PHS 2008 Consultation Workshop

Holiday Club Tampere Spa, Lapinniemenranta 12, 33180, Tampere, Finland

30-31 January 2008

Organised by: ICT for Health Unit,

DG Information Society and Media,

European Commission

Rapporteurs: Rasha Mozil & Valentina Cilli, MIP (Milan, Italy)

Table of contents

1 Introduction

1.1 Purpose

After a welcome address, Mr. Gatzoulis, from the ICT for Health Unit of Directorate General Information Society and Media of the European Commission, introduced the purpose and the topic of the consultation workshop.

He explained that consultations with stakeholders are key events in helping the Commission prepare the Work Programmes (WP) for the ICT Theme of the Framework Programmes (FP). Consultation may take place in different ways: through dedicated events (such as consultation workshops and conferences), dedicated projects (as in case of support actions and studies), and other sources (like the Strategic Research Agendas of European Technology Platforms, for instance). An example was given of how consultation and Support Action projects lead to the development of a research roadmap in the domain of Virtual Physiological Human.

This particular consultation workshop is the second of its kind concerning the area of Personal Health Systems (PHS) in the 7th Framework Programme (FP7). The first event was organised in Luzern in February 2006 and provided inputs for the ICT WP of 2007-08. The **objective** of the current workshop in Tampere was to **gather inputs for the ICT WP in the period 2009-2010, as far as the PHS research is concerned**.

Other types of consultations in PHS are also underway. A study on the application of robotics in healthcare is ongoing, aiming at providing inputs for the ICT WP in FP7 from 2011 and beyond. Moreover, a roadmap project, PHS2020, funded under an FP7 Support Action, is being carried out to provide inputs for PHS research in the ICT WP of FP7 from 2011 and beyond. Other consultations will be planned in the future.

1.2 Background on Personal Health Systems

PHS is a relatively new concept, introduced in the 1990s. PHS are about ***disruptive*** eHealth solutions that place the individual ***citizen in the centre of the healthcare delivery process***. PHS can bring significant benefits in terms of improved quality of care and cost reduction in patient management, especially through ***remote monitoring and management*** applications. PHS are seen as key components for bringing ***continuity of care*** in terms of location (extending care outside hospital settings to ordinary living environments) and time (e.g., continuous, anytime monitoring) and assisting the shift towards ***preventive***, ***personalised*** and ***citizen-centred*** care.

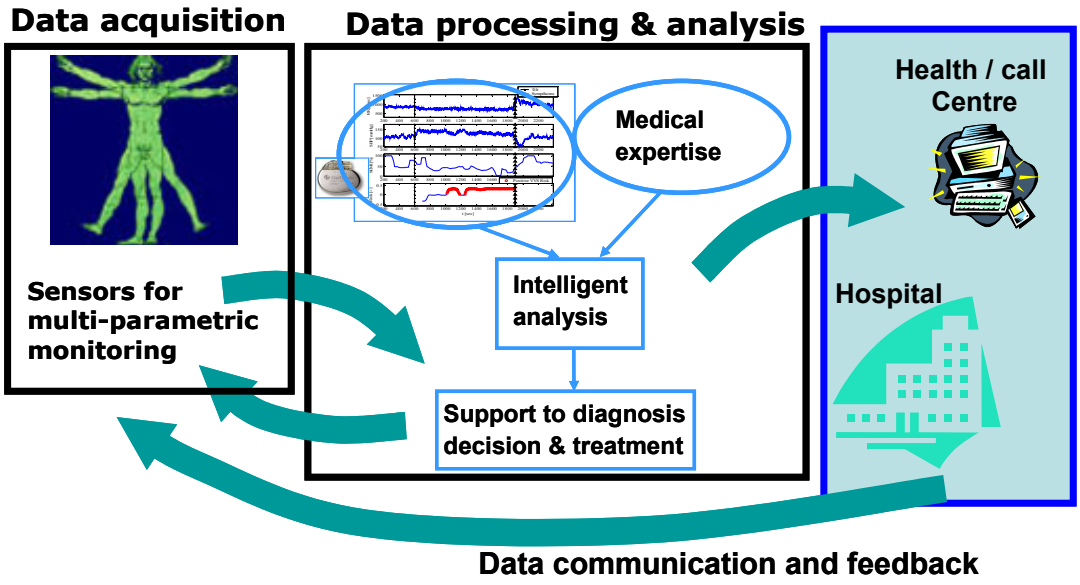
PHS cover a wide range of systems including ***wearable***, ***implantable*** or ***portable*** systems, as well as ***Point-of-Care*** (PoC) diagnostic devices. The functioning of PHS is related to three blocks:

- 1st block: Acquisition of data and information related to the health status of a patient or healthy individual, e.g., through the use of sensors and monitoring devices.

- 2nd block: Processing and analysis of the acquired data to identify what information is clinically relevant and useful in diagnosis, management or treatment of a condition. This entails processing of data at both ends: locally at the site of acquisition (e.g., with on-body electronics) and remotely at medical centres. Data processing takes into account the established medical knowledge and professional expertise where appropriate.

- 3rd block: Communication between various actors, in a loop: from patient/individual to medical centre; from medical centre that analyses the acquired data to doctor/hospital; and back to the patient/individual from either the wearable/portable/implantable system itself or the doctor or the medical centre (e.g., in the form of personalised feedback and guidance to the patient, adjusted treatment via closed loop therapy, control of therapy devices).

These blocks are interconnected, and the links between them are of as equal importance as the blocks themselves.



Research on PHS started in FP5 with emphasis on the development of technologies, components and communications infrastructure to support delivery of healthcare at the point of need. It continued in FP6 with focus on integrated systems and services and also on the personalisation of health systems and care. A number of FP projects like AMON, MOBIHEALTH, MYHEART and WEALTHY have developed and tested prototype devices and services. The first call in FP7 supported the further development of PHS for early diagnosis and prevention through Point of Care devices and intelligent multi-parametric monitoring systems. It also focused on solutions for remote management of chronic diseases, again based on multi-parametric monitoring.

Management of chronic diseases is a major issue, taking into account (i) the increasing burden which chronic diseases impose on healthcare systems in terms of human and financial resources, (ii) the demographic problem of ageing population, but also (iii) the potential for development of a market for new personalised telecare solutions as an answer to the growing pressure on healthcare systems. The industry has an increasing interest in this field. Recently, the Continua Health Alliance was set up with the aim to promote interoperable personal telehealth solutions that empower people and organisations to better manage health and wellness.

