Executive briefing

High performance drug discovery

An operating model for a new era

accenture

Pharmaceuticals & Medical Products

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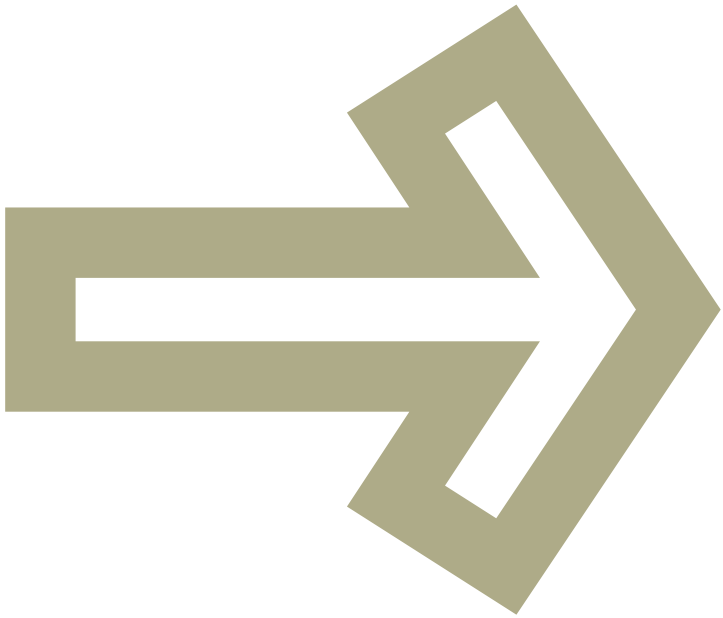
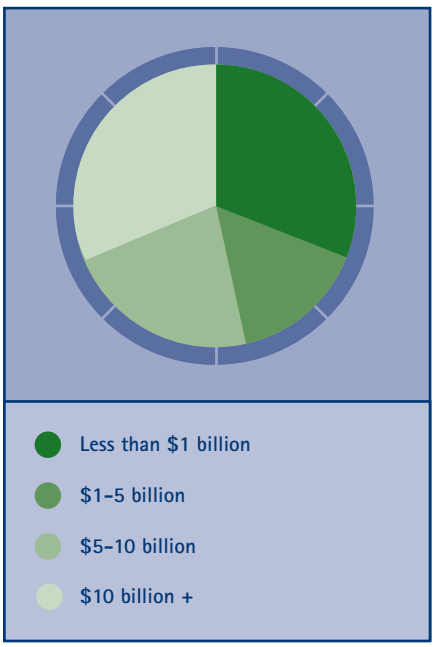


Introduction

During 2000, Accenture repeated research that led, in 1997, to the publication of the executive briefing, Reinventing drug discovery – The quest for innovation and productivity. This research evaluated the demands on pharmaceutical companies to meet pipeline needs from both clinical and business perspectives.

Accenture conducted its updated research to describe the current state of research performance and critical success factors for drug discovery in the pharmaceutical industry. Fifteen companies representing a cross-section of leading organizations in the industry participated in the research program.

Distribution of the 15 participating companies by drug revenues



Overall, companies that succeed in integrating the new technologies and science with improved processes and management, along with leveraging alliances, will have an enormous advantage in the global marketplace.

The research found that as currently designed, pharmaceutical research processes lack the ability to capitalize on the enormous potential unleashed by breakthroughs in genomics and information technology and that only a significant restructuring of the current operating model will enable the industry to realize the full benefits of these innovations.

The research also found that leading pharmaceutical and biotechnology companies have fallen short of the ambitious pipeline goals they predicted in 1997. In part, this was because the industry did not fully foresee the effect of new market dynamics, such as genomics and information technology breakthroughs, as well as the emergence of a patient-centric operating model.

Overall, companies that succeed in integrating the new technologies and science with improved processes and management, along with leveraging alliances, will have an enormous advantage in the global marketplace – and they will lead the industry in fulfilling its promise of producing better medicines more quickly.

The 1997 research identified the productivity goals of senior Research & Development (R&D) executives in the pharmaceutical industry. Specifically, by the year 2000, companies were expecting:

- to cut their discovery timelines in half
- triple the number of compounds delivered to development
- increased early attrition
- to achieve growth objectives by focusing on therapies with "blockbuster" potential.

Figure 01
Discovery timelines and improvement

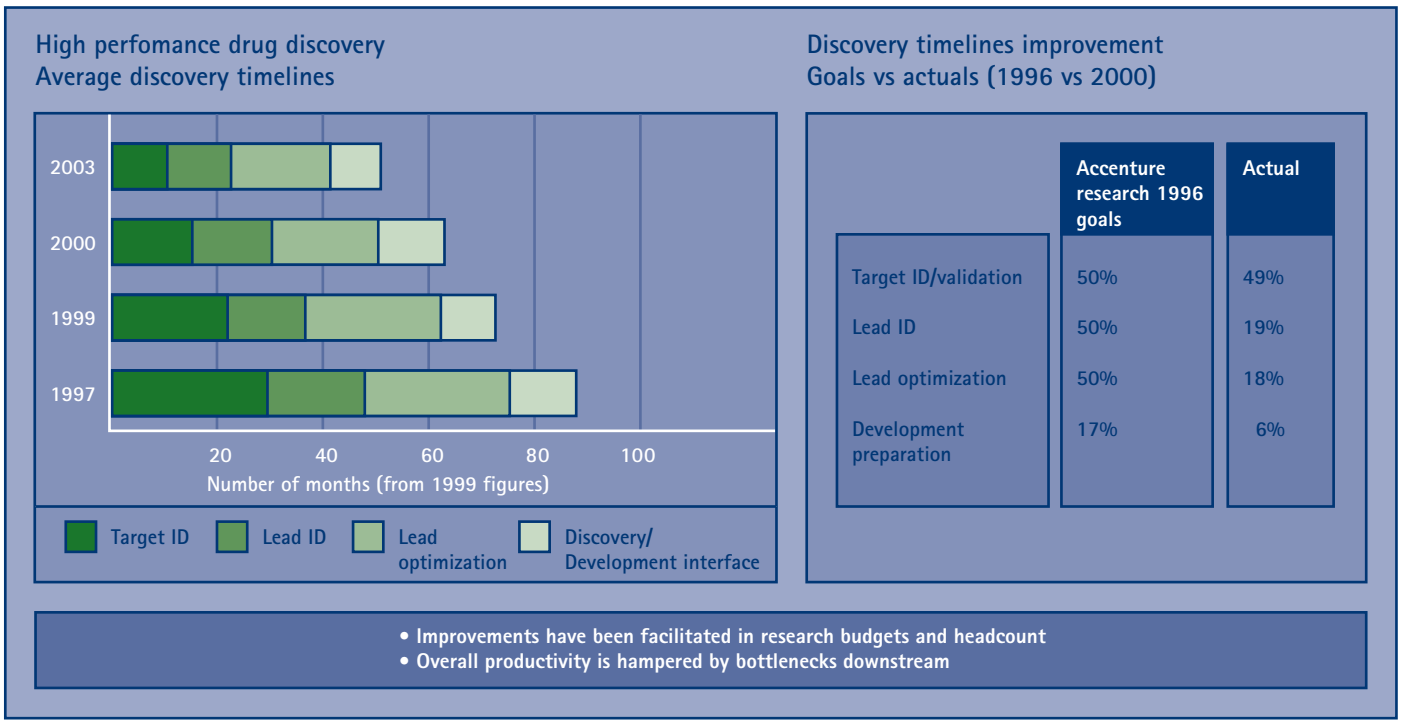
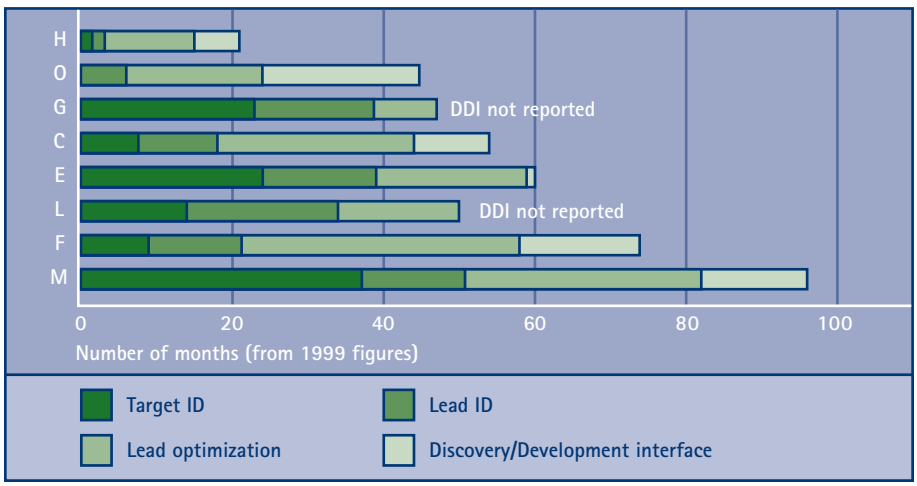


Figure 02
Discovery timelines per average target



Source: High performance drug discovery data collection form

Figure 03
Number of NMEs required to meet 10-year growth objectives

2000 Pharma sales (Example companies near size)	Anticipated sales from current products in 2010	Annual real growth target (2000–2010)	Sales gap for new products to fill in 2010	Estimated number of NCEs required to fill gap (over 10 years)	Year 2010 required NCE output	
$15bn (Glaxo Wellcome, Aventis, Bristol-Myers Squibb)	$10bn	8% 6% 4%	$ 22 billion $ 17 billion $ 12 billion	40–45 30–35 20–25	5.5–6.0 4.0–4.5 2.5–3.0	Top-tier players must average three significant NCE launches per year to continue rapid growth.
$8bn (Eli Lilly, Bayer, Schering Plough)	$5.5bn	8% 6% 4%	$ 12 billion $ 9 billion $ 6 billion	20–25 15–20 10–15	3.0–3.5 2.0–2.5 1.0–1.5	Medium sized companies must produce at least one NCE per year to sustain average growth.

