Information and Stakeholders' Day on Smart Wearables

Organised by the European Commission, Directorate General for Communications Networks, Content and Technology, DG CONNECT

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Report[1]

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1. Executive Summary

Smart wearables occupy a position between the digital and the human world. They are held to have the potential to transform the way society functions within the near future. They support immediate, real-world actions and decisions by providing directly relevant, contextual information and performing tasks precisely at the point of decision-making[2], causing the boundaries between the physical and the virtual world to blur further. It is an area which will trigger a lively debate[3] in public policy with regards to privacy, ethics, health and safety, and data security.

On December 11, 2015, the European Commission: DG CONNECT organised a major event, the Information and Stakeholders' Day on Wearables. The aims were to discuss with various actors:
- major technology advances, applications and market issues;
- to identify progress, barriers and opportunities for Europe;
- to inform stakeholders about the H2020 open call for proposals on IoT and the large scale pilot on wearables for smart ecosystems
- To facilitate networking and foster good quality proposals.

The event attracted hundreds of participants and thousands of internet interactions and followers, proving a high level of interest in wearables and the presence of a committed stakeholder base in Europe. The main event conclusions were that:
- The solution set for smart wearables comprises a platform, specific technologies and functionality to address the requirements of chosen application areas.
- For application areas, a clear focus is needed on how to use the solution – actionability- and what people/society can learn as a result of system use.
- A "black box" approach - the provision of devices without interconnectivity to a linked back end system - is now redundant.
- Despite bullish projections for future market growth, there have been false dawns already. The potential for economically sustainable industrialisation of smart wearables in Europe has yet to be realised.
- An eco-system in Europe needs to be built-up, comprising equipment providers, platform or network operators, content and app providers and the end user/final consumer. The interactions between these actors within an eco-system are complex and need to be clearly understood in order to create value.
- Europe is well positioned to scope and exploit the potential from smart wearables. EU funding is available to support R & D and piloting of solutions. Opportunities exist in a number of sectors including health, household, textiles and construction.

The overarching challenge for smart wearables in Europe (and beyond) is to showcase the significance of the area and demonstrate the potential to open up markets. Furthermore there is a general need to raise awareness of the potential of smart wearable technology to improve people's live and create value for businesses. Promoters of smart wearables will need to embrace value

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[2] http://www.deloittedigital.com/blog/the-truth-about-wearables-what-they-are-and-arent
[3] This note was drafted in the backdrop of US Food and Drug Authorities' regulatory initiative on wearables (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDoments/UM429674.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery) and of calls from stakeholders asking the EU to consider the impact of ongoing legislative initiatives on wearables (http://www.cbronline.com/news/internet-of-things/wearables/eu-urged-to-rethink-regulation-on-wearablehealth-data-4736096)

stream thinking to overcome the challenges encountered to date with sub-optimal uptake and failure of smart wearable solutions to create value and realise their expected potential.

As well as meeting the challenging requirements for baseline functionality, the eco-system must create the space for wearable solutions to deliver value, and ensure that key actors will be mobilised and committed in practice to realising potential benefits. And once a solution has been proved to be safe and efficient, end-user acceptance, approval for reimbursement and e.g. effective marketing of the solution are as critical as the preceding phases of product development, proof of concept and regulatory compliance.

This report and the discussions held on the 11th December, suggest a step-wise approach to developing smart wearable solutions:

1	Build the concept
2	Engage with the eco-system
3	Define the solution
4	Validate the concept with the eco-system
5	Cross the second valley of death

2. Introduction

A widening range of gadgets are gaining importance in our daily life. Glasses, jewellery, headgear, belts, arm wear, wrist wear, leg wear and foot wear are taking on new forms and functions; skin patches and e-textiles are emerging onto the market. There are several smart wearables readily available, and many more are on the way. Overall smart wearables aim to connect easily and seamlessly to other useful devices so as to make the users' life better, easier, healthier or more fun.

The "Smart textiles, flexible & wearable electronics" sector is heterogeneous and growing. For instance it has been estimated that the market for wearable technologies will grow from $20 billion in 2015 to almost $70 billion by 2025[4]. It includes a large variety of interdisciplinary technologies, processes and enabling applications such as smart labels for packaging, and lighting & sensing textiles. These technologies have a potential socio-economic impact in a wide variety of possible application sectors, such as health (including medical, fitness and wellness), fashion, lighting, ID tracking & localisation, industrial and manufacturing applications, automotive, and military applications.

Research and development has been supported all over the world and there is a fierce global competition on innovation and business opportunities from smart wearable devices and services. Currently being at the cross-road of emerging technologies and (new) socio-economic challenges, the European Union has been taking a leading role in supporting research and development and consulting the stakeholders to find the right framework for further growth and business development of the sector.

a. The purpose of the event

On December 11, 2015 the EC, DG CONNECT organised a major event - the Information and Stakeholders' Day on Wearables - to discuss major technology advances, applications and market issues to identify progress, barriers and opportunities for Europe. It also served to:

- Inform interested parties about the H2020 open call for proposals on the Internet of Things (IoT) and the large scale pilot on wearables for smart ecosystems,
- Facilitate networking and foster the submission of good quality proposals.

The event attracted hundreds of participants and thousands of internet interactions and followers. This proves that a high level of interest in wearables exists across Europe and provides evidence of a committed stakeholder base.

A summary of the presentations made and discussions on the day, as well as recommendations for future action, are provided in the sections which follow.

b. Definition of smart wearables

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[4] *Wearable technology 2015-2025: Technologies, Markets, Forecast E-textiles, wearable electronics, medicals diagnostics/telemedicine, Smart glasses, smart wristbands and more. By Dr Peter Harrop, Mr James Hayward, Raghu Das and Glyn Holland.*

Described initially as "wearable computing" during the 1960's, smart wearables were more recently defined as "the study or practice of inventing, designing, building, or using miniature body borne computational and sensory devices. Wearable computers may be worn under, over, or in clothing, or may also be themselves clothes" [5]. They may be considered as the most recent and specific development of the earlier and more general concepts of ubiquitous and pervasive computing.