1.3 Structure of the workshop

The workshop was organised in four parts, over two days. It explored possible research directions for PHS along three main themes:

a) ICT-enabled Artificial Organs (Wearable, Portable, Implantable)

b) Precise, minimally invasive systems for early diagnosis and treatment of diseases

c) Mental health: Early diagnosis and management of mental disorders

These themes were selected on the basis of the input at the previous consultation workshop in 2006 and the analysis of the first ICT call in FP7.

On Day 1 (30 January), the workshop consisted of two parts:

- Part A: Plenary session of short presentations on selected items related to the three main themes outlines above.
- Part B: Brainstorm discussions on the 3 main themes (with the participants split in brainstorm groups).

On Day 2 (31 January), there were two more parts in the form of plenary sessions:

- Part C: Presentation of the results of the brainstorming discussions and
- Part D: Open discussion and further recommendations.

As the workshop aimed to support the development of the ICT Work Programme, the main consideration during the discussions and elaborations on the above themes was how ICT can bring new solutions to meet healthcare needs. Other related developments, e.g., in the fields of nanotechnology or medical science were not in the focus of the workshop.

2 Part A – Presentations

2.1 Session A1 – Artificial Organs

Presentation n. 1: "Wearable artificial kidney", by Steven Schilthuizen, from TNO Science and Industry.

Renal failure results in high blood pressure, cardiovascular problems, and limited life expectancy. Current treatments consist in dialysis (haemo- and peritoneal) and in kidney transplant, both of them having high costs and limited efficacy.

A small-sized, wearable artificial kidney (enabled by micro-sensors and nano- and ICT-technologies) would allow continuous direct haemo-filtration via blood – blood plasma separation, with a highly efficient sorption filter and high clearance rate. The system would employ a number of sensors for in-flow sensing, would be capable of interpreting multi-parametric data from the sensors and of supporting direct feedback to nephrologists and patients (e.g., remove filter, contact nephrologist, check connection etc.).

Presentation n. 2 "New developments in monitoring and treatment of diabetes patients", by Jan Maria Wojcicki, from the Polish Academy of Sciences

Diabetes is a group of metabolic diseases characterised by elevated level of the glucose concentration (hyperglycaemia) resulting from defects in insulin secretion by pancreas, insulin action or both. Diabetes is leading cause of kidney failure, blindness, nervous system damage and amputations, and major risk factor for heart disease, stroke and birth defects, shortening average life expectancy. Diabetes is currently one of the most costly diseases in both human and economic terms. Currently, the main objective of the standard diabetes treatment is to prevent development and to slow down progression of the late micro- and macro-vascular complications of the disease.

This objective could be achieved by applying the standard way of diabetes treatment with modern technical support. The biggest problem in such approach refers to the invasiveness of intermittent blood glucose measurements. A new design and development of accurate, noninvasive, low-cost glucometer is currently needed. For unstable courses of diabetes, it is also very important to have continuous glucose monitoring systems that are much more accurate than the minimally invasive systems existing today (a glucose Holter system). Another really crucial problem is related to the design and development of an accurate and low-cost hypoglycemia alarm system. Avoidance of hypoglycemia can dramatically improve the quality of current diabetes treatment. Furthermore, from the patient's perspective, close contact with the physician, leading to self-confidence and comfort, is the most important. The best technical solution in this case is the application of telemedicine systems.

We are still far from developing a true artificial pancreas as such. Therefore for wider applicability in the population it is more appropriate to consider an intermediate step: the development of minimally invasive approaches for automated glycaemic control at home, including automated systems for insulin delivery and alarm systems.

Future developments could thus invest effort towards: (i) hypoglycaemia alarm systems; (ii) non-invasive glucose measurement systems (with at least 5% accuracy); (iii) telematic personalised systems, supporting also education of the patient and (iv) simple automatic insulin delivery systems operating during the night, when not eating or in other activity.

Presentation n.3: "Artificial liver – a personal update", by Dieter Falkenhagen, from the Department of Clinical Medicine and Biotechnology, Danube University Krems

The liver is a very complex internal organ which needs, in case of loss of function, complex support. Acute Liver Failure is still a Black Box - not understood well. Present technology for artificial livers is based on artificial materials developed for partial replacement of liver function. It is therefore more appropriate to indicate them as "artificial liver support systems" (ALSS), rather than artificial livers. Principle application targets are bridging to transplantation and bridging to regeneration. Currently used ALSS are mainly orientated to support the disturbed detoxification function including the removal of protein-bound substances such as unconjugated bilirubin. Future ALSS will be designed to support also the diminished immune-function of the liver and will be much more efficient and biocompatible.

Presentation n. 4: "Artificial heart", by Bart Meyns, from the KULeuven Cardiac Surgery Department

Chronic heart failure affects about 1% of total population. Current treatments include implantation of heart pumps to patients waiting for transplantation (bridging). A promising development is the destination therapy that, however, has been applied only on isolated cases until today. Data from systems monitoring heart pumps cover two areas: functioning of the pump (i.e., motor current, rotations per minute, produced flow, alarms for suction, blockage, electrical warnings, etc.) and the medical status of the patient (i.e., blood pressure, heart rhythm, weight and fluid balance, etc.). Currently, pump data are communicated during hospital visits (leaving thus room for further research and development), while medical data are communicated both at hospitals' visits and through e-mails.

Next developments will invest into getting more information from the heart itself (with the use of appropriate sensors) and steering of the running mode of the pump. In terms of ICT, this translates to (i) systems for providing an automatic self-adjusting running mode for the pump as well as monitoring and controlling the operation of the device and (ii) services for monitoring and processing of data and patient follow up (ideally, the patient should not undertake any action to have data monitored or transferred).

Challenges lie of course in the implementation of such new solutions: Who will monitor the data (24 hours a day)? Who will take the medical decision? Who will take responsibility? There is no benefit in monitoring and transferring data if no guaranteed sensible action follows.

2.2 Session A2 – Minimally Invasive Systems

Presentation n. 5: "DSP for minimally invasive medical systems and artificial organs", by Georges Kotrotsios, from CSEM

Continuous, multi-parametric monitoring systems require interconnectivity of large number of sensors. Connectivity refers to various aspects: (i) information connectivity (wireless, end-to-end, with adaptable bandwidth); (ii) hard to hard systems connectivity (connectivity of subsystems) and (iii) hard to soft systems connectivity (system to tissue).

