Technologies innovantes pour quantifier et qualifier le mode de vie pour des services de médecine personnalisée

Projet SUDOE n° SOE4/P1/F790

TEMIS COMPENDIUM

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1. FOREWORD

This compendium synthesises the activities realised within the TEMIS project. The project aimed at developing and evaluating innovative technologies to assess daily lifestyle as a support for personalised medicine. TEMIS was mainly funded by the territorial cooperation program SUDOE\(^1\) (European Commission – FEDER, program over 2007-2014) promoting translational collaborative projects in the south west of Europe (Portugal, Spain, and south west of France) to foster competitiveness, innovation, sustainable development and urban planning and to protect the environment. The TEMIS project aimed at building a sustainable cooperation network to improve competitiveness and innovation in the field of ICT for personalised medicine. The project was realised between April 2013 and December 2014 over 21 months with 6 partners representing expertise in the fields of medicine, physiology, ICT, e-health, smart textiles and innovation development.

The main objective was to develop gradual solutions to assess daily lifestyle of a person or physical activity in view of integrating them as a supporting tool for personalised medicine. The following solutions were developed: mobile equipment based on a smart T-Shirt, a Smartphone and wireless sensors targeting ambulatory physical activity monitoring for healthy persons or various patient profiles and a Kinect application dedicated to the measurement of abnormal movements for Parkinson patients. The solutions were developed and integrated following a specification phase realised thanks to a close cooperation between the medical / physiological and technical teams. They were then evaluated on 150 subjects. In parallel, the objective was to promote sustainable use of the equipment and transfer towards companies. A significant effort was thus realised to define the most suitable market approach and business models and to disseminate towards industry.

For further details about the project, please refer to TEMIS project website at http://www.temis-project.eu or to the detailed deliverables of the project including: a description of the medical and technical state-of-the art, the medical and technical specifications, the report on the experiments and results, the summary of the advisory board conclusions, the analysis of possible business models and the market analysis and the report on communication and dissemination activities. The project website presents in particular several videos on the solutions and evaluations realised during the project.

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\(^1\) http://www.interreg-sudoe.eu/
2. TEMIS: IMPROVING HEALTH THROUGH OBJECTIVE MEASUREMENTS AND PERSONALISED MONITORING

Our lifestyles are changing. These changes generally have a direct impact on our health. TEMIS offers efficient solutions to measure and assess them thanks to the use of simple and affordable technology. The solutions generate health indicators to support personalised medicine.

Simple, innovative, adaptable and inexpensive tools to quantify and qualify our lifestyles:

- A smartphone application coupled to a Smart clothe to assess physical activity and physiological parameters,
- A Kinect application to measure body movements for specific applications such as Parkinson disease.

2.1 Background

The TEMIS project seeks to build a long-term cooperation network to supply innovative technology in order to measure a person's lifestyle, for personalised medicine and medical research.

Here, measuring someone’s lifestyle means supplying objective measurements to quantify and qualify several parameters describing the day the lifestyle of a person, and particularly his physical activity.

Up until now, medical care has been based on standards defined by epidemiological studies performed on large cohorts. Medical research is currently moving towards a greater personalisation of healthcare for specific individuals. However, personalised medicine is only possible if precise information about the patient is accessible, in particular his individual and family medical history, his genetic profile but also his lifestyle and more generally his environment. The lifestyle includes among other things food habits and the type and quantity of physical activity. Medical research has shown that the lifestyle has a major impact on many diseases and in particular on chronic diseases, affecting both the risk factors and the progression of the disease. Up until now a patient's lifestyle was assessed based on an interview and questionnaires. These evaluations are therefore highly subjective and badly quantified.

Simple, innovative, accurate but inexpensive and widely accessible technologies are therefore needed to quantify and qualify a person's lifestyle in order to supply health indicators which can then be used for a more tailored form of medicine.

TEMIS proposes developing such technologies, testing them on healthy subjects and patients while also ensuring their transfer to industrial companies and service providers. The proposed technologies may be used either in combination with one another or separately in order to tackle various medical conditions or illnesses. The proposed innovation is both medical and technical. The technologies proposed by TEMIS aim to make it possible to quantify and qualify physical activity or describe the movement of person's limbs. These technologies also combine the data processing necessary to define useful indicators both for the person and the doctor, in addition
to the software platform to manage the data exchanged and to supply relevant indicators for the various possible users.

2.2 Partners

The TEMIS team:

A total of six European partners are involved in this project, representing three countries: France, Spain and Portugal.

The partnership is comprised of the following partners:

- **MEDES** – Institut de Médecine et de Physiologie Spatiales (Institute for Space medicine and Physiology): project leader, in charge of the project coordination and evaluation, the development of smartphone applications and integration of the software platform.

