A NEW PARADIGM FOR CLINICAL DEVELOPMENT

The current clinical-evaluation process is fraught with inefficiencies, resulting in numerous compound failures and exploding development costs. To offset these obstacles, a number of pharmaceutical companies are employing novel clinical-trial models.

More than 80% of compounds that begin human clinical testing fail because of efficacy or safety issues, while many marketed drugs face withdrawal or severe use restrictions.

A New Paradigm for Clinical Development: The Clinical Trial in 2015, a recent report from AdvanceTech Monitor, discusses a strategy for reinventing clinical development.

The report outlines why a complete overhaul of the clinical-trials process is feasible from a conceptual, technical, and logistical point of view.

This report suggests that a more radical solution is needed and proposes a bidirectional approach to accelerate the clinical process and make it more effective. These two avenues, which can be summarized as revamping trial design and as 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. Though radical in effect, none of these changes would involve concepts or technologies that are unknown today.

According to the strategy laid out in the AdvanceTech Monitor report, the following changes are required:

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

These new processes will be made possible through holistic mathematical models such as the "virtual patient" (representing variants of target patients of both sexes, different ethnicities, various ages, and with medical conditions that typically coexist in this target population), extensive biomarker monitoring, and "pervasive computing" that will rely on the concept of seamless capture of every elementary act and equally seamless worldwide data exchange, driven by global standards.

REVAMPING TRIAL DESIGN

Within Schering-Plough Research Institute (SPRI), all of the company's R&D disciplines follow an integrated risk-management approach for each compound. This includes

Thought Leaders

ALEXIS BORISY, A.M. President, CEO, and Founder, CombinatoRx Inc., Cambridge, Mass.; CombinatoRx is a biopharmaceutical company focused on developing new medicines built from synergistic combinations of approved drugs. For more information, visit combinatorx.com.

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JOHN LAWRIE. VP, Process Solutions, Octagon Research Solutions Inc., Wayne, Pa.; Octagon Research is a leader in the electronic transformation of clinical R&D and offers a suite of regulatory, clinical, process, and IT solutions to the life-sciences industry. For more information, visit octagonresearch.com.

Using our proprietary combination high-throughput screening (cHTS) technology, CombinatoRx combines millions of pairs of existing and development-stage drugs in search of unexpected synergies where the new medicines feature new mechanisms of action distinct from the two drugs, targeting multiple pathways.

Alexis Borisy
CombinatoRx

stringent preclinical screening to uncover unwanted side effects very early in the development process, allowing for early termination of compounds.

"Very often, developing new medicines that use new mechanisms of action poses higher risks — both in terms of the potential for failure as well as unwanted side effects," says Thomas Koestler, Ph.D., executive VP, Schering-Plough Corp., and president of SPRI. "But this approach also offers the greatest potential to significantly alter disease progression rather than simply addressing disease symptoms."

Another change SPRI has made is creating a new department, Early Clinical Research and Experimental Medicine, which integrates novel scientific tools into its early development programs.

"This approach, which replaces the traditional clinical pharmacology group, allows us to minimize or eliminate risks that were difficult to address a decade ago," Dr. Koestler says.

Similarly, Kyowa Pharmaceutical Inc. has found that it has become increasingly important to streamline drug development and secure go/no-go decisions as quickly and cost effectively as possible.

"To meet this objective, we have established an approach that balances the company's scientific discovery and the high cost of developing pharmaceuticals by concentrating efforts on speeding up drug discovery to the proof of concept stage, or Kyowa's POC Fast strategy," says Joseph Brindisi, VP of business development and general counsel at Kyowa Pharmaceutical Inc. "This POC fast strategy enables Kyowa to move projects quickly to

CHANGING THE TRIAL PARADIGM

According to a new report from AdvanceTech Monitor, A New Paradigm for Clinical Development: The Clinical Trial in 2015, a more radical solution is needed for clinical development, and it proposes a bidirectional approach to accelerate the clinical process and make it more effective. With a full implementation of all envisaged changes by the year 2015, 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 validation phase.
- **The crucial function of advanced-stage human testing will be to determine** whether efficacy is sufficiently superior compared with the established standard of therapy to warrant the cost of launch and the mandated postmarketing monitoring.
- **Developers recoup development costs earlier and enjoy a longer life cycle** under patent protection, while paying closer attention to real-life use of the newly licensed drug.

