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MAIN CONCLUSIONS

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POST-EVENT **REPORT**

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>
> *Michelle Brennan, Chair, MedTech Europe*

NEW ERA, *NEW MEDTECH FORUM*

Europe's premier medtech event has been reimagined – and is set to grow

A 35% increase in participants at the 2018 European MedTech Forum reflects the expanded scope and scale of the essential medical technology gathering in Europe. Over the next five years, with the event moving around European capitals, further growth is expected.

In her welcome message, **Michelle Brennan,** Chair of **MedTech Europe,** said the new concept for the Forum would deliver a wider variety of talks as well as more time for networking and collaboration. 'The MedTech Forum is the perfect place to come together to learn and grow so that we can seize the opportunities that await us,' she said.

The opening session promised that the Forum would cover everything from Trump and Brexit to new regulations and artificial intelligence. In keeping with its cutting-edge content, the Forum launched a new event app packed with new features that promote networking and facilitate interactions with speakers. The days of the paper programme are over.

Serge Bernasconi, CEO **MedTech Europe**, set out his key priorities for the coming year, including value-based healthcare, new EU in vitro diagnostic (IVD) and medical device (MD) regulations and a new Code of Business Ethics, along with projects on market access and international development.

The breadth of topics is reflected in the MedTech Forum programme, helping to broaden the event's appeal. 'In the next five years we hope to reach 2,500 participants,' Mr Bernasconi said. 'To do this, we will work with national associations and offer more tracks to attract people with different profiles.'

The 2018 MedTech Forum was the beginning of a new era for a rapidly changing industry.

CEO #NOFILTER

View from the top: CEOs share their insights on the hottest medtech trends

Medtech leaders need to stay on top of developments in technology, healthcare and wider society. With technological progress moving fast, as well as changes in how care is funded and delivered, life in the C-suite can be complex. The MedTech Forum invited senior industry figures to share their views – and answer questions from the audience.

What's driving the future of medtech?

Bernd Montag, CEO of **Siemens Healthineers**, sees three key trends shaping the future of healthcare delivery:

- precision medicine
- the rise of patients as consumers
- changes in how healthcare is delivered.

'Precision medicine has switched from concept to reality,' he said. 'At the same time the influence of patients is growing and providers are hiring Chief Experience Officers.' Digitisation and AI are the driving forces behind many of these changes. For Montag, companies that can turn data in knowledge the drives informed healthcare decision-making are most likely to prosper.

What's the next big healthcare disruption?

'Digitisation. We're already in it but it will take time and investment before we see huge benefits.'
Herman Verrelst, CEO Biocartis

'The next disruption will not be technological but organisational. We need to turn technology into real-life applications that benefit patients'
Cecile Real CEO of Endodiag

'AI will be a big game-changer and we are only at the very beginning'
Elie Lobel, CEO Orange Healthcare

Patients :: data :: security

Jean-Luc Belingard, Chairman of Fédération Française des Industries de Santé (**FEFIS**) and Vice President International Relations, **Institut Merieux,** said patient centricity will be at the heart of modern health systems and that health intelligence will itself become a valued product. 'Data analytics is going to be a product that we will provide to healthcare professionals,' he said.

The role of biomarkers in diagnostics will become increasingly important, according to **Herman Verrelst**, CEO of **Biocartis**. He expects biomarker testing to become faster and increasingly 'near patient'. 'There are growing numbers of biomarkers and targeted therapies but, from a patient perspective there is still a huge need,' said Verrelst.

'About one quarter of patients are put on a therapy without their doctor knowing the relevant biomarker information.'

The tension between the abundance of data and the need for privacy was also a recurring theme in the Q&A sessions with CEOs. **Elie Lobel,** CEO **Orange Healthcare,** said cybersecurity is a serious threat to devices that rely on information technology. 'Devices must be more connected but also safe,' he said. 'The new EU General Data Protection Regulation will help to ensure a homogenous approach at EU level. We should also get ready for more stringent rules on healthcare data in particular.'

What keeps medtech CEOs awake at night?

'The time-to-market takes longer and longer due to the growing regulatory burden'
Cecile Real CEO of Endodiag

'Cybersecurity is the biggest challenge'
Elie Lobel, CEO Orange Healthcare

'The way governments view our business – they must become more forward looking'
Herman Verrelst, CEO Biocartis

'Our politicians have no clue what we're talking about. A lot of education is required.'
Nadim Yared, CEO & President, CVRx

Read Nadim Yared's blog on

MedTech Views

PATIENTS & PRICING

The voices of patients are stronger than ever – do they have a role in determining value?

Patients are increasingly moving centre stage in product development, as well as policy debates on access to care and pricing. However, as patient groups take their seat at the top table, they will need professionals to engage on complex tops. Transparency on industry support for patient advocates is also essential to credibility on both sides.

Marc Boutin, CEO of the **National Health Council** – an umbrella organisation of patient advocacy groups – said patients want to support innovation that delivers meaningful improvements. However, the prices of medicines and some technologies have soared in the US.

Patients are stepping up their activity in the debate on market access. The learning curve is steep, given the complexity of containing costs without undermining innovation. 'Patient groups are playing catch-up,' he said. 'We are not used to playing at this level.'

The role of industry support has come into sharp focus as some have been slow to speak out against rising prices. 'Some organisations have been caught flatfooted,' Boutin said, adding that patient groups have been quickly developing their public affairs and communications skills.

Rick Claypool, Research Director at **Public Citizen** – an organisation focused on corporate accountability – highlighted the risk of conflicts of interests when companies support patient groups.

'Patient groups do tremendous work but the cost of treatment is a huge issue,' he said. 'Think about the 45 million Americans who don't get prescriptions filled every year because of price.'