- **Instituto Tecnológico de Aragón** - Area Operaciones Division Tecnologicas Multimedia (ITAINNOVA). ITAINNOVA has developed and tested with the CHUT a Kinect application dedicated to Parkinson patients.

- **Centre Hospitalier Universitaire de Toulouse** (CHUT / Toulouse University Hospital): partner in charge of medical specifications, assessments of healthy subjects and patients for clinical trials together with AIDFM, deployment of a pilot study regarding Parkinson patients.

- **Associação para a Investigação e Desenvolvimento da Faculdade de Medicina Universidade de Lisboa** / Faculdade de Medina (AIDFM / Association for Research & Development within Medicine faculty of the Lisbon University): medical specifications, assessments of healthy subjects and patients.

- **Fundació CETEMMISA**: development of the TEMIS smart clothing subsystem.

- **Confederacion Española de Tecnologias de la Informacion Comunicaciones y Electronica** (CONETIC/Spanish Confederation of ICT & Electronic sector): organisation of the cooperation network and promotion vis-a-vis industrial companies.
2.3 Objectives

The project targets the following main objectives:

- Building a sustainable cooperation network to provide advanced technologies for quantifying and qualifying the daily lifestyle of a person for applications for personalized medicine / healthcare and for medical research.
- Developing and testing a series of integrated and complementary products relevant for several diseases or conditions in view of contributing in the long term to the definition of indicators and influencing parameters for specific diseases, as a support to prevention, diagnostic, treatment follow-up and recovery.
- Integrating medical and technical innovation to develop new personalised solutions

These objectives can be summarised in one main proposal that was used as a basis to develop the project’s network, find viable and reliable exploitation patterns and business models, and develop solutions easily usable by health professionals and patients:

**To propose, integrate and evaluate a gradual range of products adaptable to various conditions and pathologies, affordable and acceptable to allow a continuous and transparent monitoring during the daily life of the users.**

2.4 Organisation of activities

Activities of the project are organised following three parallel and complementary processes in order to ensure the validation of the feasibility of the solutions proposed in the context of TEMIS:

1) **The technical development of TEMIS products and solutions** by TEMIS technical partners (MEDES, CETEMMS, ITAINNOVA) and their updating and improvement further to medical feedback (see point 2)

2) **The medical experimentation and assessment of TEMIS products** by TEMIS medical partners (CHUT and AIDFM) through the preparation and implementation of:
   - a clinical trial using the smart garment and the smartphone application to measure physical activity of healthy volunteers of different ages and Parkinson patients
   - a pilot study using the Kinect application and dedicated to Parkinson patients

3) **The reflexion on possible networks and exploitation models and scenarios** that could be used to ensure sustainability of TEMIS products after the end of the project. This process includes dissemination and networking activities as well as marketing studies. It was mainly steered by CONETIC, and deeply enriched by the activities of the International experts gathered into the Scientific, Technical and Medical Advisory Board of the project.
The following diagram illustrates the detail of this organisation within the project’s short timeline of 21 months.

2.5 Main results achieved

Apart from all expected deliverables, such as specifications, market studies, assessment reports, communication compendium, etc. that were delivered in time, TEMIS results can be divided in three main categories:

1) First, **the project achieved its technical goal**, developing, experimenting and assessing all scheduled applications and products within the project’s timeline, i.e. the integrated platform, the smartphone application, the smart T-shirt and the Kinect application. TEMIS has therefore proven the feasibility of the solutions tested. Of course, adaptations will be necessary to market these products, but the system works.

2) The completion of a development process of an ICT solution related to a personalised medicine issue (as far as TEMIS is concerned: the monitoring of physical activity), from the description of the state of the art in the SUDOE area and the drafting of medical and technical specifications to the intellectual property rights linked to the business models that may be used to market TEMIS products and solutions.

3) The foreshadowing of a stakeholders network wishing to cooperate around personalised medicine ICT solutions. This beginning network gathers enterprises from ICT and medical sector, health professionals, health authorities. It also rests on existing networks and clusters that were contacted during the project, of which all 13 members associations of CONETIC, National Health Cluster of Portugal, the “Mêlée numérique” in Midi-Pyrénées...
3. DEVELOPMENT OF NEW ICT TOOLS & APPLICATIONS RELATED TO PERSONALISED MEDICINE (5 PAGES)

This diagram illustrates the complementarity and integration of all TEMIS products and solutions:

- All data are collected through nomad devices (smartphone and smart garment and its sensors for measurement of physical activity, and Kinect for assessing mobility of Parkinson patients under treatment).
- Data retrieval is organised through clinical trials associating volunteers that will use and assess TEMIS device, under the control and evaluation of clinicians.
- An integrated platform collects and stores the data transmitted by the sensors and by the Kinect. It calls an external service to analyse the physical activity of the subjects to provide data analysis useful for health professionals involved in the experimentation.

