

# Innovative SCIENCE AND PRODUCTS



Recent innovations are pushing the boundaries of life sciences, technology, and state-of-the-art care.

Innovation in the life-sciences industry is widely diverse. Products range from Google's Lift Lab's "super spoon" to help people with essential tremors and Parkinson's disease to eat without spilling — in clinical trials, the Liftware spoons reduced shaking of the spoon bowl by an average of 76% — to 45 novel drugs approved by the CDER in 2015 — more than the average number approved annually in the past decade. In addition, there are dozens of products that are breaking the traditional barriers and being developed that combine a therapeutic and technology such as nanomedicines for cancer or Proteus Digital Health's ingestible digital sensor that can track physical health with the assertion that patients are not taking their medication regularly and need a tracking device inside their body to assist them in their medical care.

Among the novel drugs approved in 2015 were several recognized by The Galien Foundation for excellence in scientific innovation and humanitarian efforts at 2015 Prix Galien Awards. The Prix Galien was created in France in 1970 in honor of Galen, the father of medical science and modern pharmacology. Worldwide, the Prix Galien is regarded as the equivalent of the Nobel Prize in biopharmaceutical and medical technology research.

In recognition of the development and discovery of biotechnology products that improve the human condition, the selection committee awarded both Bristol-Myers Squibb's Opdivo (nivolumab) and Merck's Keytruda (pembrolizumab) the 2015 Prix Galien USA Award for best biotechnology product. Both Opdivo and Keytruda are PD-1 immune checkpoint inhibitors currently indicated for patients with unresectable or metastatic melanoma or metastatic non-small lung cancer, following first-line treatment failure and disease progression. The 2015 Prix Galien USA Award for best pharmaceutical agent was awarded to Janssen Biotech and Pharmacyclics' Imbruvica (ibrutinib), a first-in-class, oral, once-daily therapy for the treatment of patients with chronic lym-



The growing role of emerging technologies is changing the face of healthcare.

**VAS NARASIMHAN**  
Novartis

phocytic leukemia and mantle cell lymphoma. In the category of best medical technology, the award was given to T2 Biosystems' T2Candida Panel. The T2Candida Panel is a diagnostic panel for the detection and monitoring of Candida infection and sepsis. It is the first sepsis pathogen diagnostic panel that provides species-specific results in three to five hours without the need for a blood culture, which can take up to six days to provide a result.

There are many exciting advances in the life-sciences industry, says Melinda Richter, head, Johnson & Johnson Innovation JLABS, but one area that is particularly meaningful to her given that she started in the tech industry is the interplay between technology and health.

"Today, entrepreneurs are pushing boundaries and tapping into vast knowledge of product design, engineering, and technology and are coupling it with the latest biological advancements that are enabling potential treatments once thought to be science fiction," she says. "In our JLABS @ TMC site in Houston alone, for example, there are companies working on everything from reducing anxiety during cancer treatment through psychological interventions in virtual reality to developing tomography systems that listen to the sound of light absorbed in tissues to see inside the human body with the goal to detect and diagnose disease."

Of course, Ms. Richter says, ultimately the biggest arena of technology and health to drive true value in the system overall will be the new models and applications of big data.

"With this we can better prevent disease when possible and if not, detect and diagnose it early with the goal to intervene with the appropriate set of solutions and thereafter, provide and track care in a way that's relevant for people in their day to day lives," she says. "Without question, on a daily basis, I'm amazed by the innovation potential and impressed by the entrepreneurial spirit that dances within the fabric of our JLABS communities. We are bringing tomorrow's solutions to life today."

Amir Kalali, M.D., head, Neuroscience Center of Excellence at Quintiles, as well as a founder and co-chair of the scientific program committee of the CNS Summit, is enthusiastic about artificial intelligence, synthetic biology, nanotechnology, big data and analytics, 3D printing, and robotic technologies that will impact the life sciences.

"And it's not just innovations but societal and technological changes enabling more engaged patients with a higher expectation to be involved," he adds.