Wearable devices may also be built into the body itself and in this way become part of it. There is thus a close relationship between smart wearables and the 'Internet of Things' (IoT).

c. Rationale for Action

Europe is well positioned to scope and exploit the potential from smart wearables. Smaller companies providing small objects and components as well as larger companies are active in the field. From a relatively low base, the expected growth in market size is high, and opportunities present in a number of sectors including health, household, textiles and construction. The area is of interest to a varied audience across the innovation and value chain and presents as an important opportunity for Europe.

Over the last 15 years, the European Commission has provided R & D funding for projects in for instance: electronic components and smart systems, smart textiles, organic and large electronics [6].

Despite the huge advances in device development, miniaturization and wireless communications, some technological barriers still need to be addressed to allow for the expansion of this sector. Some of them are related to the integration of electronic devices in textiles and other flexible or stretchable substrates, particularly those related to electrical interconnection between devices. Also, the lack of bulk manufacturing capability (roll-to-roll production) due to an insufficient level of automation constitutes a significant barrier. The low capacity of energy storage (low energy density values) and power management remains considerable challenges. Significant effort will be needed to reduce the needs for power or to develop new methods for battery charging (such as wireless charging). Challenges are further discussed in Section 6 below.

In the light of the huge potential of smart wearables and the current constraints limiting large scale deployment in the digital market, the EU decided to invest more in research and innovation for smart wearables and for Internet of Things (IoT) in Horizon 2020. The challenge is to foster the deployment of IoT solutions in Europe through integration of advanced IoT technologies across the value chain, demonstration of multiple IoT applications at scale and in a usage context as close as possible to operational conditions. This will involve development of:

- Inter-operable linked platforms
- Embedded software
- Network equipment (not so much devices)

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[5] *Source: Steve Mann, Wearable Computing, in: Mads Soegaard / Rikke Friis Dam (eds.), The Encyclopedia of Human-Computer Interaction, 2nd ed., 2012 (available at http://www.interactiondesign.org/encyclopedia/wearable_computing.html).*

[6] *Wearable smart systems: From technologies to integrated systems Lymberis, A.; Engineering in Medicine and Biology Society, EMBC, 2011 Annual International Conference of the IEEE, Digital Object Identifier: 10.1109/IEMBS.2011.6090946, 2011, Page(s): 3503 - 3506*

- Applications

Relevant considerations for those seeking to realise the potential of the area include:

- Owners (e.g. Regions or companies) of IoT/smart wearable platforms may be best placed to reap the benefits;
- Some products, services or solutions will be relevant to a number of deployment scenarios: impacts across multiple sectors are expected;
- For targeted application markets, it will be critical to consider what needs to happen to bring solutions to market and to ensure that key actors will be mobilised and committed in practice to realising potential benefits. Value chain thinking will apply rather than just considering how to supply a produce to meet a demand in a specific market.
- How best to ensure user acceptance and handle testing. Liability and data protection present particular challenges; legislation may not evolve fast enough to inform design and conformance requirements or may inhibit take-up.
- Design of common, standardised or shared approaches to data handling and deployment to service end-users, so that duplication and complexity is avoided.
- Manufacturability

The rest of this report presents the major themes and a summary of the issues discussed.

3. The solution set

a. Platforms for Wearables

A platform uses technologies which are clearly defined and work to a set of standards. Collectively this then provides a platform, which can be understood as a (preferred) environment to develop applications and build an ecosystem.

General platform design considerations include:

- Responsiveness to end-user business drivers;
- User centric ergonomic functionality: a new term – 'wearer ware' – may be needed to fill a gap in terminology;
- Attention to ethics and worker privacy.

Smart wearable platforms typically address:

- Connectivity to and from the platform;
- The approach to fusion of data;
- The role of and approaches to adoption of (open) standards;
- Support for a diversity of sensors;
- Gateway, server, call centre functionality and feed-back loop (with potential to build in AI).

Additionally specific functionality can be included to address the specific characteristics of a sector. So for instance platform providers targeting the health ecosystem may include:

- Functionality to address country by country legislation requirements;
- A modality for connecting sensors in and around body of the person (as part of a Body Area Network (BAN);
- Smart system integration;
- Protect the user's privacy and life: compromises and 'break glass' procedures;
- Build large, anonymous data sets for use with data mining and Big Data techniques;
- Security functionality for audit trails, patient identification and to avoid hacking of critical data;
- Functionality to guarantee data availability/system responsiveness;
- Data fusion, analysis and assessment: alerts and alarms, an approach to analysis and interpretation of data (algorithms); support for the creation of large anonymous/anonymised data sets for use with data mining and Big Data techniques.

For sports and fitness platforms, social acceptability will be enhanced if they enhance an individual's social status as well as providing the functionality needed.

Piloting of the platform has a crucial role in validating functionality and demonstrating benefit to end-users within the chosen eco-system.

b. Technologies for Wearables

In general, wearable technologies can be differentiated by place of use, by the functionality delivered and by purpose, by the end-user impact of the information created.

MEMS (Micro-Electro-Mechanical Systems) are a key building block for Internet of Things (IoT) applications. Solution developers typically aim at fast, affordable prototyping with development continuity to final devices. This can require an open development environment, providing interoperability across all components. Industry is seeking to develop smaller, more connected devices with less power consumption.

A reliable, cost-efficient and end-use adapted integration of smart systems into textile materials is a key technological capacity for the successful realisation of smart wearables. The ideal combination of reliable functionality, cost efficient manufacturing and a high level of user-friendliness has not yet been achieved. Products typically fall short in one or several of the following:

- Functional performance;
- Durability/reliability (especially connections);
- Mass production capability;
- Mass-market price level;
- Ease of use;
- Wearer comfort (weight, bulkiness, flexibility, skin-friendliness);
- Ease of care & maintenance (wash-ability, repairability).

c. Application Areas and Eco-systems

While some devices will not function without a central hub to connect to, others, such as smart watches, could be totally independent very soon. The relationship between wearables and smartphones is incredibly complex. A hub, like a smartphone, is often required to send and receive data to the wearable device. However, in scenarios where people need the use of both hands, a mobile phone is not sufficient and wearables have the opportunity to replace smartphones entirely by combining with voice interaction.

A clear focus is needed on how to use the solution – actionability- and what people/society can learn as a result of system use. Two examples illustrate this in practice. The Swan-iCare wearable system for wound monitoring aims to develop an integrated autonomous device for chronic wounds, mainly diabetic foot ulcers (DFU) and venous leg ulcers (VLU). This involves addressing the requirements of professionals monitoring the care of patients and the personalized management of individual patients. Sonitor's wearable tags used in hospitals and healthcare for tracking patients, staff, and hospital equipment, enable real time tracking of assets.

