Medtech Insight
Issue 57
medtech.pharmamedtechbi.com
Pharma Intelligence Informa
August 21, 2017

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Artificial Intelligence Brings Wave Of Future Health Care Innovation – Embrace It Or Be Left Behind

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While technology companies have long tapped into the potential of machine-learning and artificial intelligence to develop smarter, better and cheaper gadgets, a growing wave of health care companies are now starting to take advantage of big data to try to create better outcomes and drive change.

One of the key areas in medicine where data analytics is expected to make a significant contribution is in diabetes. Diabetes is a global epidemic and the most expensive disease in the world, costing the US alone more than $245bn a year in lost wages, according to the Centers for Disease Control and Prevention. It affects millions of people worldwide and their numbers continue to rise, which makes it a lucrative disease for companies and entrepreneurs to explore.

The data-intensive nature of diabetes care and management also makes it a great fit for applying machine learning and AI to find better solutions and improve outcomes, said Joel Goldsmith, senior director Digital Platforms **Abbott Diabetes Care Inc.**, during an interview with *Medtech Insight* at the recent American Diabetes Association annual conference in San Diego.

Abbott is one of several medtech companies exploring the use of computers to try to develop ever-more sophisticated algorithms that can analyze data that will ultimately help doctors and patients improve treatment plans.

In this article, we'll discuss how Abbott and other diabetes companies are applying AI and machine-learning techniques, look at other areas in medicine where machines learning is driving change, and discuss some of the major issues and challenges surrounding this trendy area *(Also see "Advent Of Artificial Pancreas Tech To Galvanize Fast-Growing Diabetes Market" - Medtech Insight, 26 Apr, 2017.)*.

ABBOTT'S INNOVATION HUB

At Abbott, Goldsmith led the team that developed the *FreeStyleLibre* system, which consists of a small, disposable sensor that is placed under the skin and worn on the back of the arm for 14 days, and a handheld device, called *FreeStyle Libre* reader, that allows users to scan the sensor to instantly obtain current glucose levels and historical patterns and trends.

The factory-calibrated device requires no finger pricks for calibration, which gives it a competitive edge. Recently ap-

CONTINUED ON PAGE 13

FROM THE EDITORS OF: **THE GRAY SHEET, CLINICA, START-UP** AND **MEDTECH INSIGHT NEWSLETTER**

MEDICAL TECHNOLOGY EXECUTIVE FORUM

SEPTEMBER 15, 2017

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- Raising Capital
- CEO Perspective: "Do's and Don'ts" for Successful Leaders

CONFIRMED SPEAKERS INCLUDE

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- **Jeff Dunn**, President & CEO, Si-Bone, Inc.
- **Thomas Fogarty**, Physician, Inventor & Founder of Fogarty Institute for Innovation
- **Marc Galletti**, Managing Director & Founder, Longitude Capital
- **Mir Imran**, Founder, InCube Labs
- **James Mazzo**, Global President, Ophthalmic Devices for Carl Zeiss Meditec AG
- **Casey McGlynn**, Partner, Wilson Sonsini Goodrich & Rosati (moderator)
- **Reneé Ryan**, Vice President, Venture Investments, Johnson & Johnson Development Corporation
- **Jeffrey Shuren**, MD, Director, CDRH

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The shift from centralized lab testing to point-of-care diagnosis is accelerating, driven by technology advances and digitization of health care. Find out what other trends are increasing the adoption of POC testing and the next-generation innovations in this area.

Hindsight 20/20
http://bit.ly/29zivFF
Look out for our new Q&A series with medtech industry veterans sharing their war stories, as well as advice on growing your business and pitfalls to avoid. As the saying goes: "Hindsight is 20/20."

Device history record troubles
http://bit.ly/2uOI7Zd
In this Quality Replay article, we offer expert insights from our archives on difficulties manufacturers face in overlooking various key elements of device history records.

Getting together in Eurasia
http://bit.ly/2ullb1D
http://bit.ly/2v1lWyh
A two-part series on what's ahead in the Eurasian Economic Union as Russia joins with four of its neighbors to forge a common medtech regulatory framework.

Device Week
http://bit.ly/2v0IJtS
In this latest episode of *Medtech Insight*'s weekly podcast, we discuss a range of medtech regulatory updates in Asia and Eurasia. Look out for our next episode on medtech M&A trends.

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inside:

Medtech insight

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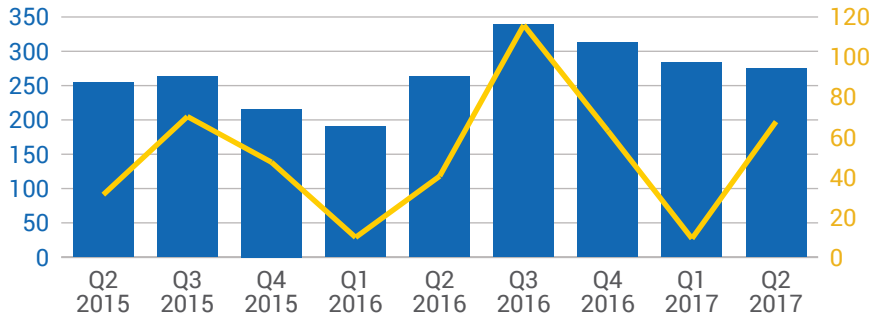
SNAPSHOT: Device Recalls Q2 2017

SHAWN M. SCHMITT shawn.schmitt@informa.com

There was a dramatic increase in the number of high-risk class I medical device recalls in the second quarter of 2017. There were 15 class I recall events logged with US FDA from April through June, up 88% from the first quarter of the year, when only eight were posted, according to consulting firm Stericycle, which gathered its recalls data from FDA Enforcement Reports. Overall, recalls fell 3% in Q2 '17, to 275 (compared to Q1's 284). Meanwhile, the number of recalled device units increased by a massive 628%, climbing to nearly 67.6 million units in Q2 '17, from 9.2 million in Q1. For a snapshot of Q2 results, see the infographic of Stericycle data below.

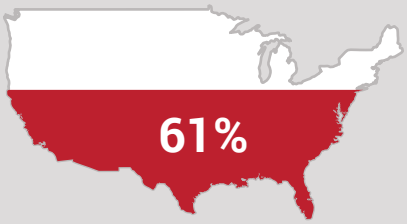
Published online 08/10/17

MEDICAL DEVICE RECALLS & UNITS (in millions)



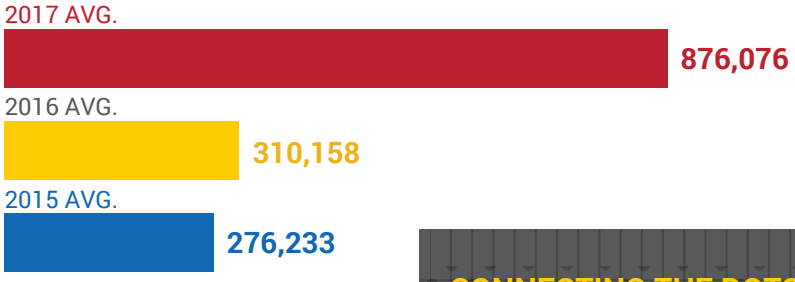
DRAMATIC INCREASE

The number of high-risk class I recalls rose 88%, from 8 in Q1 to 16 in Q2.



OF DEVICE RECALLS WERE NATIONWIDE

AVERAGE CLASS I UNITS RECALLED PER QUARTER



TOP RECALL CAUSES BASED ON UNITS

Sterility Issue	Quality Issue	Software Issue	Mislabeling Issue
55.7%	40.1%	1.9%	0.6%

CONNECTING THE DOTS

- Sterility issues was the top reason for recalled units for the second quarter in a row.
- 47.3% of recalls were for software or mislabeling – the same top causes as the previous two quarters.
- 53% of recalls were distributed both domestically and internationally, the highest percentage since Q1 2016.

Source: Stericycle ExpertSOLUTIONS Q2 2017 Recall Index

Ukraine Medtech At Last Crosses From State To DoC Regulatory System

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The transition from Ukraine's system of central regulation of medical devices ended on July 1. Medical devices can now only be imported and placed on the market in Ukraine when in compliance with the new Technical Regulations 753, 754 and 755. *(Also see "Time Running Out For Compliance With Ukraine Device Law" - Medtech Insight, 17 May, 2017.)*

And 20 days later, Cabinet of Ministers Resolution 1069, dated December 2016, also came into force, writes the Kiev medtech and pharma regulatory consultancy Cratia.

That document reportedly makes the State Administration of Ukraine on Medical Products and Control of Narcotics (SAUMP) responsible for market surveillance of medical devices. Thus, starting from July 20, SAUMP and its regional bodies began performing state market surveillance of the devices placed on the market under the new national conformity assessment procedures.

This gives the Ukraine central state authorities some residual duties in medtech regulation even as the system changes. But, generally, there is a sense of positive change. "Ukraine is aligning more with the EU framework, and it is easier now to work in Ukraine because of this," according to Anna Harrington Morozova, scientific and regulatory director of Regem Consulting, and a specialist in the Ukraine medical devices market.

Shutterstock: bzbz

Compliance Standards

Ukraine has adopted a voluntary compliance route. The harmonized standards are contained in:

- Decree 662 – a list of 29 harmonized standards for conformity assessment of active implantable medical devices.
- Decree 663 – 80 harmonized standards for medical devices.
- Decree 664 – 12 harmonized standards for IVDs.

