Health.E Lighthouse illuminates a path to market for smart health innovation

Standardisation and collaboration in the electronic medical device industry is necessary so that innovations can be commercially viable. This is the focus of work in the **InForMed** project and projects within the **Health.E Lighthouse initiative**, such as **ULIMPIA** and **POSITION**.

Medical technology is changing in nature. It's becoming smaller, smarter and even disposable. Future devices should be less invasive and easy to use, whether they are used at home or in a hospital. With a rapidly growing population that is living longer and healthcare institutions stretched to capacity, it is widely understood that healthcare innovation and smart medical device technology will come into its own as an answer to healthcare provision. Much of the smart technology we are expecting to see is miniaturised, so it's versatile and mobile.

Microelectronic and micromechanical devices of the future will be attached to the body or placed inside the body to take measurements and make an analysis, as opposed to the traditional large, fixed-in-position machines we see installed in hospitals.

Micro fabricated devices could revolutionise medical care with equipment like ultra-sound, bioelectronic medicines, continuous monitoring, Organ-on-Chip and eHealth. If Europe is to embrace the development of these new technologies, it would mean securing its stake and market share in the medical equipment sector. However, to do so requires not only consideration of the technology that is possible but also how such technology will be manufactured.

The numbers game

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 Ronald Dekker at Philips Research, 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," Dekker explains.

There are significant challenges that need to be tackled for this vision of our healthcare future to take shape. 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 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 off-putting 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," said Dekker. "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.

To accelerate innovation in the medical domain, we should move toward **open technology platforms,** to share the platforms of technology among the many different end users. People can then use those open platforms to build innovative applications. If we can work together towards technology platforms that can be shared, innovators can put all their energy into **thinking about the application.**

"Moore for Medical"

Sharing the platforms, saving the costs

If a stumbling-point 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.

The Health.E Lighthouse initiative that was established by the ECSEL Joint Undertaking, ensures there is a broad scope of innovations that can benefit from standardisation of underlying technologies. It also helps with the extra complications beyond the technology itself, like legislation and IP management.

The Health.E Lighthouse carries forward insight brought about during the InForMed project, where the initial focus for a demonstrator product was to develop a new kind of smart catheter, for better treatment of heart arrhythmias, that could measure the depth of ablation. Whilst working on this, the team involved had a 'light bulb' moment about how the nature of innovation in the medical device sector needed to change.

Dekker said: "We developed smart catheters but we thought about it and decided the way to go forward was to open these technologies and offer them to other companies, so they can use them for their products. This would generate volumes, making it feasible to do sustainable, continuous innovation. It was not an idea in our original plan and this kind of offer is something very new among medical device manufacturers, it's not customary to do this in the medical domain. It can be hard to persuade people that this really is an open technology, but this is 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, that can 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.

There were several demonstrator products the InForMed project focused on. 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, a nano-electronic platform for detecting bacterial infections and smart body patches, amongst others.

An example of the success and far reaching potential in this approach can be demonstrated when we look at the project that's 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 – with the arrival of affordable ultrasound devices, we can create devices that can look inside the body.

Minimal invasive interventions aided by smart catheters have drastically reduced hospitalisation with improved outcome for patients.

NovioScan is the first company to launch an ultra-sound smart patch product designed to help young and elderly fight incontinence.

Novioscan's SENS-U ultrasound body-patch supports people who do not sense a full bladder. (website: novioscan.nl)

Companies working with the InForMed pilot line have benefited through the development of their products which in turn will reduce the strain on healthcare provision. For example, take the partner that created a smart dressing with integrated sensors and electronics to monitor the acidity, humidity and temperature of chronic wounds to detect infection. This dressing will reduce the need for regular inspections by hospital workers.

Each of these innovations has long-term implications for transformation in healthcare provision and the results are tangible.

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"The difference is in the design and also in the algorithms and software. This is another example where you are trying to move away from every company making its own solution, where you can have open technology platforms that are offered to multiple end users, and where the IP is shifting from this specific technology implementation to software algorithms and design."

The InForMed project and the Lighthouse initiative that are now underway, essentially remove the barriers to manufacturing and offer a service to help innovators take the first steps to turn their inventions into viable businesses. The wider impact this approach will have, is to accelerate innovation in a sector that has traditionally suffered from being unable to manufacture the devices that have been conceptualised.