In addition to falling short of these predicted improvements, the price of (R&D) has continued to rise. Pharmaceutical and biotech leaders participating in Accenture's research currently spend an average of 250 full-time employee (FTE) years, or approximately $70 million, for each new molecule that reaches development.

With few exceptions, pharmaceutical companies have been unsuccessful in achieving these discovery goals. Note in Figures 01 and 02 (on the previous page) that, except for improvements in target identification that have been facilitated to a great extent by increases in research budgets and headcount, process timelines have not measurably improved. In addition, downstream bottlenecks – from lead identification to delivery of a fully vetted development candidate – still plague most organizations. The attrition rate in clinical trials is still high and the outcome of the "blockbuster" strategy has been disappointing – only one in five new product launches are deemed "significant."[01] Discovery organizations have not been able to deliver on the expectations they set for themselves.

The failure of the industry to meet the ambitious goals of 1997 has been paralleled by continued pressure from Wall Street to deliver double-digit growth and increased shareholder value. The number of New Molecular Entities (NMEs) must increase by 50 percent to meet 10-year growth objectives. Figure 03 indicates the number of NMEs required to fill the gap between future growth targets and current sales.

01 i.e., generated revenue exceeding $300 million during the same period

As Figures 04 and 04a show, simply increasing R&D spending does not appear to be the answer to the industry's pipeline challenges. In any event, at current costs and staffing levels per Investigational New Drug application (IND), as shown in Figure 05 (on the following page), pharmaceutical companies will find that they simply cannot afford to increase spending. In short, without changing fundamental practices and underlying research processes, pharmaceutical companies will not be able to achieve their productivity goals.

Figure 04
Average R&D spending (US-based firms)

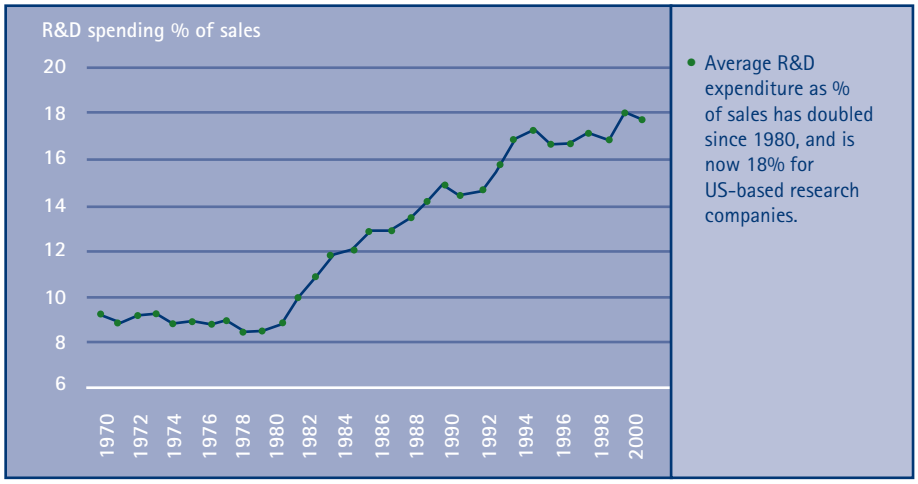
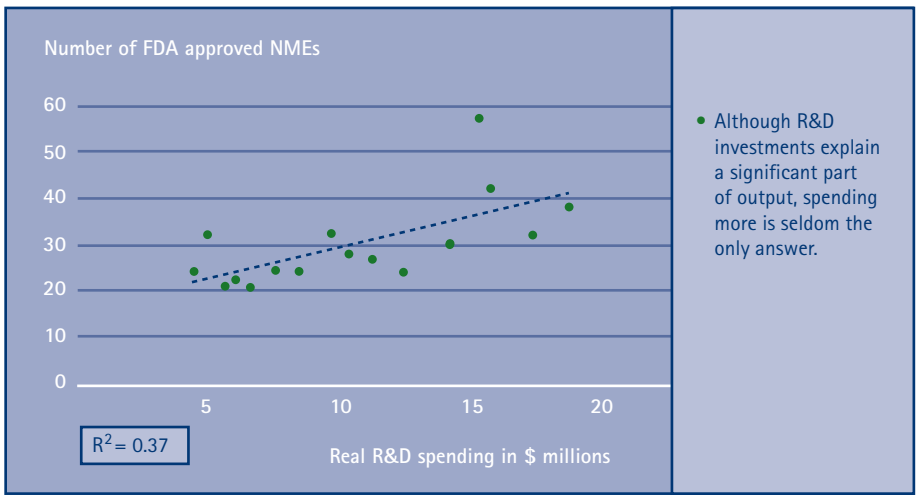
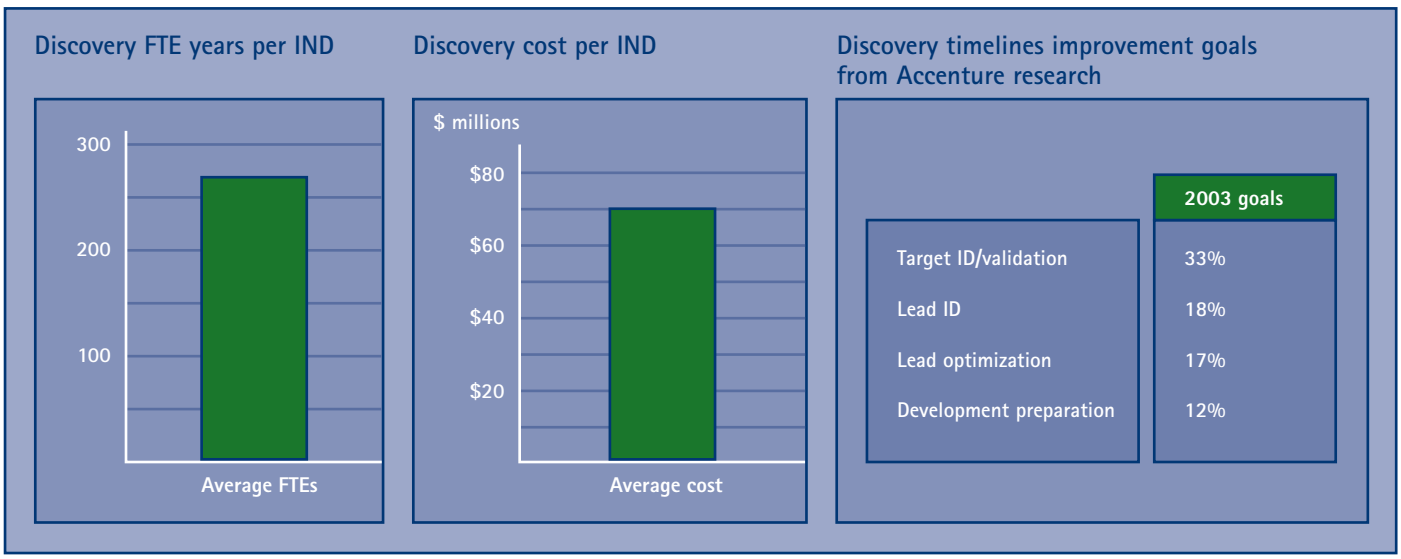


Figure 04a
Aggregate R&D spend vs. output (US-based firms)



Source: PhRMA "Annual Survey 2000" Accenture analysis

Figure 05
Current costs & staffing levels

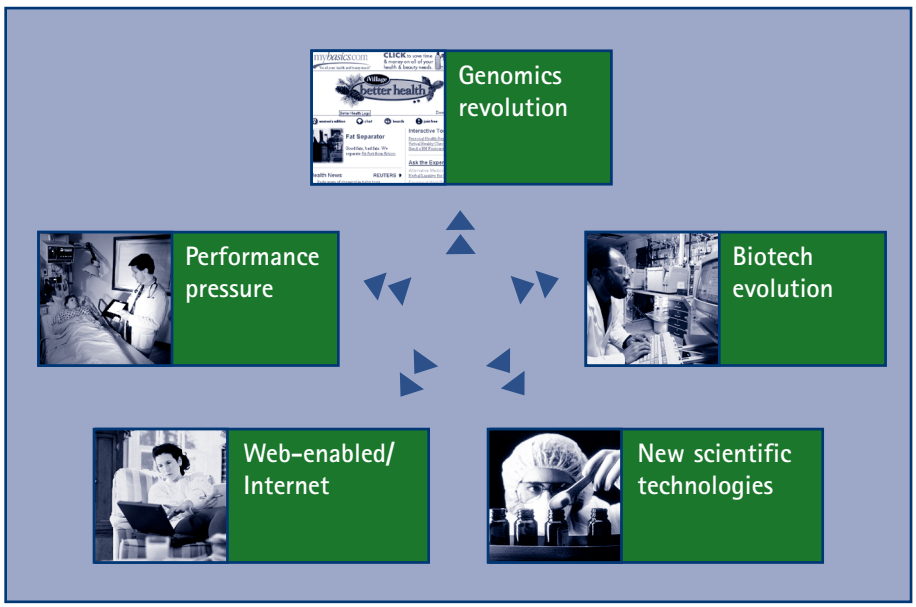


Simply increasing R&D spending does not appear to be the answer to the industry's pipeline challenges.

In short, without changing fundamental practices and underlying research processes, pharmaceutical companies will not be able to achieve their productivity goals.

Figure 06
Changes since 1997

Adding further pressure to discovery's ability to deliver area number of fundamental changes in the landscape that were unforeseen in 1997 (see Figure 06).



The sequencing of the human genome and the development of new genomic technologies

In the 1997 research, the industry had expected the sequencing of the human genome to take between eight and ten years, but in a move evoking the biotech equivalent of Moore's Law, not only is the sequencing already complete, but powerful new technologies have been developed that are poised to revolutionize and redefine the drug discovery process.