The main development steps were:

- The medical specifications
- The technical specifications
- The development, integration and testing of the mobile equipment (combination of smartphone, smart T-shirt and wireless sensors)
- The development, integration and testing of the Kinect application
- The integration with the external service that was used to analyse the physical activity of the subjects
- The deployment and support during the evaluations with regular maintenance, upgrades.
- The support to the medical teams in the use and configuration of the system components.

Despite a short duration, the consortium managed to achieve its ambitious goals thanks to a constant iterative and collaborative process.

3.1 Integrated mobile equipment to assess physical activity and physiological parameters

The objectives of the mobile solution were to:
To offer continuous ambulatory monitoring to quantify and qualify the physical activity of a user.

Using a solution combining a Smartphone and its embedded sensors, possibly combined with a smart garment or wireless sensors.

For the purpose of the project, the solution included: a smartphone with its embedded sensors, retrieving data from a smart garment, from an external wireless accelerometer and exchanging data with an integrative platform.

### 3.1.1 Mobile solution – software part (MEDES)

#### 3.1.1.1 Description of the tools

The mobile solution was built around the following bricks:

- A smartphone application dedicated to the users. This application provides the user interface to start and stop a data recording session, manages the retrieval of data from the various sensors (smart garment, external accelerometer) and manages the transmission of these data to the TEMIS platform.

- A web application dedicated to the medical teams to allow them to access to the collected data, to syntheses of processed data and to report and export functions.

- TEMIS platform for data storage and data access. It calls an external analysis services to assess the physical activity of the subjects based on the collected data.

An important requirement was to allow the management of the huge quantity of data generated by a continuous monitoring of several subjects (more than hundred for this project) possibly on a long period. The objective was as well to propose a flexible solution adaptable to other sensors or other utilisation scenarios. The whole solution and in particular the platform has thus been designed to
manage and to cope with a huge amount of data and to possibly evolve to integrate other sensors or other services for data processing depending on the utilisation scenario.

3.1.1.2 Development process and data treatment

Specifications (technical & functional)
The first phase of the development process was to translate the medical specifications into technical specifications. This work is summarised in the related specification documents. The specification phase was realized between April and September 2013. Part of the development started in parallel.

Test and validation
The medical teams defined the medical protocol and what kind of data they needed to perform their analysis. From this starting point, an iterative process started between the medical teams and the technical partners to define which kind of technical solutions would be needed to answer to these needs. In the proposal, it was mentioned that some external sensors could be included in the solution for testing. But it appeared that an external accelerometer had to be included in the technical solution as one of its key components.

The development phase included the following tasks:

- The development of the mobile application which consisted in the development of the user interface, of the communication protocol between the smartphone and the garment, and between the smartphone and the external accelerometer, of the data transmission from the smartphone to the Temis platform, and of a widget so that the subjects can explicitly declare their physical activity. The integration of the external accelerometer required significant and unexpected efforts.

- The development of the web application which consisted of the user interface (forms, tables and graphs), of exporting capabilities (so that the data can be analyzed via dedicated medical analysis software) and of the retrieval of the data that are stored in the Temis platform.

- The development of the Temis platform. Specific data storage technologies were chosen in order to handle the huge quantity of data that was expected. The development consisted in implementing the capabilities of storing, accessing and querying data using these technologies. Web services were implemented so that the Temis applications (web, mobile, kinect) could communicate with the platform. The development included also the call to the external service that was chosen by the medical teams to analyse the physical activity of the subjects taking into account the data collected by the Temis solution.

Integration tests between the different components of the solution were done as the development of the solution was progressing.

The solution was finally deployed in early May 2014 in Toulouse so that the solution could be available to the team of the Hospital of Toulouse to start the medical protocol. It was deployed in July 2014 in Lisbon.

A user guide was written down and a training session was organized with the team of the Hospital of Toulouse so that they get all the necessary knowledge about how to use the solution. Some remote exchanges were done with Lisbon to explain the system use.
During the whole protocol, a continuous support had to be provided to the medical teams in order to solve technical issues that were identified during the protocol and because the Temis solution was a sophisticated system with several components communicating wireless and collecting a huge quantity of data.

3.1.1.3 Feed-back and statistics of use

The following diagram summarises the statistics of utilisation of the system during the TEMIS project. During the project, 150 subjects were entered in the system representing 6600 cumulative hours of recording and 2.3 billion records in the database.

