Digital Healthcare Projects Policy

Action Plan

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Abstract

Whilst the policies of the centre are designed to support a focused effort researching the field of information and communication technologies (ICTs), including increasingly pervasive communication networks, it is recognised that increasing processing power and the ability to transfer more information faster through both wired and wireless systems means that the developments will also include increased ability to search, filter and share both data and information.

Our approach is to find new ways in which technologies can be used to meet the challenges facing health and healthcare in the next 10–15 years. ICTs can both enable and drive change in health and healthcare, and this raises social issues as well as technical ones. Particularly important is that ICTs may drive healthcare towards treating patients nearer (or in) their homes, putting greater emphasis upon bringing the patient more actively into the processes supporting their own healthcare contributing to the transition from the traditional 'paternalistic' model to one of negotiation and wider information sharing.
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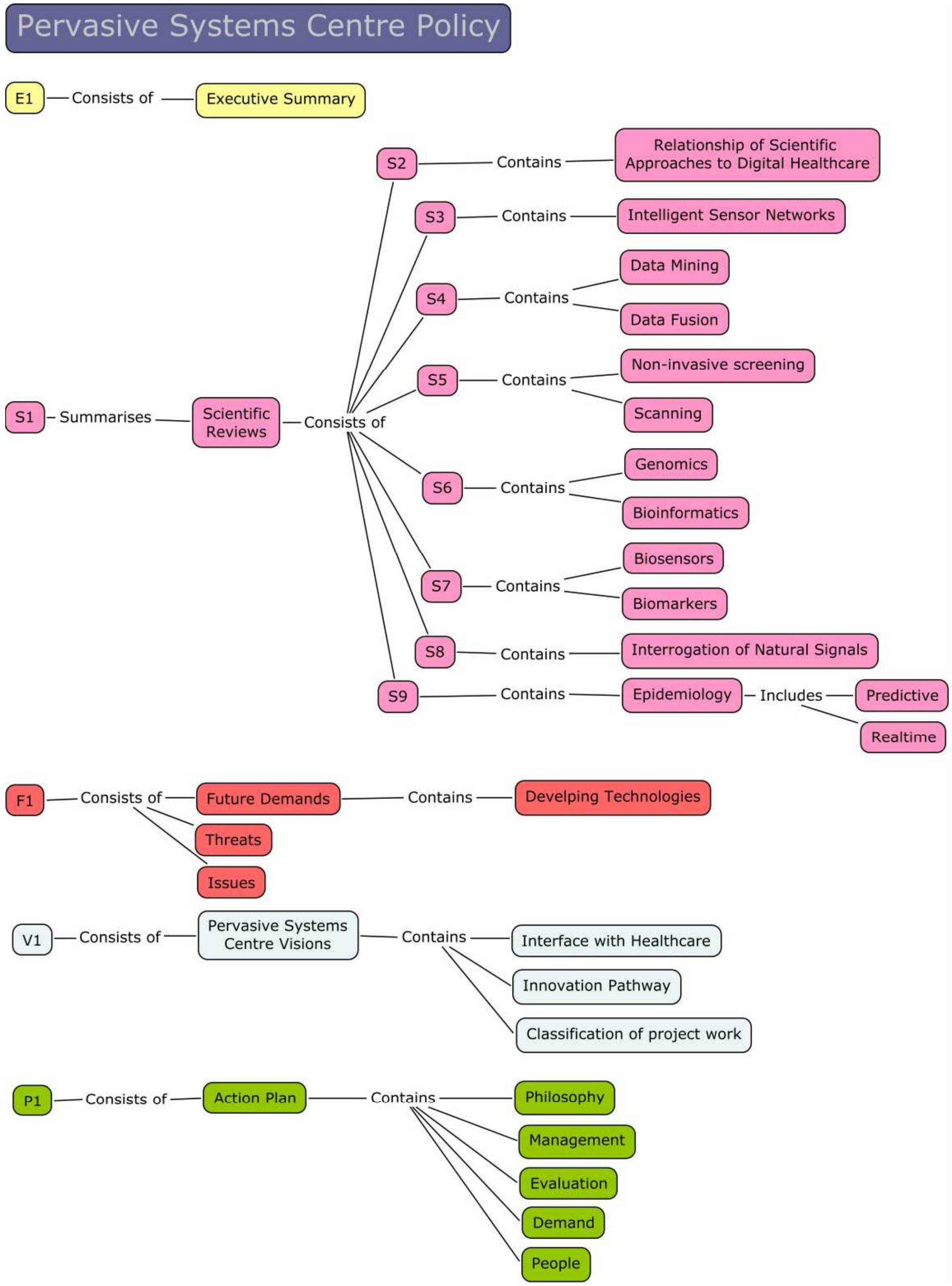
These technologies will generate vast amounts of health-related data. These data are made available to appropriate groups in a timely fashion. It must be processed to yield useful information. This raises questions about how any information generated is used. How is the data analysed? Who owns patient data? Most importantly, who should have access to patient data?

