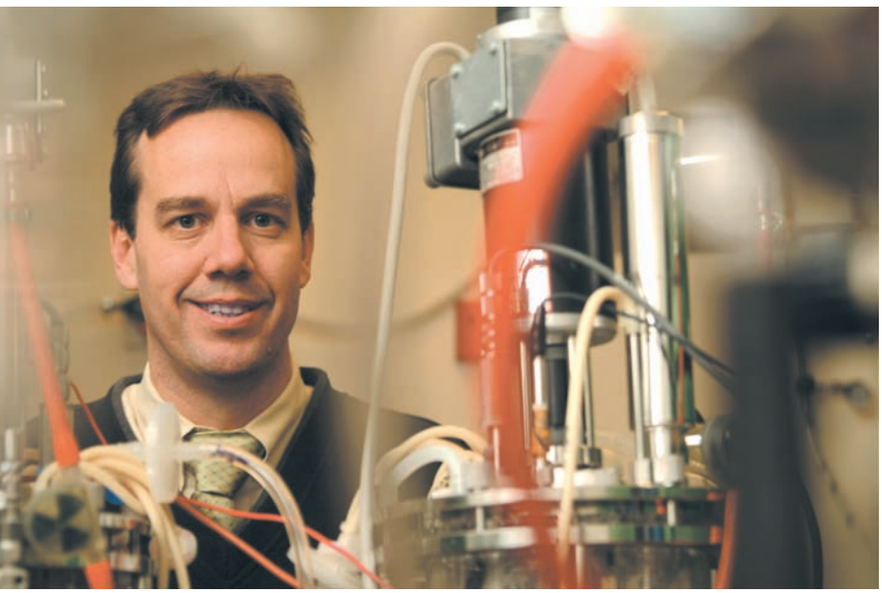
BY DENISE MYSHKO

Meet the R&D Leaders

Executives charged with R&D responsibilities within biotech and pharmaceutical organizations, both large and small, **FACE MYRIAD OPPORTUNITIES AND CHALLENGES.**



DR. STEVE ARKINSTALL Serono Research Institute

A COMPANY'S STRATEGY SHOULD BE ALL ABOUT using the right technologies at the right time for the right disease.

Drug development is a costly and risky business. The pharmaceutical industry is challenged by many factors related to discovering, researching, and developing new medicines. From translational research to the development of targeted therapies and personalized medicine to biotechnology to collaborations and outsourcing, opportunities abound. But at the same time, today's R&D leaders face many challenges, including safety, productivity, long-term sustainability, new science, and managing global organizations.

This month's Forum features the insights of these leaders as they discuss the opportunities and challenges they, and their organizations, face in the pursuit of researching and developing new therapies, as well as the challenges and lessons learned in leading their teams through a period of change.

Research Opportunities for Pharma

With the emergence of many new areas of research, leaders within biotech and pharmaceutical organizations envision a great deal of promise for the development of new therapies.

SHANNON. The opportunity for the pharmaceutical industry is to use new markers to target medicines to those patients who will benefit most and to target those patients who suffer from side effects. There are still many diseases that are not adequately treated. Even with diseases that are traditionally regarded as adequately treated, such as hypertension, many patients are not treated to goal. The same is true for diabetes, asthma, and many other diseases.

GREENLEAF. Some of the biggest opportunities are in the area of molecular biology — understanding how certain drugs work. There are drugs that have been tested in humans in the past for a given disease or for other indications, but at the time the mechanism of action for these drugs may not have been fully understood. Even if the mechanism of action was understood, there has been difficulty ascertaining the value of that knowledge because the molecular biology wasn't understood.

TESSIER-LAVIGNE. Our understanding of both basic biological processes and of disease processes has increased exponentially in the past decade. Based on this knowledge, we can now tackle diseases systematically and target very

specific molecular targets to ameliorate the disease in very defined ways. That's the opportunity that is available today that wasn't there 10 years ago, and that opportunity is great for translational medicine and drug discovery.

BONNEFOI. There are many opportunities that can come from merging therapy and prevention. For example, some of the therapeutic areas that Sanofi-Aventis is involved in are obesity and cancer. Recent research has found that obese people have a greater propensity to develop cancer than nonobese people. Therefore, there is a great deal of potential for pharmaceutical companies that are involved in both fields of research and development.

Drugs in Phase III clinical trials have the potential to add a value of more than $30 billion in additional revenue to the pharmaceutical market of 2010. Cancer drugs in development could possibly make up almost 20% of the market by 2010.

Source: Kalorama Information, New York.
For more information, visit kaloramainformation.com.

GREENLEAF. Even though a number of things have changed, including better science, the market is going to remain fragmented in the areas of oncology and hepatitis. Cancer genes will continue to mutate, and we're going to have to look for other therapies to augment what is currently being used. There are no panaceas.

WALSH. There is a major opportunity to find ways to decrease the failure rates in the

Thought Leaders

STEVE ARKINSTALL, PH.D. VP of Research, United States, and Head of Research, Serono Research Institute, Serono Inc., Rockland, Mass.; Serono is a global biotech leader that is committed to discovering and developing medicines that address significant unmet medical needs. For more information, visit serono.com.

LEE E. BABISS, PH.D. VP, Preclinical R&D, Roche, Nutley, N.J.; Roche is the U.S. prescription drug unit of the Roche Group, one of the world's leading research-oriented healthcare groups. For more information, visit rocheusa.com.

MARC BONNEFOI, D.V.M., PH.D. VP and Global Head of Drug Safety Evaluation, Sanofi-Aventis, Bridgewater, N.J.; Sanofi-Aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine, and vaccines. For more information, visit sanofi-aventis.us.

MATT COFFEY, PH.D. Chief Scientific Officer, Oncolytics Biotech Inc., Calgary, Canada; Oncolytics Biotech is a biotechnology company focused on the development of oncolytic viruses as potential cancer therapeutics. For more information, visit oncolyticsbiotech.com.

CARL M. COHEN, PH.D. Chief Operating Officer, Biovest International Inc., Worcester, Mass; Biovest is dedicated to the development and commercialization of personalized cancer immunotherapies. For more information, visit biovest.com.

OLIVER FETZER, PH.D. Senior VP, Corporate Development, Research and Development, Cubist Pharmaceuticals Inc., Lexington, Mass.; Cubist is a biopharmaceutical company focused on the research, development, and commercialization of products that address unmet medical needs in the acute-care environment. For more information, visit cubist.com.

