



*“Open platforms have clear advantages for developing technology faster and getting it to market”*



# HEALTH.E LIGHTHOUSE

## “MOORE FOR MEDICAL”: ACCELERATING INNOVATION IN MEDICAL DEVICES

INTERVIEW WITH RONALD DEKKER *by* CHRIS HORGAN

*Following on from the launch of the Industry.E and Mobility.E Lighthouse initiatives, a third beam of light is shining onto the healthcare domain: Health.E. Its aim is to enable affordable healthcare in an ageing society as healthcare moves relentlessly from centralised symptomatic treatment towards preventive, predictive and participatory care. Researchers in academia and industry are developing technologies and systems that will keep people healthy for longer and allow patients to remain independent as long as possible in their own home environment. Leading the ‘construction’ of this Lighthouse is Ronald Dekker of Philips Research, whose work focuses on the integration of complex electronic sensor functionality on the tip of the smallest minimally invasive instruments. This part-time professor in flexible and stretchable electronics at TU Delft explains some of the principles that underlie this third member of the Lighthouse family and the challenges it faces.*

## **PROPELLING INNOVATION**

"Our aim, first and foremost," Dekker begins, "is to make the ECS community aware of the existing and arising opportunities in Health by collecting and defining roadmaps for these arising opportunities. The second goal is to stimulate the development of open technology platforms. The shift towards open technology platforms, supported by roadmaps, will generate the production volumes needed for sustained technology development, which will result in new and better solutions in the healthcare domain. And if we can achieve these two goals, this will help to propel innovation along the whole medical instrument supply chain and provide solutions for a wide range of health-related societal challenges. It will keep track of a person's health or the response to medicines by continuous monitoring with smart body patches, which will reduce the need for hospitalisation. Miniaturised smart catheters and laparoscopic instruments will further facilitate keyhole surgery. Implantable neuromodulation devices will control specific organs, avoiding the side-effects of conventional medication while organs-on-chips will combine the latest developments in stem cell research with micro-fluidic devices for the development of new precision medicines. Finally, the data collected with these systems and other diagnostic equipment will be used to create digital representations of persons that can be used to predict in-silico the effectiveness of medicines and therapies."

## **GETTING TO MARKET**

Industrial innovation in medical devices and systems is lagging behind in comparison to the innovation speed in the consumer electronics industry. This is not only caused by strict quality regulations, but also by the fact that the volumes are often small compared to consumer products, which requires significant investments in non-standard manufacturing technologies. Many breakthrough innovations therefore simply do not make it to the market and end up in the "valley of death."

The Health.E lighthouse will accelerate the innovation in medical electronic systems by:

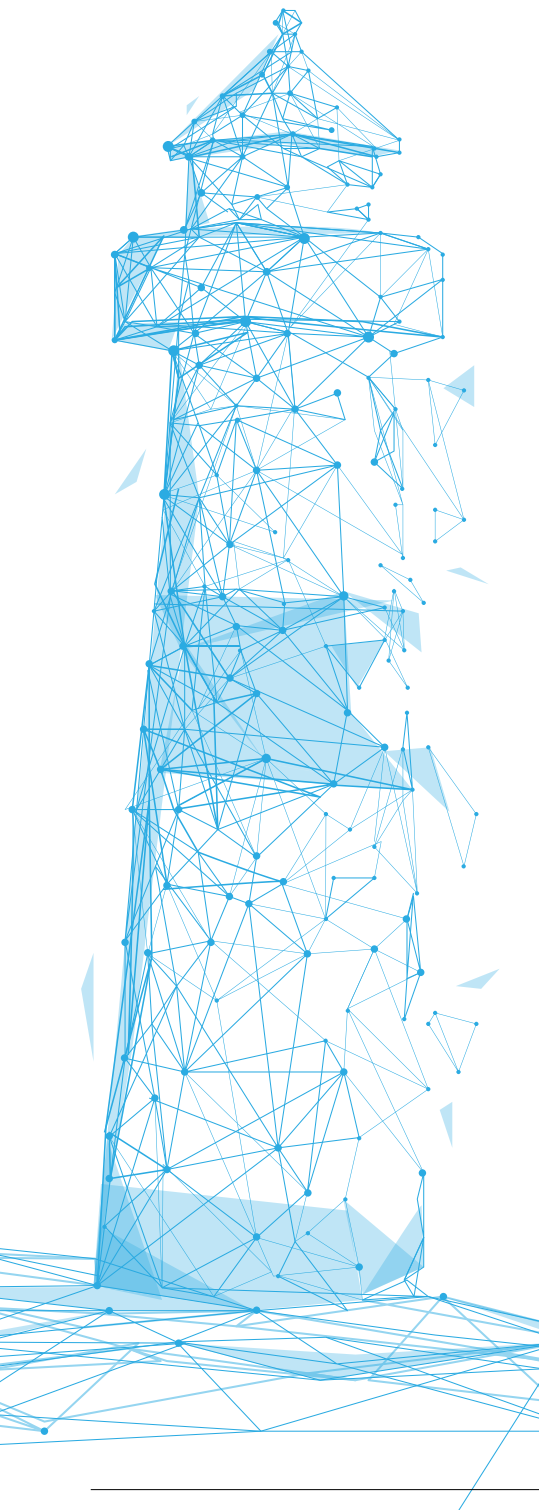
- + Serving the needs of medtech and pharma by ECS (electronic components and systems) solutions;
- + Stimulating the open technology platform model;
- + Collecting and defining roadmaps for arising opportunities in the Health domain;
- + Reducing fragmentation and duplication by creating a sustainable ecosystem that covers the complete value chain, consisting of technology suppliers, device manufacturers and end-users, transcending project boundaries
- + Reaching out to other European initiatives and communities.

