technologies involved in drug-eluting stents occurred during the manufacturing process. Spinal cage fusion solutions, regenerating dental implants, and transdermal patches are other examples where production level convergence is necessary for the core technologies to be combined. In this stage, the pathway to convergence is much shorter and less complex than at the stage of R&D, but it still involves significant resource investment and process change. Market value from convergence at this level comes from expanding and improving upon existing products in incremental ways and/or expanding production scale and scope.

- Marketing:** Convergence at the marketing level is the least complex pathway, involving joint labeling, packaging, advertising, sales, and/or distribution of related products. Some convergent solutions may be packaged together like glucose monitors with removable and refillable insulin pumps. Other combinations may be labeled for joint use but packaged separately such as diagnostic kits and related drug therapies. Convergence at this level can be faster and cheaper than at the other levels especially when existing resources, processes and distribution channels can be used. However, fewer intellectual property assets may be gained and product differentiation may be more difficult to achieve. The market value of the converged product may be significant but largely incremental given that two or more products already existing in the marketplace are simply marketed together. Market success hinges on the cost differential between the convergent solution and existing products, as well as on customer perceptions of improved effectiveness and convenience. Competition from other firms and product failure present the greatest risks.

Convergence Stage

In the current marketplace, companies have pursued convergence at three different stages:

- R&D:** Firms that seek to develop a convergent solution from the earliest phases of the R&D process may ultimately create solutions with the greatest market value if they provide fundamentally new technology platforms and products or offer products that target patients in ways that are highly effective in terms of therapeutic benefit and cost. One example of R&D convergence is reflected in current efforts to develop second generation drug-eluting stents that rely on new materials and stent designs^{42,43}. The development and use of her-2 gene-based diagnostic tests as bio-markers in efforts to design more targeted anti-breast cancer treatments is another example. The convergence process is at its most complex at this level, requiring greater resources and longer time-to-market horizons than convergence occurring at the other levels. Clinical validation and regulatory approval may also be more challenging, time consuming, and costly.
- Production:** In the case of first generation drug-eluting stents, device companies licensed drugs from pharmaceutical firms to use as a therapeutically effective coating on existing bare metal stents. While some development was certainly required to test and optimize the interface, the

Convergence Approach

Companies have also taken different *approaches* to sourcing, organizing, and integrating the capabilities needed for convergence to occur. Some have strengthened their own internal R&D, manufacturing, and marketing capabilities through additional investment in infrastructure, processes, and talent. Others have obtained necessary capabilities and technologies through licensing, outsourcing, and/or acquisition. Still others have partnered with other firms through alliances and joint ventures to bring convergent solutions to the market. Figure 5 highlights some of the pros and cons of different approaches. The potential advantages and disadvantages of each approach should be weighed in the context of a company's capabilities, opportunities, and priorities.

Figure 5. Pros and cons of different approaches for integrating capabilities

	R&D	Production	Marketing
Enhance	<ul style="list-style-type: none"> Establishes long-term view and solid foundation for growth Addresses competency gaps in ways that might also improve other parts of the business Creates new IP assets Capture end-to-end value 	<ul style="list-style-type: none"> Expanding scope/scale may strengthen competitive position Will maintain oversight and control 	<ul style="list-style-type: none"> Speed and cost advantages if targeting existing customers and can use current strategies and distribution channels
	<ul style="list-style-type: none"> May take longer than other approaches May cost more than other approaches If targeting a new customer base, current strategies and distribution channels may not work 		
Outsource	<ul style="list-style-type: none"> Gain specialized technology and processes at lower cost than building in-house 	<ul style="list-style-type: none"> Gain specialized processes and larger scope/scale at lower cost than building in-house 	<ul style="list-style-type: none"> Gain specialized knowledge and access to already-established channels
	<ul style="list-style-type: none"> Outsourcing partners may not exist Will have less oversight than if built in-house Licensing agreements may be challenging/may have to share captured value 		
Acquire	<ul style="list-style-type: none"> Can be faster than building in-house if in late stages of R&D Less risk if specialized knowledge and processes are in late stages Will assume control of new IP assets and capture all value 	<ul style="list-style-type: none"> Faster than building in-house Will assume complete oversight and control 	<ul style="list-style-type: none"> Gain access to new customers and distribution channels
	<ul style="list-style-type: none"> Will pay an acquisition premium Challenges of integrating processes and people should not be underestimated 		
Partner	<ul style="list-style-type: none"> Risk is shared Possible cost advantages over other approaches May be faster than other approaches Sharing regulatory expertise facilitates timely review 	<ul style="list-style-type: none"> Faster than building in-house 	<ul style="list-style-type: none"> May open new channels to reach existing customers May create access to new customers
	<ul style="list-style-type: none"> Compatible partners may not exist Will share proprietary control and intellectual property arrangements may be challenging May become secondary if other firm takes the lead in marketing & distribution 		

