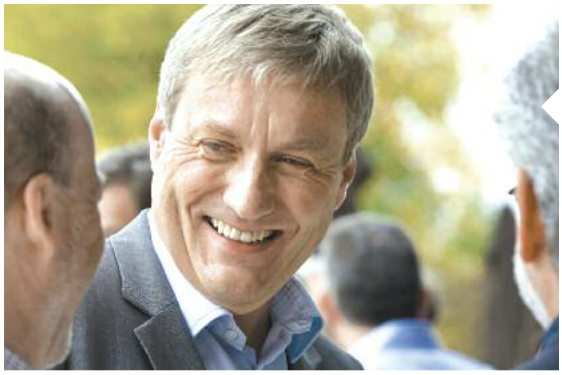
BY DENISE MYSHKO

» R&D TRANSFORMATION

TRANSFORMING R&D

Experts agree that new ways of working are needed if R&D is to continue producing innovative products now and in the future.



Dr. Jean-Jacques Garaud

Roche

"The industry is under increasing pressure from various stakeholders and, therefore, we must address a critical flaw in current R&D models: the attrition-based model."

The past generation of pharmaceutical R&D is over. Life-sciences companies are facing a perfect storm of challenges: eroding margins, decreasing R&D productivity, pressure to demonstrate health outcomes and cost effectiveness, and increased scrutiny over product safety.

The classic R&D development takes far too long and is predisposed to identify failures late in the process, which is expensive. The classic model also has a tendency to bring products to the market with little or no therapeutic advantage — at the expense of true innovation.

"The time of blockbuster-driven pharmaceutical R&D is quickly drawing to a close," says Sanjeev Wadhwa, partner and director life-sciences R&D, at Computer Sciences Corp. (CSC). "The classic laboratory-centric R&D model — where scientists would discover, protect, and develop a molecule that might have therapeutic promise — has collided with the hard realities of today's health economics. With internal development pipelines drying up, companies are turning toward increased in-licensing and semantic drug discovery as tools to bring innovative products into their development portfolios."

The industry is under increasing pressure from various stakeholders, says Jean-Jacques Garaud, M.D., global head of pharma research and early development (pRED) at Roche.

"We must address a critical flaw in current R&D models: the attrition-based model," he says. "This model does not address the true nature and biology of disease. Therefore, a better approach would be to foster interactions between discovery and research, translational medicine and experimental development. In addition, the complexity of biology and life-sciences is such that no one institution can expect to have the 'big' discovery any longer. So industry needs to build much stronger links with the outside world through public-private partnerships. This will nurture and accelerate innovation."

For example, he says Roche has about 150 actively managed partnerships worldwide and within the pRED organization; has established several translational research hubs with scientific and medical institutions; is expanding the postdoc program; and is increasing its focus on collaborations with leading academic research institutions to ignite innovation and drive value.

"These approaches will allow us to tap into external innovation, as well as gain valuable scientific knowledge and expertise," Dr. Garaud says.

Another important issue is managing R&D with a lack of infinite funding, says Val Romberg, senior VP, research and development, at CSL Behring.

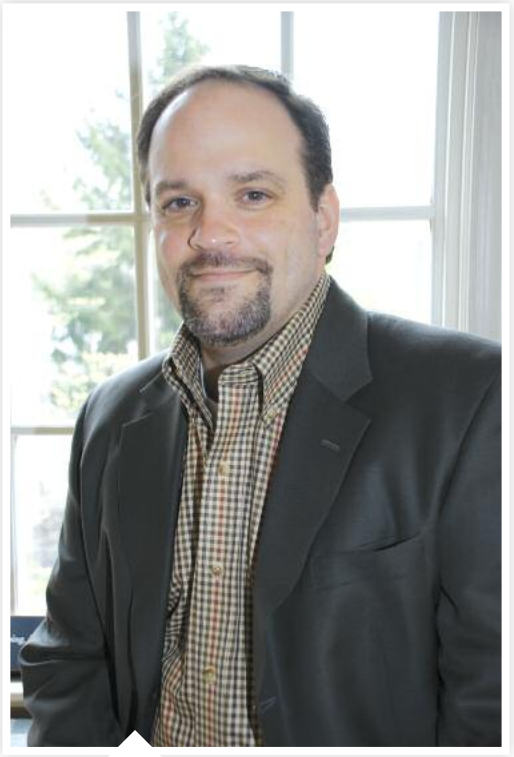
"Historically, the pharmaceutical industry has been willing to spend up to 20% of sales on R&D, thinking that returns were a given," he says. "It is clear now that R&D needs to be treated like any other investment, and sound fiscal choices must be made. Shareholder returns are also much more likely to be driven by lower-risk projects that are feasible to develop. This makes the R&D manager's job much more difficult; it is about making choices with small amounts of data."

