

# The Keys to Pharmaceutical Innovation

New technologies will drive innovation in the pharmaceutical industry in the years to come.

**T**he ability to innovate, industry leaders agree, will be a critical factor in a pharmaceutical company's success in the future. Companies will have to embrace scientific advances and technologies to move new and innovative therapies forward.

Pharma leaders believe their companies are enjoying a resurgence in innovation, according to a recent survey by KPMG. In fact, companies surveyed are confident that innovation is on the rise in their organizations, and more than half say they are satisfied with their portfolio's ability to address unmet medical needs. The survey also found that executives believe technology is at the heart of change. The use of data and technology is crucial to capturing and interpreting product information as it passes through the development process.

The industry is experiencing a technology revolution and customer expectations are having huge demands on what is possible, says James Streeter, senior director, life sciences product strategy, Oracle Health Sciences.

"The industry is looking to technology companies to handle all of the variant sources of data, as well as the large amount of data already produced to inform better study design and become more productive and efficient, while rationalizing costs," he says.

Mr. Streeter says key benefits provided by new enabling technologies include making rapid, informed go/no-go decisions through faster, better insight into cleaner clinical and operational data; reducing time from lab bench to patient by moving away from the linear Phase I to Phase IV approach; and collecting and managing multiple sources of data from patient sensors and tracking devices in real time.

"These and other capabilities will not only drive greater innovation in clinical research and development but enable us to make better and more informed strategic decisions," he says.

Broad adoption of platform technologies will enable better decision-making processes and fewer, less redundant procedures that can

help drive faster, less expensive and safer clinical trials, says Glen de Vries, president of Medidata Solutions.

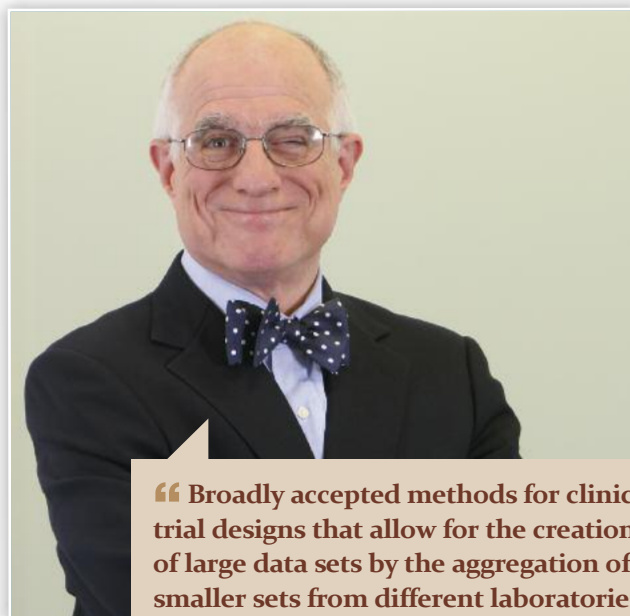
"Cloud-based platforms, for example, offer unified operating models that can facilitate the processes of designing and managing clinical trials, as well as knowledge sharing and collaboration among users, sponsors, CROs, and other trial partners," he says. "Such platforms can aggregate patient data across studies and drug programs, allowing life-sciences companies to benefit from quick and easy access to relevant, high-quality, and analysis-ready data. And as we move beyond the clinic to incorporate data gathered from patients' mobile devices, a single technology platform can capture richer data sets — without increasing the cost of monitoring and data cleaning or the burden on clinical trial sites."

Industry leaders also say emerging technology is leading to radical change. Microchip modeling within clinical trials, 3D and 4D anatomical printing, and other sophisticated new and emerging technologies are expected to have the potential to disrupt the current research paradigm.

Frost & Sullivan, in a report in May 2014, finds that technologies such as nanobots, combination devices, electroceuticals, and genome sequencing will have a tremendous impact on the industry, and by 2020 the 3D printing market will be \$7.1 billion with medical and dental accounting for 16% of that.

## The R&D Paradigm Shift

Advanced technologies will change the R&D paradigm not only by reaching new heights in the labs and clinics of the developed



**“ Broadly accepted methods for clinical trial designs that allow for the creation of large data sets by the aggregation of smaller sets from different laboratories will be the key to major breakthroughs in omics-scale medicine. ”**

**STAN LAPIDUS / SynapDx**

world, but also by bringing them into the developing world much sooner, says Nick Colucci, CEO of Publicis Healthcare Communications Group.

"New technology is often noted for its portability, ability to function independently of an existing infrastructure, and its high capability-to-cost ratio," he says. "Think of the power packed onto microchips, the way a 3D printer can create items seemingly out of thin air, or the ability of handheld devices to handle increasingly complex tasks. These new technologies are viable not only in cutting-edge labs, but also in bare-bones facilities at the edge of civilization. Groundbreaking research will increasingly come from new places as the playing field levels."