The PSC policy documents aim to be both specific yet offer general advice. The intention is to provide cohesive guidance for projects and collective research effort yet provide specific direction to individuals that focus upon their needs. The field cross sections healthcare, pervasive systems and ECS groups. For this reason computer scientists offer to support this process through the provision of tools to steer users through establishing the most appropriate contacts and technology bases inside the pervasive systems centre so as to help find the 'right' technology partner and assist in building comprehensive records for collaborative efforts.


Pervasive Systems Centre Policy
E1
Consists of
Executive Summary
S1
Summarises
Scientific Reviews
Consists of
S2
Contains
Relationship of Scientific Approaches to Digital Healthcare
S3
Contains
Intelligent Sensor Networks
S4
Contains
Data Mining
Data Fusion
S5
Contains
Non-invasive screening
Scanning
S6
Contains
Genomics
Bioinformatics
S7
Contains
Biosensors
Biomarkers
S8
Contains
Interrogation of Natural Signals
S9
Contains
Epidemiology
Includes
Predictive
Realtime
F1
Consists of
Future Demands
Contains
Develping Technologies
Threats
Issues
V1
Consists of
Pervasive Systems Centre Visions
Contains
Interface with Healthcare
Innovation Pathway
Classification of project work
P1
Consists of
Action Plan
Contains
Philosophy
Management
Evaluation
Demand
People

The documents that provide the structured project reports are arranged as follows;

- E1: Executive Summary
- S1: Science Review Summaries
- F1: Future Demands, Threats and Issues
- V1: Centre Visions
- **P1: Action Plan**

Each of these is outlined separately and is available from the PSC website.

Contents

1 Introduction

The trends are clear - computing devices are becoming smaller in size and greater in number. In addition to handheld products like phones and PDAs, devices are increasingly deployed in our environment, homes, cars, clothes and even bodies. They interact with each other through a variety of communications technologies, as well as being interconnected to the global communications and information infrastructure of the Internet, Web and Grid.

Designing and building future computing systems is not a solved problem and it demands a broad set of multidisciplinary skills. Furthermore it requires a systems perspective - as we move into this future there will be increasing numbers of deployed, interacting devices, behaving autonomously and interacting to combine their behaviours in various ways. How do we understand and engineer the behaviour of these new systems?

The Pervasive Systems Centre (PSC) tackles these crucial challenges by drawing multidisciplinary expertise from across ECS research groups, ranging from sensors, wireless communications and electronic systems design to computer science theory and practice. Additionally, ECS brings the systems perspective at all physical scales - from Systems on Chip and biological and nature-inspired systems through to building the next generation Grid and understanding the science of the Web.

This document is formulated from the excellent policy documents of the Royal Society (Digital Healthcare)(1) and the FORESIGHT documents from the Office of Science and Innovation(2). This document aims to provide a route for prospective and established partners of Electronics & Computer Science (ECS)(3) Pervasive Systems Centre (PSC)(4) .

