



Smart Integrated Biodiagnostic Systems for Healthcare



Project Coordinator:

Professor Calum McNeil

Newcastle University, UK

Project Manager:

Mr David Wenn

iXscient Ltd., UK

Project Administrator:

Ms Heather McGrath

Newcastle University, UK

Project PA:

Ms Becci Sharrock

Newcastle University, UK



SmartHEALTH Integrated Project



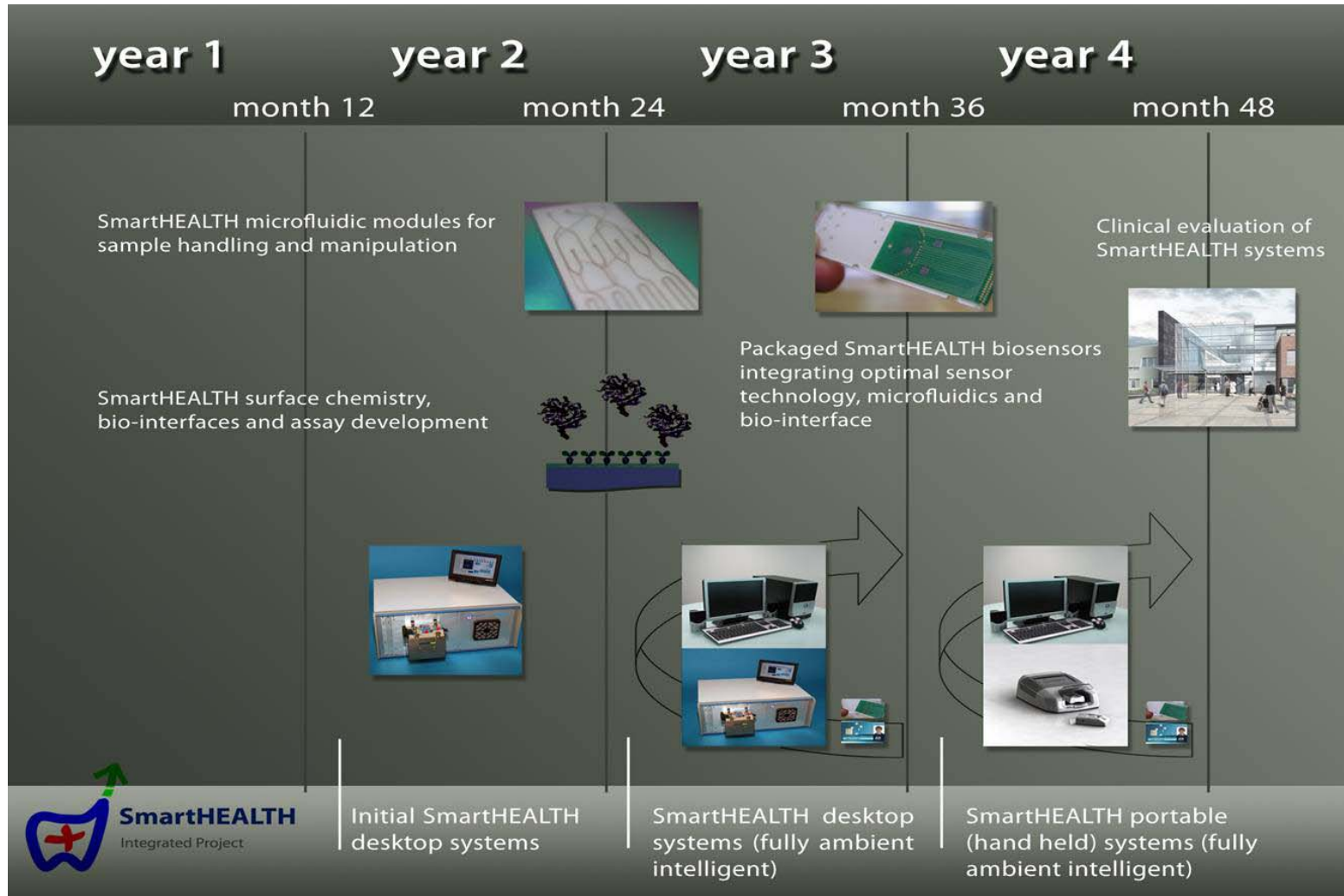
FP6-2004-IST-NMP-2: Bio-sensors for Diagnosis and Healthcare (Joint Call between thematic priorities 2 and 3, issued 15th June 2004)

SmartHEALTH objectives include:

- ◆ Introduce new SmartHEALTH sensor systems into future healthcare services to improve and better existing services.
- ◆ Demonstrate the role of Ambient Intelligent (AmI) medical devices and online services for pervasive healthcare provision.
- ◆ Demonstrate clinical evaluation of systems for targeted applications in breast, cervical and colorectal cancer.
- ◆ Demonstrate the economic benefits and means of healthcare provision for the targeted clinical applications.
- ◆ Develop new manufacturing technologies for realization of unique sensor solutions integrating fluidics, transducers and biological assays.