The scientific advances in genomics and other emerging technologies, such as proteomics, biochips, signal transduction, and toxicogenomics, while not yet fully realized or mature, are forcing companies to rethink their discovery processes, how their discovery operations are organized and the linkage between discovery and development. The opportunities for exponential growth in targets, the ability to develop innovative therapies and the impact on improved lead quality are yet to be fully understood.

The evolution of the Internet and other new information management infrastructures

The evolution of the Internet has created unprecedented opportunities to obtain rapid access to, and to more effectively manage, both internal and external data. However, the challenge lies with converting the data into an integrated source of knowledge.

In a business where knowledge is often the most valuable asset, the Internet, if properly harnessed, provides pharmaceutical companies with an unprecedented opportunity to reduce their discovery costs and increase their productivity. These improvements will be generated through new operating structures within the organization that enable new collaborative relationships, more cost-effective management and the ability to provide greater knowledge at the point of need.

The continued maturation of the biotechnology market sector

Since the 1997 research, the biotechnology industry has rapidly matured, producing organizations that look more like lean pharmaceutical companies with integrated technology platforms rather than small businesses seeking to license an asset. The growing business value, market capitalization and entrepreneurial culture of biotechnology companies has enabled them to grow less dependent on the security of partnerships with large pharmaceutical companies, providing them with greater leverage to attract top-tier talent and acquire the necessary resources. The relationships between pharmaceutical and biotechnology companies have evolved from transaction-based to value-based partnerships, and the pharmaceutical companies, in particular, have had to adapt by finding new ways of forming and managing alliances, facilitating the use of new technology platforms in a virtual manner, creating new business entities by leveraging intellectual and physical assets and allowing these new entities to create new rules for the industry.

Based on the research, Accenture identified six discrete but integrated areas that can significantly improve the cycle time, productivity and quality of discovery organizations:

- Operational optimization of R&D
- Prioritization and decision-making
- Information and knowledge
- Genomics and other technologies
- Economies of scale
- Partnerships and alliances

Maximizing value creation

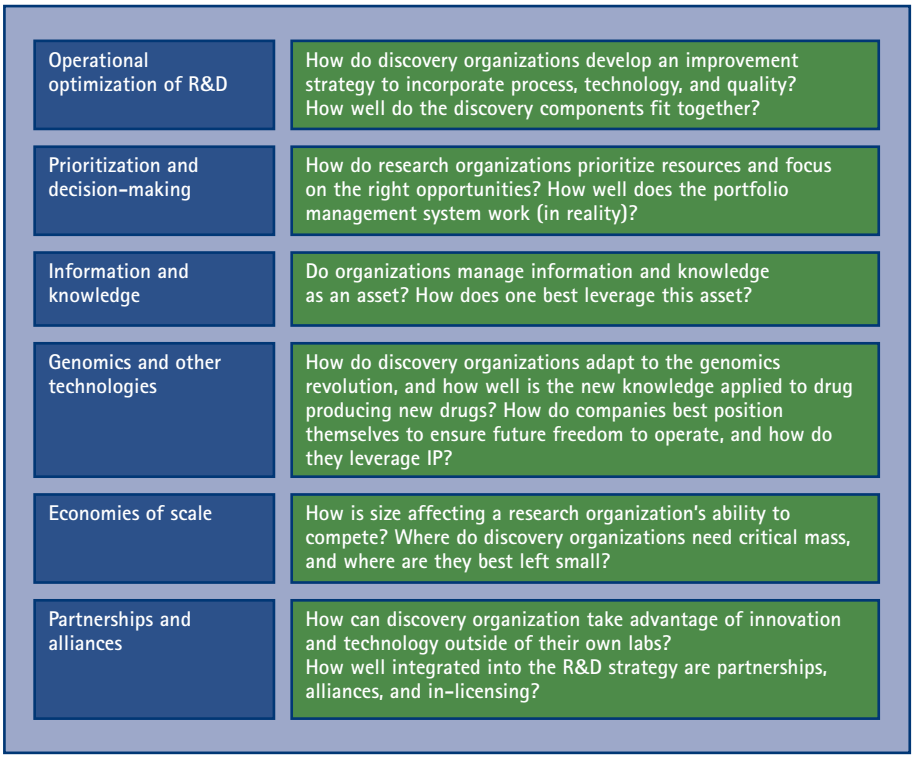
The results of the 2000 research suggest six major areas where pharmaceutical companies must make changes that will enhance the value delivered by their discovery organizations.

These six areas are:

Operational optimization of R&D
The discovery operating model needs to change significantly to align more closely with the research strategy. Companies must improve their performance and quality of output by aligning discovery processes to strategy and integrating new scientific and information technologies with discovery-related components of the organization.

Prioritization and decision-making
Expediting portfolio strategies will entail the elimination of management bottlenecks and the replacement of top-down decision-making with empowered, multi-disciplinary teams and leaders that have budgetary authority and consistent portfolio management guidelines, as well as the tools to balance resources across multiple products and teams.

Figure 07
Six key areas to drive performance



Information and knowledge

Industry leaders will need to embed a new, integrated technology platform in R&D processes to connect disparate data, information and technology. Additionally, they must ensure the capture and leveraging of intellectual property as an asset.

Genomics and other technologies

Companies must integrate genomics, proteomics and other technologies to improve target identification and attrition; enhance lead optimization and improve clinical trial designs that speed approval; and shift from broadly targeted drugs to more focused medicines with much higher therapeutic value for the target population.

Economies of scale

Successful companies will re-evaluate the thought that "bigger is better" and will look to achieve critical mass in vital areas through alliances and the virtualization of research. They will optimize capabilities in recruiting and developing scarce skills and drive enhanced human performance.

Partnerships and alliances

The role of alliances has changed from a complement to existing programs or a source of select technologies to an integral part of the discovery process. Creating partnerships and alliances will enable companies to become "virtual" entities of streamlined parent companies tied to outside alliances that provide fast access to critical capabilities. They also offer the opportunity to experiment with emerging technologies and facilitate involvement in specific disease or therapeutic areas.

Figure 07 shows how these critical success factors reflect a series of questions posed throughout the research. These questions provide a useful means by which companies can begin to evaluate their internal operations.

Operational optimization of R&D

Since Accenture's last survey, many companies have solved the troublesome interface between discovery and development, yielding a smoother transition. However, the number, quality or speed of delivery of candidates to development has not generally improved, despite considerable investment in new technologies and approaches. Most companies need to radically restructure their R&D operating model to improve output quality and volume.

At current productivity levels, the companies participating in the research spend an average of 250 FTE years for each molecule that reaches clinical development. This translates into approximately $70 million per molecule.

Breaking through the discovery – development barrier

Most companies have improved the transition of compounds from discovery into development by implementing a number of different approaches. Among the most common of these are:

- Greater involvement of development and commercial activities in research planning and decision-making.
- Alignment of goals and objectives across the entire value chain.
- Organizational expansion of research activities as far as Phase 2a – such that research resources and funding is occupied on compounds until proof of principle has been reached.

Moving from 'Shifting the bottlenecks' – to 'Integrated process excellence'

At current productivity levels, the companies participating in the research spend an average of 250 FTE years for each molecule that reaches clinical development. This translates into approximately $70 million per molecule. Technology advances highlighted in the 1997 research generally delivered higher or better quality output, faster cycle times or lower costs, but only in the specific area of the pipeline in which they were implemented. However, these point improvements were not integrated to provide savings throughout the complete discovery process. Molecular biology has provided a higher number of targets but not necessarily valid targets. Assay development remains a bottleneck. High Throughput Screening (HTS) and ultra-high throughput screening succeeded in shifting bottlenecks to lead identification and optimization – areas that were already struggling with shortages of scarce resources.

HTS is now a basic technology necessary to remain in the game rather than a determinant of success. Following disappointing results screening massive random libraries, most companies are now taking a more strategic approach to building focused libraries.

The new discovery operating model – strengthening the link to the strategy

There is an opportunity for most discovery organizations to enhance productivity by redefining their basic operating model – the totality of its business rules, processes, resources, information systems and capabilities. Accenture's 2000 research showed that there is not a single correct answer. Instead, a high-performing discovery operating model must fit the company's product strategy and effectively leverage its research strengths and downstream capabilities. The components of the operating model must be mutually supportive and re-enforce each other to maximize organizational performance. In some cases, explicit tradeoffs must be made – in the case of one major company in the research, a determined strategy to focus on blockbusters and only to deliver well qualified compounds to early development resulted in necessarily long cycle times in the lead optimization phase as compounds were cycled back through the process several times.

The significant learning is that the operating model in the winning companies is designed to specifically support a clearly defined strategy.

Consider one of the participants in the research, Company X, which is pursuing an aggressive target-by-class strategy. Company X has chosen not to organize into therapeutic areas until very late in the discovery process in order to fully capture the operational synergies and organizational learning that come from focusing on a limited number of target families. In this company's model, investments in molecular modeling are made up-front and assays are screened at higher concentrations in order to learn more about the targets.

In contrast, Company Y, pursuing novel genomics-based targets, has streamlined lead identification processes based on maximizing capacity and efficiency. Since 90 percent of the novel genomics-based targets will not yield an interesting lead series, this company's operating model is optimized to quickly narrow the field of targets and validate the most promising ones. Company Y's best-in-class HTS capabilities, high-quality and efficient assay development, large chemical library and in silico hit validation process all complement each other to effectively operationalize the organization's research strategy.

New operating models must also tap into the potential of emerging genomics technologies, which have the potential to rapidly and fundamentally change the drug discovery process by intervening at multiple points, potentially increasing the speed, attrition rate and quality of product candidates. Many of the companies in Accenture's research are questioning whether the traditional discovery process is the most efficient route to creating new products. The linear discovery process will change into a more iterative one in which target validation runs in parallel with lead discovery/optimization activities, with genomics/proteomics and genetics intervening at several points in an iterative model. Figures 08 and 08a (on the facing page) compare the timeframes and sequence of the traditional process with a more dynamic, multi-functional model incorporating new technologies.