1.1 Relevance to PSC

Each project team will have different responsibilities, access privileges and agendas. Each will have established different relationships – the roots and branches of research, business and clinical practice. Such a system allows users to build upon these rather than exclude them.

With respect to the way we develop this, the department in Southampton is a world leader, working closely with MIT in the USA upon the next generation of web technologies. Our expertise is in the development of systems that provide a virtual environment that gives secure access in the same way as one's bank does. It allows users to register their profiles so that the system can accommodate their educational and technical background, and privileges which allow / restrict access to the foreground environment.

Users can manage trials through the whole life cycle, from inception, through authorisation and monitoring to preparation of trials data and analysis. The outcomes are presented initially as internal technical reports whilst preparing for review and formal publication.

'It isn't just our broad range of key skills that make the Pervasive Systems Centre unique, but having them in one place enables the collaborative working and co-design that is essential in tackling the engineering and operation of future computerised systems through their entire design lifecycle… Our methodology involves designing and building real systems and deploying them "in the wild", not just in the lab.'

Professor De Roure.

ECS is a unique entity. It is big. Consequently, it can draw upon experts in almost every area of electronics and computing that allows us to collaborate on a very broad range of ICT projects.

As work evolves over the next 15 years, we need to maintain focus as ultimately the world is building a digital map of ourselves and our actions. Some aspects of the virtual human or humanity are already well mapped out, such as the visible human project in the 1990s, others are in their infancy. The purpose of the policy therefore is to provide a cohesive approach to the process of building a theme that crosses the subspecialties in both ECS and healthcare.

We can perceive projects as being situated in a matrix on the spectra of healthcare and ECS sub-domains, with often overlapping healthcare requirements and mapping onto ECS areas of expertise in different inputs (signal management) processes (automated functions) and outputs (deliverable packages). We therefore ought to collate the various metadata to support the thematic approach. No one is better placed than ECS to do this being world leaders in adaptive systems.

Many healthcare projects in ICT flounder because the objectives are blurred and so initially they are not adequately scoped. The two sides are unable to successfully co-design and the project goals either run over budget, overtime or worse, fail to deliver. It is therefore only sensible to use the expertise and wisdom from observing previously successful projects to develop and employ 'best practice' for projects so that groups are able to collaborate productively with ECS.

By clearly registering the modalities of input, processes and outputs required to achieve the goals of the different healthcare projects, we are able to support healthcare projects in the pervasive systems centre. By using a previously evaluated ICT healthcare project management tool, this allows us to seek or allocate appropriate funds and staff resources to the projects and help project start-up.

P1: Action Plan

2 Philosophy

PSC employs a Hegelian philosophy where the proven hypothesis of one experiment helps to build a greater understanding of the complexity of our biological world through constructing a foundation for the next round of experimentation and study.

To achieve this there is a feedback loop where the results of a proven hypothesis are directed toward the next round of research and audit. The users require the processes to be reasonably logical, employing the same overall format and logic during each step. The principles that PSC adheres to are that;

The steps are sequential and a single thread can be followed by each researcher to find their way through the various steps

- To allow researchers to retrace these steps at any time.
- PSC provides and integrated development environment for research and audit
- Each step starts with a purpose which outlines the reason for the step

2.1 Digital Healthcare Project Planning and Management through PSC;

The approach is already being employed in international collaborations where there is the need to work with academic, commercial and governmental organisations. To accommodate the different needs at different stages of the healthcare projects, PSC will provide access and help support the 'research base services' framework that ECS runs for medical research initiatives.
Specific examples of this are found at www.orbs.ecs.soton.ac.uk which is piloting this approach in the field of orthopaedics.