Further discussion about how best to address the needs of specific eco-systems is provided in Section 5 below.

4. The Market

a. Market evolution

According to BI Intelligence[7], the global wearables market will grow at an annual rate of 35% over the next five years, reaching 148 million units shipped annually in 2019, up from 33 million units shipped this year.

Devices like UP by Jawbone, Nike FuelBand, Fitbit and Apple Watch have been followed by Google Glass. However, unable to overcome the technical and social challenges that stifled its adoption, Google stopped selling the product in January 20015. Attention shifted to smart watches, with the launch of devices like Samsung Gear S2 and Apple Watch. Apple's most personal product ever, the Apple Watch, led to achievement of the number two spot in the wearables market, on its very first entry to the market.

b. Who needs to be involved?

A black box approach – the provision of devices without interconnectivity to a linked back end system - is now redundant. Four sets of actors now become involved in taking solutions to market:

1. Equipment providers: an important revenue stream results from business symbiosis between device manufacturers and other partners;
2. Platform or network operators;
3. Content and app providers. Significant value can be created: by content, Apps, Big Data and Devices as enablers (but not always);
4. The end user / final consumer.

The interaction model between layers is complex, and a number of critical relationships between the actors need to be fully understood, so that win-win situations result. The market opportunity lies less in hardware or software and more in addressing the needs of an entire eco-system or value chain.

c. What does it take to succeed?

Despite the great market potential, so far only a handful of companies appear to be succeeding as large scale commercial suppliers of smart wearables. They include for instance:

- Wrist bands for heart rate monitoring for fitness are widely deployed;
- CuteCircuit, an East London fashion house is pioneering interactive clothing design and wearable microelectronics;
- Chip and fibre connections for digital shirts are under development but not yet on the mass market;
- DAQRI initial trials of the 'smart helmet' are complete, with information about lessons learned available, but further trials will be needed.

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[7] Go to http://www.techinsider.io/the-wearable-computing-market-report-2014-10

Key factors to enable economically sustainable industrialisation are not limited to technological developments. The right conditions to support new operational capabilities, manufacturing and service delivery processes need to be created to simulate technology penetration in the target market. Tools to assess the added value and risk of digital and service experiences, and forecasting and planning smart wearables are lacking.

d. Textile-based smart wearables are not yet realising their potential

Textile-based smart wearables have a broad range of potential application markets such as sports, health, personal protection or entertainment. Smart clothes that reveal information on our posture, heart rate or body temperature are being developed. However hype has been followed by commercial disappointment, even if knowledge and capacity has been developed (through for example EU funded R & D). Misunderstandings have persisted between the textile and electronics industries.

While many functioning smart wearable prototypes have been developed over the last 10-15 years and some niche products have been launched on the market, killer apps and sound business models appear largely absent. However some small players may offer a possible spring board. These factors combined with a lack of must-have functionality which would persuade users to accept shortcomings, are mainly to blame for the fact that textile-based smart wearables are not more widely in use.

e. Europe's opportunity

Against this background, Europe is well positioned to scope and exploit the potential from smart wearables: smaller companies providing small objects and components as well as larger companies are active. From a relatively low base, the trend is positive, and opportunities present in a number of sectors including health, household, textiles and construction. The area is of interest to a varied audience across the innovation and value chain and presents as an important opportunity for Europe.

Key enablers are interconnects and appropriate use of textiles; it is also critical to fully understand the use case, and money flows.

5. Addressing the requirements of promising ecosystems

As discussed Sections 3 and 4 above, the market opportunity lies less in hardware or software and more in addressing the needs of an entire eco-system or value chain. With this in mind, pioneers have highlighted some of the important characteristics of the healthcare, construction and industrial work eco-systems.

a. Healthcare

Smart wearables need to address the broader healthcare context:

- Increased prevalence of chronic illness and demographic trends: people are living longer and are aiming for healthy life years. It will be important to consider the role of wearables in preventing illness as well as providing better care and cure;
- Patient expectation of improved user experience and the implications this for health professionals / providers;
- Technology devices do not offer a complete solution, rather they should deliver quantified value within a broader care pathway or business process;
- The ecosystem is very diverse and complex , with relatively low levels of standardisation;
- Dominant design solutions may be expected to emerge for different places on the body.

Design considerations need to take account of:

- Logistics – disposables, re-usables;
- Regulation and country by country legislation requirements – see Section 6.f. below;
- User requirements in terms of:
    - Where and how the patient will use the wearable and how to integrate it into his or her life;
    - Clinician requirements for the form and presentation of information and the need for instance for summary longitudinal monitoring information over time;
    - Hospital needs for information to support scheduling of activity;
    - Payers – what solutions can safely be approved for reimbursement and how to develop standardised approaches;
    - Societal considerations – how will the contribution of the care cycle help to keep young people healthier?

Deployed solutions need to be capable of:

- "Serious" and high-quality sensing: 'better than the doctor';
- Providing reliable, accurate and medically relevant measures, compatible with existing information;
- Reliable alarming;
- Medical environment compatibility and acceptance;
- Supporting more sensors networked around the body: Body Area Network (BAN, SmartBAN).

b. Construction

Smart wearables for construction need to deliver improved safety and security: two growing concerns in the construction sector.

There are specific construction scenarios which involve complex working environments with more demanding safety requirements for guaranteeing the workers' health, preventing accidents and ensuring a rapid response in case of emergencies. One example is the construction of underground infrastructures, using for instance Tunnel Boring Machines. In these scenarios there is a lot of advanced machinery and means of transportation involved which may share working areas with humans; there may be onsite temporary manufacturing facilities (e.g. for producing precast concrete segments for tunnel construction) with their own safety implications, and there are harsh working conditions due to temperature and humidity levels, as well as possible presence of gasses within the tunnel.

But even the simplest construction use cases have strict safety requirements. The most common injury types, such as falls and workers struck by falling objects, can happen in virtually all construction environments.

Design considerations need to take account of:

- The other needs in the fields of security (e.g. access control);
- Logistics (e.g. time logs for quantifying hours spent in each work site);
- Quality/environmental management (e.g. perform onsite inspections for validation of finished works);
- The temporary and changing scenarios at construction sites, constrained by the timeline of a construction project.

