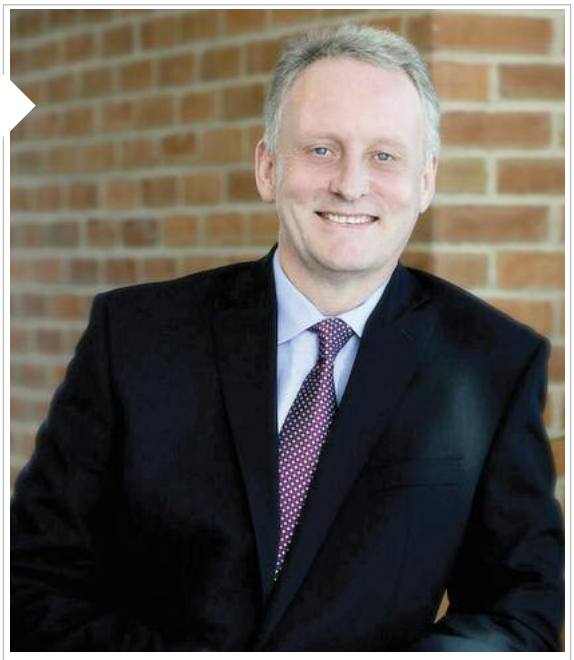
by Taren Grom

Key Partnerships and Innovation: KEYS TO R&D SUSTAINABILITY

The current pharmaceutical R&D model is untenable, collaboration is the key to future drug innovation and success.

A growing emphasis on academic and nonprofit organization partnerships could rescue the pharmaceutical industry from the redundancy of an inefficient R&D model and plug the so-called innovation gap, according to a new report from research and consulting firm GlobalData.

We need to have an efficient way of moving forward with relatively small, very well-trained research and development organizations that can partner in different ways with external partners of all types.



DR. PHIL VICKERS, *Shire Human Genetic Therapies*

GlobalData's new report argues that collaboration in drug development benefits both parties, with academia constantly looking for sources of research funding particularly as governments cut the amount of aid dedicated to federally funded research, while the pharmaceutical industry would gain a partner to share in the high risks and substantial costs of bringing new medicines to market.

The current R&D paradigm is bloated, duplicative, expensive, and in the long run, untenable, says Adam Dion, healthcare industry dynamics team analyst, at GlobalData.

"There is a growing consensus in the industry that these challenges must be met collectively by bringing together public, private, and government organizations to create multilateral collaborations to drive the next wave of scientific discovery," he says.

Mr. Dion explains that the dearth of innovative drugs on the current landscape is at least partly the result of wasteful R&D activity.

"2012 may have boasted the highest number of FDA drug approvals since 1996, but many of these were for me-too drugs or medications aimed at niche therapy areas," he says.

Many companies are now putting in place strategies to drive innovation, one of which is open source collaboration.

Many industry participants are now considering a move from an old and inflexible R&D paradigm to a more collaborative and open ecosystem that fosters creativity and information sharing. This is a substantial cultural shift for an industry with a high level of reluctance to share anything, Mr. Dion says.

Greater cooperation between rival drug companies and nonprofit organizations may be a difficult pill for big pharma companies to swallow, Mr. Dion says, but this approach may ultimately prove advantageous in the long run.

Miguel Barbosa, Ph.D., VP of immunology research, scientific strategies, Janssen Research & Development, a company of Janssen

The Industry's Research Commitment Remains Strong

John Castellani

Investment in research and development by members of the Pharmaceutical Research and Manufacturers of America (PhRMA) remained strong at an estimated $48.5 billion in 2012, despite economic, scientific, and business challenges. More than 5,400 medicines are in development globally, representing future opportunities for new, cutting-edge medicines to improve patient care and bring value to the U.S. healthcare system.