SmartHEALTH Development Path





Sensor Technology Development: Vertical Integration

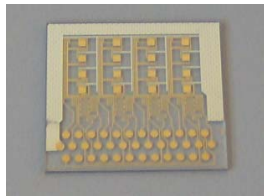


- ◆ Three "**Sensor Theme Teams**" designed to address seamlessly the requirements of each of the 3 SmartHEALTH sensor technologies
 - ✦ Ensured focused programmes of work which will ultimately produce the SmartHEALTH devices, instruments and systems

	<i>Electrochemical (EC)</i>	<i>TPB</i>	<i>CDR</i>
Integration Champion	IMM	MFCS	MiniFAB
Sensor Developer	URV	IMEC	UNEW
Microfluidics	IMM	MFCS	MiniFAB
Readout Interface	CSEM	IMEC	UNEW/IBMT



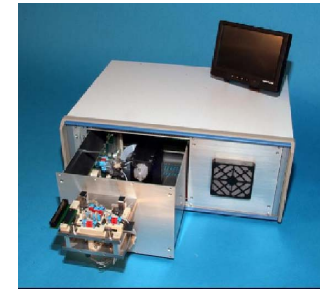
**Electrochemical
Biosensor Array**



**General Detection Chip
for Bench-top Instrument**



**Multi-channel
Potentiostat**



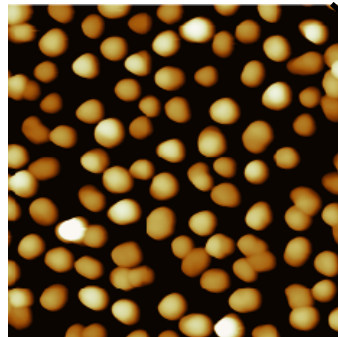
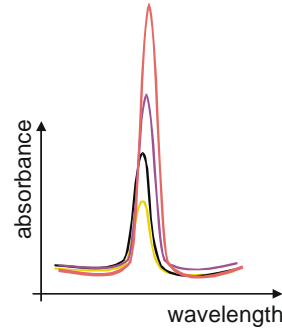
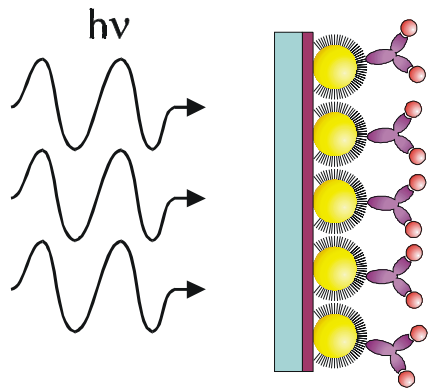
**Bench-top
Instrument**