Deployed solutions need to be capable of:

- Interworking with other smart wearables are already in use in these scenarios, e.g. COTS badges based on WiFi or active RFID for identification and localization functionalities required for safety procedures;
- Adding functionality such as sensors for measuring environmental conditions, or for detecting a fall of the worker, communication capabilities for triggering alerts, etc.;
- Supporting increased computing and power requirements and balancing this with need for device autonomy and affordable;
- Localizing workers within the construction site and analysis of their interactions with site elements to ensure the correct use of protective equipment;
- Easy deployment;
- Re-configurability;
- Functioning in an adverse environment (interferences due to machinery, dust, extreme temperature/humidity conditions, blows, etc.).

c. Industrial work environments

Design considerations need to take account of:

- Ergonomic comfort, performance and battery life;
- Existing end-user habits and expectations;
- An open ecosystem to enable software developers to author and distribute new applications;
- End-user privacy and security, e.g. camera awareness and location tracking.

Deployed solutions need to be capable of:

- Interoperability with existing environments and systems;
- Minimising adoption stress.

A representative example of state of the art devices supporting workers in industrial environment is the DAQRI Smart Helmet, an augmented reality wearable device. It uses a sensor, software and optics package, powered by embedded electronics and computer vision algorithms to deliver augmented reality work instructions, data visualisation, and safety notifications. Benefits claimed include 94% reduction in errors, replacement of stand-alone devices and 34% faster job completion.

6. Challenges

The overarching challenge for smart wearables in Europe (and beyond) is to show the significance of the area and demonstrates the potential for opening up the market.

Additional challenges are considered under the following headings

a. Market readiness

There is a general need to raise awareness of the potential of the technology to for instance improve people's live and create value for businesses. Given the multi-disciplinary nature of a smart wearable solution – requiring for instance electronics, textile and ecosystem specific expertise, there is a need to foster and improve collaborative thinking and development.

b. Customisation for eco-systems and value stream thinking

Some of the challenges involved in addressing the requirements of promising ecosystems are discussed in Section 5 (see above). Whilst these may be challenging enough for some promoters of smart wearables, it is perhaps not obvious that failure to address eco-systems effectively can be expected to result in:

- ***No/sub-optimal uptake:*** The solution is not adopted or does not sell - a hygiene factor for this ecosystem has not been met. See the further discussion at 6.c. below.

In the case of the health eco-system for instance, issues leading to No/sub-optimal uptake might include for instance:
- Non-compliance with applicable regulations – see discussion at 6.f. below;
- Applications which do not mesh with a pre-existing healthcare infrastructure, already dealing with a myriad of challenges with interoperability, regulatory compliance, security and the ability to manage the exponential growth of the volume of data;
- Lack of medical validation.

- ***The potential has not been properly identified/is not realised:*** expected prices or volumes are not achieved. Insufficient value is being created from the perspective of the end user. See the further discussion at 6.d. below.

Again in the case of the health eco-system, issues leading to the potential not being realised uptake might include for instance
- Failure to present a convincing business model for preventive care;
- Inappropriate expectations of or engagement with the processes or key clinicians

c. Delivering baseline functionality: hygiene factors[8] for smart wearables

To make sure that the solution is adopted or sells, it is important that 'it does what it says on the tin'. This typically involves designing to ensure that the principle of economy of effort informs data handling and service deployment and consideration of manufacturability.

The washing machine kills many research dreams. In addition to washability in water, there is also a need to consider temperature, mechanical wear, the effects of detergents, and requirements for flexibility and stretch.

It is crucial to get the following aspects right:

Device / sensor level:	Ergonomics that take account of end-user requirements and capabilities;
	Trust and security functionality;
	Device size / Miniaturisation;
	Sensors that support several functions on same silicon;
Energy management	Reduced power consumption;
	Autonomy requires energy harvesting, storage;
	Architecture for low power;
Data & communication:	Extraction of data from different sources;
	Effective traffic management;
	Interconnectivity and use of harmonising standards;
Information management:	Automated computation and effective communication;
	The right architecture for trust and security;
	Effective data privacy.

d. 'Making it sing' / Self Actualisation[9]

Costs and investments required to take a solution to market can be expected to be significant – see also Section 5 and 6.b. above. It will be necessary to take practical steps to ensure that the upside in the ambitious business plans required can be realised. The challenge in delivering value –starts with:

o Providing 'must-have' functionality capable of persuading users to accept any shortcomings;
o Identifying what needs to happen - in the market, for an end-user, within a process - to create the space for the solution to deliver value;
o Ensuring that key actors will be mobilised and committed in practice to realising potential benefits in practice.

Non-technical aspects include:

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[8] *Maslow Hierarchy of Needs – Go to for instance http://www.21stcentech.com/transportation-part-6-the-21st-century-and-the-automobile-what-will-we-use-to-make-them/maslow/*
[9] *Maslow Hierarchy of Needs – Go to for instance http://www.21stcentech.com/transportation-part-6-the-21st-century-and-the-automobile-what-will-we-use-to-make-them/maslow/*

o The approach to promoting user acceptance and handle testing is critical. Liability and data protection present particular challenges; legislation may not evolve fast enough to inform design and conformance requirements;
o How to provide for end-user governance and the strategic capacity required to realise benefits;
o Collaboration across domains;
o Focus on unique value propositions;
o Sound business model;
o Standards and test methods.

Technical considerations include:
o The ability to interact is what is new. To build user retention – use gamification for visualisation;
o The right IoT architecture for the overall solution - design for scalability. The requirements for device/product functionality should emerge from this (and not the other way round).
o Integration of textile and non-textile components;
o Scalable processing;
o To build user retention – use gamification for visualisation;
o Durability and system maintenance – disposable or not; Recycling;
o Comfort;
o The design, demand and operations planning of smart wearables involve dealing with multiple information and phenomena (e.g. technical, sensory-enabled services, market behaviour with scenario dimensions) and multi-objective modelling; challenges that are not yet resolved.

e. Crossing the second valley of death

The 2nd valley of death[10] occurs after a solution has been proved to be safe and efficient. In health for instance, clinical acceptance, approval for reimbursement and effective marketing of the solution are as critical as the preceding phases of product development, proof of concept and regulatory compliance. In that context, involvement of R&D entities may be of added value to adapt the technological solutions to these frameworks.

f. Regulation

Effective management of legal conformance processes represent a critical success factor, as innovators seek to realise the potential of smart wearables in the market place and to benefit end-users.

