STEM-CELL TECHNOLOGIES Could Improve Preclinical Testing


Bruce Carlson

The excitement around stem cells has understandably been in the potential for therapy, but drug development is where stem cells may have the most impact on healthcare, says Bruce Carlson, Publisher of Kalorama Information.

With more than 90% of drugs entering clinical development failing to get to market because of lack of effectiveness or adverse side effects not detected in animal tests, a solution is needed. Early toxicity testing is a particular problem, since there are currently no good models for determining whether a drug will be toxic in humans. Some unsafe products advance through testing and approval, only to be pulled from the market later at huge expense.

Many of these issues could be avoided with preclinical tests using stem-cell technologies, potentially saving drug developers millions of dollars.

Kalorama Information's report, Stem Cells: Worldwide Markets for Transplantation, Cord Blood Banking, and Drug Development, finds that although stem cell-based drug development technologies are in an early stage of development, and will most likely not become available before 2012 at the earliest, their prospects are promising.

Stem-cell technology could provide a virtually endless supply of liver or heart cells.

"The excitement around stem cells has understandably been in the potential for therapy, but drug development is where stem cells may have the most impact on healthcare," says Bruce Carlson, publisher of Kalorama Information. "Stem-cell technology could provide a virtually endless supply of liver or heart cells for testing, saving developers tens, if not hundreds of millions of dollars in direct testing fees, as well as indirect costs related to drug recalls."

Recognizing the potential of stem cells, GlaxoSmithKline, AstraZeneca, and Roche established a new venture in 2007, Stem Cells for Safer Medicines Ltd., to develop effective ways of using human embryonic stem cells to screen for potentially dangerous side effects of new drugs before they go into clinical trials.

DRUG DEVELOPERS AND MAKERS OF DELIVERY DEVICES Continue to Partner

A number of factors are converging to create both risk and opportunity for drug makers and their device-manufacturing partners. These factors are giving rise to a new generation of sophisticated, application-specific combination drug-device products designed to satisfy patient preferences while addressing managed care initiatives and the limitations of new classes of therapeutic drugs. Because of their ability to safely and reliably satisfy treatment protocols and compliance goals, these devices will have a significant impact on the future of patient self-administration.

Developers are addressing this evolving marketplace environment by working closely with delivery device designers.

A recent report from Greystone Associates, Drug Delivery for Self-Administration: Technologies, Combination Products and Pipeline Prospects, offers an evaluation and analysis of the technology, products, and participants providing the driving force behind this growing segment of the pharmaceutical industry.

The report projects that therapy-specific, drug-device combination products will continue to expand as device designers and drug developers collaborate to create delivery systems that address the specific needs of end users. For example, the recent escalation in new biological drugs, such as antibodies and recombinant proteins, is placing renewed emphasis on drug-delivery technologies capable of delivering drug therapies while avoiding the digestive tract. Other factors driving the category include new classes of drugs for previously refractory conditions, the growing trend toward self-administration for chronic diseases, shifting patient demographics in industrial countries, and continued pressure to control healthcare costs.

As patients live longer and are increasingly diagnosed with chronic and often debilitating ailments, pharmaceutical decision-makers find themselves examining ways to adapt their organizations to address the resulting healthcare needs in both human and business terms.

According to the report, the potential for drug therapy to impact the quality of life has never been higher and is now seen as exponential, as biotechnology techniques and computational drug modeling converge with the genomic knowledge base and bioinformatics to provide powerful tools to researchers.

But to fully realize the healing and market potential of advancing drug discovery techniques, designers and developers must deal with a diverse spectrum of challenges that include limited drug stability and bioavailability, and patient-compliance issues stemming from compromised physical and/or cognitive function.

Developers are addressing this evolving marketplace environment by working closely with delivery device designers from early on in the drug-development cycle to define the optimal combination of dosing and administration. Drug-delivery providers are applying advanced technology to control drug-release characteristics. The elimination of spikes in blood concentration and the lengthening of delivery times are aimed at reducing side effects related to immediate release and providing the convenience of less-frequent dosing.

Medical Affairs Shift to Meet DEMANDS OF INCREASED REGULATIONS

The increasingly stringent regulatory environment has had a dramatic impact on the organization and support of pharmaceutical companies' medical affairs function.

