

## UBISTART

A new US–France initiative offering payouts to the best new start-ups

## Fixing the MedTech Disconnect

The Future of Safety Signal Detection and Risk Management



## Technology Focus

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# US–France Partnership to Promote New Technologies

UBISTART seeks to develop commercial tie-ups between US and French companies active in the pharma, biotech, e-health, and medical device sectors.

William Looney looks at UBISTART, a new transatlantic payout for the best in start-up innovations, and profiles three young French companies demonstrating fresh approaches to unmet medical need.

Collaboration in pharma requires the active intervention of many different players

representing not only industry but academia, professional associations and government as well.



The task of building such multi-disciplinary networks is slowly gaining momentum. One fresh example is the partnership kicked off last month between the Galien Foundation, which administers an annual global awards program for medicines innovation, and the French government investment and trade promotion agency, UBIFRANCE.

Called UBISTART [for Synergistic Transfer of Advanced Research Technologies], it seeks to develop commercially relevant tie-ups between US and

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French companies active in the pharmaceutical, biotech, e-health, medical device and process technology sectors.

The emphasis is on facilitating early-stage research, development and full commercialization collaborations between start-ups and the larger industry players that can provide access to financial capital and know-how.

The project launched on July 10 at a networking conference hosted by the New York Academy of Sciences and featuring the participation of approximately 50 French-based biotech, specialty pharma and process technology companies along with key Big Pharma players, venture capital investors, and academic research centers. Some 600 “matchmaking” meetings took place during the course of two days.

### And the winner is...

To add momentum beyond the one-off contacts, **UBISTART** is initiating a competition

in which the US-French companies will, over the next three months, submit investment collaboration projects for review by a jury panel of scientific, business development and financing experts, who will then select nine nominees and grant three cash prizes — totaling \$100,000 — as the first UBISTART award for excellence in start-up innovation.

Criteria for selection is: advancing the state of science; meeting an unmet medical need and improving the current standard of care; larger impact on society; a commercially viable business plan; and evidencing the added value from international partnering rather than going it alone.

The deadline for nominated projects is October 31, and winners will be announced at the annual Prix Galien France drug innovation award ceremony in Monaco on December 4.

### Three start-ups

The diversity of offerings on display by the French companies at the July 10 Academy event shows how good ideas continue to spread across geographies. As illustration, the following are three examples of some fresh new approaches to solving an unmet medical need.

**The UBISTART competition will see a jury panel of experts select nine nominees and grant three cash prizes, totaling \$100,000.**

### Anagenesis Biotechnologies

Located in Strasbourg, **Anagenesis Biotechnologies** specializes in new stem cell-based applications for treatment of genetic and age-related muscle degenerative

diseases. It is focused on three specific conditions: Duchenne muscular dystrophy (DMD), sarcopenia, and cachexia.

The company’s calling card is a patented cell reprogramming model that can generate healthy skeletal muscle cells from stem cells. This proprietary technology has the potential to be applied either as a screening platform to identify and differentiate diseased cell structure for targeted cell therapy, or as a biologic drug that would induce the proliferation of normal muscle cells and thus slow or halt progression of disease.

### Affilogic

**Affilogic** is a four-year old biotech based in Nantes with a mission to maximize therapeutic drug delivery applications from the rich bacterial soup of the thermal geysers in Yellowstone National Park.

The company has built an artificial protein derived from the *sulfolobus acidocaldarius*

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microorganism that acts as a safer and more effective delivery vehicle to conventional monoclonal antibody drugs.

Its patented Nanofitin platform improves the therapeutic effectiveness of drugs by improving a drug's binding capacity, enhancing tissue penetration and allowing for more patient-friendly modes of administration.

The technology is especially effective in maximizing the positive pharmacokinetic effects of inflammatory drugs, anti-infectives, ophthalmology drugs, and CNS treatments.

Affilogic has funding from the EU Commission's Seventh Framework Program on Research, under the SADEL [Scaffolds for Alternative Delivery] consortium; and the company's partnership with Ferring is slated to complete clinical work within the next 18 months. The company is seeking additional investor financing, especially from outside the EU.

## Rondol Industrie

Materials management is the mantra for another French start-up, **Rondol Industrie**, based in Strasbourg but reaches beyond France due to research ties to the UK and an established sales presence in Germany

The company's business model is to apply a venerable technology in manufacturing — hot metal extrusion [HME] — to some very modern ends, namely, in offering pharma customers new, more efficient machinery that keeps pace with pharma materials science and changing regulatory requirements.

Starting in 2008, Rondol began introducing a new line of extruder machines specifically adapted to health care sector requirements, including equipment for small batch testing and production, precision dosing, content uniformity and enhanced materials stability, at variable Ph and moisture levels.