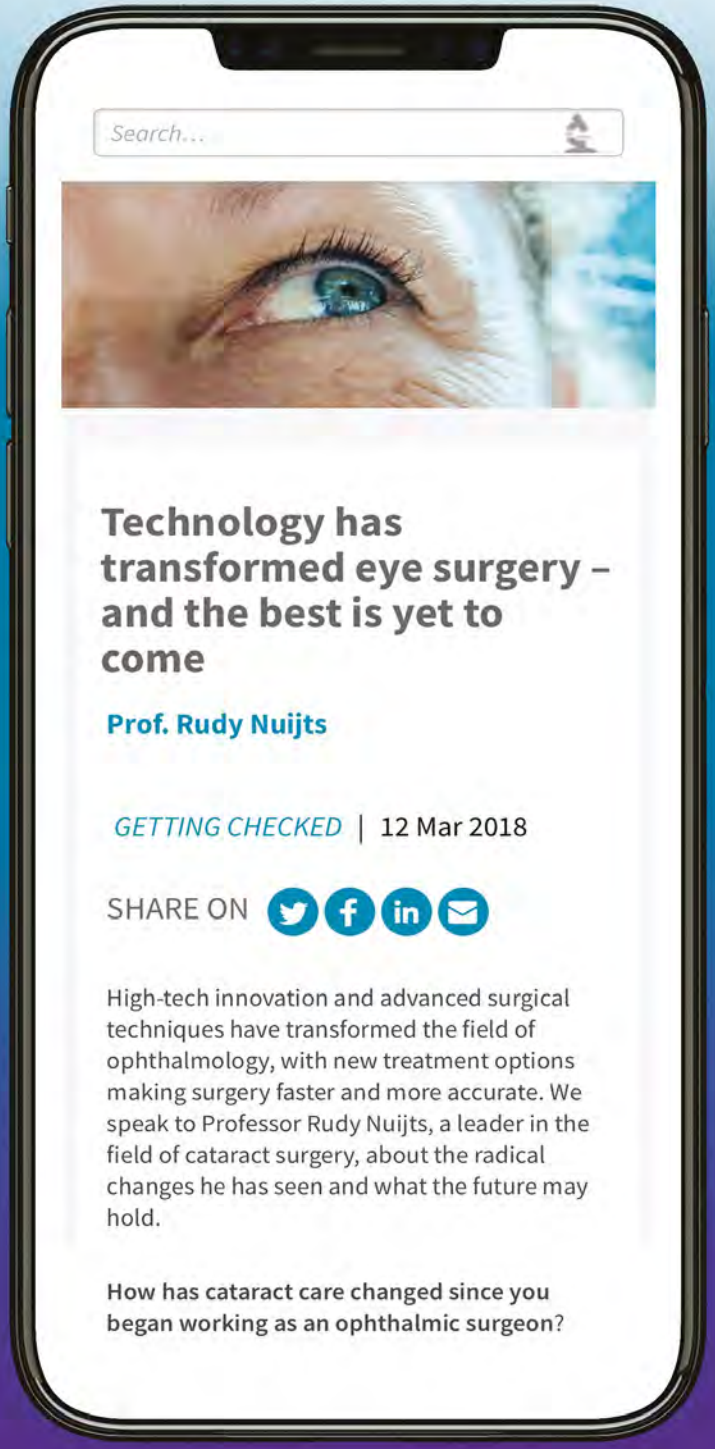
Claypool said his own mother has a rare form of cancer for which treatment costs $140,000 per year. For some high-priced medicines, patient advocates have pushed for access without putting pressure on companies to lower prices. 'It can get complex when patient groups weigh in on policy debates,' he added. 'Transparency about where their funding comes from is key.'

> **Patients want innovation – we are with you on that – but it has to be reasonably priced**
>
> *Marc Boutin, CEO, National Health Council*

Yannis Natsis, European Public Health Alliance said 'transparency is not independence' and urged all stakeholders to face the reality that governments cannot afford to pay for expensive products. 'Europe and the medtech sector can learn a lot from the US and the mistakes of the pharmaceutical sector,' he said. 'If prices go up, somebody loses. The pie is not getting any bigger.'

Francesco Florindi of **BBMRI-ERIC**, a biorepository that connects biobanks, said patient organisations need to professionalise or receive expert help if they are to sit at the top table. Small organisations with no full-time staff find it challenging to join workshops and attend meetings on complex pricing issues. 'Not every patient group has the luxury of hiring a professional with knowledge required to engage with policymakers and industry,' he said. 'I would argue that there is a role for the EU and governments to enable patient organisations to have a more independent, healthier relationship with industry. That's what governments, industry and patients need.'

MedTech Views



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MedTech Europe
from diagnosis to cure

ARTIFICIAL INTELLIGENCE GETS REAL

A ground-breaking app uses AI to diagnose disease, predict outcomes and cut costs

Imagine you feel tired and weak, you have a headache and have lost your appetite. Do you try to make a GP appointment, rush to the emergency room or stay home and drink plenty of fluids?

A new breed of 'digital doctors' can help answer these questions with increasing speed and accuracy. Instead of visiting a clinic, smartphone apps are offering an instantly-accessible alternative.

The NHS in the UK is rolling out an advanced artificial intelligence (AI) platform which diagnoses patients' illness and advises on what action to take. By walking patients through a step-by-step interactive questionnaire on their smartphone, the system determines whether they have a cold, the flu or a chronic condition.

The NHS has already made the app, developed by Babylon Health, available to over one million Londoners – the largest deployment of AI in healthcare. Up to 1,000 people are signing up to the system every day, with the app proving especially popular among younger people.