**General Detection Chip
with Sample Preparation
for Portable Instrument**

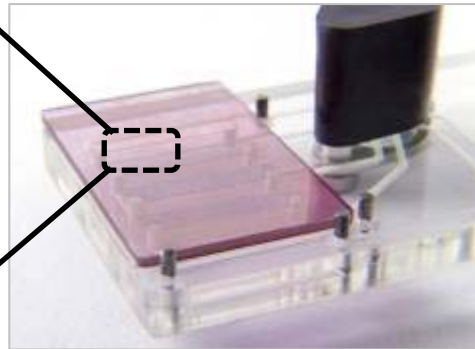


**Portable
Instrument**

TPB Biosensor System

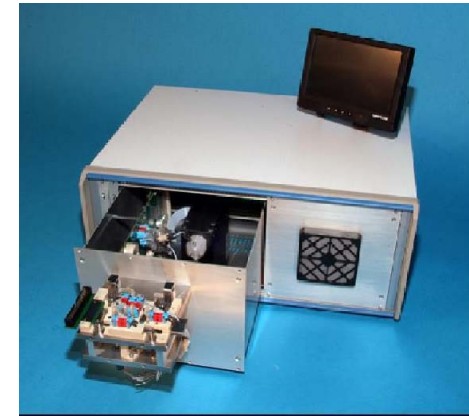


Gold Nanoparticles



TPB Biosensor Cartridge

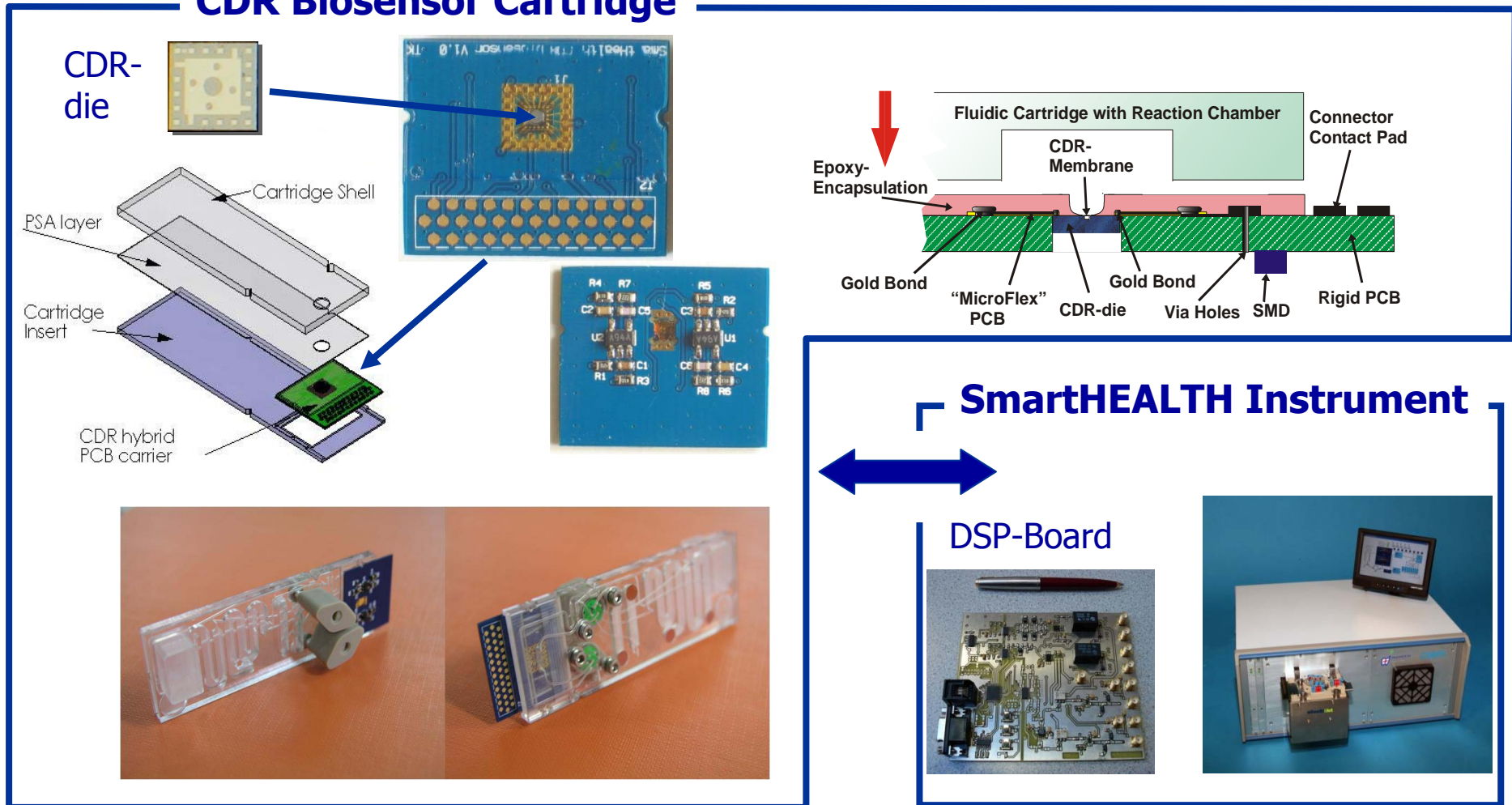
Bench-top Instrument



CCD Camera



CDR Biosensor Cartridge



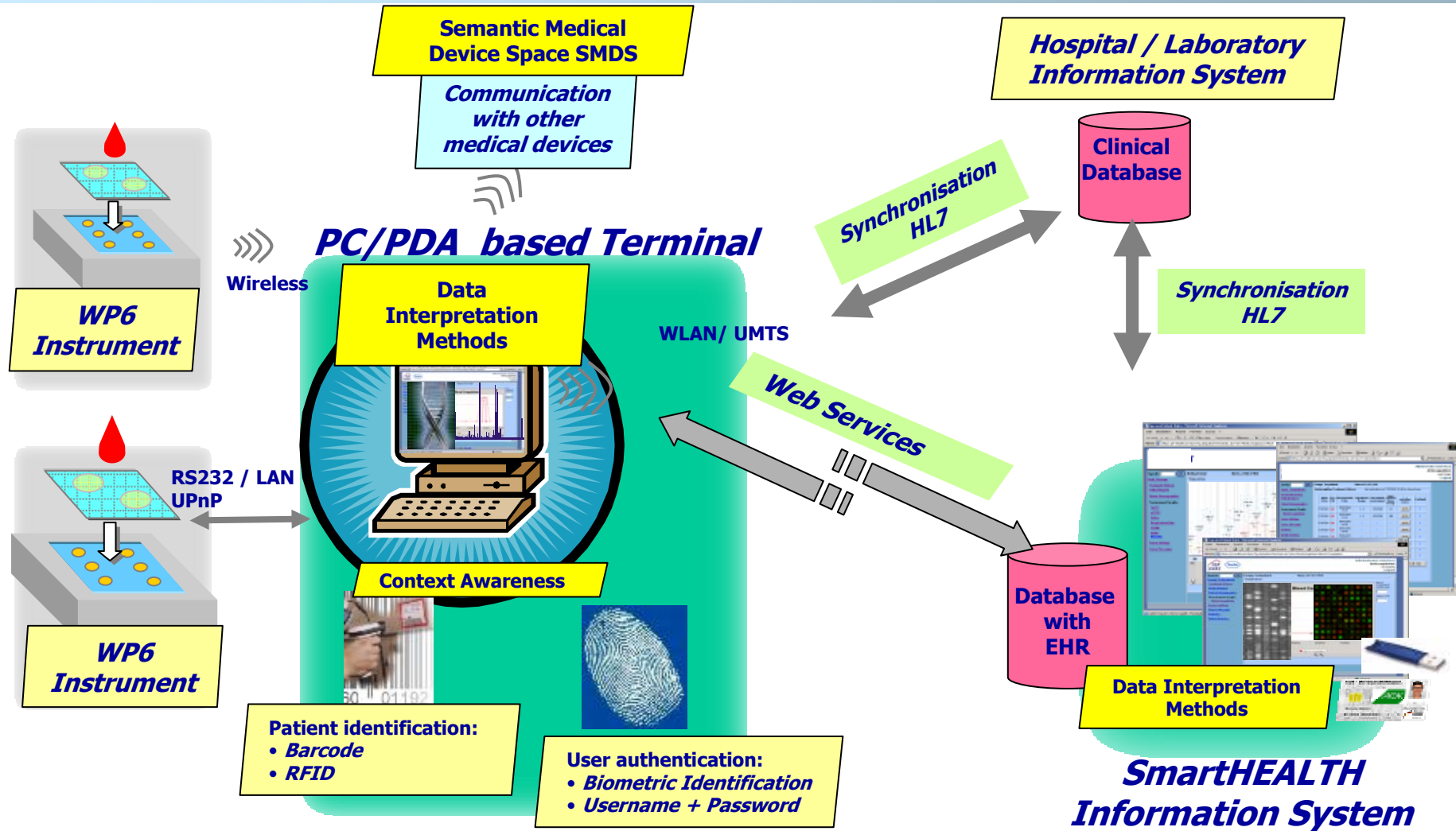


SmartHEALTH

Sensors and Chips



	Breast Cancer (Clinic)	Breast Cancer (Home)	Cervical Cancer	Colorectal Cancer
Clinical Champion	Charité, UNEW	Charité, UNEW	FSU-Jena	BIOEF
Samples	Serum	Serum from whole blood	Cells from smear	Tissue sample and potentially blood
