Medtech Insight

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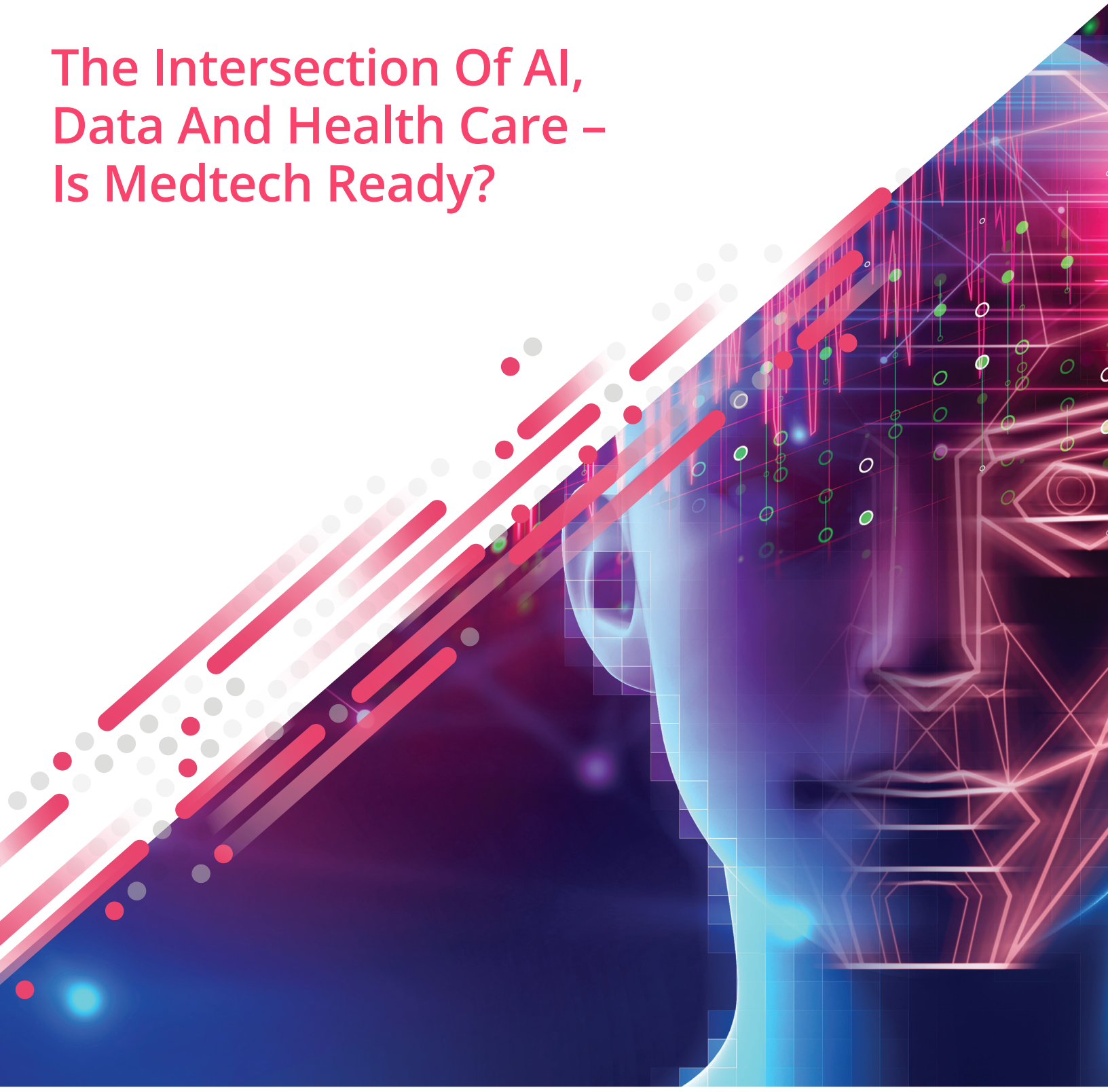
The Intersection Of AI, Data And Health Care – Is Medtech Ready?



POWERED BY MEDTECH INSIGHT AND IN VIVO

IN COLLABORATION WITH Syneos Health

Opportunities At The Intersection Of AI, Data And Health Care – Is Medtech Ready?

Has there been a more exciting time for patients than now, when health care stakeholders around the globe find themselves on the brink of a revolution in health care delivery?

Digital is the biggest health care transitional and transformational change the sector has ever seen, according to medtech experts who have been observing system changes and technology advances over several decades.

The "digital and AI opportunity" is there for the taking. It will affect how patients – or "consumers," as some stakeholders are viewing the digitally enabled health care user – interact with health care systems and with their own health, and will mean new roles and ways of viewing markets for the established medtech companies.

Long-standing players keep a weather eye on the global digital disruptors coming from the consumer world. They may not have the clinical expertise, but they have perfected the technology vehicle. Analyze, adapt and find a role for yourself in the digital future, commercial players of all sizes are told. Don't delay, be clear about where you can make a difference and pursue the opportunity hard.

This e-book brought to you by *Medtech Insight* in collaboration with Syneos Health sets out the necessary transition from product- to service-oriented business, how players factor in citizen AI – their new "co-worker" – for maximum benefit, potential winners and losers in the race to digitization, and the importance of planning to guarantee a place in the transformed health care and wellness markets.

A range of experts give their considered views on AI and use of data – is there too much already, and can overloaded clinicians derive full value from the AI revolution? Royal Philips gives a pragmatic answer. For smaller players, it's about biting off a piece of the AI pie and making it their own, in the examples of Ixico and Cognetivty.

Others, like Siemens, see "digital" as a method, a means to an end – the facilitator of cheaper, faster, more reliable health care. Medtech Europe, too, describes it as an "overlay," a functional tool to improve patient care. And others struggle with the terminology, preferring "machine learning" to "AI."

What is clear is that it's only the start of health care's digital revolution, and many in industry are still bidding to understand just how far it will alter the conventional shape of the sector.

Equally clear is that digital is now "the reality" in medicine and care delivery, and this e-book shows the steps being taken to bring it ever nearer to routine practice.

Ashley Yeo
Executive Editor
Medtech Insight

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Accenture Prescribes A New Data Management Future For Medtechs

BY ASHLEY YEO

The value of revenue streams derived from new business models is increasingly defined by how well companies manage the data within their ecosystems. Managing the data in the "last mile" subset provides an opportunity for medtech companies to generate income in that revenue stream, says Maximilian Schmid, head of the Global MedTech Practice at Accenture Life Sciences.

The life sciences industry is changing fast, and manufacturers of health technology solutions are now rapidly facing a choice: adapt to changing demand and factor in the growing opportunity – or threat – that AI, machine learning and disruptive new entrants represent to the medtech field; or lose competitive positioning in the market.

Business services and strategic consulting group Accenture Life Sciences paints a picture of this evolving health care landscape in its recently released flagship report, *Life Sciences TechVision 2018*, an annual publication that this year is entitled *Unleashing The Intelligent Enterprise For Patients*. It is in fact one of three new Accenture reports focusing on digital transformation and what it means to senior global medtech executives and the wider health care industry (*see box: Trio Of Accenture Reports With Digital Focus*).

The essential message from *Life Sciences TechVision 2018* for medtechs is that, faced with these challenges in an evolving health care delivery environment, they must "get it right, or face disruption." So says Schmid, who leads Accenture's Global Medtech Practice. Speaking to *In Vivo*, he sketched out the current pressures and outlook for commercial stakeholders, informed by all three of the reports' findings. He explained that the purpose of putting a separate focus on medtech, within life sciences as a whole, was to assess how the world appears, seen from the angle of players in the sector. Interviews with 55 medtech industry CEOs

– from an overall interviewee pool of 931 – form a central part of the *Life Sciences TechVision 2018* report, and seek to show how, from a business perspective, medtech firms can cope with changing technology, and how it will affect their business.

Five major trends were identified by the 931 executives across all industries. The three trends that have the greatest near-term influence on the health care industry were highlighted as: trust in data, how to take advantage of the new models for the free-flow of business and the growing opportunity (or threat) of artificial intelligence. "We see tremendous potential for the application of the various technologies that don't sit in 'core medtech'," said Schmid, who estimates 50% growth in the use of such technologies in the next few years.

Split View On Preparedness Levels For New Commercial Models

Of the 55 medtech CEOs interviewed by Accenture Life Sciences, 55% said they felt prepared for the transition away from a product-driven way of managing the business and towards a service-oriented way of driving the business. But the other half, more or less, admitted that they were not prepared for this kind of shift. A split of this magnitude is fairly typical among industry executives at present. "They are either strong believers, or conversely, are determined to stay with their core offering," says Schmid.

AI and big data are the technologies/concepts that the "digital converts" believe will have the most impact on their businesses. Around 40% of executives say, "If we don't get these right, someone will disrupt us." The next most disruptive themes are augmented and virtual reality, which 28% of executives consider as having the biggest impact on their activity. A typical response here is, "How can we use them to make better decisions in clinical workflow or provide better services?" Use of robotics and automation in workflows (not surgical procedures) is seen by 8% of those polled as the key change to adjust to as they conduct their business.