DANIEL GREENLEAF. President and CEO, VioQuest Pharmaceuticals Inc., Basking Ridge, N.J.; VioQuest acquires, develops, and commercializes targeted late-preclinical and early-stage therapies with unique mechanisms of action for oncology, viral, and autoimmune disorders. For more information, visit vioquestpharm.com.

MICHAEL S. KINCH, PH.D. Senior Director, Oncology Research and Development, MedImmune Inc., Gaithersburg, Md.; MedImmune is a biotechnology company focused on the areas of infectious diseases, cancer, and inflammatory diseases. For more information, visit medimmune.com.

JOHN ROTHMAN, M.D. VP, Clinical Development, Advaxis Inc., North Brunswick, N.J.; Advaxis is a biotechnology company that is developing proprietary Listeria cancer vaccines. For more information, visit advaxis.com.

JAMES SHANNON, M.D. Head of Pharma Development, Novartis AG, Basel; Novartis researches, develops, manufactures, and markets innovative prescription drugs. For more information, visit novartis.com.

CATHERINE D. STRADER, PH.D. Executive VP, Discovery Research, Schering-Plough Research Institute, Kenilworth, N.J.; Schering-Plough Research Institute is the pharmaceutical research arm of Schering-Plough Corp., a global science-based healthcare company with leading prescription, consumer, and animal-health products. For more information, visit schering-plough.com.

MARC TESSIER-LAVIGNE, PH.D. Senior VP, Research Drug Discovery, Genentech Inc., South San Francisco, Calif.; Genentech discovers, develops, manufactures, and commercializes biotherapeutics for unmet medical needs. For more information, visit gene.com.

MARK VARNEY, PH.D. Chief Operating Officer and Chief Scientific Officer, Cortex Pharmaceuticals Inc., Irvine, Calif.; Cortex focuses on novel drug therapies for neurological and psychiatric disorders. For more information, visit cortexpharm.com.

FRANK WALSH, PH.D. Executive VP, Head of Wyeth Discovery Research, Wyeth Pharmaceuticals, Madison, N.J.; Wyeth is one of the world's largest research-driven pharmaceutical and healthcare products companies. For more information, visit wyeth.com.

Photography: Hong Kong

Phase

DANIEL GREENLEAF
VioQuest Pharmaceuticals

THE IDEA OF FIRST-LINE MEDICINE IN TARGETED THERAPEUTICS IS INCREDIBLY COMPELLING. An example is diagnostic tools that can be used to predetermine which patients are most likely to respond to a particular drug.

DR. FRANK WALSH Wyeth Discovery Research

ONE OF THE MAJOR OPPORTUNITIES FOR DISCOVERY AT COMPANIES OF ALL SIZES is the use of protein therapeutics.

lab, which is an ever-present challenge for all of us. We have not done a very good job at harnessing the developments in clinical medicine and in the academic sector. There are opportunities to work with external academics to try to identify and solve the problem of attrition.

KINCH. As our understanding and knowledge about disease processes increase, oppotunities emerger for targeting the pathways that are relevant to that particular disease indication. That knowledge has come from genomics projects. Science is at a point where we have the ability with monoclonal antibodies and other technologies to target specific molecules and specific pathways.

GREENLEAF. The idea of applying first-line medicine to targeted therapeutics is incredibly appealing — using diagnostic tools that can predetermine which patients are most likely to respond to a treatment. This strategy would allow us to enroll about one half to one quarter of the patients who would otherwise be needed in clinical trials without the diagnostic tool.

COHEN. Big pharmaceutical companies are finding it harder and harder to develop the blockbuster, one-size-fits-all drugs that have historically driven their profitability. Because there is a much stricter regulatory environment and a much more intelligent and educated consumer population, people are demanding and expecting safer products. In general, personalized medicine provides those opportunities.

BONNEFOI. At Sanofi-Aventis we are trying to take a pragmatic approach. We are not looking only for the next blockbuster drug or the compound that will be huge in a few years. Our strategy is that there is no small compound or country, and we're trying to develop our portfolio by being as broad as possible in terms of compounds, country, disease, and so on.

BABISS. There are increasing investments and capabilities in the biotech sector in the area of drug discovery, and that is leading to partnerships between major pharma companies and biotech companies with mutual benefit to both. For pharmaceutical companies, such partnerships are great ways to gain entry into new therapeutic areas, novel targets, and to supplement, overall, the quality and quantity of their pipelines.

COHEN. Personalized medicine will actually open up new markets that historically have not been amenable to one-size-fits-all therapies. For the most part, however, big pharma companies have stayed away because they don't know how to do personalized medicine. The big pharma model is set up to do things on an industrial scale.

TESSIER-LAVIGNE. At Genentech, we're

Genomics and Clinical Trials

The promise of clinical genomics for improving drug development and enhancing healthcare is enormous. Potential benefits of clinical genomics include: fewer adverse drug reactions, improved clinical trials, new biomarkers, better drug design, and facilitation of personalized medicine.

Clinical genomic applications recently crossed an important threshold with the approval of several clinical genomic products and a dramatic rise in the use of the technology in clinical trials. It is anticipated that more applications will appear at a rapidly increasing rate in the next three to five years but that the full promise of clinical genomic applications will not be fully realized for at least another 10 years to 15 years.

Promising areas of growth potential include: toxicogenomics, oncology, clinical-trial design, and rare diseases.

An important consideration driving the increased use of clinical genomics is drug-safety concerns in the pharmaceutical industry. Genomics technologies are seen as a promising avenue to improve safety, and more companies are investing in these areas.

Whereas five years ago, only a handful of companies were using genomic technologies in their clinical testing, currently an estimated 20% of U.S. clinical trials use some sort of genomic approach. In addition, many clinical trials are now being designed with genomic testing in mind.

Still, the field continues to face considerable regulatory, technical, economic, and sociological hurdles.

Source: CHA Advances Report, Waltham, Mass.
For more information, visit advancesreports.com.

per•fec•tion•ism (pr-fksh-nzm)
n. a disposition to feel that anything less than perfect is unacceptable

The Perfectionist Pledge

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DR. MARC TESSIER-LAVIGNE
Genentech

A GREAT OPPORTUNITY RIGHT NOW IS FOR TARGETED THERAPY — the ability to base drug discovery on advances in scientific knowledge about basic biological and disease mechanisms.

