

Development

New Worlds of Opportunities

**THE DEVELOPMENT PROCESS NEEDS
TO UNDERGO A MAJOR OVERHAUL
TO REDUCE COSTS AND INCREASE**

EFFICIENCIES to bring new medicines to market in a more timely manner. The change agent? Technology, of course.

Analysts, experts, and CEOs alike acknowledge that the development process needs to improve significantly to reduce the time and costs associated with bringing new medicines to market.

PricewaterhouseCoopers's (PWC) analysts state that transformational technological changes will reshape the business strategies of pharmaceutical companies, and that the role of genetic-based diagnostics in the development of personalized medicines already has shortened the R&D cycle.

Some analysts and experts believe that the "highly empirical, statistical method that currently predominates most pharmaceutical research development organizations is inflexible and restricts innovation and results in overly large trials that yield information about how large populations with the same or similar conditions are likely to respond to a treatment."

The challenge is that physicians don't treat populations, they treat individuals.

According to PricewaterhouseCoopers, doctors still lack many of the diagnostic tools and medicines they need to treat patients individually because stratified medicine depends on the ability to identify the patients who are most likely to respond to particular disease subtypes. PWC analysts say, however, this is where clinical biomarkers have begun to revolutionize clinical development and medical practice alike.

BIOMARKERS MAKING A MARK

In the future, the use of biomarkers to stratify patients with related but distinct conditions will help pharmaceutical companies to make different patient treatments for different patient subpopulations, test them only in patients who suffer from those conditions, and thus reduce both the number and size of the trials required to prove efficacy, according to PWC authors of the Pharma 2020 report. The authors of the report estimate that better use of safety and efficacy biomarkers could cut development costs in half.

"This area of defining patients' genetic markers for the purpose of developing more effective therapies based upon genetic similarities and differences will increase," says John Rothman, Ph.D., VP, clin-



STEVE KENT
ClinPhone

AS CONFIDENCE IN THE METHODOLOGY IMPROVES

INTO 2008, responsive adaptive trials will increase, offering both time savings and increased likelihood of trial success.

Experts

ical development, at Advaxis Inc. “Future therapies will be increasingly targeted to the individual. Much of biotech research lives genomics and proteomics day to day. This focus will spread to other areas of the pharma industry.”

Pharmaceutical companies have long been

trumpeting the rise of personalized medicine, where patients would be selected for tailored therapies based on the biomarkers expressed either by their genetic profile or that of their disease, says Jeffrey Aroy, managing director of Leerink Swann Strategic Advisors.

“In truth, however, the big pharmaceutical

companies always lacked an incentive to pursue this ideal,” he says. “But this is changing as blockbusters are increasingly harder to find and new capabilities in genetic and proteomics make biomarker-based development more feasible.”

He says the trend toward biomarkers will

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ELIZABETH MOENCH. President and CEO,

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GREATER TRANSPARENCY OF DRUG PIPELINES IN COMBINATION WITH

more informed, empowered patients, physicians, and advocacy groups have resulted in a growing demand for investigational drugs.

During the past 30 years the biotechnology industry has evolved rapidly, resulting in changes to biopartnering dynamics. Out-licensors now command greater power and leverage over the licensing of their technologies, changing the approach of out-licensing at various stages of the life cycle and highlighting the need for biotechnology companies to adapt existing strategies to optimize this process, according to a new research report from Business Insights.

THE REPORT FINDS THAT:

- As biotechnology companies evolve in size and scope they must adapt their use of biopartnering to satisfy different combinations of funding, resource and expertise requirements.
- Pioneer biotechnology companies, in the early stages of their development, benefit significantly from finding a long-term strategic partner to secure funding as well as validating the commercial potential of their technology.
- Growth biotechnology companies, in the post-IPO stages of development, can effectively broaden their portfolios through a series of collaborative agreements, whereby the results of the biopartnering relationship are shared between parties.
- Consolidation biotechnology companies, in the post-product launch phase of development, achieve long-term success through leveraging their expertise and partnerships to generate a broader portfolio achieving an effective balance between internal and biopartnering growth.

