By Bicakcilar Corporate Marketing – No:33 October, 2019

Clinical Trends Shaping the Medical Device Space in 2019

Perhaps no other sector of the life sciences is experiencing as much growth, transformation and opportunity as the medical device industry. Globally, the medtech arena is expected to grow every year by more than 5 percent, with annual sales worldwide reaching $800 billion by 2030, according to KPMG.(1) In the U.S. alone, Fitch Solutions estimates that the medical device industry with expand from $164 billion in 2018 to $208 billion in 2023.(2)

From the effect of new technologies on clinical data management, to an ever-changing regulatory landscape, to increased emphasis on the trial master file (TMF) Reference Model as an industry standard, medtech manufacturers have their hands full just keeping up with the latest clinical trends.

This article will provide an overview of some of the top clinical trends influencing the medical device sphere now and moving into 2020.

#1 **Technological Impact on Clinical Research**

As has been the case for several years, major tech companies have seen the value and growth potential of the health care and medical device sectors and are investing heavily to move into those industries. One of the largest industries worldwide, health care rakes in $2.8 trillion annually in the U.S. alone, according to The Verge.(3) Blurring the lines between retail, IT and health products, behemoths like Google, Apple, Facebook and Amazon are emerging as key players in the medical industry and clinical research fields as consumers seek access to affordable health care.(4) These companies are utilizing cloud storage, wearable technologies and artificial intelligence in a way that is transforming the way people view and use medtech.

The development of personal health tech, such as the Apple Watch, which received Class II medical device approval from the U.S. Food and Drug Administration (FDA), is further evidence of the impact tech is having on clinical research. As more health-related personal devices enter the market there will be greater demand for expanding clinical data analytics and research in innovative ways, including the potential to be able to conduct entire clinical trials in the cloud to significantly reduce projected enrollment times, according to Deloitte.(6)

#2 **The Effects of EU MDR/IVDR on Clinical Research**

Europe's new Medical Device Regulation (MDR) and In Vitro Diagnostic Medical Device Regulation (IVDR) replace the current Medical Device Directive in May 2020 (MDR) and May 2022 (IVDR), meaning that legacy devices without the MDR CE mark won't be able to be sold in the European Union (EU), and thus won't be available in member state health care systems.(7) Device makers have to act quickly to recertify their devices against MDR. The new regulation is intended to create greater transparency of the approval and usage of devices while improving patient experiences and outcomes. MDR/IVDR will involve several changes for medtech makers, including increased clinical data requirements for medical devices. Essential premarket conformity requirements, called general safety and performance requirements, increase considerably under MDR. As such, manufacturers need to plan for and apply a systematic approach to continuously generate, collect and analyze clinical data pertaining to a device as part of postmarket follow-up (PMFU) and surveillance to verify a device's safety and performance. The summary of this data will be collected and archived by a manufacturer's Notified Body and submitted to the European Database on Medical Devices (EUDAMED).

Conclusion

Device manufactures can well position themselves in the marketplace by staying abreast of the latest industry movements that include the implications of advancing technology; the ever-changing regulatory landscape such as Europe's MDR; and an intensified focus on the trial master file as a single point of truth.

Siemens launches Acuson Redwood ultrasound system

Siemens Healthineers has launched an ultrasound system, Acuson Redwood, which offers a medical imaging solution for clinical departments including, radiology, cardiology and obstetrics / gynaecology.

Acuson Redwood holds the US Food and Drug Administration (FDA) approval and European CE-Mark. It expands the company's Acuson portfolio, which consists of Sequoia and Juniper systems.

The system is portable and lightweight with multiple artificial intelligence (AI)-based tools for smart workflows and cardiology features.

Transducers integrated into the device include micro-pinless technology and single crystal transducers for improved image quality.

Acuson Redwood also comprises coherent image formation (CIF) technology for image quality and UltraArt Universal Image Processing for image choices.

Siemens Healthineers ultrasound head Robert Thompson said: "Chronic diseases often require more imaging and additional follow up which drives costs. To meet this challenge, we worked together with input from users to transform care delivery with the Acuson Redwood.

"This system is designed to deliver premium image quality, exceptional performance, and greater workflow efficiency within the constraints of limited resources and tightening budgets."

Acuson Redwood comes with Contrast Enhanced Ultrasound (CEUS) and Shear wave Elastography applications for accurate detection and characterisation of lesions.

The applications are also said to minimise the need for invasive procedures.

Moreover, the system has been designed to provide a variety of cardiac assessments. It has a 2D quantitative tool, Velocity Vector Imaging (VVI), to examine global and regional myocardial motion and mechanics.

Additionally, the ultrasound device includes stress echo, along with wall motion scoring analysis and Left Ventricular Opacification (LVO) capability for cardiac contrast agent imaging.