Some general regulatory conformance requirements for smart wearables can be anticipated, in what is an emerging area of law. For instance, will a massive data proliferation be the consequences of smart wearables? Is this desirable? Is there a need to regulate? Is the concept of data privacy the right one? For further discussion on this aspect – see the Nature article 'Biology: The big challenges of big data' [11].

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[10] *Go to: http://www.ttopstart.com/ttopstart/news/blog-the-occurrence-of-asecond-valley-of-death-during-medical-device-developmen*

[11] *'Biology: The big challenges of big data' Vivien Marx Nature 498, 255–260 (13 June 2013)*

Of more importance in the short term anyway, will be eco-system specific regulations - in for instance construction, industrial work environment, infotainment and health. The regulatory challenges in the health sector are larger than in most others, as is further illustrated below.

The health ecosystem

Smart wearables may be worn on or close to the body and as evoked in the previous Section 3.d.i., the healthcare eco-system looks to hold promise. As is more fully described below and in Anne's Story, the implications have been explored to an extent, and are complex: a number of regulations apply and the field is still evolving.

Patient safety remains a key focus for regulation:
- Device safety remains a key requirement;
- Compensation for injury/harm must be possible (liability);
- Practice must be regulated.

Whilst the EC has pushed forward a lot of legislation which makes it easier to do business, overall legislation has not kept pace with technology developments. For instance a simple mobile phone app could be a class 1 medical device (Liverpool burns app). The way in which data protection and privacy guidance apply (and the reasons for protection) is under review. Patients can consent and over-ride normal legislative constraints. It takes time for the law to catch up: it may be necessary for solution providers to retrofit / adapt developed solutions to fit the law.

Smart Wearables = Telemedicine?

Smart wearables are expected to be classed as telemedicine solutions, at least to the extent that Remote Physician Alert and Patient Advice is involved. For such services, healthcare providers must:
- Obtain informed consent of patient;
- Ensure patient understands limits of the services;
- Ensure adequate coverage;
- Ensure adequate training;
- Ensure adequate insurance.

In addition to country specific regulation and legislation, further regulation / case law applies:
- o Directive 2005/36 on Mutual Recognition of Professional qualifications
- o Directive 1997/7 on distance contracts
- o Directive 2001/83 on medicinal products for human use
- o On-line Pharmacy - Doc Morris Case

Anne's Story

Anne has had some problems in the past with her cardiac and general health. After consultation with her cardiologist Anne entered a 'Supported Heart Health Programme' with the following components:

- Implanted cardioverter defibrillator with data report and remote reset functionality;
- Personal use sphygmomanometer with wireless data report functionality;
- Web based PHR which obtains heart rhythm and BP data from devices wirelessly;
- Integration of PHR data into EHR;
- Automated physician alert tool in PHR activated when parameters are exceeded;
- Personalised dietary advice.

From a legal perspective, such a Programme needs to take account of the following guidance and regulations:

Medical Devices

Dir 90/385/EC / 93/42/EC – Active implantable Medical Devices, amended by 2007/47/EC

The device must be safe, accredited with CE mark and supplied with and used in accordance with manufacturer's instructions. The manufacturer must foresee all reasonable uses, including any software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes. Generally manufacturer will be strictly liable.

For e.g. home use of Sphygmomanometer, there is a duty to ensure that it is used within manufacturer's guidelines, any software used with it is duly accredited as a part of the device or as an accessory and that the patient understands how to use the device (possible contributory liability of patient).

Data Protection and Privacy

Dir 95/46/EC – Data Protection (pending new regulation, note no safe harbour)

The Programme includes an on-line PHR, shared with cardiologist. A large amount of data will be collected, and there is potential secondary use.

The doctor must ensure consent is informed, specific and freely given, that the patient knows who has access to what data and for what purpose, that nominative data is treated securely, 'technical' data is treated securely or anonymised, and that specific consent is obtained for any research.

The (data) controller must ensure secure storage, processing and transmission, that processors are fully under his control and provide access and rectification opportunity.

Directive 2002/58 Electronic Communications Regulation of Security of networks and services and confidentiality of communications

Liability for Goods and Services

Regulations set out the duties of a manufacturer or vendor, the rights of a purchaser and the duties of an eServices suppliers:

Dir. 85/374/EC - Liability for Defective Products
Dir. 2001/95/EC - Product Safety
Dir. 1999/44/EC - Sale of Goods
Dir. 2000/31/EC – eCommerce

These directives apply to some medical services and apply country of origin principles. For regulated professions details of local accreditation, and local applicable rules apply.
Special rules on contract formation – right to rescind – may apply. The Telecoms service provider as a 'mere conduit', not liable for the information transmitted.

As related by Dr Petra Wilson, CEO, International Diabetes Federation

7. Opportunities

a. Smart wearables and the IoT

With the advent of the Internet of Things, linked sensors are being deployed in, under or on the skin. IoT is a service which, by combining objects and secure across different domains of application, enables added value. IoT products need to deliver better yield, time to market, provide multi-functionality, and operate autonomously. IoT crosses all areas: it needs to be interactive and reactive across domains and connected objects. This is why healthcare is a promising field. There is a need to understand each layer of IoT – the senses/muscles, the local nervous system, the central nervous system and the collective intelligence.

The ability to interact is what is new. To build user retention – use gamification for visualisation.

IBM Europe is seeking to develop a wearable platform shaped by two application areas which are of particular interest: employee safety and elderly wellness. In this work, some possible opportunities have been identified to create value:

  i. Provide a simplified process for on-boarding wearable/IoT functionality into existing business applications. And to address this, development of a better understanding of complex human behaviour, integration of multi-modal sensory outputs and how to support a rich user experience;
  ii. Enable rapid/easy development of human centric apps: turn advanced analytics into re-usable assets, capable of easy integration into different business apps;
  iii. Make analytics portable across devices, embed mechanisms to cope with key factors (power, privacy etc. – not just data). The aim is to write once and deploy anywhere, so as to leverage the power of the entire eco-system.