Source: Deloitte Research

Choosing a Pathway

To determine a convergence strategy, a firm must identify its current position and future investment orientation. In which quadrant of Figure 3 is the firm currently situated? To which quadrant should the firm move next in its pursuit of convergent solutions? Given the current level of technological uncertainty and available investment alternatives, should the company initiate convergence at the R&D, manufacturing, or marketing stage? What is the best approach for developing or securing needed components, interfaces, and integration technologies?

Answering such questions requires a careful assessment of one's capabilities and opportunities in at least six areas (highlighted earlier in Figure 4):

1. Technological: Are the necessary components, interfaces, and integration capabilities currently available or do they need to be developed? What core competencies does the firm currently have related to these technologies? What core competencies does the firm need to develop, produce, and/or market the converged product? Who might have the core competencies the firm needs?

2. Operational: In what ways might existing R&D processes, manufacturing practices, information systems, facilities, and other operational elements need to be modified to support the development of the converged product? Are the changes incremental or major? What external opportunities exist for outsourcing, partnering, or acquiring new operational capabilities? What emerging market opportunities might be present?

3. Organizational: In what ways might organizational structures need to be adjusted to support development of a converged solution? Will new skills or specialized training be needed? Will differences in organizational culture need to be reconciled if and when formerly separate business units or companies collaborate or merge?

4. Clinical testing: What adjustments might be necessary to existing clinical testing and validation practices? Will special attention and additional investment be needed to ensure that regulatory requirements are met?

5. Marketing: How familiar is the target customer? Will new marketing strategies be needed? Are distribution channels already established? Will new modes of product support for providers and patients be necessary? What marketing advantages do potential outsourcing, partnering, or acquisition options present?

6. Investment: What capital resources are available for building, borrowing, or buying the capabilities the firm needs?

Further, the convergence strategy should be aligned with the firm's priorities (also highlighted in Figure 4). Given the firm's business position and strategy for growth, how important will it be to:

- Minimize financial, brand, and other types of risk? (*risk*)
- Maintain proprietary control of activities carried out during the R&D, production, and marketing stages? (*control*)
- Bring the converged solution to market quickly? (*speed*)
- Keep investment at a minimum? (*cost*)
- Expand production scale to meet market demand? (*scale*)
- Enter new product markets? (*scope*)

As the convergence strategy is implemented, it is critical to revisit these questions to consider whether directional adjustments are needed.

Making Convergence Work: Synchronizing Expectations

Considering the most salient examples of convergence in the marketplace today, it seems most companies are securing the components, interfaces, and integration capabilities they need through relationships with other firms rather than through the development of their own in-house capabilities. Taking advantage of technologies that are already available or under development by others can save time and create access to specialized knowledge, resources, and distribution channels. But, establishing effective external relationships with other firms, especially firms in different industry sectors, presents partnering challenges that should not be underestimated. While the importance of tending to partnerships has long been recognized as common knowledge, developing and maintaining effective partnerships (especially cross-sector partnerships) is not yet common practice. For this reason, we present a framework below for assessing whether two companies engaging in convergence have thought through and put into place critical elements for effective partnering.

Companies may believe they have instituted the key elements of effective partnering, but many do not execute these elements with the rigor and intensity needed for success.