Last month, Siemens introduced two computed tomography (CT) systems Somatom go.Sim and Somatom go.Open Pro, designed for radiation therapy planning.

Robot assistant to improve elderly care in nursing homes

Overworked care staff in nursing homes and hospitals may soon have their workload reduced with the help of a Social & Autonomous Robotic health Assistant (SARA), an innovation supported by EIT Digital.

The SARA Home system is accessible through a computer or tablet and gives nurses and carers access to a personalised profile and health plan for each patient in their care.

Two pilots are currently ongoing in nursing homes in Finland and the Netherlands, with a particular focus on patients in closed psychiatric departments living with first-stage dementia.

Through specific cognitive exercises, patients in these stages are thought to be able to improve their mental and physical condition and avoid or delay the onset of the second, more acute stage of the illness. Due to limited resources in adult care facilities, staff are often unable to spend as much time one-on-one with patients carrying out these exercises as is desirable.

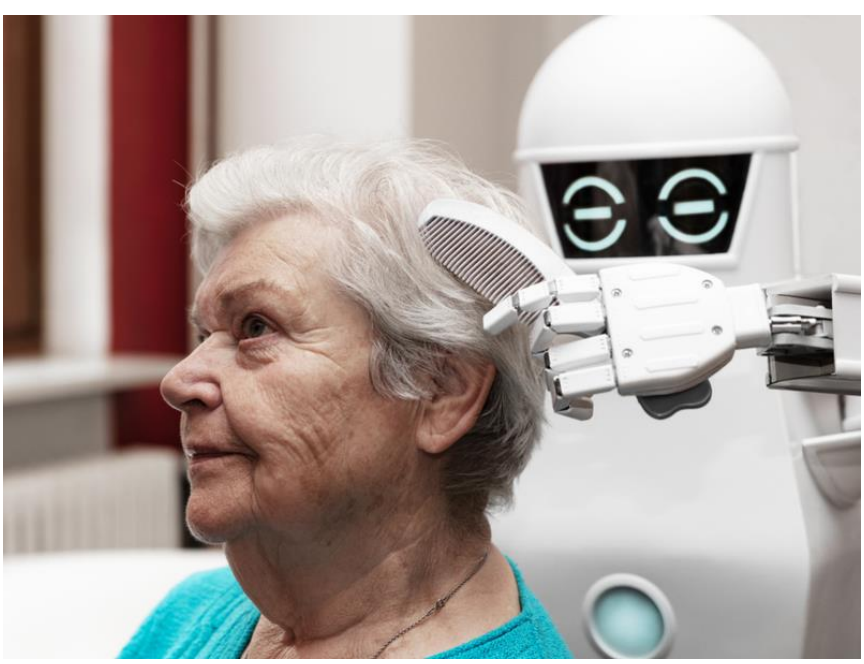
The SARA robotic assistant could take the burden away from carers by interacting with patients and presenting them with exercises designed to improve their condition. It is hoped that this will also help reduce safety incidents resulting from carers' heavy workloads, such as the medication errors 13.8% of nurses deal with weekly, according to EIT Digital.

A consortium of partners has worked on SARA, including Bright Cape, Forum Virium Helsinki, GIM Robotics, Curamatik and TU Berlin.

Bright Cape data scientist Emmy Rintjema said: "We believe that robots could give a great contribution to healthcare, not to replace nurses, but to collaborate with them and reduce their workload, so they have more time to spend with their patients. They might also help reduce the errors due to high-time pressure."

The product is currently still in the prototype stages, and is being fine-tuned in collaboration with the pilot nursing homes. The robotic system will be commercialised throughout Europe in 2020, with Germany, Finland and the Netherlands as the main targets initially.

The developers are also working on an algorithm which will allow robots to move more freely throughout specific areas of a nursing facility.



Corvia Medical heart failure shunt gets breakthrough status in US

Heart devices developer Corvia Medical has obtained breakthrough device designation from the US Food and Drug Administration (FDA) for its InterAtrial Shunt Device (IASD) in heart failure.

IASD is a transcatheter device to treat heart failure with preserved (HFpEF) or mid-range ejection fraction (HFmrEF), with implantation via a small opening in the atrial septum.

It acts as a passage between the left and right atria to allow the left atrium to decompress at rest and during physical activity, reducing left atrial pressure.

Furthermore, continuous and dynamic decompression of the left atrium could improve heart failure symptoms, enable a better quality of life, minimise hospitalisation rates for heart failure and cut the overall cost burden of heart failure patient management.

Corvia Medical president and CEO George Fazio said: “Receiving breakthrough device designation from the FDA underscores the significant unmet need for more effective treatment options for heart failure patients.