On bottom up platform validation, important dimensions include employee safety and cognitive engagement.

b. Which markets to target?

There appears to be a promising market in sports and fitness. The Federation of European Sporting Goods Industry for instance highlights exercise in general and the sports industry in particular as a clear application area and considers that implementation should be relatively easy compared to other areas.

Health is also promising but as highlighted in Section 6.f. above, the approvals required are complex to deal with. Some well-known corporates are active.

The fashion industry and commercial and military sectors are expected to follow.

Infotainment is also promising but significant marketing will be required.

Some IT services organisations see opportunity with wearables: a logical evolution could involve the development of wearables that are able to operate automatically, without user prompts.

c. Where to concentrate?

Some Regions and/or companies may be considering investing IoT/smart wearable platforms to gain a potential 'first mover' advantage, on the basis that they may be best placed to control subsequent investment or direction of technology evolution.

Textile-based smart wearables are not yet widely in use. Project should target approaches to overcome limiting factors for textile-based smart wearables by using available state-of-the-art technology combined with focused technology developments to solve existing bottlenecks. Fundamental research is not needed.

Opportunities may exist to develop and launch products, services or solutions which are relevant to a number of deployment scenarios, targeting impact across multiple sectors.

d. The importance of eco-systems

A wearables eco-system is to provide the interface between the digital 'me' (smartphone) and the digital 'it' (IoT). Without the eco-system, wearables remain optional and lack 'stickiness'; when they are part of an eco-system they are a necessity and bring value to the user. For further illustration of some promising existing eco-systems, see the discussion in Section 5 above.

8. Research and Innovation in Horizon 2020

a. The IoT Focus Area [12]

The Internet of Things (IoT) is a "hot topic" for industry, investors and start-ups in Europe. The European Commission is investing heavily in the uptake of the Internet of Things:

- In FP7 – there were 3 FP7 calls with a direct budget of 100 M€ for conceptual R&D and piloting;
- 50 M€ of EU direct support was invested in 2015 for the creation of IoT Innovation Ecosystems;
- Over 100 M€ EU direct funding is available in 2016 for IoT Large Scale Pilots and the future IoT Focus Area.

IoT ecosystems supported by open technologies and platforms will be created. Supported IoT Pilots will use the rich portfolio of technologies in real-life use case scenarios. Support actions will provide consistency and linkages between the pilots and complement them by addressing horizontal challenges critically important for the take-up of IoT at the anticipated scale. A coordination body will ensure an efficient interplay of the various elements of the IoT-FA and liaise with relevant initiatives at EU, Member States and international levels. Research and innovation effort in specific IoT topics will ensure the longer term evolution of the Internet of Things.

For the Focus Area under the H2020 work programme 2016-17, the challenge is to foster the deployment of IoT solutions in Europe through integration of advanced IoT technologies across the value chain, demonstration of multiple IoT applications at scale and in a usage context, and as close as possible to operational conditions.

Compared to existing solutions, the roadblocks to overcome include:

i) The integration and further research and development where needed of the most advanced technologies across the value chain (components, devices, networks, middleware, service platforms, application functions) and their operation at large scale to respond to real needs of end-users (public authorities, citizens and business), based on underlying open technologies and architectures that may be reused across multiple use cases and enable interoperability across those;

ii) The validation of user acceptability by addressing, in particular, issues of trust, attention, security and privacy through pre-defined privacy and security impact assessments, liability, coverage of user needs in the specific real-life scenarios of the pilot;

iii) The validation of the related business models to guarantee the sustainability of the approach beyond the project.

IoT – Large Scale Pilots in 2016 will:

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[12] The section contains information which is not legally binding. See official information at http://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/calls/h2020-ict-2016-2017.html#c,topics=callIdentifier/t/H2020-ICT-2016-2017/1/1/1&callStatus/t/Forthcoming/1/1/0&callStatus/t/Open/1/1/0&callStatus/t/Closed/1/1/0&+identifier/desc

- Involve all value-chain actors;
- Address business model validation & standardisation;
- Address user validation and acceptability;
- Up-scaling of open platforms across verticals.

Key Performance Indicators to guarantee the sustainability of the approach beyond the project, will:
  • Ensure the longer-term evolution of IoT;
  • Facilitate the emergence of critical Mass, leadership, and mobilisation;
  • Create a rich portfolio of technologies and tools.

b. Wearables for smart eco-systems

i. FP7

10 Smart textiles, flexible & wearable electronics were funded under FP7:

• 8 CP projects,
• 1 CSA
• 1 CP-CSA.

The total costs were 63.7 M€, and the EU contribution was 43.5 M€. 94 different participants were involved.

ii. Large Scale Pilot 3: Wearables for smart ecosystems (EU contr. up to 15MEUR)

Focus:
- Innovative wearable (Fabrics, Cloths, Patches, Body-mounted devices) solutions and services, which are:
  - Integrated in interoperable IoT ecosystems;
  - Driven by user needs;
  - Transferable to other application domains;
  - Demonstrate Scalability.
- Deployment, demonstration and impact assessment (across the value chain)

Possible Application scenarios include:
- Healthcare, well-being;
- Safety, Security;
- Infotainment.

Within the IoT context:
- Operation across multiple sites;
- Scalability to large # of heterogeneous devices & systems;
- Interoperability, security & privacy, liability, etc.

Scope:
- Demonstration of wearable solutions and services integrated in interoperable IoT ecosystems.
- Bring new functionalities into clothes, fabrics, patches, watches or other body-mounted devices.
- Assist humans in monitoring, situational awareness and decision making.
- Particular attention to actuating functions providing, whenever feasible, closed-loop solutions.

- Prototype development and demonstration expected for healthcare, wellbeing, safety, security and infotainment applications.
- Driven by concrete business cases, open design approaches and user requirements, taking into account data protection and liability concerns.
- Involves actors of the entire innovation value chain, potentially including creative & artistic actors.