The biopharmaceutical industry's approach to R&D continues to evolve and adapt to scientific advancements, rising drug development costs and changing regulatory requirements. Companies are increasingly focused on targeting some of the most complex diseases such as Alzheimer's, cancer and Parkinson's, and are identifying advances in technology to improve R&D productivity and efficiency.

"The U.S. biopharmaceutical sector — led by our member companies —is a major contributor to American innovation and to the domestic economy," says John J. Castellani, PhRMA president and CEO.

For more information, visit phrma.org.

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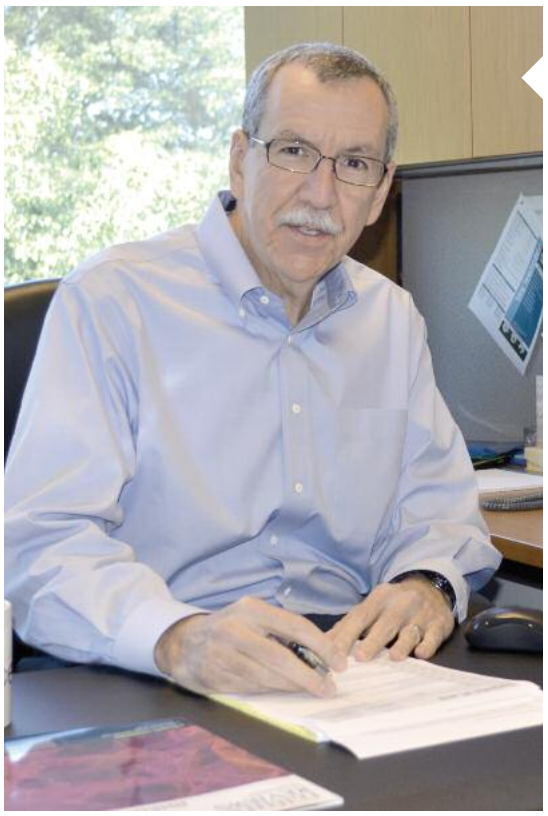

DR. MIGUEL BARBOSA
Janssen Research & Development

Innovation is essential for value creation and fundamental for driving the pharmaceutical industry.

DR. LEONARD REID
Merck

Open innovation is a term that can have a lot of variability but also a lot of possibility, if an appropriate definition can be defined.

PAULO MOREIRA
EMD Serono

Innovation will result from shifting to a partnership model based on real transparency and carefully aligned but complementary goals and interests that capitalizes on fully exploiting the strengths of each partner.

Pharmaceutical Companies of Johnson & Johnson, says innovation is essential for value creation and fundamental for driving the pharmaceutical industry.

"As we look at the industry itself, we see that it is a mature industry and as such it has a highly developed structure to harness efficiencies as well control risk," he says. "The reality is that these structures do antagonize to a significant extent creative individuals as well as the culture that drives truly transformational innovation. This is a significant challenge for the pharmaceutical industry.

"Therefore, it is most likely that disruptive innovation will come from outside the core pharmaceutical R&D communities," Dr. Barbosa continues. "And we need to find a way to tap into the highly creative individuals and teams without imposing an arching structure in process as is needed to manage a large scale industrial organization."

Open Innovation

To improve the trial process, many experts contend that open innovation is a viable solution, and one that depends on a trusted partnership between clinical trial service providers and sponsors.

"Innovation is possible between clinical trial service providers and sponsor companies, but not without a fundamental paradigm shift of the long-established partnering methods," says Paulo Moreira, VP, global head clinical strategic partnering, EMD Serono. "Historically, partnerships have been little more than financial arrangements, placing the emphasis on margins instead of on the delivery of results.

"We must break away from the traditional arrangements where duplication of effort, systems and infrastructure exist," he continues. "These duplicative activities, born out of a fundamental lack of trust and the 'I know better' syndrome have resulted in even greater inefficiencies. The first steps toward innovation between partners are transparency and trust: transparency on one's own capabilities and trust in the partner's capabilities. If the partnership is built on these tenants and accepted without fear or reservations, a world of partnering possibilities will open up to us."

