Projecte europeu WomenUp: Disseny, desenvolupament i validació d'un dispositiu mèdic

Miquel Angel Mañanas/Juan Pérez
Starting date

• Women-Up adventure started on Feb 2015
But the history had started before (I)

- Technological valorization project (VALTEC) “Development of a biofeedback system for pelvic floor muscle training in patients with urinary incontinence” (2010-12), funded by the Generalitat de Catalunya, in which a first prototype was developed.

- In 2012, a patent registration was issued, related to the prototype, PCT/ES2013/070507 “Método con bio-retroalimentación para entrenamiento de la musculatura del suelo pélvico” (UPC-Hospital Clínic) and received the finalist award VALORTEC of the Generalitat de Catalunya to the “Business and marketing plan of a technological patent” in 2013.
But the history had started before (II)

- Looking for a company to license the patent/technology was not possible (2012-14) because of the specificity of the industry on health sector and economic crisis.

- A company was attracted/convinced by proposing to participate in the proposal of a European Project in the framework of the Horizon 2020 Programme (2014).
Pros & Cons

• No consortium in place
• Lead researchers had **limited experience** in EU projects
• Very **short time** to put together a sound proposal

• No previous EU collaborative projects in the field of UI
• UI → ‘sexy’ disease
• High **degree of involvement** of the initiators
The call

PHC-26-2014 – Self management of health and disease: citizen engagement and mHealth

Specific challenge: Empowering citizens to manage their own health and disease will result in more cost-effective healthcare systems by improving utilisation of healthcare, enabling the management of chronic diseases outside institutions, improving health outcomes, and by encouraging healthy citizens to remain so.

Several clinical situations would be prevented or better monitored and managed with the participation of the patient him or herself. Care sciences may complement the medical perspective without increasing the cost. This requires research into socio-economic and environmental factors, dietary impact and cultural values, behavioural and social models, attitudes and aspirations in relation to personalised health technologies, mobile and/or portable and other new tools, co-operative ICTs, new diagnostics, sensors and devices (including software) for monitoring and personalised services and interventions which promote a healthy lifestyle, wellbeing, mental health, prevention and self-care, improved citizen/healthcare professional interaction and personalised programmes for disease management. Support for knowledge infrastructures is also required, as well as the combination of predictive personalised models with personal health systems and other sources of data.

Scope: Proposals may focus on patients or healthy persons or both. Health management should be addressed in a holistic approach, from healthy lifestyle, dietary habits interlinked with disease management, and adherence to medical plans, placing the patient in the centre and putting increased emphasis on health education, patient empowerment, secondary prevention and self-management of individual conditions including co-morbidities and frailty. Implementation of programs or applications for different target populations to capture gender- and age-dependent differences in health, behaviour and handling of devices should be included.

(ii) mHealth applications for disease management

Proposals should focus their research on application development for disease management with the following characteristics:

- Strong emphasis on co-designing and user needs as a key driver;
- Knowledge management systems to analyse and compile the data collected by applications on individuals’ health and activities in order for such information to be used by the persons themselves, health professionals and public health monitoring authorities;
- Guidance for patients, care-givers, families and patients’ social environment on chronic disease management supported by mHealth;
- Patient adherence to and compliance with medical recommendations
- Economic aspects of encouraging secondary prevention and addressing avoidable negative health and wellbeing outcomes;
- Screening for pre-fraility states
- Public health or health promotion interventions addressed to large sectors of population through mHealth applications and;
- Co-operative ICTs to support co-operative management of health and disease among patients and eco-health systems.

The Commission considers that proposals requesting a contribution from the EU of between EUR 3 and 5 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Expected impact:

- Improved self-management of health, disease prevention, management of diseases and/or expenditure.
- Strengthened evidence base on health outcomes, quality of life, care efficiency gains and economic benefits from the use of ICT in new care models, in compliance with data protection requirements.
- Increased confidence in decision support systems for wellbeing and disease / patient management.
- Strengthened evidence and improved knowledge about individuals’ behaviour related to wellbeing, disease prevention or management facilitating the creation of new personalised behavioural health interventions.
- Improved service offering and business concepts and models
- Impact in several of the following facets of mHealth e.g., patient safety, contribution to or revision of (guidelines of) relevant legal frameworks, medical guidelines, harmonisation (across borders), standards, co-ordination of therapies, recognition of mHealth as a reimbursable cost, improved accessibility, liability, inter-operability, more reliable connectivity, patient empowerment. Improved patient-health professional interaction, maturing personalised health systems, sustainability, usability and user-acceptance.
- Improved interaction between patients, their relatives and care givers, facilitating more active participation of patients and relatives in care processes.
- Improving the management of disease by reducing the number of severe episodes and complications.
- Increased level of education and acceptance by patients and care givers of ICT solutions for personalised care
Required partner profiles

• Exploitation of the solution → leading manufacturing company
• Strengthened evidence base, validation of the solution → multi site clinical trial executed by 3 hospitals
• Adherence to the treatment → serious games company + experts on health psychology
• Patient empowerment, co-designing with users, increasing acceptance by patients → UI association
• Economic and business model aspects → dedicated partner
Key points

• If your group has developed a promising technology (possible patent?) and you don’t find a company to license it → A H2020 proposal/project can be the solution
• To protect your patent (background) properly in the CA
• More collaboration between UPC units is necessary:
  • Innovation Unit
  • European/International Projects Office
  • Legal Service

• Two possible starting points for a proposal:
  • With friend partners we plan what we can do after checking the programmes/Calls
  • I have an idea/technology (maybe with another partner) and we search the best partners for each role / necessity

• To use ALL keywords of the Call /programme in your proposal
• Think about any keyword some how to be applied in the proposal
• Look for the Juan’s help
Main objective of the WOMEN-UP project

To improve the quality of life of urinary incontinence in patients through a holistic and cost-effective ICT-solution, allowing for the self-management of the chronic UI disease via a decision support system and a secure remote medical supervision.
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Overall concept of the proposed system

A web platform for patient-therapist interaction which permits to review fast, easy and remotely the home treatment. This includes a smart clinical decision support module to facilitate an efficient monitoring.

An app for the patient’s smartphone which includes games for a funny pelvic floor muscle training and real time evaluation. This permits to improve user engagement and the learning experience.

A wearable device for pelvic floor muscle training at home. This includes electromyographic recordings from both vaginal probe and a belt around the abdomen to guarantee the training is done properly.

An app for the patient's smartphone which includes games for a funny pelvic floor muscle training and real time evaluation. This permits to improve user engagement and the learning experience.
Work Packages

WP1 - Project Management

WP2 - System Requirements

WP3 - Platform for the self-management of UI, including data collection, guidance and patient-therapist interaction

WP4 - Wearable device implementation

WP5 - Enhancing patient empowerment & adherence to the treatment

WP6 - System integration, clinical evaluation & recommendations

WP7 - Dissemination

WP8 - Business Model & Exploitation
Consortium

- UNIVERSITAT POLITÈCNICA DE CATALUNYA
  Project Coordinator
- Bittium
  Medical Technology Company
- HOSPITAL CLÍNIC
  Clinical Leader
- ACADEMIC MEDICAL CENTER
  Obstetrics/Gynecology and Clinical Search Units
- REHA STIM
  Medical Technology Company
- KUOPIO UNIVERSITY HOSPITAL
  Gynecology and rehabilitation Services
- EUROPEAN UROGYNAECOLOGICAL ASSOCIATION
  Results Dissemination
- BABES-BOLYAI UNIVERSITY
  Health Psychology Research