Pilot Implementation:
- The majority of effort should be on piloting; building blocks should be proven; may include limited research and development activities;
- Effort devoted to supply (technologies) and demand (users) should be balanced
  - Important elements of supply side, e.g.:
    - Management and adaptation of involved sensing, actuating, processing, energy supply, storage technologies at node level;
    - Integration of devices, objects and systems in an IoT environment;
    - Approaches to interoperability and openness;
    - Security and privacy approaches.
  - Important elements of demand side, e.g.:
    - Design, implementation and testing of multiple use-case scenarios
    - Interoperability needs and testing
    - Security and privacy needs
    - Feedback to IoT supplier for technology optimisation
    - Users/citizen awareness, involvement and acceptance
    - Impact, added value and affordability assessment

Expected Impact:

Pilots are expected to have a high impact on citizens, both in public and private spheres, industry, businesses and public services.

Key performance indicators should be defined to measure progress on citizen benefits, economic growth, jobs creation, environment protection, productivity gains, etc.:

  - Validation of technological choices, sustainability and replicability, of architectures, standards, interoperability properties, of key characteristics such as security and privacy;
  - New industry and business processes and innovative business models
  - User acceptance validation addressing privacy, security, vulnerability, liability
  - Significant and measureable contribution to standards
  - Improvement of citizens' quality of life, in the public and private spheres, in
  - terms of autonomy, convenience and comfort, participatory approaches, health and lifestyle, and access to services.
  - Creation of opportunities for entrepreneurs, expanding local businesses to
  - European scale, etc.
  - Development of secure and sustainable European IoT ecosystems and contribution to IoT infrastructures viable beyond the duration of the Pilot.

9. Conclusion and recommendations

This report has reviewed the presentations made and discussions held during the stakeholders' and information day, 11th December 2015 (see Annex 2) as well as the proposers pitches (Annex 3). As is further discussed in Section 6, the <u>overarching challenge for smart wearables in Europe</u> (and beyond) <u>is to show the significance of the area</u>.

It has however been possible to detect an <u>implicit consensus amongst the stakeholders involved about how best to rise to this challenge</u>. To be explicit a step wise approach is being advocated as illustrated below:

#	Step		Section ref. – this report
1	Build the concept	Consider the platform, the technologies and any specific needs of the application area	3
		Understand what is available off the shelf, what needs to be developed – cost and timeframes	4
		Develop a solution architecture suited to target ecosystem	5
2	Engage with the eco-system	Engage with the supply chain but also the target end-user community within the ecosystem:	5
		Understand how and if your concept could create value within the eco-system; what and who needs to be involved in delivering this value	6
		Is there potential for the realisable benefits to outweigh the costs of the delivered solution?	
3	Define the solution	Ensure the solution is capable of delivering required baseline functionality	6.c.
4	Validate the concept with the eco-system	Engage, build and leverage the eco-system	5,6,7
		Complete R &D required	
		Pilot the solution	
5	Cross the second valley of death	Develop business plan and funding for exploitation to include provision for end-user acceptance, commercial validation and go to market plan.	6.e.

Recommendations:

A. A $70B market for smart wearables is predicted by 2025 (idtechex). However it is important to understand what is included and excluded in market definitions. Likewise, clarity is needed about which technologies are ready for the market, but not yet found in products: this requires close examination of use cases.

B. Be clear on what is on the market and not. Use of suitable off the shelf solutions with customisation was seen as a good way forward, as opposed to spending effort re-developing pre-existing solutions.

C. It is important to consider what can be used off the shelf and what requires specialised development to meet the needs of the environment or end-users. Solutions not yet on the

market represent the main domain for research. Both end-users and industry need to be involved in solving challenges.

D. The design, demand and operations planning of smart wearables require dealing with multiple information and phenomena (e.g. technical, sensory-enabled services, market behaviour with scenario dimensions) and multi-objective modelling.

E. An emerging gap to deliver operational capabilities based on smart wearables, needs to be addressed in future research, by e.g. innovative modelling, analytics and forecasting to facilitate mass market uptake of new technology enabled wearables. This involves understanding and integrating multiple information and multiple requirements into risk-controlled decision support systems, to quickly assess the added value and risk of e.g. sensory enabled new services, from early design phases and through the operations during the product-life-cycle.

Annex 1:   **Further information available**

a.   **Twitter**

Tweets from the Information and Stakeholders' Day on Smart Wearables held on 11th December can be found by subscribing to the following accounts:

> @NetTechEU
>
> @PhototonicsEU
>
> @Electronics_EU

b.   **Web streaming:**

Go to: https://scic.ec.europa.eu/streaming/information-and-stakeholders-day-on-smart-wearables

Agenda of the Stakeholders' and Information Day, 11th December 2015
Karel Van Miert Auditorium, Place Madou, 1, Belgium

Morning Session

(Go to http://ec.europa.eu/information_society/newsroom/image/document/2015-52/all-in-one-morning_presentations_12926.pdf
and https://ec.europa.eu/digital-agenda/events/cf/smart-wearables/stream-items.cfm?id=332)

5. Welcome and introduction – Khalil Rouhana, European Commission
6. Objectives for the day – Willy Van Puymbroeck, European Commission

Platforms for Wearables (Philippe Reynaert, Moderator)
7. Setting the scene: Chris Van Hoof, IMEC, BE
8. 2 HLY years: Dress to Live not Kill, Keith Baker, Philips, NL
9. DAQRI: An augmented perspective of Europe's future in smart wearables, Gaia Dempsey, Exodea Europe, IR
10. Wearables in Health and IoT (HIT), Cees J.M. Lanting, CSEM, CH
11. IBM wearable platform (workRight/LiveRight), Lior Limonad, IBM Reearch, IL

Technologies for Wearables (Francisco Ibanez, Moderator)
12. Setting the scene: Pierre-Damien Berger, CEA Tech, FR
13. Enabling technologies for economically sustainable industrialization of smart wearables, Hajnalka Vaagen, SINTEF, NO
14. Programmable wearables, Christophe Benoit, Erasmus University college Brussels, BE
15. Supplying technological development solution for MEMS, Giulio Urlini, STMicroelecrtonics, IT
16. Fibre and textile integration as key technology for smart wearables, Lutz Walter, EURATEX, BE

Application Areas and Eco-systems (Andreas lymberis, Moderator)
17. Setting the scene, Markus Strecker, Teiimo, DE
18. Which wearables will have the biggest impact in our life? Antonio Paradell, Woldwide Iberia SA, ES
19. The construction sector as a smart wearables application area, Jose Luis Buron, Acciona, ES
20. A multilevel perspective on Connected Health Technologies, Roel Smolders, Vito, BE
21. The Swan-iCare wearable system for would monitoring, Dimitris Vassiliadis, Exodus SA, GR
22. Experience Real Time Intelligence with wearable IoT, Amir Taherkordi, Sonitor Technologies, NO