Fusion of data provided by a large number of sensors and correlation of the data with biomedical knowledge are major technological challenges to be able to provide support to diagnosis, decision and treatment. Digital

Signal Processing (DSP) is a key to dealing with these challenges. DSP will be more and more embedded in PHS, and will be requested for all categories of applications, including: artificial organs (e.g. artificial kidney) where the feedback mechanism becomes critical, and diseases that due to their implicit complexity need more sensors and more intelligence. Local intelligence becomes the next big thing in this respect

Presentation n. 6: "Minimal invasive micro-system", by Pascal Besesty, from the French Atomic Energy Commission (CEA-Leti)

A number of strategic areas were presented where important research is required to advance the state of the art. These include the development of:

- Fully integrated and autonomous devices.
- New bio- or chemical sensors with special attention to issues related to reliability, calibration and operating lifetime.
- Energy saving and scavenging, including remote power supply.
- Sweat analysis.
- Micro-needles as in vivo transfection tools.
- In-Vivo packaging and biocompatibility.
- Personalized therapy with dedicated dose and flow rate in closed-loop control approaches.

Presentation n. 7: "European Technology Platform for Nanomedicine – Research priorities for 2009-2010", by Pascal Besesty, from the French Atomic Energy Commission (CEA-Leti)

The presented research priorities have been inspired by the Strategic Research Agenda of the European Technology Platform (ETP) in Nanomedicine and were discussed during the meeting of its working group on nanotech based diagnostics and imaging. The main research priorities proposed by the ETP in Nanomedicine were:

- Nanotech based diagnostics for *in vivo* and/or *in vitro* early detection and/or therapy monitoring in the cardiovascular diseases, neurodegenerative diseases and cancer.
- Integrated diagnostic test (incl. sample preparation) for rapid and early diagnosis of viral and bacterial infection.

Presentation n. 8: "Risk stratification in cardiovascular diseases: Minimally invasive devices for early diagnosis & intervention", by Xavier Navarro, from Medtronic Ibérica

Sudden Cardiac Arrest (SCA) is the cause of 20% of all natural deaths. Risk increases with age, but happens also to children and "healthy" athletes. More than 60% of SCA victims do not have a risk profile according to current markers. The development of future systems for early detection of cardiovascular diseases should therefore include the gathering of data related to new and more precise markers. Integrative risk assessment models would be required combining clinical, imaging and genetic data with data from monitoring devices. Some features of new systems were illustrated: (i) implantable sensors for collecting data, (ii) distance telemetry for sending data, (iii) patient management platform for interpreting the data and (iv) implantable devices for treatment.

2.3 Session A3 – Mental Health

Presentation n. 9: "Minimal Invasive Systems for Mental Stress Recognition", by Bert Arnrich, from the Wearable Computing Lab, ETH Zurich

Minimally invasive wearable and ambient systems can be used to help prevent chronic stress disease, by recognising mental stress patterns in daily life. Recognition of stress patterns can be made by monitoring

and analysing data about physical activity, heart rate, breathing and electro-dermal activity. The required approach is twofold. On one hand, multimodal stress patterns are analysed in controlled environments and correlated with established biopsychological markers like saliva samples and questionnaires, aiming at obtaining meaningful interpretations of the results and to increase the validity of the technical devices. On the other hand, the minimally invasive systems are embedded in real-life settings and evaluated with biopsychological methods. The challenges are to discriminate resting, cognitive load and stress, evaluate effects of stress on physiology and of course carry out the real-life validation.

Presentation n. 10: "Mental Disease Management – New tools from ICT", by Rita Paradiso, from Smartex

Technology allows continuous unobtrusive monitoring, during the day, during the night, at work, at home, at any time, even for non-verbal language. The are trends for development of sensors in textile patches, in order to monitor and correlate response to antidepressant drugs, to prevent relapse in depression, to detect drug misuse, over feeling and lack of act, loss of communication and contact, and silent anger in autism.

A multi-variables approach (including for example sleep, speech and sweat analysis; saliva and transdermal alcohol tests) would probably offer higher sensitivity or specificity for the prediction and management of events related to mental disorders. With the help of ICT, warnings and feedback can be provided to prevent manic episodes in bipolar disorders, suicidal attempts in severe depression, self-injury in psychosis, aggressive events in autism, and unnecessary, costly hospitalization. Technology can help monitor risks in patients with a deficit of verbal, or even non verbal communication. Therapy using internet can be applied for auto-treatment, which recently showed its feasibility and potential efficacy (bulimia, pathological gambling). Biofeedback needs to be explored more deeply: so far it is rather limited to the laboratory but more user friendly devices could be incorporated in daily life functioning.

Presentation n. 11: "Communication and information exchange and assessment between mental disease patients and medical personnel. Can we fill the gap through intelligent, intuitive I/Fs and quality control mechanisms?", by Nicos Maglaveras, from the Lab of Medical Informatics, Aristotle University of Thessaloniki

Mental disease generally includes bipolar disorder, depression and schizophrenia. The major issue is the lack of knowledge related with the communication and follow-up between the medical personnel and the patients. There are elements that can help indirectly such as gestures and "content of speech" via Natural Language Processing, not that much via speech analysis. Sleep analysis is considered a very important input for the assessment of the status of mental disorders.

For what concerns bipolar disorder in particular, the challenge is the objective assessment of symptoms during the patients' daily routines and the prediction of maniac phases. PHS can employ sensors for heart rate and activity monitoring in order to provide a quantitative (sleep-wake phase) assessment of sleep and motion. As far as depression is concerned, qualitative analysis of sleep is currently available only in sleep labs. Improved sensors for electrophysiological signals (e.g. dry electrodes) will enable EEG/EOG recording in home environments as well. The close relationship between mood and circadian rhythm (including the sleep-wake cycle) needs to be further investigated.

Presentation n. 12: "Management of mental health and stress – cognitive behavioural approach", by Ilkka Korhonen, from VTT

The intervention was focused on depression and its risk factors. Concerning trends for research and development, emphasis was put on an interdisciplinary approach with the involvement of psychologists and other stakeholders in technology projects, and on focusing on prevention and early phases in general, not only on treatment.

PHS can be enablers for cognitive behavioural therapy, through the facilitations of self-observations, monitoring and feedback. Some goals were formulated: making devices available, accessible for all,

anytime, anywhere; enabling mobile and pervasive computing technologies; monitoring and intelligence for objective, motivating and inspiring feedback; user interfaces; links to Electronic Health Records and iterative development in test beds to optimise solutions taking into account the acquired evidence.

