

SmartHEALTH

Smart Integrated Biodiagnostic Systems for Healthcare



Driven by clinical applications and progress in areas such as MicroNano Technology (MNT) and Information and Communications Technology (ICT), the SmartHEALTH project will develop an open integrated architecture for new biodiagnostic systems to support European companies exploiting bioassays or new application concepts.

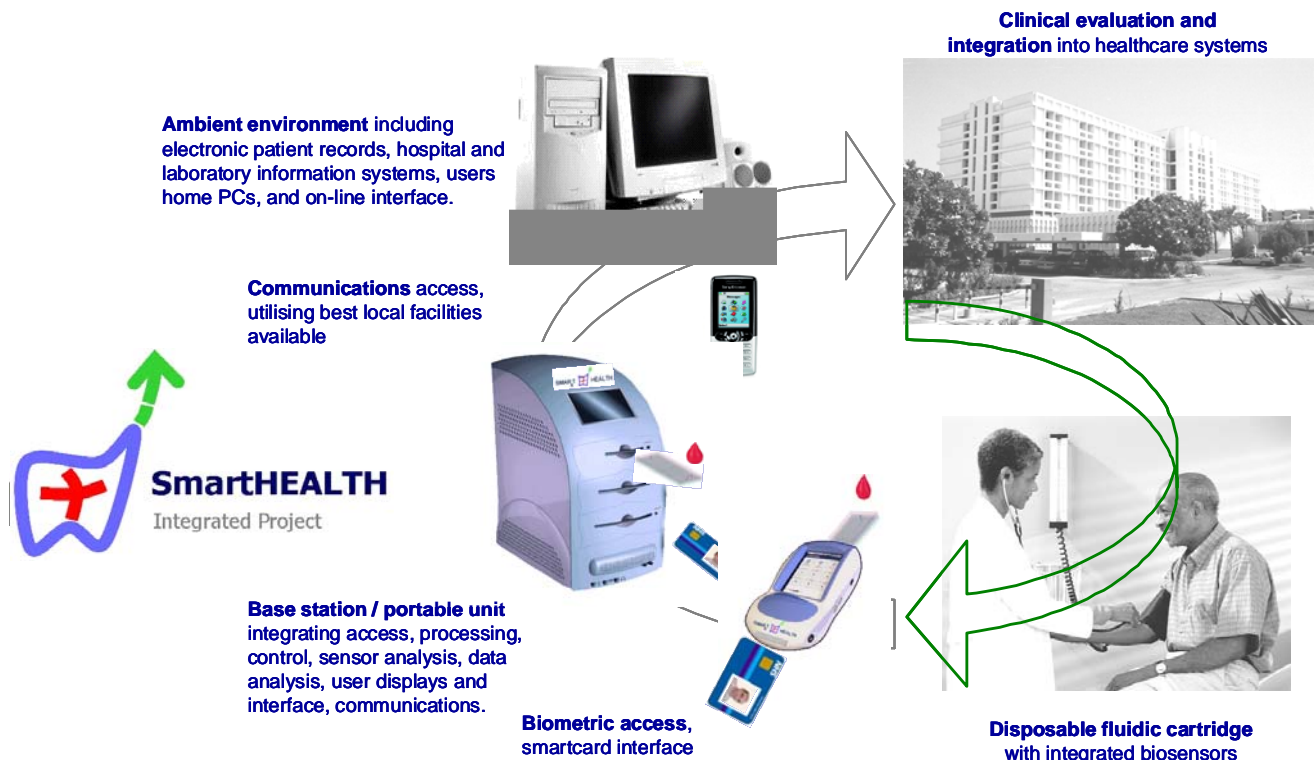
The initial system has a disposable fluidic cartridge with a desktop base-station linking to the ambient e-Health environment. Ultimately, this system will perform multi-analyte sensing and data/trend analysis for nucleic acids and proteins and will be modular to allow multiple biological sample types to be dealt with.

Results will be interpreted and presented using bio-information analysis based on trained neural networks. Systems will be healthcare "user identity-"

and "ambient environment-" aware, respecting confidentiality and information access rights. This concept will be miniaturized and cost engineered into a portable and more available system.

The project will enable enhanced medical diagnosis, leading to earlier and more precise results contributing to an increased quality of life as well as increasing the competitiveness of the European in vitro diagnostics (IVD) sector.