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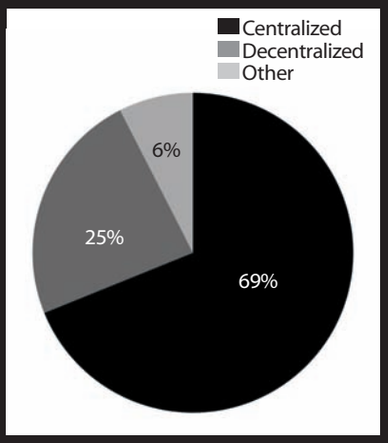
According to a report from Cutting Edge Information (CEI), the reporting structures of medical affairs departments have shifted away from marketing oversight over the past six years in response to pressures related to compliance. In fact, CEI data show that only 7% of medical affairs departments are currently housed under marketing, compared with 43% in 2002.

Medical Affairs: Delivering Strategic Value examines pharmaceutical companies' medical affairs structures, spending and staffing resources, and

COMPANIES' MEDICAL AFFAIRS STRUCTURES



• One company has both a centralized and decentralized structure

Source: Cutting Edge Information, Durham, N.C.
For more information, visit cuttingedgeinfo.com.

strategies in response to the current compliance-driven, global environment.

Based on interviews with medical affairs executives at several top pharma companies, the report provides several best practices detailing how leading companies adapt and thrive commercially while still remaining compliant.

The study also offers strategies for how medical affairs teams can improve internal communication and coordination, as well as negotiate effectively for additional resources.

"Through our research, we found that companies responded to the regulatory landscape in different ways," says Amanda Zuniga, lead author of the report. "Companies are extremely aware of the need to stay compliant, and they have learned to adjust. The most progressive companies have even used the regulatory changes as a springboard for growth and re-examination."

In the report, CEI analysts explore the different ways in which several top companies' medical affairs organizations are structured and the advantages and disadvantages of each structure. For example, nearly 70% of the participating pharmaceutical companies have established a centralized medical affairs structure, which helps streamline communication and coordination across the global markets that companies now span.

Centralization enables the medical affairs function to accomplish many objectives, including:

- Developing, implementing, and executing a unified medical affairs strategy
- Sharing tools and best practices across different markets
- Increasing functional expertise, knowledge, and specialization
- Allocating resources efficiently
- Meeting the global needs of the company with greater ease

Yet while a centralized structure facilitates medical affairs' tasks, departments continue to face challenges in efficiently completing them. Many medical affairs executives note that effective communication and coordination across geographical markets still present obstacles to even the most centralized of organizations.

By contrast, one of the biggest advantages to having a geographically decentralized medical affairs structure is the ability of these teams to concentrate on the particular needs of an individual market. Since markets can vary widely, this narrower focus allows teams to customize their efforts solely based on the necessities of their market.

A decentralized structure nonetheless lacks many of the benefits of a centralized one — in particular, the ability to efficiently share tools and processes. Moreover, decentralized medical affairs teams sometimes find it more difficult to launch a unified medical affairs strategy.

PRESCRIPTION-DRUG ABUSE Threatens Availability of Pain Medication

Abuse of prescription pain medications is a rapidly growing problem in the United States, in part because of ease of access to these products. According to the 2008 National Drug Control Strategies Report, 71% of prescription pain medication abusers obtained the drugs from family and friends, and prescription drug abuse exceeds marijuana use among 12- to 13-year-old children.

Abuse of prescription pain medications is a rapidly growing problem in the United States, in part due to ease of access.

This troubling trend is causing regulators to consider restricting certain pain medicines or pulling them off the market altogether, a situation that will hurt the United States' 75 million chronic pain patients.

Lawmakers are committed to helping pain sufferers, but their resolve is hampered by what seems to be a trade-off between allowing continued access to pain relief and public safety from drug abuse.

"Chronic pain remains undertreated in this country," says Albert Ray, M.D., chairman of The National Pain Foundation. "Every morning millions of people wake up in pain, unable to work or just live their lives. The social and economic costs for society and for people living in pain are enormous."

The National Pain Foundation hopes that greater general awareness of the importance of safe and appropriate use of prescription drugs will help maintain chronic pain sufferers' access to vital medications.

Doctors and other members of the medical community can be especially effective in preventing prescription drug abuse. About 180 million Americans age 18 or older consult their healthcare provider at least once a year. These visits are valuable opportunities to educate patients and screen for drug and alcohol abuse.