In 2012, the company initiated further extruder design improvements that meet or exceed upgraded requirements for GMP compliance from the FDA and EMA.

Persuading Big Pharma to purchase this technology has proven a bit tougher than expected, particularly in the US. To raise interest in its technology, Rondol has formed collaborative research ties to leading process engineering schools like the University of Texas/Austin and the University of Mississippi, while using its brands' quality reputation in Germany as a reference point to attract more US customers.

## Message to regulators

One perspective all three French entrepreneurs share is a sensitivity to the broader regulatory environment that enfolds not only them, but the larger players in pharmaceuticals as well.

Uncertainty about risk exposure around new

technology is compounded by the absence of clarity in the way regulators classify it.

Another issue relates to the perennial pitfalls of the so-called "valley of death," where after proof of concept is completed, and companies are poised to launch human trials, financing disappears. Regulators could help address this by moving toward a more common set of standards that eases the complexities of initiating those trials, thus reducing direct costs to the developer.

The three start-ups noted that making this happen on a transatlantic basis would be a real step forward, though progress is necessary within the EU as well.

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# Fixing the Med-Tech Disconnect

Dominating external forces are disrupting the traditional strategies of medical technology leaders.

The med-tech industry has a legacy of creating life-extending products while rewarding investors. This connection between innovation and profitability has been a key driver. But, writes Doug Mowen, change is underway.

The medical technology industry has a legacy of creating life-enhancing, life-extending

products while rewarding its investors in the process. In fact, this connection between innovation and profitability has

been a fundamental driver in the C-suites and boardrooms of many medical device, diagnostics and equipment companies.

But change is underway. Dominating external forces are disrupting the traditional strategies of medical technology leaders. Companies face greater economic pressures, a reformed healthcare system, new hospital and physician alignments, and new technological challenges.

**Our High Performance Business research** indicates that, for these and other



reasons, the disconnect between product innovation and financial performance is growing. Medical technology companies' commitments to broadly defined, clinically oriented missions are becoming less likely to hit financial success now and in the future. They will have to act immediately to address these paradigm changes in the market place and warrant their profitability.

But this is not to say innovation is out and can't generate a strong ROI today. In fact, some companies continue to generate strong profits from breakthrough products, even in the face of financial concerns, such as earnings levels that lag research investment. But now more than ever, medical technology companies must work even harder to prove their market value in driving positive financial outcomes.

### Innovation and profitability hand-in-hand

For many years, medical device companies developed

innovative, clinically oriented technologies and generally enjoyed above average investment returns in exchange for their efforts. Common anchors of profitability included strong corporate development engines, broad technology expertise, smart merger and acquisition decisions, and a clear focus on clinical outcomes.

**Some companies continue to generate strong profits from breakthrough products, even in the face of financial concerns.**

Many manufacturers also bet on companies and technologies they hoped will produce market breakthroughs. As reported in the media, two examples include Medtronic's billion dollar-plus play for

renal denervation pioneer Ardian, and Johnson & Johnson's similarly large bet on Acclarent's novel approach to sinusitis.

The foremost reputations of medical technology companies, and the industry as a whole, have created a halo effect with physicians and clinicians, who are the manufacturers' traditional market and customer base. Members of this core market appreciate the value that medical technology organizations and their sales representatives generate. They also welcome a steady output of new technologies that help their patients. This harmonious relationship has further accelerated companies' growth and financial success.

But the High Performance Business analysis shows that this paradigm is changing.

Enterprise Value is recovering from pre-recessionary levels. Yet, overall industry growth is decelerating. For example, R&D spending has been increasing faster than revenue which, in turn, has been increasing faster

than earnings. All the while, innovation output, as measured by number of 510(k) approvals, has been flat to declining.

Only four of the 19 "pure play" medical technology companies, those with more than 75% of revenue derived from medical technology products were also deemed to be high performer.

In fact, companies usually considered top innovators and aggressive acquirers of new technologies fared poorly on our consolidated scale of financial performance. Even more extraordinary, our analysis concluded the divide between technology, product innovation, and financial performance is growing.

### Growth and Profit Challenges

Several shifts in the marketplace are impacting medical technology companies' growth and profits picture. Among them:

- a changing buyer-customer who has developed different priorities — seeking product

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- value and positive health outcomes;
- continuous pressure to reduce costs;
- growing scrutiny from regulatory agencies;
- changing patient population.

For instance, US healthcare reform is increasing the size of the insured population, essentially placing greater pressure on providers. In response, medical technology companies need to consider taking a leadership role in improving care delivery and driving out costs in therapeutic areas where there is existing expertise. They should aim to work with customers to improve utilization levels, while offering a portfolio of solutions, beyond expensive, increasingly unsustainable product options.