Rather than having **ten different companies** all **developing their own patch technology with ultrasound,** what we are trying to do with this, is that we are **developing a platform with a programmable device,** where you can put one in or two in or three in, depending on what you want to do.

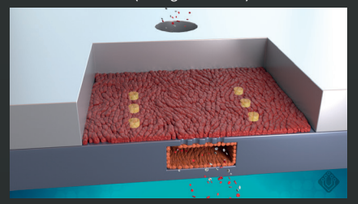
If we can work together towards technology platforms that can be shared, innovators can put all their energy into thinking about the application," Dekker explains. "Rather than having ten different companies, all developing their own patch technology with ultrasound, what we are trying to do with this, is that we are developing a platform with a programmable device, where you can put one in or two in or three in, depending on what you want to do. For instance, you might have one company investigating bladder control and they have one ultrasound device that looks at the bladder. Another company, however, might want to carry out baby monitoring and so they need to image the baby in the best position to pinpoint the heartrate. In this case you might conclude, you need to have multiple transducers in such a patch – but the technology platform is the same in both devices.

A different approach to innovation

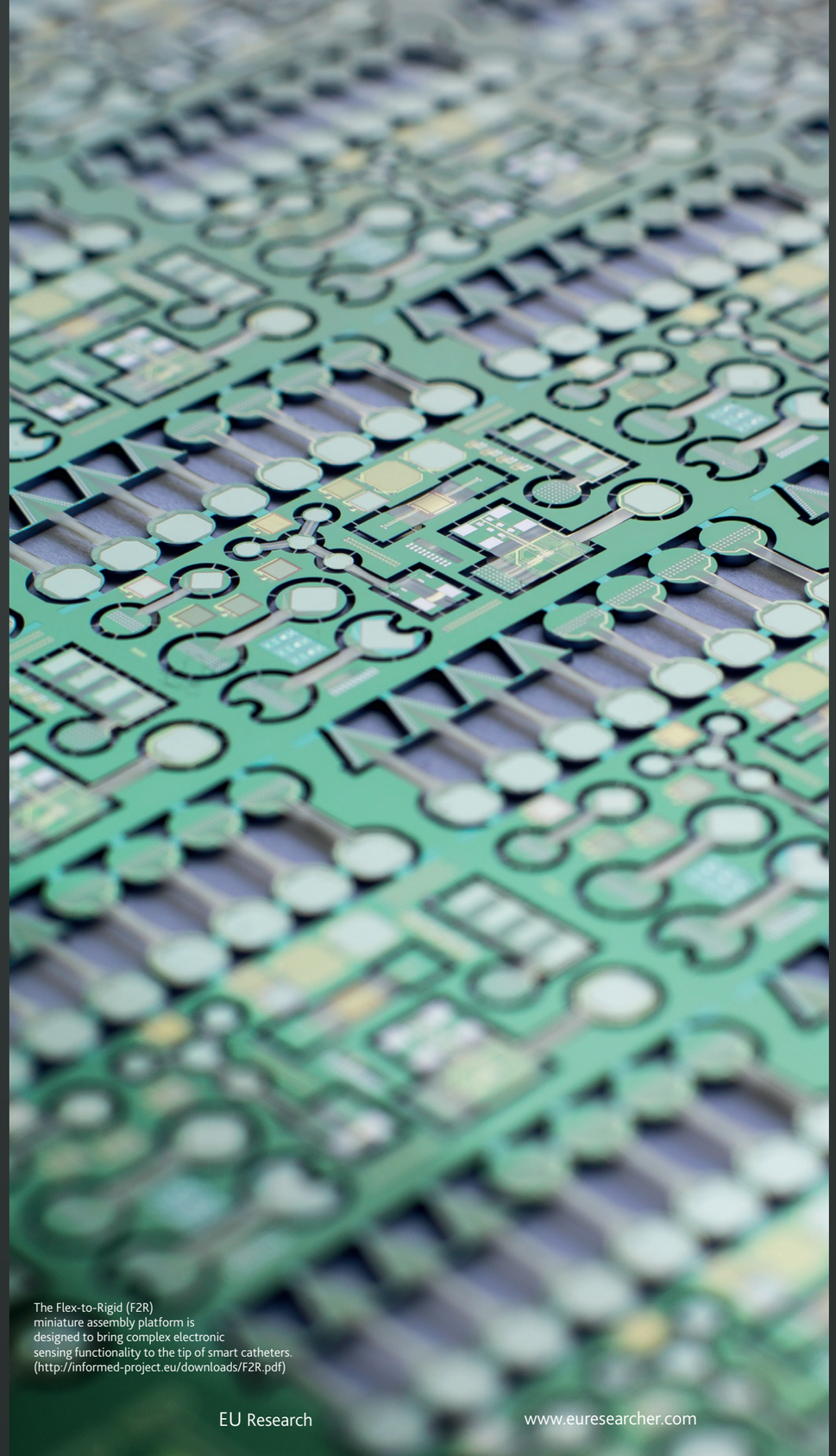
As InForMed draws to its conclusion, a series of European projects, grouped in the Health.E Lighthouse initiatives are now beginning. The foremost is the POSITION (ECSEL) project. Whereas in InForMed researchers realised the infrastructure and manufacturing networks needed coordination to make medical devices, the POSITION project goes further to develop 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, the projects provide a way to accelerate innovation, facilitating methods that work. They pull designs off the drawing board and push them into production.