No. of Patients	20-30	1 (with repeated sampling over 6 months)	Up to 200	Up to 50
Markers	CEA, CA15-3	CEA, CA15-3	1) HPV 16, 18, 45 2) E7 oncoprotein	CD, CEA, Tet, CAI
Sensor/ Detection	EC and possibly CDR	EC	1) qPCR and possibly TPB 2) CDR	qPCR and possibly TPB
Chip	GDC (Chip I or III)	GDC with sample prep. (Chip II)	1) IMM qPCR (Chip IV) 2) GDC	TNO qPCR (Chip V)
Instrument	Instrument A	Instrument C	Instrument B	Instrument B
EMI/ETOMI	EMI (EC/CDR)	EMI for handheld	1) ETOMI or EMI (TPB) 2) EMI (EC/CDR)	ETOMI or EMI (TPB)
Location	UNEW	UNEW	FSU-Jena	BIOEF/San Sebastian
Study Design Method Comparison	ELISA	ELISA	1) Standard PCR 2) ELISA	Standard PCR
ICT Platform	Assessment of data analysis and interpretation, communications and integration into HIS			
Location	UNEW			



Software development driven by 4 end user scenarios:
Clinical laboratory, hospital ward, doctor's office, patient self testing at home

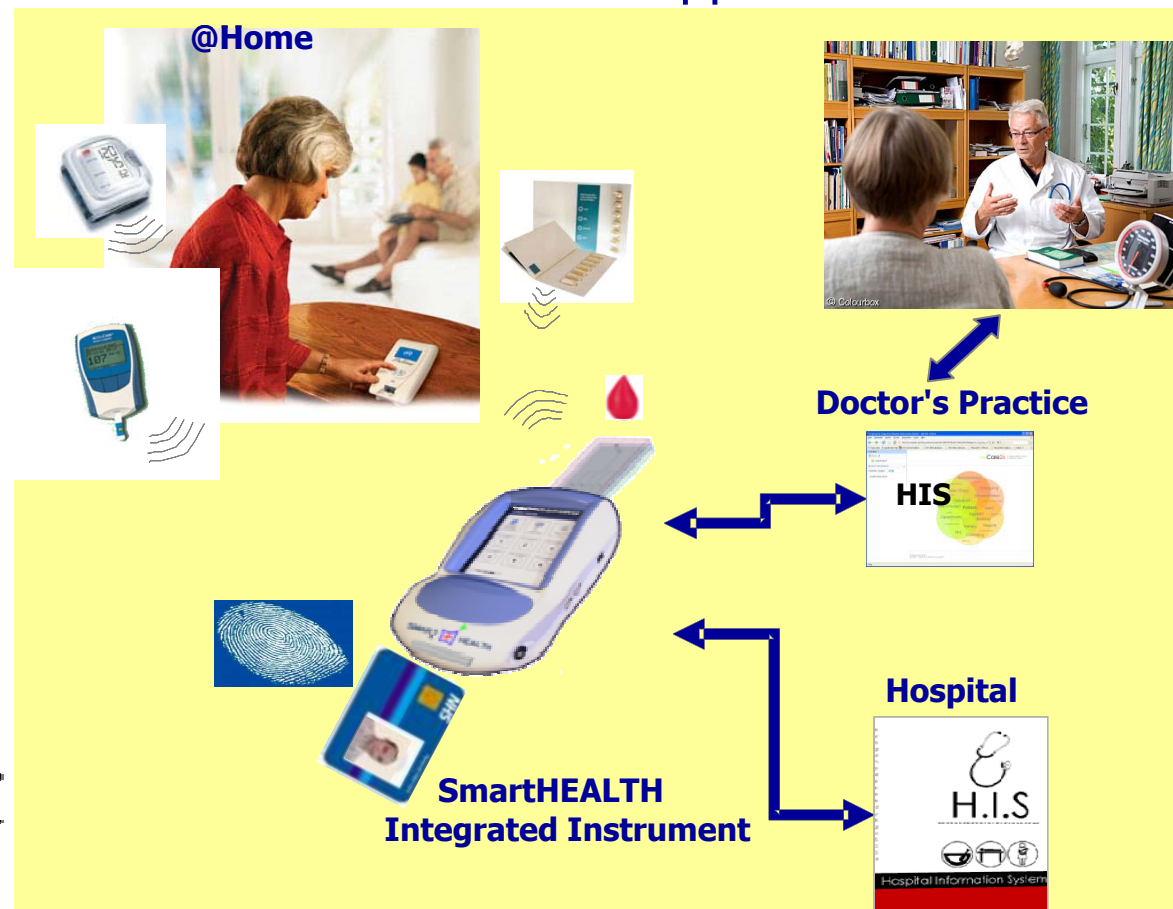


SmartHEALTH

Semantic Medical Device Space



Advanced capabilities for context awareness, ubiquitous computing in the ambient health information environment, data interpretation and for new point-of-care driven medical software applications and e-health services