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



STACEY ARRAMBIDE
inVentiv Clinical Solutions

E-CLINICAL MAXIMIZES OPPORTUNITIES FOR EFFICIENCIES,

which will reduce the overall time and money spent during the drug-development process.

require companies to master new competencies as way to compete in a changed clinical development landscape.

“Conducting a biomarker trial adds complexity; trial sites will need to have instrumentation and competencies in biomarker analysis, or developers will need to contract with vendors to centrally provide these services,” he says. “Attention needs to be paid to sampling methods, preservation, and transport to testing facilities. Greater statistical and computing power is also necessary to mine data for complicated relationships between genetic, biological, and environmental factors.”

Mr. Aroy says the area where biomarkers have had the greatest impact to date is in oncology. Oncology researchers, he says, are using biomarkers in three ways to improve odds of trial success.

The first way is to retrospectively search for markers of differential response — using retrospective biomarker analysis to identify responder subsets in trials that perhaps otherwise miss primary endpoints.

The second use is in conducting trials in biomarker patient sub-sets. This allows for the predefining of biomarker subsets and powering trials to draw conclusions about potential sub-segments.

NATALIE DOUGLAS

IDIS



And lastly, to predict patient prognosis. Mr. Aroy says by separating those patients whose genetics or tumor characteristics predict that their cancer will progress rapidly and who may be obscuring a drug's efficacy could lead to a better understanding of the drug's use in other patients.

“For example, in breast cancer, 100+ gene panel arrays better predict whether a patient is likely to benefit from chemotherapy maintenance,” Mr. Aroy says.

Bonnie Brescia, founding principal of BBK Worldwide and TCN e-Systems LLC, says there are many benefits to the development cycle by following the disease state in a targeted subset of patients.

“This will require an approach that encompasses identification of the ‘right’ patient — diagnostic tools; treatment — investigational drugs/devices; and appropriate follow up — personalized compliance programs,” she says. “Using the old model, it's not clear how pharmaceutical companies can continue to be profitable. The structures supporting the blockbuster approach require significant retooling. It's not just a matter of reorganizing, but really of reimagining and instituting a new paradigm.”



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the industry is taking a much closer look at all technologies for collection of these data.



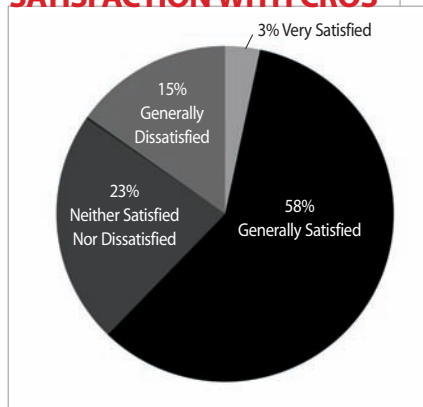
Partnering for Clinical Success

Overall satisfaction with relationships in the industry is largely good, though somewhat better from the CRO/clinical service provider side (77%) than from the sponsor side (62%). Larger (most often pharmaceutical) sponsor companies had a greater level of satisfaction with their relationships than did smaller (generally biotechnology) companies, whereas the reverse was true for service providers.

ON THE SPONSOR SIDE

- 61% of sponsor representatives provided favorable satisfaction ratings for their partner CROs
- The top 3 factors that can most positively influence a sponsor's relationship with its CRO on an outsourced project are:
 1. Shared vision going into a project
 2. Tools, templates, and formal process for documenting sponsor expectations
 3. Formal feedback mechanism
- 43% of sponsor companies strongly agreed and 89% agreed that failure of clinical service providers to be up front about problems was a significant issue
- 66% of respondents agreed that lack of defined expectations by sponsors was a significant issue for CROs