2.4 Session A4 – Technology and Health Care

Presentation n. 13: "Requirements for intelligent software for data integration, decision support and feedback", by Pirkko Nykänen, from the University of Tampere

Healthcare is moving towards a holistic, citizen-centred model, where a network of players is charged with the delivery of care. This paradigm shift leads to certain challenges as patients become active consumers, involved in care and decision-making processes and new technologies expand the possibilities for applications in healthcare. The real implementation of citizen-centred care model requires the overcoming of technological and societal obstacles. Currently, certain technologies are available, or will be available in a short time, while social aspects related to the applications of intelligent systems need to be taken into account, e.g., conceptualisation of personalised health care, socio-technical contextualisation etc. Areas that require further work and attention are:

- Non-invasive multi-parametric monitoring combined with expert feedback and existing knowledge sources and targeted to the specific context.
- Safety, security, privacy and confidentiality issues in a multi-user, multi-application environment.
- Ontologies and information models enabling interoperability of heterogeneous data sources.
- Demonstration of accuracy in terms of sensitivity and specificity.
- Evaluation in terms of usability, usefulness, effect and impact (economic too).

Presentation n. 14: "Personal Health Systems - a service based perspective", by José Ferdinando Esteban Lauzán , from Atos Origin sae

The intervention gave a description of the NESSI European Technology Platform, whose purpose is to provide a unified view for European research in Service Architectures and Software Infrastructures that enhance the safety, security and well-being of citizens. In the field of eHealth, a working group has been created (NESSI e-Health WG). This working group proposes actions aiming at accelerating the development of the European eHealth industry, increasing citizens' well-being and producing societal and economic benefits for all actors involved. Among the recommendations are:

- Provision of patient-centred services, at the point of care.
- Better links between patients and doctors, to facilitate remote monitoring and decrease the need for hospitalisation.
- Providing doctors with clinical decision support systems for disease management based on useful information automatically built upon the fusion of different sources of heterogeneous data.
- Tools for supporting disaster/crisis management by expanding clinical and administrative workflows to medical devices and external applications.

Presentation n. 15: "The EPoSS approach – Medical Technologies and Personal Health Systems", by Sebastian Lange, from VDI/VDE-IT

The intervention gave a description of the EPoSS European Technology Platform, its working Group on Medical Technologies (MedTech) and the approach to Smart systems Integration. Key research priorities of EPoSS within the context of PHS are (i) Smart miniaturized devices with advanced functionality and performance (e.g., smart implants), and (ii) autonomously operating, power efficient and networked smart devices. Applications domains include health and in-vivo monitoring, assisted therapy and assistance to independent living.

In addition to smart devices, there are other research working groups in the MedTech area focusing on Lab-on-chip and bio-sensors and robots.

Presentation n. 16: "Service model and process reengineering – Artificial organs for patient centric care", by Cristiano Paggetti, from Medea

A key message was the requirement to marry clinical needs with technology solutions into novel service models for person-centric care. New implant solutions can impact the vision of person-centric care providing diagnostic capabilities, rehabilitation of lost functionalities and activity monitoring. Examples of current applications are in restoring vision and hearing capabilities, stroke rehabilitation and tackling incontinence problems. The development of advanced implants requires technological developments in the domains of human body modelling, materials, power technology, micro technologies, wireless communications, middleware platforms and service and knowledge management.

Presentation n. 17: "Success factors for the transformation of health care systems and development of new markets", by Hannu Hanhijärvi, from SITRA

The intervention focused on the necessary steps to be taken in order to create the market for personalised care. Emphasis was placed on:

a) adopting service product orientation with quality and cost measures visible to enable comparison;
b) enabling and allowing patient choice;
c) separating service suppliers and providers;
d) providing incentives to support good performance;
e) always carrying out pilots to measure outcomes objectively; and
f) reporting the outcome openly in all occasions.

Presentation n. 18: "When Tablets Fail to Deliver…", by Ventzeslav Iordanov, from Philips

While tablets represent a huge part of all pharmaceuticals (92% of Pharmaceuticals is delivered in tablets, according to the HRI reports of July 2004), drugs are delivered also through other technologies: inhalers, syringes, creams, patches or pumps. Tablets are syringes are not always the most effective ways to deliver drugs. Controlled drug release systems and body-compatible smart systems like e-pill, e-patch, e-pump can prove more effective in some cases. The European Union can be competitive in this area, as strong technological expertise is present in its territory.

3 Part B – Brainstorming sessions

3.1 Brainstorming group 1 – Artificial organs

The discussion was focused on the developments concerning four artificial organs (kidney, pancreas, liver and heart), the main challenges and implications in terms of ICT.

Concerning the **artificial kidney,** societal challenges emerge in relation to the high number of patients affected by renal failure. From a more technical point of view, challenges were identified with respect to: blood filtration (and measuring the levels of clearance) and the safety of vascular access, in terms of hygiene and the nature of the access (open). Furthermore, continuous daily dialysis with low flow rate was seen as

both a challenge and an opportunity at the same time, for bringing major difference to treatment and quality of life.

With respect to the applications of ICT, an ICT-enabled artificial kidney would improve the current process of renal failure management in many ways. The artificial organ would be essentially a component of a more integrated disease management approach which would also encompass other non- or minimally- invasive sensors for measurement of vital signs (e.g. cardiovascular) in order to monitor the patient's health status, the response to treatment, and adapt treatment as and when required. More effective and efficient dialysis would be achieved through the use of continuous in-flow sensing, intelligent interpretation of multi-parametric data and remote control of the operation of the device by the clinician. The overall ICT system would enhance the patient-doctor interaction and would provide useful feedback to the patient him/her-self. The artificial kidney device can be realised without any real need for special membrane/filter development. The current state-of-the-art membranes and filters are suitable and the only requirement is their appropriate integration into a wearable or portable device.

Other issues emerged as points for considerations. When looking at clinical aspects, the need for taking into account the physiological background emerged. Technical developments do not necessarily need to be confined to miniaturisation: larger-sized external (portable) artificial organs could be also suitable for use at home. Due to its low maintenance requirements, peritoneal dialysis was considered as appropriate for home use. As a general remark, the term “dialysis at home” could be preferable instead of “artificial kidney”.

With regard to **artificial pancreas,** the general remark was that current research is still far away from developing a true artificial organ. The advised development, concerning also the use of ICT, would be an intermediate step, which could have wider application on the general population: the development of minimally invasive approaches for automated closed-loop glycaemic control (both hyper- and hypo-) at home, capable of generating alarms when needed (in the case of hypo-glycaemia crises, for instance).

The main challenges currently derive from glucose measurement systems. Existing devices can guarantee accuracy in intermittent measurements, but with invasive or minimally invasive techniques. In case of Holter type glucose monitoring systems, the very low accuracy of measurements and the short duration of their application need to be solved. Another crucial problem refers to the prediction of hypoglycemia events. For this purposes a new type of an accurate measurement system could perhaps be sought through the use of reduced dynamic ranges for glucose measurements or through the combination/correlation of non-invasive glucose measurements with other measurements of vital signs or body fluids.