But AI is not limited to millennial Londoners – The Bill & Melinda Gates Foundation are supporting the rollout of the system in Rwanda, dramatically improving health services for citizens with mobile phones.

The NHS app also allows patients to connect to a doctor by video for further assessment and peace of mind. Should a prescription be required, the doctor issues it electronically and the app helps the patient find a nearby pharmacy.

The system is at the cutting-edge of a wave of AI technologies promising to transform healthcare by improving access to services while avoiding unnecessary clinic visits.

'The rules of the world are changing,' says **Ali Parsa**, Founder & CEO, **Babylon Healthcare**. 'In many areas, AI will replace humans but it will also allow doctors to play to their strengths. We will make our doctors more human, and let computers do the computing.'

> **It will soon be seen as ignorant, negligent, maybe even criminal to diagnose disease without AI**
>
> *Ali Parsa, CEO, Babylon Health*

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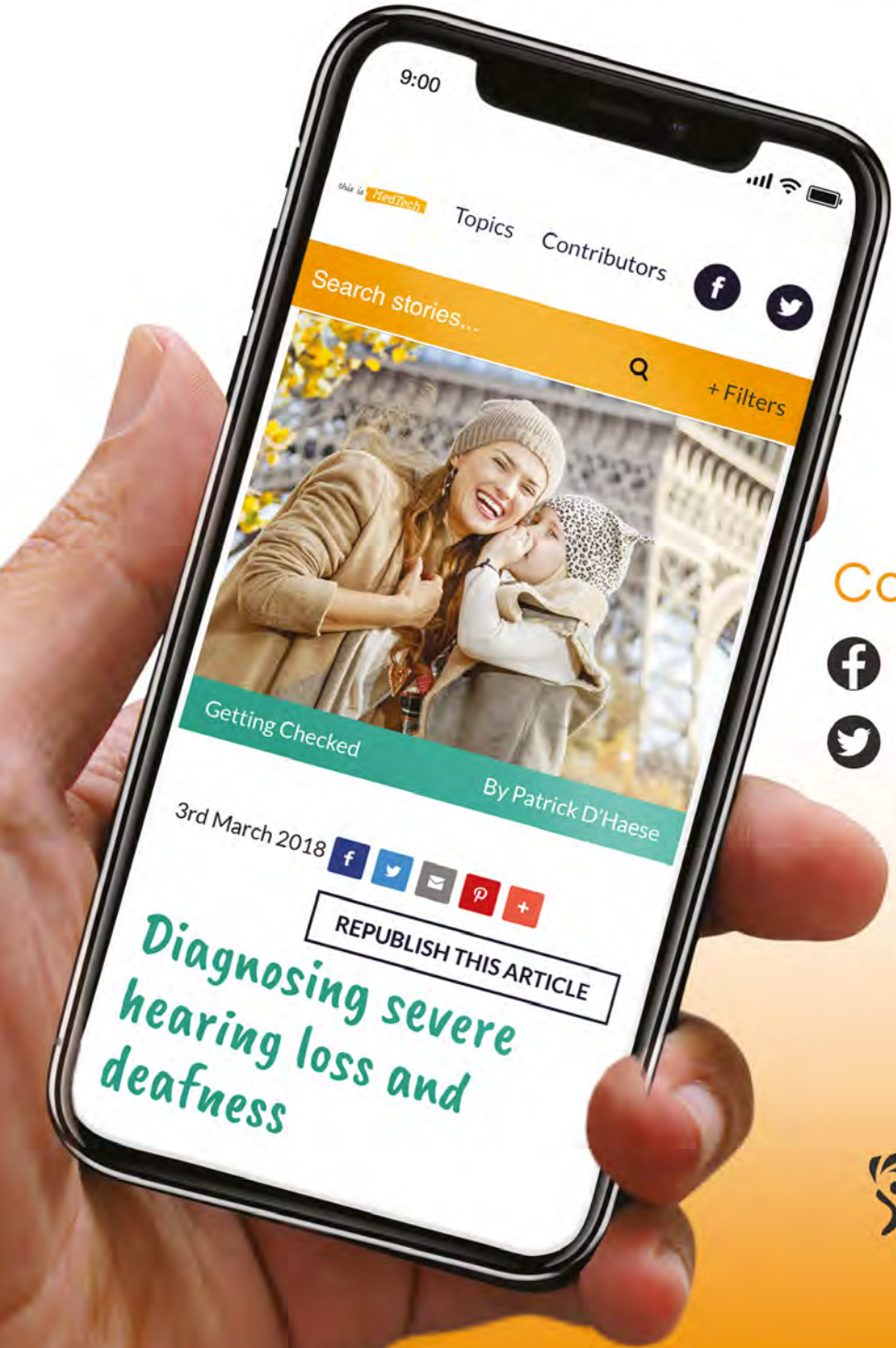

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from diagnosis to cure

DATA RULES, OK?

New EU regulation is a game-changer for data protection

> **Data protection and privacy become a hotter issue every year. From May, it will be even bigger**
>
> *Geff Brown, Microsoft*

Europe's General Data Protection Regulation (GDPR), in force from May 2018, changes how all personal data is handled. As well as clarifying responsibilities and emphasising privacy, the Regulation allows for heavy fines of up to €20 million or 4% of a company's turnover. This has focused minds at top companies.

'The impact of changes to European data protection law is driving a lot of board level discussion at Microsoft and at our partners,' says **Geff Brown**, Association General Counsel at **Microsoft**. 'It will require more documentation and more thought about how we handle data.'

The new rules have clear implications for medtech companies using connected devices, artificial intelligence and big data, but even companies with minimal direct patient contact should study the GDPR carefully.