LENGTHY TRANSITION PERIOD

The transition to the new system was extended several times, Morozova reminded delegates at the Informa KNect Life Sciences 2017 Medtech Summit. *(Also see "Ukraine Medical Device Industry Gets Hoped-For Transition" - Medtech Insight, 22 Apr, 2016.)* The new Ukraine framework relies on a system of accredited notified bodies (NBs), a voluntary framework of standards for compliance (*See box, Compliance Standards*) and conformity assessment of medical devices. It is based on the EU legacy medical device directives system. It remains to be seen if, when or how Ukraine seeks to adopt the EU's new regulations, the MDR and IVDR.

Morozova says that the transition period was "quite a painful experience," The government and the notified bodies were not ready to roll out all the changes, and applicants had difficulties understanding the dynamics around the new framework.

All devices had to be re-registered before July 1, 2017, and had to be submitted 90 days before expiry. The pre-2012-issued certificates were valid for five years. Registrations granted after 2012 had indefinite validity, but are only valid after July 1, subject to undergoing the Conformity Assessment (CA) process. There can be no imports of products that do not undergo CA.

The good news for companies that have built up stock in Ukraine is that a "soft transition period" applies – anything imported before July 1 can be sold in Ukraine until its expiry date, but not more than five years from the date being placed on the market, without undergoing the national CA procedure and affixing the national symbol of conformity, Cratia notes.

Quick Customs Checklist For Manufacturers

Documents required for Ukraine medical devices customs clearance:, based on product type:

- Class I medical devices (non-sterile; non-measuring function) require the national Declaration of Conformity (DoC).
- IVDs not shown in List A or B (lists are shown in Annex 2 of the IVD Technical Regulation) and not intended for evaluation require the national DoC.
- All other devices in classes Is, Im, IIa, IIb, III require national DoC and national Certificate of Conformity.
- IVDs in List A and B that are intended for evaluation require national DoC and national Certificate of Conformity.

Source: Craita, Kiev, Ukraine.

DRAMATIC CHANGES; SOME LOSERS; BUT, GENERALLY, MAJOR BENEFITS

But Morozova cautions that the changes in general are "quite dramatic," and five years of transition might still not be enough for every player in Ukraine.

Regarding product classifications, class I devices (non-sterile and non-measuring) can be placed on the market under a Declaration of Conformity (DoC). This is a big simplification, and means that it is now very easy to sell a broad range of products in Ukraine. All other devices must be assessed by NBs for compliance with technical regulations 753, 754, and 755 – submissions to the health ministry have been replaced by submissions to NBs.

Just before the transition ended, there were 3,764 registered devices listed under the state system. Not all will undergo CA, and it will be interesting to see, some months hence, how many products will have been lost and how many companies did not manage to comply. There are likely to be some losers under the new system, although the benefits, generally, are already being seen.

There will be more inspections and factory visits, but per-batch certification is possible, and perhaps more suitable, for some devices. Compliance with both ISO 13485 and ISO 9001 are accepted, and expected. Foreign companies need to appoint a local representative now, as happens in the EU. And a Ukraine compliance mark and registration number need to be displayed on all devices.

NBs were preparing for the new system as early as July 2015. There are 13 NBs listed in Ukraine, including companies like VMP, DMCS, UMCS, and UCMCP. All but two are based in Kiev, and the latest addition came in February, showing that the list is still expanding. It was the case that not enough NBs were accredited prior to the first Ukraine medtech system deadline (July 2014), Morozova observes. Ten of the NBs can process IVD files, and eight can handle active implantable files.

Companies with broad medtech portfolios are advised to use the eight NBs that cover all three types of device.

By way of example, UMCS (the Ukrainian Medical Center of Certification) completed its first CA in Q4 2014, and has since performed more than 140 assessments/certificate issuances. It is a transparent NB that publishes its registrations.

Published online 08/14/17

Over 170 Provisional Draft Codes Published For Notified Body Designation Under MDR & IVDR

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The European Commission's Notified Body Operations Group has published two draft lists comprising 171 codes that might be used to determine a notified body's scope of designation under the new EU medical device and IVD regulations. NBOG has also released a third document – a draft list that signals the breadth of documentation notified bodies might be asked to provide when it comes to applying for redesignation under the new regulations.

The lists, which were published in August, have not yet been adopted or endorsed by the commission and must not be regarded as stating an official position, according to NBOG. They reflect preliminary discussions by the authorities involved in preparing the implementing legislation required for the Medical Device Regulation (2017/745) and IVD Regulation (2017/746), which were published in the *Official Journal of the European Union* in May. They are designed to provide information on the preparatory work involved, and any draft implementing legislation will be made available for public feedback in due time, NBOG said.

There are 71 codes in the draft list for medical devices. As well as codes for active devices and non-active devices, there are horizontal codes that deal with the specifics of a device (e.g., devices incorporating medicinal substances) and manufacturing technologies used (e.g., metal processing and clean room production).

There are 100 codes in the draft list for IVDs. Among the IVDs covered by these codes are products for: blood grouping; tis-

sue typing; genetic testing; and determining markers of infections/immune status. There are also horizontal codes relating to IVD specifics (e.g., devices intended to be used for near-patient testing), IVD manufacturing technologies (e.g., packaging and labeling), types of examination procedures (e.g., agglutination tests); and laboratory and clinical disciplines (e.g., bacteriology).

DRAFT DOCUMENTATION REQUIREMENTS

The third draft list contains a raft of documentation that notified bodies would be required to submit in an application for designation under the new regulations.

For example, they would have to provide a compliance strategy explaining how they have fulfilled their requirements set out in Annex VII of the MDR or Annex VII of IVDR, including, in the case of notified bodies designated under the current EU medical device and IVD directives, a gap analysis explaining how the alignment to the new requirements of the regulations has been achieved.

Applicants would also have to submit documentation detailing the established (specific) qualification criteria for each function within the conformity assessment process, as well as the types of devices, technologies and areas within the subdivisions of the scope of designation applied for.

Documentation detailing the conditions governing the remuneration of all employees (including top-level management and contracted staff) would also be required, according to the draft list, as would documentation on the fees charged and financial conditions and how conformity assessment services are advertised.

The MDR and IVDR have a three-year and five-year transition period respectively, Under the terms of both regulations, notified bodies are unable to apply for redesignation until Nov. 26, 2017. *(Also see "EU Medtech Ecosystem Will Suffer Unless Notified Body Workload Concerns Are Addressed – The German View" - Medtech Insight, 2 Aug, 2017.)*

Published online 08/11/17

US House 'Problem Solvers,' AdvaMed, Aim To Repeal Device Tax

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Recent efforts to repeal the device tax include a proposed health-care reform bill including a tax repeal provision by the US House's bipartisan "Problem Solvers Caucus," and a new advertising campaign by AdvaMed.

The caucus, a House of Representatives group trying to craft a bipartisan health-care reform bill in Congress, said July 31 that their legislative effort would include repeal of the device tax.

In a notice to other members, they stated that the costs of the 2.3% sales tax on devices "are passed on to consumers, and it should be repealed." Melissa Miller, a communications director for Rep. Josh Gottheimer, D-NJ, said the caucus sees the repeal provision as an essential part of a set of principles "to stabilize health insurance markets, and provide relief to individuals, families and small businesses."

Currently the caucus includes only House members, but as it grows it might seek out Senate members, Miller added.

ANOTHER CHANCE FOR REPEAL POSSIBLE IN POST-LABOR DAY SENATE HEALTH-CARE HEARINGS

The Senate also intends to make a fresh, bipartisan start on new health-care reform revisions, likely to include a medical device tax repeal, the week of Sept. 4, Sen. Lamar Alexander, R-Tenn., chair of the Senate Health, Education, Labor and Reform Committee, announced earlier this month.

Alexander noted that his committee feels pressured to get work done on Affordable Care Act reform by Sept. 27, "when insurance companies must sign contracts with the federal government to sell insurance on the federal exchange next year."

Alexander said he will work with the HELP Committee's ranking member, Sen. Patty Murray, D-Wash., to make the hearings bipartisan and involve as many members of the committee as possible.

Members of the Senate HELP Committee who favor device tax repeal and signed onto S. 108, a tax-repeal bill introduced by Sen. Orrin Hatch, R-Utah, earlier this year, include Sens. Todd Young, R-Ind., Bob Casey, D-Pa., Johnny Isakson, R-Ga., Al Franken, D-Minn., and Maggie Hassan, D-NH.

ADVAMED ROLLS OUT DEVICE-REPEAL AD

AdvaMed has rolled out a new advertisement called "It's Time," which is slated to run from Aug. 14 through Sept. 4 across 15 states, including Texas, Pennsylvania, California, New Jersey, Oregon, Florida, Massachusetts, Ohio, Illinois, Michigan, Oklahoma, Indiana, New York, Minnesota, and West Virginia. (See story, p. 9.)

The group ran a separate advertising campaign earlier this year in February, attached to a budget reconciliation effort in Congress, that talked about the device tax as a "roadblock to medical innovation."

The wording of the ad emphasizes that it is time to "protect innovation, advance life-changing research, and to permanently repeal the device tax." The industry group's goal is to ensure that tax repeal remains on top of legislators' priority list during the congressional recess, a spokesman said.

"It's time to put innovation first," said AdvaMed President and CEO Scott Whitaker, referring to the timing of the pitch. A temporary delay that repealed the tax is due to expire Dec. 31. "Thousands of companies face a massive, billion-dollar tax increase in a matter of months. We know full repeal can make it across the finish line and become law, so it's time to do something about that when Congress returns," he added.