3.1.2 Smart T-shirt (CETEMMSA)

The smart-T-shirt is made-up of two elements: the T-shirt and ECU:

- Temis T-shirt
In the framework of Temis project, CETEMMSA has been developing a sensorized garment capable to monitor physiological parameters like heart rate, breathing rate, skin temperature and physical activity, while the person is performing daily activity.

The T-shirt has sensors embedded that provide data about: Heart rate, breathing rhythm, internal and external body temperature and physical activity. While the cabling is embroidered on to the fabric the sensor are integrated into the T-shirt in different locations. Two textile sensors in the front at chest level, and another one in the back as reference allow performing 1st derivative electrocardiogram monitoring. The breathing rate is detected through textile bands placed in the chest and in the abdominal region. Skin temperature probes are placed in the middle of the chest and under the right armpit.

A tag was added in the armpit to measure the internal body temperature, in order to obtain the information it is necessary to lift the tag and put it under the arm.

- **Temis Electronic Control Unit - ECU**

  The second element is the electronic control unit ECU, which records all signals from the sensors. The information can be stored in a uSD card or sent to mobile phone by Bluetooth 2.0. In order to measure the physical activity the ECU has an accelerometer that is able to measure the movements in the three axes. The ECU is powered by two AA batteries.
3.1.2.1 Description of the tool and related equipment

It is important to highlight that the T-Shirt is designed in a flexible way: the T-shirt could evolve to integrate additional sensors depending on the utilisation scenario.

Compared to other utilisation scenarios such as eHealth / event detection scenarios, one of the challenges was to allow a long-term continuous monitoring.

The solution is washable, comfortable and wearable during long periods of time, providing comfort to the user. The solution is portable and autonomous; the ECU records the signals and sent the information to the mobile phone. To guarantee a long signal recording the Electronic Control Unit (ECU) is powered by two AA batteries which can be interchangeable.

3.1.2.2 Development process and data treatment

Specifications (technical & functional)

The specification phase was realised between April and September 2014 including the medical and technical specifications.

Part of the specifications included the definition of the type of T-Shirt, the sensors, the requirements for the sensors, for the data collection (recording frequency) but also requirements related to cleaning to ensure relevant cleaning to support utilisation of the T-Shirt for several persons, while keeping all the technical quality / reliability despite the number of washing.

The specifications of ECU and T-shirt are listed below:

ECU
- 8h battery life 2xAA
- Serial communication with sensors
- Microprocessor
- Memory
• Bluetooth 2.0

GARMENT
• Comfortable
  o Sleeveless
  o Soft
  o Zip less
  o Breathable
  o Anti-allergic
• Washable
  o Min 7x2 = 14 cycles per garment
  o Ensure performance of the HR electrodes
• Tight – elastic
  o Ensure the right operation of the sensors
  o Ensure comfort (dress – undress)
• Unisex
  o Versatile
  o Different sizes

Development, Test and validation
The development phase lasted up to April 2014. From January to April 2014, regular integrative tests were realised with MEDES with an iterative process to improve the solutions.

Following the design and validation phase, a set of 74 garments and 35 ECU has been manufactured and tested in real volunteer patients allowing the analysis of results from the point of view of user acceptance, comfort and reliability.

The first validation was done in Cetemmsa’s laboratory. The system was tested with some users to observe the quality of signal and the functionality. The results were quite good; all the sensors worked fine except for some noise problems. During this validation it was observed that the system had problems to acquire heart rate data properly. The signal presented background noise and fast changes. To solve this problem we applied filters and signal processing to obtain a stable signal. Other problem that we observed was the skin hydration.

The skin hydration is related to the skin conductivity, is necessary to have a high conductivity for the electronic measurements. To improve the contact between electrode-skin we decided to use ECG gel. The results with the new signal processing and the ECG gel were quite good, considering all these improvements; the signal was stable even under movement conditions.

Once this problem was solved, the system was sent to Medes for a new validation, combining the system with the Smartphone.
This validation was useful to detect some problems about the communication. The data downloading had problems, the communication between mobile phone and electronic control unit sometimes lost data-packets. These errors were solved, now the system works properly. Other issues that we solved were the battery alerts, the blinking led frequency, and other modifications related to how to save data.

### 3.1.2.3 Feed-back and statistics of use

The system has been validated by more than 100 subjects in two different hospitals. This feedback has been used to see the defects of the system and to know what improvements can be applied. In terms of durability and functionality there are some important aspects that are interesting to study. During the validation has been necessary to repair some T-shirts and ECU due to eventual problems. Concretely we have repaired 20 T-shirts by problems due to short cables issues, broken connectors or problems related with the fabrics. On the other hand we have had problems with the battery contacts, some ECU lost the power due to this problem. Other problems that we have found has been problems with the internal welding of the ECU, maybe due to falls, knocking, pressure changes... maybe the ECU needs to be more robust putting some resins or protectors to avoid the welding breaks.