2.2 Principles of managing digital healthcare research

Each project must be run through a process that is understood and agreed by both the healthcare (social) and computing (technical) partners.
For this reason it has been agreed that the following steps;

1. **Ideas** – Initial Project Setup for research team review
    a. User idea for a research project recorded
    b. Team selection
    c. Type of project selection
2. **Proposal Maker** - Development of a proposal for the project for research & development (R&D) team or chief investigator (CI) review
    a. Outline Project Proposal
    b. Risk assessment
3. **Protocol Maker -** Development of a proposal for the project for R&D team or CI review
    a. Full Project Protocol - Compliance with requirements for the work
        i. Outcome Measure Selection
        ii. Data protection regulations
    b. Research & Ethics Committee (REC) approval
        i. UK, EC regulations
        ii. ICH GCP documentation

    iii. Subject Specific Information
    iv. Centre Specific Information
    v. Fulfilment of 'Control of Substances Hazardous to Health' (COSHH) obligations
  c. Internal Documentation
    i. Costings
    ii. Peer Review
    iii. Grant Applications

4. **Build the project -** for research team review
   a. Adoption of appropriate Experimental protocols for the running of the experiments
   b. Application of schemas
5. **Data Manager -** for research team review
   a. Data Recording of the data in a repository
   b. Preparation of datasets that can be managed by the end user.
6. **Data Analysis -** for research team review
   a. Access to Matlab for the presentation of results and viewing of the results in the experiment
   b. Data analysis using SPSS
7. **Preparation** - for research team review
   a. Analysis interpretation using the secure wiki to build a paper for publication
   b. Access to an experienced statistician
8. **Pre-publication**
   a. ePrints archiving
   b. pre-printing of accepted papers and technical reports
9. **Publication & Assimilation –** for external reviewers
   a. Submission of a technical paper for publication to ensure intellectual property protection.
10. **Closure -** for the project for R&D team or CI review
    a. Completion of any necessary documents

2.3 Key to simplified processes

Each step of the process for adopting a modular approach to *Healthcare Research & Development* will have certain things in common from the user's perspective. This is what is meant by PSC process mapping. These are;

- Internal Inputs (II)
- External Inputs (EI)
- Processes (P)
- Review Authority (RA)
- External Outputs (EO)
- Internal Outputs (IO)

To make this easier to follow; the following conventions have been adopted colour coding and a specific spatial layout of flowcharts outlined in figure 1 below.

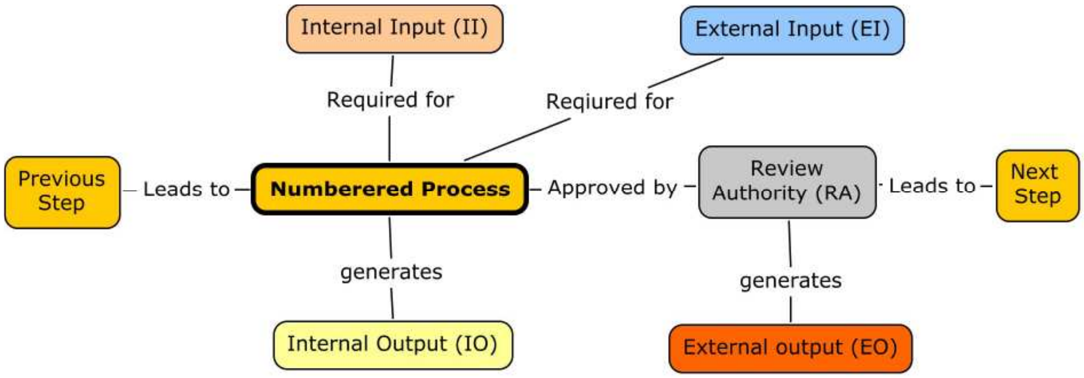


Figure 1 Key to PSC Process Mapping

2.4 Project Proposal Submission Process

Each project will undergo the following process to ensure as much work is done in advance as necessary to prevent risks emerging later, when design modification is more costly in resources.

3 Evaluation

3.1 Introduction

Given the importance of evidence-based medicine, it is crucial to have evidence to demonstrate the efficacy (or not) of different ICTs in different contexts. There will still be room for interpretation especially when extrapolated to different sites and applications.