Published online 08/10/17

'IT'S TIME': AdvaMed Device Tax Ad Campaign Sets Sights On Key Lawmakers

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After Republican senators failed to kill the medical device excise tax with their Affordable Care Act (ACA) repeal efforts, Advamed says it is running local ads around the country to keep pressure on congressional leaders to prevent the tax from coming back in 2018.

The largest medical device lobby group says it is running ads in 15 states between Aug. 14 and Labor Day to reach lawmakers in their home states and districts during recess to keep the issue fresh in their minds.

"It's not an effort to target or call out, it's really an effort to reinforce and keep device tax repeal a tier-one legislative priority with those lawmakers that sit in key committee seats," said AdvaMed spokesman Greg Crist.

Among the lawmakers AdvaMed is trying to reach are Reps. Kevin Brady, R-Texas, chairman of the Ways and Means Committee; Pat Tiberi, R-Ohio, chairman on the health subcommittee on the Ways and Means Committee; Greg Walden, R-Ore., chair of the Energy and Commerce Committee; and Lance Leonard, R-NJ, member of the health subcommittee on the Energy and Commerce Committee.

The group is also targeting key states that have a large medical device industry presence, including Indiana, Pennsylvania, Minnesota and New York.

After spending the past few years fighting to permanently repeal the 2.3% excise tax, which has been under a moratorium until December of this year, the lobby group is clearly frustrated with Congress' failure to kill the tax despite having bipartisan and bicameral support. *(Also see "Senate Approves FDA User Fee Reauthorization Bill On 94-1 Vote" - Medtech Insight, 3 Aug, 2017.)*

"It's frustrating but not defeating," said Crist. "It's frustrating when you know the soundness of the argument ... and from an industry perspective, because there are real dollars at threat."

Reflecting the frustration, the group is calling their new campaign "It's Time."

"In light of all the partisanship, the bickering, the back and forth, and the enormous weight of Obamacare and what to do with repeal, reform, *et cetera*, ... we're making an argument to lawmakers it's time to put innovation first," said Crist. "It's time to turn to full repeal, even as a standalone if we need to pass this."

The campaign will run in local news sites where congressional lawmaker and staffers get their news. While the ads will also run on various AdvaMed sites, from a social media perspective they are primarily disseminating the ad on Twitter.

AdvaMed has worked on the device tax-repeal campaign with other industry lobby groups such as the Medical Device Manufacturers Association in the past, but they are not collaborating on this particular campaign. However, they are still working together on the legislative side to find a new vehicle to repeal the tax.

AdvaMed has rolled out a new advertisement called "It's Time," which is slated to run from Aug. 14 through Sept. 4 across 15 states

AdvaMed says time is quickly running out since the tax will go back into effect at the beginning of next year unless it is repealed, but the group still has a few plays up its sleeve.

AdvaMed is now looking at other vehicles that could get the device tax repeal through, including the State Children's Health Insurance Program. The program needs to be reauthorized before Sept. 30. And Sen. John Cornyn (R-Texas), the majority whip, has already stated that Republicans are looking to use SCHIP as a means to pass popular parts of the Obamacare repeal efforts when the program comes up for discussion.

Other vehicles AdvaMed are considering to tack the device tax repeal onto include legislation to stabilize the ACA marketplace, and even a potential tax reform bill that Crist admits is likely going to be a difficult push.

Crist says a lot lies with the Congressional leadership, and they are willing to look at any possible vehicle that arises.

While the lobby group is pushing through with its work, Crist says companies are already starting to make financial decisions for next year and asking themselves whether they need to put aside a few million dollars to pay the tax or if they can use that to fund more research and development.

A few months ago, AdvaMed President Scott Whitaker assured some members that at least for next year the tax would not resurface.

"Look, I'm confident 2018 will not see a tax increase on medtech manufacturers," he said. "Beyond that, we're doing our best to ensure the tax never returns.

"But something is wrong with a system when the votes are there, the support is there, and the merits are there, yet full device tax repeal can't get enacted. That needs to change, and quickly," he added.

Published online 08/10/17

Senator Introduces Medical Device Cybersecurity Act

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Shutterstock: Carlos Amarillo

A bill recently introduced by Sen. Richard Blumenthal, D-Conn., is aimed at preventing medical device cyberattacks and providing more security for patients hooked up to networked devices by implementing more security features on the products themselves, and through other means outlined in a June HHS report on cybersecurity.

"The security of medical devices is in critical condition," said Blumenthal. "My bill will strengthen the entire health-care network against the ubiquitous threat of cyberattacks."

S. 1656 calls for providers, such as hospitals that own medical devices, to grant their consent for remote access to the device only at times specified in a written agreement – such as after sale of the device – and to spell out the types of tasks that can be performed through such access, as well as the types of software used to do so. Patients on whom the device is used would also have provide their consent, to protect their private health-care data.

Among the security protections device manufacturers would have to build into their products to make them safer from hackers would be:

- Multi-factor authentication for accessing any cyber capability of the product;
- Use of data encryption to secure data in motion and data at rest, under best practices approved by the National Institute of Standards and Technology;
- Creation of automated tools to track access and identify attempts to unauthorized access; and
- Adoption of "whitelisting" approaches and changeable passwords for accessing any cyber capability of the device.

Whitelisting – the opposite of "blacklisting" – means registration of entities that provide a particular privilege, service, access or recognition to the user.

TRACEABILITY MATRIX WOULD REDACT CONFIDENTIAL INFORMATION

The bill also calls for "cyber report cards" that would include elements in a "Manufacturer Disclosure Statement for Medical Device Security," as set forth by the Healthcare Information and Management Systems Society (HIMSS) and the National Electrical Manufacturers Association (NEMA). The report card would also contain a traceability matrix that redacts confidential content, and sets up design components traced to design compensating controls that address known vulnerabilities and exposures of the device.

Similarly, the "Report on Improving Cybersecurity in the Health Care Industry," produced by the HHS-supported Health Care Industry Cybersecurity Task Force, and released in early June, called for a strong product evaluation process for protecting access to patient-care records, not unlike a "housekeeping seal of approval."

The HHS report noted that while computer operating systems tend to have short lifespans, medical devices may be used by hospitals or physician practices for 10, 15, or 20 years, so there tends to be a mismatch between the operating systems and the devices. Vendors and health-care organizations need to identify their legacy systems like devices, and develop an approach – such as compensating controls or device updates – to mitigate the risks.

Under Blumenthal's bill, report cards would list any cybersecurity risk assessments conducted by a manufacturer or third party to explain the risk of the device to patient safety, and provide indication if the device is remotely accessed.

EXEMPTION FROM 510(K)S, PMAS, FOR CYBERSECURITY FIXES

A key feature of S. 1656 for device manufacturers would be that any cybersecurity fix made to a device, or update to it, would not require a notification under a 510(k) or PMA notice under the Federal Food, Drug and Cosmetic Act.

Blumenthal's bill also states that manufacturers "shall provide any cybersecurity fix or update to a device free of charge" unless a product update agreement between a manufacturer and a provider expires, or 10 years after a manufacturer stops marketing the device has elapsed.

Provisions of the bill would only apply to devices approved for the market under a 510(k) or PMA notice *after* the bill becomes law.

Published online 08/11/17

Medicare Proposal To Cover Outpatient Knee, Hip Procedures Raises Patient Selection, Bundling Questions

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A proposal by the US Center for Medicare and Medicaid Services in its 2018 Hospital Outpatient Prospective Payment (OPPS) draft rule to take total knee replacement surgeries off its "inpatient procedures only" (IPO) list and to let the procedures be covered under Medicare on an outpatient basis could be a boon for some beneficiaries, but patient selection will have to be carefully weighed, payment experts say.

The agency also asked for comment in its 2018 year OPPS and Ambulatory Surgical Center proposal, released July 20, on whether partial hip arthroplasty (PHA) and total hip arthroplasty (THA) if – in addition to total knee arthroplasty (TKA) – meet its criteria to be taken off the IPO list, and added to the ambulatory surgical center covered payment list.

Shutterstock: Shidlovski

Physicians will have to consider each Medicare patient's conditions and comorbidities, as well as home support, to permit payments in an outpatient setting said Advamed executive VP for payment Don May.

PHYSICIANS MUST BE VERY SELECTIVE, ADVAMED SAYS

While AdvaMed supported removing TKA off the IPO when CMS made a similar proposal in 2017, "The question is," asked Don May, AdvaMed executive VP, payment and healthcare delivery policy, "with the Medicare population on average being sicker, having much more comorbidities, is this shift to outpatient something that can happen?"

However, he stressed in an Aug. 8 interview with *Medtech Insight,* it might now be doable, as recent technological innovations in implants and procedures have made recovery from joint surgeries like THAs and TKAs faster and easier for otherwise healthy patients.

"Ultimately, the physician will need to look at the patient's other conditions, and their complexities. And for something like a joint replacement, physicians also need to look at what kind of support they have at home – such as whether the patient has five flights of stairs to climb, to get to their apartment, and there's no elevators. So there are a lot of factors that go into the decision for where is the appropriate place, and the appropriate setting, for each patient," May added.

Additionally, research in the *Journal of Athroplasty* has shown that the health of the patient – not length of stay – is the most important factor in successful and swift recoveries from TKA surgeries, commented Steve Phillips, Johnson & Johnson senior director of global health policy, on CMS's first proposal in 2016 to remove TKA procedures from the IPO.