"Whether they get it right or not can have a major impact on their market capitalizations: many may well see their market valuations increase by up to 50%. On the other hand, they can get into really difficult situations if they don't get it right," says Schmid.

Managing And Owning Data Is Now A Top Aim

But there is a growing need and determination among executives to manage and own data. Before these business models moved from the periphery to the center ground, ambitious medtech groups would tend to develop revenue streams defined by IP, or the functionality of an item of hardware on a product. The new business models say that revenue streams are more likely to be defined by how a company is able to manage data within its business ecosystems. It is what Schmid refers to as the "last mile" concept, whereby companies managing the data in a subset dubbed the last mile have the opportunity to generate income in that revenue stream. "If you're on the last mile, you own the revenue."

Life Sciences TechVision 2018 starts by flagging the notion that significant changes in the life

Trio Of Accenture Reports With Digital Focus

Accenture sets the scene and gives perspectives in each of its recent publications, namely "Industry X.O for medical technology manufacturers – Unlocking the power of digital" and "The race is on: Taking advantage of digital platforms for medical technology," along with "Unleashing the intelligent enterprise for patients." Together, they describe the altered medtech commercial and technology environment.

sciences industry are being driven by socio-economic pressures, scientific advances and the consumerization of the patient. Data availability and AI, among other things, are the tools that are allowing companies to respond to and begin to exploit these changes. As such, industry is seeing the creation of the "intelligent enterprise," as Accenture describes it, which it defines as a company that adapts as technology develops.

Meanwhile, the patient, rightly at the center of it all, is finding that the consumption of health care offerings is becoming easier, better targeted, personalized and quicker because of device connectedness and the use of algorithms that learn from electronic patient records.

The data derived from this digitally enabled chain of health care delivery is there to be exploited, and big tech companies such as Amazon and Google are already positioning themselves to be able to do just that. But "traditional" health care concerns are also active, as seen in the GSK-Novartis Consumer JV and Verily Life Sciences LLC deal to set up Galvini Bioelectronics, bringing drug discovery, miniaturization and data analytics together in a single offering to create therapies that interpret electronic signals in the body and spot and correct irregular patterns in specific disease states. *(Also see "New GSK-Verily JV Aims For Smart, 'Grain Of Rice' Neuromod Tech" - Medtech Insight, Aug 2, 2016.)*

Data Veracity, Technology Partnerships And The Value Of AI

Three themes stand out for health care and life science companies that are tracking the trends in the changing nature of health care delivery globally.

The range of data that companies will need to access – be it from wearables, genomic data or EPRs – is growing exponentially, but the "truth" of the data that are used and exchanged must be validated to ensure quality. The sense is that, right now, not enough is being done to determine or ensure "data veracity," to use Accenture's term. *Life Sciences TechVision 2018* notes that one-third of life science executives have high confidence in their data. But is one-third high enough? Clearly not, so work to secure data sets must be a priority to ensure that trust in the system is not impaired.

"Frictionless," as applied to business, might appear to be a term that has currently been hijacked by a UK government fearing that EU withdrawal will impede free trade with its erstwhile fellow EU member states. But in the evolving health care model globally, "frictionless business" means working across silos and embarking on technology-based partnerships via microservice architectures (including the Cloud) and Blockchain, enabling the sharing and release of data with partners on agreed terms. Accenture is working with DHL on a Blockchain-based anti-counterfeit medicines program, for instance.

The third trend is the ever-increasing advance and sophistication of AI, and how to factor it in for maximum benefit. It is fast becoming a "co-worker" in its ability to facilitate rapid response to the needs of patients and health care ecosystems. "Citizen AI" is another new term coined by Accenture, which it uses to reflect this new digital-stakeholder relationship, but can companies ensure that their AI remains healthily unbiased and transparent? With cautiousness starting to subside among industry players, companies must ensure they give AI the same oversight as its physical "co-workers" have traditionally enjoyed. As said, it also needs to be trustworthy. But the benefits are clear, and Accenture's report lists several recent initiatives that are taking AI forward: BenevolentAI, iCarbonX and BenchSci being among the new platforms that promise to transform health care delivery.

Three Priorities For Transformation

Schmid acknowledges that companies must change their approach and adapt their

activities to the new model. But what precisely do they need to change, in terms of internal transformation? What do medtech companies need to do that is different from what is happening in the hardware-based environment, and how do they need to change to be involved in the way pharma companies like GlaxoSmithKline PLC have begun to be?

There are fundamentally three priorities for medtech groups, says Schmid. Companies making the transition must first focus on engaging with the device user. They must identify if that user is, say, the clinician, nurse, patient, or even the lab worker. Understanding which user population is important for the company is essential, and

> **"We will need more health care 20–30 years from now, and if we don't find solutions, somebody else will – it might not be a medtech company, but could be a technology company, which might present survival challenges for medtechs in the long term."**
> **– Maximilian Schmid, Head, Global Medtech Practice, Accenture Life Sciences**

moreover, might be very different from what it is at the present time. Connecting with a community is an important stage in the process, and companies must consider questions such as, "Can I build a global community of … nurses?" for instance. Connecting and globally servicing the target community automatically gives a company the ability to sell more products, control the ecosystem and have a good view on how well its competitors are doing. This customer engagement also lets a company know what are the key drivers among the community, and over the course of the business relationship prompts customers to begin contacting the company on a voluntary basis. Those companies that are more attuned to the social elements of business generation, and those that perhaps have learnt from the Googles of this world, are more likely to succeed with this approach, Schmid observes.

Companies must secondly start thinking across the silos, that is, no longer look at business from a product perspective. The workforce might need to be reskilled. This potentially has a very big impact on R&D departments, where staff might have seen themselves as engineers whose endeavors focus around problems such as, "How do we make a certain device another 5% better?" But platforms now really mean *software* platforms, and a completely different type of innovation (as exemplified by Amazon). The new model also includes more trial-and-error and "fail-fast" concepts, rather than companies putting all their thinking into one functionality, which then goes through the approval process.

"Scale it" is the third priority. For medtech companies, the business is seen to evolve, moving away from the provision of a single service, and toward notions of, "How can I build an end-to-end service that applies across the complete spectrum of hospital sectors?" Here is where the enterprise's innate intelligence comes into play. The medtech company may typically be thinking, "I have the platform, I understand health care professionals and their needs in terms of chronic disease control, I have the reimbursement and I have the data to manage treatments in a completely different way, and for different outcomes." Couple that with their growing ability to digitally tackle inefficiencies, and the result is precisely that end-to-end service. But, Schmid warns, "If you're not the biggest, you won't survive in the long run."

New Mind- And Skill-Sets

A different mind-set and skills are needed to drive innovation in the new health care models. Over the course of their "transformation," companies will be able to better define their markets or go into new ones where they don't necessarily have a history of activity or control. "Defining them [markets], and engaging customers, are areas where these companies really need to work hard," says Schmid.

> **"Look after your core, use the 'digital switch' to transform, and select carefully the digital service business you are targeting."**

"We found that 73% of executives believe if we don't get this transformation right, we might run into big difficulties concerning our future, especially in view of the ever-increasing pressures on health care and the ageing population," says Schmid. But it is also an opportunity to visualize new digital technologies that go more into prevention and personalizing care through data as the key issues to resolve. "We will need more health care 20–30 years from now, and if we don't find solutions, somebody else will – it might not be a medtech company, but could be a technology company, which might present survival challenges for medtechs in the long-term."

In the general discussion over which type of individual will own and control health care delivery agendas in the future, in Accenture's experience, it will not necessarily be anyone with a commercial pedigree from one of the tech-heavy exponents of medtech. "What will be key is how an individual has grown up within his/her company."

It is difficult to see individuals who have come out of R&D and are very involved in feature-heavy programs becoming top decision-makers within the future system, says Schmid. "But visionaries who have grown up on the hospital side, who are much more attuned to solving clinical or lab work-flow problems, have a different view on future needs."

Seeking Visionaries

Within medtech, the "visionary executive" is not as common or widespread as the industry needs right now. It might even be said that CEOs who are not forward-looking in fact represent something of a threat to their company. Upskilling might be quite foreign to them, but equally, Schmid has observed a trend among executives to learn these skills. "That is exactly what we are seeing in these new positions; all of a sudden, we have digital technology officers at board level. Or within the R&D department, we see that people are being appointed to have responsibility for digital solutions or quality solutions."

Another trend in the medtech R&D area is that specialists are increasingly being sourced from outside the industry, especially if they have broader knowledge of digital and technology platforms. Similarly, industry "outsiders," with their new ways of thinking, are also becoming more prevalent at board level. They help to guide visionary thinking on the management side, and they look for big data "lake" patient correlations, or cross-border, Cloud-based approaches and solutions, as opposed to country-based approaches.

Winners And Losers Ahead

Looking five years ahead, there will be winners and losers as the ground continues to shift toward personalized medicine and use of smarter data sets to deliver affordable, more accessible technologies. Royal Philips NV, GE Healthcare and indeed diagnostics companies in general, already exposed to so much data, are well placed to benefit from the intelligent health care revolution.