Mr. Moreira is one of several experts who believes that it is imperative to recognize that service providers are able to do much more than the heavy lifting in drug development.

"Service providers are also purveyors of a wealth of intellectual capital, supported by a state-of-the-art infrastructure that has been accumulated throughout years of drug development on behalf of hundreds of sponsors," he explains. "Clinical trial service providers are sitting on a treasure-trove of untapped data and infrastructure that is prime to fuel an innovation boom. Service providers, however, are very selective as to whom they are willing to share these resources with. Only those sponsors who demonstrate a willingness to be transparent and open up their own competitive intelligence are likely to partake in these special offerings. The two partners must be willing to share the risks associated with such a partnering model, which is predicated on the principle that the whole has more value than the sum of its parts."

Mr. Moreira says for innovation to happen the basics must first be in order.

"Quality and compliance are non-negotiable," he says. "Performance and delivery are the ultimate success factors. Only then can clinical trial service providers and sponsors shift the focus toward transparently taking advantage of this industry's maturity and accept-

There will be more cooperation with organizations that are more nimble and that can map and adjust.

DR. PERRY NISEN
GlaxoSmithKline

ance to doing things that have never been done before. Innovation will result from shifting to a partnership model based on real transparency and carefully aligned but complimentary goals and interests that capitalizes on fully exploiting the strengths of each partner."

Reid Leonard, Ph.D., executive director, external scientific affairs at Merck, says open innovation is a term that can have a lot of variability but also a lot of possibility, if an appropriate definition can be defined.

"Open innovation to us means seeking the best science that we can find regardless of its location or source," he says. "This may translate into collaborating with entities that may be commercial competitors in a different setting."

At GlaxoSmithKline, Perry Nisen, M.D., Ph.D., senior VP R&D, strategy and innovation, says the company is increasingly finding ways to collaborate and partner with academic partners.

"We have 'coopetition' models," he says.

JULIE ROSS
Executive VP
Advanced Clinical

Automate and Innovate

Service providers must automate and innovate processes to drive efficiencies and do more with less. Given increases in outsourcing, providers must have automated processes and offer flexibility and scalability of services and talent with little notice. Providing tailored strategies based on needs, from a full-service CRO model to offering qualified candidates in a staff augmentation model with the ability to ramp up to an FSP model with deliverable pricing, is also a must-have complement in outsourcing solutions.

PETER BENTON
Executive VP and President, eClinical Solutions
BioClinica

Clinical Partner Advantages

It's difficult for companies to think creatively when they have to worry about the financial risks of making the vision a reality. Pharmaceutical companies are constantly seeking ways to reduce the cost of running clinical trials, but more importantly speed up the ability to run their trials. Partner companies that provide superior service can help sponsors get more drugs to market faster, and cloud based end-to-end solutions make trials less expensive. This allows them the ability to reinvest and allocate more funds to research and development for compounds that address a wider variety of indications and therapies. These are important elements in facilitating new drug innovation.

Service Specialization

Collaborative partnerships are vital in today's pharmaceutical development space, and that holds true for the companies that support clinical trials with technological and logistical services and solutions. The best way to run faster, more efficient clinical trials is to standardize business processes and ensure repeatable speed to market. Using service providers that specialize in their area of expertise, for example CROs for their drug development expertise and e-clinical solutions providers for technology, that have an established partnership ensures that sponsors easily exchange information and facilitate rapid trial execution.

KEITH KLEEMAN
Founder and CEO
ClinGenuity

Identifying and Filling The Gaps

Our industry is one of the most complex and scientifically rigorous. However, analyzing in depth the inefficiencies in the clinical development process can result in greatly reducing the time and cost to market. Most of the larger CROs and informatics companies are building database applications that do not greatly reduce processes. The way forward is to build not only databases, but rather automation tools that can systematically analyze where the inefficiencies are, and then adapt the process or the actual information to reduce time, but yet honor the policies and intellectual property of the pharmaceutical manufacturer.