PAIN MANAGEMENT ALSO A CONSIDERATION

But for some hospital groups, CMS should "take extreme caution" in removing joint procedures from the inpatient-only list.

An American Hospital Association spokesman, Colin Milligan, pointed to AHA's comments on a similar notice in 2016, when the Medicare agency proposed just removing TKA from the inpatient list for the 2017 year, and AHA opposed the move.

"TKAs remain complicated, invasive procedures," the 2016 AHA comments, signed by executive VP Thomas P. Nickels, stated. "While they may be successfully performed on an outpatient basis for non-Medicare individuals, we do not believe it is appropriate for the Medicare population."

The group also cited issues with spinal anesthesia and pain management in its 2016 comments. "Management of postoperative pain is best controlled in the inpatient setting," AHA wrote. Milligan said that the hospital group is still considering

the latest version of the CMS-proposed changes that includes hip procedures, and will likely file comments by the Sept. 11 deadline.

CHANGES TO PAYMENTS, JOINT-REPLACEMENT BUNDLE STILL A QUESTION

AdvaMed's May also noted that the financial implications of CMS taking TKA and THA off the IPO list are important.

"Is this going to be in an ASC [ambulatory surgical center] and outpatient payment grouping that will sustain the resources required to provide that care, plus the cost of the technology itself? We're going to be looking at that, as part of our analysis," May told *Medtech Insight*.

"We really need to understand the implications for bundled payment programs, as there are a lot of hospitals out there, that are in the CCJR (Comprehensive Care Joint Replacement) bundled payment program," he added. About 800 hospitals began participating in the CCJR bundled payment program in April 2016, which made them financially accountable for costs and quality of care of their joint replacement surgeries. *(Also see "Total Joints: Bundled Payments Driving Procedural Innovation" - Medtech Insight, 26 Apr, 2016.)*

"In our conversations with the [current] administration, they said they want to continue this push toward value payment models, including bundles, although HHS Secretary Tom Price, when he was a congressman, publicly stated he didn't approve of the mandatory nature of CCJR, and the other bundled payment programs for CABG and acute myocardial infarction," May commented.

"I do see they will have to figure out how the changes will work here, [for the bundles] and how it will implicate all their other programs. But at the bottom of all this is the patient, and making sure the patient continues to have access to this service, as you change the reimbursement scene," he concluded.

QUESTIONS ON PERMITTING OUTPATIENT HIP REPLACEMENT PROCEDURES FOR BENEFICIARIES

CMS said it already has enough information to support removing total knee arthroplasty procedures from its IPO list.

The agency is now asking interested parties to answer the following questions in their comments on the proposed changes to hip replacement surgery reimbursements:

- Are most outpatient departments equipped to provide PHA and/or THA to some Medicare beneficiaries?
- Can the simplest procedures described by CPT codes 27125 (PHA) and 27130 (THA) be performed in most outpatient departments?
- How often is the procedure described by CPT codes 27125 and 27130 being performed on an outpatient basis (either in a hospital outpatient department or ASC) on non-Medicare patients?
- Would it be clinically appropriate for some Medicare beneficiaries in consultation with his or her surgeon and other members of the medical team to have the option of either a 24-hour period of recovery in the hospital after the operation?
- Comments are due to CMS on the outpatient/ASC proposal by Sept. 11, and should include the docket number CMS 1678-P.

Published online 08/11/17

Consent Requirement Change Could Be Boon For Minimal-Risk Studies

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Researchers who want to run clinical studies with minimal risk to participants but have been thwarted by Institutional Review Board (IRB) consent-form requirements can now proceed according to a temporary guidance issued by FDA. The document harmonizes with the federal Common Rule for human research and allows non-governmental researchers to conduct studies that were, until now, limited to federal agencies.

When Congress passed the 21st Century Cures Act last year it included a provision giving FDA the authority to allow minimal-risk clinical investigations to proceed without requiring the typical IRB consent forms from patients or changes to consent forms.

"Over the years, FDA has received numerous inquiries from sponsors and investigators about conducting important minimal risk clinical investigations for which obtaining informed consent was not practicable," says the agency. "Many of these minimal risk clinical investigations did not proceed because FDA did not have the statutory authority to permit a waiver of informed consent for such investigations."

Now the agency says it will allow sponsors and researchers to conduct such studies if they meet certain requirements that are also required under the Department of Health and Human Services (HHS) Common Rule. Under that rule, consent-form exception has been in place for federal researchers if:

- The research involves no more than minimal risk to the subjects;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

FDA spokeswoman Lauren Smith Dyer says certain comparative-effectiveness

research in cluster randomized trials and analyses of large data sets, such as medical records, are the types of minimal-risk studies that are likely to benefit from the agency's new position.

"In general, FDA's regulations governing the protection of human subjects conform to the requirements in the 'Federal Policy for the Protection of Human Subjects' (the Common Rule), with a few exceptions because of differences in FDA's mission or statutory authority," said FDA in the guidance. "The Common Rule standard has been adopted and successfully employed for decades by [HHS and] numerous other Federal agencies."

The agency says it has been advised by the Secretary's Advisory Committee on Human Research Protections (SACHRP) that harmonizing the Common Rule for FDA regulated research will promote consistency and reduce confusion across the research communities, while opening up more FDA-regulated research.

While FDA issued the guidance without first putting out a draft guidance and allowing a public comment period, the agency says it will still accept comments on the guidance and revise it if it thinks it warrants it. The regulators also say they will withdraw the guidance after they revise their broader informed-consent regulations to reflect Cures Act mandates.

"Waiver of informed consent for certain FDA-regulated minimal risk clinical investigations will facilitate investigators' ability to conduct studies that may contribute substantially to the development of products to diagnose or treat diseases or conditions, or address unmet medical needs," said FDA. "In light of the Cures Act amendment to the [Food Drug and Cosmetic] Act described above, FDA intends to revise its informed consent regulations to add this waiver or alteration under appropriate human subject protection safeguards to the two existing exceptions from informed consent (i.e., in life-threatening situations and for emergency research)."

Published online 08/08/17

CONTINUED FROM PAGE 1

proved in Canada, the FreeStyle Libre system is already sold in more than 37 countries outside of the US and used by more than 300,000 people. Abbott hopes to win approval in the US.

Europeans, meanwhile, also have access to the *LibreLink,* a mobile app that enables a compatible Android phone to scan the FreeStyle Libre sensor, and the *LibreLinkUp*, an app that allows caregivers to receive notifications when a user scans the sensor.

When the company introduced its device in Europe, it also asked patients who are scanning their sensors, if they would allow Abbott access to their data through a cloud-based service to help guide treatment decisions. To date, more than 50,000 people who used the system from 2014 and 2016 granted Abbott access, yielding more than 409.4m glucose measurements, 86.4m monitoring hours and 63.8m scans, Abbott said.

Goldsmith sees the future of diabetes management moving from scripts to sensors, from proprietary devices to consumer devices and from desktop to cloud-based-services.

Now that the problem of acquiring data painlessly and effortlessly has been solved, he said, the next step will be to translate the data into different visualization formats to help doctors and patients develop better treatment plans.

"That's where we're at today," Goldsmith told *Medtech Insight*. "Where we're edging into is, we'll take advantage of machine-learning and AI going beyond simply translating data into actionable information and really adding elements of guided interpretation, which then leads to things like predictive analytics and ultimately to prescriptive analytics."

Though still in its infancy, Goldsmith foresees that this next phase of innovation will enable advancements in diabetes care to progress at a much faster pace than in the past.

AT THE INTERSECTION BETWEEN TECH AND HEALTH CARE

One of the reasons for the faster pace is that there are a growing number of companies focusing on this area. And health

Joel Goldsmith, senior director of digital platforms, Abbott Diabetes Care

> "Where we're edging into is, we'll take advantage of machine-learning and AI going beyond simply translating data into actionable information and really adding elements of guided interpretation, which then leads to things like predictive analytics and ultimately to prescriptive analytics," Goldsmith said.

care companies don't need to have the technological capabilities in-house to benefit from AI, Goldsmith said.

"There are a lot of other categories outside of life sciences, certainly outside of diabetes, where we're seeing progress being made in this area, and we're going to be able to take advantage of those advancements just like we're able to take advantage of the advancements of smart phones, Goldsmith said. "Smart phones weren't invented for health care, they weren't invented for diabetes, but it's a mass market tool that's completely pervasive now, that is an enabler for advanced forms of diabetes care. We're going to see that in many different domains."

It is well known that tech giants such as **Google, IBM**, **Apple** and **Amazon.com Inc.** are major players in medtech, finding their way into health care through partnerships with pharma and medical device companies.

One of the companies that is at the forefront of such a partnership is **Merck & Co. Inc.**, which linked up with Amazon to harness AI for developing solutions for diabetes.

The two companies announced a competition earlier this year (see box), calling on startups and individuals to develop apps that would use Amazon's *Echo* (commonly addressed as Alexa) voice-enabled software to help people with diabetes manage their disease. The contest recently announced five finalists that will compete for the $125,000 grand prize. (See box, p 6).

Goldsmith noted that all of the trendy home-assistance products such as the Amazon Echo, Google *Home* and Apple's *HomePod* are using advanced forms of AI that are now available to the public.

"It's not a far stretch to imagine even utilizing these types of devices in the on-going management of diabetes," Goldsmith said.

He pointed to Abbott's LibreLinkUp mobile app, which allows caregivers to be notified every time a loved one scans their FreeStyle Libre sensor using the LibreLink app.