On the other hand, "just being able to operate a database on a Cloud platform is something that a technology company is probably most qualified to do," says Schmid. "We are in very changing times. Look at the amount of money that technology companies can throw into this – the Amazons and the Googles can put a lot more investment behind it than medtechs, and that should worry the medtech companies." The Boston-based JP Morgan, Berkshire Hathaway and Amazon venture, designed to provide health care for its 1.2 million staff, has not yet stopped creating ripples and waves, even though its strategy has still not been unveiled. *(Also see "Amazon And The Case For Major Health Care Disruption" - Scrip, Mar 29, 2018.)* It moved forward a few steps this summer when it named Harvard surgeon and *New Yorker* magazine writer Dr. Atul Gawande as part-time chief executive. *(Also see "Citing "Incomplete Technologies," Atul Gawande Calls For Increased Automation" - Medtech Insight, Jun 10, 2013.)*

But medtech companies are eminently qualified to at least part-own their territory. As they already have the equipment and the devices, they are well placed to create the data around their offerings to keep patients healthy. They can possibly even create health insurance offerings too. But the key is being able to connect end-to-end, with a combination of medical knowledge to build an intervention infrastructure that the company then owns – a clinic, for instance. "In our view, this is the stronger value proposition," says Schmid.

Keep It In Perspective

It seems that entirely different skills will be needed to run medtech companies in the future. But Schmid advises: "Look after your core, use the 'digital switch' to transform, and select carefully the digital service business you are targeting." It should not be, "I want to set up an Amazon cloud or compete with Google," for instance. A better-targeted ambition for a renal medtech company, say, might be how the digital service is set up to treat people at home who have dialysis needs.

In short, a brief checklist from Schmid would be: "Look at your therapeutics; look at the 'digital playground'; leverage your heritage; gauge where your strengths are; and maintain your medical knowledge." The knowledge part is key: "You need to get that right – it's really all about the knowledge that allows you to grow your community, and build a sustainable business model around it." After that, next most important is software skills. At the heart of it is a mind-set that says, "We need to deliver that fast." And that means it's still all about the technology too.

The Upcoming Ecosystem Needs

If that is how medtechs are advised to face the future, other players in the ecosystem also need to play their part. Regulatory bodies must buy into this in full, or "the health care costs will kill us," says Schmid, calling for more help on innovation.

Common rules on, say, which Blockchain standard industry should be used, are still outstanding issues. They cannot be resolved by a single company alone. "Someone – governments or regulators – needs to set up an infrastructure for a set of common rules." So far, there has been no major momentum for the establishment of a health care consortium for Blockchain, which can "revolutionize the way we share patient data." Similarly, the nervousness around AI is unwarranted – at least around "small" AI, which is evidently a tool that can take away some of the pain for companies. But here too governance is needed, and, for its part, industry needs to explain its AI, while making it secure for patients. More generally, how these new tools will be reimbursed and rewarded remain outstanding issues to be tackled.

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A "Blood Pressure Test" For Dementia

BY ASHLEY YEO

The attention accorded to dementia, MCI and degenerative brain conditions has been slow to reach the levels given to the more visibly-quantifiable conditions, such as cardiovascular disease and oncology. But earlier detection of cognitive impairment is a priority, despite therapies not yet being available to halt or reverse the conditions. Playing its part to push back the boundaries is Cognetivity Neurosciences, a London-based company with an innovative tool that uses AI to test subjects for the early signs of dementia.

Fresh approaches to early testing for dementia are increasingly common, but the resulting technology has tended to fall short in terms of results. London-based Cognetivity Neurosciences Ltd. has been developing a compelling solution, the ICA (Integrated Cognitive Assessment) test using natural images that are presented quickly to participants who are asked to accurately indicate whether they have seen a pre-specified image category. The test can be performed on an iPad, potentially in any setting. The viewed images are processed in the visual cortex, a brain region associated with the earliest signs of neurodegeneration in conditions such as Alzheimer's disease (AD), and are translated to movement in the motor cortex, allowing evaluations to be made based on comparisons with an accurate data set of clinically-diagnosed subjects. It is a technology that the company

believes has applications in and beyond the clinical setting.

The involvement of Cognetivity, a Cambridge spin-out, in the technology began when one of its founders, Dr. Seyed-Mahdi Khaligh-Razavi, a computational neuroscientist, was doing a PhD at Cambridge. The central aim of his research was to understand – and quantify – how much better the human brain is than computers at analyzing images. He noticed that there was an age-related fall-off over time in subjects' speed and accuracy in reacting to stimuli. Older people were less able to analyze – as expected. But that's where the idea for the CGN_ICA technology came from.

Dr. Sina Habibi, co-founder and CEO of Cognetivity, decided with Dr. Khaligh-Razavi to look further into whether this was something worth investigating from a dementia diagnosis point of view. The decision was taken then to write a code and develop proof-of-concept data for this visual challenge method, whereby images are represented on the retina and, transferred to the visual and pre-frontal cortex, with responses made using the motor cortex.

The rationale was explained by Cognetivity's COO, Thomas Sawyer, who said, "We have constantly been improving data capture and processing computational capability, but not everything can yet be more efficiently done by computer." Speaking to *In Vivo* about the opportunity ahead, he described how the company had developed a test that seeks to quantify the mathematical elements that affect human cognitive function. "By fine-tuning the elements of the test, they were able to come up with something that was very useable and repeatable," said Sawyer, a University of Cambridge MBA. Sawyer joined the team five years ago, after meeting Habibi when Sawyer was mentoring at the business school in Cambridge. Khaligh-Razavi has MIT experience too, and was described by Sawyer as an "excellent academic," capable of building proof-of-concept software platforms.

The ICA Test

Cognetivity's ICA tool is a rapid visual characterization task, in which subjects are presented with a fairly short-duration of stimulus – a photo – and the subject is asked to determine whether or not they saw an animal in the image. It focuses on cognitive functions such as speed and accuracy of processing visual information, which have been shown to engage a large volume of cortex, while being a predictor of people's cognitive performance. Monitoring the performance and functionality of these areas can be a reliable early indicator of the onset of disease.

The reason for animals as the target visualization theme is that the human brain detects animacy as a by-product of evolutionary development. A whole chunk of the brain is specifically involved in that, the bottom line being that humans are good at spotting animals, even in harder images, such as animals foraging or in flight in visually complicated environments. At the very broad level, it's a neuroscience test that picks up very subtle changes in cognitive performance.

Clinical Applications

The technology has entered the phase of heavy validation, ahead of regulatory approval and scaling the platform. The validation trial for regulatory approval is being conducted at the Maudsley Hospital, London, and the study is designed to work for both CE marking (under the current EU Directives) and FDA and other regulatory

jurisdictions thereafter. "We're in the throes of carrying out the study, bearing in mind that the recruitment of subjects is one of the major challenges with this kind of trial."

The images presented to the subject are very tightly controlled. "We work out at what point the subjects stop beginning to discern. In simple terms, it could be a full screen shot of a horse, or a more challenging forest or in-flight scene, featuring a small animal within the frame. That's where the lack of learning effect comes in – if the subject can't discern the animal in a particular image, they do not get better at doing this, the animal remains invisible." Other tests can be learned over time, and this decreases their value as an objective measure. The ICA is a single task that engages a large proportion of the brain that no other test has used to date. It then uses sophisticated AI to analyze a multitude of data points in order to determine the likelihood of impairment.

"We deliver a wide range of images and can determine at what point the subject is unable to determine the animal." Nobody gets all the images, said Sawyer. "We're looking at the relationship between speed and accuracy for the different composition of the images," he added. The images are broken up by white noise pictures, but the exposure to the images is very short: just 100 milliseconds for the visual cortex to make some sense of what is being presented.

The fundamental design of the test has no particular data component. "We've not seen anyone else going about this problem with this design point of view. It lends itself very well to the ability to pick up small changes," he said. It is, by necessity, a very challenging task for the brain, but this means being able to test for the earliest stages of cognitive decline.

The AI side of it comes over and above that. "We're able to use results from groups of subjects that we have controlled and in whom we know the clinical circumstances, and use these to train our AI. We've experimentally examined populations of MCI and mild AD patients – measuring their particular patterns of response to the varied stimuli – as well as a group with MS."

Then, the company trains the algorithms behind the test to be predictive for each of these conditions. The algorithms can be updated. "That's where the data science comes in and that really the growth area." By conducting more and more well-controlled studies, Sawyer said, Cognetivity would be able to say more about the characteristics of the population being studied by the way that the subjects respond.

Bringing the test to market readiness for clinical use is very much tied up with the regulatory process. "We have fully functioning, cloud-based software, with several architectures that work: that's what

A Predictor Of Neuronal Damage Using Software Only?

Recent research data from ongoing studies involving the ICA technology shows a strong negative correlation between levels of blood plasma neurofilament light (NfL) and the ICA score, with the ICA score decreasing as NfL levels increase. This highly significant correlation of 0.79 "clearly demonstrates" the ICA's ability to predict the presence of neuronal damage using software only. This correlation gives further validation of the ICA test as a reliable, yet non-invasive, measure of cognitive impairment caused by damage to nerve cells. Blood plasma biomarkers, such as NfL, have potential to be effective as a diagnostic procedure for clinicians, but these procedures are invasive and highly time-consuming.

we're testing and validating." Sawyer is confident of successfully crossing these bridges with what is essentially a non-invasive medical device.