Artificial Intelligence Can Provide the Solution

Software solutions must be intelligent enough to handle information from almost anywhere. Software vendors cannot continue to build tools that mandate sponsors use specific file or data formats different from their internal processes produce. Instead, tools need to accommodate the sponsor. We can no longer dictate the structure of the front-end of information to get the back-end solution. As open innovation continues to grow and partnerships sprout, software solutions cannot be focused on individual sources of information, but rather they must be flexible enough to handle information from all sources. This is why artificial intelligence will be the key differentiator between software providers. Artificial intelligence based software solutions can be source agnostic, and therefore work seamlessly between and among different sponsors.

BHASKAR SAMBASIVAN
VP and Head of Life Sciences
Cognizant

Pharma as Innovation Champion

Pharma has to champion its role primarily as providing the platforms, data, and technologies to foster innovation from outside while retaining TA specific expertise in evaluating molecules and taking lead compounds to the commercial world. Converting research into a P&L center could cut costs dramatically and drive innovation. Coupled with externalization, producing NMEs for sale to TA-based development organizations will force them to make sure they produce the best molecules with highest success rate. Also, there

VIEWPOINTS

needs to be better alignment with healthcare issues in the U.S. market — from R&D on illness to R&D on wellness. This broader view of omics and patient health will increase possibilities of patient wellness and increase commercial success with payers and patients.

Technology Leading the Way

Life-sciences companies need to leverage more innovative ways of conducting clinical trials, including remote and risk-based targeted monitoring while leveraging proactive decision-making tools and better team collaboration. A new master IT architecture that blends social, mobile, big data analytics, and cloud technologies is emerging to catalyze organizational productivity and business competitiveness. Technology-driven innovation and the use of SMAC — social, mobile, analytics, and cloud technologies — can enable life-sciences companies to work in more connected, collaborative, and real-time ways to improve their clinical and patient outcomes. With mobile devices and smartphones being so pervasive in the patient community, simply integrating patient, physicians, payers, and provider data can give us the insights to enable preventive, predictive, and personalized care. The best way to accomplish this is through global service providers that can help with strategic thinking, integrated process, technology expertise, and a willingness to invest in better business outcomes.

MARK WHEELDON
CEO and Founder
Formedix

A Standards Checkup

There is a wave of external standards coming from CDISC, TransCelerate, and the FDA that will impact studies from data acquisition to submission. What do you do when your regulator insists on a newer version of these standards or to manage content changes? We suggest a standards health check to understand how compliant your company is, a standards balance sheet service to bring you up-to-date, and an ongoing aftercare service ensuring study designs/standards are current.

JOY FRESTEDT, PH.D.
President and CEO
Alimentix, the Minnesota Diet Research Center
Frestedt Inc.

Food for Thought

Understanding how to develop the scientific substantiation of a claim for a particular formulation of a food, ingredient, or dietary supplement is critical. Unfortunately, clinical trial costs in the food industry are not supported by any data protection and competitors use the information once it becomes public. As a clinical trial provider in this niche market, it's important to expertly design clinical trials for food-related products to exploit the differences while supporting open innovation for claims.

LAURIE HALLORAN
President and CEO
Halloran Consulting Group

Overcoming a Risk-Aversity Mindset

The biggest barrier is a risk-averse mindset. Many of the companies we deal with are either unable or unwilling to shake up what they do because they are afraid of making mistakes, of getting in trouble, and of speaking out to suggest alternatives. The phenomenon is pervasive, and seems to be at almost all levels of participants at conferences at which I speak, and within teams at many clients with whom we work.

Making Innovation the Norm

During a recent roundtable to discuss how to improve performance between sponsors and vendors, there was frank, open, and productive conversation about practical approaches: sharing lessons learned, admission on how the parties could improve, ideas that work. This should be much more the norm instead of the exception. I don't yet see open innovation trickling down from initiatives like TransCelerate, but there is an enthusiastic anticipation to adopt recommendations and improvements.