In addition, payers and providers are increasingly skeptical about the value of incremental product improvements. For example, companies could develop a solid health economics

story and communicate it to customers. Or they might rebrand some products to increase differentiation based on economic benefits. Another option: develop non-product offerings, including as patient service programs and educational initiatives.

As levels of regulatory scrutiny rapidly increase, demands for evidence tighten, and regulatory approval times expand, medical technology companies must appropriate uncompromising attention

## Medical technology companies must appropriate uncompromising attention to improving R&D efforts...

to improving research and development efforts as well as supply chain and back office operations. The

objective should be to offset additional regulatory burdens by increasing operational efficiency.

The issues are requiring medical technology companies to revise their strategies and operations. But at the same time, these shifts are also creating new opportunities for pioneering companies to redefine and elevate their relationships with their customers.

### Repairing the disconnect

Medical technology companies now have the opportunity to work together with their customers to deliver comprehensive cost-effective solutions that increase quality of care and meet their information needs. For best results, we recommend companies take three courses of action.

### 1. Innovate your business model

Both customers and investors are increasingly less likely to value product innovation.

This is particularly the case when technology enhancements only incrementally improve patient clinical outcomes. Moreover, they will hold R&D investments and M&A strategies to higher standards. Customers will now want to see more robust clinical data and they may hesitate to adopt new technologies. Investors, on the other hand, will demand more assurances and higher, more-rapid returns.

Innovation of the business model will be required as product innovation becomes less valued. Some companies may continue their focus on disruptive, breakthrough technologies that significantly alter the future of patient outcomes. But their go-to-market strategies will need to demonstrate an ability to achieve a level of consistent product value to economic buyers and payers. For most companies, those whose offerings are often incremental enhancements, economic benefit will be an increasingly

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essential justification for adoption.

Innovating the corporate business model can also involve streamlining the process of healthcare delivery and lowering its cost. In this manner, medical technology companies can help their customers develop standardization programs, rationalize inventories, improve utilization levels, and procure more cost effectively. In addition, innovative pricing models can offer novel concepts, such as risk-sharing and outcome-based pricing.

Companies that market electronic medical products can also seek opportunities to transform therapies by using device connectivity. Advanced connectivity can enable more flexible care in alternative, lower-cost locations, such as acute-care facilities. Technology can also significantly help differentiate a company's products and services from competitors in the medical industry.

Depending on the spaces in which they play, companies that overspend on R&D and M&A activity may incur as much risk as those that do not spend enough. Medical technology organizations must be sure their spend and activity levels are appropriately scaled to and aligned with targeted clinical opportunities, as well as match broader corporate goals and strategic missions.

## 2. Connect with the new customer

As economic pressures reshape healthcare delivery and customer business models, medical technology suppliers will need to understand how those shifts alter buyer perceptions of products. Product features and benefits are becoming less significant, and industry value propositions have to change. Even truly innovative technologies will have to exhibit strong value. To address the interests of new customers, companies must market different kinds of offerings, including adjunct

services and information-based packages that help customers deal with economic pressures.

**As the power of the economic buyer rises, med-tech companies may need to incorporate new sales and marketing models.**

Companies will also need to emphasize the value of those offerings to a wider variety of stakeholders — beyond physicians and nurses to economic buyers, such as administrators, payers, providers and patients. If companies do not do this, their customers may define their products for them.

As the power of the economic buyer rises, medical technology companies may need to incorporate new sales and marketing models. More

product decisions are being made by in-hospital purchasing and value-analyzing committees. The influence of these committees is likely to go on rising while sales rep access to physicians continues to fall.

**Benefits that appeal directly to hospitals and their patient customers will become an important part of the med-tech value proposition.**

To address this issue, companies should look to realign their sales and marketing efforts to address the changes in decision making. One option can be for suppliers, especially those with novel product technologies, to partner with hospitals and other channel partners on marketing campaigns.

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Marketing strategies will also have to take into consideration the role of patients and consumers, as customers in their own right and as key members of the overall hospital and physician customer base. Device and technology benefits that appeal directly to hospitals and their patient customers will become an important part of the med-tech value proposition.

**Companies must pursue operational excellence and address issues that many other industries have already faced...**

Additionally, there will likely be a need to implement new approaches to hiring and training sales reps in order for them to obtain a more complete understand of a

hospitals' operational realities and how devices align with these entities' larger missions. Sales rep effectiveness is becoming less about physician relationships and product knowledge, and more about the ability to partner with a broad set of economically-driven stakeholders to help ensure better care at a lower cost.