Mr. Romberg says companies are the victims of their own success.

James DeSanti

PharmaVigilant

"Greater transparency will be required so regulatory agencies can ensure all protocols and guidelines are being adhered to."



Michael Naimoli
Microsoft
"Research and development organizations are in need of innovative business practices that allow them to streamline their portfolio management processes."

Dr. Paul Chew
Sanofi-Aventis US
"Our goal with translational science is to make discoveries in the lab, determine clinical applicability, and bring them to the patient as quickly as possible."

Todd Reul
ClearTrial
"To deal with operational inefficiencies, companies are looking to improve both processes and technology."

"In the last 20 years, pharmaceutical and biotherapeutic companies, such as CSL Behring, have developed many new therapies that improve patients' quality of life and in many cases save lives," he says. "New therapies in development can't simply treat the condition. They have to be a better therapy than what is already available. The bar for new therapies is getting higher and higher."

THE CHANGING R&D MODEL

Over the next five years, because of a number of irreversible change drivers, the pharmaceutical industry's current R&D model will continue to undergo a dramatic transformation, according to experts at Accenture. Pharmaceutical companies have been under pressure for R&D cost reduction over the past decade. These pressures will continue to increase and intensify as products come off patent in the next several years and the value proposition for future differentiated products becomes more difficult for companies to define.

Pharmaceuticals companies are working to establish the most effective operating model to drive cost and efficiencies throughout the entire development process without impacting quality, says Terri Cooper, principal and national leader, life-sciences R&D practice, at Deloitte Consulting.

"It is imperative that individual life-sciences companies recognize the activities where they are able to leverage lower-cost providers while maintaining other activities in-house that truly drive competitive advantage," she says. "Entering into new financial arrangements to maximize the full potential of their entire portfolios through effective out-licensing or risk-sharing deals is also gaining significantly more momentum."

In addition, companies are working to increase the ROI of their research investment dollars through acquiring new modalities, more effective portfolio management to kill products earlier, and establish new partnering models that increase the risk-sharing burden as a way to drive more innovation within early research.

"These initiatives are all linked to our view that companies need to embrace a new R&D operating model that is designed on the formation of a number of strategic partnerships, which will serve as the critical means of adding capacity and managing the risk necessary to maintain pipeline flow," Ms. Cooper says.

ATTRIBUTES OF A TRANSFORMED R&D MODEL

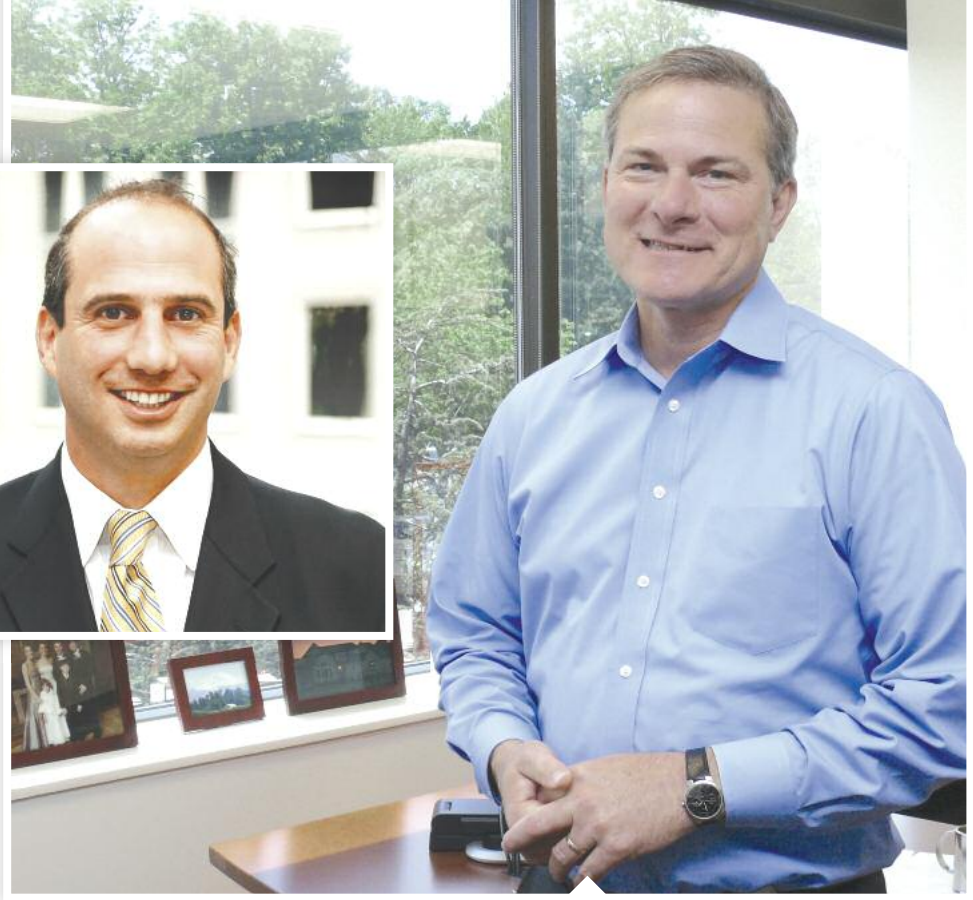
1. Networked: The increasing complexity of cost and value demands being placed on the R&D organization requires the traditional, company-constrained R&D model to give way to a networked approach, in which different players are integrated into virtual teams. Members of these teams require the ability to work not just across the organization, but in acquisitions, alliances, and partnerships that stretch across the industry and beyond.