3.2 Design, implementation and evaluation

There are many issues raised when preparing a new technology for health care;

- Urgency of healthcare needs
- Intolerance to system failure
- Interface with vulnerable people when most at risk
- Unrealistic expectations
- Serious cost constraints
- Enormous scale and complexity of the NHS organisation
- Poor record to date in large-scale public sector IT projects

Consequently in line with the Royal Society recommendations; PSC advocates an incremental and iterative approach to the design, implementation and evaluation of new ICTs where healthcare professionals and all other users are involved at all stages.

To this end, tools have been developed and are now being prototyped for the delivery of such a service to support new projects from inception to closure through the iterative project life cycle. This will form the foundation for future work developing a semantic grid to support his area of research.

Clearly identified objectives in the form of user requirements are determined at the start of the design process to prevent the initial scope being added to or extended. It is accepted that existing technologies designed for non-healthcare solutions may not meet the healthcare-related objectives.

Since ICTs should be able to cope with likely structural and social change and be usable by people of varying needs and abilities as well as different backgrounds, it is essential that a modular approach is established allowing flexibility in design and modification at later stages.

Experimentation is essential to the development of new ICTs so that successful and unsuccessful parts of systems are identified, adapted (or dropped) and then refined in an iterative process. Small trials will help define these issues and so a approach which considers scalability from micro to macro is a key part of the R&D cycle.

3.3 The Need for Evaluation

We need to ‘talk from the figures’. Not only for the publication of research results but to prime the next round of the iterative design cycle. Much like a Catherine wheel, subprojects and developments will fly off from the main projects and initiatives. The aim is to be able to evaluate the need for these and the effort (resource allocation) to dedicate to them.

3.4 Methodologies -Outcome measures

Identifying, measuring and valuing benefits of ICTs for usability in healthcare is not yet a mature science. The author has written one paper on the validation of outcome measures in this domain and developed two scoring systems in this area (neither validated) and sees that this is a high priority to ensure reliable comparison of results from various systems in the future.

3.5 Methodologies – Cost Assessment

Identifying, measuring and valuing costs of ICTs is as important as the evaluation of the effectiveness. Whilst we are unlikely to ever really evaluate the fill costs and benefits of ICT implementation as this often cuts across budgets (*e.g.* social services, healthcare, education, unemployment, disability and pensions) the need is for justification of costs within the healthcare arena itself. To this end instruments have been developed to evaluate this.

3.5.1 Discrete choice experiments (DCEs)

These attribute-based measures of benefit can value

- Health outcomes
- Non-health outcomes
- Process attributes (as well as trade-offs between these various dimensions).

The technique is based on the premises that

1. Any good or service can be described by its characteristics (or attributes)
2. The extent an individual values a good or service depends upon these characteristics.

The technique involves presenting choices to individuals that vary with respect to the levels of attributes. It is possible to estimate the relative importance of attributes, how individuals trade between the attributes and, if a price proxy is included as an attribute, willingness to pay for defined services (Ryan et al. 2003).

3.5.2 Contingent valuation

These attribute-based measures of benefit can value

- Health outcomes
- Non-health outcomes
- Process attributes (as well as trade-offs between these various dimensions).

It is based on the premise that the maximum amount of money that an individual is willing to pay for service is an indication of the value to them of that service.
This is a choice-based approach where individuals are presented with a choice between not having the commodity and having the commodity but forgoing a certain amount of money.

3.5.3 Quality Adjusted Life Years (QALYs)

QALYs were developed to take account of the fact that the quality of life matters as well as the length of life. To estimate QALYs, expected life years gained from given healthcare interventions are estimated and combined with information on the quality of these life years. QALYs gained from one healthcare intervention may be compared with QALYs obtained from alternative healthcare interventions. Incidentally the three most effective interventions are cataract replacement surgery, Total hip and knee arthroplasty (joint replacement).

3.6 Long Term Issues

Even if we are able to succeed in getting adequate levels of care delivered to patients in their preferred surroundings and health is maintained as long as possible, which should help to maintain high levels of morale, the fact remains that the patients will need to feel secure in the knowledge that the communication which motivates them – normally provided by human contact with health care professionals will be there in some form.