### **3. Excel at operational excellence**

As pressures to reduce costs continue to reshape healthcare delivery systems, medical technology companies will no longer be able to rely primarily on innovation to ensure top-line revenue growth and profitability. Some suppliers, whose sole focus is clinically meaningful technology, could face scrutiny about their products' affordability. They will be forced to make significant cost-benefit arguments for their novel technologies and products. For companies playing in lower-tech spaces, the pressure for

economic justification will be even greater.

In addition to justifying product affordability, medical technology companies will be increasingly unable to overcome the liabilities associated with inefficient back office functions: from R&D and supply management to HR, finance and IT. They must pursue operational excellence and address issues that many other industries have already faced: the need to dissect every process for its value to customers and for ways to increase efficiency. The result can only be positive: an increased agility to respond to inevitable future marketplace changes.

**Medical technology companies need to act now...**

Powerful external forces are disrupting the traditional strategies of medical technology leaders.

Companies face greater economic pressures industry-wide, a reformed healthcare system, new hospital and physician alignments, and new technological challenges. Our research confirmed that this disconnect between product innovation and financial performance is expanding.

Medical technology companies need to act now to address this issue. Their focus in innovating their business models, connecting with the customer, operational excellence are core areas to target. Approaching the repair work for the disconnect in this way will help companies prove their economic value by driving positive financial outcomes and while at the same time continuing to offer products that improve patients' lives.

### **About the Author**



Doug Mowen is Managing Director, Medical Technology, **Accenture Life Sciences.**

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# The Future of Safety Signal Detection and Risk Management

Safety signal detection is an ongoing process that plays a critical role in risk management for healthcare products.

Suhasini Sharma and Chitra Lele explain safety signal detection's important role in pharmacovigilance and look at the latest developments in the field.

**N**ew drugs are placed on the market with limited clinical experience of safety.

Healthcare companies and regulators have an ethical and a legal obligation to monitor safety of drugs throughout

their life cycle, and safeguard public health by identifying risks associated with their use and putting in place appropriate risk mitigation measures.

Post-marketing pharmacovigilance helps detect new safety issues and rare adverse reactions associated with use of drugs in actual clinical use

Safety signal detection is an important component of pharmacovigilance. It is an ongoing process and plays a critical role in risk management for healthcare products.



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Safety signals thus identified, are evaluated, monitored and confirmed, mandating appropriate risk mitigation measures.

### Sources of drug safety information

Post-marketing safety depends largely on voluntary reporting systems for adverse reactions and safety issues reported in biomedical literature.

Healthcare companies and regulators receive and process safety reports on an ongoing basis and use the data for signal detection. In addition to the individual company data, adverse event data reported to WHO, FDA and other regulatory agencies such as Health Canada and UK MHRA, has been available to a limited extent and has been used in a limited manner for safety signal detection.

The data is often incomplete though, and it is well known that there is considerable under-reporting of adverse reactions, which significantly affects timely detection of

safety signals. Independent data sources are available and can be harnessed to augment post-marketing safety signal detection for medicinal products.

## The vast amount of publicly available biomedical literature contains rich information on adverse experiences with drugs at all clinical stages.

The vast amount of publicly available biomedical literature contains rich information on adverse experiences with drugs at all clinical stages.

In addition, there are structured data sources such as post approval studies, pharmacoepidemiology studies, patient/disease registries and health surveys which are especially important

as they attempt systematic data collection during post-approval phase and these data could also be medically validated.

In today's digital world there is a significant amount of health-related data waiting to be explored. The data exist in the form of electronic health records (EHR) at multiple locations (hospitals, physicians' clinics, health management organisations (HMOs) and claims databases), and millions of health-related conversations and exchanges (many of which involve adverse drug reactions) taking place on social media.

If these data sources could be mined and put to use to supplement existing data for signal detection, it would significantly positively impact safety and risk management for drugs.

Realizing the importance of this yet untapped information, both private enterprises and governmental agencies have recently launched new initiatives which will

enhance the signal and risk management process.

### Recent developments enabling access to untapped data

FDA has been collecting adverse event reports (AERs) from manufacturers, clinicians and other healthcare professionals, and the public since 1998. It now accumulates between 300,000 and 500,000 new reports each year.

While FDA currently publishes quarterly bulk files, they are difficult to decipher making it incredibly challenging to derive any meaningful knowledge from the data. FDA's open FDA initiative announced early this year makes the world's most extensive record of adverse drug reactions more widely and readily available. It will let software developers tap directly into the data to build user-friendly and easily searchable programs that can be used not only by the pharmaceutical companies,

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but even by doctors and consumers.