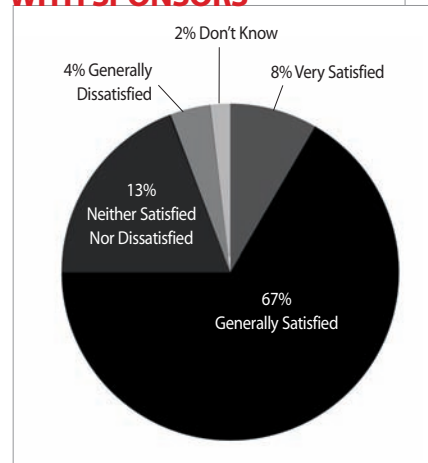
SPONSOR SATISFACTION WITH CROS



ON THE CRO SIDE

- 75% of CROs provided favorable satisfaction ratings on their relationships with sponsors
- The top 3 factors that can most positively influence a CRO's relationship with a sponsor on an outsourced project are:
 1. Sponsor interacts with CRO in a collaborative fashion
 2. Shared vision going into a project
 3. Sponsor is up front and honest with feedback throughout the project
- 40% of service provider respondents strongly agreed and 90% agreed that mismatched expectations were a significant problem
- 57% of CROs believe that change orders have a negative impact on sponsor-service provider relations

CRO SATISFACTION WITH SPONSORS



The Avoca Group, Princeton, NJ. For more information, visit theavocagroup.com.

STRATIFYING PATIENTS

Dr. Rothman says a focus on biomarkers will likely give rise to vendors who specialize in defining patient attributes for the purpose to clearly delineate Phase III populations and efficacy determination based, in part, upon genomic class.

"Vendors may specialize in goods, in the form of tissue preparation procedures and reagents, or assays, or new devices, or perhaps as a contract provider if a sufficient body of specialized knowledge becomes too extensive or expensive for small companies to bring in-house," he says. "This evolution will move slowly as regulators will require various forms of technical and empirical validation at every step along the way."

Byron Hewett, who is president and CEO of Immunicon Corp., which offers assay development and clinical-trial testing services to incorporate circulating tumor cells (CTCs), says they already work with the top names in big pharma with the goal to risk-stratify patients, assign patients to the right arm of a clinical trial, and perhaps some day use CTCs as a surrogate endpoint as opposed to waiting for overall survival.

"A validated surrogate endpoint could significantly reduce the length and cost of clinical trials, which means that new therapies get to market earlier, thereby extending cancer patients' survival," he says. "The use of CTCs and other biomarkers points to more efficient and more cost-effective drug development. Ultimately, the promise of biomarkers is to select the right therapy for the right patient at the right dose at the right time."

Elizabeth Moench, president and CEO of MediciGroup Inc., says as the use of biomarkers increases and patients are stratified, patient recruitment strategies will evolve to include



ELIZABETH MOENCH
MediciGroup

OUTSOURCING THE HIRING PROCESS ITSELF

will emerge as the most efficient and effective way to leverage existing best practices for finding top talent.



PETER FERGUSON
Yoh

multiple approaches and programs directed to pre-identified specific subpopulations, and programs directed to populations yet to be stratified via biomarkers.

"The adoption of biomarkers to stratify patients will not occur overnight," she says. "It will evolve over the next five to 10 years."

Dealing with patient-level information is a metamorphic change for pharma organizations both in terms of capturing the information and leveraging it, says Nagaraja Srivatsan, VP, head of life sciences, North America, at Cognizant Technology Solutions Corp.

"Clinical-trial management systems that now track relationships with healthcare professionals will have to be modified to be able to track and build relationships with actual patients," he says.

Janice Hutt, VP of The Avoca Group, says patients will continue to become more informed about their health and treatment options and will demand more time with physicians to better understand clinical trials and the anticipated health outcomes.

"Pharmaceutical companies and their clinical service providers need to continue to improve patient education and make it simpler for people from all backgrounds and cultures to understand informed consent and outcomes

AS THE USE OF BIOMARKERS INCREASES AND PATIENTS ARE STRATIFIED,

patient recruitment strategies will evolve to include multiple approaches.



THE DEVELOPMENT CYCLE WILL NEED TO FOLLOW

the disease state in a targeted subset of patients.

BONNIE BRESCIA
BBK Worldwide

based clinical trials," she says. "The public needs to understand the benefit

and necessity of clinical trials and weigh their opinions about participation carefully based on this understanding and the risks involved."

Natalie Douglas, CEO of IDIS, expanding on this trend adds that greater transparency of drug pipelines in combination with more informed, empowered patients, physicians, and advocacy groups have resulted in growing demand for investigational drugs.