DR. JOHN ROTHMAN Advaxis

Science is moving quickly, and there are inevitable disparities between good science and good regulatory practice. THE SCIENCE IS MOVING SO FAST THAT REGULATORS ARE BEING EXPOSED TO NEW SITUATIONS THAT THEY MUST ACCOMMODATE.

now tackling dozens of defined molecular targets, and our pipeline is brimming with candidate therapeutics. Our optimism is high that many will make it through, and this is really based on advances in knowledge.

WALSH. There are opportunities to partner with governments. Increasingly in the European countries, we are witnessing government agencies wanting to kick start research and work with different aspects of pharmaceuticals. We've been forming very close collaborations in Italy and elsewhere that allow us access to high-quality science. If pharmaceutical companies and biotech companies are to carry out innovative research, they need to work with the other part of the triangle — the academic community. The academic community is very good at identifying interesting science and perhaps not as adept as big pharma and biotech in terms of exploiting that knowledge. There are also opportunities in the area of outsourcing. All companies have huge pressures on their budgets. We've made a major investment in India and have enhanced our chemical capabilities by working with Indian companies.

VARNEY. China and India have been very important to companies and have made significant contributions with quality research. The quality of CROs is particularly good in China, India, and Russia, which employ professionals of probably the same caliber as in the United States at only a fraction of the cost. It's become clear that CROs can add to an organization. Without having to build up an infrastructure internally, one or two key individuals within the company can leverage the external resources they need.

TESSIER-LAVIGNE. Historically, biotech companies were defined as companies that used protein and antibody therapeutics. I think this definition has morphed into drug discovery based on a deep understanding of biology and disease mechanisms.

ARKINSTALL. We believe in the realm of biotherapeutics. There are real opportunities there, particularly in the oncology area. Most large pharmaceutical companies have jumped on the monoclonal antibody bandwagon. There is immense competition for generating antibodies in the oncology area.

STRADER. The biggest opportunity is the ability to put small molecules and biologic projects into the same portfolio. There are different ways that pharmaceutical companies are

Strategies to Address Attrition

In an increasingly complex, competitive global market, improving R&D productivity is essential to success. Achieving lower attrition rates in late-stage development, and doing so cost-effectively, is imperative. But according to Tufts Center for the Study of Drug Development, getting from here to there poses a particular challenge. As returns within the pharmaceutical industry in recent years have dropped, many drug developers have become more risk-averse.

Achieving optimal transformational change in clinical development will require a new way of thinking about safety, according to the executives at a Tufts CSDD discussion. The issue today is that exemplary compliance with regulatory safety requirements in clinical development does not guarantee accurate or timely identification of risk. Information systems and processes are typically optimized for compliance, which can sometimes hinder, rather than help, identify safety issues.

To achieve lower attrition rates in late-stage development, higher-quality safety data need to get to the right people across the organization faster. Those people, in turn, need to have the right relationships and the tools to make and communicate robust decisions sooner in development.

In the future, the safety function will more closely resemble the way organizations address efficacy: it will have dedicated project management, medical writing, and informatics support that will develop statistics for deriving probability of toxicity in real-time. Moreover, understanding of drug safety, instead of being parsed by organizational silos, will become a seamless and evolving picture across all phases of drug development and commercialization.

Source: Tufts Center for the Study of Drug Development, Boston.
For more information, visit csdd.tufts.edu.

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approaching this strategy. For example, we've created a new entity called Schering-Plough Biopharma, which is part of the discovery group, not a separate organization. This structure allows us, from day one of the identification of the new target, to discuss what would be the best approach. We were expending an awful lot of energy getting everybody together after a project was under way to assess whether there were ways to create synergy. Instead, the company decided to make a single discovery group, bringing together scientists who have expertise in biologics and those who have expertise in working with small molecules.

Sound Bites from the Field

PHARMAVOICE ASKED THOSE WHO PARTNER WITH PHARMACEUTICAL AND BIOTECHNOLOGY COMPANIES TO IDENTIFY THE TRENDS IMPACTING DRUG DEVELOPMENT AS WELL AS THE CHALLENGES OF DEVELOPING NEW MEDICINES.

NANCY A. DREYER, PH.D., is Chief of Scientific Affairs at Outcome, Cambridge, Mass., a provider of solutions to meet the needs of the postapproval market. For more information, visit outcome.com.

"There is an increasing trend toward personalized medicine. This has the potential to fragment the market. It presents additional challenges to pharmaceutical R&D departments for documenting clinical and cost-effectiveness. At the same time, personalized medicine presents a significant opportunity. It will allow the healthcare industry to be more selective with treatments and to get them to people most likely to benefit. This will result in better outcomes. Documentation of good outcomes — clinical and cost-effectiveness — will increase the likelihood of coverage by CMS for Medicare Part D. This represents a large revenue opportunity."

LISA FELL is VP of Recruitment Operations at MediciGroup Inc., King of Prussia, Pa., a provider of comprehensive clinical-trial marketing services. For more information, visit patientrecruitment.com.

"Conducting and completing clinical trials on schedule is one of the biggest challenges in developing new drugs. Recruiting patients is one of the most critical issues in achieving that objective. Before the study begins, every study team needs to have objectives, strategies, and programs in place that are going to drive recruitment momentum. This requires a coordinated plan of action provided by sponsors to sites for recruiting, screening, and randomizing patients into the study. This maximizes the chance for study completion on time and within budget."

MARTHA R. FELLER is Senior VP, Global Clinical Development - North America, at Kendle, Cincinnati, a global clinical research organization. For more information, visit kendle.com.

"Costs and timing will continue to be significant challenges to drug development. New molecular entities (NMEs) have declined, but biologics license application (BLA) approvals have increased; and the trend should continue. The strong emphasis on safety will continue to significantly raise the cost of drug development. Pharma will continue to depend on support from CROs to help them manage product-development efforts more efficiently and cost-effectively. As noted in the January/February 2006 Tufts Center for the Study of Drug Development Impact Report, drug-development resources have shifted from pharma to CROs. The report found that projects involving CROs were completed faster while maintaining data quality and regulatory compliance."

JAMES C. FOSTER is President, CEO, and Chairman of Charles River Laboratories Inc., Wilmington, Mass., which provides research models and laboratory animal support services, preclinical services, and clinical services to the biomedical market. For more information, visit criver.com.