Non-Clinical Applications

Professionals will use the clinical product as an aid to diagnosis/or for diagnosis, but the company is also developing non-clinical applications. The platform delivers a very objective measure of cognitive function. It tests how quickly and accurately the brain can react to difficult stimuli. It is a test that could find use in the airline or other industries, for instance to check the state of pilots' health and take-off readiness. Sawyer sees the potential of the technology as a personal health monitor. The company has already signed a commercial deal, a few months ago, with a provider of health monitoring software, dacadoo, to provide cognitive monitoring.

The ICA will be used in this case as part of a suite of health monitoring applications, providing vital information on users' cognitive health, where the primary customers are health insurance companies. They would get access to the platform for their clients, who, in return, would pay a lower premium. The personal applications extend to a person proactively self-monitoring their own heath. This would involve the subject looking to baseline themselves over a period of time, learning normal ranges and checking themselves against that. And against how well they are performing for their age range.

The databank being accumulated includes sleep patterns and heart rate. "You're able to chart yourself – it fits in with the whole trend of personalized medicine, allowing you to track your own progress and work out what is best for the individual, rather than being only able to compare to very crude population measures." Sawyer said the technology's ability to be used frequently and at home would allow much higher resolution monitoring than had been traditionally achieved using comparator technology.

The potential is great. Sawyer pointed to the biggest market, the US, where there are over 200 million visits to a primary health care practitioner every year. In Cognetivity's eyes, a large proportion of these are potential testing opportunities. Medicare has an insurance reimbursement code for cognitive assessment, at $48 per test, which gives an idea of the size of the clinical market segment that can be addressed.

Conveniently for users, the test can be delivered through existing hardware and a cloud-based system. "There is potential for significant revenue. It's an enormous market based in the idea that we can alert people early to deterioration of cognitive function-related dementia." The company suggested that people should start testing around the age of 50–55, given that the outcomes are so much better if a diagnosis occurs at an earlier stage. "Our thought is that this market would take a lot of our focus," said Sawyer.

The Consumer Offering

Although the personal and consumer potential of the screen-based test, with its user-friendly touch-left/touch-right method of use, is very large, Cognetivity has been reluctant to be branded a B2C company. There is the sense that many have jumped on the Apps bandwagon, and Cognetivity wanted to ensure it is not seen as part of that trend, given that it is "a very serious science company" that has developed "a very serious clinical tool." Sawyer noted, "Until the point where we are well established as a professional and highly validated platform, we believe we should hold off from going into the consumer market."

Patient dementia groups see a huge gap in the treatment pathway. Sawyer said, "We have always described our technology primarily as a clinical tool, and associations like Alzheimer's Research UK say there is a definite dearth of practical,

A Rising Incidence With Hidden Costs

Providing sustainable care across the continuum from diagnosis to the end of life requires timely diagnosis before treatment and care come into the equation. The WHO's Global Action Plan on the public health response to dementia 2017–2025 also notes that people with dementia are less likely to be diagnosed for comorbid health conditions, which, when left untreated, can cause faster decline. In 2015, dementia affected 47 million people worldwide (or roughly 5% of the world's elderly population), a figure that is predicted to increase to 75 million in 2030 and 132 million by 2050. Recent reviews estimate that, globally, nearly 9.9 million people develop dementia each year.

useable tools capable of early detection." The benefit of this clinical tool is that testing 15–20 years earlier than currently happens today leads to early results and provides the information that allows for behavioral adjustments. Two types of patients generally present: the worried well, in whom there is usually nothing very much wrong; and the late diagnosis subjects, who are already heavily impaired. "You would like to be seeing pre-symptomatic dementia sufferers, so you can make the necessary behavioral and social adjustments."

"This is expensive to do at a later stage." But also, a longer functional period allows people to prepare for what is before them. A recent study by the Alzheimer's Association calculated that if all people with dementia in the US were diagnosed early, the savings for the health care system would be $7.9tn over the cost of their lifetimes – so there are strong economic as well as social arguments for earlier diagnosis.

Studies into attitudes toward the onset of dementia in the US and UK show broadly that the majority of people would like to know early. And if disease-modifying therapeutics are also brought into the argument, better brain function retention will be the overall result. While none of the therapeutics currently in Phase II and III are proposing to regrow dead brain cells, if they are already helping to deal with amyloid buildup to stop the advance of the brain impairment, early diagnosis will become even more important when effective therapeutics do become available.

Cognetivity is currently doing a small funding round to finance work on developing the opportunities, including on the non-clinical side, and would raise capital for scale-up costs after US FDA approval, which is expected any time after the beginning of 2020.

Developing a new platform for clinical practice is an ongoing process, and brings in the need to work with different stakeholders over time. So far, the work has mostly been jointly undertaken with the scientific community. Building up the body of science is a priority, as is growing awareness in terms of the clinical community. The NHS in the UK, for example, is famously difficult to engage with, necessitating a lot of careful preparation work. But Cognetivity is building up momentum in that area. "Clinicians like it," said Sawyer of the ICA test.

The BP Test Equivalent For The Brain

But the type of application that the NHS really needs is something more akin to a blood pressure (BP) test, noted Sawyer. The idea is that clinicians can check that things are OK, or verify whether it needs further examination, and/or whether to get on a treatment pathway very early. "There is a crying need for this type of application." Sawyer said. "We're just

at the early stages, but an equivalent of a blood pressure test, in that it is a simple, cost effective and meaningful measure for the mental health arena is the impression we want to give."

Cognetivity has also realized the need to factor in the bandwidth of clinicians to take on new or extra tasks. Senior NHS people, for instance, tend to be more open to trying something new if it does not disrupt what they already do. "We are working on some validation studies within the health care system so people can see what it does, and how simple it is," Sawyer said. If it appears to be just another extensive and time-consuming task that will place even more pressure on already stretched clinicians then it will be unlikely to be adopted. "If that's the case, then it won't happen: many systems and projects have fallen by the wayside for not being compatible with clinicians' current working practices, so it is important to make sure that any solution fits in with clinical practice."

The NHS England Long Term Plan and the revamped Accelerated Access Collaborative (AAC), with its promise of championing early diagnosis, seem to be two innovation-promoting vehicles that are coming out in the UK just the right time for Cognetivity and its outcomes-based, non-invasive, value-based health care tool. "There seems to be quite a shift in awareness of the need to be able to bring innovative solutions into the NHS."

Clinical Trials Opportunities

The pharma clinical trials advantages of using a technology like Cognetivity's is a further promising avenue. It is set against the premise that companies are sinking billions of dollars into trials that are failing, and probably for a number of reasons. But Sawyer said it seemed obvious that if you're looking for subtle system signals from a cognitive standpoint, and the trial is using older tools, that these signals might not be detectable, with a resulting impact on the potential for a successful outcome for these extremely expensive trials, and a corresponding effect on the value of the company.

The pharma industry needs a tool that is sensitive enough in trials to pick up some kind of signal. "There is potential for our platform in that area. In terms of social impact, it could be very profound in helping find signals that are hard to pick up. It's what we are trying to do," he said. It would appeal to slow-moving, risk-averse clients as a secondary endpoint. "There is a crying need for a tool that can be used to reliably measure and monitor small changes repeatedly."

Cheaper, More Efficient, And Ready For A Pharma Link

The precise business model adopted by Cognetivity with regards to clinical trials remains to be seen. But it is able to integrate with other platforms, plug into data platforms, and manage data. "There is likely to be a quite obvious link between a large pharma company and what we do," said Sawyer. Indeed, a partnership with a large pharma company on a non-exclusive basis is an important aim for the company. He added, "If you could pick up a signal in a clinical trial, you would also be able to detect it in a potential patient once the drug has been approved for the treatment." Recruiting early-stage patients for trials is notoriously difficult. "There needs to be a much cheaper and more efficient way of doing it, and we feel our ICA can definitely help with that."

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Data, Data, Everywhere, But How Much Of It Makes A Real Difference?

BY ASHLEY YEO

Having a single patient's complete health care information all in one place was a dream that US visionaries began to talk up around a decade ago. The idea was that fast, electronic support for doctors would aid clinical decision-making and efficiency. Ten years on, there is still much work to do before the dream is realized, says Philips' Carla Kriwet. But a solution is within reach.

Doctors ostensibly have a single, clear task – easy to describe maybe, but usually anything but to deliver. And the two questions they need answers to have never changed: what is the next best thing to do for the patient and what are the risks associated with that course of action? This is what they require, yet the device technologies and data intelligence offerings available are still not delivering the targeted answers they need for the patient sitting before them.

Carla Kriwet, CEO of Connected Care and Health Informatics for Philips Healthcare, told *In Vivo* that in spite of the volumes of data available to health care professionals, too little of it is meaningful. And the sheer volumes of data can bring risks too: data copied from one place to the next potentially carries the risk of copying

the same errors along the way. “Basically it means we are not getting the value out if it,” she said, urging a change of approach if the major opportunities that the data era are bringing are not to be missed in health care.