She says this will foster a growing willingness on the part of companies to make their pipelines more transparent; an increased responsiveness by drug developers to provide access to investigational drugs; continued expansion of online registries to create more awareness of and greater participation in clinical trials; as well as proactive implementation of compassionate use programs to address the demand.

CLINICAL OPERATIONS

Mr. Srivatsan says pharmaceutical organizations do not have the information infrastructure to be nimble enough to react to the data

they receive during the clinical development process, which limits their adaptability and flexibility.

"Pharmaceutical organizations are starting to create reference architectures that allow information to be shared and analyzed in a standardized manner," he says. "The adoption of standards from organizations such as CDISC provide a good mechanism to share information across the clinical-development processes to ensure that information can be appropriately leveraged early in the decision process to help pharma develop more targeted therapies."

Stacey Arrambide, VP of statistics and data management at inVentiv Clinical Solutions LLC, says e-clinical has the potential to be the single-most important factor in reducing the time and costs associated with development of new products.

"The opposition EDC faced and overcame to gain acceptance will prove to make the transition to, and acceptance of, e-clinical much easier," he says. "Advancement in data capture and data integration technology, along with the global standardization of file types and formats, makes the transition to e-clinical easier than originally imagined. As with any new enterprise, acceptance and training are obstacles. Finding the right combination of technical skill and clinical experience are cru-

JOHN VARAKLIS

Novartis Pharmaceuticals

AT NOVARTIS, NEW DEVICES ARE BEING CONSIDERED BASED ON IDENTIFIED NEEDS, and careful review of the robustness and ease of use of the technology is assessed.

cial to mitigating these challenges. But the reality and overwhelming benefit e-clinical promises to deliver and will produce is putting more complete results into the hands of physician and other decision makers more rapidly."

Steve Kent, CEO of ClinPhone, says there are a number of very exciting technologies that are in a fledgling position right now.

"The ones that are likely to have an impact in 2008 have been discussed and vetted in previous years," he says. "There are currently two main market drivers in this area: responsive adaptive trials and integration of data."

"The trend for responsive adaptive trials has been gathering pace in 2007 and will

accelerate as more companies adopt this approach in 2008," he says. "As confidence in this methodology improves into 2008, responsive adaptive trials will increase, offering both time savings and increased likelihood of trial success."

The second area is the integration of clinical data.

"In a complex trial, data will be sourced via different collection methods and technologies," Mr. Kent says. "By integrating data into different systems, speed of decision-making can improve and data transcription errors can be avoided. Market demand for integration has doubled over the past year."

PERVASIVE HEALTHCARE

Another area that is generating a great deal of interest is "pervasive healthcare," the use of remote devices to monitor patients on a real-time basis. This will allow the industry to test new medicines outside a clinical setting.

"We are working with several new technologies that are intended to leverage the pervasive healthcare concept," says John Varaklis, head of operations and innovation for transitional medicine, Novartis Pharmaceuticals Corp.