"It's up to each of us to make sure that irresponsible use of prescribed pain medications does not make it harder for legitimate pain patients to have access to drugs that can greatly improve their quality of life," Dr. Ray says.

New Therapies Won't Outperform Current LUNG-CANCER REGIMEN

Despite the impending emergence of a promising new wave of treatments for non-small-cell lung cancer (NSCLC), physicians believe they will not match the current gold-standard regimen for treating the disease.

That's the finding in the Decision Resources report, Non-Small-Cell Lung Cancer (Advanced): Current Gold-Standard Therapy Continues to be Most Efficacious. The current regimen used as a first-line treatment for the disease is comprised of Avastin, from Roche and Genentech; and Taxol and Paraplatin, both from Bristol-Myers Squibb.

Physicians believe newer therapies will not match the current gold-standard regimen for treating the disease.

"Although some therapies in development for advanced NSCLC hold promise, most have efficacy, safety and tolerability, and/or delivery features that merit inferior scores compared with the Avastin/Taxol/Paraplatin regimen," says Andrew Merron, Ph.D., analyst at Decision Resources.

"A therapy's effect on overall survival is the attribute that most influences prescribing decisions in advanced non-small-cell lung cancer," Dr. Merron continues. "Data and the opinions of interviewed thought leaders indicate that Avastin/Taxol/Paraplatin has advantages over the sales-leading combination of Sanofi-Aventis' Taxotere and Bristol-Myers Squibb's Platinol-AQ on overall survival."

According to the report, AstraZeneca's next-generation NSCLC therapy, Zactima, is expected to launch this year in the United States and Europe, and in Japan in 2010. The report projects that Zactima will earn 4.7% patient share by 2016. Surveyed oncologists indicate that they would prescribe Zactima to 30% of their patients with advanced non-small-cell lung cancer. But 38% of the physicians surveyed indicate they will use Zactima as an adjunct to current therapy rather than as a replacement.

Use of Multiple Sources Strengthens **COMPETITIVE INTELLIGENCE**

The key to collecting meaningful competitive intelligence (CI) is using multiple information sources to gather data. Best-in-class CI groups use a variety of methods and often experiment with new collection sources to ensure data-gathering efforts cover as much ground as possible.

A company's salesforce can prove to be an invaluable resource for gathering, communicating, and incorporating competitive intelligence into strategy.

Research conducted by Best Practices, Competitive Intelligence Case Studies and Techniques for Excellence, outlines the benefits of collecting and synthesizing data from public documents to spot operational changes, as well as integrating the salesforce into the CI communication process to transmit information learned from customers.

Companies surveyed for the Best Practices study use tools and techniques ranging in complexity, from picking up the phone and calling a competitor to monitoring the air emissions outside a competitor's manufacturing plant.

Additionally, benchmark companies leverage other groups' analyses to supplement competitive intelligence collection efforts. For example, CI groups engage the salesforce and other field operations in gathering competitor data, review win-loss analyses, and interview employees who previously worked for other companies.

These methods help keep data collection costs down while increasing the CI group's exposure in the organization.

A company's salesforce can prove to be an invaluable resource for gathering, communicating, and incorporating competitive intelligence into strategy. The salesforce can learn a great deal of information about competitor products and messages through dealings with customers. In turn, CI teams can provide the salesforce information to help them sell to customers.

Perhaps the most direct method that illustrates the integration of competitive intelligence into market strategy is to provide the salesforce promotional material that reinforces one product over a competitor's brand.

IMPORTANT LESSONS IN COMPETITIVE INTELLIGENCE GATHERING

- Ask why the information is needed. If you can explore with the clients what would happen if they did or did not get that information, you can determine what and how to deliver the information back to the client.
- Involve product team members in CI efforts. Since CI groups often act as industry generalists, product team members must supply the specific topic expertise. CI groups are experts at getting the information, but they need to partner with the brand teams to optimize both groups' knowledge.
- Keep it timely and keep it quick. A 300-page CI report is often useless to the stakeholder. Lengthy reports are nice to have but tough to implement.
- Keep communication informal. Formal reports look nice on the shelves, but they are not often acted upon. Informal communication works better with CI.

Source: Best Practices, Competitive Intelligence Case Studies and Techniques for Excellence. For more information, visit best-in-class.com.