2. Global: The diverse array of worldwide differentiation/value and pricing requirements placed on products demands a truly global R&D model, in which team members are able to bring together requirements from a variety of sources and geographies into uniquely defined R&D strategies.

3. Capable of providing bundled healthcare capabilities and services. Growing requirements for all healthcare consumers, e.g., patients, physicians, patient advocacy groups, and payers, require that the model focus on bundled healthcare capabilities and services. The R&D organization will need to expand its thinking away from a traditional "product plus information" model into a broader healthcare capability in which the emphasis is placed on overall patient outcomes in the context of the total clinical picture.

4. Transparent. The new model will be a transparent one, in which the R&D organization will require the ability to synthesize and react to the growing wealth of information that is becoming available on its own assets, services, and capabilities and those of companies throughout the industry, ultimately permitting more informed decisions to be made.

Source: Accenture. For more information, visit accenture.com.



Devin Gross
Emmi Solutions
"Emerging techniques enable organizations to deliver information-rich messages to keep trial participants informed and engaged."

Glen de Vries
Medidata Solutions
"Like the dinosaurs, the days of large pharma R&D budgets, and the often-bureaucratic organizations that support them, are similarly numbered."

Glen de Vries, president of Medidata Solutions, says as discovery, development, and the target markets of new treatments reduce in size and become more specialized, life-sciences companies will need to reorganize their teams into smaller, more specific groups, as well as adopt dynamic business processes and the infrastructures to support them.

"65 million years ago climate change eliminated an abundance of plant life and ended the reign of the large animals that fed on it, giving way to a world favoring smaller, more nimble species," he says. "Like the dinosaurs, the days of large pharma R&D budgets, and the often bureaucratic organizations that support them, are similarly numbered."

According to experts at Deloitte, biopharma's traditional operating model has not only performed poorly, it has added to the industry's current problems as high fixed costs drag on earnings and revenue lost to patent expiration. Adapting to the current challenges requires a new type of R&D organization, one that has a different set of operational and cultural values. Traditional operating models have resulted in R&D organizations that are saddled with inflexible capacity and are unable to react to changing demand as corporate and R&D strategies shift from blockbusters to more targeted and specialized products.

Roche has reorganized its R&D structure into preclinical research and early development (pRED and gRED) and late-stage development, Dr. Garaud says.

"Within pRED, which I have the privilege to lead, the goal was to deepen our understanding of disease biology and the molecular basis of disease heterogeneity; deliver on individual patient needs by using biomarkers and personalized healthcare strategies; and fully leverage new technologies and capabilities to progress compounds into the portfolio," Dr. Garaud says. "We have made great progress since implementing the new organization and now use a diversity of approaches and therapeutic modalities. We are also continuing to expand our access to external innovation via translational research hubs in Singapore and Basel, Switzerland, as well as with key partnerships with universities and hospitals."

In June 2009, Sanofi-Aventis announced plans to transform its research and development organization, says Paul Chew, M.D., senior VP, U.S. chief medical officer/chief scientific officer, at Sanofi-Aventis US.

"The new R&D model is centered on the following priorities: a closer cooperation between Sanofi-Aventis researchers and external partners, for example, large public research institutes; a more flexible organization that fosters the emergence of innovation; and the creation of entrepreneurial, patient-centric research units focused on high priority areas, for example, oncology, diabetes, and aging, linked to public health needs," he says.

Val Romberg
CSL Behring
"New therapies in development have to be better than what is already available. The bar for new therapies is getting higher and higher."

Dr. Chew says Sanofi-Aventis aims to speed innovation by translating bench science to bedside clinical practice.

"We have realigned our structure to recognize new mechanisms and bring them to patients in the most benefit-efficient and cost-efficient manner," he says. "Our goal with translational science is making discoveries in the lab, determining clinical applicability, and bringing them to the patient as quickly as possible. This includes increasing the identification of biomarkers that could serve as clinical endpoints."