## **LACK OF TANGIBLE PRODUCTIVITY**

There is a very noticeable 'elephant in the room' anyone involved in miniaturised, or smart health technology innovation will understand. The problem is that the huge amount of technological innovation that is possible, is not appearing in our homes and hospitals. Too often, innovation remains a concept on paper and doesn't make it past the first challenges toward a useable, beneficial technology. Whilst there is no shortage of ideas and research for this new pedigree of medical technology, there is a realisation that manufacturing it can fast become impractical and overly expensive. This is one of the biggest challenges Dekker has identified. "At the moment, every university and every research institute is investing a lot of effort into research into advanced technological medical devices because it's assumed everyone will see the necessity of that. However, if you comprehend the sheer amount of money that is going into smart healthcare and then you see what is reaching the market, in reality it is very, very little. There are significant challenges that need to be tackled for this vision of our healthcare future to take shape."

## **PLAYING THE NUMBERS**

Whilst smart healthcare technology is feasible, for it to become a reality depends on combining standard semiconductor manufacturing with materials like polymers, uncommon metals and sometimes even



proteins. These devices will use new packaging techniques involving advanced moulding, micro-fluidics and heterogeneous integration. Therefore, to make these devices requires specialist knowledge and adherence to strict regulations. Manufacturing such devices can also be prohibitively expensive when starting from scratch, which is offputting for start-ups, innovators and entrepreneurs. "Where microfabrication is involved, developing the basic underlying technology becomes very expensive, very quickly, and you can only afford to do it if you have enough turnover to justify those developments," Dekker explains. "In consumer markets there are those high volumes needed – for example, making microphones for mobile phones or accelerometer sensors. In markets with high consumer demand, those high volumes make it justifiable and if you have a good business plan it is not so difficult to get the money to do that innovation but if you compare that with the medical domain, the volumes for applications are relatively small. That's why there is this challenge in the sector." A significant problem is justifying relatively small volumes with a disproportionately expensive and technical production line. A new approach is needed.

### **SHARING PLATFORMS, SAVING COSTS**

If a stumbling block for progress is the 'how to' with manufacturing and the large expense of creating a specialist pilot line, what's needed is a pre-existing pilot line open for third parties, with the express purpose to help develop these kinds of innovations and to manufacture technologies that can be shared for different applications. It was while working in the InForMed project aimed at developing a new kind of smart catheter for better treatment of heart arrhythmias, one that could measure the depth of ablation, that the team involved had a 'lightbulb' moment about how the nature of innovation in the medical device sector needed to change.

Dekker: "We developed smart catheters but we thought about it and realised that the way to go forward was to open up these technologies and offer them to other companies for use with their products. This would generate volumes,

making it feasible to do sustainable, continuous innovation. It had not been part of our original plan and this kind of offer is actually something very new among medical device manufacturers. It is certainly not customary in the medical domain. It can be hard to persuade people that this really is an open technology, a way to bring innovation to the market."

As one of the biggest issues with development is generating volume to justify the cost of creating the pilot line, a good way to tackle this is to create open platforms, to share the technology – meaning the pilot line will continue to be in use with various innovative projects able to use the same initial technology, as a standard requirement. This will shift the uniqueness of a device from the technology inside it to the application of it and the design of the device around it. This is another way for innovation to speed up, to be more efficient with the processes toward a product launch. For example, advanced devices for electrophysiology that make advanced drug safety testing available at earlier stages in a drug's development, deep brain stimulation via minimally invasive neurosurgical therapy or a nano-electronic platform for detecting bacterial infections and smart body patches. An example of the success and far-reaching potential in this approach can be demonstrated when we look at a project that is developing body patches that conform to and monitor the body. Whilst we are used to seeing technology that can sense things that are on the surface of the body, like a pulse, the arrival of affordable ultrasound devices means that we can create devices that can look inside the body.

### **A DIFFERENT APPROACH TO INNOVATION**

A series of European projects grouped in the Health.E Lighthouse initiatives is now beginning, led by the POSITION (ECSEL) project that is developing the TRL8 platform technologies for the next generation of smart catheters and implants. It is much more the 'open platform' that was envisaged. The same applies for the ULIMPIA (PENTA) project where an open technology platform will be developed for ultra-sound body patches. A

supporting Lighthouse project is ORCHID (H2020) where a European roadmap for Organ-on-Chip is being defined, and in the future, other projects will be added to the Lighthouse initiatives. Key to success for progress in the sector is that the projects provide a way to accelerate innovation, facilitating methods that work, pull designs off the drawing board and pushing them into production.

### **LIGHTING THE WAY**

"Open platforms have clear advantages for developing technology faster and getting it to market" Dekker stresses, "and what the Health.E Lighthouse initiative can do is to provide the means to advance and refine the methodologies, thereby stimulating the development of open technology platforms for medical devices and systems. There is no better way to justify the value of research into new technologies than by bringing innovation to market. This is what makes the Health.E Lighthouse so crucial – it champions a coordinated approach to produce new technologies more consistently and also ensures there is a broad scope of innovations that can benefit from standardisation of underlying technologies."