"From the perspective of a contract research organization, we find the continuing momentum of outsourcing by drug makers remains a major trend. This growth is due primarily to pharma's shift from doing all work across the entire drug-development process internally to focusing particularly on the discovery phase and relying more on external partnerships to provide preclinical capabilities. Most drug makers do not have the infrastructure necessary to address new routes of drug delivery, such as specialty toxicology and, in particular, infusion and inhalation studies. Outsourcing is the cost-effective answer. It allows all players to focus on what they do best, and it provides drug makers with the flexibility to address their toxicology requirements according to their pipeline needs."

SUZANNE GAGNON, M.D., is Senior VP, Medical Affairs and Late Phase Services, at Icon Clinical Research, Philadelphia, a global provider of outsourced development services to the pharmaceutical, biotechnology, and medical-device industries. For more information, visit iconclinical.com.

"Currently, in what is being touted as the 'post Vioxx regulatory environment,' there is a major refocus on drug safety and a renewed understanding that products enter the marketplace long before everything about their safety profile is known. The FDA is mandating that Phase IV safety commitments be performed, and the agency is sometimes requiring that studies commence during the peri-approval period. We are seeing large global endpoint studies of simple design, as well as drug and disease registries, much more frequently as pharmaceutical companies attempt to obtain additional safety information in a time- and cost-efficient manner."

BABISS. There is a much greater focus on drug discovery. There also is more emphasis on projects in general, portfolio management, and managing all the assets to progress compounds at each phase of the development process.

ROTHMAN. We're beginning to reap the fruits from the IT boom of 10 years to 15 years ago that led to the creation of very large mineable databases. The ability to integrate and extrapolate from existing data has increased by leaps and bounds. And as technologies get older, they tend to get less expensive. Some of the technologies that were cutting edge five years or 10 years ago are more economical now in developing countries.

DAVID GINSBERG, D.O., is Chief Medical and Ethical Officer at Omnicare Clinical Research, King of Prussia, Pa., a global full-service CRO. For more information, visit omnicarecr.com.

"One of the most significant issues impacting the drug-development paradigm today is an enhanced standard of pharmacovigilance. We must vigorously explore all potential safety signals throughout the commercial life of a product — and not lower that commitment following FDA-approval. Global literature searches, spontaneous case reports, and reviews of issues involving drugs in the same class must be collected and reviewed on an ongoing basis and in a timely fashion. Additionally, we should implement proactive strategies to clarify potential problems before they arise. Structuring Phase IV trials to meet the most intense scientific scrutiny is a part of that solution."

CHRIS JOCK is VP and General Manager, Kelly Scientific Resources, Troy, Mich., a provider of scientific and clinical-trial staffing services. For more information, visit kellyscientific.us.

"On the drug development side, essentially clinical trials, several dynamics are in play. The available patient pool for trials is shrinking in the United States and Western Europe; there are increased regulatory pressures; there is a growing need to have trial data that are reflective of a larger, diverse (ethnically and culturally) global population to maximize treatment strategies; there is increasing pressure to offer lower-cost treatments to underserved geographies; and the cost of trials continues to grow faster than the financial return. This means that U.S. and Western European pharma companies need to expand/outsource more trials to India, China, South Africa, South America, and Eastern Europe. On the research side, that is essentially preclinical efforts, productivity in the traditional pharma sense is declining while the cost to conduct research is rising. There is now availability of better, larger chemical entity structure information, the use of informatics tools for PK/PD determinations, and the creation of multidiscipline/functional project/program teams — coupled with the growth within India and China of specialty/active ingredient manufacturers and contract lab services' capacities and capabilities. All will act to have a profound effect on how industrial research is conducted and delivered for companies to achieve sustainable business results. The transformation will lead to quicker go/no-go project milestone decisions at lower cost."

STEFANIE KUHNER is Sales Director at Acurian Inc., Horsham, Pa., a full-service provider of patient-recruitment services. For more information, visit acurian.com.

"Drug-development challenges continue to center around creating, maintaining, and completing timelines according to the associated activities of clinical development. Issues arise over delays to study design based upon scientific/commercial input, patient recruitment/site commitment, the introduction of new internal processes, and the constant reorganization of team models."

HEATHER MELLON is Associate Director, Project Management, BioCor, Yardley, Pa., a clinical research organization that specializes in clinical-data services and consulting to support Phase I through Phase IV programs. For more information, visit biocor.com.

"Some of the trends in pharmaceutical research and development include: the need to demonstrate the cost-effectiveness of drugs for both private and government insurers; continual developments in areas of medicinal chemistry and genomic research; and a more knowledgeable consumer. Patients want more disclosure of safety information; and those who take medicaitons for chronic, long-term conditions, are not willing to accept much safety risk. For pharmaceutical companies, the opportunities lie in regaining the respect of patients who are looking for companies to provide safe, cost-effective, and important drugs to treat serious conditions. The image of pharma has taken a dive in recent years, and this is an opportunity for pharma to show that, though the need to be profitable will always be of great importance, there is an equal desire to provide drugs and devices that really make a difference in people's lives."

MYCHELLE MOWRY is VP, Global Health Industries, at Oracle Corp., Redwood Shores, Calif, an enterprise software company. For more information, visit oracle.com.

"One of the trends impacting the pharmaceutical industry is the move toward outsourcing research and development. Investment in research and development conducted outside the United States is at an all-time high. For the first time, more life-sciences research is being conducted outside the United States than in the United States. The industry is witnessing tremendous growth in research and development from countries outside North America and Europe (for example India, China, and South Korea). In addition, the pharmaceutical industry — in addressing its product pipeline needs — has increased its investment in the biotechnology sector. When targeting biotech investments, however, pharma manufacturers increasingly look for opportunities further down the development chain to mitigate risk. The focus is moving toward drugs that improve or preserve wellness, as well as drugs that address chronic diseases, such as obesity and Alzheimer's. But the greatest opportunities will come from pharmacogenomics, which will create targeted drugs for specific traits and human propensities. There is heterogeneity in the way diseases develop and progress in humans, and there is variability in the human response ▶

Challenges for R&D

Safety, productivity and long-term sustainability, new science, and managing global organizations are some of the challenges identified by the pharma and biotech leaders in this Forum.

SHANNON. R&D in the pharmaceutical world is an ever-changing business. An increased focus on safety has been very pronounced in the past 12 months. Right now, the discussion about drug safety is not very balanced. Somehow, the public is under the impression that approved drugs are totally safe, but drugs are quite powerful. There is no such thing as an absolutely safe drug; drugs do have side effects in some patients.