Source: AdvanceTech Monitor, Woburn, Mass.
For more information, visit advancetechmonitor.com.

JONATHAN E. LIM, M.D. CEO and President, Halozyme Therapeutics Inc., San Diego; Halozyme is a development-stage biopharmaceutical company dedicated to developing and commercializing recombinant human enzymes for the infertility, ophthalmology, and oncology communities. For more information, visit halozyme.com.

JOHN MCKEARN, PH.D. CEO and President, Kalypsys Inc., San Diego; Kalypsys is a clinical-stage pharmaceutical company that is advancing the way drugs are discovered and developed. For more information, visit kalypsys.com.

WILLIAM J. NEWELL, J.D. President, Aerovance Inc., Berkeley, Calif.; Aerovance is a privately held biopharmaceutical company exclusively focused on developing and commercializing breakthrough medicines for asthma, cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD), and eczema. For more information, visit aerovance.com.

JAMES A. SCHOENECK. CEO, BrainCells Inc., San Diego; BrainCells is a leading-edge neurogenesis-based drug discovery and development company targeting novel therapies for depression, mood disorders, and other CNS diseases. For more information, visit braincellsinc.com.

RICK TARANTO. President, WorldCare Clinical LLC, Cambridge, Mass.; WorldCare Clinical (WCC), part of ProScan, is an imaging CRO, offering end-to-end imaging services in support of clinical trials for the pharmaceutical, biotechnology, and medical-device industries. For more information, visit wcclinical.com.

ARTHUR J. TIPTON, PH.D. President and CEO, Brookwood Pharmaceuticals, Birmingham, Ala.; Brookwood, a wholly owned subsidiary of Southern Research Institute, is a product-focused drug-delivery company. For more information, visit brookwoodpharma.com.

clinical-development process

We overcome failure to execute by operating between strategy, focus, and action in an extremely dynamic and seamless manner.

Dr. John McKearn
Kalypsys

We are seeing some great opportunities where pharma and drug-delivery companies can collaborate, such as our collaboration with Genzyme Pharmaceuticals, on designing particular drug molecules to be a better fit for drug-delivery technologies.

Dr. Arthur Tipton
Brookwood Pharmaceuticals

Phase IIa human efficacy clinical trials in a streamlined development plan that establishes POC and identifies those drugs that offer the most promise for future investment."

Kalypsys Inc. is another company that is taking a new approach to its Phase I designs. For its lead compound, the company used a combined single- and multiple-dose escalation design that allowed for the combination of two studies in one and established a more complete safety assessment using extensive traditional and novel biomarkers.

"The design of the Phase Ia clinical trial that we are wrapping up for our lead compound in metabolic disease is an example of the focus we put on being a fast, efficient, and effective pharmaceutical company," says John McKearn, Ph.D., CEO and president of Kalypsys. "This development model will help guide our dose selection for the Phase Ib study that we expect to initiate in early 2007. We will look to strategically implement innovative trial designs into all of our clinical programs moving forward."

Within specialty areas, many pharmaceutical companies are finding success by, for instance, focusing trial designs on specific mechanisms of action.

One such company is Aerovance Inc., which is limiting its expertise to biotherapeutics in the

respiratory and inflammatory areas, including asthma, cystic fibrosis, COPD, and eczema.

"We believe that there will be a focus on developing drugs that target novel and specific mechanisms of action and that act on upstream targets," says William Newell, J.D., president of Aerovance. "For instance, in developing our asthma and eczema programs, we are focused on blocking IL-4 and IL-13, both of which are targets that appear early in the cell-signaling cascades involved in the disease process."

Fovea Pharmaceuticals SA, a biopharmaceutical company that specialized in drugs for the treatment of ocular diseases and with a special focus on retinal pathologies, has since evolved into a company that offers a vertically integrated supply-chain approach to drug discovery, drug development, and drug commercialization with a multiteam structure.