Below there is a list with the main observed defects, as well as the possible solutions:

1. **Connexion between T-shirt and ECU**
   The cable length has been a problem to place the ECU in the correct position. In some cases the cables were too short and the user couldn't place the ECU properly. The ECU position on the T-shirt is very important to measure the physical activity. A solution could be changing the place of the belt loop, a part of making the cables longer.

2. **Batteries**
   The quality of the batteries is important for the ECU autonomy. It has been observed big differences between high quality batteries and the low quality, in terms of duration hours. The batteries used in the system were non-rechargeable batteries, for ecological issues would be better to use rechargeable batteries. To apply these changes is necessary to revise the power stage of the ECU.

3. **Fitting problems**
   Some users have had problems to wear the T-shirt. The T-shirt needs a high fit to obtain correct measures. One of the solutions could be to put a zipper or some mechanism that facilitates the user to putting on the garment.

4. **Heart rate measurements**
   About the Heart rate measurements, two problems have been observed:
   
   - The first problem is the close-fitting of the T-shirt, is very necessary that the size to be the correct one to the user and of course ensure that the electrodes are in contact to the skin.
• The second problem is the skin hydration of the user, depending of the skin conductivity the measures are feasible or not. There are people that have a good conductivity and the system works fine and others that the conductivity is low. For this reason in this project it has been recommended to use ECG gel to improve the contact between skin-electrode.

Another solution to solve this problems it could be to use hydro-gel electrodes. This kind of electrodes providing a good contact without ECG gel or other elements, it is only necessary to hydrate the electrode every day with some water.

3.2 Tools dedicated to patients suffering from Parkinson disease

The objectives of the tools specifically dedicated to monitor Parkinson’s disease patients were:

- To have a useful monitoring tool providing numerical and graphical information for assessing the performance of UPDRS (Unified Parkinson’s Disease Rating Scale) exercises.
- To use a cheap, affordable and easy to use non-invasive device to monitor the movements of the patients.
- To evaluate the usability and possible improvements that the physicians could have with this tool for monitoring the patients exercises.

Following these guidelines, the Kinect device was chosen as the most proper one to achieve the aforementioned specific objectives.

3.2.1 Adaptation of physical activity measurement tools to Parkinson patients

The main challenge of developing a Kinect application for the measurement of the parkinson’s disease patients physical activity was to adapt the Kinect usual output to the medical specifications required. More specifically, for every UPDRS exercise implemented in the solution, a new algorithm was developed to extract the required medical numerical/graphical information. This process is better explained in the next points:
3.2.2 Exercises with Kinect (ITA)

The exercises performed by the Parkinson’s disease patients (described in the Unified Parkinson Disease Rating Scale - UPDRS) at CHUT were carried out with the TEMIS Kinect Application, described below:

3.2.2.1 Description of the tool and related equipment

The TEMIS Kinect solution is complete evaluation tool based on the following elements:

- PC software application developed for Windows environments: An easy and usable program based on WPF technology, with a simple interface defined closely with the physicians needs and requirements.

- The Kinect device: The Kinect for Windows v1 device and SDK were used to interact with the Parkinson’s disease patients. Although Kinect v2 was launched during the execution of the project (July 2014), all the requirements and proposed exercised were reachable with v1 device.

- Communication with TEMIS platform: All the data generated with the Kinect application (this means numerical, graphical and video data) is transferred to the TEMIS platform, with anonymous patient identification. This way, the physicians are able to check, compare and monitor the patient exercise any time after the execution. Also, the application is prepared to allow the use by the patient at home.

3.2.2.2 Development process and data treatment

Specifications (technical & functional)

The specifications phase had its first and more important milestone when technical and medical specifications were described, in a collaborative work between technical and medical partners of the project. This work was done during year 2013 (April-December), and had as deliverable the technical and medical specs. docs.

But the collaborative work with physicians have been continuous during the whole development of the TEMIS Kinect solution. Several iterations were carried out closely with CHUT, including pre-test with volunteers that also lightly modified the specifications, in order to have a completely useful tool.

Test and validation

As it was stated in the previous point, the collaboration between ITAINNOVA and CHUT was an asset and a constant key point during the whole project. Thus, as in the specifications phase, also during development and testing phase the solution was built with the continuous feedback from CHUT.
The main development works were performed during the period January-July 2014, whilst the second part of the year had several testing and evaluation iterations (both with only physicians and with physicians + volunteers).