Pharmacy Automation Could Help Reduce **PRESCRIPTION ERRORS**

One-third of the United States' 225 million prescription-takers say they have either personally experienced a prescription error or know someone who has. An estimated 1.5 million people become sick, injured, or die annually as a result of medication errors, and 88% of medication errors result from the wrong drug or dose.

One-third of the United States' 225 million prescription-takers say they have either personally experienced a prescription error or know someone who has.

Yet most consumers choose their pharmacies for speed and convenience, rather than safe prescription practices, according to a national consumer survey conducted by Parata Systems.

More than half of survey respondents cited proximity to work or home as the No. 1 reason for choosing a pharmacy, followed by pricing at 23%. But a pharmacy's use of automated dispensing equipment, a proven strategy for reducing prescription errors, ranked last in importance, cited by just 2% of respondents.

The Parata Prescription Safety 2008 survey, available at myprescriptionsafety.org, notes that more than half of American adults take at least one prescription daily.

As the country prepares to sustain a generation of aging baby boomers, the number of people taking multiple prescriptions will only increase; the estimated number of prescriptions filled in the United States exceeded 4 billion in 2007, compared with 2.6 billion just 10 years ago.

Consumers decisively ranked pharmacists (49% of respondents) over doctors (15%) as principally responsible for ensuring their prescriptions are accurate, the survey found. While 91% of consumers asked could name the doctors who wrote their last prescriptions, only 36% could name the pharmacists who filled them. Further, the vast majority of prescription-takers (80%) spend less than two minutes speaking to their pharmacists when they pick up their medications, and almost half (45%) don't talk to them at all.

"People think nothing of waiting an hour to spend 10 minutes with their doctors, while at the pharmacy their focus is on speed," says Tom Rhoads, executive VP of Parata. "Yet, spending that same 10 minutes with their pharmacists can literally save lives."

With the average pharmacy filling more than 60,000 prescriptions a year, automated dispensing technology is an important tool to help these busy pharmacies handle their prescription load with a greatly reduced risk of error.

ONCOLOGY MARKET Offers High Risk, Reward

The oncology market has experienced significant change in recent years, creating opportunities for a range of new and established biotechnology players. New product development still presents significant risk for industry players but is essential to remain competitive within the category.

The Cancer Market to 2012 is a new report from Business Insights that provides comprehensive coverage of the major markets in global cancer care. The report analyzes current leading treatment brands within each cancer indication and profiles eight of the market's leading players.

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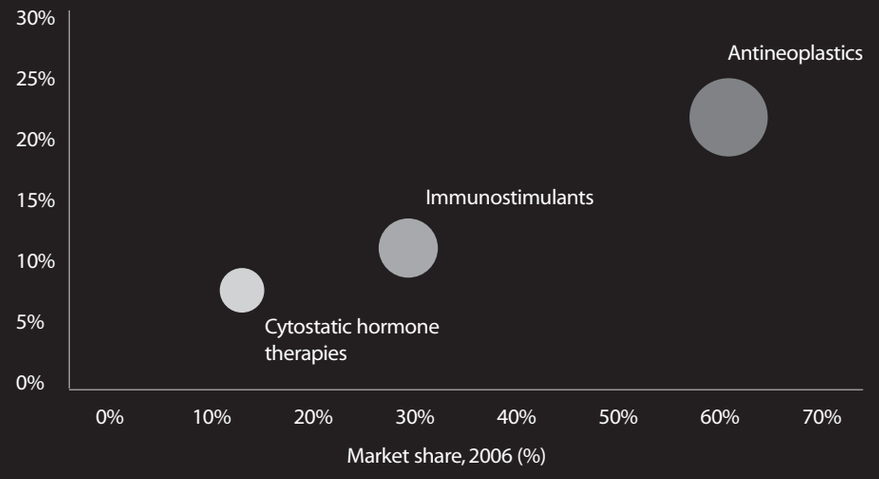
Oncology accounts for the third-largest source of revenue within the pharmaceutical industry.