There is a fundamental shift in the way new drug candidates are tested, made possible



BulletinHealthcare



# Our Associations Make Us Unique



### Exclusive association reach.

Every morning, we deliver to more than 700,000 physicians and 50,000 other medical professionals a concise distillation of medical news related to their specialties. These physicians are members of 24 prestigious medical associations.



### Targeted messaging.

Our targeting capabilities allow advertisers to segment our network by specialty and geography so that their message reaches the most relevant audience. Whatever your target is, we'll build you a custom plan to optimize results.



### Mobile made simple.

Physicians have gone mobile – 60% of our briefing opens are on mobile devices. Your standard web creative will seamlessly integrate into our news briefings. To learn about mobile behavior among various physician specialties, please visit the link below.

Download a report on physician mobile usage and behavior.

VISIT: [BULLETINHEALTHCARE.COM/HCP](http://BULLETINHEALTHCARE.COM/HCP)

## Innovation Trends

**Our industry thought leaders identified several areas where multiple factors are converging that will lead to innovative treatments in the future.**

### CELL THERAPIES

Groundbreaking 3D technology for the expansion of human cells could make it possible to develop cell therapy products that are tailored to treat specific diseases, says Zami Aberman, CEO of Pluristem Therapeutics.

“Expanding mesenchymal cells with this technology could produce cells that, once injected into a patient’s body, can achieve an extended, controlled release of a cocktail of therapeutic proteins,” he says. “The types of proteins that the cells secrete can be influenced with a 3D expansion process, allowing for the development of multiple products.

“Companies developing new classes of biologic therapeutics need to invest the time and effort and resources required to achieve a deep understanding of the mechanism of action of their treatments,” Mr. Aberman continues. “In the case of cell therapy, the process of manufacturing the cells has a huge impact on the product. Cells are sensitive creatures, and even small variations in the environment in which they are grown will affect them. Manufacturing must be precisely controlled at all times in order to mitigate the risk of producing batches of cells that differ in potency or quality. Failure to do so can doom trials and prevent development of a marketable product.”

### DEVICES

Terrence Norchi, M.D., CEO of Arch Therapeutics, predicts that advanced medical devices will more commonly deliver therapeutic benefits over some biopharmaceuticals, with the added advantage of providing improved safety profiles and commercialization pathways associated with shorter timelines and lower capital costs.

“A device achieves its primary effect without

requiring metabolic or chemical activity in the body,” he says. “If a product’s therapeutic benefit does not rely on body metabolism or chemistry, doctors and regulators should feel more comfortable that its behavior is more predictable and its risk profile is less threatening.”

### ONCOLOGY

For decades researchers were stunned by the striking ability of cancer to evade the immune system and initial attempts to develop cancer immunotherapies failed, says Ingmar Hoerr, Ph.D., CEO of CureVac.

“A deeper understanding of how cancer progresses and the complex interactions between cancer and immune cells have led to major treatment breakthroughs for a number of cancers,” he says. “Many immunotherapeutic approaches have shown promising results for the treatment of cancer. Novel approaches, such as checkpoint inhibitors and mRNA-based cancer vaccines, have shown promise and are taking immuno-oncology to the next level.”

Peter Culpepper, chief operating officer, Provectus Biopharmaceuticals, says treating cancer is complex because there are many different types of cancers.

“Treating cancer with one agent is particularly challenging because each type of cancer is different,” he says. “Treating disease locally versus systemically is particularly challenging since cancer is by definition a systemic disease; the local treatment standard of care often fails. Treating different cancers locally with another drug safely and effectively is a paradigm shift in treating disease. We are in the realm of the new emphasis on cancer treatment: combination therapies.”

It is highly unlikely in most diseases, including cancer, that a single agent will lead to a cure, says Lawson Macartney, Ph.D., president and CEO, Ambrx.

“The challenge is adapting the R&D paradigm so that the combination of therapies needed can be tailored for the specific patient,” he says. “We will need to understand combinations of drugs, both small molecules and highly specific biological agents such as ADC, that will give synergistic efficacy, without increasing toxicity. Well-defined ADC that are homogenous and optimized for increased efficacy and decreased toxicity will be critical. This requires the industry to adapt, academia to adapt, and regulatory agencies to view approaches to both molecule discovery and clinical studies somewhat differently from current practice.”

### RNA INTERFERENCE

RNA interference (RNAi) is used by cells to regulate protein expression. Its discovery has transformed the understanding of gene regulation and ways for researchers to manipulate it. RNAi-based therapeutics have the potential to specifically silence gene expression, but initial attempts to develop drugs based on this technology have failed.

Industry leaders say recently, great strides have been made and novel approaches have tackled shortcomings such as delivery and side effects.