"Fovea is driven by a sound business model that melds clear and rapid pathways to new products for short- and medium-term horizon programs, coupled with a strong discovery engine for longer-term horizon programs," says Bernard Gilly, Ph.D., cofounder, chairman, and CEO of Fovea Pharmaceuticals. "This model has

U.S. CLINICAL-TRIAL SPENDING INCREASES

Spending on clinical trials in the United States was almost **$24 billion** in 2005, according to research by BCC Research. This number was expected rise to **$25.6 billion** in 2006 and then to **$32.1 billion** in 2011, an average annual growth rate (AAGR) of 4.6%.

Biotechnology and pharmaceutical companies spent about **$51 billion** on research and development efforts, with **$21 billion** (41%) spent on clinical trials, according to a recent BCC report, The Clinical Trials Business. In comparison, government contributions to clinical trials were considerably smaller. The National Institutes of Health spent **$2.9 billion** on clinical trials in 2005 and budgeted **$3.0 billion** for 2006.

U.S. SPONSORED CLINICAL TRIALS WORLDWIDE

MARKET	2003	2004	2005	2006	2011	AAGR% 2006-2011
Number of clinical trials	5,517	6,655	8,386	9,967	13,211	5.8%
Clinical-trial spending	$17.6	$22.6	$23.9	$25.6	$32.1	4.6%

Note: Dollars are in billions
Source: BCC Research, Wellesley, Mass. For more information, visit bccresearch.com.

MAKING A CASE FOR DATA STANDARDS

As of Jan. 1, 2008, all electronic regulatory submissions to FDA's CDER will have to be in eCTD format. Implementation of eCTD requires process and technology changes and affects all functions that are contributing data and documentation across the drug-development life cycle.

John Lawrie
Octagon Research Solutions

According to John Lawrie, VP of process solutions at Octagon Research Solutions Inc., emerging standards such as eCTD (electronic common technical document) and CDISC SDTM (study data tabulation model) are having a significant impact on R&D professionals who are responsible for the documents and data that go into a submission. These standards require a focus on content, format, and development of processes that support the creation of new deliverables.

"For example, eCTD documents will require different quality checks that address the format of the document, as well as metadata associated with the document," Mr. Lawrie says. "CDISC compliant data sets will require new processes and quality checks as well. Smart companies that implement these standards and use them as an impetus for organizational initiatives to improve quality and manage processes will gain added and recurring efficiencies across functional lines."

Companies will also have to keep pace with new technologies, such as XML (eXtensible Mark-up Language), which according to Mr. Lawrie, is appearing everywhere in the drug-development and drug-approval process.

"All of the evolving industry standards have an XML component," he says. "The use of XML in the eCTD simplifies the drug-application process because it enables sponsors to reference previously submitted data from an investigational new drug application instead of resubmitting large amounts of information to the original marketing application. This saves time and money and also provides ease of access to all components of a drug application."

Mr. Lawrie says 2007 will be a transition year for many sponsor organizations as these companies move toward eCTD submission formats. In a draft proposed final rule, the FDA recently announced the withdrawal of three electronic submission guidances and has identified eCTD as the preferred format for electronic submissions.

"This means that as of Jan. 1, 2008, all electronic regulatory submissions to FDA's CDER will have to be in eCTD format," Mr. Lawrie explains. "Implementation of eCTD requires process and technology changes and affects all functions that are contributing data and documentation across the drug-development life cycle."

Mr. Lawrie says there is a silver lining for companies because the regulatory agency's electronic gateway is up and running, and electronic submissions are now being sent, accepted, and processed through this method, alleviating the need to send CDs, DVDs, or DLT tapes to the agency.

To access a FREE Podcast on this topic, featuring John Lawrie, go to pharmavoice.com/podcasts.

The Roche/Genentech acquisition/alliance model of diversification by separation remains the gold standard of success that has the potential to be replicated as the pharmaceutical and biotech industries converge. Opportunities also exist for pharmaceutical companies to leverage their internal biotechnology assets by forming separate subsidiaries to focus on biologicals.

