

# GEN

## Genetic Engineering & Biotechnology News

Biotechnology from bench to business

Volume 29, Number 14 August 2009

### Molecular Diagnostics & Infectious Disease

One fast-emerging molecular diagnostics market is screening for methicillin-resistant *Staphylococcus aureus* (MRSA).



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For more information, see page 20

OMICS

Drug Discovery

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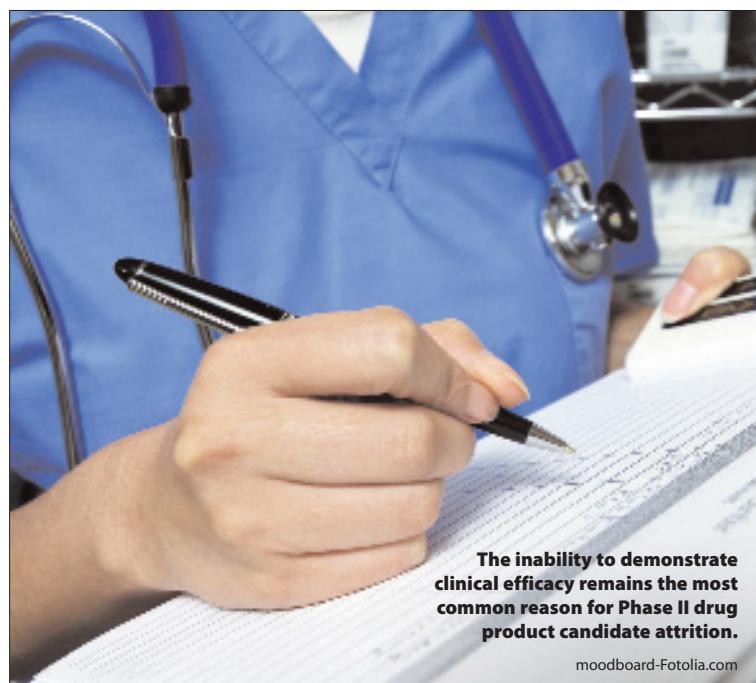
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Multiple factors must be considered in order to streamline operations.

## Overcoming Phase II Attrition Problem



Success Here Should Help Pharma Industry Boost Its R&D Productivity

Allan B. Haberman, Ph.D.

The most important challenge facing the pharmaceutical industry in 2009 is the need to improve R&D productivity. Since the mid-1990s, the total number of novel drugs, including new chemical entities (NCEs) and biologic license applications (BLAs) approved per year, has generally declined.

At the same time, the cost of bringing a drug to market has risen precipitously. In 2001, the cost to discover and develop a drug that successfully reached the market was approximately \$800 million; it had risen to approximately \$900 million by 2004. Some R&D executives have predicted that the cost to develop a marketed drug will reach \$2 billion by 2010.

Declines in the number of approved drugs in a given year are mainly the result of high rates of attrition of pipeline agents during the preceding 10–12 years.

For example, in a 2004 analysis in *Nature Reviews Drug Discovery*, See Phase II Attrition on page 64

## Bringing Greater Efficiency to Antibody Manufacturing

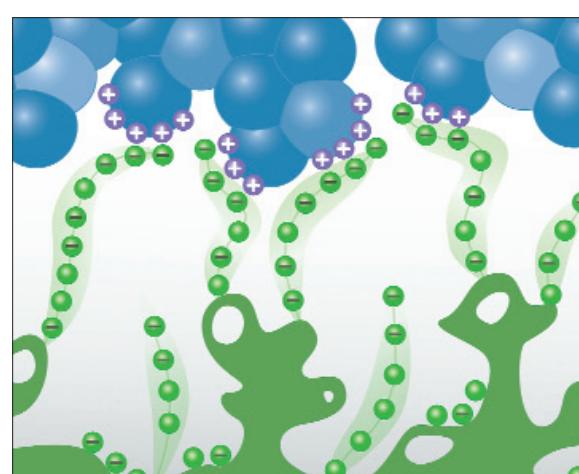
### Biological Production Challenges Form Basis for Debate at Annual Bioprocessing Forum

Susan Aldridge, Ph.D.