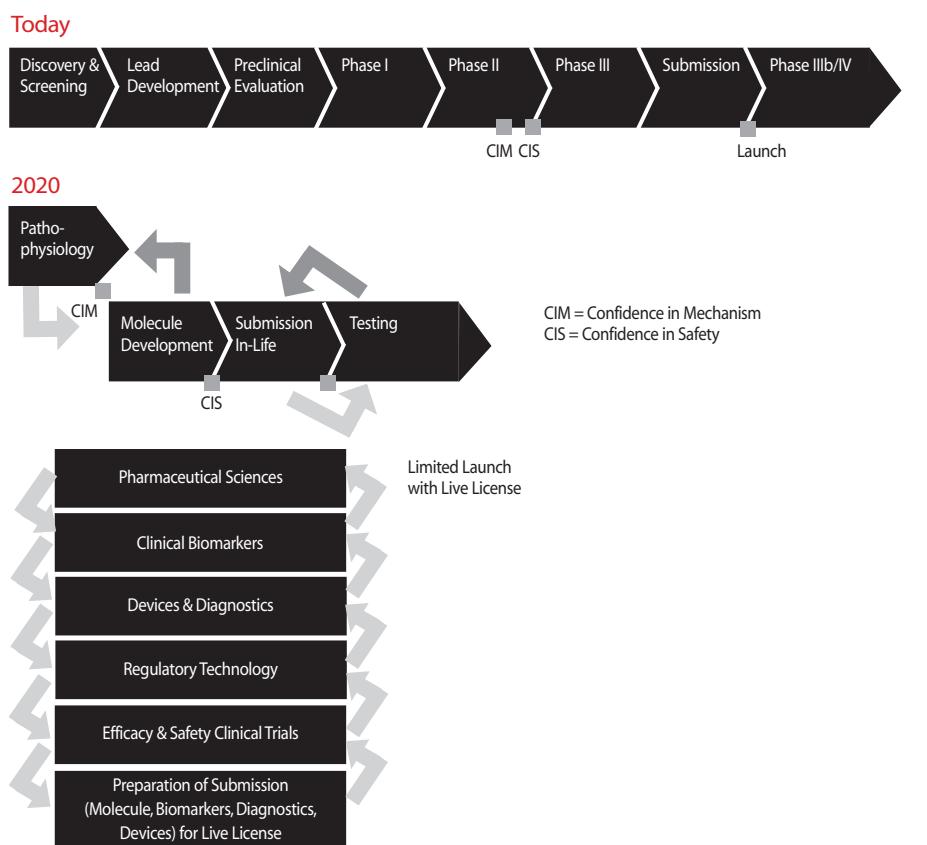
Among these are interactive informed consent tools (Clinaero), digital pen and paper tools, novel noninvasive ambulatory blood pressure devices (Healthstats Bpro), wireless blood pressure, glucometer, and weight scales, (Carematix Wellness products), home-based electronic peakflow meters for asthma management (Ferraris/Carematix), continuous real-time glucose readings, and several other novel devices, which should enable Novartis to define new approaches to trial design, conduct, safety monitoring, and overall quality improvements.

"Regular discussions are held with the various teams and stakeholders in the group to look at the portfolio of compounds and trial on an ongoing basis," Mr. Varaklis says. "The trial endpoints — both safety and efficacy — are looked at carefully to determine if the design or conduct can be facilitated, or improved by the use of the available pervasive healthcare devices. In addition, new devices are being considered based on identi-



More Refined

The Development Process of the Future:



Source: PricewaterhouseCoopers, New York, Pharma 2020: The Vision Which Path Will You Take?
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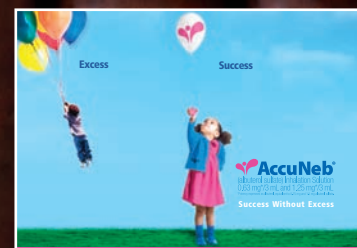
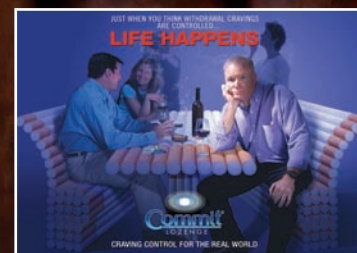
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IMAGINE THE POSSIBILITIES





JEFFREY AROY

Leerink Swann Strategic Advisors

THE TREND TOWARD BIOMARKERS WILL REQUIRE COMPANIES TO MASTER NEW COMPETENCIES as a way to compete in a changed clinical-development landscape.

fied needs during this review, and careful review of the robustness and ease of use of the technology is assessed.”

He says the key to the success of the adoption has been the positive mindset that management has instilled in the group to embrace innovation in all aspects of the group’s work.

Ms. Moench says over the years, technologies to monitor patients’ behavior specifically related to compliance have come and gone.

“For many patients these compliance monitoring technologies undermined a patient’s sense of freedom and liberty, there was the feeling of intrusion that Big Brother was watching,” she says. “On the other hand, technologies that monitor bodily functions and vital signs offer patients a sense of security, a safety net. These are viewed to be less intrusive. Such technologies stand a greater chance of patient acceptance and use.”

One challenge that will always exist to some point will be training sites and patients sufficiently on ePRO devices, says Michael Burton, director, eClinical Solutions, Omnicare Clinical Research.