AMY KISSAM
Executive Director, Integrated Clinical Processes
INC Research

Tapping Therapeutic Expertise

Sponsors can benefit greatly from working with therapeutically focused CROs. The CRO's therapeutic experts are able to evaluate the protocol and assist in the development of the operational plan, which includes effective recruitment and retention strategies. When executed efficiently, such programs support patients and sites alike, keeping studies on track and helping sponsors avoid delays, which can cost up to $8 million each day their product is not on the market.

Open Project Portals

When it comes to open innovation, communication, and transparency are key. One tool many companies are employing to aid such interactions is a Web-based project portal. Such portals can serve as a conduit through which all study information flows, allowing for improved project oversight and faster decision-making.

JENNIFER ZIMMER
Partner
Insigniam

Check the Pipeline For Clogged Data

Check the pipeline. It might be clogged with dated criteria for yesterday's ideas. Once the screening parameters are adapted to the level of innovation being sought, challenge the organization to this next level of innovation that is more focused on tomorrow's opportunities. Tip: Be prepared to support the challenge with resources, money, and time or the challenge won't be taken seriously.

Open Innovation Equals Co-Creation

Service providers can best partner with pharmaceutical sponsors by building solid working relationships with team members, creating a mindset of one voice, i.e. "we are all in this together," creating a clear governance structure, and maintaining the alignment of team within the partnership. Open innovation is all about co-creation — people support what they help to create.

ALLISON KERSKA
VP Global Life Sciences Solutions
Kelly Services

Corporate Culture Drives Talent

When it comes to the organizational attributes that influence job applicants, talent across all industries is most influenced by an organization's corporate culture (23%) and strong market presence/leadership (22%), according to the Kelly Global Workforce Index survey. Job candidates in the life-sciences industry see things a little differently. Compared with talent across all industries, reputation for innovation is important to significantly more workers in the life-sciences industry sector in terms of their decision to apply for a job.

RICH PENNOCK
VP, Life Sciences Vertical
Kelly Services

Trusted Partners are Pivotal

Companies withing the pharmaceutical and life-sciences industries must quicken their pace to develop, test, and safely deliver drugs to market. Knowledgeable service providers can play a pivotal role in the process through an open engagement platform in which both sides can be confident that each other's business interests are secure. Once a platform has been established, ideation and process improvements can have a significant impact on profitability.

BRIAN SWEENEY
VP, Business Development
MedNet Solutions

Cloud-Based Solutions Erase Barriers

Sponsors are continuously struggling with clinical research initiatives that are too time-consuming and excessively expensive. Part of the blame can be placed on older information technologies that, while beneficial in some respects, actually introduce their own set of roadblocks to achieving research efficiencies. Today's leading cloud-based eClinical technologies can eliminate these barriers and go a long way toward streamlining clinical studies. Technology delivery via the cloud insulates sponsors from many technology issues and costs, including software and server installation and support. These systems can also provide more comprehensive features, eliminating the need for multiple systems and redundant data entry. Further, study creation can be greatly simplified through study replication and reusable fields and forms. Finally, software as a service (SaaS) pricing can dramatically lower overall costs as sponsors only pay for the services they require, and only during the timeframe they're needed.

SHEILA ROCCHIO
VP, Marketing and Product Management
PHT Corp.

The Pros of Employing ePRO

The 2009 FDA Guidance for Industry Patient Reported Outcome Measures: Use in Medical Product Development to Support Label Claims highlights the importance of patient reported outcomes (PROs) and other clinical outcome assessments (COAs) in clinical research. PROs and electronic PROs (ePRO) directly elicit the patient experience with a given treatment and identify gaps and opportunities for clinical innovation.