At the “Biological Production Forum” held recently in Dusseldorf, there were many lessons for those involved in monoclonal antibody manufacturing. In a wide-ranging presentation, Günter Jagschies, Ph.D., senior director R&D, strategic customer relations, GE Healthcare ([www.gehealthcare.com](http://www.gehealthcare.com)), spoke about future requirements for monoclonal antibodies.

According to a recent PhRMA (Pharmaceutical Research and Manufacturers of America) report, there were over 190 antibodies in clinical development in 2008. Given that the success rate in Phase I is low, it is unlikely that more than 50 new antibodies will actually come onto the market. But how many of these will require large-scale manufacture?

Dr. Jagschies has reviewed the best-selling antibod-



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ies and determined that the annual amounts needed range from 1,197 kg (Remicade) to 25 kg (Vectibix). He believes few future monoclonals will need large-scale manufacture, and that the chance of winning

See mAb Production on page 48

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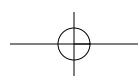
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## Phase II Attrition

Continued from page 1

Ismail Kola and John Landis found that the ten largest pharmaceutical companies experienced an average success rate over all therapeutic areas of only 11%—only about one in nine drugs made it from first-in-man to approval by U.S. and/or European regulatory agencies.

Moreover, since the R&D cost per successful drug includes costs for both drugs that reach the market and those that fail, pipeline attrition (especially in late-stage

development, where costs of conducting clinical trials are the greatest) is the major contributor to the alarming rise in R&D costs. Thus, reducing developmental attrition is a central issue both in increasing R&D productivity and containing R&D costs.

### The Problem

Industry analysts have determined that the greatest amount of attrition occurs in Phase II. Kola and Landis found that 62%

of compounds entering Phase II trials failed. Phase III attrition was also high, with 45% of compounds entering Phase III failing. Based on such analyses, the pharmaceutical industry speaks of the “Phase II attrition problem”, which carries over into Phase III and in some cases into the preregistration and postmarketing phases as well.

According to Charles Gombar, Ph.D., vp of R&D strategy and business improvement at Wyeth, “Phase II attrition definite-

ly got a lot of people’s attention in the industry. Quite frankly, I was more worried about Phase III attrition, because that’s the very expensive part of development.”

Low R&D productivity, increasing R&D costs, and the impending patent expiration of blockbuster drugs (with a dearth of new high-valued drugs to replace them) have been major factors in the wave of mergers, acquisitions, and restructuring in the pharmaceutical industry in the late 2000s. A major goal of large pharmaceutical company mergers has been to reduce R&D costs via consolidation and staff reductions. Some corporate restructurings have been aimed at making large pharmaceutical companies more biotech-like, to achieve the R&D productivity of the best biotechnology companies.

However, as shown by the results of an earlier wave of big mergers in the late 1990s and early 2000s, pharmaceutical companies cannot merge or restructure themselves out of the industry’s productivity crisis, at least over the medium to long term. They need to also develop viable R&D strategies that can enable them to improve productivity.

### Factors Behind Increases in Attrition

During the past decade, the largest causes of attrition have been lack of efficacy and safety issues (toxicology and clinical safety failures); each of these factors accounted for 30% of attrition.

Pharmaceutical industry executives and researchers often attribute the high rates of attrition seen in development since 2000 to the fact that companies have been addressing more complex diseases with high unmet medical need (e.g., cancer, CNS diseases, autoimmune diseases, HIV/AIDS), and establishing higher standards for success in clinical trials, and for approval due to improved standards of care in many diseases. Ironically, the latter is a result of the success of the pharmaceutical industry in developing improved therapies.

These two factors are usually concerned with efficacy. A third issue often given is increased scrutiny by regulatory agencies, usually about safety.