One of the leaders in the 3D printing is Organovo, which began operations in 2007 and in November 2014 commercially released

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**JOAN BACHENHEIMER**  
Co-founder,  
BBK Worldwide

Patient-centricity is pushing the boundaries — boundaries that should have been pushed more than a decade ago. The patient is what unites all efforts in clinical research. A focus on the patient transcends boundaries.



**MÁRTA BENCSÁTH, PH.D.**  
Scientific Coordinator,  
Diagon

3D pharma and regenerative medicine, the biomarker approach in medication, the means of telemedicine and wearables, the accelerated use of informatics in personalized medicine, they all show the way to a future that demands well-trained patients participating in — and not passively suffering — targeted therapy. For this future a supporting medical staff with better time schedule is presumed.



**PRODEEP BOSE**  
Executive VP,  
Innovation and Product  
Development, theBloc

Connected health covers not just biometrics but also seamless data flow between a cause and its effect — treatment choice, compliance, behavior, and mood change — and being able to intervene effectively. The imminent merger of computing and biology is an innovation area with extraordinary consequences — be it genomic modeling of the impact of drugs on cancer cells, affecting neural circuits to treat Alzheimer's or depression, or being able to re-route brain circuits so a paraplegic can operate his own legs. The path is being paved for a moment when computing and biology merge to create a singular conscious being.

**LANCE CONVERSE**  
Chief Innovation Officer,  
WIRB-Copernicus Group

The remote monitoring of patient care in both



the clinical research and standard practice settings will have a transformational impact on the life-sciences industry. Data can now be collected through wearable devices and mobile apps, allowing patient and study monitoring visits to be completed without traveling to and from the doctor's office. The result is fewer burdens for the patients and healthcare providers, higher quality clinical data, and significant reductions in the overall time and cost of providing quality healthcare.



**CHRIS EVANS**  
VP, Innovation, West  
Pharmaceutical Services

Connected health shows great promise in improving patient treatment and expected outcomes. By coupling unique adherence software with drug delivery, we can reach levels of patient engagement and education previously unimaginable. One example is electronically connected wearable patch injectors that can track in real-time when patients take their medication, and can incorporate a gamified environment that educates and rewards patients, motivating them to adhere to their treatment regimen. Additionally, these data can be harnessed to inform development of future treatments.



**AARON FLEISHMAN**  
Healthcare Innovation and  
Market Expansion,  
BBK Worldwide

Clinical trial products and services such as mobile apps, wearables, and travel programs should extend beyond condition — or study-specific tools and go broader. As we move forward, developers must look beyond a specific study to create solutions that support improved patient care and clinical research, and consider a wider variety of factors, including dietary and general wellness considerations and easy access to real-time data. Much like efforts to remove silos relating to data management over the last decade, removing silos relating to tech innovation will foster improved collaboration and

ensure maximized budgets, increased adoption and greater value



**DEBBIE HART**  
President and CEO,  
BioNJ

There are many innovations making a dramatic impact on the therapies and cures being discovered and developed for patients. For instance, CRISPR, which allows gene editing and regulation, has enormous yet unrealized implications; the potential of immuno-oncology therapies is now being realized through the approvals of Yervoy, Keytruda, and Opdivo; and precision medicine, wherein treatments and therapies can be tailored to the individual patient, will increase effectiveness rates. Biotechnology is a relatively young area of science with tremendous untapped potential to be developed and discovered for years to come.



**WANQIU HOU, PH.D.**  
Founder,  
Scientific HealthSense

Recent innovations in smart spending with maximizing patient benefits within the healthcare system are pushing boundaries of life sciences, technology, and state-of-the-art care. On the drug value front, we will see whether real-world performance will be integrated into how drugs are valued. On the patient adherence and education front, especially mobile health and digital medicine technologies, we will find out whether clinical interventions with these technologies will lead to improved health outcomes and reduced healthcare costs. Lastly, on the patient assistance front, we will see more programs being developed to help low-income patients get access to drugs.

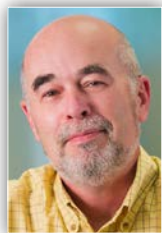


**CHRIS HRIVNAK**  
Director,  
The Nemaclin Group

There exists a dire human need for innovations worldwide. Digital health as a field of innovation is coming to

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prime time in terms of big data and analytics. Traditional and pharma company VC funds are investing in this field on the order of billions of dollars per year in order to bring about information liquidity to disrupt healthcare and health insurance business models. Further, genomic bioinformatics have already stimulated much discovery-based research in understanding neural networks.