Joseph Brindisi
Kyowa Pharmaceutical

allowed us to assemble a portfolio of near-term preclinical and clinical products that address major unmet needs in ocular diseases, with product candidates directed to the anterior segment as well as the retina."

IT-DRIVEN MODELING AND MONITORING

Kalypsys has focused on overcoming failure to execute by operating between strategy, focus, and action through a dynamic, yet seamless process.

"We overcome failure in models, assays, and measures by directly measuring the influence of model changes, the influence of known bias, and by multilayering very different test systems and conditions and mapping differences in the results," Dr. McKearn says. "We also are not afraid to stop a program if the results in the discovery phase are equivocal or inconclusive. We counter a failure from

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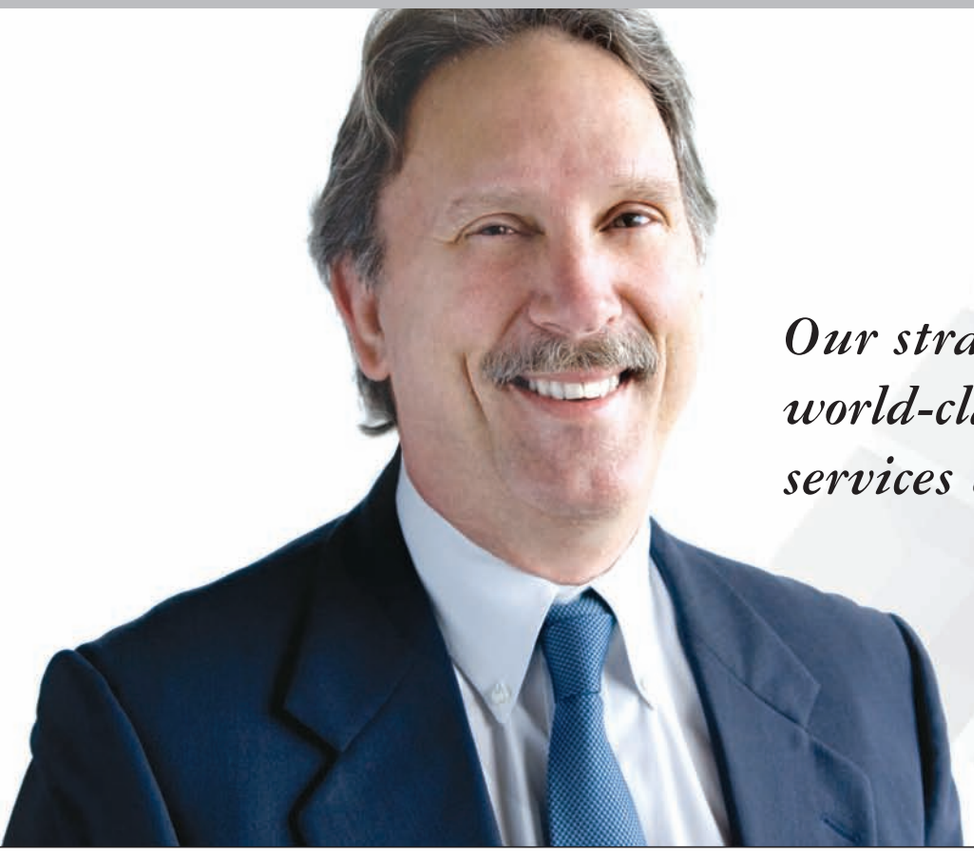

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John Hudak
Founder and President
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Fovea's business strategy is to build a valuable portfolio of clinical-development candidates from its own discovery platforms and complement these product candidates through acquisitions and collaboration with pharmaceutical or biotechnology partners. This strategy serves to balance our portfolio of drug candidates and life-cycle management.

Dr. Bernard Gilly
Fovea Pharmaceuticals

risk by feeding and reinforcing a learning laboratory culture in every aspect of our business."