SmartHEALTH

Achievements



Work carried out to date has led to a number of significant achievements

These include:

- ◆ Studies on clinical utility of mRNA biomarkers in blood for colorectal cancer have produced highly promising results for a panel of a minimum of 3 gene markers
- ◆ Determination of functional sensitivity and cut-off values for the HPV E7 oncoprotein assays (HPV16, HPV18 and HPV45) and validation using clinical samples
- ◆ Development of multiplexed electrochemical detection of HPV sequences and the design of an EC-RT-PCR detection platform
- ◆ Multiplexed protein detection by combination of a sample spotting technique and TPB sensor technology
- ◆ Functional validation of the CDR sensor, naked dies as well as fully integrated and packaged sensors
- ◆ Implementation of the Semantic Medical Device Space concept in the SmartHEALTH terminal software
- ◆ International symposium and open discussion with key stakeholders on the ELSIs surrounding the future implementation of SmartHEALTH
- ◆ Completion of study on how SmartHEALTH could change patient informed choice in cancer testing
- ◆ Market studies and User Group workshops to further define the potential exploitation routes for the SmartHEALTH technology
- ◆ SmartHEALTH educational material used for teaching delivery to undergraduate and postgraduate students in Bachelor's and Master's programmes and to school pupils and teachers



SmartHEALTH

Technology Opportunities



- ◆ Have published on the web some 13 SmartHEALTH technology opportunities for partnership and collaborative exploitation
 - ✦ <http://www.smarthealthip.com/output.aspx>
- ◆ These include:
 - ✦ Hand-held instrumentation platform for PoC devices
 - ✦ SMDS software for semantic coordination of ambient intelligent medical devices
 - ✦ MEMS sensor devices and packaging solutions
 - ✦ Tailored sensor surfaces for biomolecule immobilization and patterning
 - ✦ Microfluidic systems for mRNA isolation
 - ✦ Microfluidic chips for qPCR
 - ✦ Panel of RNA markers in blood for colorectal cancer diagnosis and prognosis
 - ✦ Immunoassays for HPV oncoproteins
 - ✦ Solutions for fluorescence detection in disposable lab-on-a-chip cartridges
 - ✦ Neural network modules for bioinformation analysis for disease diagnostics
- ◆ Open to collaboration for further development and commercialization



SmartHEALTH Dissemination



Significant dissemination activity in the last period has included:

- ◆ SmartHEALTH Roadshow/Workshop at Medica/ComPaMed, Düsseldorf, November 2009
 - ✦ SmartHEALTH dedicated display stand and presentations at ComPaMed forum
- ◆ SmartHEALTH dedicated workshop on cancer diagnostics at pHEALTH 2009, Oslo, June 2009
 - ✦ Including SmartHEALTH video interviews on pHEALTH web site
- ◆ SmartHEALTH International Symposium: "Integration or Disruption?: Implementing SmartHEALTH into Healthcare", Ethical, Legal and Societal issues of SmartHEALTH, Newcastle, May 2009
- ◆ Presentations at over 29 international conferences and trade shows including: Medica, ComPaMed, COMS 2009, AACC, Photonics West, Analytica, Lab-on-a-Chip, Microtechnologies in Medicine and Biology, μ TAS, SPIE Smart Materials, Enabling Point of Care Diagnostics, LabAutomation, qPCR 2009, BDigital Congress, AusMEDTECH
- ◆ SmartHEALTH flyers produced and distributed or included in delegate packs at all conferences
- ◆ Some 9 full research papers published in internationally-leading journals

In the next period SmartHEALTH will:

- ◆ Have a considerable presence at Analytica 2010, including a SmartHEALTH showcase, workshop and dedicated project booth
- ◆ Have a presence at pHEALTH 2010 in Berlin



Acknowledgements



- ◆ The SmartHEALTH project is partly funded by the European Commission (IST-NMP-2-016817)

www.smarthealthip.com



Fundación Vasca de Innovación e Investigación Sanitarias

Forschungszentrum Karlsruhe
in der Helmholtz-Gemeinschaft

Friedrich-Schiller-Universität Jena