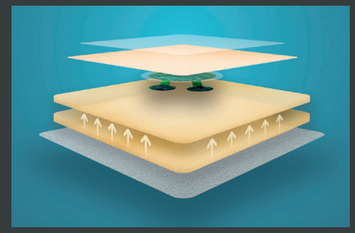
Organ-on-Chip devices like this one developed in InForMed and produced by BI/OND will result in better and safer medicines (www.gobiond.com).



In the InForMed project (ECSEL) an ablation catheter has been developed that monitors the depth of the lesion during an ablation to treat heart arrhythmias.



The Flex-to-Rigid (F2R) miniature assembly platform is designed to bring complex electronic sensing functionality to the tip of smart catheters. (http://informed-project.eu/downloads/F2R.pdf)



Smart bandages and plasters monitor the condition of chronic wounds eliminating unnecessary painful manual inspection.

Lighting the way for all industries

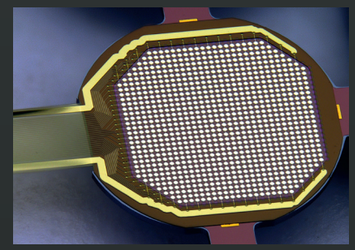
Open platforms have clear advantages for developing technology faster and getting it to market and The Health.E Lighthouse Initiative provides the means to advance and refine the methodologies.

The Lighthouse concept is introduced by ECSEL Joint Undertaking to signpost specific subjects of common European interest that call for coordinated activities. At the moment the Lighthouse initiatives include Health.E, Mobility.E and Industry4.E.

Whilst Health.E stimulates development of open technology platforms for medical devices and systems, Mobility.E is focusing on the deployment of zero emission/zero accident mobility systems for intelligent vehicles, and the Industry4.E initiative is working on platforms for 'digitalisation' of industry.

There is no better way to justify the value of research into new technologies, than bringing innovation to market. This can only be accomplished with improved methods such as those proposed by The Health.E Lighthouse initiative, that champions a coordinated approach to produce new technologies more consistently.

CMUT MEMS ultra-sound transducers like these on the tip of a 2.5 mm diameter catheter are key in the realisation of small and affordable ultra-sound products. (www.innovationservices.philips.com/cmut)



Health.E lighthouse

Objectives

Health.E will stimulate the development of open technology platforms and standards for medical devices and systems, thereby moving away from the inflexible and costly point solutions that presently dominate electronic medical device manufacturing. Open technology platforms, supported by roadmaps, will generate the production volumes needed for sustained technology development, resulting in new and better solutions in the healthcare domain. In this way Health.E will accelerate innovation along the whole medical instrument supply chain enabling "Moore for Medical".

Health.E lighthouse projects

- InForMed: 39 partners in 10 countries total budget M€ 58
- POSITION: 46 partners in 12 countries total budget M€ 41
- ULIMPIA: 18 partners in 6 countries total budget M€ 17

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Ronald Dekker

Ronald Dekker received his MSc in Electrical Engineering from the Technical University of Eindhoven and his PhD from the Technical University of Delft. He joined Philips Research in 1988 where he worked on the development of RF technologies for mobile communication. Since 2000 his focus shifted to the integration of complex electronic sensor functionality on the tip of the smallest minimal invasive instruments such as catheters and guide-wires. In 2007 he was appointed part time professor at the Technical University of Delft with a focus on Organ-on-Chip and bioelectronics medicines. He published in leading Journals and conferences and holds in excess of 50 patents.

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