Not Just Data, But The Right Data

“We need a smart EMR [Electronic Medical Record], which is not just about data, but about the right data, that is, where data is limited and targeted to precise and immediate needs,” she said. For instance, health care professionals focusing on breast cancer would have access to the data that were limited to and relevant for that situation: and they would be used in an analytical way, sourcing information from people who are in the same health care situation and age group, and who have the same behavior patterns. “That way, we can crystallize it to that person specifically, and make it relevant.”

“That was the trigger for our vision to make available meaningful clinical decision support that really makes a difference,” said Kriwet, paraphrasing the biologist and theorist E.O. Wilson quote, “We are drowning in data but starving for lack of wisdom.” Maybe the biggest hurdle is “trust” in the data and that stage has not been reached yet, she said. “Do doctors trust the data? Is it compiled in a way that’s actionable for them in terms of clinical support decisions? Or is it more like searching through a telephone directory?”

Health care practitioners cannot yet see the wood for the trees, according to comments expressed at a recent UK conference on the future of digital technology in the NHS, organized by Westminster Health Forum (Nov. 23, London). “We need to reduce data flows, but improve utility,” NHS Digital’s director of data Professor Daniel Ray told the meeting, noting that this is an aim of the forthcoming NHS Ten-Year Plan. And it is vital that the benefits of data collection are conveyed to the patient, for without the patient and without their

“It’s not about anecdotes, it’s about performance data and securing the completeness of outcomes jointly with health systems.”

– Carla Kriwet, CEO of Connected Care and Health Informatics for Philips

trust, digital health care cannot happen.

Philips' actions to help establish digital methods within national health care systems are guided by its Quadruple Aim, which states that company projects must deliver the right care and at the right time for the right person. Also, they must enhance the satisfaction of those delivering the care. But do doctors always get the right data at the right site at the best time? Does it give the insights needed on a certain population in a certain area? The answers are: not yet.

> **"If you are serious about outcomes, you can't keep your device business isolated – you have to integrate it into a solution that really hits the spot."**

"A clinician might even have to put all the sources together themselves, get on the phone and access pathology and genomics information in a bid to find meaningful data," said Kriwet. Are the sources complete, is the data structured, and have interoperability issues been addressed?

Health care has a lot of catching up to do on the best-in-class example of data-smart relevance to the user: the mobile phone. While a smartphone knows every detail about the user, a traditional PACS medical image storing system just cannot compare in terms of utility – not recognizing the clinician/user except in the most generic way, flooding them with data of little or no relevance and generally not providing smart support.

AI Integration For Predictive Systems

AI is not being used properly in health care delivery. For Philips, AI means adaptive intelligence, rather than artificial intelligence, and is applied in an environment where the doctor's skills are *always* needed, never redundant, and where he/she is supported by smart insights. The aim of AI integration is to develop and use a predictive system that provides clues about what will or could happen, what the likely disease development is, and how best to treat it.

Philips' *Illumeo* is an example of clinically intelligent software that augments the skills of clinicians and redefines how they interface with images. Designed to empower radiologists and work for them, within a single workspace it provides the technology and tools that enhance their expertise and efficiency.

IntelliVue Guardian is another example: it is designed for the general ward and based on biosensors that wirelessly monitor vital signs, posture and activity, and can detect falls automatically. It can predict a cardiac arrest up to eight hours before the event, which is really valuable time in which medication or transfer to the ICU can take place, noted Kriwet. And it is cost efficient, as it can keep those who have been diagnosed early out of the ICU. The sensor-based approach can also make triaging more effective, providing longitudinal data rather than just spot checks, and identifying the right solution correctly and early.

The chest-worn Guardian patch devices, the size of two fingers, transfer data by wifi, delivering continuous measurements to the Guardian system, which automatically updates the patient's EMR. They are used in general wards where the ratio of caregivers to patients can be up to 1 to 12. Single caregivers, on night shifts especially, cannot always tend effectively to all patients, but a data-enabled system can predict where acute needs might arise. Up to 70% of unexpected hospital deaths occur in the general ward, hence Philips' major focus on this area.

Another example where Philips is leveraging

telehealth and connected digital remote patient monitoring is a hub and spoke model focused on the eICU or Tele-eICU. One centralized care team can manage a large number of geographically dispersed ICU locations to exchange health information electronically, in real time.

Considering The User

Digital delivery provides access to health care for many who would otherwise have none, and it saves health care system costs. But crucially, it delivers expertise at the right time, and importantly can better meet the job satisfaction needs of caregivers. For instance, as older nurses find their job becoming too physically demanding they often must face leaving the profession. But the fact that they can no longer lift patients should not mean their skills should be lost. Digital capabilities mean they can remain employed and share their knowledge – often decades-long – with other nurses. This means the gray intelligence is retained, and the other aims – better care, better outcomes, higher satisfaction generally and lower cost – are all more easily met.

Data-enabled care also offers the real opportunity to fit the therapy around the targeted outcome. "We no longer live in a world where devices with incremental functionality are automatically something to get excited about. The thinking now more often revolves around notions of 'Can we reduce the mortality rate, incidence of infectious disease and cost, at the same time as make sure our staff retention issues are being addressed?'," Kriwet commented.

Risk-Sharing Models

Kriwet envisages a time ahead when manufacturers like Philips would even bring into play certain business models where they no longer sell equipment up front, but rather do deals where equipment is paid for only if targeted and measured outcomes are achieved. "It's not about anecdotes, it's about data – performance data – and securing the completeness of outcomes jointly with health systems." Philips' sales staff are trained not to upsell *per se*, but to sell into the Quadruple Aim – majoring on the targets that providers have set for themselves – and fitting Philips' solutions and devices into those plans.

But there is a big difference in adoption readiness of these concepts among hospitals. Advanced, networked hospitals that have the financial power to buy up other clinics are the ones with the networks to make data interoperable and flow. They are driving outcomes and have philosophies for executing the concept. Hospital groups are consolidating at a rapid rate, Kriwet observes: in the US, there are expectations that the current 5,500 hospitals might in 10 years' time all belong to perhaps just 20 hospital groups. The same consolidation is happening in Europe too, with Spain and the UK leading the charge.

Taking A Leadership Role: Philips' Approach

Doctors are beginning to look afresh at workflows and how to organize them around patients, not just to optimize data management, but for speed, and mobility of the patient. They understand that it is more complex than "just" the clinical outcome, but that patient satisfaction is crucial, and companies like Philips are looking at that more closely and changing their value proposition accordingly.

Having said that, Philips is in a "unique position," Kriwet said. Alongside its hospital solutions including smart devices, systems, software and services, it also has a major out-of-hospital business in areas such as personal care, home care facilities and in nursing homes. "We have the whole continuum of care, from healthy living, to prevention, diagnosis, treatment and home care – in fact the whole care value-chain – covered. That gives us a unique opportunity to develop solutions in workforce, triaging," she said. "We *should* be helping when hospitals are flooded with

patients; and chronic patients *should* be treated at home, not risking infections by attending hospital appointments."

More Important Than A PR Initiative

Philips has become more vocal about the fact that systems must change, and has ramped up its interview count in the general press, where it sees itself as a useful ambassador on the need for system change. "Our mission is to improve

> **"Nobody can win this game alone, we jointly have to build an effective ecosystem for better care at lower costs."**

the lives of 3 billion people per year by 2025. That's something that we take very seriously – we measure it and track it," said Kriwet. The company has also done a "deep dive" into less developed geographies, such as India, Africa and South-East Asia, using its Community Life Centers (CLC) platform to improve access to care, extending health facilities into social and economic community hubs, using innovative technologies and services.

Kriwet is clear about the part industry will have to play in the future health care model: "It can't just be sell more ultrasound, sell more patient monitors, that won't do the trick. We're not a charity though, and our goal is to learn what devices will meet the needs in these countries and how we can make the equipment as cheap and effective in the local environment as possible. That's a real challenge."

The changes of approach can prompt unexpected – even uncomfortable conversations – within commercial organizations. Kriwet said her initial exchanges with Philips colleagues about her sensor-based care concept led to group colleagues wondering if Philips was cannibalizing its own patient monitoring business. "It's a good, profitable business, so why come up with patches?" was a typical early response.

"But if you are serious about outcomes, you can't keep your device business isolated – you have to integrate it into a solution that really hits the spot," she said. While devices for highly acute patients might well need multiple functionality, many others do not, and can even use the same software. "It's a mind-set thing," Kriwet noted.

Negative Connotations Of Data Overload

The danger of information overload for clinical teams is very real. They can easily become disheartened and fatigued by the sheer volumes of data around that ostensibly should help them but do not, in their current form. "We really need to make it easy, flexibly save time and improve efficiencies," said Kriwet, acknowledging that volumes of data for data's sake is far from "job done" in the health care sector.

Time-poor clinicians can be overburdened by new technologies and data applications. Only 5%–10% of the functionality of existing devices is used anyway, and Philips says there is a pressure to add ever more functionalities to its monitors – up to 10 start-ups contact Philips every month in the hopes of teaming up on a new algorithm for its monitors. (Philips has moved its US headquarters to Cambridge, MA, to be closer to where the digital expertise is accumulating.)

In developed countries, specialists are not connecting data around their patients, and that needs to change, Kriwet added. Some hospitals are getting down to changing their architecture, but it is not the standard approach. Reimbursement is not really being tailored to support the outcomes-based environment – even in Germany, Kriwet's birth country, the 18-year-old DRGs system supports processes, not outcomes.