At Daiichi Sankyo, the research and development organization is structured to use talent across the globe to develop medications to meet unmet needs, says Glenn Gormley, M.D., Ph.D., chief science officer, co-head, research & development, Daiichi Sankyo, and global head of development, president, at Daiichi Sankyo Pharma Development (DSPD).

"We collaborate with academic institutions and other enterprises so we can bring first-in-class medicines to market," Dr. Gormley says. "Our model of the global executive meeting of research and development (GEMRAD) brings together senior management from both R&D and commercial operations to

TIPS FOR ADOPTING A NEW R&D MODEL

As large pharmaceutical companies proceed to adopt new models, they must:

- Address and align the divergent motivations of R&D and sales and marketing. Given the realities of the marketplace, this means that it will be the development arm that must change. Regardless of whether projects derive from start ups or from in-house benches, large pharmaceutical companies must take the lead in insisting that projects meet payer criteria. Thus, health economics and outcomes research (HEOR) approaches need to be integrated into the R&D effort from the outset.
- Manage expectations. Addressing areas of real unmet need is expensive and risky. Thus, shareholders will need to be conditioned to the fact that R&D projects may have to take longer, cost more (in some cases to address smaller patient segments), and carry incremental risk.
- Lay to rest, finally and definitively, the "not-invented-here" syndrome. If this is to happen, large pharmaceutical companies must foster greater flexibility and openness within their research units than have existed in the past.
- Foster an entrepreneurial spirit among researchers. Typically, those who've wanted to work as entrepreneurs have gravitated to biotechnology firms, and those who felt more comfortable with the structure of a large, established organization stayed in large pharmaceutical companies. Entrepreneurial qualities will be equally valued in both types of firms.
- Be open to new ways of working. This includes forming partnerships — sometimes with competitors — at earlier phases of development. Such an early collaboration is unprecedented between major players.

Source: IMS Health. For more information, visit imshealth.com.

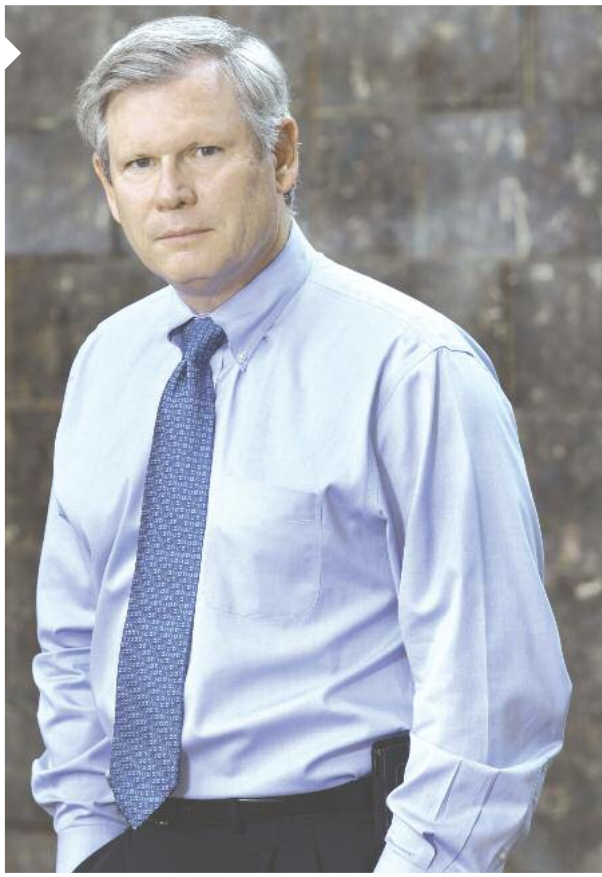
identify the attributes of the product that are needed by the healthcare community."

Dr. Gormley says the company's organizational structure allows for nimble decision making.

"By integrating research, marketing, and regional management into a centralized R&D decision-making body, we can quickly incorporate critical information and perspectives from across our company and foster strategic and timely decision-making to bring the best medicines to market as quickly as possible," he says. "We continuously seek strategic partnerships and collaborations with CROs to benefit all parties with key insights and new learnings."

Deloitte executives say while organizations may be aware of the current challenges facing them, few have successfully identified and responded to the internal and external root causes that have spawned those challenges.

Dr. Glenn Gormley
Daiichi Sankyo
"There are data that point to declining R&D productivity, and part of this is due to the complexity of the science."



Sanjeev Wadhwa
CSC
"With internal pipelines drying up, companies are turning toward increased in-licensing and semantic drug discovery to bring innovative products into their portfolios."