Targeting complex diseases typically involves discovering drugs that have novel mechanisms of action and/or address unprecedented targets. Drugs that address unprecedented targets are much more likely to fail in Phase II (by a factor of two- to four-fold) than are drugs that address preceded targets. The most common reason for this attrition is failure to demonstrate clinical efficacy.

“On the Phase II attrition issue, I think that what we saw over the past decade was a big change in the drug development game,” Dr. Gombar added. “Part of that change stemmed from the fact that you must have novel drugs. You have to bring new value and real medical value to the marketplace. That naturally drives people to novel targets, which carry higher risk and much more uncertainty. I’m not sure whether Phase II attrition is really an issue or simply a manifestation of how the drug development game has changed.”

Many industry commentators attribute the

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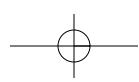
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low numbers of approvals in recent years to increased FDA scrutiny. The high rate of attrition in the drug development process, however, has been severely limiting numbers of NDA and BLA applications submitted to the FDA, especially high-quality applications that can withstand the agency's scrutiny.

Also, the FDA is asking for more information than in previous years, not only to avoid postmarketing safety problems, but because there has been less scientific and medical literature available for novel drugs submitted in recent years. These drugs have often been designed to address unprecedented targets. FDA reviewers are unfamiliar with these mechanisms and so require more information.

Thus, the high rate of pipeline attrition and the need to address unprecedented targets and mechanisms of action have greatly affected relationships between the industry and regulatory agencies.

#### Centrality of Translational Medicine

Since the mid-2000s, the pharmaceutical industry has been attempting to reduce Phase II attrition by implementing strategies centered on the discipline of translational medicine, which is aimed at obtaining evidence that can help clinical researchers predict outcomes of treatment with experimental agents. This especially involves obtaining proof of concept (POC) that a drug is likely to be safe and efficacious early in development by carrying out clinical trials that are designed to determine POC rapidly and at relatively low cost.

Biomarkers for determining pharmacodynamic, efficacy, and safety parameters are key to these clinical studies; they can also be used to give an indication of likely efficacy much more quickly than clinical endpoints, which are required for registration trials.

In a survey of drug development researchers conducted by Insight Pharma Reports, in conjunction with its recently published report, "Approaches to Reducing Phase II Attrition," the largest number of respondents' companies have adopted translational medicine programs aimed at improving the efficiency and effectiveness of early drug development (Figure 1). This is in accord with the widespread reliance on such programs by pharmaceutical and biotechnology companies in recent years.

The report discusses a strategic framework for reducing the risk of Phase II and Phase III attrition due to addressing unprecedented targets. These strategies are designed to identify those targets that have the best chance of success in the discovery phase and employ early-stage POC clinical trials to

**Allan B. Haberman, Ph.D.**  
(allanhab@biopharmconsortium.com), is principal of Haberman Associates. This article is based on "Approaches to Reducing Phase II Attrition," an Insight Pharma Report published by Cambridge Healthtech Institute. For information about the report contact David Cunningham. Phone: (781) 972-5472. E-mail: cunningham@healthtech.com.

weed out drugs and targets that do not achieve POC.

The general strategy proposed in the report thus involves both improving the drug discovery and preclinical phases, as well as early development.

#### Reducing Pipeline Attrition

Leading-edge strategies for improving drug discovery include development of multitargeted therapeutics, whole-pathway

approaches, biology-driven drug discovery, analysis of multigenic complex diseases, and network pharmacology. These approaches are aimed at discovery of drugs to address complex diseases, for which more conventional drug discovery methodologies have proven to be inadequate.

Notably, biology-driven drug discovery, which starts with a disease model, a pathway, or a biological process has proven to be much more successful than technology-

driven drug discovery based on genomics. Biology-driven drug discovery has often utilized academic research into pathways, disease models, and other biological systems, which have often been conducted over a period of years or of decades.

Targets derived from this research are usually better understood and validated with respect to their role in disease than targets that have recently emerged from genomic studies

See Phase II Attrition on page 66



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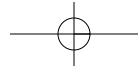
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## Phase II Attrition

Continued from page 65

and were validated by laboratory testing in pharmaceutical or biotech companies.