Developing a converged product clearly goes beyond physically integrating disparate technologies. Convergence requires synchronizing the goals, knowledge, capabilities, and—perhaps most importantly—the expectations of separate and often very different companies (or business units within the same company). Only through synchronization can delays, dissatisfaction, and the risk of no returns be mitigated.

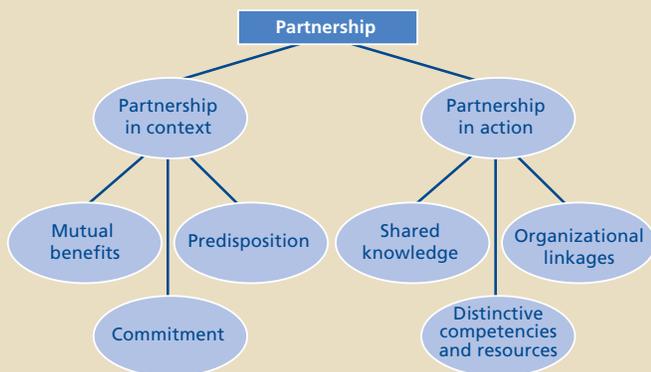
Pharmaceutical, biotech, medical device, and diagnostic companies (or business units) function very differently, in large part because the tasks and timelines needed to develop, manufacture, and market their products are fundamentally very different.⁴⁴ Product and market differences, as well as company age, size, and scope, give rise to dissimilar business strategies, organizational and management structures, corporate culture, financing mechanisms, research and development processes, manufacturing processes, regulatory requirements, distribution channels, and commercialization strategies.

Consequently, two companies (or business units) crossing sector boundaries to form a partnership are likely to have different motivations for entering into the partnership, as well as different—maybe even conflicting—perspectives and expectations regarding the processes, timelines, and costs associated with developing and commercializing a combination product. While the companies may share the ultimate goal of developing a converged product, one may be aiming to expand incrementally upon an already well-established product portfolio while the other may be seeking business growth that will be critical to the survival of the company. Such differences can create conflicting views about the importance and urgency of achieving the goal. Planning and implementing the processes required to produce the converged product can also become complicated and prolonged if differences in perspective are not recognized by both partners and addressed early and explicitly.

Perhaps one of the biggest challenges to a partnership's success arises when the partners differ in their views regarding the role each is playing and the proportion of value each is contributing to the converged product. Should the two parties be considered equal collaborators who deserve equal shares of the returns? Should one party be considered a supplier providing a necessary but relatively minor component and, therefore, be entitled to a smaller share of the returns? Establishing early agreement on this can be critical to the success of the venture. Moreover, adjustments may be necessary to preserve the partnership over time as competitive pressures shift and new opportunities arise that tempt one or both of the parties to betray the relationship.

So, how can companies with such different perspectives and operating contexts form and sustain successful partnerships? We propose six critical factors for effective partnering, adapting a framework developed by J. C. Henderson (Figure 6)⁴⁵. *Mutual benefit, commitment, and shared expectations* are related to the context of the partnership, while *shared knowledge, distinct contributions, and organizational linkages* are related to the day-to-day execution of the partnership. All of these factors are important to consider, but the specific circumstances surrounding the development of the converged product may require that some factors be emphasized more than others.

Figure 6. Critical determinants of successful partnering



Source: Adapted from Henderson, J.C. (1990). "Plugging into strategic partnerships: The critical IS Connection." *Sloan Management Review* 31(3): 7-18.

Partnership in Context: This dimension refers to the contextual factors that determine and influence each partner's belief in the viability (the sustainability, stability, and interdependence) of the partnership.

- **Mutual benefits:** Have the partners explicitly articulated and agreed upon the benefits of the partnership for each company? How will each partner be compensated for the contributions it provides to the converged solution? How will the risk of the venture be shared? How will the financial rewards be divided?
- **Commitment:** Are the partners equally committed to the goal of producing the converged product? Do they share the same understanding and expectations of the development process and timeline? Are they equally committed to meeting project milestones? Are incentive systems in place within each company to reinforce the goal of the partnership? Have contracts been negotiated to specify each partner's roles and responsibilities?
- **Predisposition:** Does each partner trust the other to honor the commitment? What personal relationships already exist between the partnering companies that can be used to build and sustain trust? What attitudes and assumptions do managers from each firm have regarding each other?