BABISS. Our ability to assess and predict safety isn't where it needs to be. Today, most drugs are not failing early because of lack of efficacy; they're failing because of safety issues. We have to do a much better job of assessing safety issues earlier. We have to do a better job of in-silico prediction, and to use all of the data we've generated for different chemical scaffolds. We should then use those data to test algorithms to apply the results to large chemical data sets and filter out those compounds that have potential toxic liabilities from those that don't.

SHANNON. There has to be a realization that drugs are powerful chemicals; and with those powerful chemicals, there is a risk that some

Sound Bites from the Field (CONTINUED)

to disease. Personalized medicine means we will be developing therapies targeted to individuals as opposed to a universal treatment regime. This trend will require an entirely new business model — moving away from blockbuster drugs and toward targeted products."

MONIKA PIETREK, M.D., PH.D., is Executive VP of Global Scientific and Medical Affairs, at PRA International, Reston, Va., a clinical development organization. For more information, visit praintl.com.

"I see three major trends. First, there is a move toward more personalized medicine using gene therapies and biomarkers. As this science grows, we are no longer necessarily looking at the development of blockbuster drugs but identifying specific molecule targets to treat smaller groups or even an individual patient. Second, I see a strong emphasis on preventive medicine through a renaissance of vaccines for infectious diseases; a new generation of vaccines, e.g., in oncology and interventions at early disease stages, which we find very exciting. Third, new types of formulations, such as dietary supplements and medical devices, will need to be developed under stricter regulatory guidance. We see a big opportunity for pharmaceutical research in emerging markets, especially in China and India. As these countries develop, they represent potentially huge new markets for pharmaceuticals. In addition, we see opportunities for greater patient access and the prospect of furthering our global development capabilities with an expanded presence in these countries."

STEPHEN RAYMOND, PH.D., is Cofounder, Chief Scientific Officer and Quality Officer at PHT Corp., Charlestown, Mass., a provider of electronic patient reported outcome (ePRO) solutions. For more information, visit phtcorp.com.

"With e-source data capture methodologies, further opportunities for new streams of insightful patient information are created. Technologies such as measurement devices wirelessly integrated with e-diaries allow sponsors to evaluate subjective self-reported patient data in conjunction with objective measurements, such as physical activity, blood sugar level, heart rates, or peak expiration flow (PEF). Cognitive assessments, not possible on paper diaries, can help research scientists determine, for example, subjects' ability to concentrate or their level of drowsiness while undergoing a study treatment. With these emerging applications and e-source data capture methods, there is a significant opportunity for clinical-trial sponsors to take full advantage of longitudinal records of a subject's changing health status to more thoroughly and convincingly evaluate a drug's safety and efficacy potential."

ROBERT SAMMIS is Chief Operating Officer of etrials Worldwide Inc., Morrisville, N.C., an e-clinical software and services company offering a suite of technology-based tools, including electronic data capture, electronic patient diaries, interactive voice response, and reporting. For more information, visit etrials.com.

"The use of e-clinical technologies, such as EDC, e-diaries, and IVR, offer incredible benefits to pharmaceutical and biotechnology companies and CROs conducting clinical research. With these types of technologies, sponsors can gain insights into the status of their trials far faster and easier than with paper-based methods. In addition, this near real-time access to data enables better decision-making across multiple disciplines about the safety and efficacy of new treatments. By taking this adoption a step further, many sponsors can gain even higher efficiencies and save costs by in-licensing and internalizing e-clinical technologies. This allows the sponsor to drive the implementation and training of technology to get drugs to market faster."

RONNY SCHNEL is Executive Director, Business Development and Client Services, at Criterium Inc., Saratoga Springs, N.Y., a full-service, global contract research organization. For more information, visit criteriuminc.com.

"Expensive failures, inefficiencies, and increasing regulatory hurdles are serious industry obstacles that challenge the way in which organizations are approaching new drug development. Studies that are managed without real-time analysis for patient enrollment and compliance, and regulatory agencies that do not honor their timelines, result in serious complications. For the CRO, establishing early buy-in, credibility, and commitment with clients are the most important challenges we currently face to solve these obstacles."

EDWARD M. SELLERS, M.D., PH.D., is President and CEO of Ventana Clinical Research Corp., Toronto, an early-phase clinical research organization that provides science-driven clinical services for companies developing compounds that treat central nervous system disorders. For more information, visit ventana-crc.com.

"Biopharmaceutical companies are increasingly relying on outsourced specialist expertise for their clinical study needs. Increased regulatory and

patients will have side effects. The discussion needs to be around what the real benefit of the drug might be, such as does it improve the quality, length, or standard of life of the patient? And is the risk worth it?

FETZER. Every drug has certain risks, and it is very easy to overemphasize the risk and to lose the nuance that a life-saving therapy may involve more risks. The industry is unable to provide a useful framework of how to think about the benefit/risk ratio. The public now has the perception that the greedy pharmaceutical industry is just trying to put patients at risk, when in fact, some patient groups understand the risk of a rare and devastating event and want to be able to make a choice.

The years 2003 and 2004 marked a 25-year low point in worldwide market launches for new active compounds.

Source: Cambridge Healthtech Associates, Waltham, Mass. For more information, visit chadvisors.com.

ROTHMAN. There is a disparity between good science and good public policy. Often, public policy is driven by public perception, which can be driven by the media. As a result, there can be a lack of understanding of the greater good and a cost-benefit determination that makes sense. When a drug could theoretically cure 500,000 patients a year from a life-threatening disease and three patients die as a result of studies has created the misleading impression of the TQT study as the latest 'check box' among an already long list of development requirements. Unfortunately, focusing exclusively on the TQT can provide a false sense of security, an unnecessary rush to halt development, or, in the case of mixed results, complete confusion. Developers must realize that the TQT is not a proxy for cardiac safety but one of many tools used to determine a drug's complete cardiac-safety profile."

scientific scrutiny requires that the most rigorous study design, implementation, and analysis be used. The timeframe for making the go/no-go decision is shortening, and companies are looking more and more outside their own walls for advanced scientific capabilities and innovative technologies to help them make the decision. With an increasing demand for more effective compounds and depth in therapeutic areas, the pharmaceutical industry is under pressure to perform. This need will most keenly impact the earliest phases of the drug-development process, where we will see major expansion over the course of the next few years. Partnerships with reliable service providers who can provide timely information for quick decision-making will be of utmost importance to the success of these new compounds."