While the full impact of changes associated with R&D transformation will take years to fully emerge, Deloitte experts say there are several benefits, including:

- Improved organizational alignment and decision-making: Emphasis on improved visibility into demand and translation of expectations into actionable targets provides a consistent understanding across the organization.
- Creating a sustainable pipeline flow: An increased focus on a sustainable and scalable pipeline improves quality and choice of products delivered through the pipeline.
- Access to external science: Improved access to partners and external science provides a platform for sustaining innovation, access to expertise, and risk sharing.
- Improved asset utilization: Simplified network structure reduces complexity and improves effective utilization of assets. Emphasis on a flexible cost structure allows for variability and effective reallocation of resources.

TECHNOLOGY SOLUTIONS

Industry experts say technology solutions can help address some of the R&D challenges facing companies today.

"The R&D process is getting more expensive even while trials are taking longer and regulatory guidelines are tightening," says James DeSanti, CEO of PharmaVigilant. "Organizations want to get to their go/no-go decision phases quicker, but right now the opposite is true. A strategic technology investment is one of the quickest and most effective methods for addressing these issues. In the next five years, trials will become even more dispersed and globalized as emerging regions grow in popularity. As such, greater transparency will be required so regulatory agencies can ensure all protocols and guidelines are being adhered to. With paper-based trials, transparency and access is near impossible. A true transition to automated processes is necessary for sponsors to stay ahead of regulatory shifts."

There are massive operational inefficiencies in clinical development, and companies are

looking to improve both processes and technology, says Todd Reul, director of clinical services at ClearTrial.

"They are devising and setting clear organizational goals, centralizing their study planning functions, and incorporating new software and systems that enable integrated planning, forecasting, and project tracking across departments from both operational and financial perspectives," he says.

Michael Naimoli, worldwide managing director at Microsoft Health and Life Sciences, says pharmaceutical companies are notorious for having disconnected silos of data trapped by various technologies that don't talk to one another or in offices throughout the globe.

"Scientific data must be readable, searchable, and usable across the entire organization to enable better scientific collaboration, more efficient scientific processes, and ultimately, drive faster discovery," he says.

Mr. Naimoli says scientists and researchers are in need of innovative and easy-to-use technologies that will help them do their jobs better and faster; they can no longer afford to work with data stored in disparate systems that don't talk to one another, for instance.

"Globally distributed pharmaceutical companies or contract research organizations can use cloud-based services to build repositories of research tools and data for use by all dispersed branches of the organization, ensuring real-time collaboration and streamlined communication to help life-sciences organizations bring new drugs and therapies to market more quickly," he says.

Many R&D organizations have invested in technologies such as EDC, IVR, ePRO, CTMS, data warehouses, and others but are not taking full advantage of these capabilities and are still doing things the old way, says Sheila Rocchio, VP of marketing at PHT.

"Monitoring is a great example," she says. "Companies are still using paper sourcing and spending time doing the low-value task of 100% source verification. This needs to change. R&D organizations need to do a better job of analyzing the disparate data collected across the clinical development process to optimize resources and increase patient safety."

Ms. Rocchio says companies are investing more in e-clinical systems and analytics, automating more tasks, adhering to industry-wide data standards, and developing strategic outsourcing models to focus on core competency functions such as specific therapeutic area development and late-phase development, along with marketing and sales.

Devin Gross, CEO of Emmi Solutions, says one growing trend is the use of interactive Web-based technology to improve the clinical trial process for all stakeholders: the pharma company, the investigator site, and especially the patient.

"Clinical trials have always faced patient communication challenges with regard to patient retention and informed consent," he says. "Now emerging techniques enable organizations to deliver information-rich messages to keep trial participants informed and engaged. In the near future, these methods will become more accepted and more widespread." ✦

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EXPERTS

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GLEN DE VRIES. President, Medidata Solutions, a global provider of SaaS-based clinical development solutions that enhance the efficiency of clinical trials. For more information, visit mdsol.com.

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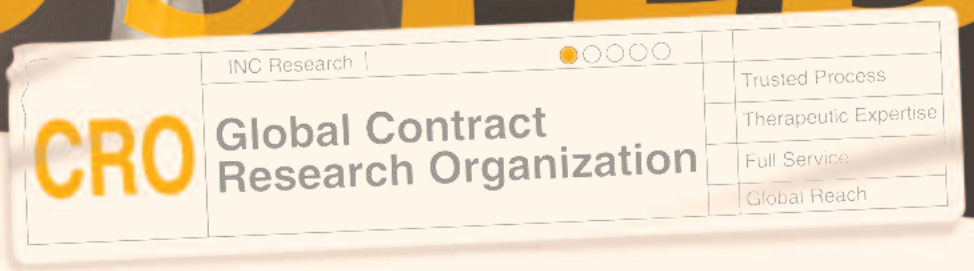

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Top Trends Impacting R&D

INDUSTRY EXPERTS PROVIDE THEIR INSIGHTS ON THE TOP TRENDS THAT WILL SHAPE RESEARCH AND DEVELOPMENT IN THE COMING YEARS.

