

Towards a Roadmap for Cancer Diagnostics Using Smart Systems Technologies

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In addressing the high economic burden of the healthcare sector, prevention, early diagnosis and informed therapeutics are indispensable. But this is not an easy matter; tests must be highly accurate and well integrated into medical management to avoid unnecessary treatment and stress to users. Smart Systems based on novel (micro nano technology) sensor approaches combined with new communication concepts can be a solution.



P. Salomon

The Smart Integrated Biodiagnostic Systems for Healthcare (SmartHEALTH) Integrated Project addresses these complex issues by developing intelligent diagnostic technologies that are fully integrated into healthcare systems, optimising their impact on the patient's wellbeing and medical work practice. The project is driven by key applications in cancer diagnostics (breast, cervical and colorectal) and plans to deliver prototype systems with the aim of moving instrumentation from the laboratory, through to portable devices localised at the Point of Care (PoC). The aim is to deliver better and improved solutions for diagnostics, with the main focus being on cancer screening, monitoring and therapy.

The objectives of the SmartHEALTH project include:

- Introduction of new SmartHEALTH sensor systems into future healthcare services to improve and better existing services
- Demonstration of the role of on-line services for pervasive healthcare provision
- Clinical validation of smart systems for targeted applications in breast, cervical and colorectal cancer
- Demonstration of the economic benefits and means of healthcare provision for the targeted clinical applications
- Development of new manufacturing technologies for realisation of unique sensor solutions integrating fluidics, transducers and biological assays
- Facilitation of ethical and social acceptance of SmartHEALTH technology

Market and Trends in Point of Care diagnostics

The market for diagnostic devices is expected to rise dramatically in the coming years. However, this is not an easy market to access. There are barriers due to the complexity of the device, the large number of stakehold-

ers (patients, doctors, insurance companies, government, hospitals, central labs, etc), the strict regulations and the diversity of reimbursement models. The specific markets targeted by the SmartHEALTH project are: Breast cancer, Cervical cancer, and Colorectal cancer.

The diagnosis of breast cancer is made using a combination of radiological, surgical and pathological assessment. The radiology approach of X-ray mammography is the most reliable screening method in asymptomatic patients. A major limitation of this technique is that it often fails to detect tumours less than 5 mm in size.

The most common test for cervical cancer is the "pap" - a morphological method where cells are collected by a swab scrape of the cervix, fixed and stained on a glass slide, and analysed by a pathology department using optical microscopy to look for abnormal cells. The pap requires extensive infrastructure (technicians, pathologists, equipment...) and costs around €5. Pap testing introduces a high rate of false positives (specificity) and negatives (sensitivity) and is insufficient for full diagnosis, being limited in accuracy in some cases to below 50%. It relies on repeated screening to catch the disease.

Although it is one of the world's leading causes of cancer death (ranking second in developed countries), colorectal cancer has a 90% cure rate when caught sufficiently early. This is due to the fact that it takes a relatively long time for the malignant transformation from adenoma to carcinoma to occur, with the majority of colorectal cancers resulting from polyps (adenomas) that have developed in the lining of the bowel 10-15 years earlier. Therefore, the development and implementation of successful screening tests should have a noticeable effect on the detection of adenomas and early cancers and the reduction of mortality



Figure 1: The SmartHEALTH System Approach



Figure 2: The SmartHEALTH initial Project Roadmap

rates. This is one cancer type that is largely preventable and treatable. But, it relies on early detection through screening!

SmartHEALTH is working on issues that are therefore meaningful and very relevant, while the smart diagnostics offered by the proposed PoC tools can reduce the cost impact to the health insurance agencies and national health systems. SmartHEALTH is an "early diagnostic" tool that can reduce the impact of highly expensive in-vivo imaging diagnostic approaches that cost €100-1,000s, or even new drugs (many €1,000s) when cancers are in the later stage and cannot be operated on.

The global PoC testing market amounted to \$10 billion in 2005 according to Espicom Business intelligence (The Global Market for Point of Care Diagnostics, June 2006). This accounts for 36% of the total \$28 billion in-vitro diagnostics testing market. The major applications are for diabetes cardiac markers, blood gas, coagulation, sepsis, etc. In many hospitals, PoC testing is estimated to account for 20% of testing, extending into primary care surgeries. PoC is the highest growth sector in the in-vitro diagnostics market with 9% CAGR expected from 2003 to 2009 (BBI Newsletter, 2003, 26, p.308). The market is made up mainly of small

and medium-sized non-centralised laboratories and testing locations, such as physician office laboratories, special mobile clinics, emergency room and rapid response labs in larger medical centres.

Furthermore, the market for a key SmartHEALTH underpinning technology, microfluidics, is growing at over 20%, from \$400 million in 2004 to \$1,000 million in 2008, driven mainly by life science applications. The market is fragmented with many different products and diverse production volumes from a few thousand units through to a few million units. Plastic microfluidics, which are key for the development of low-cost, high-volume disposables for diagnostics, have already reached a market share of about 30%.

Importantly, SmartHEALTH technologies do not aim to directly compete with centralised testing facilities and pathology laboratories, since the application space for the SmartHEALTH PoC platforms will be different and will provide an invaluable service, greatly enhancing the overall provision of care.

The need for a roadmap and a user group

New products based on MNT for the diagnostics market rely on a combination of factors: development of enabling technologies for the modu-

lar components; integration of key components into systems using novel, low-cost manufacturing techniques; interfacing of systems to the external environment and, most importantly, understanding the requirements of the user community and target market trends. To achieve this successfully (both technically and commercially) is a significant challenge and requires the combination of multi skills and disciplines, often residing in multiple partners and diverse stakeholder groups.

In addressing these issues, the SmartHEALTH project produced an initial development roadmap (Fig. 2) at the outset of the project (December 2005) to help schedule, plan and implement the underlying technological developments. However, as the project is now in its 3rd year of operation, a re-assessment of technologies used, market trends and routes toward the optimal exploitation of results will be necessary. To achieve this, the following actions are planned in upcoming months:

- Interviews with potential stakeholders

SmartHEALTH Open Day and User Group Launch Event

28 Nov 2008, 9:00-13:00, London

The aim of this 2nd Open Day in the course of the EC-funded SmartHEALTH Integrated Project is to introduce the technology being developed within SmartHEALTH and to explore the opportunities and barriers for its commercialisation in the healthcare arena - a SmartHEALTH User Group is to be launched.

The event will take place after the IoN/Mancef Conference on **21st Century Medicine: Breakthroughs and Challenges**, 26-27 Nov 2008 (www.nano.org.uk/events).

Participation in the SmartHEALTH Open Day is free of charge but registration is required. www.smarthealthip.com

For more information, please contact Calum McNeil (Open Day) or Patric Salomon (User/Experts Group).

- Launch of cancer diagnostics user group
- Two user group workshops to discuss:
 - o expected project results versus user needs
 - o markets and market strategies
 - o commercialisation routes
 - o ideal partners for commercialisation
 - o further development needs

The aim of the SmartHEALTH roadmap is, firstly, to ensure alignment of the needs and restrictions of

the principal stakeholders to the program's objectives. Secondly, it is to ensure alignment of the project partners' individual inputs. From this it is already clear that, in order to ensure the roadmap reflects the real issues, discussions between with stakeholders and project partners are needed. Those discussions are not only beneficial for the project partners; the stakeholders will also be sure that the developments fit neatly into their needs. For this purpose, the SmartHEALTH project is now setting up a user/expert group.

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