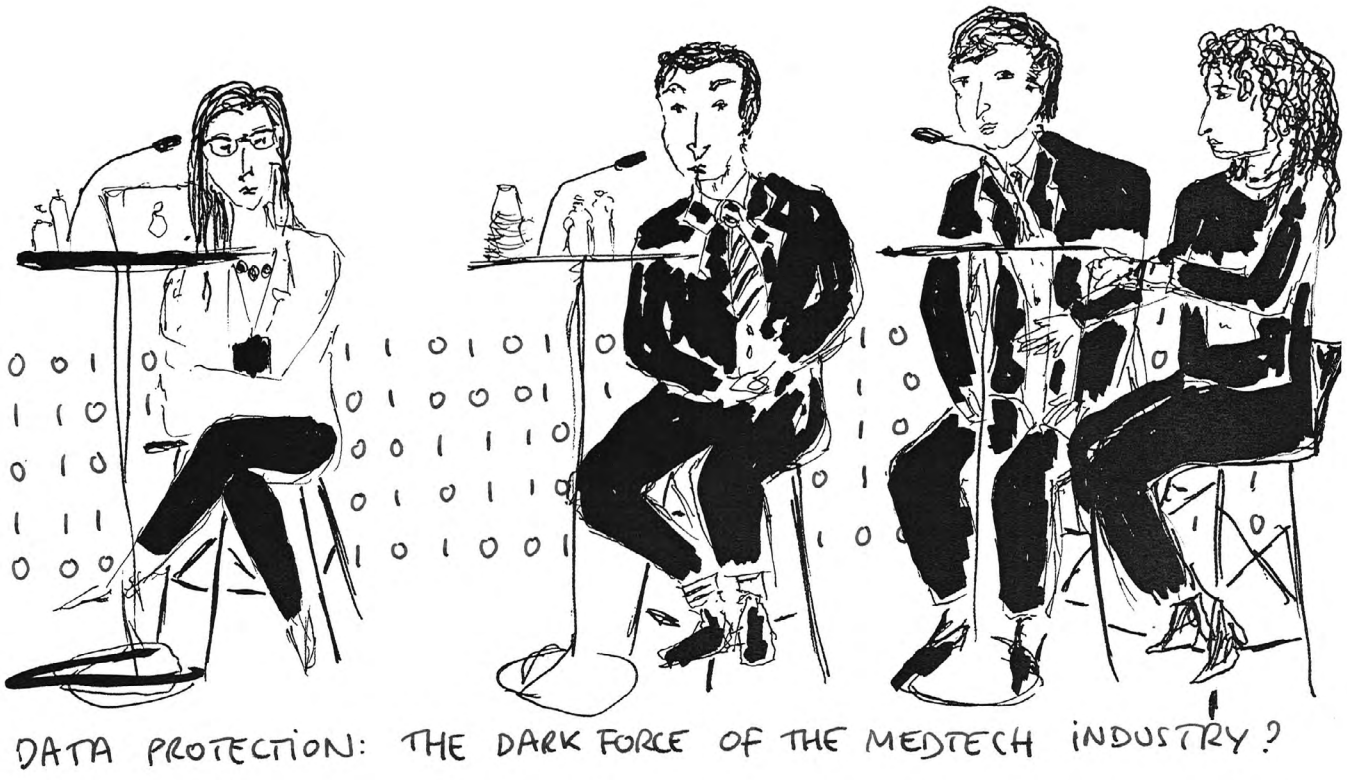
Surgical reports, x-rays and clinical data may contain personal patient information, requiring carefully handling. Employee data is also covered, meaning the rules are for everyone.

Bill Doherty, Managing Director of **Cook Medical's** Irish operations & Executive Vice President EMEA, said the company is reviewing all its documentation 'through the lens of GDPR'. They have worked with a consultant, appointed data coordinators in each of their corporate functions, and hired a European data protection officer. 'We've done a lot already but there is still more to do in terms of our contracts with third parties,' he explained.

Rachel O'Connell, Co-founder of **The Trust Bridge** and CEO of **Trust Elevate**, says the GDPR promotes transparency and accountability, requiring companies to know where their data is and how it is used.

She advocates being up front with patients about how data is used. 'Psychological research shows that people are more willing to share personal information when they are clear about the purpose of data collection,' says O'Connell.

The 2019 MedTech Forum will look at how companies are coping with the new data protection regulation.



Read Roman Lysecky's blog on MedTech Views

WAR ON HACKERS

Cyberware is here to stay. Are you ready?

If you ask **Bill Hagestad** to consider the 'worst-case scenario' for hacking in medtech, be prepared for a terrifying answer: 'Imagine someone hacks an implantable device in a patient on an airplane,' he suggests. 'Then think what would happen if the hacker could access the airplane's control system!'

This may seem a little far-fetched but Hagestad – an ex-Marine and seasoned hacker now working in medical device security – says most people dramatically underestimate the threat of cyberwarfare.

Security should be a fundamental feature of medical devices – not an afterthought

Roman Lysecky, University of Arizona

However, he says companies are beginning to sit up and take notice. In the past 12 months, a growing number of devices have been compromised and the WannaCry attack on NHS hospital operating systems led to the cancellation of patient operations.

Companies, regulators and policymakers will need to significantly expand their expertise and collaborate to detect and deter cyberattacks. Product designers must factor in security from the outset, according to **Roman Lysecky**, Associate Professor of Electrical and Computer Engineering at the **University of Arizona**.

Lysecky's team is developing systems for connected devices that would identify and disable malware. 'We believe security should be a fundamental part of the device itself, not an afterthought or a nice-to-have feature,' he says.

For now, there have been no cases of cyberattacks causing the death of patients with implantable connected devices. However, some say it's just a matter of time. 'Eventually there will be a patient death attributed to hacking – or the lack of an updated security patch,' Hagestad warns. 'That will change everything.'