During the first phase of the development, several mock-ups with the User Interface were developed, and also the 5 selected UPDRS exercises algorithms were designed and developed in parallel. After the first pilot was finished (May 2014), a first testing with a volunteer was performed at CHUT, and the important feedback obtained from that helped to build a better application. The main efforts and achievements of the application development were:

- A simple and useful User Interface for the PC application, in order that the Physicians could just focus on the patient performance and the data analysis.
- 5 specific algorithms for each of the UPDRS selected exercises. These algorithms are undoubtedly the main achievement of the application, since all the data required for the physicians had to be obtained from a device (Kinect) which was initially designed for just gaming purposes.
- Communication with TEMIS platform via Web Services, in order to send all the data generated by the exercises execution.

During the period September-November 2015, and with the Kinect application deployed at CHUT laptops, it was conducted all the testing with volunteers. Also light modifications were included in the application, thanks to the feedback that each test provided.

### 3.2.2.3 Feed-back and statistics of use

During the testing phase, a very positive feedback for the Kinect application functionality was received. Also, the evaluation of the tool itself as a valuable asset for monitoring Parkinson’s disease patients activity was very positive, as well as possible improvements to be faced in next steps.

### 4. CLINICAL TESTING AND VALIDATION OF TEMIS TOOLS IN FRANCE AND PORTUGAL

#### 4.1 Coordinating a French-Portuguese trial

##### 4.1.1 Specifications, protocols and processes: from paper to trial

The following steps were performed in collaboration between CHUT (CIC – Clinical Investigation Center) and AIDFM. The first step was to carry out the state of the art on the existing ambulatory methods designed to measure physical activity and techniques available to assess movement’s disorders in patients with...
Parkinson Disease (PD). Information about the techniques already used and. This state of the art summarized publications in which measurements of physical activity assessment were performed for medical applications including the limits and advantages of the techniques.

Following this review, medical specifications were given to other partners in charge of material development.

The second step was to define and implement the two clinical research protocols – the first one on the use of the smart T-shirt to assess physical activity; the second one on the use of the Kinect to assess mobility in PD patients. The preparation of the clinical trial on healthy volunteers and patients included the following steps: - writing of the protocols, - regulatory aspects: submission to Toulouse Hospital (CHUT) to sponsor the study - submission to local ethics committees for approval (Toulouse and Lisbon) – Case Report Form preparation - recruitment of volunteers and patients and protocols realization - results analysis

In the same time an algorithm was developed to assess physical activity with the data from the physical and physiological sensors of the Temis System (consultancy CHU Angers) –

The protocol preparation took time and needed many contacts and meetings with CETEMMSA and ITA to adapt the technical characteristics of the mobile equipment, of the Kinect system and with MEDES to check the interface of the smartphone application and the quality of the information transmitted to the web server and.

ANSM (agence nationale de la sécurité du médicament et des produit de santé) agreement was received on the 28th of March 2014. CPP (Comité de Protection des Personnes SUD-OUEST et OUTRE-MER) agreement was received on the 14th of April 2014. The study started on the 4th June 2014 with the inclusion of the first volunteer.

4.1.2 Exchange of data: conditions and exchange

All the data were anonymized and stored on a website developed by MEDES. CHUT, AIDFM and MEDES could access to anonymised data using a personal code. Physiologic data provided by the TEMIS system were analysed together by CHUT and AIDFM for healthy subjects. CHUT analysed data dealing with PD patients

CHUT r) assessed the physical activity characteristics from data recorded (from sensors and accelerometers) thanks to the algorithm developed by Angers CHU (subcontractor). This algorithm was updated and available on the web service for all partners.

4.2 Mobile equipment evaluation

4.2.1 Organisation of trials (selection of volunteers, organisation, …)

51 healthy volunteers were included at CHUT and 49 finished the study (31 women and 18 men); 2 volunteers were eliminated after screening. CHUT included 17 among 20 selected PD Patients finished the study 65 healthy volunteers were included in Lisbon

Organisation
Two visits were performed for each volunteer, at the start of the study and at the end, one week later.
At the First visit, the volunteers signed the consent form. This first visit included the following steps:

- Checked of the selection criteria
- Explanation on the equipment by the CHUT (CIC) or AIDFM staff,
- Training of the subjects to the material, and equipment testing.
- PD patients also performed the UPDRS, a rating scale of Parkinson’s disease.

During the Week of recording, the volunteers used this system at home during 4 non-consecutive days (8 hours of recording by day) and one night. Each subject had to report the type of physical activity he/she performed with the smartphone application. The different activities were standing, walking, sitting, lying, running, standing vehicle, sitting vehicle and cycling.

During two half days, the subject had to do 4 following specific activities as running, cycling, walking and sitting vehicle. Each activity had to last at least 5 minutes. The main objective was to compare the real physical activity as reported by the volunteer to the physical activity as analyzed by the algorithm of the Temis system.