GIL BASHE is Executive VP, Makovsky + Company, an independent global public relations, investor relations, and branding consultancy, focused in financial services, professional services, healthcare, technology, branding, and investor relations. For more information, visit makovsky.com.

1. The risk-benefit ratio. There is reduced industry tolerance for risk, as failures impact stock valuation. This threat creates corporate paralysis.
2. Comparative effectiveness will impact R&D dramatically. R&D priority will be driven by new therapies that are differentiable enough to warrant payer coverage.
3. Our basic science knowledge base has become diminished. We need more partnerships between the private and public sectors and fund research to increase the knowledge base from which discoveries can be made.

JAY BOLLING is CEO and President, Roska Healthcare, a full-service direct advertising agency with proven expertise in engaging prospects through communications that integrate data and insight-driven marketing and advertising solutions. For more information, visit roskahealthcare.com.

1. While patient recruitment will continue to be a critical focus, the concept of patient compliance and retention will take on greater importance because of the fact that poor patient compliance and retention can lead to: inaccurate evaluation of efficacy; increased variances in study statistics; increased study costs; selection of inappropriate dosage; misrepresentation of the drug's safety profile; and poor patient outcomes.

SUSAN BORNSTEIN is Executive VP, eClinical Solutions, a division of Eliassen Group, which takes a strategic approach to managing clinical trial data by combining data management with statistical programming, reporting and customized training solutions integrated with a clinical data repository to deliver a complete end-to-end data management solution. For more information, visit eclinicalsol.com.

1. The high cost of executing clinical research.
2. The ability to find treatment-naïve patients.
3. Uncovering new compounds with low safety profiles to treat unmet medical needs.

SUSAN CIOTTI, PH.D., Director of Formulation R&D, NanoBio Corp., a privately held biopharmaceutical company focused on developing and commercializing novel products for the prevention and treatment of infectious diseases, based on its patented NanoStat technology platform. For more information, visit nanobio.com.

1. The traditional vaccine development and manufacturing process is very time and labor intensive, which can lead to a gap in healthcare when a pandemic strikes. The development of safer, more effective, shelf-stable, and easy-to-administer vaccines is a high priority, particularly in the developing world where populations are at greater risk of contracting transmissible diseases.
2. Nanoemulsion-based vaccine adjuvants are an area of research that has great potential to address these needs and lead to breakthrough therapeutic and prophylactic treatments that provide more robust and relevant immune responses.

MARK CORRIGAN is CEO, Zalicus Inc., which discovers and develops treatments for pain and inflammatory diseases. For more information, visit zalicus.com.

1. Continuing poor productivity from discovery.
2. Increasing expense of clinical trials.
3. The lack of clear regulatory guidance.

DOUG FAMBROUGH is CEO, Dicerna Pharmaceuticals, a private, venture-backed, second generation RNA interference (RNAi) company developing novel therapeutic agents in multiple therapeutic areas. For more information, visit dicerna.com.

1. There is an urgent need for novel drugs to fill weak pharma pipelines and sustain revenue.
2. The need for efficiency and productivity is driving an externalization of R&D from large organizations to smaller, more nimble ones.
3. Decreasing productivity of R&D — fewer drugs are making it through development. And those that do face increased regulatory hurdles and higher market barriers.

DAVID FISHMAN is President, Snowfish LLC, which integrates clinical, marketing, and quantitative information to answer a client's specific business objectives. For more information, visit snowfish.net.

1. There is a lack of financial resources.
2. There is a need for immediate return by investors.
3. Investors are requiring that companies demonstrate proof of concept to provide funding, but many small companies need funding to get to the proof-of-concept stage.

LEON HENDERSON, M.D., is Medical Consultant, Wolters Kluwer inThought, which brings together the vast data assets and resources available at Wolters Kluwer Pharma Solutions to provide a portfolio of analytical and forecasting products and services to both the financial and pharmaceutical markets. For more information, visit in-thought.com.

1. Comparative effectiveness studies and debates: For marketed drugs, pressures rise as physician and hospital performance initiatives, as well as third-party payers, demand optimal results. Cost-effectiveness will address this resource-strapped, unsustainable system.

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Bernice Welles, MD, CEO, **Alquest Therapeutics**

Travis Wilson, Morningside Group and CEO, **Stealth Peptides, Inc**

Fred Zheng, PhD, Research Scientist, Clinical Biomarker Group, Oncology Early Development, **AstraZeneca**

Wei Zhou, PhD, JD, President and CEO, **Centrillion**

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2011 YEAR IN PREVIEW

2. Molecular innovation: For developmental drugs, optimism is high for a new wave of innovation. Novel approaches include protease inhibition in hepatitis C, thrombin and factor Xa inhibition in oral anticoagulation, RANKL blocking in osteoporosis, urate oxidase stimulation in gout. A bit further in the future there will be drugs that target relaxin in heart failure and PAR1/thrombin receptor in acute coronary syndromes.