The agency is also opening up records of product recalls and drug labels to commercial and public use. As big data analytics capabilities improve, this move will enable researchers and developers to put the latest knowledge and technological innovations to good use.

## Social media is a rich data source for drug safety related information...

Commercial enterprises have already developed search engines and web applications (e.g. OpenVigil, FDABLE) for querying FDA datasets. These can be commercially available to pharmaceutical companies to supplement signal detection and signal validation for their products. A team of private researchers recently developed a system for tracking adverse

drug interactions using queries ('search logs') from Internet search engines like Google and Bing. This will allow internet searches on adverse drug experiences to be mined for safety-related information.

Social media is a rich data source for drug safety related information. Patient forums such as Yahoo Health and Wellness, and PatientsLikeMe collect self-reports of drug side-effects and patient experiences with medications. These along with networking sites such as Twitter, Facebook and private blogs can provide valuable supplementary information on drug effectiveness and side-effects.

Moreover, these sources cover large and diverse populations and provide unsolicited, uncensored data directly from patients. With big data analytics it is now possible to conduct combined analysis of regulatory data, information from digital biomedical literature, electronic health records and information mined from social media for

more effective safety signal identification. For effective signal identification, it is critical to comprehensively look at all safety data — from preclinical to post approval and for validated sources to that from social media.

Computational methods in statistics, computer science and biological disciplines, referred to as data mining algorithms (DMAs), can translate data from diverse sources into meaningful knowledge to benefit patient safety.

### Sifting 'signals' from 'noise'

The ultimate objective of all signal detection and evaluation activities is to provide an effective risk management mechanism by identification of risks and the population that would be most impacted and further assessing the impact of those risks on individual and public health. This would allow appropriate evaluation of benefits versus risks in different uses, and

populations, resulting in effective use of the drug only in those conditions and populations which benefit the most from its use.

To this end, the real challenge in harnessing these extensive data in drug safety would be to separate chaff from the grain — sifting true signals from the 'noise'.

## ... but we need to determine if all data sources are equally reliable and dependable.

Hence, we need to determine if all data sources are equally reliable and dependable. Information from the social media, while first hand, can often be questionable, coloured by perceptions, peer experiences, and media coverage; whereas information from biomedical literature is usually more accurate and

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reliable as it has already been processed and evaluated by clinicians.

Information from spontaneous reporting lies somewhere in-between. While analysing this information, is it possible to give weightage to information based on reliability/dependability of the data source? Equally important is the medical evaluation of information and clinical judgment required to assess the impact of safety signal on

**It is not the technology itself that is crucial, but how it is applied to achieve a useful purpose.**

individual patient's clinical course and public health.

Many important safety signals have previously been identified by astute and vigilant clinicians just by observing a few patients'

experiences. In the flush of big data and technology would these clinical skills become less important?

### Conclusion

In the battle between the 'old' and the 'new', the 'new' may always seem to have an upper hand since it comes in the garb of superior technology.

While embracing new technology may have multiple advantages, we must keep in mind that it is not the technology itself that is crucial, but how it is applied to supplement human intellect and skill to achieve a useful purpose. In this case the ultimate goal is to enhance safety of medicines, and technology and human expertise play complementary roles!

### About the authors

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# Apple or Big Pharma: Who Will Lead in Wearable Healthcare Devices?

The vision is that the data captured by wearables will offer physicians insights into patient wellbeing.

Apple's iWatch may not have happened yet, but eyes are still fixed on the company to see what it does in the healthcare wearables space, writes Peter Houston.

In the media world, it's easy to see when a market is really taking off — someone starts a magazine or

a website about it. Well, I just heard about some journalists from one of the UK's leading gadget magazines who have

headed out on their own to launch a **wearable computing title**. So I thought it might be time to take another look at wearables in the Pharma space.

It's been about a year since I last wrote about wearable technology for Pharm Exec and, unsurprisingly, a lot has happened since then.

**My previous article** was triggered by the Apple iWatch no-show. They still haven't released a device and "Apple will not introduce an iWatch or any other wearable device until it offers something that will become as central to



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everyday experience as the iPod, iPad, iPhone or Mac,” according to **Johnny Evans** on the Computerworld blog.

That game-changing device was **imagined last summer** by The Next Web co-founder Boris

## The good news is that the tech giants are on the case.

Veldhuijzen van Zanten. He saw it as a health and medical tracking device, imagining it monitoring blood pressure, movement, temperature and a host of other parameters. He said he would buy six and I concluded ‘Smartwatches need health data to matter’. More on Apple later.

A sector that looked like it might be limited to the gadgets geeks has moved on from smart watches and wristbands to include glasses, jewellery, shoes and sportswear. If you haven’t seen it yet, you need to check out the **Sensoria Fitness** range of smart garments:

T-shirts, sports bras and socks made with textile sensors that gather heart rate, force and pressure data.

