

## 6 Publishable summary

### An integrated pilot line for micro-fabricated medical devices



The goal of the InForMed project is to establish an integrated pilot line for medical devices, covering the complete innovation chain from technology concept to system qualification. It will include micro-fabrication, assembly and even the fabrication of smart catheters.

The integrated pilot line will be uniquely hosted by a large industrial end-user. It is specifically targeted and equipped to bridge an existing gap in the landscape of micro-fabrication of medical devices. This gap is caused by the following characteristics of micro-fabricated medical devices:

- Their volume is, at least initially, too low to justify production in a standard foundry, but they nevertheless initiate vital value chains in in-vitro/in-vivo diagnostics, imaging and therapy;
- They cannot be fabricated in the cleanrooms of universities and or other institutes, because these lack the required quality instruments and ISO certifications for the fabrication of medical devices;
- They require capabilities that are new in micro-fabrication, such as the processing of biocompatible polymers and other materials.

At the heart of this chain is the micro-fabrication and assembly facility of Philips Innovation Services (PInS) - formerly known as MiPlaza - which will be qualified for small/medium-scale production of medical devices. The pilot facility will be open to other users for pilot production and product validation on a normal commercial base. The demonstrators products defined in the InForMed will link the pilot line to European:

- Research institutes and universities for concept creation;
- Foundries for mass production of validated products;
- Technology partners who complement the competences of the pilot line to avoid unnecessary duplication.

The reason for Philips to take the unprecedented initiative to establish a shared micro-fabrication infrastructure is not only to safeguard its own 4 billion euro turnover business in medical diagnostic equipment, but also to create an environment and eco-system where new medical devices can be seeded and nurtured to grow into new business opportunities for Europe, in a time when there is a paradigm shift from large and expensive diagnostic machines towards small, disposable, minimally invasive and un-obtrusive diagnostic and therapeutic tools. It is the aim of the pilot line:

- To safeguard and consolidate Europe's strong position in "traditional" medical diagnostic equipment with a pilot fabrication facility close to concept creation;
- To enable emerging markets, especially in smart minimally invasive instruments and point-of-care diagnostic equipment, by offering a fabrication facility for market demonstration and validation;
- To stimulate the development of entirely new markets, by providing an industrial micro-fabrication and assembly facility where new materials can be processed and assembled.

These three market segments are addressed by six demonstrator products which constitute an important part of the InForMed project. These demonstrator products are real products, linked to end-users such as manufacturers of medical therapeutic and diagnostic equipment. Next to the tasks related to the realisation of the demonstrator products, part of the work is reserved to define and explore roadmaps towards product innovation. Apart from being innovative products, the demonstrators additionally serve the following purposes:

- Test the pilot line in demonstrating and validating new medical devices in the different market segments covered by the demonstrator products;
- Test and demonstrate the protocols to be developed in the project for the efficient transfer of concepts from (academic) research to (pilot) production;
- To form manufacturing networks amongst expert groups in Europe to bring together the competences needed for the fabrication of these highly heterogeneous devices.

The demonstrators that are listed below address societal challenges in: “Hospital and Heuristic Care” and “Home care and well-being,” and demonstrate the trend towards “Smart Health” solutions:

1. A smart ablation catheter with ultra-sound ablation depth monitoring and revolutionary optical shape sensing technology for a more successful treatment of heart arrhythmia;
2. Novel devices for electrophysiology for the development of safer and better drugs;
3. Thin photo detectors and novel assembly technologies for spectral Computed Tomography (CT) which will allow for “color” X-ray pictures;
4. A revolutionary implantable steerable probe for Deep Brain Stimulation for a much more targeted treatment of Parkinson’s disease with strongly reduced side-effects;
5. A point of care cartridge for the early detection of “streptococcus pneumonia” bacteria for a faster and more effective treatment of pneumonia;
6. Smart body patches for: intelligent wound healing, unobtrusive heart monitoring, toxic gas screening and foot-pressure sensing.

The project consortium consists of 43 partners originating from 10 countries. The project is structured around the seven work packages listed below, whereby each demonstrator has its own task leader in order to create the delegated management structure required for the relatively large consortium:

- Micro-fabrication pilot-line set-up (WP1);
- Assembly and catheter pilot-line set-up (WP2);
- Linking the pilot line to research and high-volume production (WP3);
- Demonstrators I: “Hospital and Heuristic care” (WP4);
- Demonstrators II: “Home care and well-being” (WP5);
- Knowledge management: dissemination, exploitation, standardization (WP6);
- Project management (WP7).

The InForMed project will enhance the competitiveness of Europe in the rapidly emerging field of micro-fabricated medical devices, it will enable the further development of the European R&D and manufacturing capability in an extremely innovative industrial segment with a high economic importance, not only encompassing the micro-fabricated device itself, but also the various value chains that they enable.

As a result, the project will generate societal benefits. The ageing population and the increasing costs of healthcare constitute a major global challenge. Potential technology solutions are being developed by multidisciplinary efforts in medicine, biology, physics and engineering, but these can only be implemented successfully if the research results can be transferred to economically viable products. The central objective of the InForMed project is the establishment of an infrastructure dedicated to this task.