A possible development to be considered was that of micro-needles, which could be used both for blood sampling and for insulin injection (dual function).

The importance of telemedicine links, in the form of home and mobile telecare, was stressed in various respects: to have availability of information from treatment of diabetes (blood glucose measurements, blood pressure) and therapy of late diabetes complications (teletransmission of foot images from patient’ home, ECG courses etc.), or to develop personalised services, or to support the continuing education of patients and their access to information.

Challenges affecting the development of **artificial liver** were considered to come from different directions. On one hand, demographic trends lead to increasing prevalence of liver failure, with high mortality rates. On the other hand, the complexity of liver failure makes it difficult to have a complete understanding of the disease (acute liver failure is not totally understood at the moment), with the overall picture complicated by the fact that liver failure is accompanied by many other correlated problems. Finally, existing devices for liver support do to offer satisfactory performance.

Concerning the ICT relevance of future developments, the belief was that the creation of a well functioning artificial liver is still very far. More suitable progress, also in terms of ICT, was identified in the form of portable minimally invasive devices (prostheses) for transient therapy, which carry out continuous detoxification and allows for enhanced liver regeneration capacity at the same time. Such devices would be combined with anticoagulation systems and would have on-line sensors for coagulation monitoring (calcium and oxygen monitoring, for instance). It was underlined that high biocompatibility is a basic requirement for

any device in this field. It was also remarked that anticoagulation systems were applicable to heart and kidney patients too.

Finally, an issue regarding the development of devices for liver patients was pointed out. It is not always clear if artificial livers are regarded as drugs or as medical devices. Such an ambiguity poses problems for validation and certification of new developments in this field, in terms of the types of trials to be carried out, the number of people to be involved, etc.

Current practice in the field of **artificial heart** refers to heart pumps which are essentially implantable prostheses: left ventricular assistive devices. Identified technological developments relevant to ICT relate to the provision of automated, self-adjusting running mode for such devices.

Starting from the consideration that the existing heart pump technology is quite mature, future research was suggested to focus on optimisation of existing devices (with additional functionalities/capabilities for example), rather than on developing new ones. Heart pumps could be seen within the framework of an extended monitoring system for health status, activity and lifestyle monitoring. This would help (i) identify the status of the patient's heart, (ii) monitor and control the device's operation (iii) see how the device reacts to activity changes (e.g. running). Other suited developments involved intelligent processing of data, services for monitoring and patient follow up as well as support to health professionals in decision making when required.

Finally, some **common issues** were pointed out for all four types of artificial organs. The first remark was that besides the development of the artificial organs themselves, there are additional requirements for ICT systems for **autonomous** (on-body) **regulation** of the artificial organ performance. The second concerned the **validation** of new solutions and developments, i.e., the provision of quantitative and statistically relevant evidence supporting the introduction of new devices. As a minimum requirement, validation should demonstrate the proof of concept in clinical environments, following ethical approval for tests. The size of tests should be proportional to the capacity of recruiting patients (implants can pose restrictions) aiming ideally for statistical significance, even with small sample statistical methods. A further development was that of creating **services for supporting new medical devices**, aimed at all the actors involved in the caring process: specialists, general practitioners, nurses, patients, etc. This includes also patient education and training on the use of devices and, importantly, ICT systems for remote support to and management of artificial organ users. The latter should address the issues of "where does the data go to" and "who responds to adverse events".

A general opinion drawn after the discussion was that the domain of ICT-enabled artificial organs is "merging" with that of minimally invasive systems.

3.2 Brainstorming group 2 – Minimally invasive systems

Three main topics were debated during the brainstorming session:

- Technological trends in "minimal invasive systems in the healthcare domain".
- Technological requirements for "minimal invasive systems" project take up.
- Organisational and managerial requirements for "minimal invasive systems" project take up.

Technological trends in "minimal invasive systems in the healthcare domain"

Discussion on trends in this field had a specific focus on **sensor** development; mainly into two different approaches: distributed (high number of) sensors and concentration of sensors in micro-/nano- systems.

Several challenges were identified referring to whether sensors can meet the requirements of the future. The challenges related mainly to the following subjects:

- Stability
- Calibration
- Data quality
- Standardisation
- Interoperability

Another trend discussed was the importance of reducing the **energy consumption** in these systems, in order to reach a longer life-span and avoid invasive operations to replace or plant new devices in place. A suggestion was the possibility of auto-regeneration using the energy of the body.

The amount of **data** transferred between different stakeholders is also of major concern, since too much data can do more harm than good, and actually reduces the number of patients the physicians can receive. Future systems must include data reduction, customisation of data depending on who the stakeholder is, and improved methodology of how to, intelligently, extract knowledge out of the available data.

It is further important to have a **holistic approach** where the invasive systems are not to be considered as stand alone products. Additionally, it is important that the integration between the invasive systems and biotech products, in general, is assessed, by looking at possibilities for integrating minimally invasive systems with drugs, clothing, and new material developments (e.g. plastics). To better understand the condition of the human body, there also need to be better and improved **interfaces** for the interaction with the human being, e.g. better visualisation techniques. Finally, the **interoperability** of systems is a key to guaranteeing improved conditions for both patients and physicians.

Regarding the trends for **services**, these are identified into three interconnected fields: diagnosis, monitoring and treatment. In diagnosis, it is very important to identify the diseases early on in order to limit their negative effects. This requires, as mentioned above, customisation of the transferred data in order to also assess risks early on. Concerning the monitoring case, the quality of data needs to be improved, in addition to including intelligent data processing. Lastly, in the case of treatment, the trend is more towards localised treatment of the affected area (localisation of medication delivery for instance), avoiding treatments that affect the whole body and have more side-effects.

The following **applications and target groups** were considered to be best suitable to concentrate on in the coming research programmes:

- Teenagers:
  - Systems that encourage young people to adopt healthy lifestyles by preventive actions (hypertension, cholesterol).
- Healthy people:
  - Wellness applications, heart arrest and stroke (interventions and timing of interventions).
- Elderly persons:
  - Monitoring of mobility decrease, constipation, catheters and infections.
- Chronic patients:
  - Epilepsy, hypertension, asthma, respiratory, smoking, treatment and medication.

Technological requirements for "minimal invasive system" project take up

Research projects should have higher take-up than what is the case today. In order to improve the conditions for that, technology should enable better physician-patient-clinician collaboration and be interoperable. Another consideration could also be the standardisation issues for sensors and systems in order to facilitate inter-communication.