Alexis Borisy, A.M., president, CEO, and founder, CombinatoRx Inc., believes that because the success rate of new chemical entity discoveries and ultimate commercialization opportunities continues to decline, some of the biggest opportunities in the next year and beyond are new technologies that allow for the evaluation of previously untapped sources, such as existing drugs for new and additional indications.

"Many drugs that are in use today — even aspirin, for example — are not fully elucidated with regard to their mechanisms of action," he says. "What is known, largely, is that they are safe and work for their specific, approved indication. But as we learn more about biology and pathways of disease, it is likely that we will continue to find additional — and surprising — uses for these drugs."

CombinatoRx is working on a new field of synergistic combination pharmaceuticals and is going beyond traditional combinations to create product candidates with novel mechanisms of action striking at the biological complexities of human disease, including immunoinflammatory, oncology, metabolic, neurodegenerative, and infectious diseases.

"Our proprietary combination high throughput screening (cHTS) technology rapidly screens millions of pairwise combinations from the existing body of about 2,000

CLINICAL IMAGING: THE KEY TO REDUCING DRUG-DEVELOPMENT COSTS

According to a Tufts Center for the Study of Drug Development report, drug-development costs were $802 million in 2004 compared with $231 million in 1991.

These increased costs can be attributed to a number of factors, says Rick Taranto, president of WorldCare Clinical.

"Some increases, such as inflation, are expected," he says. "Other causes are more complex. For example, today there is a higher failure rate of drug candidates during the clinical-development process and a plateau in the drug-development pipeline. Out of 200 million possible drug compounds, fewer than one in every 10,000 will make it through the FDA process and actually become an approved drug for public use."

There are other factors as well, he says, such as the fact that easy drug targets have already been taken and the chronic diseases are harder to study. Pharmaceutical companies are not able to develop as many blockbuster compounds to generate R&D revenue.

At one time, the generation of these compounds was able to outpace the exclusivity patent of 20 years, and companies were able to secure large revenue for future R&D expenditure.

"Now, with the length of time it takes to develop a drug, the average revenue-generating time of an exclusivity patent has decreased from eight years to two years, according to Tufts researchers," Mr. Taranto says.

With pressure from the public and the Food and Drug Administration to reduce their retail costs, the industry is looking at ways to decrease research and development expenditure yet still maintain quality.

Since the average time to bring a new drug to market is about 10 years to 15 years, a reduction in this development time will have a significant impact not only on bringing the drug to the public faster, but also on the cost decrease that can be passed on to the public.

Mr. Taranto says clinical imaging is a technology that is rapidly becoming a critical component in the drug-development process.

"The use of imaging biomarkers in the early stages of pharmaceutical testing is helping companies make go/no-go decisions in the early stages of the drug-development process, thereby making the development process more efficient and cost effective," he says. "Data are available sooner, which allows companies to make critical decisions regarding the progress of a compound's development, increasing development efficiencies, and decreasing drug costs."

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FASTEST DRUG DEVELOPERS OUTPERFORM THEIR PEERS

There is no single way for companies to be the fastest drug developers; it is all about each company's commitment to consistently apply strategies and practices across its portfolio.

Kenneth Getz
Tufts CSDD

Drug companies that develop and launch new products faster than their peers perform consistently better across a number of dimensions, earn higher revenue, and have lower development costs, according to analysis from the Tufts Center for the Study of Drug Development.

Between 2000 and 2005, drugs developed by the fastest companies each gained an average of $1.1 billion in incremental prescription revenue and saved an average of $30 million in out-of-pocket development costs compared with those of the slowest companies, Tufts CSDD reported.

"Speed-demon companies — the fastest drug developers — are consistently implementing efficient R&D practices across their portfolios," says Kenneth A. Getz, senior research fellow at Tufts CSDD and coauthor of the study. "These companies have far less development and regulatory time variability, kill projects sooner, and are better at setting resource priorities."

There were broad themes common to companies that were identified as being faster than others: active interaction with regulatory agencies; enterprisewide adoption of e-clinical technology solutions; high use of contract clinical service providers; and effective management and prioritization of resources, including the termination of poor projects sooner.