“An RNAi approach may provide treatment options or even cures for many serious diseases that have been undruggable thus far,” says Vincent Anzalone, VP, investor relations, Arrowhead Research. “Emerging strategies have managed delivery issues for RNAi therapeutics, enabling them to reach the proper target tissue/cells. RNAi triggers will be tailored to the target and will be able to silence disease-causing genes of serious diseases.”

by new technologies ranging from organs-on-chips to 3D tissue modeling to microinjections directly into tumors, says Richard Klinghoffer, Ph.D., chief scientific officer at Presage Biosciences.

“These new technologies are already making it possible to enable direct study of drug efficacy in the only context that matters: the human patient, without exposing patients to systemic toxicities,” he says. “This will be a

game changer, particularly for cancer drug development. Currently, cancer drug efficacy observed in translational preclinical models translates poorly to treatment in humans: nine out of 10 drugs that work in preclinical models don’t show efficacy in late-stage trials and don’t make it to the market. We all know this ratio but up to now have had to work within the confines of the existing assessment models. I believe this will change, and soon. Technolo-

gies that enable multi-drug studies without inducing systemic toxicities will release drug developers from the confines of poorly predictive preclinical models for human diseases.”

Three-dimensional printing certainly has the potential to be a disruptive technology in many ways in the healthcare industry, says Fran DeGrazio, VP, global R&D, strategic program management and technical customer support, West Pharmaceutical Services.

© 2017, PAREXEL International Corp. All rights reserved.

# *INCEPTION*

TO

# *LONG TERM*

CHOOSE YOUR GUIDE WISELY.  
AFTER ALL, THE JOURNEY  
TO MARKET IS OFTEN  
QUITE LONG.

As your new drug embarks on the long journey to market, having a dedicated partner can make all the difference. At PAREXEL we not only understand this, we pioneered strategic partnerships between biopharmaceutical companies and their service providers. From reductions in outsourcing costs to enabling access to new patients and markets, a strategic partnership with PAREXEL can help streamline processes and accelerate development cycles. The result is greater efficiencies across all phases of your product's development. Here's to a better journey.

To learn more about how we can help your journey, visit [Partner.PAREXEL.com](http://Partner.PAREXEL.com)

**PAREXEL**  
YOUR JOURNEY. OUR MISSION.™

## Innovation Needs Strong Leaders

**Moving innovation from the lab to the clinic to the market requires champions.**

While disruptive technologies are important for moving innovation forward, we must consider changes in corporate structure that support and accelerate adoption of new technology, says Michael Griffith, executive VP of inVentiv Health, and president of inVentiv Health Commercial.

“Often, this involves making the most of limited corporate resources,” he says. “That’s one reason we are seeing important changes in pharma C-suites. Instead of selecting top executives who came up through sales or research, companies are promoting people who can achieve operational or financial objectives. This shift will likely be combined with significant restructuring of staff, and the end result will be greater reliance on strategic partnerships. The business of outsourcing will, itself, be reinvented. And the structure of CRO/CMO relationships in pharma will be refashioned to route around the limitations and bottlenecks of traditional contract partnerships.”

Nick Colucci, CEO of Publicis Healthcare Communications Group, says innovation in the pharmaceutical industry is enabled by a serious top-down commitment. This includes the willingness to not only accept but also encourage both experimentation and failure. Without the freedom to take risks, innovation

can’t succeed, and risks don’t come without a certain amount of failure.

“Most companies pay lip service to innovation, but successful ones act on their commitment every day, with leaders guarding that freedom for employees at all levels and honoring those who take advantage of it to do new things,” he says.

As the life-sciences industry continues to push the boundaries of existing clinical development models, companies, researchers, regulators and other stakeholders must all embrace change, says Glen de Vries, president of Medidata Solutions.

“Fortunately, more and more managers, especially those in the C-suite, understand that we need to figure out how to plan and run studies differently,” he says. “And while such commitment to innovation continues to gain momentum, the industry must take advantage of the growing willingness to rethink existing processes and bring about meaningful change.”

Mr. de Vries says this means quickly adapting to emerging and rapidly changing technologies.

“As an industry, we need to adopt solutions that have the potential to dramatically lower development costs, reduce time to market, mitigate risks, engage patients and increase the probability of trial success,” he says. “Process change is hard, but embracing disruptive change is essential to ‘skating to where the puck will be’ and remaining competitive over the longer term.”

Richard Klinghoffer, Ph.D., chief scientific officer at Presage Biosciences, says the No. 1 factor for enabling innovation is courage.

“Courage is needed both on the side of the scientist entrepreneur and on the side of the funding partner, whether that be VC, large pharma, or established biotech,” he says. “It’s a lot safer to maintain the status quo or to simply follow the herd versus being the first to investigate and support the paradigm shifting potential of novel technologies. It takes guts to enable innovation in the traditionally conservative drug development industry.”

Dr. Klinghoffer says the greatest obstacle is getting the key players in the drug development community to believe in and support the tremendous effort required to advance something that is truly novel.