On The Journey To Outcomes Payments

How companies get paid for their technologies and processes in the new outcomes-driven era is another conundrum. Kriwet assessed the situation for the health care sector as "at the beginning of the road on that journey, and just walking, nowhere near running." Things will speed up, and "once we are on the trip, it will be irreversible." Industry is still working on the shape of future reward systems, and is talking to the C-suite decision-makers in hospitals, providers in general, including the large IDNs (Integrated Delivery Networks), key opinion leaders who have an impact on payers, the payers themselves and governments.

"We play on all levels," said Kriwet, but she noted the rising power of the hospital C-suite and the perceived change in their role. And within commercial organizations, the balance has shifted markedly too: just five years ago, only 15% of chief information officers (CIOs) reported to the CEO in the hospital, and most of them were "technical guys," Now, they are the key decision-makers. "In the real world, experts are getting less important in the decision-making." The C-suites are now making decisions on digital, data and outcomes. And fully 90% of CIOs report to the CEO.

This was a positive change, said Kriwet, acknowledging that, although these claims are based on US findings, they show a very clear trend. The US in fact remains the pace leader in transforming care based on outcomes, but other countries are very open to the concept, the Netherlands, Scandinavia, and the UK, with its regional pilots, among them.

Keeping An Eye On The Disruptors

Health care disruptors do not have the patient databases that the traditional medtechs do, but they do have a potentially huge advantage in size and power. "We don't underestimate them. They have a passion for health care too, and deep pockets, and we take them seriously." Kriwet added that Philips has an understanding of the relationships in clinical workflows, and access to rich data – from 275 million patient monitors collecting data every second.

Elsewhere, Philips, like others, is monitoring the increasing talent shortage, and factoring in the more demanding patient: a trend that must be welcomed even if it brings challenges by introducing more complexity.

In all this Philips has identified its priorities as teaming up with large IDNs, getting scale, pursuing radical innovation and challenging the status quo more often, and using open source approaches to encourage and optimize data flows.

Some recent M&A successes have been targeted in that area. In December 2017, Philips acquired Forcare, an innovator in open-standards-based interoperability software solutions for fast data flows between medical systems and at departmental and enterprise levels, and VitalHealth, a provider of cloud-based population health management solutions for the delivery of personalized care outside the hospital. Kriwet said, "We are always looking for systems integration capabilities, partnerships in health economics and solutions partners. Nobody can win this game alone, we jointly have to build an effective ecosystem for better care at lower costs."

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Winners Are Beginning To Emerge In Digital Health – But Without Planning Medtechs Risk Missing The Boat

BY ASHLEY YEO

The leading medtechs are starting to develop models for providers that show how to implement successful digital strategies, a trend that is serving to put pressure on companies that are yet to make a commitment, says ZS Associates' Pete Masloski.

Navigating from concept through reimbursement and market acceptance can be a long haul for a traditional medical device company, so consider how much more complicated and potentially lengthy the process can be for digital and connected care products. And also consider the risks of being behind the curve, because some medtechs are already mapping out their digital futures, says Pete Masloski, a managing principal at ZS Associates.

Speaking to *In Vivo*, Masloski, who also leads ZS' global digital and connected health practice, put it flatly: manufacturers of devices that don't have an explicit plan to incorporate data collection, software or technology components into their development pipeline are missing an opportunity – and may even be missing the boat entirely.

Just as it is with that other medtech talking point du jour – value-based health care – successful manufacturers are seeking to enhance value to providers through digital solutions by adding functionality and integrating with providers' operations.

Forward-thinkers see new opportunities across the whole spectrum, including tapping into whole new businesses and markets that are centered

around digital technologies. Areas such as remote monitoring and clinical decision support are now emerging as significant drivers.

"It's also an opportunity to gain more insight and capture value from the data collected from these solutions," says Masloski, adding, "This is one of the biggest untapped opportunities out there, and even companies that are capturing the data aren't yet gaining enough insight from the data they are collecting; the promise is substantial."

Why is the insight eluding the manufacturers still? It's a field full of complexities, and interpreting the data requires a steep learning curve. Typically, understanding big data needs new sets of capabilities. Manufacturers need to know the right questions to ask. Equally, it's hard to fund a research effort based on a hypothesis that "something" will be found in the data, says Masloski. Add to this the fact that the quality of the data is evolving rapidly, and it also becomes something of a moving target.

On the other hand, innovators are rushing to fill the space with new technologies, and literally thousands of digital health care start-ups are racing toward their goals, with billions of dollars having already been spent on connected technology research. The larger companies have the advantage, as they have the ear of the clinician, and for them it's a great opportunity to get differential attention from providers. But from the provider's perspective, there is no way to keep a handle on it.

Device Manufacturers And Other Players To The Fore

But this whole area that is unfolding is not just about device manufacturers, Masloski stresses. Many large providers have their own digital or connected health groups, and are partnering with companies around population health management programs, or productivity and quality control initiatives, or have set up ways of devising care coordination programs or reducing readmissions. And pharma companies, pharmacies and payers are also developing digital strategies.

But the device industry is perceived as a leader in integrating digital technology. Medtronic PLC, for instance, was one of the first companies to capture data from a device and send it over the phone (via its *CareLink* platform). And the device industry pioneered the whole remote monitoring charge, but so much has happened so fast and, as mentioned, innovators are vying for the attention of providers who are now finding it hard to keep track of it all.

Where the smaller companies come into their own is in the ability to move quickly, and be nimble in their digital development projects. They can do product iteration and evolution at low cost and be very focused on single tasks. Larger companies often struggle with this in the fleet-footed digital technology world, necessarily moving at the slower speed of a large enterprise that has complex infrastructures.

Much as they might wish, many larger medtechs cannot easily be that organization that puts two dedicated technologists on a project to create, say, an app, very quickly and at very low cost. They must weigh what to do internally, what to outsource, and who to partner with and on what. And crucially, they must build an operating model that lets the company move at the speed of digital that also recognizes the need to live within the boundaries of compliance.

It can be a challenge, says Masloski, but many organizations are up meeting it head on. Device manufacturers in the cardiovascular industry have perhaps made the biggest and deepest inroads, with Medtronic being an obvious example; whereas diagnostics and monitoring companies like Philips Healthcare are investing heavily in their segments; and diabetes device companies have been both very opportunity- and patient-focused in their approach to digital applications, such as

Dexcom Inc., with its real-time continuous glucose monitoring system *Dexcom G5Mobile*. There are many other examples.

Payment Models – The Barrier Still

Payment models remain the key barrier to the growth of these solutions. Many of the digitally enabled solutions and connected devices are focused on population health management or chronic disease management, where the payment structures, in the US say, are not aligned to support investments in these areas in a significant way.

"Reimbursement for these solutions is really lagging the innovation," Masloski observes. The longer-range payoffs mean than not many systems are aligned. Integrated payer providers, the Veteran's Association and Accountable Care Organizations (ACOs) are closest to developing the required integrated structure, but it's a work in progress and for now the US, in particular, is still mostly on a fee-for-service (FFS) payer basis. For these reasons, payers in the US are questioning the value of these solutions and want the evidence to prove value, but that data will take a while to collect.

Winners Emerging Now

In spite of the perceived hurdles, the market has now evolved to the point where winners within the digital and connected health landscape are starting to emerge, says the ZS principal. These are companies that are showing significant health outcomes and are able to garner the attention of the payer and provider communities. For them, experience has been building, momentum is gathering and the data have started to come back. Reimbursement is also in prospect, as payments will follow the data and the evidence that comes with it.

"We'll see a lot more growth of the leading solutions in this space in the next three to five years," Masloski predicts. While solutions are available now, this will likely be the time frame for major uptake of these new technologies, in particular those focused on population health or care coordination. But the implications for the device industry are getting more serious: players don't want to be left out in the cold – but that will likely happen if solutions are being developed that can disintermediate the products of rivals that are not playing in this space.

The three- to five-year time frame is needed, he insists, as there are so many moving parts in the digital segment: patient behavior, the evolving technology, provider acceptance, and more. For these patient-centric solutions and chronic disease management tools to really get traction, a physician needs to be "on board" and the solutions must suit providers' workflows, connecting with EMRs. They also must be supported by payers, and be aligned long enough to develop the evidence to convince the broader market that adoption at scale is simply worth it. "These are some of the reasons it's taken us so long to get to where we are, and an illustration of why it's so hard to change health care," explains Masloski.

> **Crucially, companies must build an operating model that lets them move at the speed of digital while also recognizing the need to live within the boundaries of compliance.**

Furthermore, the data are only as good as the design of the study from where they were collected, and many providers might agree that the data are interesting, but then push back and ask for more evidence of how the results would be applied in their own organizations. But payers are now looking to conduct trials or longer pilots to demonstrate solutions that have data collected elsewhere. There are a lot of trials and experimentation going on in this space right now,

and that can make it hard for the innovators in the trials, especially the start-ups with an eye on their burn rate, and fears over funding drying up as investors become impatient.