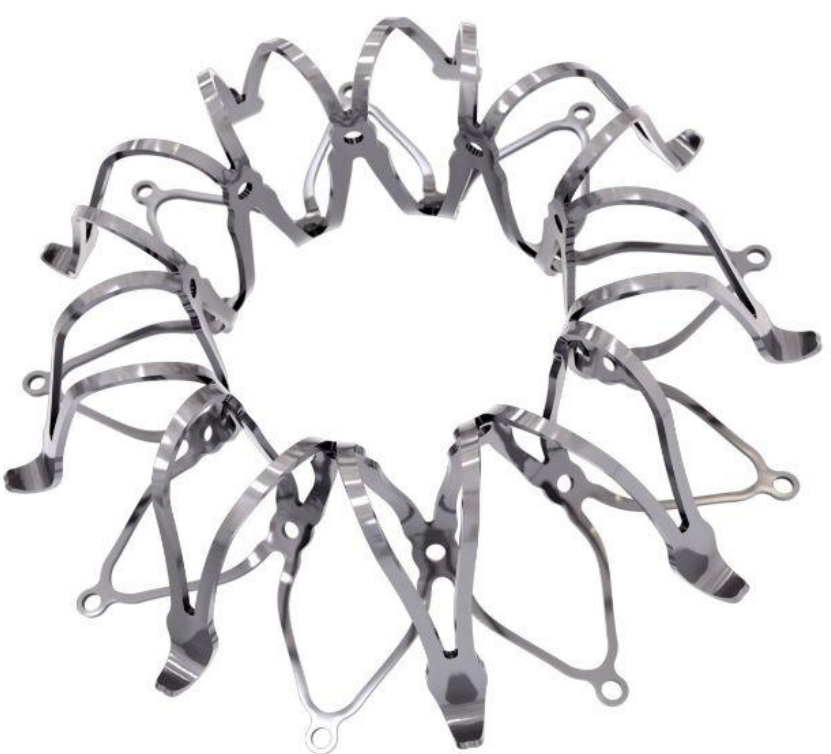
“We look forward to continuing our work with the FDA through our ongoing pivotal trial in more than 100 hospitals, and providing the clinical evidence which will accelerate the timeline to bring the IASD to the US market.”

The FDA Breakthrough Devices Program offers patients and healthcare providers with timely access to medical devices by accelerating their development, assessment and review.

Corvia Medical quality and regulatory affairs vice-president Kate Stohlman said: “The FDA programme should accelerate market access and adoption of novel treatments for heart failure patients in the US.

“Demonstrating reduced recurrent heart failure hospitalisations and improved quality of life for these patients, through rigorous clinical trials that generate real evidence, is the company’s primary objective.”

Currently, the IASD is undergoing a multi-national prospective, double-blind, sham-controlled trial, REDUCE LAP-HF II, in 608 HFpEF and HFmrEF patients across the US, Canada, European Union, Australia and Japan.



Abiomed gets pre-market approval for Impella 5.5 in US

Medical devices maker Abiomed has received pre-market approval (PMA) from the US Food and Drug Administration (FDA) for its Impella 5.5 heart pump in cardiogenic shock treatment.

The minimally invasive, forward-flow device provides coronary flow and renal perfusion. It can be implanted through the axillary artery or anterior aorta, eliminating the requirement for a sternotomy or left ventricle coring.

Impella 5.5 offers full unloading to minimise the heart's oxygen demand, said Abiomed.

Furthermore, the pump comes with SmartAssist, which features weaning algorithms to optimise survival and heart recovery. The functionality also has data informatics such as left ventricular pressure (LVP), end-diastolic pressure (EDP) and cardiac power output (CPO).

The SmartAssist fiberoptic pressure sensor is designed to enable accurate positioning, management and repositioning of the pump in ICU.

Moreover, Impella Connect facilitates the view of the Impella control screen through a website, for tracking and reviewing cases.

FDA approved Impella 5.5 as a temporary ventricular support device for short-term use up to 14 days.

The device will provide treatment for ongoing cardiogenic shock, which occurs within 48 hours after an acute myocardial infarction, open heart surgery or cardiomyopathy.

Patients with cardiogenic shock associated with myocarditis from isolated left ventricular failure, not responding to optimal medical management and standard treatment may also benefit from the device.

According to the company, Impella System Therapy is meant to minimise ventricular work and offer circulatory support for heart recovery and early evaluation of residual myocardial function.

The company is planning a controlled launch of the Impella 5.5 with SmartAssist, which also holds the European CE-Mark, at select hospitals in the US.

Abiomed's portfolio includes Impella heart pumps designed to treat advanced heart failure and cardiogenic shock indications.