During the second visit (one week later), the volunteers returned the equipment. The CHUT and AIDFM staff checked all the recording sessions were transferred to the TEMIS platform.

The volunteers also filled in a questionnaire of acceptability to know how the system was «perceived» by the users.

4.2.2 Main obstacles addressed and solved

Since the system was a prototype, several technical issues listed hereafter occurred which needed to be solved during the project to ensure a good quality of the data. These dysfunctions were notified to the technical partners by the volunteers and/or by the CHUT and AIDFM staff:

- Synchronization between the smartphone and the external accelerometers (see technical issues)
- Rapid battery discharge of the ECU
- Variable quality of ECG signal
- ECU bugs (constant heart rate at 79 bpm - Negative Temperature) (reported on some ECUs)
- Needed improvement of the T-shirt (Cable problems - ECU fastening)
- Difficulty to transfer data to the server

4.3 Focus on the monitoring of Parkinson patients

4.3.1 Development of Kinect exercises

ITAINNOVA developed a system and an application to analyze body movements. The performance of the Kinect was assessed in standardized movements usually performed in clinical practice in PD patients. Because of the limits of the Kinect system, only 5 exercises were chosen among the different exercises proposed in the MDS UPDRS (Movement Disorder Society revision of the Unified Parkinson’s Disease Rating Scale) a validated widely used rating scale for PD patients.

The five items were the following: leg agility, arising from a chair, gait, posture, postural stability.
4.3.2 Iterative process between medical and technical partners

Different trials were necessary to improve the application on the Kinect system. ITAINNOVA developed an algorithm in order to study the characteristics of the movements performed during the protocol: speed of movements, amplitude, angle of some joints...

The main objective was to assess if the Kinect system provides a usable recording for a neurologist to rate some items of motor activity of the UPDRS scale. This aspect was based on the movie and data recorded by the system.

There was a progressive update and improvement of these two aspects of the system by ITAINNOVA during the study.

4.4 Main indicators, feedback and conclusions so far

Physical activity assessment thanks to the Angers CHU algorithm:
- the percentage of concordance between the activity performed by the subjects and the activity estimated by the algorithm during scheduled activities was good (80.94 percent) in healthy volunteers
- the percentage of concordance between the specific activity performed by the subjects and the activity estimated by the algorithm during scheduled activities was good but lower in PD patients (70.2 %)

The percentage of concordance calculated on all the sequences analysable during the 4-day recordings in 142 Subjects was also good for %.

Acceptability results:
The analysis showed a good acceptability of the system by the users. The acceptability for each group (elderly, middle aged, and young healthy subjects and PD patients) was around 80 percent of good acceptability.

For the Kinect study, the data obtained are preliminary because of the limited number of subjects. Physicians performed a blinded analysis of the Kinect recordings. There was a good concordance of the rating using the Kinect video and the rating in real-time (about 80%)

Physicians considered the quality of the recordings was sufficient to analyse afterwards the movements performed during the 5 exercises. There were some difficulties to evaluate the gait because of the camera angle which limits the distance of evaluation of walking.

5. DISSEMINATING TEMIS RESULTS

The general objective of the dissemination activities is to present the project and its result as broadly as possible in seek of support market implementing. In addition, we are expecting to create a sustainable collaborative network within the sectors susceptible to benefit from the TEMIS results, which is likely to last beyond its ending.

In order to achieve the widest scope, we are starting with a market analysis to identify likely scenarios where the TEMIS resulting products/services can be applied, as well as to identify
substitutes and/or competitors and with a study of the possible economic models or operation scenarios where they may appear.

The disseminating strategy is based on
1. Identifying target audience
2. Specific key messages for every audience typology
3. Appropriate communication tools and means.

5.1 Addressing TEMIS’s main stakeholders
A priori, from the perspective of the project value chain, TEMIS has potential to create solutions for different uses and clients from diverse segments, so the project was initially addressed to several target audiences whose views and interest may vary.

Market models and scenarios analyses have confirmed the main interest groups linked to the project framework:
- **Industry and healthcare sector**, interested in implementing and making use of the results on the market
- **Scientific community**, as recipient of the developed technology efficacy and their use maximization.
- **General public**: The objective is to bring to the public the knowledge of how customization based on technology will provide better healthcare.

5.1.1 Health sector (professionals & authorities)
The main conclusions drawn from the aforementioned studies warn us:
- The products resulting from the project find their opportunity in medical contribution due to their specialized focus addressed to health professionals.
- They are solutions to commercialise under a medical information solution for specific illnesses. They value lies on ‘data.’