Key Notes
23. Regulation, Data Protection and user acceptance, Petra Wilson, International Diabetes Federation (IDF), BE
24. Smart Wearables and the second valley of death, Thomas Kallstenius, iMinds/AIOTI-WG7, BE

Afternoon Session

Moderators: Francisco Ibanez, Andreas Lymberis, Philippe Reynaert

(Go to: http://ec.europa.eu/information_society/newsroom/image/document/2015-51/ec_presentation_on_iot-wearable_call_2016_12765.pdf)

25. The IoT Focus Area - Rolf Riemenschneider, European Commission
26. IoT Large Scale Pilots - Francisco Ibanez, European Commission
27. Wearables for Smart Eco-systems - Andreas Lymberis, European Commission
28. Q&As

Proposers' Pitches:

(Go to: http://ec.europa.eu/newsroom/dae/document.cfm?action=display&doc_id=12927 and https://ec.europa.eu/digital-agenda/events/cf/smart-wearables/stream-items.cfm?id=333)

Proposal ideas (4 minutes)
Expertise Offered (2 minutes)

Wrap-up and closure – Willy Van Puymbroeck, European Commission

Annex 3: Proposers' Pitches:

a. Proposal Ideas

(Further information at:
http://ec.europa.eu/newsroom/dae/document.cfm?action=display&doc_id=12927
and https://ec.europa.eu/digital-agenda/events/cf/smart-wearables/stream-items.cfm?id=333)

Proposer Name	Proposal Title / Detail
Carla Hertleer Un. Gent	Clothes in the Internet of Things
Jim Ang, Un. of Kent	"Internet of Skin" for Personal Informatics
Christos Efstratiou, Un. of Kent	"LifeSense" – Quality of life collaborative sensing for people withlong-term health conditions
Gaia Dempsey, DAQRI	WARP4.0 (Wearable A.R. Pilot for Industry 4.0)
Aileni Raluca Maria, UPB-MONS	Wearable Wireless Body Sensor Networks (WWBSNs) for Health Monitoring / WearSense
Brendan O'Flynn, Tyndall	Kneehabilitation: A Low-Cost Wearable System for Physiotherapy Post-Surgery
Antonio Jara, HOP UBIQUITOUS	Wearables Live!
António Marques, Centi	Swearables (Smart Wearables + IoT)
Beatriz Sedano, CEIT	Smart Wearable System for Work Safety Improvement - Wearable4Safety
Filippo Cavallo Scuola Superiore Sant' Anna	Wearable devices in IoT infrastructures for Neurological disorders
Touradj Ebrahimi, EPFL	Wearables for an improved quality of life
Jeroen Langendam, ItoM	Breath In Balanz
Luis Cordova-Lopez Liverpool John Moores Univ.	iWearNonSense; Innovative Wearable Non-Invasive Health Sensors for Everyday Clothing
Jukka Vanhala Tampere Univ of Technology	Disappearing sensors - DISSE
Antonio Paradell Worldline Iberia SA	Wear4You
Andrew Cobley, Coventry Univ.	Selective Metallisation of Fabrics
Cees Lanting, CSEM	Body Area Networks in Health and IoT (HIT)
Lior Limonad, IBM	Live Right / Work Right (Pilot 3)
J Luis Buron, Acciona	Smart wearables for safety and security in construction

Name	Expertise offered
Raffaele Derrico, CEA	CEA Technical Expertise: Wireless comm., Sensors Design and Integration, System Integration, IoT middleware, TOLAE CEA Added value: Multi-disciplinary expertise, International cooperative research & innovation, Demonstration platform for IoT, Full value chain through European Clusters
Jukka Hast, VTT	COLAE Project: CSA project (FP7-ICT-2011-13) leading to the largest consolidation of European TOLAE platforms and the first portfolio of TOLAE services towards the industry
Anastasios Economides, CONTA Laboratory	Access to Conta Laboratory
S.A.G. Wensveen, TU Eindhoven	Design Expertise for Smart, Soft & Personalized Wearables
Toon Poppe, Heart Link Online	Access to Heart Link Online services
Ana Villacampa, Eurecat	Platforms for management, monitoring and control; Mobile platforms; Platforms for interoperability in complex environments; Workforce and task management; Embedded systems; Traceability applications
Greet Bilsen, KULeuven	Wearables enabling advanced security services
Gulio Urlini, STM	Technological development solution for MEMS
Géraud Guilloud, Ideal-ist	Controlled, certified & labeled Partner Search

Annex 4:

Information and Stakeholders' Day on Smart Wearables

Published on 29/09/2015

If you are involved in wearable platforms or technologies, then don't miss this Infoday. Challenges and opportunities of the smart wearables sector as well as the launch of the Internet of Things (IoT) Call for Large Scale Pilot on wearables will be discussed.

SHARE THIS

Date:
11/12/2015

Venue:
Karel Van Miert Auditorium, Place Madou, 1, 1210 - Saint-Josse-Ten-Noode, Brussels, Belgium

Organiser:
European Commission

This Infoday focused on what should be done on smart wearables in Europe. Furthermore, participants got first-hand information on the launch of the 2016 call on the Internet of Things.

Follow the webstreaming of the Infoday on Information and Stakeholders' Day on Smart Wearables

The Infoday will consist of two parts.

Stakeholders ' View

Three main topics were discussed: platforms, technology and eco-systems. Each topic was introduced by an expert and followed by presentations from the participants.

A keynote on the role and importance of regulation, ethics and user acceptance completed the morning session.

Proposers' Pitches

In the afternoon, the Large Scale Pilots (LSP) as defined in the Internet of Things (IoT) call and zoom-in on the LSP 3 on wearables (with a budget of 15 M€) was presented. After this introduction, participants had the opportunity to present project ideas and network.

You can follow our twitter account (#InfoWearables) for more details.

Workshop Documents

- [Registered participants](#)
- [Published stakeholders views (abstracts only)](#)
- [Pitches presentations](#)
- [European Commission presentations](#)
- [Morning presentations](#)
- [Afternoon presentations](#)

Contact:
[Mr Andreas Lymberis](#)