When it launched a ‘Wearable Technology Storefront’ back in the Spring, Amazon dedicated two of the five categories in the store to health-related devices — Healthcare and Fitness and Wellness.

Writing around the time of the launch, a post on the In-Touch solutions blog said, the Amazon move ‘effectively legitimizes the consumerization of the wearable tech market.’ The authors advised, “As the popularity and accessibility of health-related wearables increases, pharmaceutical companies should consider the opportunities these devices — and the data they produce — hold for improving consumer health and treatment outcomes.”

The vision is that the data captured by wearables will offer physicians insights into patient wellbeing, but we’re

not there yet. When you really look at Amazon’s storefront, wearables are more about tracking pets and toddlers or how far you’ve jogged than real health insights.

The Atlantic’s Alexis Madrigal recently wrote an article, ‘**How Wearable Devices Could Get Doctors’ Stamp of Approval... Step 1: actually work.**’

Madrigal quotes Young Sohn, chief strategy officer at Samsung, as describing digital health as, “the single greatest opportunity of our generation... to better understand our physical well-being, to give a voice to what is happening in our bodies”. But even he isn’t happy with current performance, “there are battery issues, data exchange issues, and also accuracy issues”, he said.

The good news is that the tech giants are on the case.

Samsung has set out to create an ‘open ecosystem that uses common hardware and common data platforms to simplify the creation of new

devices. It is collaborating with the University of California, San Francisco, to create the **Center for Digital Health Innovation**, which will work to validate data against rigorous, regulatory-style protocols.

## Apple is still without a device, but definitely not without a healthcare strategy.

Google has entered an agreement with Novartis to develop “**smart**” **contact lenses** that could help diabetics track blood glucose levels. The smart contact lens would measure glucose in tear fluid and send data wirelessly to a mobile device. Novartis believes another possible application would be to use lens technology to help restore the eye’s ability to focus, almost like the autofocus on a camera. And that brings us back to

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Apple, still without a device, but definitely not without a healthcare strategy. In a post in the middle of this month In-Touch Solutions' Wendy Blackburn even asked 'Is Apple the new Big Pharma?'

Wendy was looking at Apple's Health app and Health Kit platform, a framework on which third-party device apps can be integrated. Her point is that Apple may not have a device, but it is positioning itself for expansion in the healthcare space. Forbes describes it like this: "Apple is positioning its Health app as the point of aggregation for all the user's different health data, and Health Kit the development platform to enable that integration."

Wendy notes that Apple is hiring 'healthcare bigwigs' and asks if Pharma has even noticed. She believes that through the delivery of aggregated health data, Apple has ability to change how consumers think about health, to get them to pay attention to all of it in a way that Pharma



PETER HOUSTON

has never managed to do.

"Perhaps the question isn't whether Apple might be able to compete with Big Pharma, but whether Big Pharma will be able to step up their game to play with Apple," she concludes.

iWatch or not, it's going to be really interesting to watch what Apple does in the healthcare wearables space.

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# Google Glass — A User's Guide in Healthcare

The big question for sales professionals is whether Google Glass will work well in practice.

Three medical affairs experts — Sean Turbeville, David A. Wells, and Charles Wolfus — review the capabilities of Google's latest technology for delivering information to healthcare professionals in the field.

Google Glass represents a technological advance in the form of a wearable computer product. In the health sector, Google Glass is envisioned

to provide unique benefits for communicating medical information to healthcare professionals (HCPs). Private communication is achieved via the built-in bone

conduction speaker and small screen, which is discernible only to the wearer; therefore, HCPs can privately receive information when others are present.

Since the entire device is housed within a glasses-like head mounting, the hands are free to take notes or perform other related tasks while receiving information.

The big question for sales professionals is whether this will work well in practice. To test Google Glass in real-world settings, we purchased three Google Glass units and went to work.



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## Google Glass has not yet matured to a level consistent with modern computers, tablets, and smartphones.

We configured Glass by connecting to an existing Google account and installing the MyGlass app on an Apple iPhone 5. Initial configuration was straightforward and took only a few minutes.

By default, Glass enables reading email and SMS messages, performing voice-based Google searches, accessing webpages via emailed URLs, recording video, and taking a picture. Additional apps like Evernote and YouTube are enabled using the MyGlass app via mobile device or computer web browser.

Google Glass does not provide any mechanism for accessing private file data

on company servers sitting behind a firewall on the corporate network. There is currently no browser access to user-requested web pages as is common on a computer browser or mobile device. Webpage text field entry capability does not exist, inhibiting entry of usernames, passwords, and entering data on web forms. Therefore, information presented in Glass required access to information only from publicly Internet accessible sources.