KEVIN HRUSOVSKY is President and CEO, Caliper Life Sciences, a provider of cutting-edge technologies enabling researchers in the life sciences to create life-saving and enhancing medicines and diagnostic tests more quickly and efficiently. For more information, visit caliperls.com.

1. With significant growth in biologics, the FDA is calling for drug applications that include quality by design (QbD) data. Gathering the raw data needed for this endeavor can be prohibitively time, labor, and cost intensive. The most efficient way to collect these data is to incorporate design of experiment approaches into research methods. By employing technologies that provide robust, high-throughput, predictive results for critical quality attributes such as titer, purity, aggregation, fragmentation, and size, researchers can speed adoption of QbD processes and produce high-quality data in days versus weeks or months.

THOMAS HUGHES, PH.D., is President and CEO, Zafgen, a biopharmaceutical company dedicated to developing innovative obesity therapeutics that directly target and shrink fat tissue by helping the body to reestablish a proper balance of fat metabolism. For more information, visit zafgen.com.

1. There is poor productivity and mid-innovation cycle blockade because of a drive for perfection over innovation.
2. The lack of novel targets are a result of too many rational gates being applied to projects.
3. Large companies lack or discourage innovators by imposing too many rules, leaving decisions to committees, and discouraging risk and adventure.

HARRIS KAPLAN is CEO, Healogix, which provides marketing research and consulting for the pharma and biotech industries. For more information, visit healogix.com.

1. First-in-class, best-in-class medicine is dated. It's all about durable differentiation. With payers controlling access, being first only matters if no other companies are entering near term, and best only matters if that differentiation really makes a difference.
2. More head-to-head trials will be needed to support adoption and premium pricing. Trials vs. placebo — where there is a clear market leader — is no longer sufficient to guarantee access.
3. Pharma will have to quickly cull its losers in order to overfund its winners. Early commercial development's input will increase in importance as companies prepare to make these difficult but necessary decisions.
4. The battle for future market share is often won before a drug enters Phase III. Therefore, more extensive commercial input is needed before a drug enters this phase.
5. PROs to prose is the new opportunity. Patient reported outcomes studies need to be translated into a message that makes patients willing to pay their share of the cost. WTP is the final hill new products need to climb. PROs are the engine for doing it.

KEN KRAMER, PH.D., is Senior VP, Medical Director, Alpha & Omega Worldwide, part of The Core Nation, a medical communications agency. For more information, visit aandomeded.com.

1. Mergers and acquisitions: Today, the bigger companies are looking to acquire, not develop from scratch, their pipelines. The trend is to grab a promising product in Phase I or II and bring it to market — if all goes well. While this is a sound strategy, from a business point of view, the question is how do repeated changes in ownership affect the original medical and financial expectations for the compound?
2. Can big pharma adapt to a biotech world? When pharma giants make a big splash and enter the rare disease market, it makes one ask, do they know what they are getting into? The business model for a disease state with an incidence of 1:50,000 is very different from one that works when the number of prescriptions can be measured in the tens of millions.

R.J. LEWIS, President and CEO, e-Healthcare Solutions is a vertical Internet advertising network dedicated to the healthcare industry. For more information, visit e-healthcaresolutions.com.

1. Open source has greatly impacted the software industry. While pharma has historically been very secretive and proprietary about its research, increasingly stymied research will be shared for the greater good because it's the right thing to do, and innovation feeds off innovation.
2. The shift toward "intrapreneurial," smaller focused R&D groups in order to be competitive with smaller biotech and start-up firms in both culture and compensation will likely continue as well.

SYED MOINUDDIN is Account Director, MedThink Communications, a healthcare agency that provides full-service offerings with a focus on scientific and promotional communications. For more information, visit medthink.com.

1. Small start-up biotechnology companies are becoming more widespread.
2. Big pharma continues to downsize investment in R&D.
3. Increased specialization of R&D continues at pharma companies.

JAY NORMAN is President, Consulting Group, Quintiles, which provides data-driven recommendations and advice to help companies achieve success in pharmaceutical, biotech, and medical-device development. For more information, visit quintiles.com/consulting.

1. The demand for evidence that a new product is superior to the existing standard of care.
2. The increased demand for specialty care products.
3. The demand for real-world outcomes data on a regional/local basis.

ANDRIN OSWALD is Head of Novartis Vaccines and Diagnostics, a division of Novartis, focused on the development of preventive treatments. For more information, visit novartisvaccines.com.