"Imagine that same concept now being routed to say an Amazon Echo device," he said. "That caregiver that happens to be working in the kitchen that moment and that Amazon Echo device is sitting there in the kitchen, it announces out loud 'hey, your loved one just scanned their sensor and here is what the value is, maybe you should give them a call.'"

He noted that tech companies such as Google, IBM, **Samsung Electronics Co. Ltd.** and Amazon all recognize that health care is a universal need and an economic burden in virtually every developed country where they can contribute to find solutions.

He said while it may be a stretch that these companies will become health care companies themselves, he foresees more partnerships ahead.

"There is plenty of evidence that we're already moving in that direction," he said.

Asked whether Abbott is eyeing such a partnership, Goldsmith said the company hasn't made a public announcement. But he added "we're a good candidate for it also."

REVERSING DIABETES USING AI

While Abbott wants to leverage big data to develop solutions that can help individual patients better manage their disease, some smaller companies are using advanced algorithms to try to reverse the disease.

Virta Health, an online specialty medical clinic, announced this March its uses an app-based software platform that leverages AI from information diabetics provide on their smartphones to help them – under a physician's guidance -- make better decisions on diet, medications and other health-related issues.

Patients who sign up with the program use the app to upload their blood sugar levels, blood pressure, body weight and other vital information about their health. A health coach reportedly monitors the information and checks in with patients to discuss problems and offers encouragement. A doctor works behind the scenes, using the data to adjust the patient's diet, medications and addresses issues.

The company's announcement on Mar. 8 coincided with a study, conducted at Indiana University, that backed their claims.

In a 10-week trial of 262 people with type 2 diabetes, the findings showed that 56% of patients lowered their blood glucose to non-diabetic ranges (as measured

On July 19, Merck announced the following first five finalists who will compete for the $125,000 top prize for its app competition. (See p 5).

DiaBetty, made by a group at the University of Chicago, Illinois is a mood-sensing virtual voice assistant and educator and at-home coach that aims to help patients self-manage their disease.

MyGluCoach, made by HCL America, Inc. in partnership with Ayogo, leverages health pattern intelligence from patient conversations and wearable and medical devices to aid patients' specific needs.

PIA (Personal intelligent agents for type 2 diabetes), submitted by Ejenta, is a connected care intelligent agent that uses NASA-licensed technology integrated with IoT (Internet of Things) device data to encourage healthy habits, detect at-risk behaviors and abnormalities and alert care teams.

Sugarpod, made by Wellpepper, provides voice, mobile, video and web interactions to support patient adherence to comprehensive care plans and offers tips, education and tracking tools, including a smart foot scanner, to identify abnormalities.

T2D2 (Taming type 2 diabetes, together), created by Elliot Mitchell, a biomedical informatics PhD student at Columbia University and his team, is a virtual nutrition assistant that uses machine-learning to provide in-the-moment personalized education and recommendations as well as meal planning and food and glucose logging. Its companion skill authorizes caregivers with a patient's account to easily engage from afar.

“It is acknowledged that the ‘black-box’ nature of machine-learning algorithms, in particular neural networks, can be difficult to interpret,” researchers noted, referring to the inherent complexity in how the risk factor variables are interacting and their independent effects on the outcome.

by A1c below 6.5%), 87% reduced or completely cut their dependence on insulin and 71% achieved clinically significant weight loss of 5% with the digital program. More than 90% of initial patients completed the individualized care plan.

Sami Inkinen, Virta Health’s CEO, who co-founded the San Francisco-based company with two researchers, and previously launched the real-estate website Trulia, said in a company statement the firm’s mission is to “reverse diabetes in 100m people by 2025.”

Virta is backed by $37m in funding from investors including **Venrock**, **Allen & Co.**, **Ev William’s Obvious Ventures, Redmile Group** and **PayPal** and **Affirm** founder Max Levchin’s **SciFi VC**.

But Virta isn’t the only digital health startup trying to tackle diabetes.

Roche made its way into the digital health arena with the recent acquisition of **mySugr GMBH** the diabetes management platform **mySugr**. **Novo Nordisk Inc.** announced on July 12 it teamed up with diabetes software company **Glooko** to launch the new *Cornerstones-4Care Powered by Glooko* app (C4C app), which is free to patients who enroll in the program.

OTHER AI APPLICATIONS IN HEALTH CARE

Other medical areas in which AI is making significant strides in is radiology, heart disease and cancer.

“Machine-learning is now being applied to image processing so that electronically captured radiology scans can be analyzed by software to identify tissue,” Goldsmith said.

In May, **GE Healthcare** and **Partners HealthCare System Inc.** announced a 10-year partnership to integrate AI at Massachusetts General Hospital and Brigham and Women’s Hospital Center for Clinical Science Data, aiming to create tools that can enhance diagnostic imaging.

The initial focus will be on developing applications to improve clinician productivity and patient outcomes, GE said on May 17. Over time, the partners will apply AI to develop products for molecular pathology, genomics and population health.

“The vision for the collaboration is to implement AI into every aspect of a patient journey – from admittance to discharge,” GE said in the company statement.

In addition, the partners also want to create an open platform that GE Healthcare, Partners and third-party developers can use to validate and share the applications with hospitals and clinics globally.

On the West Coast in the US, meanwhile, Stanford researchers are also looking at deep learning tools to try to identify patterns and predict outcomes even better than the most highly trained humans or using current guidelines.

In a new study that sought to compare the use of the American College of Cardiology/American Heart Association (ACC/AHA) guidelines (based on eight risk factors including age, total cholesterol, smoking, blood pressure, and diabetes) with four machine-learning algorithms to analyze data from electronic medical records of 378,256 patients in the UK to find patterns associated with cardiovascular event, the AI performed significantly better than ACC/AHA guidelines, according to the abstract published in PLOS ONE on April 4.

The goal of the study was to evaluate whether machine-learning can improve accuracy of heart risk prediction within a large primary care population and which class of machine-learning algorithm has the highest accuracy prediction.

With 17.5 million deaths from heart disease each year (in 2012), many doctors rely on well-established guidelines by the ACC/AHA to predict risk of heart disease, but according to the authors, a large number of people remain at risk who fail to be identified by these tools.

Several risk factors that the machine-learning algorithms identified as the strongest predicters were not included in current ACC/AHA guidelines, such as COPD and severe mental illness. However, none of the algorithms considered diabetes, which is prominent in many heart disease patients and part of the ACC/AHA guidelines.

The researchers also acknowledged that machine-learning has its limitations.

“It is acknowledged that the ‘black-box’ nature of machine-learning algorithms, in particular neural networks, can be difficult to interpret,” researchers noted, referring to the inherent complexity in how the risk factor variables are interacting and their independent effects on the outcome.

In another cardiology study, Stanford researchers from the Machine Learning Group collaborated with the heartbeat monitor company **iRhythm Technologies Inc.** to collect a massive dataset that they could use to develop their deep neural network model from iRhythm’s wearable ECG monitor to diagnose difficult-to-diagnose arrhythmias, according to Stanford University’s news service.

In seven months, the researchers were able to diagnose arrhythmias as accurately as cardiologists and even outperform them in some instances, according to the university.

The researchers believe that their research could someday help patients who don’t have access to a cardiologist be treated and diagnosed as readily as people who

are suspected of having arrhythmias and can get an ECG in a doctor's office.

In the cancer field, researchers and companies are also tapping into the power of AI to detect abnormalities and analyze results.

Swiss-based **Sophia Genetics SA** developed an AI application that clinicians can use to analyze liquid biopsy results in the hope to diagnose cancer early *(Also see "Sophia Genetics' AI Brings In More Standardization To Liquid Biopsies" - Medtech Insight, 26 Jun, 2017.)*. Sophia is linked up with 305 hospitals in more than 50 countries to use the company's technology to analyze circulating tumor DNA (ctDNA), contained in patients' liquid samples including blood, urine and cerebral spinal fluid.

As the company learns from thousands of patients' genetic profiles, clinicians' knowledge improves, which should translate into better diagnosis and treatment.

Another company, San Franciso-based **Enlitic Inc.** uses AI deep-learning systems to scan medical images to help diagnose cancer.

Liquid biopsy will also be one of the hot areas for discussion at the 69th AACC Annual Scientific Meeting & Clinical Lab Expo, which will be held in San Diego from July 30-Aug. 3, 2017 in San Diego.

CHALLENGES

As with any new technology, AI needs to overcome limits.

During the recent Digital Health Summit in San Diego a panel entitled, "How Artificial Intelligence is Transforming All Dimensions of Healthcare," discussed some of the challenges that they are facing at their companies in applying AI.

Gini Deshpande, CEO of Palo Alto, California-based **NuMedii Inc.** and Michael Nova, CIO and co-founder of San Diego -based **Pathway Genomics Corp.** told the audience their companies are both leveraging machine-learning and AI, though in very different capacities.

Deshpande, a molecular biologist by training, said NuMedii applies AI and machine-learning coupled with big data technology to discover and advance effective new drug candidates and biomarkers predictive of efficacy for subsets of patients in rare diseases such as inflammatory disease and oncology.

> "I think that even specialists in the field do not understand yet what exactly happens in these algorithms that then allow it to draw these conclusions – and that's the scary part," said Edward Kliphuis, Merck Ventures BV.

"Big data and AI can be like a wingman for helping scientists and clinicians get better at what they do," Deshpande told the audience.

Meanwhile, at Pathway Genomics, which offers digital healthcare and genetic testing, Nova said that AI is being applied as the "consumerized buddy" that "grinds" through people's genetic information and precision clinical information on a daily basis and offers recommendations.