More Support Coming From Government

In the US, there has been growing recognition that further adoption of these tools really can affect cost and outcomes. The new US administration has shown interest in working with industry, and the forward-thinking FDA, for its part, has a team focused on digital health. The agency has established the Pre-Cert program for digital innovators as a means of speeding new processes and iterations to market. It is seeking to establish guidelines for software as a medical device, and aims to avoid the need for companies to have every iteration of their software approved. *(Also see "Coming Together On Pre-Cert: Digital Health World Engages With FDA To Hash Out Regulatory Future" - Medtech Insight, Feb 6, 2018.)*

As part of the generalized move into the digital age, AI solutions will start to appear with more regularity in areas like diagnostic imaging. Home assistant technologies (such as Amazon's Alexa) are getting traction and to a certain extent are helping to demystify the space for the public. In health care, there is still a lot of room for innovation, and given the time it takes to prove a technology and bring it to market, most of the impact from digital and connected care is still some way off.

But the momentum is unstoppable, and new FDA guidance on Clinical and Patient Decision Support Software is part of the agency's evolution of its policies to enable advancement of beneficial innovations and greater consumer access to technologies.

And as more data and evidence become available, the advantages of providing physicians with meaningful assistance – not to replace but to augment their skills – will be all the more evident and compelling. There will always be the skeptical physicians, and there will surely be some bumps along the road to digital and AI acceptance, perhaps in areas such as ensuring security and quality of data input, Masloski suggests. But that is to be expected.

Where Should Industry Focus?

Patient-centric solutions that involve some type of wearable device or sensing device that collects data is a big focus of the industry right now. The leading companies are starting to develop models that show how to make these successful – such as using medical-grade sensors that are very non-intrusive to the patient. In addition, the data must come back to the physicians in a way that fits into their workflows. Industry players need to work toward that space. "If you're in the device space and you're not part of developing that solution, you risk being left out in the cold," Masloski warns.

In addition, there is much focus on patient behavior change. A lot of device industry revenues come from treating conditions in patients whose medical therapy has failed – in part because their own behavior hasn't changed. But as the device industry becomes a more effective player in prevention and digitally assisted behavioral change among patients – or prospective patients – the "pipeline" of potential patients will change and the industry could start to see a slowdown in the progression of disease that needs surgical intervention.

That makes it all the more necessary for the device industry to be part of the solution in the evolving health care industry. It can champion change by leading the charge, leveraging its resources and expertise in getting the clinical community to adopt digital technologies. It must not simply wait for patient flows to dry up based on improved patient behaviors, says Masloski. He adds a warning for the device industry: "If you're not playing at the top of the funnel you risk being disintermediated."

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Digital's Big Moment Has Arrived Say CEOs At Medtech Europe Panel

BY ASHLEY YEO

CEOs' panel at MTF 2018: Jean-Luc Bélingard speaking, with AdvaMed's Nadim Yared and Siemens Healthineers' CEO Bernd Montag to his left

Photo credit: MedTech Europe Forum 2018

The waiting is over and digital technologies are being adopted at pace, according to a CEOs Unfiltered panel at MedTech Europe's 2018 Forum. Connected care is at the top of the priority list, say Siemens Healthineers' Bernd Montag, AdvaMed Chairman (2017–2019)/CVRx President and CEO Nadim Yared and former bioMerieux President and CEO Jean-Luc Bélingard, although it's not the only pressing issue on the bill.

Digital technologies, artificial intelligence and value-based health care create opportunities to improve health care delivery and affordability, and also provide the tools to make those positive changes happen. These were absorbing themes for the record number of medtech industry attendees at the Medtech Europe Forum 2018, convened January 23–25 in Brussels, Belgium.

Connected care is no longer the future, according to a panel of CEOs comprising Siemens Healthineers' Bernd Montag, AdvaMed Chairman (period 2017–2019) and CVRx Inc. President and CEO Nadim Yared and former bioMerieux SA President and CEO Jean-Luc Bélingard: it is the present. Fast- and future-thinking players are already factoring this long-awaited efficiency tool into their business strategies.

For "digital" is a method, a means to an end – the facilitator of cheaper, faster, more reliable health care. That was the essence of Bernd Montag's comments to the Medtech Forum. The event convened this year in Brussels once more, but next year moves to Paris to entice more input from the vibrant local medtech community and thereafter to Germany.

Montag of course has much on his mind besides

digital strategies and macro industry trends: Siemens Healthineers AG announced its keenly anticipated IPO in mid-February, which the CEO described as an opportunity to create a dedicated pure play in medical imaging and diagnostics. (The shares were listed in Frankfurt on March 16 at an initial price of €28 per share – valuing its equity at €28 billion and yielding gross proceeds of €4.2 billion – to $5.2 billion). *(Also see "Siemens Healthineers Floats On Frankfurt Stock Exchange" - Medtech Insight, Mar 15, 2018.)* But globally, he identifies three overriding medtech trends.

One is the rise of personalized medicine, where there has been a switch from talking and concepts to reality. Another is consolidation among providers, as the logic of health care delivery changes. "We are looking now at the overall picture as we move from fee-for-service to value-based health care," Montag told the MTF audience. This has everything to do with the rising power and influence of the patient as a consumer of health care – providers have reacted and "are really putting this on their agenda now."

And underlying it all is digital and AI, and the past year was *the* "big moment" when these tools became the main event, says Montag. CVRx's Nadim Yared agrees, believing that "we are only just scratching the surface" of the potential of the Internet of Things. Devices in the future will all have some form of connectedness, says Yared, who is mid-way through a two-year term as AdvaMed chairman. Today connected health care technologies are outside the body, but eventually they will also move inside the body, he believes.

One key advantage that digital will bring to researchers and clinicians is the ability to "make sense out of biological complexity with data analytics." So says Jean-Luc Bélingard, who believes that the sector is undergoing change that goes beyond merely the impact of digital. He says the future of health care will be "transversal," where medtech will be combined with other elements of health care in the drive toward patient centricity. Bélingard stepped down from BioMerieux in December 2017.

"Planning for the future is probably the most difficult job right now," he says, an assertion that will do little to comfort those traditional medtechs yet to devise a digital strategy. These are precisely the organizations that risk missing the boat.

> **"Planning for the future is probably the most difficult job right now."**
>
> **– Jean-Luc Bélingard, industry expert and former bioMerieux President and CEO**

One of our duties is to make sense out of the data, says Bélingard. It needs to be brought together, and the industry has initiatives to do just that, but this is a delicate issue, because once companies start talking to patients on data harvesting, this can prompt the regulators to start stepping in. Montag agrees. Healthineers is striving to be "more relevant" when it comes to clinical decision-making. Some 240,000 patients every hour come into contact with Siemens systems, he says, and in the past, there had been "no learning" from these interactions and decisions. While that's probably overstating it a little, the difference now is that the data can be turned into knowledge, which is the core of what Montag says Siemens is aiming for.

But this is not a revolution that can be carried by industry alone. Other stakeholders need to be brought along too. "Are we prepared?" asks Yared, answering his own question in the negative, but adding quickly that the sector is making steps in the right direction. New players like Google and IBM Watson are also showing the value of data generated by biomedical devices, but there is an education piece to maintain, especially regarding politicians in the US and elsewhere.

The Education Piece – Vital For Digital And Medtech Themes Across The Board

Which is not to say that it's a thankless or fruitless task. Far from it. Yared recalls for the MTF audience the original meeting some four and a half years ago between AdvaMed and US members of Congress that in April 2014 led then-House Energy and Commerce Committee chairman Fred Upton (R-MI) to announce the launch of the 21st Century Cures Act. This is proof, were it needed, of the value of lobbying, education, and medical breakthroughs; and meetings like MTF and AdvaMed are useful in getting policymakers on board.

Industry fears competition still, and naturally so, but there is a greater need for collaborations and partnerships, says Yared. And this is happening at the highest level. The FDA is becoming more collaborative with companies, simplifying processes and reducing the timelines. Bélingard agrees, adding, "The FDA comes to us to ask us about data analytics." Europe, sadly, appears to be going in the opposite direction and adding layers of complexity. Where can that lead? Yared notes that the FDA is now aiming for first-in-man studies to be done in the US, which used to be the province of Europe. Where the US gets pressure from industry groups, the EU gets pressure from politicians, Yared suggests. "I'm very worried about what is going on in Europe," he confided to the Brussels audience.

Pricing, Getting Paid And Investment

The pressure in fact comes from all sides. While the public debate on health care cost often defaults to pharma pricing, it has not gone unnoticed that medtech prices have been rising below inflation in recent years. Thus, the industry is losing ground, even though it re-invents products, incrementally, at least, every 2.5 years on average. "Prices are going down but we get the same amount of pressure from the public as does pharma, where prices are rising 9% year-on-year," claims the AdvaMed chairman.

More strategically, the medtech industry sees the need ultimately for a change in the way technologies are paid for in the future. Pricing depends to a large extent on the prevailing health care structures, but who pays over the longer term? "We need to think differently – the winners will be those who can adapt; the losers will be those clinging to old models," says Yared.

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>
> **– CVRx President and CEO Nadim Yared**

But it's not quite happening yet, not in the US at least. Montag notes that there has *not yet* been a fundamental shift in US decision-making. But Siemens Healthineers, a company where 55% of the revenues come through services and reagent sales, has an insurance against the vagaries of pricing and the investment climate. "There is procedure growth and typically, we are not in a pricing discussion," he asserts, even if SMEs and small companies would disagree.