Files cannot be “downloaded” to Glass in the traditional sense, though they can be accessed as attachments to emails, SMS, or otherwise from the timeline or application.

At this time, Google Glass has no built-in capability to display Microsoft PowerPoint slides, which are the standard in the medical industry.

To achieve the aim of delivering slide-based data to HCPs, we first converted slides into individual JPEGs

so they could be viewed in Glass. These files were then placed on a publicly accessible webserver. Emails with the URL were sent to a Glass attached account so the URL could appear in the timeline. In Glass, clicking on the card and choosing “View Website” allowed the Glass wearer to view this information.

### What we found

Google Glass has not yet matured to a level consistent with modern computers, tablets, and smartphones. Its current functionality is limited, in the following ways. Bluetooth and Wi-Fi radios are built-in but it lacks native cellular mobile data capability.

There is no menu option for browser access; the browser is accessed by emailing URLs to the account linked to Glass.

There is no video player capability, nor can one view PDF or Office documents. Glass cannot be used to complete any type of web-based form and is without

a keyboard (at the time of testing). It, therefore, cannot log into private websites and enter any personal information or credit card data; likewise, adding terms to search boxes as if you were searching the medical literature cannot be done.

## In spite of limitations, Glass has many potential applications across the medical information landscape.

Glass does not browse content well; the card user interface and resolution provide severe limitations. By default, moving from card to card requires hand gestures that require some practice to achieve consistent results. This is problematic for uses that require handing the device to a HCP unfamiliar with the device.

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## A useful application of Glass in the clinical arena may be through physician-administered quality of life instruments.

In spite of existing limitations, Glass still has many potential applications across the medical information landscape.

In the commercial setting, sales reps can use Glass to access any approved information in response to a physician request and can hand Glass over to the medical information group for off-label requests.

Glass can also direct access to patient support services and be used to record on HD video unsolicited requests and all interactions when making office visits. All sales training material can be accomplished through Glass, and, as a hands-free device,

the tool may allow people in remote areas to participate in training.

Potential benefits in the area of medical affairs include recording and disseminating presentations in real-time; posters and podium presentations at medical congresses, especially in sharing those with colleagues in remote areas; and gathering competitive intelligence,

though, here, caution is advised.

A useful application of Glass in the clinical arena may be through physician-administered quality of life instruments.

In conclusion, given its present configuration, Glass merits consideration for some specific information-based uses. Continued evaluation is recommended.

### About the authors

Sean Turbeville is Senior Director, Medical and Scientific Affairs, at **Sunesis Pharmaceuticals**; David A. Wells is Principal Consultant at Wells **Medical Research Services**; and Charles Wolfus is a biotech IT leader.

Glass is a trademark of Google Inc.



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# APPOINTMENTS

## EUROPE

Oxford BioTherapeutics (Oxford, UK and San Diego, USA) appointed **Dr Keith E. Wilson** as Chief Scientific Officer. Dr Wilson joins from AbbVie where he was the company's Global Leader for Antibody Drug Conjugates.



ELC Group (Cambridge, UK) appointed **Inna Demidova** as a Senior Regulatory Affairs Expert for Russia and the Commonwealth of Independent States (CIS). Previously with Ferring Pharmaceuticals as Regulatory Affairs Manager,

Ms Demidova is an expert on both the Russian and CIS regulatory environment. She will also be tasked with heading ELC Group's planned Moscow office, due to open later in 2014.



**Deborah O'Neil**, Chief Executive Officer of NovaBiotics Ltd (Aberdeen, UK), was named an EY Scotland Entrepreneur of the Year 2014 last month. Dr O'Neil will now compete for the title of UK Entrepreneur of the Year, to be awarded this October at a ceremony in London, UK.



**Wolfgang Baiker** has been appointed to the advisory board of start-up biotech firm Neuway Pharma (Munich, Germany). Baiker heads the biopharmaceuticals and operations division at Boehringer Ingelheim.

## USA

AMAG Pharmaceuticals, Inc. (Waltham, MA) announced the appointment of **Robert Blood** as Vice President of Legal Affairs and Chief Compliance Officer. Mr Blood comes to AMAG with extensive experience in the industry serving most recently as

Associate General counsel at EMD Serono, Inc.

Ocera Therapeutics, Inc. (Palo Alto, CA) named **Rajiv Patni, M.D.**, as Chief Development Officer, commencing September 2, 2014. Prior to joining Ocera, Dr Patni served as Senior Vice President for Actelion U.S.