The company's program with IBM Watson is a smartphone app that merges AI and deep learning with personalized genetic information. The app provides users with personalized health and wellness information based on their health history.

Both agreed that machine-learning is fundamentally different from creating software, in that it learns from training data rather than being programmed for a particular outcome, and still requires human input.

"Artificial intelligence, the state of the art today, at least in our sector is still very much dependent on human input," said Deshpande. "Train a computer system with data and say this is a good pattern and say this is a bad pattern and then let the system go … but at the end of the day, you're still depending on training the system with a positive data set or a pattern of some sort."

While machines are very good at looking at complex problems to discover certain patterns, a major challenge for researchers is to find good reliable, quality training data sets that they can feel comfortable with is the "truth," she said.

Machines deal with statistical truth rather than literal truth, which can make it difficult to verify that the answers are correct.

"The other challenge is we don't have all the unknown variables," she said. "We don't know all of the components that come into play in terms of how a disease manifests or how a disease progresses. We start to understand it, but there are still a lot of unknowns. You can leverage IT to help find patterns faster and to identify connections faster. At the end of the day, you still need a human expert to validate what's coming out of the computational technology to say is this real."

She said AI is essentially "a means to an end" and a "tool in our toolkit we can use" to improve the predictability of their technology. The hope is that as the company is using more data and datasets, predictability will improve.

"So, when we predict that a certain drug would modulate a certain disease, we have more confidence in that. But at the end of the day, we still have to test it, so that's where you see the hybrid approach where you're using technology to speed up the discovery process," she said.

With millions of dollars at stake in drug development, researchers need to exercise caution.

Nova agreed with Deshpande that finding "high-quality data" remains a challenge, adding that there's all kinds of data out there.

He noted that every human over a lifetime generates 3-4 terabytes of health care data. Most of that data is lab work and a lot of junk, given that health care data can become irrelevant or obsolete in just a few years. This makes extracting data that is relevant to train algorithms a very difficult task.

However, he noted, that companies can also take advantage of existing data. He gave the example of certain governments

in Latin American countries, which have accumulated some 25 years' worth of data on type 2 diabetes. He said type 2 diabetes is a major problem in Latin America.

"We try to figure out what is accurate before using machine-learning," Nova pointed out.

He explained that this is done via "classification" where algorithms are trained to put information into different buckets. This basically entails feeding the machine lots of information and then train the system to come up with the correct answer.

Then there are the privacy and regulatory concerns.

With the success of IoT (Internet of Things) where health care companies can use commercially available devices such as smartphones, wearable technology and other connected devices, security and privacy protection becomes a real issue.

On the regulatory side, **Tesla** and **SapceX** CEO Elon Musk recently made headlines, calling on the government to consider regulations for AI. He feels that AI "poses a fundamental risk for human civilization." Musk reportedly made these comments during the National Governors Association's meeting in Providence, R.I.

Finally, given that AI is still in its infancy, with all of its challenges, some investors may also consider it too much of a risk to bet on the technology.

Edward Kliphuis, investment director in the New Business Fund in digital health and solutions at **Merck Ventures BV**, Amsterdam, told *Medtech Insight* that AI and machine-learning are definitely on his radar for investments.

"We've come to the realization that a lot of the companies in which you invest in is not the actual machine-learning part, it's the datasets," Kliphuis said. "What you actually invest in is the proprietary data or a trained algorithm that could give you, for example, a headstart in the market," Kliphuis explained.

> "We need a couple of really good successes to show how it's done for people to say 'Yes, I can do this.' IBM has been doing this for six-plus years, and I haven't seen one success story we can show the world," Gini Deshpande, CEO of NuMedii, said.

Merck is looking at companies, but he said AI remains a "vague" area.

"It comes down to the data and the team (that develops the algorithms) more than the engine," Kliphuis said. "I think that even specialists in the field do not understand yet what exactly happens in these algorithms that then allow it to draw these conclusions – and that's the scary part."

Deshpande agreed that even in the health care industry where AI is being leveraged, skepticism prevails with data analysts and scientists not sitting at the same table.

"We need a couple of really good successes to show how it's done for people to say 'yes, I can do this,'" she said. "IBM has been doing this for six-plus years, and I haven't seen one success story we can show the world."

Yet, everyone agrees that AI and machine-learning is the wave of the future, leaving pharmaceutical companies no choice but to adopt these technologies.

"The pharma industry tends to be more risk-averse," Nova said. Meanwhile, tech companies such as Facebook, Microsoft and Google that have long embraced AI technologies are snapping up the best talent.

"They know they can win in the pharmaceutical business, if they apply this technology and that's what they're going to do," Nova said. "I wouldn't be surprised if Google ends up a partial pharmaceutical company 10 years from now, because they'll have a lot of horsepower."

Goldsmith said that in the area of diabetes, there have been meaningful milestones, such as the development of glucose sensors and insulin pumps, but as companies are getting better in leveraging AI and machine-learning, the pace of innovation will only get faster.

"We've seen a pace of innovation in the last five plus years that is unprecedented in this space," he said. "As we come up with more advanced algorithms that deliver the promise of personalized medicine, we honor and respect the personal privacy requirements, but we are potentially able to offer the personalized treatment recommendations on demand. That's the holy grail."

Published online 07/28/17

Gastric Balloon-Makers Respond To US FDA Warning

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Manufacturers of gastric balloons used to treat obesity are defending their products' safety in the wake of an Aug. 10 FDA letter informing providers that multiple deaths had been linked to the products.

FDA is still investigating the exact causes of the deaths, the letter said. The letter primarily cites five deaths that occurred within the first month after balloon placement, with three of the deaths coming in the first three days. *(Also see "US FDA Warns of Deaths Tied To Gastric Balloons" - Medtech Insight, 11 Aug, 2017.)* Four of the patients who died were treated with **Apollo Endosurgery Inc.**'s *Orbera* intragastric balloon, and the other was treated with **ReShape Medical Inc.'s** *integrated Dual Balloon System*. The letter also referenced two additional reports of death in the same period, one linked to Orbera and the other to the Reshape device.

Apollo said in a statement that it had self-reported to the FDA all five deaths linked to the company's *Orbera* intragastric balloon since it earned FDA approval in August 2015. The reports were part of the company's Global Product Surveillance program. The five deaths are in line with Orbera's overall reported casualty rate of less than 0.01% since the product was introduced globally in 2006, Apollo said. Overall, the company has recorded 21 deaths out of 277,000 Orbera balloons distributed.

The firm further noted that it has not received any indication from hospitals or physicians that Orbera directly caused the five deaths reported to FDA, and none of the families have filed a product liability claim. The deaths took place in Brazil, the US, Great Britain and Mexico, Apollo said.

"Patient safety is a key priority in everything we do at Apollo Endosurgery, and we take adverse event reporting obligations related to our products very seriously," said Apollo CEO Todd Newton. "The FDA letter is an important reminder to the physician community that obesity is a serious disease and many obese patients are affected by one or more co-morbid conditions due to their obesity."

ReShape said in a statement that it is "committed to supporting the continued safe and effective use of the dual balloon and is proactively communicating with physicians about this FDA update." The company instructed patients with questions to contact their physicians.

In February, FDA issued a safety alert warning that the balloons carried potential risks of acute pancreatitis and spontaneous over-inflation. *(Also see "US FDA Warns Docs On Gastric Balloon Adverse Events" - Medtech Insight, 9 Feb, 2017.)*

Published online 08/14/17

Pelvic Mesh Cases Continue As Endo Moves To Settle

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Endo International PLC closed out one chapter of ongoing pelvic mesh litigation in the US on Aug. 7 when the company announced it reached agreements to settle almost all outstanding mesh suits. But court battles involving other manufacturers continue.

Tens of thousands of women have sued device manufacturers over complications allegedly experienced when mesh products used to treat gynecological problems eroded within the body. In addition to American Medical Systems, which was purchased by Endo in 2011, major mesh manufacturers involved in the court cases include **CR Bard Inc.**, **Boston Scientific Corp.**, and **Johnson & Johnson Medical Inc.** division **Ethicon Endo-Surgery Inc.**

Endo expects to pay $775m to settle 22,000 US claims and an unknown number of international claims, the company said. The firm plans to make installment payments beginning in the fourth quarter of 2017, continuing through the fourth quarter of 2019.

Jane Akre, who monitors the litigation as editor of the Mesh News Network, says the Endo settlements may be a harbinger of a coming trend.

"[Endo] seems to be going down for the count on so many fronts, and when one falls, I'm just waiting for others to follow," she said. "Bard and Boston are both settling their cases. . . .But J&J's got the deepest pockets, and they pay their attorneys very well, so they'd rather duke it out in court."

But she expects J&J to also begin negotiating settlements soon. "They can't keep this up," she said. "In the Pennsylvania courts, they lost everything but one aspect of one case."

The partial win came in the case of Kimberly Adkins, who said she was injured by Ethicon *TVT-Secur* mesh implanted in July 2010. On June 12, a Philadelphia Court of Common Pleas jury said the mesh had not caused her injuries, although it agreed the mesh had been defectively designed and Ethicon had not properly warned of its risks.

But Judge Michael Erdos reversed the win for Ethicon on July 19, ordering it to face damages on the defective design claim.

Ethicon faced four trials in the Philadelphia court before Adkins', resulting in verdicts of $12.5m, $13.5m, $20m and $2.16m in favor of the plaintiffs. *(Also see "Court Rules Against Ethicon In Pelvic Mesh Case, But Without Punitive Damages" - Medtech Insight, 2 Jun, 2017.)* A trial in a sixth case began on July 31.

