INNOVATION ARTICLES
THE IDEA SUBMISSION PORTAL FROM MEDTRONIC

2014 IS OVER. LONG LIVE 2015.

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The year has drawn to a close, and as is tradition we take the chance to look back at the innovations that caught our eye in 2014, and to predict what 2015 has in store for the industry.

WIRELESS PACEMAKERS

The prestigious Cleveland Clinic has tipped leadless pacemakers as one to watch for 2015 1. We wholeheartedly agree, having reported back in June how leadless pacemakers were setting the cardiology field abuzz 2. Medtronic is leading the pack, with positive interim results presented at the 2014 Cardiostim

both bulky implanted batteries and the notoriously fickle leads that feed into traditional pacemakers. The leadless device can be slipped directly into the heart using a catheter, meaning less invasive painful procedures for the patient.

PROSTHETIC HAND TOUCHES, USER FEELS

Medtech hit the headlines in February with news that a sense of touch was restored to a hand amputee using a sensor studded prosthetic hand hooked up to the user's nervous system 3. Four electrodes were implanted into the peripheral nervous system on the upper arm. The volunteer then underwent intensive training with the prosthetic hand, learning how to process the real time sensory information coming from the sensors on the prosthesis. In a video explaining the EU-funded NEBIAS project 4, the volunteer said "the feedback was totally new. You can feel round things, hard things and soft things. I could feel what I was doing instead of looking at what I was doing".

BEATING PARALYSIS

Medtech was back in the headlines in June when the 2014 World Cup in Brazil was kicked off by a 29 year old paralysed man. This remarkable feat was achieved thanks to a robotic exoskeleton from the international Walk Again consortium (coordinated by Duke University, USA). Personal exoskeletons (from ReWalk, for example) are not new. The novelty this time was that the volunteer instructed his exoskeleton to kick the ball using mind control. His brain waves were picked up by a skull cap he was wearing and relayed to the robotic legs via a computer worn in a backpack. The information feed is two way, with the sensory information from the soles of the feet feeding back to the brain.

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In April, a quadriplegic US patient regained movement in his hand after the Neurobridge microarray implanted onto the cortex translated his neural impulses into functioning electrical signals 5. In another US project, four paralysed men regained leg movement as well as partial bowel, bladder and sexual function following implantation of a 16-electrode bridge in the base of the spine which restored signalling from the brain to the legs 6.

We talked to Ingmar de Gooijer from MedTech Europe, an alliance of European medtech companies about how the year ahead. “Our narrative for the coming year is technology enabled healthcare. It‘s going to be a complete convergence of medtech with pharma, diagnostics and even with food and imaging,” he says, “For the simple reasons that governments are increasingly going to pay on outcomes rather than procedures and input. So that will require much more collaboration between industries.”

DIAGNOSTICS

The Deloitte 2015 Global life sciences outlook report 7 predicts that in vitro diagnostics will be the top sector in medtech by the year 2018. De Gooijer agrees. “With all the new players entering the field such as Google and Apple, we see diagnostics becoming more important, because people are using wearables, implantables, monitoring devices etc. How this is going to end up with insurers and privacy issues we‘ll have to see, but we‘re very excited about it.”

Diagnostics is already a hot topic this year with scientists racing to develop fast accurate tests for Ebola. The FDA has already given emergency approval to 5 tests, all based on real time RT-PCR 8. In addition, WHO, MSF and the Foundation for Innovative New Diagnostics (FIND) issued a collaborative call in November for the perfect Ebola diagnostic device 9. They want scientists to develop a device that can be used without laboratory infrastructure or a power supply, that produces results in less than 30 minutes and has no biosafety requirements except personal protection equipment.

BIG DATA, BIG SECURITY

Healthcare has truly gone digital and the industry is drowning in data from digitised health records, telecare systems, fitness and diagnostics devices. And devices are now linking up in body area networks (BANs), as we reported earlier this year 10. But with this growing connectivity comes vulnerability, to the point that USA vice-president Dick Cheney disabled the wireless function of his pacemaker as a security measure 11. Recent scares about the security of devices such as insulin pumps, pacemakers and hospital equipment had led to a general tightening of device security as well as more protection against malware. This is now enforced by FDA guidelines 12. According to de Gooijer, potential problems in tightening security include “proprietary issues, legacy issues, platform issues, role of responsibility problems. It‘s a very complicated debate,” he says, “but regardless of whether industry wants it or not, it‘s going to happen.”

3D BIOPRINTING

The hype around 3D printing has been building in the medial world, with bioprinting finally finding its stride. Organovo, USA is the world‘s first commercial bioprinting company. In November, they launched the multi award winning exVive3DTM Human Liver Tissue system 13, featuring the various subtypes of liver cells arranged in a micro and macro structurally accurate tissue. These systems could eventually replace animal testing for screening new drugs for toxicology and other preclinical tests, but Organovo are aiming higher. Their long term goal is to bioprint implantable tissues and organs to treat transplant patients, using the patient's own cells as a starting point. This would increase the likelihood of rejection and would avoid lifelong anti-rejection immunosuppression therapy.

We can expect to hear more about bioprinting in the coming year with the recent launch of two commercially available 3D bioprinters 14. According to 3Dyanic Systems, a spin out from Swansea University in Wales, the Alpha bioprints bone tissue and the Omega produces soft tissues.

DIY BIOLOGY

While we're on the subject of hacking and implanting synthetically generated organs, let's talk about biohacking. Do it yourself biology (DIYbio) is taking off. Hubs are springing up worldwide, including the largest European hub in Paris 15. DIYbio has already produced a low cost crowd-funded open-source polymerase chain reaction machine 16. It's only a matter of time before the DIYbio revolution, with its low-cost open-source community ethic, starts to generate innovations and start-ups that will make major medtech players sit up and take notice. Eyes should be kept firmly on this ball in 2015. De Gooijer is optimistic about the potential for DIYbio. "I hope it would disrupt the whole model," he says, "I only encourage innovation whether it comes from a garage or from a big company. It's not something we would view as a threat but more as an encouraging outlook."

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13 ORGANOVO - CHANGING THE SHAPE OF MEDICAL RESEARCH AND PRACTICE

14 An Introduction to Swansea University spinout, 3Dynamic Systems Ltd

15 La Paillasse - Anyone can be a Biohacker!

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PATIENTS AND CAREGIVERS

Overview

HEALTHCARE PROFESSIONALS

Overview

ABOUT MEDTRONIC

Overview

Leadership

Mission

Facts and Stats

Citizenship

Career Opportunities

Locations

Medtronic Europe

TRANSFORMING HEALTHCARE

Transforming Healthcare Overview