Examples of drugs derived from biology-driven drug discovery include such large molecule drugs as Genentech's Herceptin (trastuzumab) for breast cancer, Biogen Idec/Genentech's Rituxan (rituximab) for non-Hodgkin's lymphoma and rheumatoid arthritis, Genentech/Roche's Avastin (bevacizumab) for colorectal, breast, lung and renal cell carcinoma, and Erbitux (cetuximab) from ImClone Systems, a subsidiary of Eli Lilly, for colorectal and head and neck cancer.

Notable small molecule drugs include the numerous protein kinase inhibitors for treatment of cancers that have reached the market in recent years.

The value of biology-driven drug discovery is reflected in measures of success in development. Kola and Landis noted that biologics showed higher rates of success than small molecule drugs (approximately 24% as compared to 11%). Biologics tend to be discovered via biology-driven R&D, often beginning in academic research laboratories or in companies that conduct basic

research such as Genentech.

A recent analysis also found that among 974 anticancer agents that entered clinical trials between January 1995 and September 2007, the clinical attrition rate was 82%. For the subset of these drugs that consisted of targeted kinase inhibitors only 53% attrition was seen. The lower attrition rate of kinase inhibitors was attributable to a lower Phase II attrition rate.

Kinase inhibitors have been developed via biology-driven drug discovery (based on studies of signaling pathways in normal and cancer cells). Because of the highly targeted nature of kinase inhibitors, researchers can often also identify biomarkers that allow for better patient stratification and improved design of clinical trials of these drugs.

Industry researchers and other experts, as well as the FDA, also cite animal models that are poorly predictive of efficacy and/or safety in humans as a major cause of pipeline attrition. The respondents in Insight Pharma Reports' drug attrition survey agree, since over 50% of them cited poorly predictive animal models as a major

reason for the low productivity and high cost of drug development.

Since animal models are used both in drug discovery and in preclinical testing, this issue affects both these stages of drug development, and the results of poorly predictive animal studies often cause attrition in Phase II or Phase III. Therapeutic areas in which animal models of efficacy are notoriously unpredictable, especially oncology and CNS diseases, are also the therapeutic areas with the highest rates of Phase II and Phase III attrition, usually due to efficacy failures.

"I think that it's important to understand how predictive the animal models have been, and which ones translate well into humans," said Bruce H. Littman, M.D., president of Translational Medicine Associates, and the former vp, global head of translational medicine at Pfizer. "Some will be very mechanism specific, and some will be more disease specific."

### Proof-of-Concept Studies in Humans

In early clinical development, translational medicine strategies emphasize designing clinical trials aimed at obtaining rapid POC in humans. The goal is to enable companies to rapidly and cost-effectively advance drugs that achieve POC into Phase II trials, and to eliminate drugs that do not achieve POC. Biomarkers are key to the design of POC clinical trials.

For example, Novartis ([www.novartis.com](http://www.novartis.com)) has adopted a drug discovery and development model based on biochemical pathways. In many cases, rare Mendelian inherited familial diseases are caused by mutated genes that disrupt pathways that are also involved in more common, sporadic diseases. Novartis researchers design small POC clini-

cal trials in patients with the genetic disease. Upon achieving POC, the drug may also be tested in patients with complex, sporadic diseases that involve the same pathway.

The first drug that Novartis has been developing using this strategy is the mAb drug Ilaris (canakinumab), which specifically targets the proinflammatory cytokine interleukin-1 $\beta$  (IL-1 $\beta$ ). The company conducted its initial POC trial in three patients with Muckle-Wells syndrome. This is a rare autosomal dominant disease caused by a mutation in a gene involved in processing IL-1 $\beta$ .

Macrophages from Muckle-Wells patients constitutively secrete this cytokine, resulting in chronic inflammatory symptoms including skin rash, periodic arthritis, deafness, and chronic fatigue. When the patients were treated with Ilaris, their rashes, as well as biochemical markers of inflammation, resolved in several days, according to the company.