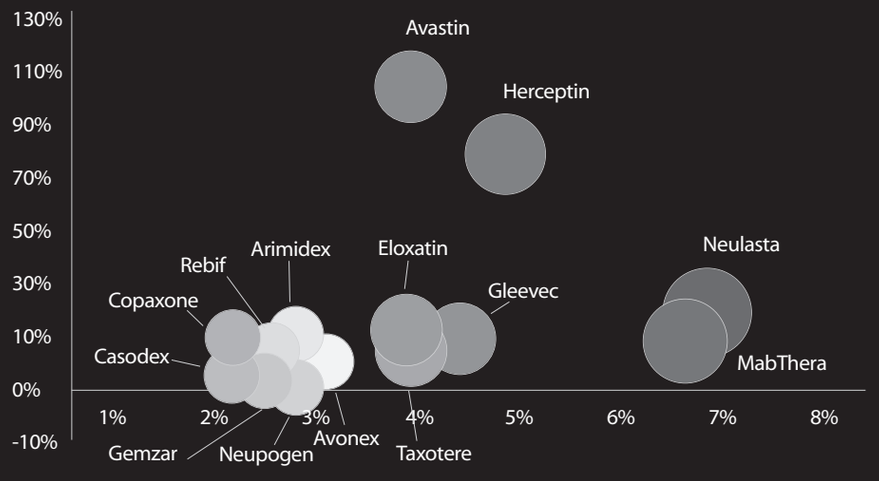
Major companies have begun to focus

COMPETITIVE DYNAMICS OF THE GLOBAL CANCER MARKET BY DRUG CLASS, 2006



Source: Business Insights, London. For more information, visit globalbusinessinsights.com.

COMPETITIVE DYNAMICS OF THE LEADING BRANDS IN THE GLOBAL CANCER MARKET, 2005-2006



Source: Business Insights, London. For more information, visit globalbusinessinsights.com.

R&D activities upon the development of compounds with strong prospects across multiple indications, as efforts to create blockbuster products intensify. The subsequent increases in product sales volumes are rapidly changing the competitive landscape of the cancer market.

Some key findings of the report:

- The cancer market expanded by 17.9% during 2006 and is forecast to reach $40.9 billion by 2012. The highest growth will occur in the antineoplastic class of drugs, which is expected to become the primary growth driver of the cancer market over the next four years.
- The leading eight companies represented $17.9 million, or 65%, of the global cancer market in 2006. AstraZeneca and Novartis are forecast to achieve the most rapid growth in their cancer portfolios over the forecast period, with modest gains expected for Amgen, Sanofi-Aventis, and Lilly.
- New launches such as GlaxoSmithKline's Tykerb, Pfizer's Sutent, and Nexavar from Bayer and Onyx Pharmaceuticals will continue to drive rapid market growth because of their utility across multiple indications and specific side-effects profiles.
- With several leading blockbuster oncology products set to lose patent protection over the forecast period, immense opportunities will open up for generic manufacturers.
- Major companies have begun to focus R&D activities upon the development of compounds with strong prospects across multiple indications, as efforts to create blockbuster products intensify. Future blockbusters are forecast to include AstraZeneca's Zactima and Recentin, as well as Merck's cervical cancer vaccine, Gardasil.
- Colorectal cancer, non-small-cell lung cancer, breast cancer, and ovarian cancer are the most common indications targeted by oncology drugs in development. Additional indications, such as renal cell carcinoma and non-Hodgkin's lymphoma, offer significant incentives for drug developers if the molecules are granted orphan-drug status.

Follow up

BEST PRACTICES LLC, Chapel Hill, N.C., is a research and consulting firm that studies the best business practices, operating tactics, and winning strategies of world-class companies. For more information, visit best-in-class.com.

BUSINESS INSIGHTS, London, is a market analysis company. For more information, visit globalbusinessinsights.com.

CUTTING EDGE INFORMATION, Durham, N.C., provides research and consulting to the pharmaceutical industry and the financial services industry. For more information, visit cuttingedgeinfo.com.

DECISION RESOURCES INC., Waltham, Mass., provides market research and advisory services on significant drug markets. For more information, visit decisionresources.com.

GREYSTONE ASSOCIATES, Amherst, N.H., is a medical and healthcare technology consulting company that provides services in strategic planning, venture development, product commercialization, and technology and market assessment. For more information, visit greystoneassociates.org.

KALORAMA INFORMATION, New York, a division of MarketResearch.com, conducts independent market research for the life-sciences industry. For more information, visit kaloramainformation.com.

THE NATIONAL PAIN FOUNDATION, Englewood, Colo., is a nonprofit advocacy group that provides information, education, and support to chronic pain patients and their communities. For more information, visit nationalpainfoundation.org.

PARATA SYSTEMS LLC, Durham, N.C., makes automated dispensing systems and other safety technology solutions for pharmacies. For more information, visit parata.com.