Auxilium Pharmaceuticals (Chesterbook, PA) appointed **Andrew Saik** as Chief Financial Officer. Mr Saik was most recently Senior Vice President, Finance and Treasurer at Endo Health Solutions.

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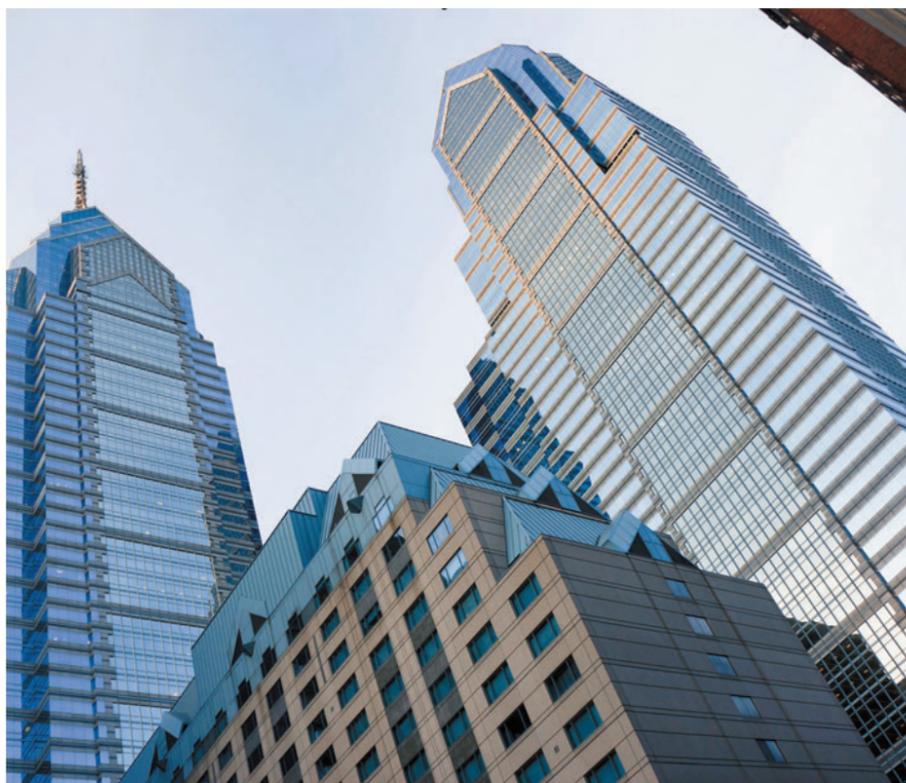
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## REAL-WORLD DATA/LATE-PHASE SUMMIT

November 5–6: Philadelphia, PA



Real-World Data/Late Phase Summit brings together the best minds in late phase research and real-world data utilization to identify practical business strategies for clinical trial optimization. Attend this conference to benchmark against and brainstorm with clinical executives for best practices to meet internal goals and regulatory requirements for maximized real-world data.

For further information, visit <http://www.cbinet.com/conference/pc14275#.U-jZCP2dzfM>

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## 9TH ANNUAL VALUE-BASED ONCOLOGY MANAGEMENT

October 28–29: Chicago, IL

Take a closer look at new payment systems and coverage policies in oncology. Hear about successus among payers and providers. Distinguished speakers include Peter Bach, Director of the Center for Health Policy and Outcomes.

<http://www.cbinet.com/conference/fc14121#.U-jZTf2dzfM>



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## 10TH ANNUAL SUMMIT ON BIOSIMILARS

Jan 29–30, 2015: Washington, DC

Now in its 10th year, CBI's Annual Summit on Biosimilars places unique focus on the assessment of market access, strategies for effective commercialization and options for interchangeability

<http://www.cbinet.com/conference/pc15014#.U-oO5P2dzfM>



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## INTERNATIONAL PHARMACEUTICAL COMPLIANCE CONGRESS

October 21–22: Brussels, Belgium

CBI's International Pharmaceutical Compliance Congress offers the opportunity for global companies to come together, share ideas, network and learn from one another. The International Compliance Congress will cover topics such as transparency, FMV, third party due diligence, the role of compliance and many other issues faced by the industry.

**For further information, visit [http://www.cbinet.com/conference/pc14084#.U2Dz\\_f2dzfM](http://www.cbinet.com/conference/pc14084#.U2Dz_f2dzfM)**

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# Pharmaceutical Executive

Global Digest

## Mission

*Pharmaceutical Executive Global Digest* provides industry intelligence so managers in the international pharmaceutical community can advance their business, management and marketing practices to gain competitive advantage. PEGD interprets the current and future challenges the industry faces and enables pharmaceutical professionals to overcome them with cost-effective, time-saving solutions.

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