Clinical areas for SmartHEALTH application are in Cancer Diagnostics - breast cancer recurrence monitoring, cervical cancer case-finding, and colorectal cancer diagnostics, prognostics and theranostics. Each application includes clinical instrument evaluation and commercial exploitation partners.



Recent Achievements

The SmartHEALTH project has made significant progress towards developing both **desktop** and **portable instruments** with **integrated ICT capabilities** related to **secure data transfer** and **device interoperability** to achieve working, **ambient intelligent systems** which will be employed in the **clinical evaluation studies** scheduled for the next period.

Additional progress has resulted in successful development of **instrument interface modularity** to realize the capability of a **plug-and-play** type instrument system which will **allow sensor-based technologies and fluorescence detection for nucleic acid amplification to be exploited**.

In all of this work, particular attention has been paid to **system quality, manufacturability and traceability** according to international standards for medical devices.

Microfluidic packaged sensor systems have been developed using a combination of injection moulding and milling to achieve the demands of the sensor and PCR systems for the clinical evaluation studies. The project is now in a position to supply sufficient cartridges to the clinical centres involved in the evaluation studies.

Studies on **clinical utility of mRNA biomarkers** in blood for colorectal cancer have produced highly promising results for a panel of 4 gene markers. If validated in further work, this may be an extremely significant outcome for the project.

Benefits and Impact of the Project

The economic impact of the results of SmartHEALTH is potentially considerable with proposed technologies that will **facilitate improved healthcare provision, from improved centralised screening systems, through to fast and flexible point of care systems**.

Expenditure for diagnostics generally represents less than 1% of total patient management expenditure, thus increased testing cannot significantly increase healthcare costs **but can significantly contribute to the quality of healthcare** as it:

- Allows earlier and more appropriate, and therefore less costly, treatment.
- Helps to rule out expensive treatments.
- Reduces costs of treatment of complications.
- Potentially shortens the length of hospital stay by making therapies more effective and therefore more cost-effective. Thus improving overall patient management

Partners:

Newcastle University (UK), MiniFAB (Aust) Pty Ltd (Australia), microfluidic ChipShop GmbH (Germany), Institut für Mikrotechnik Mainz GmbH (Germany), Fraunhofer Institut für Biomedizinische Technik (Germany), Netherlands Organisation for Applied Scientific Research TNO (Netherlands), Ikerlan (Spain), Fundación Gaiker (Spain), IMEC (Belgium), Universitat Rovira i Virgili (Spain), Dublin City University (Ireland), Centre Suisse d'Electronique et de Microtechnique SA (Switzerland), Università degli Studi di Trento (Italy), TATAA Biocenter (Sweden), iXscient Ltd (UK), Fujirebio Diagnostics AB (Sweden), Olivetti I-Jet (Italy), Forschungszentrum Karlsruhe GmbH (Germany), Telecom Italia S.p.A. (Italy), Charité – Universitätsmedizin Campus Buch (Germany), Frauenklinik der FSU-Jena (Germany), Fundación Vasca de Innovacion e Investigación Sanitarias (Spain), SINTEF (Norway), MultiD Analyses AB (Sweden), 4M2C PATRIC SALOMON GmbH (Germany).

Timetable: from 12/05 – to 05/10

Total cost: € 21.768.293

EC funding: € 12.298.211

Instrument: IP

Project Identifier: FP6-2004-IST-NMP-2-016817

Important Links:

Project website: www.smarthealthip.com

eHealth Research: http://ec.europa.eu/information_society/activities/health/research

eHealth FP6 Projects: http://ec.europa.eu/information_society/activities/health/research/fp6projects

For further information:

ICT for Health - European Commission – Information society and Media DG

Office: BU31 06/41 B-1049 Brussels | Phone: +32 (0)2 296 41 94 - Fax: 02 296 01 81

Email: eHealth@ec.europa.eu | http://ec.europa.eu/information_society/eHealth

Project co-ordinator:

Diagnostic and Therapeutic Technologies, Institute of Cellular Medicine, Medical School, Newcastle University - UK

Prof. Calum McNeil | Tel: +44 191 222 8259 | email: calum.mcneil@ncl.ac.uk