DISRUPTING HEALTHCARE

Technologies are turning healthcare on its head – regulators, payers and companies must be ready

'Today, the world's biggest taxi company – Uber – owns no taxis. The biggest travel company – Air bnb – has no hotels. In future, the largest hospitals may have the fewest beds.'

Peter Fitzgerald, Professor of Medicine & Engineering and Director of the Center for Cardiovascular Innovation at **Stanford University Medical Center**, foresees radical changes in healthcare delivery thanks to a combination of disruptive technologies.

Advances in big data and AI are colliding with breakthroughs in gene editing tools and new organisation structures in ways that could reinvent healthcare delivery. This will make healthcare more personalised, preventative, predictive and participatory, says Fitzgerald. For patients, the biggest benefits will come from less invasive diagnostics and less variation in health outcomes.

Companies can find supply chain efficiencies by deploying algorithms that use diagnostic data to predict when a patient will need medical interventions.

Data from catheter labs, for example, will be used to create virtual treatment plans for patients. By planning the implantation of a stent – long before the patient reaches a crisis point – the system will become more efficient. The era of responding to emergencies will be replaced by nipping problems in the bud.

Regulators will struggle to keep up with exponential technological advances and new payment models will be needed, he adds, but overcoming threats to data security is among the biggest hurdles. If these problems can be solved, the future will be patient-centred – even if patients are long distances from their healthcare providers.

'Virtual hospitals will have nurses and doctors – but no patients. Driven by underlying AI algorithms, the team can do their rounds online, caring for patients who could be miles away.'

By triaging patients up front using predictive algorithms we can save millions – maybe billions

Peter J Fitzgerald, Stanford University Center

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> **European countries must remember that supply chains are heavily exposed to US**
>
> *Trevor Gunn, Medtronic*

SPOTLIGHT ON THE US: RHETORIC VS REALITY

Trump era has been less radical than expected – but fears of trade war remain

One year after the election of US President Donald Trump, the US economy is booming, corporate taxes have been cut and a tax on medical devices has been postponed. The President's campaign trail threats to repeal Obamacare, abandon free trade agreements and spark a trade war have yet to become reality.

Experienced Washington lobbyists say that while there is an air of uncertainty and unpredictability, surprisingly little has changed since President Trump took office.

Ralph Ives, Executive Vice President, **AdvaMed** who has served six US Presidents, said the fact that the US economy is growing is good news for the medtech sector. The US accounts for 40% of the global medtech market. 'The stock market is up, unemployment is down and inflation is very low,' he notes. 'Many economists say it has nothing to do with the President.'

Foreign policy and trade issues – including the United States' relationships with Russia, Iran and China – remain a concern, but the change of administration has not led to widespread disruption in its first year.

'It's remarkable how little has changed from a business perspective,' says **Trevor Gunn**, Chair of International Affairs Committee MedTech Europe & Vice-President International Relations, **Medtronic**. 'The accuracy of our forecasting has increased quite dramatically.'

Anne Oswalt Bruce, Director Federal Affairs, **Johnson & Johnson** worked on Capitol Hill for ten years. She highlighted the Trump administration's plan repeal and replace Obamacare as a source of uncertainty. 'Ultimately, the President could not get the votes but he may come back to it at a later date,' she said.

There was good news for medtech companies when the administration shelves an Obama-era plan for a 2.3% excise tax on medical device companies selling into the US. 'There has been a two-year delay, which is welcome, although we hope for a total repeal,' says Oswalt Bruce.

Meanwhile, despite severe understaffing in many government departments and the resignation of the Secretary for Health and Human Services, the industry was content with President Trump's choice for FDA Commissioner. Scott Gottlieb is seen as the most reasonable candidate from a colourful field and has plans to combine several FDA functions into a new 'super office'.

'From a compliance perspective, it makes sense to put all sides of the FDA in the same room,' says **Michael S Heyl**, Partner at **Hogan Lovells**. 'It will make the Administration more consistent.'

For now, cautious optimism prevails but so does a sense of foreboding. 'We're only two tweets away from a trade war!' joked one speaker.

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ARE YOU READY FOR THE NEW IVD REGULATION?

Survey: Just 7% of diagnostics companies say they are fully prepared

Diagnostics companies are worried as they prepare to comply with the new EU Regulation on in vitro diagnostics.

They are not alone. The European Commission is working to meet deadlines on developing the EUDAMED database while Notified Bodies will need to acquire expertise in diagnostic products.

A survey conducted by Deloitte for MedTech Europe found that 7% of respondents believe they are fully prepared for the new Regulation. Just 21% have a plan in place and have started to implement it.

Preliminary data from the survey found that 16% believe the new rules will have a positive impact on their business while one third of diagnostic firms say the rules will prompt them to engage with a Notified Body for the first time. **Michel De Ridder**, Partner, **Deloitte**, said companies are looking for more guidance on how to handle the IVDR.

The current Directive will be ¼ of a century old by the time the new Regulation is in place

Salvatore D'Acunto, European Commission

Salvatore D'Acunto, Head of Unit Health Technology and Cosmetics, **European Commission**, outlined how the Commission is preparing for the new Regulation which replaces a 20-year-old Directive. The Regulation will provide a more stable, uniform framework for diagnostics across Europe and make European industry more competitive internationally. 'The IVDR will be a global yardstick,' he said. 'Some third countries will base their regulations on our system, creating opportunities for European companies.'

Simon Richards, Vice-President, Regulatory Affairs EME and RCIS, **Abbott**, said most large medtech companies are quite well prepared but SMEs will struggle to adapt to a complex Regulation. 'There is a long road to travel for SMEs who drive innovation in our sector,' he said. 'MedTech Europe and national bodies have a lot of regulatory expertise and will provide vital support for smaller companies.'