“I see a lot of support for novel technologies that are simply a derivative of what’s been around for a decade or so,” he says. “True innovation requires pharma leadership to recognize that maintenance of status quo and incremental tech advances are unlikely to lead to timely substantial breakthroughs in therapies for patients in need. It’s time for our industry to make a leap forward and take full advantage of the discoveries and advances made over the last year that have the potential to change drug development as we know it.”

“It is something that, from a packaging and delivery systems standpoint, we are evaluating as a potential way to build efficiencies into some of our processes,” she says. “It may also have potential in the future as a new option or different way of manufacturing. However, there is a lot more to the current business than just the printing capability. Material, chemical, and functional characteristics are also very important to the industry. Although three-dimensional printing may have the ability to produce an item, the industry must ask: does it ultimately function in the way it needs to? It’s a technology to keep watching long term.”

While it’s easy to think about the Internet of Things as wearables and platforms and 3D printers and data, it’s time to think bigger than that, says Wendy Blackburn, executive VP of Intouch Solutions.

“What makes a difference is not so much these devices’ individual functions, but their interactivity and interoperability,” she says. “It’s ambient health; all of these tools and data sets are working together seamlessly behind-the-scenes.”

Garth McCallum-Keeler, managing partner in the San Francisco office of Calcium, says one of the most interesting ways in which technology is changing research and development is through the use of big data or meta-data to inductively search for possible linkages between drugs and cell surface markers.

“As one example, NCBI — the National Center for Biotechnology Information — GEO registry of microarrays now allows researchers to search across an aggregate national database to identify possible associations; these known associations and known

markers of disease activity can then be assessed via traditional clinical research approaches,” he says.

Currently, much of the health innovations are coming from the technology sector versus the healthcare sector, Mr. McCallum-Keeler says.

“Infusing healthcare market expertise and knowledge of HCP adoption patterns into the technological development process will be critical not only for acceptance of these technologies but also essential for innovations that add immediate, real value to patient care,” he says. “Groups such as the Exponential Medicine arm of Singularity University, Rock-Health, and Health 2.0 — and all the companies they support — are at the forefront of supporting this integration and deserve attention from anyone interested in the forefront of



“ In the years to come, there will be new and more effective models that will more reliably inform efficacy and safety decisions, and improve outcomes. ”

DR. BRIAN WAMHOFF / HemoShear



“ Complementary partnerships also pertain to academic life-sciences R&D centers, which themselves are often struggling for survival. ”

DR. TERENCE NORCHI / Arch Therapeutics

health technology and the rapid pace of its evolution.”

But new technology for R&D isn't limited to tools on the lab bench, says Lisa Stockman, president, global PR/medical communications, of inVentiv Health.

“In clinical research, regulators are now placing greater weight on patient reported outcomes (PROs) and other means of grasping the patient experience, an area that's ripe for a technological upgrade,” she says.

Ms. Stockman cites as an example ongoing research that shows that patients are more comfortable discussing personal information with “virtual humans” than with real doctors. In a recent study, published by University of Southern California in September, participants



“ A deeper understanding of how cancer progresses and the complex interactions between cancer and immune cells have led to major treatment breakthroughs for a number of cancers. ”

DR. INGMAR HOERR / CureVac

dates are being delayed or left on the shelf, says Ibraheem Mahmood, president and CEO of DrugDev.

“The sad truth is drug development is as inefficient as it's ever been,” he says. “If we look at a long-trend view, efficiency has

were questioned about disease symptoms by a computer-simulated interviewer. Half were told the process was entirely computerized; the other half believed there was a human in another room controlling the interface. Those who thought no human was involved were more open and honest about their symptoms and experiences. The funders, the Defense Advanced Research Projects Agency, were interested in implications for soldiers with PTSD, but there's broader importance.

“The research suggests that advances in artificial intelligence and human-machine interfaces could have a remarkable, positive impact on clinical research, disease diagnosis, and many other areas of healthcare,” she says.

### Challenges Impacting Innovation

With drug development cost estimates reaching between \$800 million and \$1.2 billion for each product, biopharmaceutical companies are trapped between pressure to reduce development costs and the need to ensure better outcomes and provide enhanced value for patients, all while navigating increasingly complex clinical trials, says Paula Brown Stafford, president of clinical development at Quintiles.

“In addition, companies are faced with incongruent regulatory requirements for drug approval, making it difficult to ensure compliance,” she says. “We believe these challenges can be addressed — and clinical research modernized — by an equal focus on patients, processes, and pathways. By creating better ways to find the right patients for the right clinical trials, eliminating redundancies in current processes through standardization, and introducing alternative development pathways, we will enable clinical development transformation and help foster innovation across the industry.”

The tremendous time and expense of the clinical process means some promising candi-

dropped continuously over the last 60 years. Developing a drug costs 10 times as much as it did 30 years ago and 100 times as much as it did 60 years ago. Today for every \$1 billion spent the result is one product, where the output was 10 products years ago from that same investment.”