"Most striking was the commitment by these companies to implementing targeted initiatives to address carefully identified process inefficiencies," Mr. Getz says.

According to Tufts CSDD, Bayer, AstraZeneca, Allergan, Boehringer Ingelheim, and Merck are the five fastest development companies in the 2000 to 2005 period; each was able to shorten its development and regulatory cycles by as much as 17 months, compared with average performing drug developers.

To assess the fastest drug developers, Tufts CSDD evaluated 104 approved drugs for 29 companies.

The Tufts CSDD study also found:

- As a group, the fastest third of companies reduced their median development period by 20% (from 66.5 months between 1994 and 1999 to 53.0 months between 2000 and 2005) and held regulatory cycle times flat at about 13 months in the 2000 to 2005 period.
- In each therapeutic area where they compete, speed-demon companies beat the median overall cycle time more than 83% of the time.
- Fastest companies terminate 56% of discontinued projects in Phase I clinical development vs. 36% for the slowest companies.
- A one-day speed advantage typically saves $37,000 in out-of-pocket development costs and nets an additional $1.1 million in daily prescription revenue for an average performing drug.

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

Our strategy to ensure the quality of our drug-development efforts is to focus on the people we attract to the company. We want to ensure that we are using the skills of people who know the ins and outs of the development process.

William Newell
Aerovance

drugs to discover novel synergistic combination drug candidates," Mr. Borisy says. "These candidates have new mechanisms intended to approach disease treatment from multiple biological pathways."

To date, he says the company has discovered and developed a broad and growing product portfolio through this process.

"This approach has been tremendously successful, allowing us to rapidly move drug candidates from preclinical to Phase II proof-of-concept clinical trials in about two years and at a development cost of less than $10 million," Mr. Borisy says. "To date, our success rate from our pipeline is about 67%, a dramatic improvement compared with the industry average of 10% to 20%, according to recent industry studies."

At Halozyme Therapeutics Inc., the strategy to improve the drug-development process includes the use of a proprietary drug-enhancement system, called Enhanze Technology, which facilitates the penetration and

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Dr. Jonathan Lim
Halozyme

With our breakthrough neurogenesis-based technology and the processes we've established, we can identify compounds with neurogenic properties, select those with the highest probability of success in the clinic, and direct their repositioning and development for a wide range of CNS diseases.

James Schoeneck
BrainCells

All of our R&D disciplines follow an integrated risk-management approach for each compound. This includes stringent preclinical screening to uncover unwanted side effects very early in the development process, allowing for early termination of those compounds.

Dr. Thomas Koestler
Schering-Plough Research Institute

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Another company that is employing a drug-delivery technology to improve the development process and create value and better treatments is Brookwood Pharmaceuticals.

"Specifically, drug-delivery technologies have the potential to take drugs discarded during development because of half-life or other challenges and turn them into blockbusters," says Arthur Tipton, Ph.D., president and CEO of Brookwood Pharmaceuticals. "Local drug delivery has tremendous applicability in a number of clinical opportunities, including ocular disease, orthopedics, and some cardiovascular and oncology applications. The great clinical and market successes of the drug-eluting stents have provided optimism for other drug-device applications."

A neurogenesis-based technology is the platform that BrainCells Inc. is employing to speed up drug development. Neurogenesis is the process by which preexisting stem cells in the adult human brain produce new brain tissue, including neurons.

"We can identify compounds with neurogenic properties, select those with the highest probability of success in the clinic and direct their repositioning and development for a wide range of CNS diseases," says James Schoeneck, CEO of BrainCells Inc. "This approach increases efficiency while significantly reducing the risk inherent in drug development."

Mr. Schoeneck says there is a growing trend to focus on repositioning drugs that meet safety endpoints in the clinic but fail to meet efficacy endpoints. But new technologies allow companies to effectively identify a potential new use for a compound and shift the focus in the development process.

"By using this formula, we can cut the development time in half to a four-, five-, or six-year timeframe and gain a better understanding as to which drugs can succeed in the clinic," he says. ✦

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