**NICHOLAS KENNEDY, PH.D.**  
Executive VP, General Manager, Global Oncology and Hematology, INC Research

The landscape for state-of-the-art care for cancer patients is moving quickly. Advances in NGS, liquid biopsies, combination therapies, rapid development, and approval of immunotherapies — all are practice-changing. Multiple myeloma is a good example, where we are now seeing all oral therapy regimens are possible, and significant life and quality extension for patients are realized, which is remarkable when compared with even five years ago. Combined with innovations that interrogate electronic patient data and align the right therapy or trial to the right patient quickly, especially in rare diseases/patient subsets, these developments will revolutionize access, care, and ultimately clinical value.



**SHAUNA KEOUGH**  
Managing Director, Biosector 2

The FDA approved 45 first-of-a-kind drugs in 2015, the most in 19 years. We've seen breakthroughs in women's health, rare diseases, and many cancers. Analysts say drugmakers are getting better at picking the most promising drugs in their pipelines, but the FDA's role in advancing innovation cannot be overlooked. Dr. Richard Padzur, oncology chief for the FDA, noted in a recent New York Times article that he has "been on a mission to streamline the review process and get things out the door faster. I have evolved from regulator to regulator-advocate." The true value of innovation is fully recognized when collaboration is at its greatest.



**EILON KIRSON, M.D., PH.D.**  
Chief Science Officer, Head of Research and Development, Novocure

While we've seen continued innovations in cancer research in recent decades it's the advent of an entirely new modality that may impact cancer treatment worldwide. Tumor Treating Fields or TTFs are low intensity, alternating electric fields that disrupt cell division during mitosis. Exploration of electrical fields as a cancer treatment began in the late 1990s. However, it was only less than five years ago that our device that delivers these fields, Optune, received its first FDA approval for recurrent glioblastoma. Since that time, thousands of patients have been treated with Optune.



**MELANIE LEE, PH.D.**  
Chief Scientific Officer, BTG-Interventional Medicine

The emphasis on sparing the whole body and treating localized disease is changing therapeutic opportunities. For these technologies to be successful there needs to be a convergence — a combination of imaging, targeting, and local delivery. A whole host of treatments are opening up by combining technology, chemical and biological agents, and devices to treat local tissues. Digitalization is also transforming the connections between patients, their physician, their disease, and their therapy. The potential to monitor patients, influence their behavior, and ensure their safety is vast through the smart use of digital detection, monitoring, and transmission of data.



**CHITRA LELE, PH.D.**  
Chief Scientific Officer, Sciformix

Penetration of the digital revolution across the globe, and extensive adoption of social media has led to the generation of unprecedented volumes of structured and unstructured data pertaining to safety and effectiveness of medicinal products. The need for big data solutions

in the life-sciences industry is fueling collaborations and innovations. Patient-centric innovation will be at the heart of the transformation of pharmacovigilance (PV) over the next couple of decades and this will likely forever change PV as we know it.



**JOHN LOPOS**  
Executive VP, Client Services and Commercial Strategy, Triple Threat Communications

Big data, personalized medicine, and the quantified self are said to promise dazzling — and still mostly unrealized — potential for health, and they'll also spawn all kinds of opportunities for businesses to develop and sell things. But the real innovations allowing these and other fields to advance are attitudes and behaviors that groups demonstrate at the earliest stages to realize ideas: open collaboration between competitors, transparency, and trust; and giving up turf, breaking away from traditional models and methods. See what's happened in immune-oncology, infectious disease, and Alzheimer's R&D; or, what groups like Sirum have done out west for access to medicines.



**MATTHEW MAJEWSKI**  
Consultant, Charles River Associates

The renewed focus on value-based care by payer stakeholders is invigorating prescribers to locate and operationalize innovative care models. The results of these efforts are expected to be greater fiscal responsibility demonstrated by healthcare providers and patients. Healthcare manufacturers need to find a way to insert themselves into the value-based care equation or they'll be left behind in terms of defining new treatment paradigms.