1. Two long-term trends are the genomic revolution and the emergence of Asia. More than 10 years ago, our research colleagues started to work with Craig Venter to decipher the genome of Meningococcus Type B bacteria. In the past, it was not possible to develop a vaccine against this deadly disease due the complexity and variety of the bacteria. Today, we are close to filing the first. Embracing genomic and proteomic technologies to deepen our understanding of infectious agents and how they interact with our immune system is our long-term strategy.
2. As priorities on the world map are changing, so is our footprint. We are building up research capabilities in China and Brazil, for example, to tap into an increasingly important pool of scientists and innovators, as well as to be able to understand disease relevant to these geographies and develop vaccines tailored to the respective public health needs.

MICHAEL PARISI is Managing Partner, Ogilvy CommonHealth Worldwide, which provides 360-degree marketing services. For more information, visit ogilvycommonhealth.com.

1. Innovation.
2. The development of biomarkers.
3. Collaboration between the public and private sector.

AHNAL PUROHIT is CEO and President, Purohit Navigation, a full-service, independent, integrated healthcare brand solutions company positioned to creatively navigate the full potential of small-to-midsized specialty brands. For more information, visit purohitnavigation.com.

1. The impact that the economy has had on the industry affects everyone, of course. Reduced budgets and revenue have a direct influence on the investment into research and development.
2. More specialized brand development is also impacting R&D. The industry's pursuit and expansion into the areas of prevention, gene sequencing, and genetics may involve heavy investment of personnel, equipment, and technology.
3. Another factor impacting R&D is licensing. Big pharma is doing less research these days, often relying on mergers and acquisitions of up-and-coming smaller companies that already have established proof of concept in Phase I or II development.

GRAHAM REYNOLDS is VP, Marketing and Innovation Pharmaceutical Delivery Systems, West Pharmaceutical Services Inc., a global manufacturer of components and systems for injectable drug delivery, including stoppers and seals for vials, and closures and disposable components used in syringe, IV, and blood collection systems. For more information, visit westpharma.com.

1. Increasing regulatory challenges and hurdles will definitely impact research and development. Risk assessment, control, communication, and review, as well as critical quality attributes and product lifecycle management, will evolve and manufacturers will shift to upstream controls that build quality into the product's packaging system earlier and with better controls that will ultimately reduce risk and increase patient safety.
2. Manufacturers are facing higher costs and longer timelines to bring new drugs to market. Effective packaging and delivery can help drug manufacturers meet regulatory requirements and industry standards for safety and quality. It can also help manufacturers differentiate their drugs by equipping them with packaging components that maintain the effectiveness of the drug and prevent contamination.

CHARLES SALDARINI is CEO, Sentrx, a provider of drug safety services to the life-sciences industry. For more information, visit sentrx.com.

1. There will be more adaptive trial design.
2. Safety assessment will be used as an early indicator of commercial value.

AMAR SETHI, M.D., PH.D., is VP, Science and Technology, Pacific Biomarkers (PBI), which provides biomarker laboratory services and contract research services to support pharmaceutical and diagnostic manufacturers conducting human clinical trial research. For more information, visit pacbio.com.

1. The current global economic environment will not allow the pharmaceutical industry to keep ramping up its internal R&D efforts. Therefore, a greater amount of R&D outsourcing will occur in the future.
2. As the result of the outsourcing trend, we will see a shift of R&D in pharmaceutical industry toward a wider range of more targeted therapeutic products. The blockbuster era will end.
3. Very specialized requirements from pharma will develop because of a more targeted therapeutic focus and specialized therapeutic niches. Small companies with focused therapeutic interest and small R&D budgets will be looked to for outsourcing of drug discovery, and for preclinical and clinical drug/biologic product development.

JONOTHAN TIERCE is General Manager, Health Economics & Outcomes Research, IMS Health, which offers market intelligence products and services. For more information, visit imshealth.com.

1. There will be more postmarketing scrutiny — for safety and comparative effectiveness, followed most certainly by cost-effectiveness — of products under actual conditions of use completely or substantially out of the control of the companies.
2. Increased requirements by regulators will continue for demonstrations of safety in the clinical trials process, leading to dramatically increased study sizes and the proliferation of relevant end points.
3. The trend toward personalized medicine, which in practice will impact study design, will again lead to larger studies to be able to generate valid sample sizes in study sub-populations and a wider range of endpoints will continue.

JOHN WATSON is Corporate VP and President of Strategic Partnering and Integrated Drug Development, Covance, a comprehensive drug development services company. For more information, visit covance.com.

1. This is a time when the pharmaceutical industry needs to challenge traditional thinking to improve R&D productivity, including: lower, more flexible cost structures; tighter focus on core competencies; plus aligning existing resources and optimizing R&D utilization of facilities.
2. Companies also are looking to establish R&D partnerships to leverage proprietary tools and processes focused on reducing cycle times.