The growing complexity of discovery operations and the increasing importance of managing functional interfaces have some companies examining how to best create "discovery operating platforms." Recognizing the shortcomings of focusing solely on sub-processes, these organizations are now looking at how to optimize end-to-end performance and proactively manage pipeline bottlenecks. New models must integrate the concepts of "parallel processing" and organizational interface management. Streamlining capacity, increasing speed and shifting attrition upstream are the keys to achieving breakthrough productivity, but few of these sources of improvements can be tapped on a micro level.

The discovery operating platform – which incorporates both internal and external resources and capabilities – must pursue more than technology solutions. It must integrate processes, decision-making and resource management if it is to improve overall productivity and quality of output.

Figure 08
Evolving approach

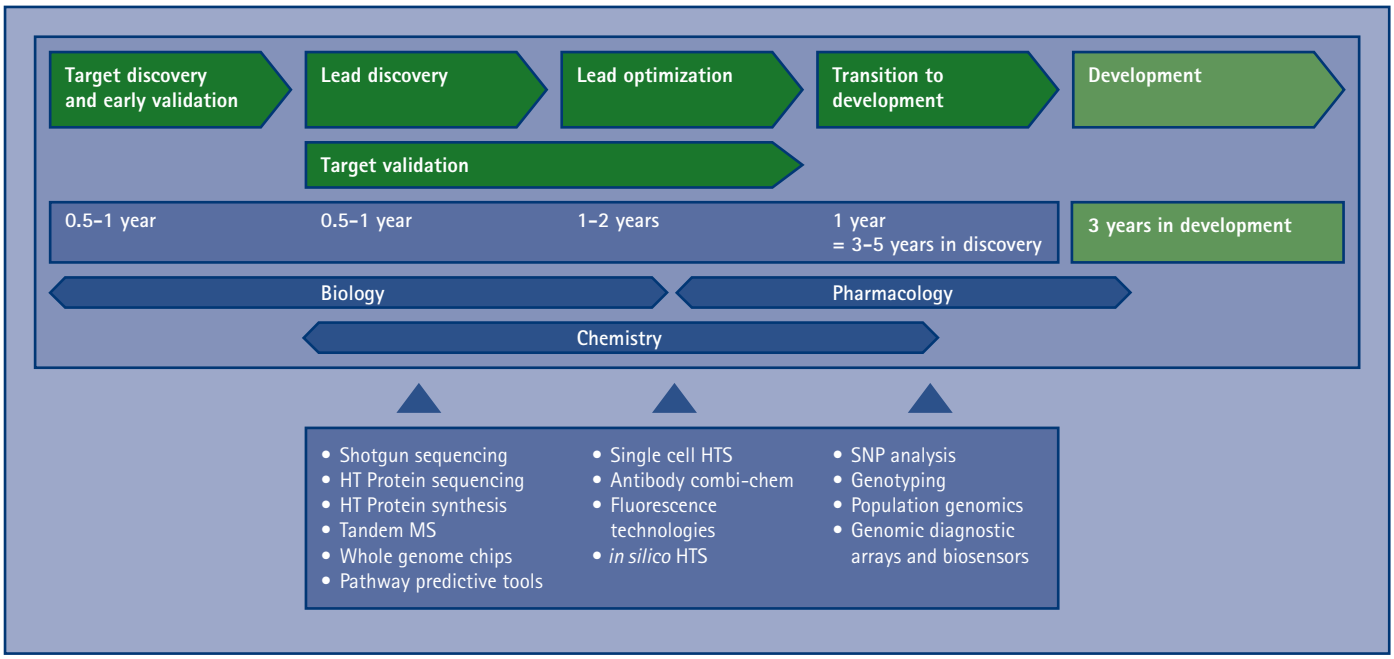
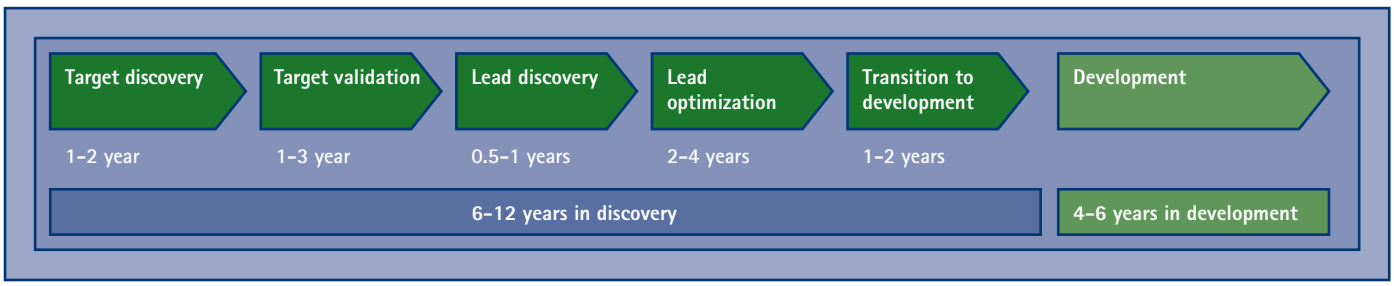


Figure 08a
Traditional approach



Prioritization and decision-making

The need to efficiently manage the flood of genomics derived targets without increased resources and to increase attrition in lead identification and optimization means that rapid and accurate prioritization and decision-making will become vital skills in discovery.

Accenture's 2000 research revealed a number of improvements in the industry since 1997. These include:

- better methods for establishing direction – and therefore better frameworks for decision-making
- better methods for analysis of projects and portfolios
- enhanced involvement of non-discovery functions in setting direction and in decision-making
- the implementation of predictive modeling to increase attrition rates in discovery.

Areas that continue to need development include:

- the ability to make fast and effective decisions
- effective execution of decisions
- empowerment of project managers to take decisions.

Project and portfolio analysis not management

Portfolio management is an important tool in making the right decisions, and most pharmaceutical companies have, to some extent, implemented a portfolio strategy that defines the disease area focus – using this to drive resource allocation at the disease area level, often as part of an annual process.

Since 1997 companies have improved their ability to evaluate the risk/return potential of projects (compounds) although some use unnecessarily complex analytical techniques. Ninety percent of the companies in Accenture's research have implemented portfolio analyses and use similar sets of criteria, often focusing on commercial value and risk, technical risk and competitive situation. In a few companies, novelty, time to clinical candidate and the intellectual property (IP) position are also considered. Project value continues to be a challenging criterion to evaluate with approaches in our survey, ranging from risk adjusted Net Present Value (NPV) or Peak Year Sales to more complex multiple surrogate measures, which are aggregated to provide a single assessment of what has become comparative 'value.'

The majority of companies track and analyze projects in lead optimization, and the research found one instance of a company which analyzes and manages its portfolio of targets as a separate entity. As higher risk genomics targets flow into the systems in high volume, it will become increasingly important for companies to manage the investment they make in the target portfolio more closely.

Companies are generally investing in predictive techniques to enable earlier and better characterization of leads. In vitro and in silico models are in fairly widespread use but are not, at this stage, always validated. The companies with large amounts of lead related data will advance fastest in this area as the 'predictiveness' of their models is tested and improved. The research suggests these to include the mega-companies resulting from merger activity in the industry. However, the industry and often companies are divided on two important points:

- the utility of the predictive models
- formal processes and criteria as a substitute for experience – several companies prefer to rely on the experience and 'gut feel' of their senior people when evaluating leads.

Despite the richness of information that these various improved analytical techniques provide on the composition of the portfolio, few companies actively manage projects at the portfolio level – taking decisions based on these analysis and driving through to execute those decisions. Those that do so successfully, providing better quality decisions and easing the transition of projects across major process stages, have created portfolio management bodies that span traditional functional barriers.

While 90 percent of participating companies have developed resource planning systems for discovery since 1997, these are rarely directly linked to the portfolio management system.

One of the barriers to implementing portfolio decisions will continue to lie with poor linkages to resource planning systems. While 90 percent of participating companies have developed resource planning systems for discovery since 1997, these are rarely directly linked to the portfolio management system. In the majority of cases, the system is used only to track utilization rather than for forecasting or modelling resource usage. The result is that resource allocations often become disconnected from and out of alignment with the portfolio strategy and supply and demand mismatches of resources arise.

Better decision-making for breakthrough results

Effective decision-making is becoming a critical competence throughout discovery. Decisions must be made with an eye to:

- Aligning with the research and portfolio strategies – ensuring that decisions that are taken directly support the goals of both discovery and the business in general.
- Delivering more and higher quality compounds at greater speed without increasing the resource and cost base.
- Ensuring that the decision-making process itself does not become a bottleneck.

Clear research strategies must define the priorities that drive decision-making, and these have improved greatly in clarity and utility since 1997. The key changes are commitment to the creation of a research strategy by senior management and the increased involvement of the development and commercial functions in setting direction, in determining product profiles at an early stage and in some aspects of decision-making in discovery. In some cases the remaining weakness lies with the ability of the commercial function to provide a truly strategic medium term perspective versus the more common shorter-term viewpoint.

Decision-making itself, however, also remains a weakness in the industry. Approximately 50 percent of the participants in the research considered decision-making within the discovery organization to be ineffective and generally slow. Some of the reasons identified for this include:

- The need to elevate decisions to an unnecessarily high level in the organization, causing delays.
- Decision-making bodies that are too large or are mis-constituted – lacking vital input from other functions.
- Decisions that are applied inconsistently and with a lack of transparency.

There is a clear need in many companies to define a hierarchy of decision types and identify the bodies best able to take them. One common approach has been to more fully empower project leaders to make more of the decisions, particularly concerning the progression of projects along the discovery process.

Success has been slow, caused in part by differing perceptions of who is ultimately responsible for each decision and also through variable interpretations of milestones and inconsistencies in transitioning from one to another. Perhaps most harmfully, there is often a shortage of true project management skills among discovery scientists and tools to support their decision-making processes.