“Clinical research sites already have extensive training requirements for each study, so there will need to be a commitment from everyone involved to make adoption a priority,” he says.

Mr. Burton says most biopharma compa-



BYRON HEWETT

Immunicon

A VALIDATED SURROGATE ENDPOINT could significantly reduce the length and cost of clinical trials, which means that new therapies get to market earlier.

nies probably won’t want to bring ePRO technologies in house. As a result, companies will have to partner with vendors who provide these technologies and services.

Mr. Kent says another challenge is the adoption of clinical standards throughout the whole organization.

“Adoption of a consistent, standard system throughout the business is increasing, with improving degrees of success,” he says. “Adoption of clinical standards drives efficiencies into the process, and in the case of software reduces the effort to program, customize, validate, and test the system, all of which are time consuming, and similarly reduce the time to build the studies, as well as ensure that data from all trials undertaken are consistent.”

CLINICAL DEVELOPMENT **TALENT**

The talent shortage currently taxing other tech industries is forecasted to affect pharma hiring at a similarly acute rate, and will last well into the next year. But the high quality of available workers, particularly in R&D, ensures that companies that do capture talent will gain a competitive advantage, says Peter Ferguson, president of health and life sciences for Yoh.

Some of the most in-demand jobs in the pharma industry for 2008, he says, will be clinical lab scientists, clinical research associates, drug safety associates, clinical data managers, and clinical project managers.

“The staffing process will look much the same tomorrow as it does today,” Mr. Ferguson

says. “What will be different is that more discovery and development teams will be placed, as companies recognize this strategy as a scalable and cost-effective alternative to CRO and CMO outsourcing.”

According to Jeff Dodson, life sciences practice at Heidrick & Struggles, globally, the life-sciences sector will need to keep working hard to attract the most skilled and committed scientists and researchers, in addition to top-quality senior general management executives capable of leading and driving change across complex global organizations.

“This will necessitate a global talent search,” Mr. Dodson says. “For more junior people, a broad approach using universities and other industries is appropriate. For more senior-level talent, however, companies will need to focus their efforts on finding the best talent throughout the life-sciences spectrum.”

When assessing a move to outsourcing, Mr. Dodson says, biotech companies will need to ensure they are able to access similar talent pools and resources to those they have in their current locations. Existing biotech clusters have the competitive advantage of being located close to many highly respected universities, for example the cluster in Northern California, which has 12 major research universities and laboratories in the region helping to drive innovation.

“Outsourcing the hiring process itself will emerge as the most efficient and effective way to leverage existing best practices for finding top talent,” Mr. Ferguson says. “This way, pharma companies can forego time-consum-



JANICE HUTT

The Avoca Group

THE PUBLIC NEEDS TO UNDERSTAND THE BENEFIT AND NECESSITY OF CLINICAL TRIALS and weigh their opinions about participation.

ing recruiting, orientation, outboarding, performance reviews, and other hiring steps, and instead focus on integration and training."

He says success will come from combining all the essential pieces — namely, competent consultants, hands-on recruiters, and knowledgeable product managers who can work together for design and training.

"It will also help if the hiring firms recruit people with skills that fit the job at hand, rather than drawing from an established pool," Mr. Ferguson says. "This ensures a better overall fit in terms of skill sets and responsibilities, and lessens the learning curve."

Pharma companies may also end up with greater control over their processes and content after placing discovery and development teams.

"Scalability to firms' SOPs and GMPs is another benchmark and helps the hiring firm bring the

right people on board, at the right time, and in the right numbers," he says.

As with other high-growth sectors, not just the recruitment but the retention of talent will be a major headache for the life-sciences sector over the next five years, Mr. Dodson says. To address this, pharmaceutical companies will need to start looking at recruiting outside of their traditional hiring range.

"To build the scale of talent needed in markets such as China and India to better serve large local markets, pharmaceutical multinationals will need to play an active role in recruiting and developing people at junior, middle, and senior levels in their organizations," Mr. Dodson adds.

Being aware of these emerging trends and making the recruitment, development, and retention of top talent a strategic imperative is critically important for every life-sciences company competing in the global market, Mr. Dodson says. ♦

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