Today's methods for predicting safety and efficacy of new drug candidates haven't changed much over the years with the same animal and cell models being used despite lack of success, says Brian Wamhoff, Ph.D., VP R&D at HemoShear.

“Unfortunately, the high cost of bringing a drug to market coupled with the rate of failure is not sustainable,” he says. “We seem to have arrived at a breaking point where scientists and government officials are recognizing that the current paradigm is broken and a fundamental change in drug discovery and development is necessary if we are to improve the odds.”

The principles of clinical trial design and methods of validation haven't really changed since the 1940s, says Stan Lapidus, president, CEO and founder, SynapDx.

“Broadly accepted methods for clinical trial designs that allow for the creation of large data sets by aggregation of smaller sets from different laboratories will be the key to major breakthroughs in omics-scale medicine,” he says.

In the coming year, and years to come, there will be new and more effective models emerging that will more reliably inform efficacy and safety decisions, and improve patient outcomes, Dr. Wamhoff says.

“The traditional models that have long disappointed will be replaced by laboratory human tissue systems that are capable of recreating healthy and disease biology to more accurately predict human response at human-relevant dosages,” he says. “2015 could be the year that these new and more predictive models are finally given their rightful place, and new drug success rates will begin to improve.”



**“The FDA has implemented new expedited pathway options to offer more proactive and timely communications, which will have a positive impact on enabling innovation.”**

**DR. ROBERT RYAN / Scioderm**

James Powers, CEO of HemoShear, says the pharma industry's appetite for funding transformational innovation is also limited by shrinking budgets.

“Not long ago, pharma was flush with cash and had significant funds available for exploring new technologies,” he says. “Today's focus by major pharma companies is heavily weighted toward later stage drug assets, while there is little money remaining for investments in new technologies. When budget cuts are made, external technology collaborations are often the first to be cut. Successful mid-stage biopharma companies have more money to spend, but often do not have the bandwidth to explore and validate new technologies, while emerging companies generally do not have the cash or bandwidth.”

Mr. Powers says pharma's limited bandwidth remains an obstacle to assessment and acceptance of new technologies.

“The pharma industry cannot sustain itself at present failure rates and high costs of failure,” he says. “In-licensing more compounds will simply lead to more expensive failures. In the coming years, pharma companies will increasingly recognize that the current paradigm is failing them and they will more aggressively embrace new technologies that could significantly impact new drug success and ROI on their R&D investments.”

The fundamental issue for the biopharmaceutical R&D community is about the willingness to take and the capacity to manage risk in seeking competitive advantage, says Timmy Garde, managing partner/chief operating officer at Calcium

“Today's disruptive technology is now to-



**“Treating cancer locally versus systemically is particularly challenging since cancer is by definition a systemic disease; the local treatment standard of care often fails. Putting the treatment of different cancers locally with another drug safely and effectively is a paradigm shift in treating disease.”**

**PETER CULPEPPER / Provectus Biopharmaceuticals**

tomorrow's norm,” he says. “It's no longer good enough to be ahead of the curve; competitors can catch up too fast. The wise R&D-based company will be looking hard at its ‘intrapreneurs’ and its extended R&D collaborations to optimize options, invest wisely in opportunities with very high risk, but balance the risk portfolio.”

Analyzing data captured by multiple, disparate IT systems remains a critical challenge to bringing a product to market, Mr. de Vries says.

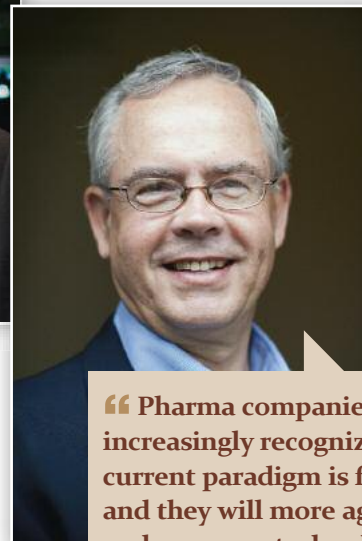
“Over the years, life-sciences companies have made substantial investments in a range of technology solutions from third-party vendors and customized internal IT systems to support R&D,” he says. “Today, such varied and proprietary systems are hindering the implementation of common standards. This has created an environment that is slowing down cross-industry collaboration, and as a result, is impeding innovation in drug development.”

To overcome this challenge, Mr. de Vries says life-sciences organizations are adopting cloud-based technology solutions that offer an interoperable model based on service-oriented and standards-based architecture.

“With the flexibility to interface with legacy systems, these technology solutions are equipped to support the complexity and rigorous needs of clinical research today,” he says. “Moving into the future, cloud-based solutions will enable the knowledge sharing and collaboration needed to stimulate innovation across the broader life-sciences industry.”