**DAVE MIHALOVIC**  
Executive VP, Experience & Innovation, Evoke Health

It's amazing the amount of innovation happening in the life-sciences space today. The combination

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of health policy, technology, and science has provided the climate for a renaissance of sorts. Companies outside of the traditional pharmaceutical and biotechnology sector have started contributing real value to health consumers, physicians and patents. Companies such as Proteus, are combining wearable technology with Bluetooth pill wraps and mobile technology to help patients to become more compliant and reach better outcomes. These solutions monitor not only pill consumption, but biomarkers that help healthcare professionals and caregivers personalize the healthcare they are delivering. Or a company such as BioBots, which introduced affordable 3D biological printing technology that generates tissue that can be used in clinical and R&D settings. BioBots' technology is revolutionizing our understanding of disease while providing clinicians with the ability to manufacture tissue for use with actual patients. These are two very different examples, but highly innovative companies changing the face of healthcare today.



**BRIAN MONDRY**  
Global Head of  
Digital Innovation,  
Kantar Health

The healthcare industry is already one of the biggest adopters of virtual reality technology, and its use will continue to grow and be truly transformative in terms of medical training and patient treatments. It's already used for things such as surgery simulation, treatment of phobias (e.g., fear of flying), PTSD, and even smoking cessation. With the availability of affordable virtual reality head mounted displays (HMDs), such as Google Cardboard, virtual reality will soon be used for marketing applications as well, especially in the areas of patient education and compliance optimization. Patient education applications are obvious but, for compliance, imagine experiencing a virtual "you" undergoing the long-term effects of non-compliance with a drug that treats a chronic condition, or a virtual "you" gaining 30 pounds. The visceral shock of that would certainly change

patient behavior more effectively than current methods.



**EDMUNDO MUNIZ, M.D., PH.D.**  
CEO, Certara

Biosimulation, the science that integrates computer-aided mathematical simulation and biological sciences, has evolved from a research tool into an indispensable part of the drug development process trusted by global sponsors, academic institutions, and regulatory agencies. It enables clients to make data-driven decisions at all stages; leverage all available data to achieve the required product profile; design safer, targeted, and more efficient trials and sometimes eliminate the need for them; select the right dose for the right patients, the first time; and simulate virtual patients in hard to recruit or test populations, such as pregnant women, pediatric, elderly or organ-impaired patients.



**DREW SCHILLER**  
Chief Technology Officer  
and Co-Founder, Validic

Digital health is disrupting the way the pharmaceutical industry gathers data from clinical trial participants and stands to completely revolutionize how trials are conducted. By arming participants with wearable and FDA Class II medical devices, sensors and applications, pharmaceutical companies can remotely collect activity data along with key biometrics. This not only allows for more streamlined and cost-effective trials, but also increases subject enrollment and ongoing engagement, which is vital to starting a trial on time and meeting timelines.



**JIM STREETER**  
Senior Director,  
Life Sciences Product  
Strategy, Oracle

Technology-based innovations are emerging within the life-sciences industry at a rapid fire rate. In fact, the life-sciences community is only at the beginning of its innovation journey. The next five years alone promise sweeping change in how we

collect, analyze, and leverage patient and clinical trial data to develop safer, as well as more effective and precise, treatments. Our ability to collect and act on real-time data from multiple sources is advancing precision medicine pursuits, changing how organizations select treatments for patients and, as a result, where patients select to go for treatment. For example, connected wireless devices, such as Internet of Things devices integrated with cloud-based clinical trial platforms, are helping health professionals to collect data from patients, advancing accuracy in clinical trial data analyses.



**SCOTT WEISS**  
Senior Director of  
Product Management,  
IDBS

The pharmaceutical industry is in a period of radical change in the way companies approach the prevention and treatment of disease. The transition to biopharmaceuticals and precision medicine is of course being driven by a greater understanding of the genetic and environmental factors of disease. These discoveries are in turn only possible through the rapid advancement in analytical and diagnostic technologies and their supporting informatics systems. For the life sciences, managing the quantity of data will not be the challenge. It will be our ability to deliver the informatics tools to help us digest this data in a meaningful way.