As mentioned earlier, physicians are handling too much data; it is thus important to ensure that future systems can intelligently extract relevant only data. Since the systems are to be used by end users, a user oriented approach should be adopted to ensure usability and increase the possibilities for adoption. Furthermore, with today's rising healthcare costs in mind, it is of major importance to consider the cost effectiveness of the systems.

Organisational and managerial requirements for "minimal invasive" project take up

In current and past projects, it has been difficult to involve users, since their payback is not clearly defined. In order to improve the situation in future projects, to ensure the above mentioned usability and applicability, it is suggested to fund more efficiently the demonstration part of the project. In order to attract the users and keep them motivated for the work, improved payment alternatives are required. Another suggestion is by highlighting the possibilities to help doctors in their scientific carriers through their involvement in the research projects.

In the field of healthcare, evidence based medicine is of major importance in order to be able to market healthcare products and make use of research results. Evidence based medicine is however, not included in the scope of European projects. The "clinical proof of concept" should be better defined in order to get it accepted by the community. This is required in order to facilitate and improve the possibility of exploiting project results, but in order to do so the validation part of the project needs to address all the value chain with clear/sustainable business models. This requires stakeholder analysis and impact analysis as well as the development of business models with the involvement of insurance companies or/and National Health Systems.

3.3 Brainstorming group 3 – Mental Health

Mental Health is a key area given the rising prevalence throughout Europe and the sheer size of its direct and indirect cost and related loss of productivity. It is also a less consolidated area when considering the possible implications for ICT to support prevention, monitoring and treatment. The need for adoption of a **multi-parametric approach** seems to characterise the field, including different types of metrics (bodily, brain, behavioural).

A key distinction was made between **primary** and **secondary** prevention. In the first case (primary prevention), the target are the healthy individuals who may want to monitor their lifestyle and activities and avoid that stress leads to depression (self-management). In the case of secondary prevention, the focus is on patients: individuals already being treated for mental health problems (depression and bipolar patients). Accordingly, ICT supported solutions can address directly the citizen, tackling the issue as one of lifestyle, as well as the patients and the professionals treating them. In particular, in primary prevention the focus is on healthy individuals and more towards sensitive systems able to recognise early warning signs, and to support management and guidance. On the contrary, in secondary preventions the focus is on patients and ICT-based systems that can support the monitoring of therapy, use of drugs, and other standard parameters of a clinical system[1].

Monitoring and data gathering are key factors, which currently can rely on devices and approaches similar to those used in other areas. The challenge however is to find ways to **close the loop** and use ICT to enable treatment and self-treatment. Two parallel routes for research were identified:

- the development of new technologies on one hand and,
- the development of new management and treatments models, on the other hand.

Other issues for development were also identified:

- adaptation of elements from psycho-therapeutic practice into ICT based systems, and
- citizen-empowerment through ICT-supported self-treatment.

Concerning the prevention side, the consideration was that many technological devices and supports are currently available but not entirely appropriate to monitor and help maintain mental health in daily life. These devices work in laboratory settings, but data from real-life situations are scarce. Therefore, new instruments are needed, in order to gather long-term data not only about bodily functions, but also behavioural aspects.

Furthermore, the need for designing multi-parametric systems was stressed, which include data from e.g.:

[1] This distinction between primary and secondary prevention is equally valid for all PHS application domains, not just those referring to mental health.

- observation of behaviours,
- brain activity and sleep,
- related to bodily and bio-chemical functions

In the development of new tools and systems, a stronger involvement of mental health professionals, such as neuroscientists, psychotherapist and psychiatrists is required. Moreover, the need for including **Artificial Intelligence** applications in order to bring together all markers and to define condition and treatment was stressed.

Consistently with the two types of prevention identified (primary and secondary prevention), having different targets and different tools, two **business models** were distinguished. One business model was considered in relation to primary prevention, and addressed the development and implementation of non-medical systems to support personalised lifestyle, empowerment and self-treatment of individuals. The other business model was related to development and implementation of systems providing support to individuals being treated and to professionals treating them. However, the latter raised some issues to be further discussed, such as the identification of individuals entitled to use and monitor the data.

Some **conclusions** were drawn at the end of the session. At first, the general consideration was that Personal Health Systems for Mental Health is a relatively new development and needs closer **integration** between technological research on the one hand, and neuro- and behavioural sciences on the other. Then, the need for multi-parametric predictive systems to fill the current gaps in both monitoring and treatment was stated once again.

With particular reference to research instruments in the Framework Programme, two considerations were made. On one hand, **support actions** bridging and tying ICT findings with socio-economic, neuro- and behavioural sciences were considered as extremely relevant for future developments in the area. On the other hand, IPs were considered more appropriate than STREPs to develop complex and multi-parametric systems in this domain.

4 Parts C & D: Presentation of Brainstorming results and further recommendations

4.1 Presentation of results from Brainstorming discussions

In Part C of the workshop the results of the three brainstorming discussions were presented to all participants in a plenary session. Each presentation highlighted the key points and main messages that emerged from each brainstorming group. Following this update, the last part of the workshop took place in the form of an open discussion.

4.2 Open discussion and further recommendations

Instruments to support research

Initially the open discussion dealt with the research instruments. IPs and STREPs were compared, recalling that the former should support more holistic projects, whereas the latter are meant to support more focused projects. STREPs could be more suitable in the case of artificial organs for example, because this domain is more sharp edged. It was recognised however, that IP projects can address better the wider potential range of impacts which a research innovation can produce.

On one hand STREPs are more manageable but present challenges into fully integrating all aspects of a given research topic. On the other hand, IPs have greater potential to fully address a topic but also entail greater risk due to the possibility that their focus is not well defined.

Overall, the discussion did not lead to any clear cut and strong positions or conclusions. The use of both instruments in all domains seemed appropriate, and the exclusion of one of the instruments was not suggested.

Support Actions were also discussed and specific recommendations were made for their use in support of the Work Programme development (details on page 18).

Ground-breaking developments

Debating further on the brainstorming sessions of the previous day, the first issue tackled was what would be considered fruitful and challenging research for the ICT domain. The view was that any new solution which helps people to avoid spending a lot of time in hospitals and being taken away from everyday life would be regarded as ground-breaking development. Examples may well include home dialysis, intelligent heart pumps, "intermediate" artificial pancreas for diabetes management and non-invasive glucose measurements. More focus should be directed towards the development of new appliances in this respect. Those in use today require spending much time at hospitals and are too far away from use in everyday life.