MICHAEL O'GORMAN
CEO
Sentrx

Investing in Big Returns

The biggest barrier in moving forward is the lack of confidence that investments in drug development innovation will yield high returns. The exuberance of investors throughout 80s and 90s on Web-based technology companies caused a tremendous influx of innovation enabling us to live in a high-tech world. Today, the fact is that financial performance of these companies was not as expected, which has caused major shrinkage of valuations and investing. I believe that pharma companies need to convince Wall Street that a dynamic is already happening within drug development that will return exuberance to investors, which in turn should provide significant returns to those who are most innovative. Some examples of such innovation include techniques to reduce cancer growth, examining genetic composition to deliver personalized care and find cures, utilization of data within electronic health records to study patients and outcomes. Much like technology, these innovations will have long-lasting impacts on the world and our future.

The Measure of Success

Similar to what's being explored regarding prescriptions, I believe that there will be a greater push to compensate clinical service providers on success, especially those that are involved in the in-depth research and development of compounds, methods, processes, devices, etc. Accordingly, becoming the vendor of choice should be viewed as an opportunity to partner toward a significant outcome that benefits both sides of the partnership. This means that clinical trial service providers should strive to go way beyond the required tasks of the engagement to ensure the overall success of the partnership. This may include evaluating outcomes for possible additional treatment areas possibly across multiple therapeutic applications and possibly further exploration into such therapeutic applications.

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"We come together with other big sponsors as well to work together. We are constantly seeking ideas and opportunities externally."

Phil Vickers, Ph.D., global head of research and development for Shire Human Genetic Therapies, says any R&D organization has only a tiny sliver of the individuals who have the knowledge or ideas to solve the challenges in bringing forward therapies to patients.

"We need to have an efficient way of moving forward with relatively small, very well-trained research and development organizations that can partner in different ways with external partners of all types, accessing knowledge and individuals who have knowledge, and who are creative to solve some of our problems — this is really an exciting opportunity," he says. "There is lot of external talent outside our walls who would be excited to solve our problems."

Dr. Barbosa agrees that open innovation really provides a potential mechanism upon which companies can tap into the highly creative scientific teams who exist in many different areas of the globe as well as different sectors from academia to the biotech sector.

"We need to be able to access this innovation and tap into that creativity without having to manage within the structural systems that we have within the pharmaceutical industry," he says.

Hugh Davis, Ph.D., VP and head of biologics and clinical pharmacology, Biotechnology Center of Excellence, Janssen Research & Development, LLC, Janssen Pharmaceutical Companies of Johnson & Johnson, says through open innovation the company is engaging with as many strategic partners as possible.

"We've initiated four different innovation centers: San Francisco, Boston, London, and Shanghai," he says. "These are geographical areas with concentrated research expertise. The centers will be focused on onboarding the most promising early-stage opportunities at the local universities, academic centers, and even the biotech companies that are set up in these area. We are hoping to gain access to really novel approaches, data management approaches, data mining approaches, and be able to address significant unmet medical needs."

Innovation Opportunities

Analysts say innovation is needed to refill the diminished pipelines, and there are both opportunities and challenges associated with putting innovation, even disruptive innovation, on the front burner.

"The place for disruptive innovation is at the very front end of the process as a way to leverage the latest and greatest innovations coming out of academia and biotech and picking from among those exciting opportunities to discern which can be translated into a real drug discovery program," Dr. Leonard says. "We continue to see great innovation in handling very big data sets that allow us to start to tease out a better picture of the relative importance of molecular targets relative to others. This is particularly true in cancer biology and increasingly so in immunology."

Companies will need to think about how they can be more effective in getting quantitative data from clinical trials more efficiently.

Dr. Leonard says there are tools emerging that will give researchers greater predictive power in determining at the earliest stages of testing of whether a new drug, vaccine, or biologic might have the potential to be effective in a human disease.

"The earlier we can apply that data to animal testing or in virtual modeling systems, more intelligent choices can be made about the very time-consuming and expensive testing phases that come later in the early clinical space," he adds.