Novartis went on to test the drug further in patients with cryopyrin-associated periodic syndromes (CAPS), a group of rare inherited auto-inflammatory conditions that includes Muckle-Wells syndrome as well as several other conditions, all of which result in overproduction of IL-1 $\beta$ . In June 2009, the FDA approved Ilaris for treatment of CAPS, which affects approximately 7,000 patients worldwide.

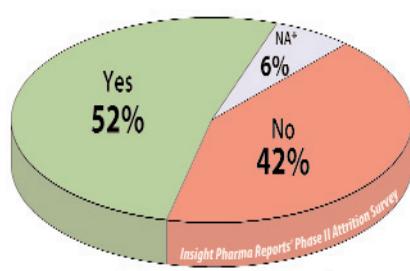
Novartis is currently testing Ilaris in more common diseases in which the IL-1 $\beta$  pathway is thought to play a major role, including chronic obstructive pulmonary disorder, rheumatoid arthritis, type 2 diabetes, and gout. The company reports that it is using biomarkers to predict response to treatment, with the goal of providing patients with a personalized approach to treatment of their disease.

In June, Novartis presented a Phase I/II study of treatment of children with systematic juvenile idiopathic rheumatoid arthritis at the "Congress of the European League Against Rheumatism." In this open-label study of 19 patients with acute disease, a single dose of Ilaris enabled the 59% of patients who were responders to reportedly achieve 50% control of their disease (as measured by standard American College of Rheumatology criteria) within 15 days.

More generally, Novartis' early clinical trial strategy involves testing drugs in POC clinical trials in small homogeneous populations, either with a rare genetic disease or defined by biomarkers. Upon achieving POC, Novartis then goes on to conduct conventional Phase II–Phase III trials aimed at registration of the drug.

Other companies are also using biomarkers to define patient populations for POC clinical trials and to help determine the results of these trials.

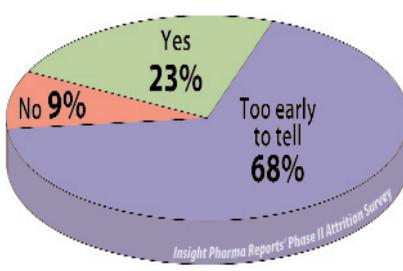
Biomarkers constitute a young discipline, and there is a need to identify more biomarkers and to qualify and validate them for use in POC trials and other types of early clinical studies. The FDA's Critical Path Initiative emphasizes biomarker development and use in drug development. Such research consortia as the Biomarkers Consortium, the Alzheimer's Disease Neuroimaging Initiative,



**Translational Medicine Program to Improve Early Drug Development**

**Figure 1. Has your company adopted a program of translational medicine aimed at improving the efficiency and effectiveness of early drug development?**

\* No early-stage drug development; drugs acquired in mid- to late-stage development.



**Accelerating Drug Candidates into Mid-Stage Clinical Trials**

**Figure 2. If you have adopted a translational medicine program, has it been helping you to accelerate movement of promising drug candidates into mid-stage clinical trials and to weed out unpromising candidates?**

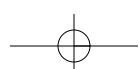
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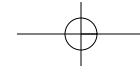
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and the High-Risk Plaque Initiative are attempting to improve the state of biomarker science and technology via collaborative, precompetitive studies. The vast majority of biomarker development, however, takes place in individual academic laboratories and companies.

"Biomarkers and translational medicine are something the whole industry is struggling with, to be honest," said Evan Loh, M.D., vp of clinical R&D at Wyeth. "With the biomarker concept, we are struggling to determine the true value that any biomarker gives us relative to increased confidence in decision-making."

According to Peter Lassota, Ph.D., divisional vp, imaging biology and oncology at Caliper Life Sciences, "Biomarkers have many flavors. We need better markers for early detection of disease, particularly cancers, in order to improve therapeutic outcomes. We are in need of surrogate markers of efficacy. Pharmacodynamic markers used in preclinical drug discovery and development will accelerate moving the compounds through the pipeline."