When individuals become ill, and require secondary or tertiary services, the extra tiers of staff with lower training levels will need suitable mechanisms for referring top the highly trained and highly skilled professionals for opinion and treatment. It is not clear if the present model will in fact help this process.

Cultural change will take longer than technical change due to the perceived risks of new technology introduction and the impact upon personal care. For this reason the education and training of staff in the use of the new technologies and the reasoning behind this should be an integral part of the strategy employed. This is discussed in the recommendation for a second edition of the ICT skills for Healthcare professionals' book that could be prepared quickly by the PSC team.

4 Perceived Demand for Pervasive Systems in Healthcare Services

4.1 Realising the potential of healthcare ICTs through new and existing technologies

New and existing technologies will be used at individual, local and national levels to face the predicted challenges, such as the ageing population with the increase in numbers chronic diseases and the emergence of new diseases

The NHS philosophy means that it is slow to exploit existing ICTs resulting in a gap between what is available and what is widely used in healthcare. Much improvement cold be achieved by using existing technologies as part of regular health and healthcare practices as well as introducing new ones. Healthcare professionals are well placed to identify potential healthcare ICTs because of their understanding of healthcare delivery systems and should be an integral part of the co-design of new ones.

PSC should monitor both existing technologies and developments in new technologies so that those with net benefits to health and healthcare can be designed, built, assessed and effectively deployed. This should be assisted by monitoring the following UK agencies;

- NHS National Innovation Centre
- Purchasing and Supply Agency (PASA)
- Medicines and Healthcare products Regulatory Agency (MHRA)
- National Institute for Health and Clinical Excellence (NICE)
- British Computer Society
- Institution of Engineering and Technology
- Medical Royal Colleges

Internationally there are others of importance;

- National Institute for Health
- Health Level 7
- EC initiatives

5 People

Directors: Prof Bashir M Al-Hashimi and Prof David De Roure
Medical Advisor: Dr Simon Grange

5.1 Current Projects

- System-on-Chip: Design methods and Tools (SoC)
- Next generation of interconnection technology for multiprocessor System on Chip (NoC)
- Test Resource Partitioning: A Low-Cost Test Scheme for Systems-on-Chip (TRAP)
- Low-Power Built-in-Self-Test (LOBIST)
- Wireless Sensor Networks
- Analogue project http://www.ecs.soton.ac.uk/~bmah/projects.php - #On-chip Low Cost Time Measurement Circuits for Embedded Memory Characterization
- Power minimization in behavioural synthesis http://www.ecs.soton.ac.uk/~bmah/projects.php - #DFT for DVS systems
- Orthopaedic Research Base Services (ORBS)

Rest of the team;

- Andrew Brown
- Seth Bullock
- Michael Butler
- Tim Chown
- Dave Cliff
- Nick Gibbins
- Hugh Glaser
- Simon Grange
- Lajos Hanzo
- Nick Jennings
- Kirk Martinez
- Danius Michaelides
- Vladimiro Sassone
- Colin Upstill
- Mark Weal
- Neil White
- Mark Zwolinski

6 Reference

Reference List

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Ref Type: Internet Communication

(4) Pervasive Systems Centre. 8-3-2007.
Ref Type: Internet Communication

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Digital Healthcare Projects Policy

P1: Action Plan

University of Southampton

March 2007
ECSTR-PSC07-005

PSC DEVELOPMENT PROGRAMMES
Project Document Cover Sheet

Digital Healthcare Projects

Project

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Project Title	Digital Healthcare Projects Policy Generation		
Start Date	15 March 2007	**End Date**	31 March 2010
Lead Institution	University of Southampton		
Project Manager & contact details	Dr Simon Grange Intelligence, Agents, Multimedia Group School of Electronics and Computer Science University of Southampton Southampton, SO17 1BJ		
Project Web URL	www.orbs.ecs.soton.ac.uk		
Programme Name (and number)	*Pervasive Systems Centre*		
Programme Manager	Prof. David De Roure		

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1v2	13/06/2007	2nd draft for ECS publication with formatting