EMMA SERGEANT is President, Clinical Trials Worldwide, at Fast4wD Ogilvy, New York, which offers specialized clinical-trial services, including recruitment and retention expertise. For more information, visit fast4wdogilvy.com.

"Pharmaceutical companies are recognizing the urgent need to invest in and speed up their pipeline development. In recent years, biotech companies that have molecules to fill pipeline gaps have been purchased. Ultimately, once studies are initiated, there is still a problem with the profile of the pharmaceutical industry and low awareness of clinical-research benefits in the public arena. The need to have a clear communications plan, including patient-recruitment and retention strategies, is imperative. Delays in study delivery and bringing products to market are impacted greatly by slow patient recruitment and poor retention in study programs. While there is always a need to separate the clinical development from the marketing program, there is a growing requirement for cross-functional teams to work together. The pipeline-development program provides an opportunity to position the pharmaceutical company's corporate responsibility and profile, develop, and map current and future opinion leaders. It is also an opportunity to establish public perceptions and needs in therapy and product areas, which can help to shape future branding, messaging, and positioning as the product approaches the market."

NANCY SMERKANICH is VP, Regulatory Affairs, Octagon Research Solutions Inc., Wayne, Pa., a provider of electronic solutions for clinical R&D in the life-sciences industry. For more information, visit octagonresearch.com.

"I can sum up my thoughts on this in two words: electronic processes. The process for electronically creating and storing information related to drug development is more than just a trend in the pharmaceutical research and development space, as these processes are being employed in all areas of R&D (chemistry, manufacturing, control, and clinical and nonclinical testing). Yet if they are not being fully integrated into the overall endgame, they will create both a challenge and an opportunity for those companies that want to leverage industry standards and technology throughout their business process. The endgame in terms of integration is the regulatory submission. The challenge is in creating compatible and compliant formats, and the opportunity is in using electronic submissions to put it all together."

POLINA VOLOSHKO, M.D., is VP, Clinical Cardiovascular Services, at Gentiae, San Bruno, Calif., which delivers core ECG lab and imaging services. For more information, visit gentiae.com.

"The recent guidance on QT prolongation is already presenting several challenges for the industry. The emphasis on thorough QT (TQT)

JOHN WATSON is VP of Corporate Sales and Marketing at Covance Inc., Princeton, N.J., which provides a portfolio of preclinical and clinical development and commercial service offerings. For more information, visit covance.com.

"In the face of continued pressure on R&D productivity, biopharmaceutical firms of all sizes are embracing a new approach that is dramatically reshaping the topography of the drug-development continuum. We see a shift of resources from Phase III into preclinical and Phase I/II testing to improve the likelihood of success in the much more expensive late-stage clinical-trial environment. The expectation is that this approach will yield higher quality candidates, resulting in fewer late-stage failures, thereby reducing the overall cost of development and improving R&D productivity. In support of this new approach, a number of leading-edge companies are evaluating ways to optimize their own R&D spend by engaging full-service CROs in innovative, trust-based, strategic partnerships." ▶

of previously unseen idiosyncratic reactions to the drug, is that grounds for bankrupting the company in court? The answer, perhaps, is to try to achieve some kind of consensus as a culture as to what makes sense to provide the best possible care to the most people.

SHANNON. Within Novartis we are incorporating a new model for drug development using markers and building much stronger modeling and simulation techniques into the early process. This way we will be able to make better decisions on statistical models in much the same way as other industries do, for example the aerospace or automobile industries. As a company, we are going forward with in-silico modeling; we want to incorporate a totally novel clinical-trial methodology with different statistical methodologies from those we've used for the last 20 or 30 years.

BONNEFOI. I believe one of the biggest challenges is the complexity of the research and development landscape in the pharmaceutical industry. The public's interest in what we are doing is increasing. The challenge is to manage that complexity and still be able to get to market great drugs that satisfy medical needs.

WALSH. Another challenge involves long-term sustainability and keeping the pipeline filled. Any company's pipeline has gaps. A company may wish to move into a new area but will have to start from scratch, which can take a long time.

Member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) alone invested an estimated $39.4 billion in 2005 in discovering and developing new medicines. Industrywide research and investment reached a record $51.3 billion in 2005.

Source: PhRMA, Washington, D.C.
For more information visit, phrma.org.

BABISS. There is such a push for more productivity and for creating quantity-based pipelines that most pharmaceutical companies are following each other in terms of the targets and the diseases. My concern is whether the overall investment in biology being made will provide enough insights into high-quality targets that are novel and can be first in class.

TESSIER-LAVIGNE. We're trying to understand the specific disease areas that we're targeting — cancer, immune disorders, and disorders of tissue growth and repair — at a detailed molecular level. We don't think of breast cancer as breast cancer; we think of it as a HER2 positive breast cancer or HER2 negative breast cancer. In this way, we start to deconstruct the disease into groups that are more cohesive. We can then deploy all of the firepower available to develop the right therapeutics for that disease.

COFFEY. In biologics, the challenges are regulatory and manufacturing in nature. To a great extent because targeted therapeutics are new, often the mechanisms can't be predicted and only become evident later in the clinical progression. Many companies find themselves with a compound in Phase III trials, and the perceived mechanism of action is only a small part of why the agent works in a particular patient population.

SHANNON. Translating the new science — genomics — into new targets and real value-added medicines is a challenge. One of the challenges is making the right decisions in drug development. Drug development is a business of making decisions because we start with 10,000 chemicals, but only one of those will become a drug on the marketplace. And of the drugs that come to the marketplace, only one third will recoup their development costs.

WALSH. The industry is approaching attrition in a number of ways. One way to counter this is to strengthen and enhance activities

Sound Bites from the Field (CONTINUED)

LINDA WOLF is a member of the Media and Industry Public Relations Group of BBK Healthcare Inc., Newton, Mass., which provides patient-recruitment services for clinical trials. For more information, visit bbkhealthcare.com.

"Our research shows that no matter where in the world clinical trials are run, patients are interested in participating but want more information about what they're getting into. The opportunity here is for the pharmaceutical research industry to build education and communication programs into the design, planning, and implementation of clinical trials, whether they are in North America, Western Europe, or the emerging markets in Eastern Europe, Asia-Pacific, South America, and Africa. The more we can do as an industry to support and enhance communication processes and tools for investigative sites, the more patients will commit to ongoing participation, with the result being clinical studies that enroll on time and complete with low attrition rates."