Partnership in Action: This dimension refers to the operational factors that determine and influence the day-to-day working relationship between the partnering companies:

- **Shared knowledge:** How well does each company know the other? Do managers recognize, understand, and respect key differences in work processes, operating environments, and corporate culture? What mechanisms are in place to support understanding and joint organizational learning? How well does each company understand the technological components each is bringing to the convergence project? Is there a formal process for exchanging technical knowledge? How well do the companies know the market they are targeting for the converged product? Are they sharing market knowledge?
- **Distinctive competencies and resources:** What are the unique contributions each firm is offering to the partnership? In what specific ways are the partners establishing dependency upon one another? How might this change over time?
- **Organizational linkages:** What organizational linkages are needed? What technical and physical processes must be integrated? What information systems need to be linked or created? What organizational structures should be set up to facilitate the partnership? How can personal relationships be established and supported at each organizational level? What governance structure is appropriate for guiding the effort and resolving disputes?

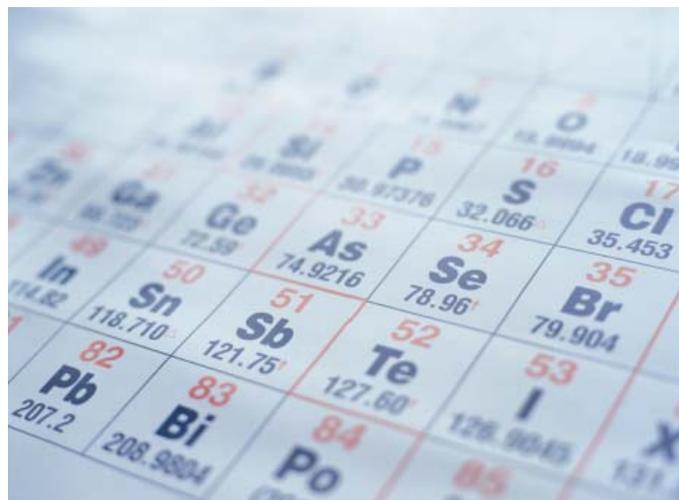
As companies come together to develop converged products, they must recognize the different contexts from which they come and work together to establish a common set of perspectives and expectations for the initiative. This can be facilitated through a joint planning process that is ongoing, iterative, and truly collaborative; establishment of cross-functional teams and promotion of relationship-building at all organizational levels; cross-training that supports knowledge exchange, skills transfer, and appreciation of company differences; co-design and implementation of measurement and monitoring systems; establishment of an effective governance structure that can direct the effort and resolve disputes; and effective use of information technology to support all dimensions of the partnership⁴⁶. To be effective, convergence teams may need to be allowed to function independently of traditional business operations in order to jointly define and execute the chosen approach. The most successful efforts may be those that view convergence not as a transaction between two firms, but as a transformation that enables two firms to work together in an entirely new format and mode.

Emergence of Alliance Networks

As firms pursue innovative product development through convergence, alliance networks (clusters of firms working together through various formal relationships) will likely form, shift, and expand. Partnering with one other firm may not be sufficient for developing a particular combination product; bringing the resources, knowledge, and capabilities of multiple firms together may be both necessary and advantageous (for example, to compete with other networks that have formed)⁴⁷. Moreover, companies may choose to pursue multiple convergence projects simultaneously.

Creating and managing an alliance network involves various challenges and strategic considerations. Some companies may see more advantage and less risk in becoming an ancillary player in another firm's network, while others will want to establish themselves as the network hub to maintain greater control and access to various specialized capabilities, components, and integrative interfaces from multiple sources. By holding the central position in the network, a firm may be able to capture a relatively greater share of the value created by the network. Optimizing the value of the alliance

network can be achieved by the central firm in various ways: facilitating knowledge exchange within the network; ensuring that each partner captures their fair share of the returns; and building network stability by establishing effective leadership and sustaining multiple ties among network partners⁴⁸. Perhaps most importantly, the central firm can facilitate the processes through which a common set of expectations for the development of the converged product can be created. As firms expand globally, alliance networks will involve partners from different regions of the world, as well as different industry sectors, making the central firm's role in synchronizing expectations across partners all the more challenging and critical. Other reports by Deloitte discuss creating and managing alliances in more detail⁴⁹.