Some of the more successful methods used to drive empowerment include:

- Creating strong, empowered, multi-disciplinary discovery teams with appropriate dedicated membership, accountable leadership, formal coordination processes and team-based, outcomes-focused performance measurements and rewards.
- Providing team leader(s) with the skills to manage project budgets and milestones, determine required process steps, and identify and mobilize required skills.
- Improving the coordination and communication with project teams by instituting co-leadership between biology and chemistry professionals to maximize integration and reduce friction.
- Assigning budgetary authority at the project level to permit rapid and appropriate mobilization of resources.

Information and knowledge

Over the past few years, discovery operations have experienced the same information revolution as other sectors of the economy. The Internet, the explosion of available data and the advent of new bioinformatics tools have all made themselves felt. While this revolution has produced improvements in a few focused areas, it has not delivered the dramatic benefits that all companies appear to believe can be derived from the effective management of information. Pharmaceutical companies have primarily seen isolated "point" solutions rather than integrated improvements. The result is continued widespread discontent with informatics.

Since Accenture's 1997 research, senior management at companies have come to recognize the importance of informatics as a research tool. Most companies have established an Information Technology (IT) strategy that integrates into their discovery strategy and helps guide their activities. Investment in informatics has increased since 1997 and is projected to continue to increase out to 2003 as a constant percentage of the total research budget. Companies have focused on improving those systems that provide fundamental capabilities such as registration, compound management, and the capture of chemical and biological activity information. However, there continues to be significant frustration within discovery organizations over the quality of the results from informatics and the level of effort and time required to achieve those results.

Drug discovery is a knowledge-based business

There is a growing recognition that pharmaceutical companies must become more effective at developing and managing knowledge to achieve their targeted time, quality and cost improvements. To maximize the value of information, companies need to establish a foundation architecture that enables consistency and accuracy of data, sharing of knowledge across the organization and with alliance partners and support of common analytic models. Accenture's research demonstrated that discovery organizations continue to face several challenges as they attempt to improve the speed and quality of information provided to the organization:

Establishing standards that increase the value of data by enabling organization-wide information sharing across project teams and therapeutic areas.

Implementing integrated rather than isolated solutions focused on the needs of a specific function or therapeutic area.

These companies were able to see how information technology must integrate cohesively with operations, process and project management.

Obtaining value from the Internet. Most companies lack an eCommerce strategy in discovery that goes beyond using the Internet as an application delivery vehicle, or as a means for viewing electronic publications. Companies tend to view the Internet as an extension of what they are currently doing rather than as providing an opportunity to fundamentally change their structure or operating processes.

Enabling a knowledge-based organization. Though most pharmaceutical companies are not satisfied with the integration and accessibility of information, most are looking beyond these issues to the delivery of knowledge to scientists. Accenture's research discovered a growing recognition that organizations must become more effective at developing and managing knowledge to achieve their objectives for time, quality and cost improvements. However, the participants in the research primarily viewed knowledge as a one-dimensional technology issue. Establishing the technical, organizational and process elements required for effective knowledge management is a significant challenge that pharmaceutical companies will need to face.

Supporting the attainment of critical mass. Each of the companies involved in the research had focused on maintaining critical mass in key scientific areas. Whether through acquisition, alliances or organic growth, each organization saw itself expanding to capitalize on the growth in new targets and to meet the demand for new NMEs. Informatics will be the critical element that provides cohesion throughout the growth period. It is therefore critical for organizations to have information systems that support integration and collaboration across organizational boundaries and are easily expandable as organizations grow. Few of the companies involved in the research had any plans to support collaboration or integration of project teams across facilities or organizations. This, however, will be an important aspect of achieving and leveraging critical mass.

To greater or lesser extents, the research participants have begun addressing some of these challenges. Those that have been most effective appear to have addressed the issue as more than just an information technology problem. These companies were able to see how information technology must integrate cohesively with operations, process and project management.

Information integration

Since 1997, the companies involved in the research have established basic information capabilities including genomics searching and target tracking, sample and compound management, registration and HTS and biological data capture. While some participants have begun to develop databases that venture across the Drug Discovery Interface (DDI), consolidating chemical and biologic data, most companies lack such integration and the analytical tools that enable easy, rapid and robust evaluation of integrated data. For these companies, one of the prerequisites for integration remains tackling the organizational challenges of establishing assay and data standards across therapeutic areas. These include:

- Establishing integrated data and application architectures that allow companies to easily add and remove both custom and third party applications.
- Implementing a technical architecture that extends outside the company and enables real time integration of applications and data from alliance partners.
- Enabling two-way data flow between discovery and development operations.

Information integration initiatives are cross-disciplinary, multi-functional efforts that must serve the needs of diverse internal constituencies. The sponsorship, support and stewardship of senior R&D management is the critical success factor needed to achieve the objectives of richer, more effective analysis as well as more sophisticated management of intellectual property.

Early adopters will become more prevalent in the coming two years, forcing companies to evaluate these new options or fall behind in the race for innovation and excellence.

Extracting value from the Internet

eR&D is still an emerging concept in most research organizations. Most discovery professionals recognize the potential of the Internet as a vehicle for sharing information and providing new access to and interface with both technological and expert resources, but they have not thought through how it could impact their operational approach or performance. For example, while embracing information integration, companies in the research have not begun to view the integration of the Internet and their own knowledge management tools as a means to more effectively manage alliances. Only recently have most pharmaceutical companies evaluated the Internet as providing a different means of sourcing software. The more progressive companies in the research have begun to:

- Review research processes and look for opportunities in which integration of Web-based information/ communications infrastructure (e.g., eCommerce) could fundamentally change the cost or performance.
- Dedicate a group or individuals to monitor trends and provide insights in this area.
- Develop an alliance strategy for developing solutions collaboratively with leading Web infrastructure players such as Cisco, SAP or Microsoft.

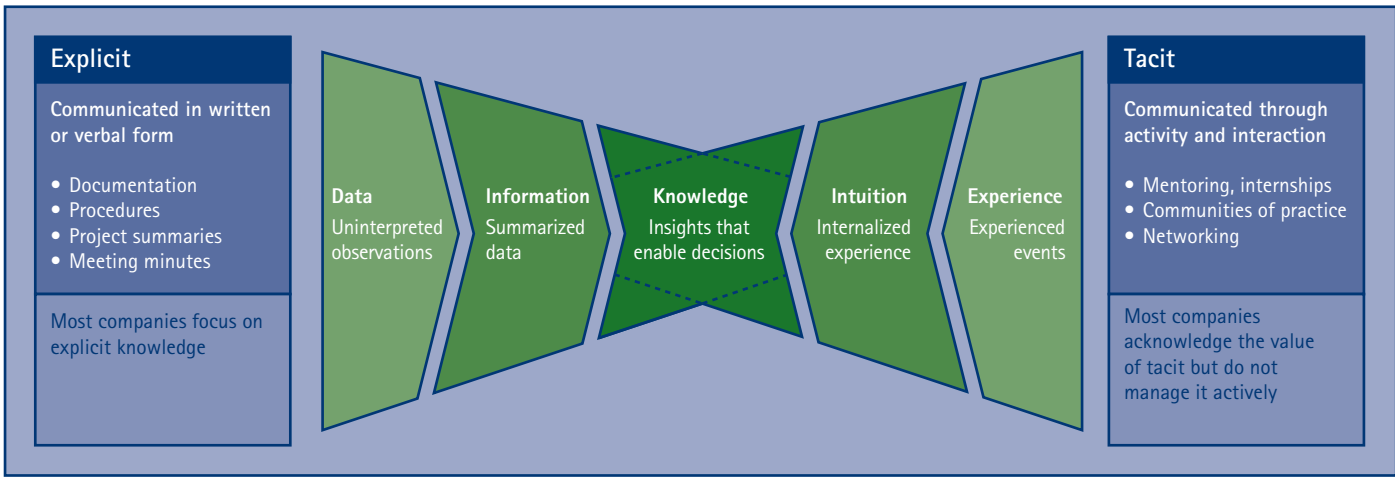
The Web itself is evolving rapidly; though starting slowly, applications and utilities are being developed specifically for the drug discovery community. Early adopters will become more prevalent in the coming two years, forcing companies to evaluate these new options or fall behind in the race for innovation and excellence.

Knowledge management is NOT only information technology

Knowledge management is an objective of each company that participated in Accenture's research. Though universally acknowledging the importance of information technology, companies have applied different approaches to gain the greatest value from their investments in this area. Beyond implementation of isolated improvements, those companies that have most effectively addressed the current and emerging challenges appear to be those that focus on the process and organizational elements as well as the technical dimension.

Two elements seem to differentiate companies that have made the greatest progress from others.

Figure 09
Shifting management focus



First, companies realizing the greatest value from their investment in knowledge management are addressing organizational, cultural and process issues as they also establish the necessary technical infrastructure. Instead of simply looking at knowledge management as an implementation of portals, the more progressive companies are working on issues such as motivating people to share knowledge, putting in place processes for the capture and categorization of knowledge and developing a strategy for prioritizing knowledge capture.

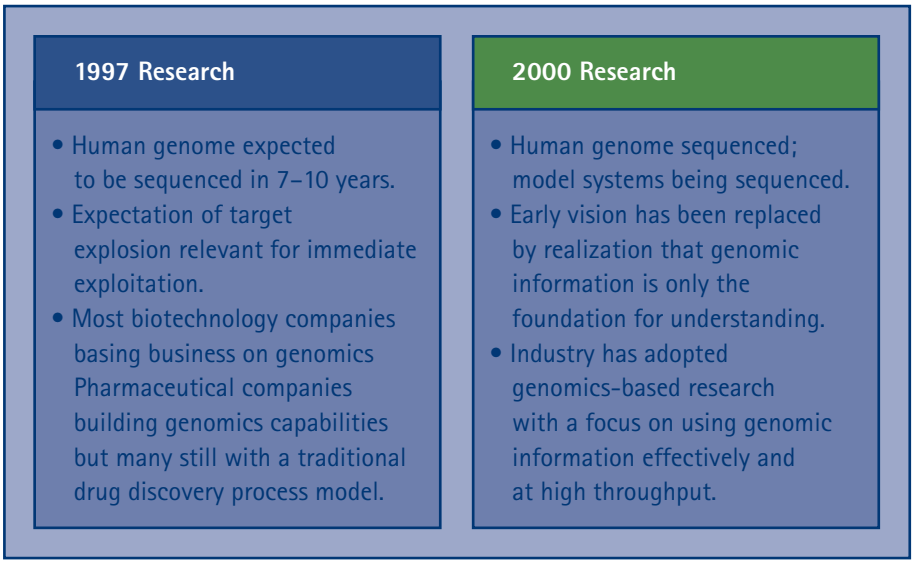
Second, companies are viewing knowledge as having two components: explicit information such as documents, data and publications; and tacit information that comes from communities of interests, collaboration or networking. As a result, these companies are looking to enable sharing of both of these components.