JOHN BALDONI, *GlaxoSmithKline*

Dr. Vickers says the industry is just scratching the surface with applying innovations around information to pharmaceutical R&D.

"For example, a lot of fantastic science has gone into the human genome," he says. "We are now starting to reap the benefits of this data and applying it to pharmaceutical R&D is in its infancy. I think we will soon get to the point where everyone's human genome will be

Impact of Rare Diseases

It can take more than five to seven years for a patient with a rare disease to receive a proper diagnosis, which has a significant economic and emotional impact on patients and their families. On the journey to diagnosis, a patient typically visits up to eight physicians on average and receives two to three misdiagnoses, according to a recent report by Shire. The report, Rare Disease Impact Report, uncovers the health, psycho-social, and economic impact of rare diseases on patient and medical communities in the United States and United Kingdom.

Rare diseases are conditions that affect a small portion of the population but are often chronic, progressive, degenerative, life-threatening and disabling. While individual rare diseases are uncommon and disparate, collectively, there are about 7,000 different types of rare diseases and disorders affecting an estimated 350 million people worldwide.

Despite the progress that has been made over the past few decades to help improve the quality of life for patients managing these complex diseases, there are still significant gaps in care and barriers facing the community at large. There is a lack of resources and information to address these less common illnesses.

Physicians (both primary care and specialists) often don't have the time, resources, and information to properly diagnose/manage patients with rare diseases, compared with more common diseases. The majority of physicians surveyed say it is more difficult to address the needs of a rare disease patient in a typical office visit (92% in the US, 88% in the UK agreed) and more visits are required to diagnose a rare disease patient (98% in the US, 96% in the UK).

From a patient and caregiver perspective, around half of those surveyed stated they received conflicting information from different healthcare professionals about treatment options (60% in the US, 50% in the U.K. agreed). The economic impact of diagnosing and managing rare diseases is significant. The journey comes with a steep price tag for many coping with a rare disease. The long road, which includes numerous tests and physician visits, can be financially overwhelming, particularly for those in the U.S. compared with the U.K

For more information, visit rarediseaseimpact.com.

sequenced very cheaply. There will need to be innovations around managing vast amounts of information and translating data into meaningful impacts for patients."

The Future of R&D

"It seems clear from the current landscape that we will continue to see a greater stratification of effort along the discovery and development chain with greater reliance on academic innovation and innovation sourced from biotechnology companies on the front end of the process, which means target identification, target validation, and in many instance, the discovery of early proof of concept that a disease can be approached given a certain type of molecule or vaccine or biologic," Dr. Leonard says. "Academic collaboration can only take a project so far, and then the work has to move into a translational setting. There is a natural progression into the biotech realm where there is a higher tolerance for risk, multiple sources of capital available, and the ability to focus on small numbers of projects deeply. Then enter the larger companies, which have large and powerful drug development machines that are looking for the best possible venue in which to apply these useful but expensive resources. But even in those areas where we fully expect many of our programs to come from outside investors, we will still have a healthy and vigorous scientific culture within Merck to identify and select targets and then through collaborations improve those external opportunities."

Dr. Nisen says increasingly there will be a need to rewire partnerships with academia and between sponsors and other companies.

"I think there will be more cooperation with organizations that are more nimble that can map and adjust," Dr. Nisen says. "We will define our critical capabilities are around execution and implementation and we will see some changes in experimental design."

John Baldoni, senior VP, platform technology and science, GlaxoSmithKline, says in the future chemistry will undergo a resurgence.

"The companies with the best chemists will be the ones that go from hypothesis to the chemical and biochemical matter the most quickly," Mr. Baldoni says. "As a consequence, the cost of clinical trials is getting too expensive, and companies will need to think through how they can be more effective in getting quantitative data from clinical trials more efficiently." PV

PODCAST

DISRUPTIVE INNOVATION IN R&D PROCESSES

Thought Leader: Hugh Davis, Janssen Biotech

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