For the UK, the added complexity of Brexit complicated the work of regulators as it is unclear whether the UK will adopt the EU Regulation or develop a new one. **John Wilkinson**, Director for Devices at the **MHRA**, said regulators across Europe are working closely together with the Commission to ensure national authorities are ready for this new era. 'With IVDs, the main worry is the expertise and capacity of Notified Bodies,' he said. 'If we cannot employ or train enough people with the right skills there will be quite a few bumps in the road.'

Johnson & Johnson MEDICAL DEVICES COMPANIES

Operation Smile

Imagine a world where no child suffers from lack of access to safe surgery. Over the past 30 years, Johnson & Johnson has helped Operation Smile provide more than **100,000 smiles** to children around the world who suffer from cleft lip, palate or other facial deformities.

Change a Smile, Change a Life

Every 3 minutes, a child is born with a cleft lip or cleft palate and may suffer from torments, malnourishment and difficulty with speech. It takes as little as 45 minutes to repair a cleft lip and/or cleft palate. It is estimated that two billion people, or one-quarter of the world's population, lack access to basic surgical care. Billions more lack access to safe and well-timed surgery.[1] Access to surgery through an organization like Operation Smile can transform their futures.

Since 1988 Johnson & Johnson has partnered with the international medical charity Operation Smile contributing nearly $30 million in financial and product donations to bring safe, effective and well-timed surgeries to the most vulnerable in our world. As a long-time sponsor and exclusive provider of every suture used in Operation Smile missions, J&J help bring smiles to children around the world who suffer from cleft lip, palate or other facial deformities. Employees around the world are engaging in voluntary, employee-driven fundraising campaigns or are donating their time on medical missions. In 2015, Johnson & Johnson announced a commitment to provide more than $25 million to Operation Smile through financial and product contributions over the next five years.

During the 2018 MedTech Forum, delegates were invited to make an impact live-on-booth by donating a photo. Each photo was matched with a $15 donation to Operation Smile by Johnson & Johnson Medical Devices EMEA. The activity raised funds that will restore 18 smiles[2].

About Operation Smile

Operation Smile, headquartered in Virginia Beach, Virginia, is an international medical charity with a presence in more than 60 countries, whose global network of thousands of credentialed medical volunteers from more than 80 countries is dedicated to helping improve the health and lives of children. Since its founding in 1982, Operation Smile has provided more than 220,000 free surgical procedures for children and young adults born with cleft lip, cleft palate and other facial deformities. To build long-term sufficiency in resource poor environments, Operation Smile trains doctors and local medical professionals in its partner countries so they are empowered to treat their local communities. Operation Smile also donates medical equipment, supplies and provides year-round medical treatment through its worldwide centers.

1. Source: http://www.operationsmile.org/surgery/global-need
2. 1 smile/surgery equals $240

UNDER CONSTRUCTION: NEW MDR REGULATION

The foundations have been laid but some building blocks are not yet in place

The new EU Medical Devices Regulation will provide a much-needed update to the rules underpinning the sector. However, key elements of the system – including dozens of Notified Bodies which are currently reapplying for designation under the Regulation – are not yet ready for their new tasks.

The Regulation builds on the existing system in order to retain its best elements and make the transition to the new rules as seamless as possible. 'It's like renovating a house,' said **Rita Peeters**, Senior Director, Regulatory Affairs Policy and Intelligence EMEA, **Johnson & Johnson**. 'It's easier to build a new house but, in this case, we need to keep the old one. We have the basis of our building and are applying new rules and requirements to the existing house.'

> We need designated Notified Bodies so that we can begin to prepare for the future together
>
> *Rita Peeters, J&J*

There is much to do and the clock is ticking. A new survey conducted by Deloitte for MedTech Europe, shows that 8% of medical device manufacturers say they are fully prepared for the new Regulation. Half of all respondents expect their costs to increase as a result of new rules, particularly those requiring the generation of data.

Industry, competent authorities, notified bodies and the European Commission will have to collaborate closely to be ready for 2020. 'We all have to live in this house together,' said **John Wilkinson**, Director of Devices at the **MHRA** in the UK. 'We won't be living separately – it's communal living.' National authorities are committed to working with others, including through the CAMD website.

The European Commission – the architect behind the blueprint to which Member States will work – is also actively preparing guidance and other building blocks required by the Regulation. 'To solve our problems, we must share resources and work together,' said **Erik Hansson**, Deputy Head, Health Technology and Cosmetics Unit, DG Grow, **European Commission**. 'This is the only way to build the beautiful house Rita described.'

> **Power has shifted to patients – they demand more accountability**
>
> *Nadim Yared, CVRx & AdvaMed*

CRACKING THE CODE

Code of Practice prepares industry for era of value-based healthcare

Since January 2018, direct sponsorship of healthcare professionals attending third-party conferences has been phased out. This follows the introduction of new rules for indirect sponsorship which have been in force since 2017.

It's a big change. But perhaps the most remarkable feature of this cultural shift is that it has been voluntary. The MedTech Europe Code of Ethical Business Practice, agreed by industry leaders in 2015, enhances the reputation of the medtech sector and raises the bar for corporate transparency.

So why bother? Leading companies view the Code as a 'business enabler', although there is still work to do to ensure that the industry and health professionals appreciate the benefits. 'For companies, embracing the Code is not necessarily an easy thing to do,' says **Roeland Van Aelst, Johnson & Johnson**. 'We must ensure we all understand why we are making this effort.'

Michele Perrino, Medtronic Italia, said it is better to lead the change than to wait for others to demand more transparency. 'Our reputation is good,' he says. 'There is nothing to hide regarding our relationship with health professionals.' The next step, said Perrino, will be for national associations to implement the code by 2020.