MARTIN YOUNG is VP Services, North America, Phase Forward, Waltham, Mass., a provider of data-management solutions for clinical trials and drug safety. For more information, visit phaseforward.com.

"Three key trends in research and development come to mind: development capacity and productivity, safety, and globalization. Increased capacity and productivity are critical if companies are to realize the value of the significant investments in research technologies made in recent years that are now producing an increasing number of prospective drug candidates in early-phase research. These increases are not possible with the traditional paper-based clinical development paradigm. At the heart of increased capacity and productivity is electronic data capture (EDC). Some estimate that EDC technologies are now used in almost half of all clinical research studies. EDC is critical as it empowers clinical-research teams with real-time information and then enables them to plan for, and quickly implement, seamless changes in response to that information. Improved efficiencies afforded by technology continue to present powerful opportunities for positive change. Like companies within other industries, pharmaceutical companies continue to leverage the power of technology for safer, more reliable, and scalable trials."

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around translational medicine. Wyeth has been investing heavily in this discipline over the last year and has entered into a number of collaborations to identify gaps and fill them with short-term actions.

TESSIER-LAVIGNE. A big challenge is to get the right balance between translational research in drug discovery and continued basic research. If a company focuses totally on drug discovery and development then it weakens its biological base, which becomes a long-term problem when trying to figure out the best entry point to tackle various diseases. Of course, if companies do the opposite and push too hard on the basic research at the expense of developing drugs then they are left with an empty pipeline. The challenge is to develop a model that allows for both. One of the ways we do that at Genentech is to give scientists discretionary time when they can focus on what they want; it doesn't have to be pipeline research. This is a way to advance basic understanding and knowledge.

Leadership Issues

R&D executives say identifying the right drugs, hiring the right people, and, for smaller organizations, ensuring the right financial backing are the challenges they face in leading their teams.

SHANNON. We have a very large R&D organization that is spread across the world. We have talented researchers in China, India, Japan, the United States, Europe, and the United Kingdom. We conduct about 60% of our clinical trials outside the United States. With people everywhere, the challenge is maintaining communications across the organization.

BONNEFOI. The main challenge has been the size of the team and the number of locations. Also, our company is the product of several mergers. Developing a common culture and maintaining passion for what we do is something I pay a great deal of attention to.

WALSH. The challenge for me is to have a clinical organization that is consistently productive and one that is staffed by the best scientists and physicians so that we can deliver the best candidates to the clinical organization. The productivity issue is one of the major challenges that I have. The company has invested extensively in R&D, and productivity in recent years has been reasonable but certainly not outstanding.

GREENLEAF. The right team has to be in place; that's where it all starts. The management team invariably is going to make or

A Look at Late-Stage Development

Drugs in Phase III trials have the potential to **ADD MORE THAN $30 BILLION** in additional revenue to the pharmaceutical market by 2010, according to a recent report by Kalorama Information, the publishing division of MarketResearch.com.

Drugs in the **ONCOLOGY SEGMENT** are expected to make a significant impact to current markets, increasing competition and providing advanced alternatives to current therapies. Cancer drugs in development could possibly make up almost **20% OF THE MARKET** by 2010.

NEUROPYSCHOTHERAPEUTIC DRUGS in development will increase the market by **MORE THAN $5 BILLION** by 2010. Products in the mental illness arena will add the significant portion of revenue, followed by movement disorder products such as those for Parkinson's disease.

CARDIOVASCULAR DRUGS in development will continue to fuel the market because of an aging and growing population and increasing incidence of cardiovascular diseases worldwide. By 2010, drugs in development for cardiovascular conditions will add additional value of **ALMOST $5 BILLION**.

Drugs in development for **INFECTIOUS DISEASE** will add **ABOUT $3 BILLION** in revenue. Innovative treatments will be key in this segment, as the anti-infective market is concentrated with competitors and choices for therapy.

Drugs focusing on **UNMET NEEDS AND RESISTANCE** will show promising revenue. Other drugs in development have an **ESTIMATED VALUE OF $6 BILLION**. These drugs focus on products in areas such as diabetes, gastrointestinal disorders such as Crohn's disease, asthma, sexual dysfunction, rheumatoid arthritis, and others.

Kalorama researchers conclude that the contributors to R&D success are based on a pipeline with some breadth that balances stages of development and high- and low-risk projects, including innovative drugs and follow-on products. They say pipeline quality can be improved by rigorously assessing product candidates against financial expectations, market analysis and input, and high goals for advancing compounds. The drivers right now are an aging population and producing lucrative long-term therapies for life-long conditions. Focusing on blockbuster prospects is attractive but considered high risk. If they fail, there could be gaps in the pipeline, and companies risk not advancing projects that could have achieved market potential.

Source: Kalorama Information, New York.
For more information, visit kaloramainformation.com.

Products in Phase III Trials

Drug type	No. of products in Phase III	Anticipated approvals through 2010	Potential market opportunity ($ in millions)
Cardiovascular	49	20	$4,821
Neuropsychotherapeutic	101	44	$5,084
Infectious disease	68	32	$3,120
Cancer	156	50	$11,509
Other	128	39	$6,028

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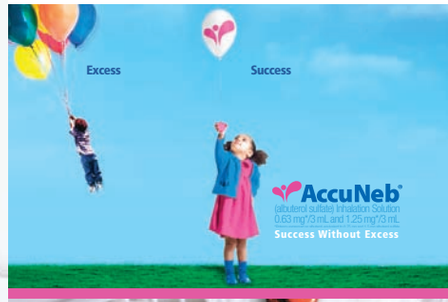

DR. MATT COFFEY Oncolytics Biotech

As we become more adept at handling the science and the regulatory hurdles, THERE WILL BE A GENERAL SHIFT AWAY FROM THE CYTOTOXICS TOWARD COMBINATIONS OF MORE TARGETED THERAPIES THAT WILL BE MORE PATIENT FRIENDLY.

break the company. A company has to have good technologies, but ultimately it's the management team, the personnel, and the organization that will make the difference.

STRADER. One of the biggest challenges is the global nature of research. We have research sites in Massachusetts, California, New Jersey, and Italy. This provides for a tremendous amount of diversity of scientific opinions, scientific backgrounds, and expertise. The challenge is to use that expertise and make sure the teams are comfortable and secure in communicating the data.