Figure 09 indicates that an organization's abilities to create, use and store both its explicit and implicit information assets will affect the quality of its insights and decisions.

Genomics and other technologies

Participants in the 1997 research were hopeful of a quick and highly valuable pay-off from investments in genomics. By 2000, the promise remains, but the scale of the challenge in deriving value from genomic information is better understood.

Headcount in genomics has increased gradually since 1997, with some companies building internal headcount dramatically. For certain organizations, however, external sourcing of genomics capabilities is a viable long-term strategy. Drug companies are also establishing numerous alliances with genomics pure players to complement their internal capabilities. In 1999, 381 genomics deals were reported, the highest ever. Each of the top 20 pharmaceutical companies participated in at least one genomics deal.



Since 1997, advances in areas such as proteomics and related functional genomics technologies, pharmacogenomics, toxico- and pharmacogenetics will substantially improve companies' abilities in finding, developing and bringing new successful drugs to the market. Indeed, despite a slow start, genomics technologies may fundamentally change the nature of the discovery process and the industry overall.

The winners in the ensuing race will be those companies that successfully integrate these new technology approaches, adapt to the re-segmentation of drug markets based on genetic information and exploit the emerging opportunities in personalized medicine (including the challenges associated with capture of intellectual property on genetic material). For the majority of companies, this will also involve radical change to established processes and operating models.

The impact of genomics and the potential for companies to respond appropriately can be considered at three levels:

Level 1: Technology integration
Emerging technologies such as functional genomics, proteomics, use of microarrays, high-throughput expression systems, bioinformatics and three-dimenstional target structure are felt to be the answer to the challenge of validating genomics targets.

They have the potential to fundamentally change the drug discovery process, by facilitating a shift from the traditional linear approach to target creation to an evolving model in which target validation is conducted in parallel to lead discovery and optimization. They can intervene at multiple points potentially increasing the speed and attrition rate in early discovery, as well as the quality of product candidates.

The use of genomics beyond target generation is generating great interest, but there is no clear picture yet as to how to best utilize genetics for value creation. In discovery, pharmacogenomics may facilitate the targeting, understanding of disease pathways, and design of interventions for diseases with multiple genetic etiologies (e.g., breast cancer) and variants of the same gene in a disease pathway. Differences in genes can also impact drug kinetics (i.e., absorption, distribution, metabolism and elimination); variations in genes not directly related to disease may result in adverse events.

Most pharmaceutical companies have begun exploratory efforts in these areas, but they are cautious regarding their validity and predictive ability. Taken to another level, genetic variations among individuals may suggest the need for individualized treatments and tailored drugs. Most companies, however, still lack viable approaches to finding "drugable" targets. Using bioinformatics, several organizations are finding a large number of "in silico" targets – a majority of which have not been translated in "drugable" targets.

Level 2: Genomic portfolio strategies
In development, pharmacogenomics may improve the success rate of clinical trials through use of patient subsets with specific genetic risks and reduced chances of toxicities and side effects. This genetic profiling can reduce clinical trial costs and increase the success rates of drugs after launch. Some drugs that have been shelved may be revived after a re-examination in light of specific genetic subsets.

While revolutionary, the tailoring of drug targets to genomic population subsets, or even individuals, proffers great commercial and financial concerns. Time and resources must be expended to develop genetic profiles and market sizes, for tailored drugs are much smaller, resulting in the need for completely different portfolio management strategies. If this approach is to be taken, corporate goals and mandates in discovery, development and marketing will have to be realigned, and the Food and Drug Administration (US) and other regulatory authorities will also have to support changes in the design and evaluation of clinical trials and eventually in approval criteria.

Level 3: Personalized medicine or genotype-driven blockbusters

Exploiting this opportunity will require companies to leverage genotype-based diagnostics into personalized medicine, completely shifting the end-game equation from high-volume/high-value (e.g., blockbuster drugs) to small-volume/higher-value (individualized) drugs. Accenture's research revealed a polarization in views in the industry concerning the potential for personalized medicine to make a significant impact on the pharmaceutical industry. While some believe that personalized medicine will be of limited importance, others are convinced that it will have broad impact in the industry and further, that using genotype-based elimination/exclusion of major side effects will actually create even larger blockbuster products than is possible based on today's approach to developing and prescribing medicines.

Intellectual asset management

Regardless of the overall end game, intellectual property is viewed as a major issue in developing gene-based products.

The protectability and value of gene-based patients remain unclear; most companies are taking an aggressive "wait and see" approach. A handful of researched companies felt they had winning IP strategies and competencies, and early genomics players felt their "patent everything" approach was well considered, resulting in a strong bargaining position. But no company felt they had a well thought out "best practice process." One participant had taken no action at all in capturing IP on genetic material, leaving itself at substantial risk.

Pharmaceutical companies may wish to consider new research organization models that better capitalize on gene-related value. Unlike the biotechnology sector, traditional pharmaceutical companies traditionally capture no equity value from their target research intellectual property.

The need for new operating models

Accenture's research participants have built up internal and external genomics capabilities since 1997. But without integration of the genomics capabilities into target identification, validation and other discovery processes, discovery and genomics groups may be working toward different goals; operational interfaces may result in process inefficiencies and communication problems. Best practices dictate a dedicated and fully integrated genomics group closely interacting with all aspects of the target management process. This operating structure can also serve to assist the corporation in tracking emerging technologies and developing and maintaining both the internal capabilities and external alliances necessary to access them.

Best practices dictate a dedicated and fully integrated genomics group closely interacting with all aspects of the target management process.

Economies of scale

Companies approach the issues of size and scale in different ways, but there has been a general assumption over the past several years that bigger is better. Size advantages are assumed to come from economies of scale, the ability to invest in cutting-edge scientific and information technologies, deep expertise in functional areas and disease categories and the ability to attenuate risk through portfolio management.

Yet there is much evidence that size alone does not guarantee success – all but one of the pharmaceutical companies involved in a merger between 1990 and 1998 lost market share. Indeed, increased size can create new challenges of it's own. The need to manage across multiple sites slows processes and decision-making, and corporate cultures that dilute individual ownership and motivation are common problems in the bigger discovery organizations.

The key to success is not sheer scale but a focus and operating philosophy that delivers critical mass.

The keys to obtaining critical mass

Through the research it was evident that many companies are achieving critical mass in needed areas regardless of their absolute size. The keys to doing so are:

- Organizational dedication to priorities that enable it to achieve and maintain focus.
- Resource management that emphasizes core capabilities and allocating them to high-priority needs.
- Knowledge management that ensures that personnel across multiple facilities have access to and share relevant data, information and knowledge.
- Access to external capabilities that provide economies of scale.

However, there remain a number of substantial challenges for the companies striving to create critical mass – some of which have emerged relatively recently.

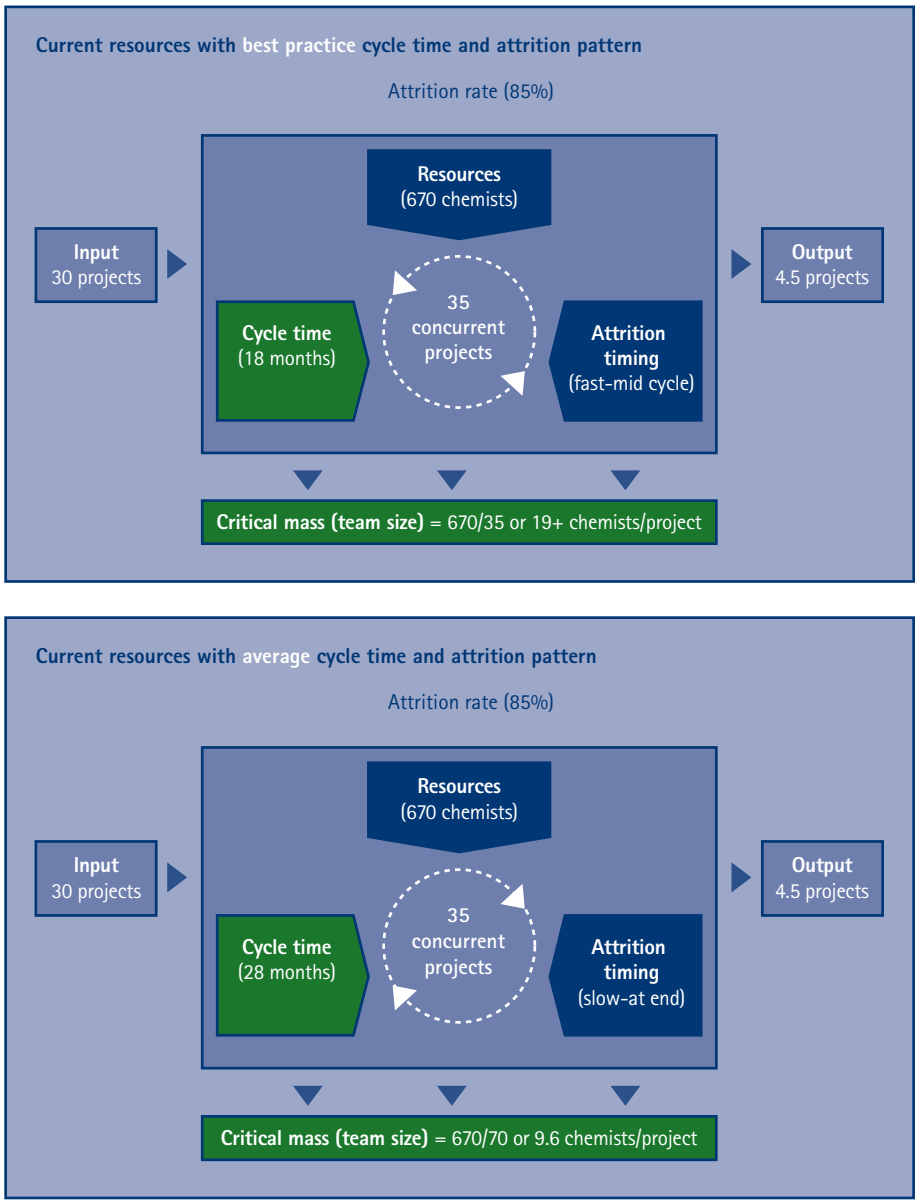
Shortages of traditional skills

Across the industry, there is an increasing need for chemists in the discovery process and competition to attract them is intensifying. Among the companies participating in the research, there are plans to increase the number of chemists, on average, by more than 30 percent over the next three years. Many companies will fail to deliver against this goal for a number of reasons:

- An anticipated shortfall of chemists as young scientists reflect new interests in genomics and molecular biology.
- Spend on R&D as a percent of sales is flat and companies will have to pay for these increases in resources with significant gains in productivity.
- The established pharmaceutical companies will face increasing competition from the biotechs for chemists as they drive towards their goal of becoming integrated pharmaceutical companies.

The number of chemists per project is a critical factor in the success of discovery projects, and discovery organizations must determine how to maintain a critical mass of chemists with higher project volumes and an increasingly competitive recruitment environment. As shown in Figure 10 (on the following page), applying improvements in operational optimization, prioritization and decision-making, which can shorten cycle times, enables an increase in project team size – even with current manpower resources. Without significant improvements in cycle times or higher success rates, it is unlikely that there will be an adequate number of chemists to meet industry needs and the effective number of chemists per project could actually decrease in the coming years.

Figure 10
Leveraging size advantage by focusing on resourcing, cycle time and/or timing



Improving human performance and the emergence of vital new skills

It is fast becoming clear that the productivity goals imposed on discovery will not be delivered without a substantial improvement in human performance. In part this depends on the recognition that scientific excellence is not in itself sufficient to guarantee output and that other complementary people and task oriented skills must be demonstrated and rewarded in discovery scientists. In addition the promotion of teamwork, results orientation, knowledge sharing, the development and application of new skills and the identification and management of intercultural issues are becoming substantial challenges for management.

Nowhere is the challenge greater than in the need to identify, attract and retain the rare individuals who have true insight – the ability to integrate information from many different sources and use it to approach a problem in a totally new way. This is the source of innovation but it is one that is difficult to manage and to integrate into mainstream discovery.

Elsewhere the appropriate mix of skills in a discovery organization will take on new dimensions beyond scientific ability in the future, as companies begin to adopt a more holistic view of the behaviors and competencies needed to be successful. There will be a need for flexible resources capable of broad understanding outside their own discipline – the 'multi-lingual' scientist will be in great demand (e.g., chemists with an understanding of molecular biology).

In addition, demonstrable competencies such as teamwork, customer focus and people management are becoming strongly desirable traits in discovery scientists.

In a highly competitive "seller's market" for scientific talent, R&D managers must concern themselves with the issue of recruiting and retaining driven, entrepreneurial, new breed scientists. Less than 40 percent of the survey participants considered themselves to be both successful at attracting new people and providing opportunity for employees to grow and develop their skills; 80 percent considered the recruitment and retention of top talent to be their prime current strategic challenge.

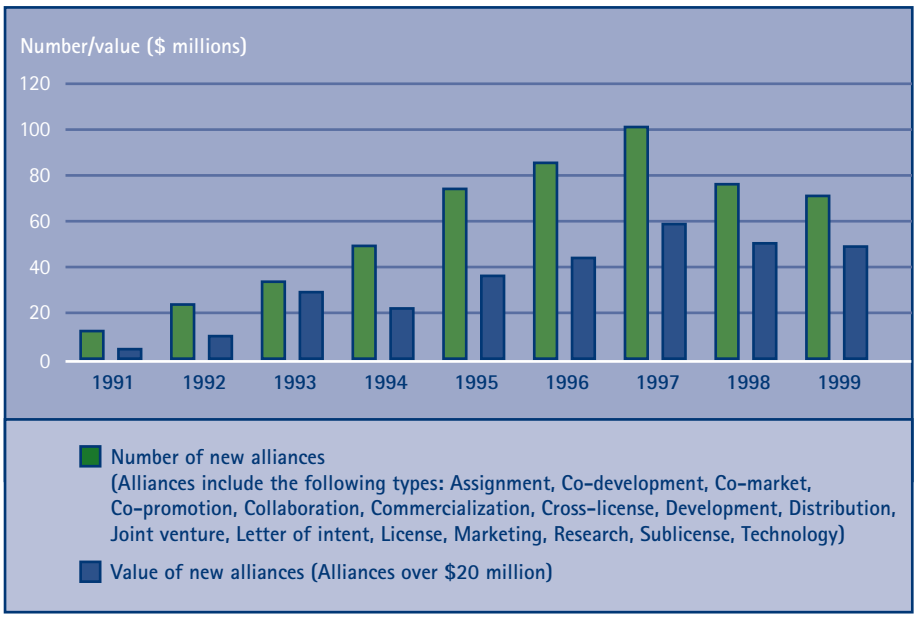
To address these challenges, discovery organizations are experimenting with novel ways of attracting candidates from the early identification and sponsorship of talent in academia to the extended use of Web-sourcing. They are also overhauling the various ways in which innovation is recognized and rewarded, payouts being based on criteria ranging from competence-based (vs. traditional time-based) promotions, incentives for team achievements and/or individual performance, leaderships skills and commercial orientation/ performance of team efforts.

Partnerships and alliances

The nature and importance of alliances has changed from a complement to existing programs and a source of select technologies to an integral part of the discovery paradigm and a critical success factor. Accenture's research reveals that companies are spending approximately 14 percent of their R&D budget outside the company.

The number of alliance deals has fallen sharply since 1997 (Figure 11 on the facing page); but value has fallen less so, suggesting that companies are entering into larger deals. The research results bear this out with evidence of many more complex value-based partnerships rather than transaction-based deals. The research also found that discovery organizations are using alliances to move beyond in-licensing of compounds to access a broader range of innovation – from targets to informatics.

Figure 11
Number and value of new alliances



Source: Recombinant capital databases

The biotech factor

Much of the innovation needed to fuel the growth expectations of leading pharmaceutical companies is occurring in the biotechnology sector. This sector is strong and expanding, and there is a flow of funding and talent to these companies. To survive, leading pharmaceutical companies will need to more extensively and effectively leverage innovation residing in the biotechnology sector. As the competition for value-delivering partnerships with biotechnology firms increases among the pharmaceutical companies, they will need to respond by overcoming some of the existing barriers to effective alliances between the two sectors and by developing new competencies in alliance evaluation and management.

The changing nature of alliances

Accenture's research found that leading pharmaceutical firms are using alliances in a variety of new ways, including to:

- Access critical capabilities in a timely fashion.
- Experiment with emerging technologies before bringing them in-house.
- Actively support specific disease or therapeutic area strategies.
- Access strong platform solutions through an integrated solution (e.g., genomics platform, bioinfomatics IT platform).

Alliances are increasingly viewed for the opportunities they offer for collaboration, knowledge sharing and resource sharing and as a catalyst for fundamental change.

The research also found that alliance and partnership deal arrangements are becoming more complex and variable in nature. There has been a shift from straightforward contracts and licenses to "invasive" deals in which people, technology and strategies are shared, as well to "multi-partner networks".

The most common reason for failure of alliances is poor governance.

Why do alliances fail?

Previous studies have suggested that as many as 75 percent of alliances fail to meet expectations. The most common reason for failure of alliances is poor governance. Slow decision-making, underachievement, lack of an empowered leadership team and neglecting to take into account the evolution of organizations and their agreements may be costing leading pharmaceutical companies up to $10 billion per year in alliance investments that fail to deliver adequate returns. In addition to governance issues, Accenture's research revealed a number of barriers to the effective extraction of value from alliances.

These include:

- Process barriers. Lack of clearly stated objectives/measures and adequate alliance leadership; inadequate communication and lack of investment in communications infrastructure.
- Cultural differences. Mistrust regarding technology/best practices; discrepancies in openness to external ideas; differences in philosophical or operational "fit".
- Innovation absorption. Difficulties in internalizing innovation sourced outside. This is often a particular weakness for multi-site operations where innovation tends to travel slowly between sites.
- Distraction from mergers. Mergers or acquisitions can cause companies to be unresponsive to approaches by external organizations for up to two years following the merger; a merger can also confuse the decision-making structures for licensing/external collaboration as two separate processes are merged.
- Competing corporate agendas. Different levels of urgency/priority; the reluctance to share information openly with the partnering firm.

What makes a model alliance?

Overall, the industry needs to radically improve its alliance management competencies. In order to do so, pharmaceutical companies will need to invest in improving the following capabilities:

Becoming a preferred partner

Many large pharmaceutical companies have some major barriers to overcome in this area. Figure 12 (on the following page) depicts the attributes of preferred partners identified during a previous Accenture research initiative.