A lot of potential exists in developing systems for intelligent decision support, which integrate and process multi-parametric data and include also algorithms for identifying trends and making projections. When talking about measurements and diagnosis, it is important to know under which conditions the diagnosis was made and how the measurements were taken. This calls for embedding context awareness into the multi-parametric systems and developing devices which are able to also use environmental information and data.

Higher accuracy, precision, sensitivity and specificity are both requirements and differentiating factors in new personalised diagnostic and therapy systems. Avoiding information overload, false alarms, false positive and false negative diagnoses are of paramount importance, as well as accurate drug delivery (e.g., through smart pills). Furthermore, there was common consensus that future systems need to be more intelligent and more secure from a privacy point of view. In particular, artificial organs and minimally invasive systems come under strict regulatory requirements, especially as in the future they may also be combined with pharmaceutical products. Consequently, having ICT embedded in them and linking them to centralised resources puts stringent requirements on the software dealing with safety, reliability and resilience aspects.

Other important developments can be expected in the area of mental health - an area where a rising number of people are being affected and healthcare resources are limited. Particularly relevant are the (linked) cases of chronic stress and depression, both of which have high prevalence and major impact on labour productivity and economics. In addition to the technological challenges mentioned in the relevant brainstorming group, the importance of Natural Language Processing in the communication and follow-up between the medical personnel and the patients was mentioned.

Validation

Regarding the issue of validating any new solutions developed in research projects, the extent of the required effort was discussed. Validation needs as a minimum to aim at proof-of-concept in clinical settings: "clinical proof-of-concept". This implies demonstrating, even with a small group of users, that the new solution is:

- technically valid and the devices operate as intended,
- safe to use and efficient,
- useful and has positive effect on therapy or disease management.

Validation needs to be quantitative, including two groups of users: one receiving the traditional treatment/disease management approach and the other group receiving the traditional method plus the new solution. Measurements can then be made to investigate the success of the interventions. This kind of approach can be used as basis for future clinical trials, which are outside the scope of the research projects and need to be assessed in a different matter.

Stakeholders' involvement

Concerns were expressed about the fact that European projects do not have a high success rate in terms of delivering project results onto the market. A reason for this is the lack of involvement of the right stakeholders who would have a key role in using projects results.

A general comment was expressed about how difficult it is to push the results of ICT projects if the users are not enough experienced and confident in the application of ICT supported systems. A suggested solution was to have Support Actions to increase the links between the ICT and health domains. Another suggestion was to have more frequent brainstorming sessions with physicians, whereas now the projects are very industry oriented. A reason for this is reported to be that it is difficult to get physicians outside their daily work at the hospitals. A way to overcome this problem could be to bring the brainstorming sessions closer to the physicians, and in order to get the most out of the sessions, they should be well planned and focused. An additional suggestion was to have the mentioned sessions in connection with large medical congresses, where there is a great opportunity to put medical and ICT people together.

There was also agreement on the fact that, consultation workshops should probably occur more frequently than what has been the case so far.

Business models

Another issue, surfaced and debated several times, concerns the business models to support the financially sustainable exploitation of project results. This is particularly urgent for chronic disease management and early prevention applications.

Firstly, there is difficulty in finding viable business models for such applications as today's healthcare systems are still very much focused on clinical interventions rather than on remotely performed disease management and preventive actions, even though the latter are recognised as promising solutions.

Secondly, there is a need to design business models with clear incentives to attract investments from industrial players. Any future technology should take into account a global, worldwide perspective. In this way, it could be a real target for companies. Without strong economic incentives on their side, it is difficult to develop technologies that can possibly be deployed.

Thirdly, and related to both points above, there is a need for robust evaluation and measurement methodologies that can prove the positive benefits of such systems. In the management of chronic conditions, PHS present a "disruptive technology" which requires structural changes to the current healthcare practices concerning both the roles of patients and healthcare professionals and the reimbursement of costs. In primary prevention, PHS are potentially even more "disruptive". Consequently, demonstration of the value of PHS to all stakeholders (citizens, patients, healthcare professionals, health service providers, reimbursement agencies, policy makers etc.) is a prerequisite to the development of viable business models for PHS. However, a dilemma arises from the difficulty to study preventive actions. In most cases, in order to study the preventive paths, it is necessary that the patient has already the disease. Further on, to see the real effect of preventive measures, extended time is needed, which is outside the duration of European research projects.

Focusing the Work Programme

Given the high oversubscription in the calls of ICT for Health, there were suggestions that the calls should be more focused and specific as far as application domains are concerned. A two-step project evaluation approach was also put forward as an attractive alternative to the current practice.

Regarding the focus of the calls, there was discussion on what kind selection criteria could be considered. These could refer, for example, to the broadness of a disease, the need for further research and the associated cost (e.g., what could be available to a large part of the population at reasonable cost). Overall, there was a widely held view that the focus should be on a certain number of diseases and clinical aspects

that put a lot of pressure on healthcare systems, i.e. focusing on disease and application domains rather than on technology. Reflecting the discussions of the brainstorming groups, some application domains for consideration can be cardiovascular diseases, diabetes, respiratory diseases, renal failure, liver failure, epilepsy, stress, depression, bipolar disorders and schizophrenia.

Additionally, Support Actions need to be considered for specific purposes:

- To strengthen the links between ICT and medical domains, where there is need for medical evidence and improved understanding.
- To explore what research directions can be supported in the future in the field of primary prevention, by looking into technological needs and opportunities but also issues like validation, business models and reimbursement. This is to run for approximately 12 months in order to provide input to future calls in the ICT Work Programmes.

Topics for consideration in future Work Programmes beyond 2010

There was extensive discussion about research related to **primary prevention**. As mentioned in the previous section it was suggested that a Support Action project be launched to prepare the ground for research projects on preventive care in the next calls of the ICT Theme.

Our understanding of what works in preventive actions is not enough and there are needs to fill knowledge gaps. There are very few examples where primary prevention has worked and succeeded; it is very difficult to achieve and demonstrate successful results. Primary prevention is related to lifestyle and behaviour. Some guidelines for behaviour already exist to help prevent the onset of diseases, but most people do not follow them. ICT could be extremely useful in terms of motivation and adherence. Furthermore, as PHS extend monitoring, diagnostic and therapeutic capabilities to the natural environments of individuals, the conditions under which measurements are taken are not clinically controlled (in the way that they are in a hospital or a doctor's office). This particular point needs to be tackled, since all our golden standards on what is reliable and can be acted on are based on controlled environments[2]. Large, evidence generating studies with real users and testbeds could contribute to guidelines on how the information produced by PHS may be used in decision making. Nevertheless, to see the real effect of prevention, a lot of time is required, which runs beyond the life time of the project. These issues as well as that of business models need particular attention.