BABISS. Keeping people motivated and focused is always a challenge. In large companies, there are many distractions and opportunities: seminars, training opportunities, and career development. These opportunities are important because we want our people to grow, develop, and stay with the company. At smaller companies, there aren't as many distractions. I meet with all new research employees about two to three months after they've joined the company. I ask them the million-dollar question: how can they foster change within the organization through the experiences they've had before. I'm looking for someone who has that motivation, who wants to bring his or her thinking into my organization, and who strives to drive change.

About 20% of U.S. clinical trials use some type of genomics approach. Promising areas of growth potential include: toxicogenomics, oncology, clinical-trial design, and rare diseases. But the full promise of clinical genomic applications will not be realized for at least another 10 years to 15 years.

Source: Cambridge Healthtech Associates, Waltham, Mass. For more information, visit www.chadvisors.com.

WALSH. We found that we didn't have the necessary processes in place. Although scientists were working very hard, they didn't necessarily have their eyes on the finish line. With some relatively small but important changes in our processes and procedures, without turning the organization into a bureaucratic environment, we were able to harness the creative energy of our scientists into productive activity.

ARKINSTALL. One area of focus is to harness the energy and enthusiasm of our scientists on a focused project; this is where the world of clinical project management and science come together. There is a real need for effective project management.

KINCH. Most medical research doesn't work. As managers, we have to keep people motivated and encourage them to think up that next idea. I look for people who are not afraid to challenge me, people who are self-starters, both in terms of doing work and coming up with new ideas.

VARNEY. There are elements of recruiting that are problematic, and it seems to me that it's somewhat cyclical in nature. There have been times in the past when it has been extremely difficult to find people with experience in regulatory affairs and medicinal chemistry. With chemists especially, that's changed enormously. One area that continues to be difficult to recruit quality people is in whole-animal pharmacology.

Lessons Learned

The leaders interviewed for this Forum have had various experiences and have taken with them many lessons about drug discovery and development as well as about managing and leading their teams.

DR. LEE BABISS Roche

THERE ARE GROWING INVESTMENTS AND CAPABILITIES IN THE BIOTECH SECTOR WITHIIN THE AREA OF DRUG DISCOVERY. This is leading to significant partnerships between the major pharmaceutical companies and the biotech companies.

SHANNON. One of the key things that I've learned from different experiences is not to hold on to the past. It's more important to look toward the future. Another thing I've learned in my career is that we often underestimate what is possible. That's a mistake I've seen myself and others make, and I believe we should be more ambitious in setting objectives.

BABISS. I've learned to avoid second-guessing. I'm not a big believer in learning by mistakes; I think one should learn by success. We spend far too much time trying to understand why things didn't work as opposed to trying to learn what things did work and how can we can apply those learnings in the future.

KINCH. It's important not to assume anything. Most ideas are wrong, and it's impor-

tant to recognize that sometimes people have to cut away from an idea. The upside is if people look at the experiment or the result in a different way, they may actually get more out of it than they initially expected. There is a natural tendency for people to try to prove a great idea, but I think that is where research can go bad. Some scientists have a tendency to want to prove their idea, rather than test their ideas.

WALSH. I spent the majority of my career in the academic sector. About eight years ago, I moved into the industrial sector. One lesson from my academic experience that I have brought with me is to understand the value of group science as opposed to individual science. Industry can learn from the academic sector and from the creative energy, vision, and scientific know-how of academics. For me, the learning has been to harness the best from each of the two communities and think as a single community where all can benefit from the creative energies.

TESSIER-LAVIGNE. The most important lesson is having a clear vision and focusing on the long term. It's important to carefully think through where you want to go and then stick with the plan. Solving important problems requires a long-term investment.

VARNEY. It's important not to specialize and to stay as broadly focused as possible. Specialization tends to force one down a particular career path, whereas generalists have a better understanding of the big picture.

COHEN. The biggest lesson that I've learned is that it's not all about the science. People in biotech come from a science background. Very often there is an attitude that if we get the science right, everything else will fall in place. It's really the opposite. People in the sciences need to know and understand management, how to interact with people, and how to negotiate. These skills are every bit as important as the underlying technology. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

DR. JAMES SHANNON Novartis

DRUG DEVELOPMENT IS A BUSINESS OF MAKING DECISIONS. The questions for development always are: how do we make decisions; how early can we make decisions so that we maximize the use of resources — people and money — and are we making the right decisions.

The Productivity Crisis

The pharmaceutical industry is trapped in a deepening productivity crisis, according to researchers from CHA Advances Reports. The years 2003 and 2004 marked a 25-year low point in worldwide market launches for new active compounds. At the same time, the number of investigational drug applications to the Food and Drug Administration reached a new high in 2004, passing a record mark that had been held since 1998. The discovery and preclinical development process appears to be highly productive, but a fraction of these candidates make it to the market.

Although the changing characteristics of early-stage compounds that emerge from the discovery process and animal models are part of the problem, the way that human trials are presently designed and conducted make greater contributions to the delays, failures, and exploding costs that are the current hallmarks of the clinical process.

Researchers at CHA Advances Reports say a bidirectional approach is needed to accelerate the clinical process and make it more effective. These two avenues — revamping of trial design and truly pervasive modeling and monitoring driven by information technology — are fundamentally different from each other but need to be implemented in a closely linked fashion. And none of these changes would involve concepts or technologies that are unknown today. Their suggestions include:

TRIAL DESIGN. Phase I would assume a new role as a brief confirmatory testing stage for the model for drug-human interactions that the sponsor has proposed. Phase II and Phase III would merge into a single, advanced-stage human testing phase that involves fewer patients than today, relying on relatively small populations that are highly homogenous with respect to key criteria of pharmacologic response. Systemic postmarketing studies and a significantly improved and extended postmarketing surveillance system that goes beyond adverse-event reporting will be integrated into a postmarketing monitoring phase that documents real-life use of the newly licensed drug.

PROCESS. New processes will be made possible through holistic mathematical models, such as the "virtual patient," which represents not the average human but variants of target patients of both sexes, different ethnicities, and various ages, with medical conditions that typically coexist in this target population; extensive biomarker monitoring; and pervasive computing, which will rely not so much on vastly improved software algorithms or hardware but more on the concept of seamless capture of every elementary act and seamless worldwide data exchange.

If these changes are implemented by 2015, CHA researchers say the stage would be set for a new world of drug development. The preapproval clinical-trial phase might be shortened to about three years, and 40% to 50% of all candidate compounds that enter this stage could complete it, with the majority of the failures occurring in the early human phase.

Source: CHA Advances Report, Waltham, Mass. For more information, visit advancesreports.com.