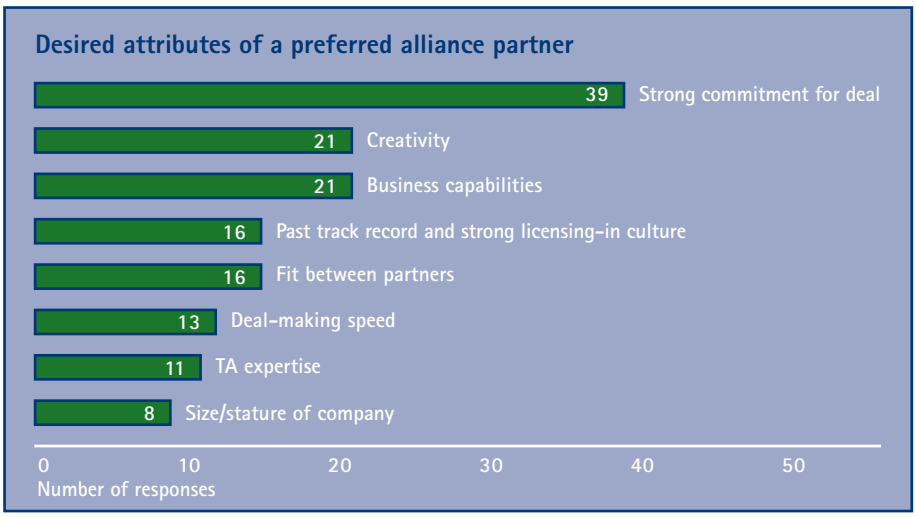
Evaluating potential alliances

Companies need to clearly define and communicate throughout their organization the role that alliances are to play in helping to achieve their strategic objectives. They must transfer the strategic clarity into clear and consistent evaluation criteria focused on strategic, cultural and operational fit.

Deal construction

Deals need to be created on a win-win basis and should not be too rigid at the outset, allowing flexibility for change as discovery progresses and new information becomes available.

Figure 12
Attributes of attractive alliance partners



Source: Accenture research, 1998

Alliance management

Skills need to be built within most organizations and senior managers must be accountable for the success of major alliances. Defined governance and processes that emphasize speed, value and accountability must support management of alliances. Alliance activities must be coordinated throughout the organization, potentially through a central function with responsibility for supporting unit managers, capturing and documenting best practices and ensuring that partnerships are consistent with the company's strategic focus.

Alliance portfolio management

Many companies have limited information on the nature and extent of their alliance portfolios and how those portfolios support achievement of their strategic objectives. Companies must begin to track their performance and evaluate value delivery once the deal is signed. They must also establish a clearly defined set of criteria indicating when to terminate an alliance. Combining these processes with better information on the collection of alliance and the link to strategy begins to provide a robust portfolio management capability.

The winners in this intensely competitive environment will be those companies that recognize external innovations as critical to their future success and therefore build the strategy, organization, process and technology elements needed to support and enhance the effectiveness of their alliance activities. Increasingly, these competencies will lie within the discovery organization as opposed to corporate licensing or business development – their traditional homes.

Conclusions

Discovery organizations will need to undergo significant change to successfully meet the challenge of today's environment. Future winners in the race to develop new molecular entities and meet both clinical and financial expectations will integrate elements from each of the six areas identified in this research.

These discrete but integrated areas can significantly improve the cycle time and productivity of discovery organizations:

- Develop an operating model for research (and its interface with development) in order to leverage the value of new technologies and deliver new performance objectives (i.e., reducing timelines, cutting costs by 50 percent on average and doubling outputs).
- Establish new portfolio/project management strategies and systems focused on improving success rates.

- Acquire, allocate and utilize new kinds of skills based on critical mass, not size and scale.
- Create a genomics-driven operating model in the context of broader business objectives (i.e., the "end game").
- Use alliances and partnerships to create "virtual R&D" environments to gain critical mass and improve shareholder value.
- Optimize, leverage and create value from the knowledge capital internal and external to the organization.
- Invest in creating integrated informatics and eR&D platforms to facilitate decision-making based on comprehensive sets of information and offering operational flexibility. This needs to be tailored to reflect the new process and organizational models.

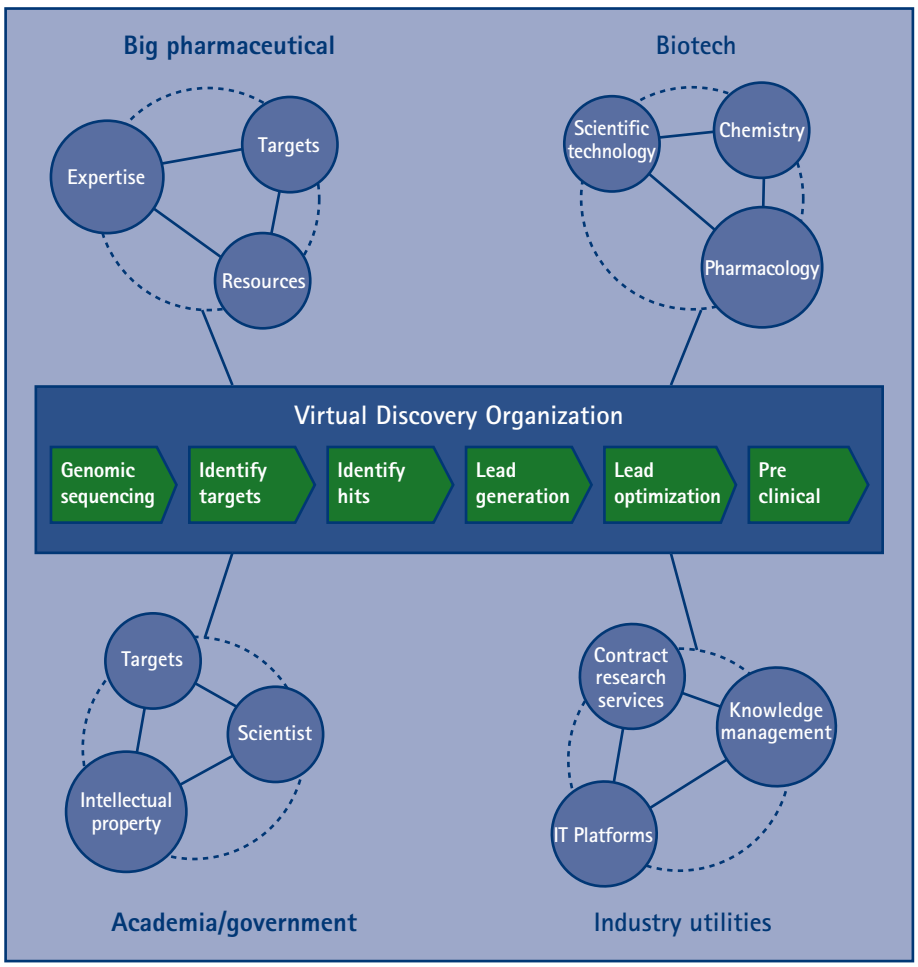
The challenge in the short term will be to create the critical paths for each of these areas based on organizational and industry imperatives.

Overall, this research suggests that the industry will continue to undergo dramatic changes over the next several years in structure, leadership and fundamental approaches to R&D.

However, a longer-term vision emerges from the information gathered in Accenture's most recent research that combines all of these opportunities into a virtual network drawing on the skills and competencies of others to produce innovations. The integration of the resources and expertise of leading pharmaceutical companies and the intellectual property and knowledge of academia and governments could combine with the technology and manpower assets of biotechnology, supported by emerging "industry utilities" such as information services, databases, IT platforms and contract technologies. This could very well lead to the emergence of a new type of organization.

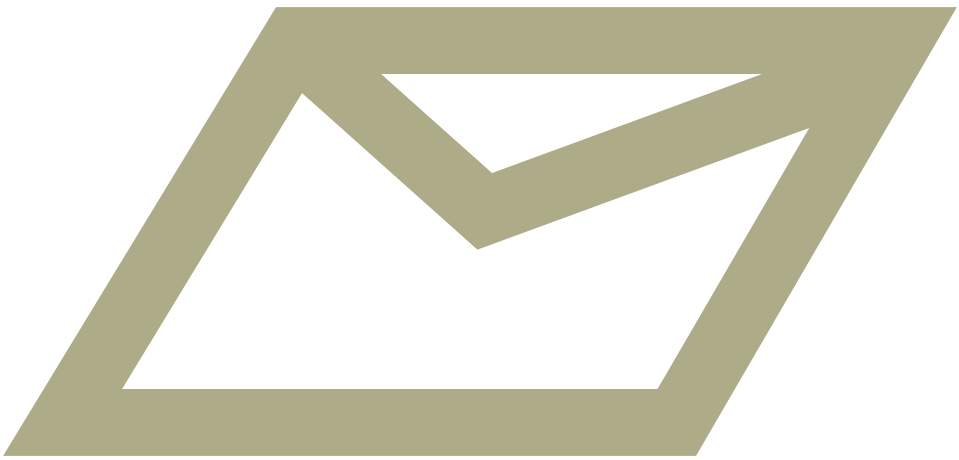
As seen in Figure 13 (on the following page), it is possible to envision a small number of global and highly networked discovery companies that understand the value of using this virtual network to reduce costs and gain agility. These companies will understand the importance of alliances, knowledge capital, intellectual property and portfolio management-retaining in-house only those activities where their specific expertise truly adds value.

Figure 13
Combining all these opportunities could lead to the emergence of a new organization – a virtual network drawing on others to produce innovations



The other group of winners in this model will be the network suppliers that provide global scale, highly robust capabilities and solutions to pharmaceutical companies on an outsourced basis. They will offer lower cost and/or better service than in-house capabilities. Additional winners will be the network builders that provide the infrastructure for this virtual network model.

Overall, this research suggests that the industry will continue to undergo dramatic changes over the next several years in structure, leadership and fundamental approaches to R&D. These changes are driven by new breakthroughs in genomics, new advances in scientific technologies and IT, and the rapid evolution of patient-centric consumerism that demands better therapies faster and at a reasonable cost. Companies that are embracing these changes proactively will have a tremendous future ahead of them and will be positioned to fulfill the industry's promise of revolutionizing healthcare.



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