Two other strategies for early clinical design are Phase 0 human clinical studies using microdosing (i.e., administering doses of a drug that are too low to induce pharmacologic effects), and adaptive clinical trials. Phase 0 trials are first-in-human studies that may be used to evaluate pharmacokinetics, pharmacodynamics, and/or mechanism of action, or to evaluate imaging of specific targets.

Adaptive clinical trials constitute a flexible trial design that allows, for example, for continuous dose selection and refinement of hypotheses. In early clinical development, a company may use adaptive design to look at dose-response relationships. The goal is to reduce failed late-stage trials due, for example, to using the wrong dose of a drug or treating the wrong group of patients.

#### Conclusions

Translational medicine programs have been widely adopted in the pharmaceutical industry, and most drug development experts believe that these programs are the best approach to reducing attrition and thus to reducing costs and improving productivity of drug development.

Most of these experts believe that it is too early to tell whether current translational medicine programs are useful in accelerating the movement of good drug candidates into mid-to-late stage development and weeding out poor ones. The survey respondents agree with this assessment (*Figure 2*).

"I think that the Phase II survival data that comes out of industry over the next two to five years will be critical," explained Dr. Littman. "It's going to indicate whether or not the changes made by experimental medicine and translational medicine groups within these companies are really going to impact Phase II survival rates."

The ability of researchers to successfully identify and validate biomarkers and to design and carry out POC clinical trials depends to a large extent on an under-

standing of disease biology and disease pathways. Thus biology-driven strategies of drug discovery carry over into the new paradigm of early drug development.

Although researchers' limited understanding of the biology of complex diseases has been hampering drug development, researchers over the course of the past several decades have elucidated areas of disease biology that have enabled pharmaceutical and biotechnology companies to

develop new breakthrough drugs.

The majority of these discoveries in disease biology were made in academic laboratories.

It therefore seems reasonable that increased collaborations between industry and academia might also catalyze improvements in translational medicine.

Nearly 80% of the surveyed respondents said that their companies work with academic laboratories to improve aspects of their translational medicine programs,

which indicates that these companies realize the importance of this collaboration.

Collaboration between industry and academia in translational medicine can be challenging. For example, academia is mainly focused on basic research, not translational studies. Forging more effective industry-academic collaborations in translational medicine therefore remains an important task for industry, academia, and governmental agencies.

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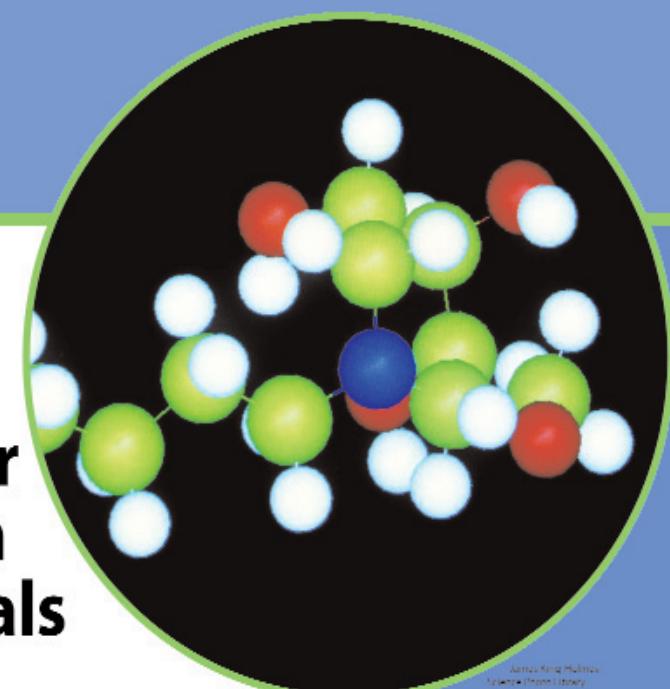
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