In another complicating factor, Court of Common Pleas judge Arnold New recently granted J&J's motion to review whether the court had jurisdiction over 91 pending claims filed by out-of-state patients. The decision came in response

to a July US Supreme Court ruling, *Bristol-Myers Squibb v. Superior Court of California*, which said out-of-state plaintiffs can't sue companies in states where the company isn't based and didn't conduct business directly linked to the claimed injury.

New is asking for briefs on the issue to be submitted this month. If he agrees to toss the cases, the claims would then go back to the plaintiffs' state courts. Three Delaware residents agreed to withdraw their Pennsylvania claims over the jurisdiction issue before New's Aug. 1 decision.

Published online 08/11/17

US APPROVALS ANALYSIS:

Drug-Coated Balloon, Valve Tech Are July Highlights

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The third drug-coated balloon to reach the US market for peripheral artery disease headlined FDA approvals during the month of July. **Spectranetics Corp.** gained PMA approval for its *Stellarex 0.035"* drug-coated angioplasty balloon on July 26.

The paclitaxel-eluting balloon, approved under the original PMA process, will compete with **CR Bard Inc.**'s *Lutonix* (also marketed by **Boston Scientific Corp.**) and **Medtronic PLC**'s *In.Pact Admiral* paclitaxel-coated balloons.

The approval cashes in on Spectranetics' $30m acquisition of the drug-coated balloon platform from Covidien in advance of that firm's merger with Medtronic. *(Also see "Covidien Sells One Peripheral Device While Touting Data On Another" - Medtech Insight, 6 Nov, 2014.)* Philips is now in the process of acquiring Spectranetics for about $2bn. *(Also see "Philips Grows Image-Guided Intervention Focus With Spectranetics Buy" - Medtech Insight, 28 Jun, 2017.)*

The Stellarex approval drew primarily on data from the 300-patient US ILLUMENATE trial, which were reported last fall at the Transcatheter Cardiovascular Therapeutics conference. *(Also see "TCT Round-Up: The Next Generation Of Drug-Eluting Stents, Drug-Coated Balloon Featured At Washington Conference" - Medtech Insight, 8 Nov, 2016.)* Spectranetics touts Stellarex's proprietary *Enduracoat* coating technology, allowing the drug delivered by the balloon to stay in the vessel wall longer to prevent neointimal hyperplasia, as a competitive advantage.

But, currently, Stellarex has the most limited clinical indication of the three competitors. The Lutonix balloon enjoys the most expansive clinical indication, labeled for use in *de novo*, restenotic, or in-stent restenotic lesions, up to 300 mm in length in superficial femoral or popliteal arteries. In.Pact Admiral is limited to the same categories of lesions, up to 180 mm. Stellarex is also limited to 180 mm and is not approved for "in-stent" use.

The other major FDA approvals in July were heart valve devices. Medtronic gained an original PMA approval (in parallel to getting a CE mark in Europe) on July 31 for its *Avalus* pericardial aortic surgical valve for the treatment of aortic-valve dis-

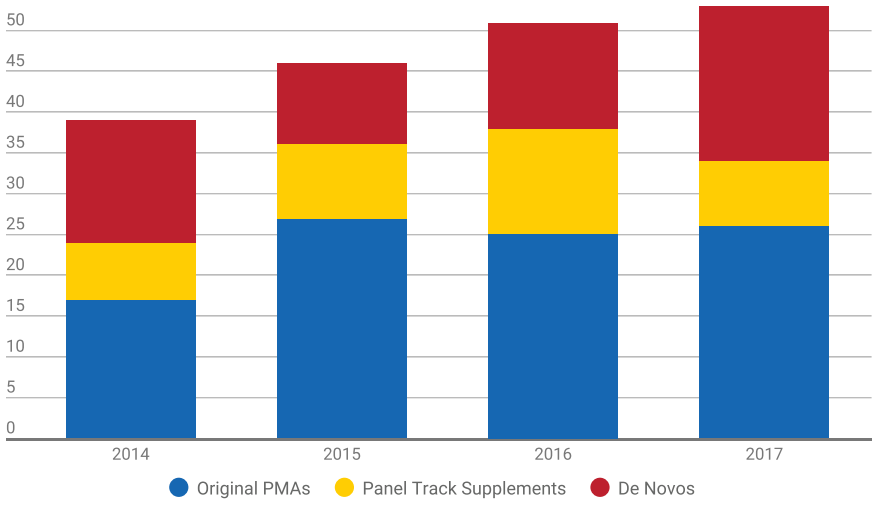
Stellarex Drug-Coated Balloon

Photo credit: Spectranetics Corp.

FIGURE 1

Novel Device Approvals, Through July

Total original PMA, panel-track PMA supplement and *de novo* approvals recorded January-July, 2014-2017



Source: Medtech Insight Approval Tracker

ease. Medtronic says it is the only stented surgical aortic valve on the market that is MRI-safe, without restrictions.

Although transcatheter heart valves are increasing their share of the market, July is the second month in a row in which FDA has approved an original PMA for a pericardial surgical heart valve. In June, **Edwards Lifesciences Corp.**gained approval for its *Pericardial Aortic Bioprosthesis* and *Inspiris Resilia* aortic valve.

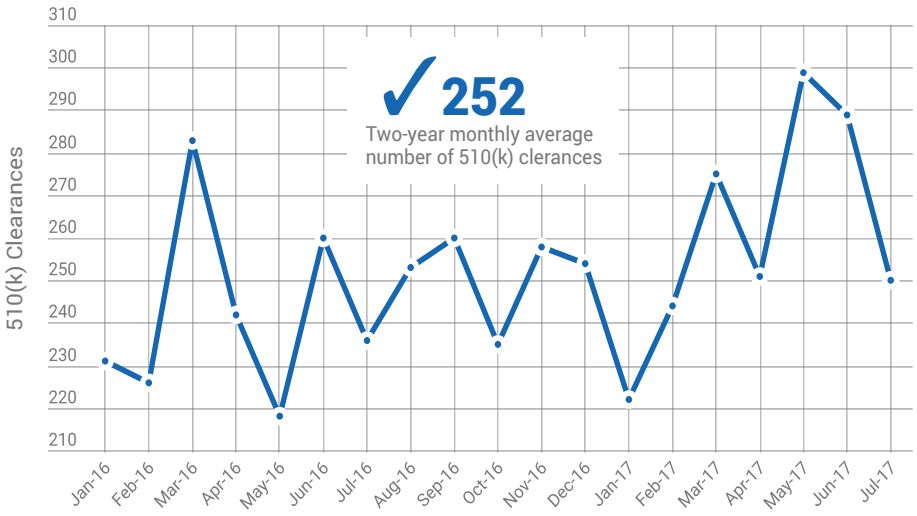
In addition, two minimally invasive surgical valves, Edwards' *Intuity Elite* and **LivaNova PLC**'s *Perceval*, recently gained new-technology add-on payments from US Medicare, providing further illustration that surgical heart-valve replacements are not going away anytime soon. *(Also see "'Sutureless' Surgical Aortic Valves Gain Medicare Bonus Payments" - Medtech Insight, 4 Aug, 2017.)*

There were two *de novo* approvals last month, one for Quantitative Insights Inc.'s *QuantX* computer-aided diagnosis software to assist radiologists in assessing breast abnormalities using MRI data, and another for Safe Obstetric Systems Ltd.'s *Fetal Pillow*, indicated to elevate the fetus' head to facilitate Caesarean Section.

Overall, the volume of novel-device approvals was relatively light in July, with two original PMAs, one panel-track supplement and two *de novo*s. But, year-to-date, FDA is close to on pace with the past two record-setting years. (See Figure 1.)

FIGURE 2

510(k) Clearances, Monthly Totals



Source: Medtech Insight Approval Tracker

Meanwhile, the agency cleared 250 510(k)s in July, close to FDA's monthly average. (See Figure 2.)

Among the devices cleared last month was **GE Healthcare**'s *SIGNA Premier* wide-bore 3.0-Tesla MRI system, based on a four-year collaboration with the US National Football League (NFL) and other research institutions to design a new imaging tool to aid researchers in the detection of biomarkers for the potential diagnosis of mild traumatic brain injury.

FDA also approved 50 non-panel-track PMA supplements in July (excluding 30-day notices). The monthly-total average for these supplement approvals through July is about 71.

Published online 08/09/17

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Abbott Launches Feasibility Trial Of Tricuspid Version Of MitraClip

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Abbott Laboratories Inc. announced the start of the TRILUMINATE feasibility trial evaluating a minimally invasive clip-based *Tricuspid Valve Repair System* (TVRS) to treat tricuspid regurgitation that's based on the same technology as Abbott's established *MitraClip*, which treatsmitral valve regurgitation.

The tricuspid valve is the valve between the right ventricle and the right atrium, and tricuspid regurgitation leads to blood flowing backward into the right atrium, which can lead to heart failure, atrial fibrillation and eventually increase the risk of mortality. Like MitraClip, TVRS is a minimally invasive catheter-developed clip that simply clips two of the valve leaflets together. This reduces flow in both directions, but has been shown in multiple clinical trials to improve patient outcomes, and Abbott and the TRILUMINATE investigators expect TVRS to improve outcomes in a similar way.