Newer technologies allow for access to real-time data, says Xavier Flinois, president of Parexel Informatics.

“For example, the trend toward wearables will continue to rise over the next 10 years,” he says. “Part of the challenge, however, is that regulators typically take four to five years to clear the impact on patient safety and efficacy assess-



**“Pharma companies will increasingly recognize that the current paradigm is failing them, and they will more aggressively embrace new technologies that could significantly impact new drug success.”**

**JAMES POWERS / HemoShear**

ments with new technologies. Using real-time data will also increase data quality and, ultimately, improve outcomes. Instead of sampling information as we do today, the technology will allow for a continuous stream of data.”


Matthew Howes, senior VP, head of strategic services, at Palio+Ignite, an inVentiv Health company, says one of the most imminent threats the healthcare industry needs to prepare for is data security.

“New innovations in healthcare are adding to an already high volume of digital health data and creating an attractive target for cyber thieves,” he says. “In addition to the usual forms of financial, medical, and insurance fraud conducted with individual data, a breach of clinical trial data can also expose organizations to competitive threats and legal risk. With more data moving to the cloud and seamlessly across borders, these risks are multiplied.”

### Enabling Innovation

Mr. Mahmood says to transform the business of clinical trials the industry must create a uniform use of technology, a standard way of running trials.

“We have strict regulations and we have peoples' lives at stake,” he says. “We also have



Introducing the essential nutrient  
for nourishing stronger growth.

## **NEW**TRICIOUS

The Star Group has made a splash by creating the new agency Calcium from the merger of Star Life Sciences, Vox Medica, and Calcium NYC.

The new Calcium offers clients best-in-class strategic, creative, scientific, and interactive solutions— which are formulated to fuel strong brand and business growth even in this challenging healthcare environment.

So, whether you're preparing for a launch, or have an in-line brand that needs some added muscle, get a taste of the new Calcium—because building stronger brands is in our bones.

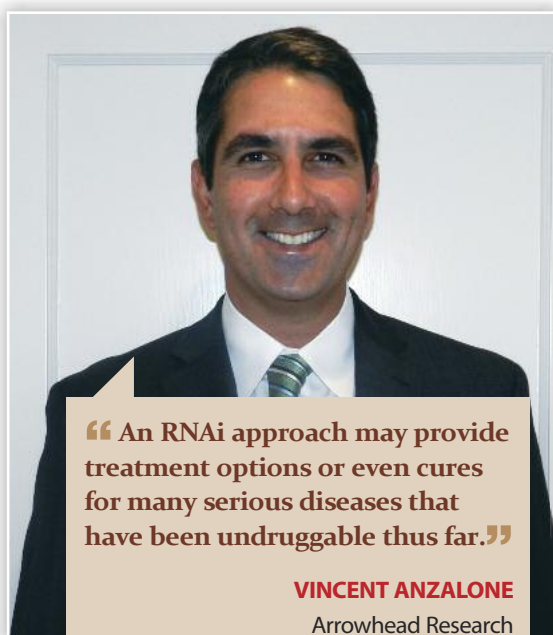
**calcium**<sup>TM</sup>  
**BRAND NOURISHMENT**

A Star Group  
Company



Start getting stronger. Contact  
Steven.Michaelson@CalciumUSA.com  
or 917-612-3290



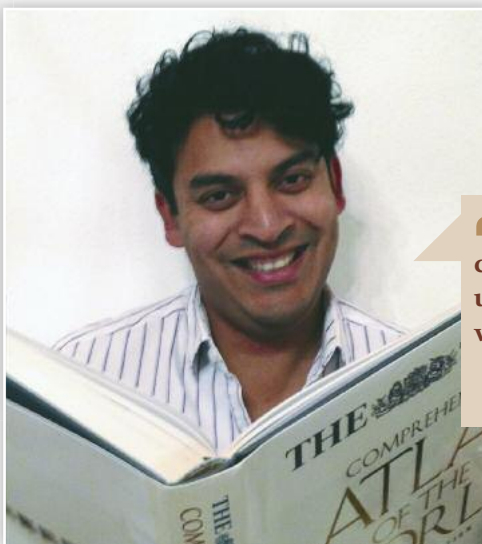


**“ An RNAi approach may provide treatment options or even cures for many serious diseases that have been undruggable thus far.”**

**VINCENT ANZALONE**  
Arrowhead Research

**“ Technology is changing research and development through the use of big data or metadata to inductively search for possible linkages between drugs and cell surface markers.”**

**GARTH MCCALLUM-KEELER** / Calcium



**“ To transform the business of clinical trials, we must create a uniform use of technology, a standard way of running trials.”**

**IBRAHEEM MAHMOOD** / DrugDev

a culture that came out of a world where a lot of money used to be made, but not so much anymore. Put those things together and there isn't the same catalyst and process for change.”