The Code will not end the industry's key role in supporting medical training, stressed **Philippe Jacon**, President, Emerging Markets, **Cepheid**. 'We will not stop providing healthcare providers with the education they need,' he said. 'Otherwise physicians' knowledge would remain the same from the day they leave medical school until the day they retire.' The key is to work with partners who can train physicians, putting a buffer between the manufacturer and health professionals.

AdvaMed, the US medtech trade association, already has a Code of Ethics. They were proactive in establishing their own code because they wanted to 'stay ahead of the curve'. 'If we hadn't introduced the code some years ago we'd be under pressure to do it now,' says **Nadim Yared**, CEO & President of **CVRx.** 'Power has shifted to patients and they demand more accountability.'

POWERS OF PREDICTION

Artificial intelligence is powering earlier interventions – preventing serious and expensive illnesses

For patients with urinary tract infections, beginning antibiotics early can reduce the risk of hospitalisation. The trouble is that diagnosing the condition can be tricky. By the time symptoms are clear, the window for early intervention may have closed.

Artificial intelligence (AI) can spot the first warning signs of many illnesses. 'Algorithms use information about patients' wellbeing to flag infection risks,' explains **Dr Ben Maruthappu**, CEO of **Cera Care**, a UK company managing care for older people. 'In some cases this can lead to prompt prescription of antibiotics which may avoidlater hospital admission.'

This is just one example of how digital solutions are bringing real value to over-stretched health services, says Dr Maruthappu who cofounded the NHS Innovation Accelerator in the UK. 'We are now identifying 85% of conditions earlier and initiating care within 24 hours,' he says. 'Patients are very happy – our satisfaction rate is 99%.'

Dr Maruthappu says the proactive management of disease is one of the major benefits of digital health. However, while many technologies recoup their costs in a single year, adoption can be slow. By rethinking payment and reimbursement models, policymakers can use technology to make healthcare more sustainable, he says. For example, in the UK, the uptake of digital health technologies increased 100-fold when they were placed on reimbursement lists.

'People are living long but are more likely to have obesity, diabetes and lifestyle-related diseases,' Dr Maruthappu says. 'Technology allows us to do more with less; to put patients in control of managing their own health, often using their own devices.'

Technology must be front and centre of a sustainable health services

Dr Ben Maruthappu, Cera Care

SMES NEED HELP TO ENSURE THEY ARE 'REGULATION READY'

'I'm one person doing three jobs'

> My advice? Have a plan, have a budget – and know that it will take more than you expect
>
> *Patricia Forest-Villegas, i-Sep*

Patricia Forest-Villegas knows how challenging it can be for small medtech companies to prepare for the new MDR. As Scientific, Regulatory Affairs & Quality Manager at **i-Sep** – a start-up with 10 staff developing an autotransfusion device – she wears many hats.

'I'm dealing with scientific, regulatory and quality,' she says. 'It's one person doing three functions.' Add to that the constant fundraising work required to keep all start-ups afloat, and you begin to see how hectic life can be for the thousands of SMEs that comprise Europe's medtech sector.

With a new MDR on the horizon in 2020, many smaller companies are struggling to estimate the human and financial resources that will be required to comply.

They are also reaching out – often for the first time – to Notified Bodies now rather than leaving it to the last minute. 'Some Notified Bodies are not taking on any new clients,' warns Forest-Villegas. 'We have already signed a contract in preparation, even though we still have work to do on our product.'

She says if it were possible to apply for a CE mark now, under the existing rules, she would go for it and immediately begin collecting clinical data in preparation for the new MDR.

Hein Van Den Bos, Partner at **Hogan Lovells** law firm, said larger companies can afford consultants, lawyers and in-house expertise for dealing with regulatory bodies but smaller firms do not have this luxury. 'However, SMEs are often flexible and can adapt more quickly, so being small comes with some advantages.'

HEAR FROM OUR

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EXHIBITORS

For Deloitte, the MedTech Forum is part of an ongoing relationship with MedTech Europe and support to the industry. We had several opportunities to interact with experts and share our insights, knowledge and capabilities on challenges and opportunities in the industry.

Koen Segers, Director Strategy, Deloitte Belgium

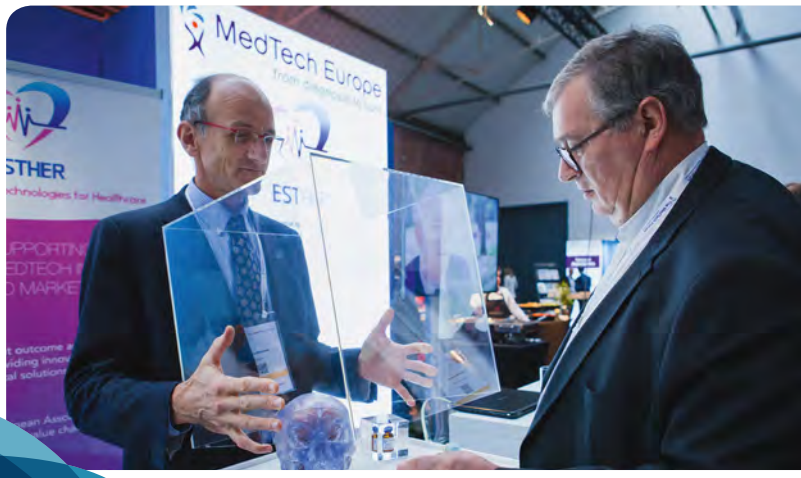
We had some great conversations with new and existing Veeva customers and we left the MedTech Forum with several leads to follow up.

Melonie Warfel, Vice President, Global Medical Device & Diagnostics, Veeva

EXHIBITORS

The conference app helped us to connect with participants.