Other areas mentioned as worth considering for support in future work programmes were:

- Orphan diseases (e.g., haemophilia) can be expensive to treat now. But in the future, these diseases could be treated by methods similar to what PHS offer in other domains. It could be worth investigating this in upcoming meetings.

- Rehabilitation is a topic for which effective and affordable applications can be envisaged to meet real needs. Resources dedicated to rehabilitation are severely limited. PHS can be instrumental in mitigating this and in supporting patients carrying out their rehabilitation exercises independently, whilst still being monitored by healthcare professionals. This should be explored further in a separate occasion.

- Mobility-related diseases were also mentioned. People with specific mobility problems can present another domain of application, perhaps in conjunction with rehabilitation.

[2] This comment applies to all PHS applications, not just primary prevention.

5 Final Agenda

Wednesday 30 January			
Part A: Presentations, 13:00 – 14:50 hrs			
Introduction, 13:00 – 13:20 hrs			
Name	**Affiliation**	**Topic**	**Country**
Gatzoulis Loukianos	EC, INFSO H1	Background and Orientations	EC
Session A1 – Artificial Organs, 13:20 – 13:40 hrs			
Schilthuizen Steven	TNO Science and Industry	Wearable artificial kidney	NL
Wojcicki Jan Maria	Polish Academy of Sciences	New developments in monitoring and treatment of diabetes patients	PL
Falkenhagen Dieter	Department of Clinical Medicine and Biotechnology, Danube University Krems	Artificial liver – a personal update	AT
Meyns Bart	KULeuven Cardiac Surgery Department, Gasthulberg University Hospital	Artificial heart	BE
Session A2 – Precise minimally invasive systems for early diagnosis and treatment, 13:40 – 14:00 hrs			
Kotrotsios Georges	CSEM	DSP for minimally invasive medical systems and artificial organs	CH
Besesty Pascal	CEA-Léti	Minimal invasive micro-system & ETP for Nanomedicine – Research priorities for 2009-2010	FR
Navarro Xavier	Medtronic Ibérica	Risk stratification in cardiovascular diseases: Minimally invasive devices for early diagnosis & intervention	ES
Session A3 – Mental Health - early diagnosis and management, 14:00 – 14:20 hrs			

Arnrich Bert	Wearable Computing Lab, ETH Zurich	Minimally invasive systems for mental stress recognition	CH
Paradiso Rita	Smartex	“Mental Disease Management – New tools from ICT	IT
Maglaveras Nicos	Lab of Medical Informatics, Aristotle University of Thessaloniki	Communication and information exchange and assessment between mental disease patients and medical personnel. Can we fill the gap through intelligent, intuitive I/Fs and quality control mechanisms?	GR
Korhonen Ilkka	VTT	Management of mental health and stress – cognitive behavioural approach	FI
Session A4 – Technology and healthcare, 14:20 – 14:50 hrs			
Nykanen Pirkko	Department for Computer Sciences, University of Tampere	Requirements for intelligent software for data integration, decision support and feedback	FI
Esteban Lauzán José Ferdinando	NESSI ETP (Atos Origin sae)	Personal Health Systems - a service based perspective	ES
Lange Sebastian	EPoSS ETP (VDI/VDE Innovation + Technik GmbH)	The EPoSS approach – Medical Technologies and Personal Health Systems	DE
Paggetti Cristiano	MEDEA - MEDical and Engineering Applications	Service model and process reengineering - artificial organs for patient centric care	IT
Hanhijärvi Hannu	SITRA	Success factors for the transformation of health care systems and development of new markets	FI
Iordanov Ventzeslav	Philips	When Tablets Fail to Deliver, Smart Delivery Systems Come Into Play	NL
Coffee Break 14:50 – 15:30 hrs			
Part B: Brainstorm Sessions, 15:30 – 18:00 hrs			
Brainstorm Group 1 – Artificial Organs			
Brainstorm Group 2 – Minimally Invasive Systems			
Brainstorm Group 3 – Mental Health			

Thursday 31 January
Part C: Plenary Session, Presentation of Brainstorming results, 13:00 – 14:30 hrs
Brainstorming results from Group 1, 13:00 – 13:30 hrs
Brainstorming results from Group 2, 13:30 – 14:00 hrs
Brainstorming results from Group 3, 14:00 – 14:30 hrs
Coffee Break 14:30 – 15:00 hrs
Part D: Plenary Session, Open Discussion and Further Recommendations, 15:00 – 16:30 hrs

6 List of Participants

Arnrich Bert	ETH Zurich
Bardram Jacob	IT University of Copenhagen
Beretta Claudio	General Directorate of Health, Lombardy Region
Besesty Pascal	CEA-Léti & ETP Nanomedicine
Cavanillas Jose Maria	Atos Origin sae & ETP NESSI
Cilli Valentina	MIP
Codagnone Cristiano	MIP
Doukas Charalampos	University of Aegean
Edwards Jonathan	Gartner
Esteban Lauzán Jose Ferdinando	Atos Origin sae & ETP NESSI
Falkenhagen Dieter	Department of Clinical Medicine and Biotechnology, Danube University Krems
Gatzoulis Loukianos	European Commission
Gelderblom Gert Jan	Vilans
Hanhijärvi Hannu	SITRA
Iordanov Ventzeslav	Philips
Junai Arun	TNO Science and Industry
Korhonen Ilkka	VTT
Kotis Takis	Royal Brompton Hospital
Kotrotsios Georges	CSEM
Kouki Vassiliki	University of Pireus
Lange Sebastian	VDI/VDE Innovation & ETP EPoSS
Maglaveras Nicos	Lab of Medical Informatics, Aristotle University of Thessaloniki
Maglogiannis Ilias	University of Aegean
Merilainen Pekka	GE Healthcare
Meyns Bart	KULeuven Cardiac Surgery Department, Gasthulberg University Hospital
Mozil Rasha	MIP

Navarro Xavier	Medtronic Ibérica
Nykanen Pirkko	Department for Computer Sciences, University of Tampere
Paggetti Cristiano	MEDEA - MEDical and Engineering Applications
Paradiso Rita	Smartex
Perez Manuel	Atos Origin sae & ETP NESSI
Reiter Harald	Philips
Robinson Simon	empirica
Roca Josep	Hospital Clinic I provincial de Barcelona
Saranummi Niilo	VTT
Savoldelli Alberto	MIP
Schilthuizen Steven	TNO Science and Industry
Vienken Jorg	Bioscience Department, Fresenius Medical Care, Bad Homburg
Walker Nick	iXscient
Wals Jeroen	Philips
Wojcicki Jan	Polish Academy of Sciences