In the discussion on the affordability of value-based health care were IVD tools, which optimize the notion of cost-effective care, says Bélingard. "It is very important that we position our industry as one that is affordable, and we need to think of both value and cost." Pricing is structural, and pricing will go down further in medtech, he forecasts. Industry should be ready for pressure on pricing in the US as well, he warns. A new approach is needed. The perception is that the industry typically sets a price and adds to the cost of the health care system. Instead, it should get ahead of the game, talk to the authorities about pipeline needs and address the demand side in ways that have never been done before. "It needs to be tested at least."

"We are still not forward-looking enough, and there should be more spent on prevention." – Siemens Healthineers CEO Bernd Montag

Montag echoes the sentiment. "We do need to look at how money is spent in health care. We are still not forward-looking enough, and there should be more spent on prevention. More pathology tests will lead to more imaging and the ability to get the right diagnosis, at the right time, at the right place."

Health Care Needs More Medtech, Not Less

Technology is increasingly sophisticated, and medtech research is aimed at the continual improvement of treatment, but the fact is that health care needs more medtech, not less, says Montag. It has so many fundamentals – emerging economies' demand, demographic change, growing knowledge and power of the customer base – that make for an attractive industry and an investment opportunity. But views on investment trends differ, depending on where a company sits in the wider industry.

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Siemens Healthineers' CEO does not think that medtech is being left behind in investment trend comparisons with other industries. But the CVRx boss has a different take. Yared's company is still in the start-up and investment phase. CVRx manufactures implantables to treat high blood pressure and heart failure and is said to be a top-five medtech company in terms of VC raised. But funding for the wider medtech start-up ecosystem, as different from large cap investment, has not been very good for several years.

Cost From Inception To Exit

The rise in costs to fund a medtech company's life cycle from inception to IPO or exit over the past 10 to 15 years has been driven by:

- demand for larger clinical trials,
- lengthier duration of regulatory and reimbursement pathways,
- "frothiness" of consolidators to acquire businesses earlier (many acquirers are requiring small companies to prove the adoption of a novel technology, which entails the small firm investing in distribution channels and manufacturing before being acquired), and
- the slow to non-existent IPO market for pre-revenue companies.

Source: CVRx President and CEO Nadim Yared

Smaller entities often need 12 years before reaching liquidity, hence a VC investment for any shorter period "does not add up." The cost of creating a start-up, from inception to IPO or to exit, as measured by the venture investment that needs to be made in these companies, has risen from $32 million in 2004 to $74 million in 2014 (*see box*). Compared with 10 years ago, there are a quarter of the number of medtech companies being set up today.

But this should be seen as an opportunity, for now is a good time to come into medtech, says Yared. "We as an industry are still undervalued and we are living in exciting days." And in the transition to digital, the industry is barely scratching the surface. There is all to play for as the medtech industry continues to evolve.

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Medtech's AI Pioneers – Where Are We Headed?

BY CATHERINE LONGWORTH

Artificial intelligence (AI) is quickly becoming part of our day-to-day routines, and health care is one area in which AI stands to make the biggest impact. But where is the technology headed? Leading figures from the medtech industry gathered at the Medical Design & Manufacturing (MD&M) East meeting held in New York City to discuss.

The medtech world is experiencing an explosion of devices incorporating artificial intelligence (AI). Panelists convened at the annual Medical Design & Manufacturing (MD&M) East meeting held in New York City to discuss some of the challenges and opportunities presented by AI.

With AI already used in diagnostics, imaging and pathology, the panel discussed where the technology could have the greatest impact in the next five years. Jeff Headd, principal data scientist at Johnson & Johnson said, sensors and wearables are a huge opportunity for the medical device industry. "When you think of things from a patient perspective, patients aren't that interested in yet another device that is going to be a hassle for them. But just about everybody carries a phone and lots of people wear a connected device like a Fitbit or Apple Watch," said Headd.

"The question is how we can develop technologies that piggyback on or take advantage of the data those devices are already collecting and apply that to answer a medical question," he added. "Because then we're transforming from the model of a patient having surgery that uses some of our products and then gets reevaluated weeks later by their surgeon to a model where as soon as they leave the OR, we're collecting real-time data, and we can follow them on every step of their recovery. Then, if there is an issue, intervention can happen immediately, rather than waiting for that follow-up. So, there's a tremendous opportunity there."

Within companies, AI could help deal with consumer complaints from patients or physicians, Headd said.

"These complaints are often being listened to or read by teams that are evaluating data," he noted. "With AI, you can train models to classify these complaints automatically and identify whether it's a product quality complaint or some other category."

Clinical Impact

J&J is highlighting its collaboration with Apple to assess the impact of wearable technology on earlier detection of atrial fibrillation (AF).

"We are taking advantage of the fact that the latest Apple watch has ECG capabilities and can tell you a lot about your heart, then combining that with our company's experience and knowledge in atrial fibrillation, which is a very widespread condition. But often you don't know that you have it unless you're diagnosed by a cardiologist," said Headd. *(Also see "FDA: Apple De Novo Approvals Signal Innovation To Digital Health Firms" - Medtech Insight, Sep 12, 2018.)* "It's a fantastic trial where we will be able to see [if we] can identify patients who need early intervention for AF before they experience a serious impact like a stroke or some other major medical event. So, I think that's a tremendous opportunity where [with] very little intervention, we can conduct a clinical trial, leveraging algorithmic methods to potentially identify those patients more quickly."

Bob Bouthillier, global director of embedded development at Radius Innovation, said the company designed an AI application to work with hand sanitizers in hospital rooms, which had proved to be a success.

"It's a human challenge trying to get the health care workers to clean their hands before and after touching patients," Bouthillier said. "We put a counter on the dispensing device in the room, and that counter was synchronized with all the other counters in other wards of the hospital. [We] found that it promoted use of the hand sanitizer. The result boiled down to showing everyone, 'This is how many people in the hospital in your profession and in your ward have washed their hands today.' And that got everyone wanting to wash their hands, as they wanted to be part of the group doing the right thing."

According to Jeet Raut, co-founder of Behold.ai, a Madison, WI-based radiology start-up developing diagnostic software that flags abnormalities in medical images, educating clinicians on technology is imperative. "Radiology is one of the specialties in medicine where they really rely on technology," said Raut. "We are making a lot of effort to explain to radiologists [that] we are not trying to replace them or automate what they do. We try to demonstrate there's a lot of benefit of AI plus humans and that's really to drive down the error rate."

He added that AI technology was set to cause a radical shift in health care, but mentalities needed to change.

"I think clinically it's a paradigm shift and after a few years people will be more comfortable and AI will become like other technologies that have now been rapidly adopted in hospitals like cloud-based applications," he said.

Regulation And Reimbursement

In terms of regulation, the medtech world continues to face uncertainty, according to the panel.

"The big challenge is the question: 'Is it a software or medical device?'" said Headd. "I think the FDA is not clear on where that line should be drawn, and certainly, on a case-by-case basis, you must evaluate whether you're going in that direction or not. In any type of product we try to bring to market in the near term, it's all about the bilateral conversation with the FDA or whoever the global regulator is on what is an appropriate path of regulation for the AI component of the device."

> **"We are in uncharted waters with devices that can change their behavior based on learning."**
>
> **– Jeff Headd, Principal Data Scientist, Johnson & Johnson**

He added that, with artificial intelligence capabilities and algorithms that can continue to learn, the question of how the technology is tested or validated becomes tricky. "Just recently, FDA had an open call to industry about what's the appropriate way to regulate such a device. Leaders in the industry have sent comments back and it's a continuing and evolving dialogue as technology advances," Headd said. "We will see what happens, but I think it will be something certainly to follow.

"We are in uncharted waters with devices that can change their behavior based on learning," he said. "The worry with the FDA now, and frankly for all of us, is that we would like to have things just behave in a known fashion, so we're not surprised either, any more than the patient."

Regardless of the technology, the "blueprint" for reimbursement remains the same, he said. "The equation for reimbursement doesn't really change. You're always looking to generate value and reduce overall health burden in the system," commented Headd. "If you drive toward better outcomes, earlier intervention [and] reduce cost of long-term care, then there's always going to be a value proposition."

However, according to the panel, the real challenge with the US health care system is in obtaining CPT codes that reimburse technologies. Raut said, "No one wants to reimburse anything unless they know it is absolutely advantageous and benefits patients. So, companies must consider this first."

Bouthillier added that with new CPT codes for home-health monitoring recently approved, the floodgates for this technology have opened. "The guidance hasn't come out yet about what technologies these reimbursement codes apply to, but it could be everything or almost nothing," he said. "All the companies that have any kind of monitoring or sensing device are lining up to push them as a medical device. We need to watch for the guidance about what will be included, but what's interesting is this is promoting the home monitoring market. There could be a little storm coming in this marketplace but, essentially, they've attempted to break down all the barriers so all these types of devices that can connect – which include AI and machine learning technology – will be covered. So hold onto your hats, and let's watch and see what happens. But I think it's going to be an exciting ride."

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