Ernst Elhorst, Director Corporates, NLC | the Healthtech Venture Builder

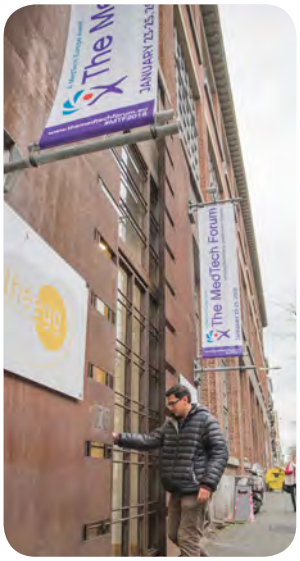


17 SPONSORS

The Forum reflects the diversity of the medtech industry. It brings experts from companies, large and small, under one roof – that presents opportunities to connect with specialists in diagnostics and devices as well as leaders from large multinationals. I was also impressed by the range of public policy topics covered, including health technology assessment, value-based healthcare and Brexit.

Dr Mark Lloyd Davies, EMEA Leader, Medical Devices, Consumer Med Tech, and Western Markets, Government Affairs & Policy, Johnson & Johnson

THE MEDTECH FO



729
DELEGATES

100
SPEAKERS

RUM IN NUMBERS

41 PLENARY, PARALLEL SESSIONS & WORKSHOPS

662 DOWNLOADS OF THE APP

CREATING BUZZ

Barry Shrier @Barry_HealthTec 6m
RT medtecheurope: More great speakers at #MTF2018! Join us starting tomorrow and follow our live coverage! We look forward to welcoming elie_lob and OrangeHCare!
twitter.com/OrangeHCare/st…

> **Orange Healthcare** @Orange…
> MedTech Forum 2018 : intervention d'@elie_lob demain sur la table ronde tendances, défis et opportunités dans le domaine de la #sante ow.ly/mCoo30hl6F5 #MTF2018 #medtech #MedicalDevices #Pharma #hcsmeufr

BVMed
@BVMed

@OrangeHCare CEO @elie_lob: "Artificial Intelligence #KI will be a big game changer in #healthcare the way medical doctors will work in the future - it will be not only a technological, but an organisational change"
CEO session at the #MTF2018 #Medtech

Patrick Boisseau @P_Boisseau 46m
Replying to @medtecheurope @apars…
#MTF2018 fantastic talk by Ali Paras on Practical implementation of #AI in #Healthcare

Christopher White @CWhiteA… 4h
Sweden and UK lead Europe in adoption of #value based care models: risk sharing combining #medtech co-investment & services solutions. These Medtech models benefit patients and innovation. #MTF2018 @medtecheurope @AdvaMedUpdate

Swedish Medtech @Swedish_… 1h
Nu om MedTech Europe Code of Ethical Business Practice. Var befinner vi oss och vilka är utmaningarna? #swemedtech #MTF2018

André Jacinto Retweeted

Fenin @fenin_es 23h
Varios miembros del equipo de @fenin_es en MedTech Forum, Bruselas, con #APORMED donde se están debatiendo novedades del sector de la tecnología médica. @medtecheurope @fenin_es #MTF2018

+3000

engagements/interactions on Twitter, Facebook and LinkedIn

8 MEDIA MENTIONS

Irish Medtech @IrishMedtech 1h

Seven steps to get ready for most economic advantageous tendering (MEAT): 1) community practice 2) branding 3) get your team right 4) define value prop and evidence 5) engage in pilots 6) engage commercial 7) roll out and track impacts @BCG Götz Gereck #MTF2018 @medtecheurope

Richard Charter
@RichardCharter

Excellent to see the entire #Medtech industry focus on value-based healthcare (#VBHC) at #MTF2018. Delivering outcomes that matter to patients, while managing total costs to the system, WILL improve #EU #healthcare systems. @medtecheurope

Amanda Maxwell
@MedtechAmanda

Digital strategy at core Commission health strategy -citizens' better acces,sharing data, how to get digital services to consumers #MTF2018

800 TWEETS

MEDICALPS
@medicalps

CEO Cécile Real: getting connected is now a standard for medical devices. #ceonofiltersession #MTF2018

Mecomed
@mecomed_me

To ensure patient-centric approach, we need to think through the security continuum, data continuum and care continuum, say Joseph Fernando of Arm #MTF2018

Cook Medical Europe @Coo… 9m

Social media and rating sites help to empower patients according to Danny Van den Ijssel, Product manager for Zorgkaart Initiative, a patient group website in the #Netherlands @ZorgkaartNed #MTF2018 #patientpower

Thank you to our exhibitors

3D surgical visualization system
3D MediVision

Abbott

AlloTech
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MAW

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MD-CLINICALS

MedTech Europe
from diagnosis to cure

Medtronic

MEINNTECH
MEDICAL INNOVATION TECHNOLOGY

NLC
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Medical Technologies Belgium

BIVDA
British In Vitro Diagnostics Association

BVMed
Enhancing Health

czechmed
Česká asociace dodavatelů zdravotnických prostředků

EHMA
European Health Management Association

federación española de empresas de tecnología sanitaria
fenin

IMEDA

IMSTA

Irish Medtech Association
Ibec

ipd

Mecomed

MEDICO INDUSTRIEN

MedtekNorge
Norwegian Association for Health- and Welfare Technology

medical technology
Association of New Zealand

Sailab
MedTech Finland

SAMED
south african medical device industry association
advancing innovation responsibly

SBA
Sterile Barrier Association

Syndicat de l'industrie du diagnostic in vitro
sidiv

snitem

SPA
health

SPECTARIS
Medizintechnik

SWEDISH LABTECH

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