Niklas Morton, VP, global biostatistics, programming and medical writing, PPD, says there needs to be a true commitment to innovation and a recognition that not all ideas will drive through to successful innovation.

“If we are truly taking risks to innovate then some ideas and innovations will fail by definition,” he says. “A safe environment needs to exist where idea generation, proof of concept, and idea failure are supported; where enthusiastic leadership support and budgets can be accessed through a known process; and where project planning and data analysis are supported through corporate resources.”

Mr. Morton says some best practices to consider in the development of data-driven insights include: integrating or centralizing key data sources to minimize the footprint for the analytics involved; ensuring data are collected and aggregated for analysis as close to real time as possible in order to be able to adapt; using industry or corporate data standards to minimize development effort around data assimilation; and focusing the development effort on interactive analytics software that allows users to answer their developing questions or raise new questions by diving down through the data to develop appropriate insights.

Fear of change is common throughout the corporate world, but those industries that are highly regulated suffer from this paralysis more often, says Ari Schaefer, VP group account director at Klick Health.

“The ability to face the regulatory questions surrounding new technologies will always be an obstacle to overcome when imple-

menting innovative approaches to existing problems,” he says. “Proactive education of all stakeholders in the process is critical to assuaging the fears of the organization. Many of the concerns pertaining to the implementation of digital solutions are grounded in a lack of understanding as opposed to a concern grounded in experience. Working with teams to train regularly on new technologies will drive a sustained awareness of risk that is grounded in reality as opposed to unfounded fears.”

True innovation only happens when people talk to each other, when the various parts of the health system come together to understand each other's challenges, spark dialogue, and collaborate on solutions, says Lynn O'Connor Vos, CEO of ghg.

“Healthcare innovation cannot happen in a silo,” she says. “We have a healthcare system where physicians hold the intellectual capital, payers hold the purse strings, and patients control their care. This disjointed approach makes solving our industry's problems difficult. But bringing people together from all sorts of specialties and parts of healthcare will yield the greatest results. We need to tear down our siloed walls and commit to working collaboratively to improving outcomes.”

Generating and cultivating ideas within and across organizations is crucial, Mr. Morton says.

“Eureka moments rarely occur in isolation,” he says. “Most innovations are the collisions of multiple ideas or the timing of an idea versus a specific context/environment. Organizations and industries need to cultivate and store ideas

until the right collision or right-time/right-place moment.”

Some leaders have pointed to the positive changes taking place at regulatory agencies. One such change has been the breakthrough therapy designation for new products. This designation was provided for in the Food and Drug Administration Safety and Innovation Act, which was signed into law in July 2012.

“Breakthrough therapy designation can have a significant impact on a drug's development pathway and corporate strategy,” says Robert Ryan, Ph.D., president and CEO of Scioderm. “The level of engagement with the FDA for products receiving this designation is great, which could allow the product development to be quicker and market entry earlier.”

Dr. Ryan says the increased interaction with the FDA, especially early in the development process, is an important factor for enabling innovation.

“The ability to have interactions with the FDA in a more frequent time frame than the current meeting requests is important for innovation,” he says. “The efforts by the FDA have been with the new expedited pathway options to offer more proactive and timely communication, which again will have a positive impact on enabling innovation.”

But Dr. Ryan also points out that companies along this expedited path have the added challenge of making sure their own development and commercial infrastructure grows at the pace of their journey through the regulatory development pathway. **PV**



USE YOUR QR CODE READER  
OR GO TO  
[bit.ly/PV1114-YIP-Disruptive](http://bit.ly/PV1114-YIP-Disruptive)





# Accelerate Your Clinical Trials

DrugDev gets clinical trials rolling, with site selection and contracting solutions, global payments by CFS Clinical, and a trial optimization platform by TrialNetworks. DrugDev provides technology-driven solutions to improve quality, shorten timelines and reduce costs, enabling sponsors, CROs and investigators to do more trials together. **Learn more at [drugdev.com](https://drugdev.com)**



1 King Street, London, W6 9HR | [uk.office@drugdev.com](mailto:uk.office@drugdev.com) | +44 208 741 0918  
1000 Madison Ave, First Floor, Audubon, PA 19403 | [us.office@drugdev.com](mailto:us.office@drugdev.com) | +1 888 650 1860

# Alliances and Partnerships Will be Critical to Innovation in the Future

Successful companies will embrace partnerships with nontraditional stakeholders in healthcare.

Only 27% of health executives said their companies formally manage innovation, according to a recent study conducted by PwC. In order to integrate and bring innovation to the market, pharma companies must consider a number of strategies, including adopting and shifting to a fail-fast and frugal mentality.