The results of the 75-patient trial will evaluate the safety and effectiveness of the TVRS for treating symptomatic moderate-to-severe tricuspid regurgitation (TR) in patients currently on medical management who are deemed appropriate for percutaneous transcatheter intervention. The primary endpoints will be the number of patients whose tricuspid regurgitation has been reduced by at least one grade within 30 days of treatment, and a composite of major adverse events within six months.

The first patient in the trial was treated at Abbott Northwestern Hospital in Min-

neapolis by Paul Sorajja, one of the trial's primary investigators, Abbott announced on Aug. 9. The TRILUMINATE results will support a CE-mark application in Europe, as well as an application to US FDA for an investigational device exemption to run a pivotal US trial. The TRILUMINATE investigators expect the primary outcome data to be collected by August 2018.

Sorajja told *Medtech Insight* that tricuspid valve disease is less common than mitral and aortic disease – both of which are being addressed by transcatheter technologies already – but that it is still highly prevalent and in need of a solution. About 15% to 20% of those people with mitral regurgitation in need of repair have severe TR, and there is no reliable data on how many people have moderate TR.

"The bottom line is that when you look at the field of valve therapy, a lot of things are moving toward transcatheter work," Sorajja said. "It's very clear that the field of transcatheter valves will be limited if there are no tricuspid valve therapies, simply because patients who have tricuspid regurgitation that is untreated do very poorly, and their hazard for death is two to three times worse when there's presence of TR versus none. It's important for the whole field – as well as for the patients – that there are minimally invasive or catheter-based options, and the MitraClip, which has been redesigned for the tricuspid valve, is meant to be that way."

Patients with tricuspid regurgitation commonly also have left-sided heart disease and mitral regurgitation, Sorajja explained. This causes pressure to build up in the lungs causing pulmonary hypertension, which leads to tricuspid valve regurgitation. However, some patients develop tricuspid regurgitation because of abnormalities of the valve itself or lung disease.

TRILUMINATE will enroll patients with moderate to severe tricuspid regurgitation for any of these reasons, and regardless of their surgical risk. This is unique in TR trials, Sorajja said "Most of the research on TR has been in the context of left-sided disease, so the TRILUMINATE trial is incredibly unique, because its investigating the impact of treating TR by itself. This is pioneering. This is addressing a complete clinical question that has gone unexamined."

He pointed out that the current professional practice guidelines for the treatment of tricuspid regurgitation are "incredibly deficient" because they only focus on treating TR in the context of surgical therapy for the mitral valve. There are currently no guidelines for treating TR by itself, because it has not been studied very much, he said. Because of this lack of research, one of the goals of TRILUMINATE will be to better understand the relationship between a reduction in tricuspid regurgitation and patient outcomes. Currently, there is little understanding in medical literature of how much TR should be considered "acceptable" and how much reduction in TR must be achieved by a repair to improve outcomes.

Sorajja expects the trial enrollment to proceed quickly because the inclusion criteria are broad and "there are a lot of motivated people in this field."

MULTIPLE APPROACHES TO TRANSCATHETER TRICUSPID REPAIR

Abbott is not the only company developing a minimally invasive device for tricuspid repair. In November 2016, **Mitralign Inc.** reported the successful first procedure with its *Trialign* system, a catheter-based system for implanting two anchors and a suture that pulls the sides of the tricuspid annulus closer together. The SCOUT II trial is evaluating Trialign in 60 patients with symptomatic chronic functional TR – TR caused by tricuspid annulus dilation and right ventricular enlargement and dysfunction – with a minimum of moderate tricuspid regurgitation.

Likewise, Galway, Ireland-based **4Tech Inc.** is developing the *TriCinch* system, which puts tension on an anchor on the tricuspid annulus to make it smaller. The 24-patient PREVENT trial evaluating TriCinch in functional symptomatic tricuspid regurgitation has completed enrollment but has not yet reported results. *(Also see "4Tech Takes On "The Forgotten Valve" With TriCinch Transcatheter Repair System" - Medtech Insight, 17 Mar, 2016.)*

And **Edwards Lifesciences Corp.**is developing the *Cardioband* technology, acquired as part of its 2016 acquisition **Valtech Cardio Ltd.**, to treat both mitral and tricuspid regurgitation. Cardioband is an annuloplasty ring that can be delivered by a catheter through a transseptal approach. *(Also see "Edwards To Pay Up To $690m For Cardioband-Maker Valtech" - Medtech Insight, 28 Nov, 2016.)*

Published online 08/10/17

START-UP SPOTLIGHT:

Rapid Medical, A New Era Of Neurovascular Devices

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Israel-based **Rapid Medical** is developing *Comaneci* adjustable remodelling mesh to treat brain aneurysms and the *Tigertriever* stent retriever to treat ischaemic stroke.

The company was founded in 2008 when the father and son team of Shimon and Ronen Eckhouse recognized the potential for dramatic growth of neurovascular treatments. "The neurovascular field is the future of endovascular treatment and in many ways resonates with the cardiology of two years ago," CEO Ronen Eckhouse told *Medtech Insight*. "Neurovascular treatment will be the next cardiology, so that was basically the notion with which we started the company. We had a few ideas, all in the ischaemic stroke market, and then we started working on our first device, Comaneci, for aneurysm treatment. And then out of the Comaneci

came our second device, the Tigertriever, which is for treating ischaemic stroke."

Accounting for more than 85% of strokes, ischemic stroke is the most common type of stroke, caused by an obstructed artery that supplies blood to the brain. For years, the gold-standard treatment was the clot-dissolving medication called tissue plasminogen activator (or Alteplase IV r-tPA). The medical therapy is the only US FDA-approved treatment administered for ischemic strokes, and works by dissolving the clot and improving blood flow to the part of the brain being deprived of blood, but the drug must be administered within four hours of the stroke and is not effective in all cases.

In 2015, the mechanical thrombectomy market experienced a major breakthrough following favorable results from five studies showing stent retrievers could improve patient-outcomes following ischaemic stroke. Stent retrievers are catheter-mounted scaffolds that grab large clots from a blocked artery within the brain.

Official guidelines recommend the procedure should be done within six hours of acute stroke symptoms, and only after the patient receives tPA. To remove the clot, a catheter is thread through an artery in the groin up to the blocked artery in the brain. The stent opens and grabs the clot, allowing physicians to remove the stent with the trapped clot.

"The big difference with our devices is they're user controlled so the physician can have real-time control and decide things like how much to expand to the device, how much force should be applied to the clot, so it's much more interactive," Eckhouse said.

Comaneci is a controllable, aneurysm neck–bridging mesh device intended to provide temporary assistance for embolization of intracranial aneurysms. The device is based on Rapid's *FlexiBraid* technology, a braiding capability that allows the device to be adjusted by the operator. Three versions of the device are currently available, each designed to treat aneurysms in different anatomical locations. Tigertriever is a controllable, stent retriever that can be adjusted by the physician during embolization procedures. While standard devices are self-expanding stents, Rapid's products can be controlled by the physician to fit the dimensions of blocked blood vessels.

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Contact: Ronen Eckhouse, CEO

Industry Segment: Neurovascular devices

Business: Neurovascular interventional devices: *Comaneci*, a controllable, aneurysm neck–bridging mesh device intended to provide temporary assistance for embolization of intracranial aneurysms, and *Tigertriever*, a controllable stent retriever that can be adjusted by the physician during embolization procedures

Founded: 2008

Founders: Shimon Eckhouse, Ronen Eckhouse

Employees: 20

Both Comaneci and Tigertriever are CE-marked, and currently available for sale in Europe and Israel following a commercial launch in 2016. In July, the company completed a Series B financing of $9m, led by BRM group from Israel and Shanghai-Israel Investment Fund from China, with participation from Winnovation and Gefen Capital. The funds will be used by the company to advance European commercialization of both devices, including building a direct salesforce in Germany.

"There are two things that make Germany different to other countries," says Eckhouse. "Firstly, it's a big market so for that reason most companies sell direct, and as a result there are not many good distributors available. The second thing is, prices in Germany tend to be low, so the margin is more difficult to share with another party. For these two reasons – both the size and the price – it makes sense for us to go direct."

Rapid also plans to initiate the TIGER clinical trial to support US regulatory clearance of both devices. The study will begin enrolling patients at selected medical centers in the US, Europe and Israel in the first half of 2018.

"We've seen a lot of enthusiasm from various medical centers that want to join the study, and we've already recruited leading centers. Since commercializing in Europe, we've received very positive feedback from physicians using the device. Another big bonus of our products is they are fully visible, so you have control and visibility," Eckhouse said. "It's a relatively easy sell, and the devices are performing better commercially than we would have anticipated so far."

With stroke being the No. 1 cause of death in China, Rapid's neurovascular technology has attracted Chinese investors who are recognizing the big opportunity within this disease market. Heart disease has been on the rise in China over the past 20 years, with more and more people experiencing high blood pressure, high cholesterol, high blood glucose and soaring obesity levels.

"When Far East anatomical differences and Western habits come together, the neurovascular system is not very happy. When you add pollution and smoking in, too, it creates a dangerous mix, and smoking is a very big issue in China," Eckhouse said. "Our investors in China were specifically looking for a neurovascular company which has commercially proven its devices in other places in the world and had excellent market feedback. Once they can see that, then they feel much more comfortable taking that technology to China."

Rapid wants to develop a pipeline of neurovascular technologies behind Tigertriever and Comaneci. "The big two buckets for us are commercialization and bringing the devices to the US, but the third one is also building new products," says Eckhouse. "We have developed a very unique technology that allows us to make these products; we manufacture everything on our own and we have several other things we are working on. I think the community will like what we have in development."

Published online 08/10/17

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