Important Note on Regulatory Issues

As mentioned earlier, pharmaceuticals, biologics, and medical devices are subject to different regulatory requirements that govern pre-market applications, manufacturing practices, and post-market reporting of adverse events. Combination products present a difficult regulatory challenge: which regulations should apply?

In the United States, each of the product types is regulated by a different office within the Food and Drug Administration (FDA). A separate Office of Combination Products (OCP) was established in 2002 to develop regulatory guidelines and compliance systems for products that combine two or more product types. Because a “one-size-fits-all” approach would not accommodate the diversity of product combinations, a specific application for combination products has not been developed⁵⁰. Instead, the OCP reviews combination product applications and assigns them either to the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), or the Center for Devices and Radiological Health (CDRH) for review, depending upon the combination product’s ‘primary mode of action.’ Although the pre-market review is led by one center, consultation with another center is not uncommon.⁵¹ Whether a single application or multiple applications are submitted to the FDA depends on the nature of the combination product, the OCP’s determination, and the companies’ business strategy. For most combination products, a single application is appropriate for seeking market approval. In some cases, however, the OCP may require multiple applications or the companies involved may choose to submit separate applications in order to obtain the benefits of new product exclusivity, proprietary data protection, or approval under a particular type of product designation, such as an orphan drug designation⁵².

Similarly, among countries in the European Union (EU), the method by which the principal intended action is achieved determines which set of regulations is applied to the combination product⁵³. For most combination products, however, the principal intended action is achieved through a synergistic effect that neither component could create alone. Manufacturers must choose which component is most responsible for the effect and present clinical evidence and scientific reasoning to regulatory agencies in defense of the

choice. When potentially equally strong cases can be made for applying different regulatory requirements, manufacturers can sometimes make adjustments to the intended use, patient population, or labeling of the combination product to strengthen the argument that one regulatory process should be applied instead of another⁵⁴. Even then, countries within the EU may vary in their views of which regulations should apply for borderline cases. When a drug is involved, manufacturers can seek approval through separate applications to national authorities or through a single application to the European Medicines Agency (EMA). While the latter provides the advantages of a centralized process, it can be the longer, more expensive option⁵⁵.

In general, devices typically offer incremental improvements over existing products, so they often qualify for an expedited review that does not require new clinical trials. Pharmaceuticals and biologics that offer incremental improvement over existing therapeutics may also be put on a fast track, but most are submitted as new products that necessitate extensive clinical trials and a lengthy review. When devices are combined with drugs, the generally shorter, less costly regulatory path that many devices follow may no longer apply.

Given the challenges and uncertainties involved in regulating combination products, conferring with regulatory agencies early in the product development process is clearly important, if not essential, for avoiding extra costs and delays. A firm’s typical testing and validation approach may not be the most appropriate approach for a converged product. By engaging regulators in devising the testing and validation strategy, companies can reduce the likelihood of pursuing an approach that has been dismissed by precedent or that requires unexpected supplemental studies at a late stage. Moreover, frequent consultation with regulators can ensure that regulatory changes are not missed and adjustments are made at the earliest possible stage. Regulatory experience with combination products is relatively new. As innovative product combinations continue to challenge existing approaches and experience accumulates, regulatory requirements are likely to undergo further modification.

Conclusions

To realize the promise and value of convergence, firms will have to move beyond traditional industry boundaries, resolve technological uncertainties, and learn to operate within a network of companies that have substantively different business models, product life cycles, organizational structures, and corporate cultures. If life sciences firms can overcome these challenges, convergence seems certain to become a significant driver of innovation, growth, and improvement in health care delivery and outcomes. Since most convergent technologies are in various stages of incubation and development, it is premature to estimate the impact convergence will have on industry growth and health care costs. However, early examples suggest that convergence has tremendous potential to drive new business opportunities and meet consumer demand for safer, more effective health care solutions.



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