“The most innovative pharma companies will need to look beyond traditional R&D outlets to source new ideas. This includes the broader ecosystem of customers, partners, competitors, and even the start-up culture to widen their funnel of ideas and become more in tune with their own customers,” says Larry Gioia, director, IT strategy and enterprise architecture at PwC. “Companies that don’t move to reinvent their own innovation culture are likely to find themselves at the mercy of what we call new entrants — nontraditional players from outside healthcare who are placing big bets to grow their business through health innovation. The tech giants and telcos have created dedicated healthcare divisions to drive the connected and ‘always on’ experience that consumers are demanding from our industry.”

Ingmar Hoerr, Ph.D., CEO of CureVac, says biotech companies with innovative technologies and technology platforms need to have a solid financial situation to maintain best quality in everything they do.

“Biotech companies need to maximize the opportunities for advancing pipeline candidates through clinical trials by pursuing programs in partnership with pharmaceutical and biopharmaceutical companies as well as on their own,” he says.

Pharmaceutical companies continued to externalize their research operations in 2013, increasing early-stage partnering activity with biotech companies and academic institutions, according to Burrill & Co. Of the \$35.4 billion in potential value of partnering deals with disclosed values, \$14.2 billion were discovery or preclinical collaborations. Global disclosed partnering values were up just 3%. This trend

will continue as big pharma and big biotech look for platform technologies that can be used to generate innovative molecules and targets.

Terrence Norchi, M.D., CEO of Arch Therapeutics, says he noticed more than a decade ago, when he was a life-sciences investor, that some of the best innovation emanates from small companies.

“Successful companies seem to recognize their place in this paradigm, and embrace partnerships to capitalize on their relative strengths and complement their relative weaknesses,” he says.

Dr. Norchi says the complementary partnership conversation also pertains to academic life-sciences R&D centers, which themselves are often struggling for survival as a result of structural shifts in the funding environment.

“Many companies have embraced this partnership opportunity, and many others should explore it,” he says.

As disruptive technologies get cheaper, it is important for the industry to work with regulators to secure their approval and adoption,” says Xavier Flinois, president of Parexel Informatics.

“The industry must prove to regulators that using these technologies will ensure fair trials and maintain patient safety,” he says. “It is also important for individual stakeholders, especially those conducting the trials, to find a way to invest or provide investment capabilities that allow innovation through use of disruptive technologies. Partnerships between sponsors and third parties are essential because they allow for a focus on innovation and R&D spending.” **PV**

## Strategy for Enhancing Innovation

### 1. Balance governance and administrative burdens with the size and complexity of the project.

Designing a lean governance and project management function can improve decision-making and support scientists to focus on the discovery of breakthrough innovations.

### 2. Strengthen collaboration and adapt the R&D model to support innovation across networks.

Getting the most out of a collaborative partnership will require proper joint development that will lead to licensing agreements earlier in the product development process. Companies will need to continue to promote an open culture that encourages scientific dialogue and sharing findings.

### 3. Bring commercial, finance, and R&D closer together.

To preserve scientific innovation, pharmaceutical companies need to foster the right balance of power between their commercial and research executives.

### 4. Bring the customer and patient to the heart of the R&D process.

Adapting to the changing healthcare ecosystem requires that companies start assessing the ‘value’ of a project from a patient perspective as early as possible in the R&D process.

### 5. Develop an environment that attracts and retains world-class scientists.

Scientists are motivated by scientific discovery and the publication of their research in peer-reviewed journals. Pharmaceutical companies need to foster this environment for scientists if they intend to recruit and retain top talent.

Source: KPMG

January 28-30, 2015

Boca Raton Resort & Club · Boca Raton, FL

19<sup>th</sup> Annual



# DRUG DELIVERY PARTNERSHIPS™

Accelerating the Path to Market by Leveraging New Partnerships,  
Breakthrough Innovation and Unique Business Models

## VISIONARY KEYNOTE



Bridging Science and Technology to  
the Healthcare of Tomorrow—Lessons  
Learned And New Paths to Explore

**John Ludwig**

SVP, BioTherapeutics Pharmaceutical Sciences,  
**Pfizer**

Save 15%

Use code  
**XP2078PV**



Overcoming Challenges in Delivery of Biologics:  
Combining Patient Centric Devices with  
Improved Formulations

**Anand Subramony**

Vice President, Drug Delivery & Device Development,  
**MedImmune**



Pharmacogenomics and Personalized Medicine:  
Providing Patient Specific Therapies to Monitor  
Adherence and Therapeutic Outcome

**Sven Stegemann**

Professor for Patient Centric Product Design  
and Manufacturing, **Graz University of Technology, Austria**

**NEW**  
for 2015!

- › Regulatory Guidance for the \$100 Billion Combination Products Market
- › Delivering Effective Patient-Centric Therapeutics
- › Digital Medicine—Improving Patient Adherence and Outcomes

Back by Popular Demand

**partneringONE®**

Jumpstart your next multi-million dollar deal

Register at [www.DDPEvent.com](http://www.DDPEvent.com) | @DrugDeliveryIIR #DDP15