**GEORGE YEY**  
President  
TLC

The ability to deliver therapies to specific tissues in the body with new technologies has increased dramatically in the last five years. For example, many approaches involve the use of antibodies to target specific cells or proteins. Now, we have the ability to use antibodies or antibody fragments conjugated to therapeutically active molecules. For example, TLC is using antibodies attached to lipid-encapsulated drugs to develop more effective therapies in oncology.



It's not just about innovations, but societal and technological changes are enabling more engaged patients with a higher expectation to be involved.

**DR. AMIR KALALI**  
Quintiles

the exVive3D human liver tissue. The company and its 3D printed tissues are widely recognized for their innovation as well as their future applications.

Keith Murphy, chairman and CEO of Organovo, says a convergence of innovations is the driving force behind pushing boundaries and creating breakthroughs that deliver value to the healthcare industry.

"To continue to innovate in drug discovery and development, many technologies are coming together to build reproducible and predictive in vitro models of human biology and disease," he says. "For example, by combining engineering and biological advancements in 3D bioprinting with the growing omics fields — genomics, proteomics, metabolomics — we can interrogate biological patterns, pathways, and mechanisms and find new ways to intervene in human disease as well as better predict human response to drugs."

Vas Narasimhan, global head drug development and chief medical officer at Novartis, agrees the growing role of emerging technologies is changing the face of healthcare.

"Particularly in drug development, digital technologies allow us to expedite data collection and analysis, better engage with patients, and also better track and quantify patient outcomes, allowing us to more effectively demonstrate the holistic effects



Today, entrepreneurs are pushing boundaries and tapping into a vast knowledge of product design, engineering, and technology.

**MELINDA RICHTER**  
Johnson & Johnson

of treatment on quality of life," Mr. Narasimhan says. "We are also seeing entirely new therapeutic approaches emerge, such as

### Innovation: Drugs for Rare Diseases

**About 47% of the novel drugs approved in 2015 (21 of 45) were approved to treat rare or orphan diseases that affect 200,000 or fewer Americans. This is significant because patients with rare diseases often have few or no drugs available to treat their conditions.**

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| ▶ Alecensa  | ▶ Orkambi   |
| ▶ Cholbam   | ▶ Portrazza |
| ▶ Cotellic  | ▶ Praxbind  |
| ▶ Cresemba  | ▶ Repatha*  |
| ▶ Farydak   | ▶ Strensiq  |
| ▶ Darzalex  | ▶ Tagrisso  |
| ▶ Empliciti | ▶ Unituxin  |
| ▶ Kanuma    | ▶ Upravi    |
| ▶ Lenvima   | ▶ Xuriden   |
| ▶ Natpara   | ▶ Yondelis  |
| ▶ Ninlaro   |             |

\* Repatha was submitted with two indications. One indication received Orphan designation while the other did not.

Source: FDA

cell therapy, gene editing, and modulating the microbiome. At Novartis, we are in the process of unifying drug development across our core businesses, and I see emerging technology playing a huge role in that integrated model moving forward."

Outcomes continue to remain a key focus for all stakeholders, it's no wonder that one of the areas of innovation is to identify shortfalls in practice and to develop strategies to improve care.

For example, David Meek, executive VP and president of oncology at Baxalta, says within the oncology space, recent advancements in immuno-oncology are transforming the way treatments and personalized medicine are provided to patients with cancer, indicating significantly improved outcomes for a variety of cancers, both as single agents and as combination therapies.

"The industry is seeing an unprecedented level of innovative collaborations forged between leading biotech and pharmaceutical organizations to accelerate discovery and development of these novel cancer immunotherapy drugs," he says. "For instance, we recently partnered with Symphogen to actively advance the development and worldwide commercialization of novel immune checkpoint therapies within Baxalta's diverse pipeline." <sup>PV</sup>



A convergence of innovations is the driving force behind pushing boundaries and creating breakthroughs that deliver value to the healthcare industry.

**KEITH MURPHY**  
Organovo

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