Because of what has been exposed, healthcare professionals are considered the most suitable interest group to foster their use as eHealth solutions and, by extension, hospitals and public healthcare institutions are considered to be important value axes so they get implemented on the health systems.

In addition, we need to take into account that the demand is emerging, but there is much interest on health solutions and only low risk solutions are being accepted on the short term by health professionals. Besides we are facing a health-professionals community who considers health insurance companies, pharma and technology entities not to be the most convenient organisers to develop the eHealth care

5.1.1.1 Key messages
The medical approach should focus on data, not the product, thus appealing to professionals’ receptivity to introduce solutions that provide them with accurate information and reliable measurements, and, additionally, should emphasize that these are simple technologies and they are well-accepted by the users. The message for the public authorities is substantially oriented towards presenting the personalized service as a measure of substantial budget savings.

5.1.1.2 Actions and supports
2. **Conference ‘Ciudades digitales, la tecnología aplicada a un nuevo concepto de sociedad’, Arona 13th-14th March 2014.** Under ‘Smart Living’ TEMIS is presented, stand and collaborative network meeting.

3. **Conference on Sensors for Medicine, London, 25th y 26th March 2014.**

4. **Conference on Innovation and Cooperation ICT for the healthcare sector, Pamplona (Spain), 4th November 2014.** Focused on introducing the new TEMIS products to the ICT and health sector and the public health authorities.

5. **Conference on Health and Technology: market, opportunities, trends and knowledge implements, Zaragoza 19th November 2014.** TEMIS products introduction to the ICT and health sector.

6. **Project introduction final Conference, Toulouse 27th November 2014,** addressed to health professionals and healthcare industry.

7. **Other activities:** collaboration with the health study carried out by the Government of Navarra, presenting objectives and results to date.

### 5.1.1.3 Indicators (number of persons/organisations reached...)

<table>
<thead>
<tr>
<th>ACTIVIDAD DE DISEMINACIÓN</th>
<th>PARTICIPANTES (Profesionales y Autoridades)</th>
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<tr>
<td>Jornada Toulouse</td>
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### 5.1.2 Enterprises (ICT and medical sectors)

eHealth sector and personalized medicine analysis show an emerging market with high potential and complex business, more than 30 different types of actuators organised into five strategic groups (Big Players, eHealth Specialists, Performance Caregivers, Health Caregivers) and 5 business models (Own Initiatives, Global collaborations, Specialized long-term ventures, Project-driven Ecosystems, Open models), many possible combinations to define strategies and business models, not presenting dominant positions.

#### 5.1.2.1 Key messages

TEMIS is a medical information solution addressed to specific illnesses and based on:

1. Measuring and characterising physical activity, supporting decision making
2. Characterising and evaluating Parkinson's patients' movement
3. Clinical trials in the medium-term

The message is based on the exactitude of data, supported by test results achieved, and particularly on the specialization in Parkinson's patients.

#### 5.1.2.2 Actions and supports

1. **Implement on ICT Industry Conference, Madrid 18th December 2014.** TEMIS products presentation to 5 companies interested in launching them on the market.
2. **Specific presentations to ICT sector agents**
3. **Specific presentations to ICT companies**
4. **Specific presentations to health sector agents and patients**
5. Participation in the Debate conference on Trends and innovative applications for better and more efficient citizen attention.

6. News, Newsletters and specific mailing

5.1.2.3 Indicators

<table>
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<tr>
<th>ACTIVIDAD DE DISEMINACIÓN</th>
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5.2 Initiating a sustainable transnational network

5.2.1 Joint reflection between health professionals, authorities and enterprises

Una de las tareas más importante del proyecto es construir una red de cooperación entre los sectores de actividad económica susceptibles de beneficiarse de los resultados del proyecto, en particular el campo de la tecnología de la información, comunicaciones y electrónica y el sector salud. En este último caso agentes tanto del sector público como del privado.

Para la identificación de este colectivo, se realizó una primera recopilación de contactos, a partir de organizaciones, agentes de interés, entidades públicas y privadas, trabajo que fue útil para constituir los nodos de la red y a partir de ahí ir sumando otros agentes relevantes.

Se elaboró abundante material para la difusión del proyecto, específico para cada colectivo que se difundió a través de diversos canales. Se creó un foro virtual como punto de análisis, debate, intercambio de opiniones y con la finalidad de generar interés por el avance y los resultados del proyecto y se estimuló desde las redes sociales. Se organizaron mesas de salud y TIC que permitieron el acercamiento entre los colectivos y especialmente recibir información del avance del proyecto y de sus resultados, como la organizada en Arona, con ocasión de la celebración del Congreso de ciudades Inteligentes.

NETWORKING MEETING

Carlos Carena Espinosa, CETEMMSA
Carlos González, ITAINNOVA
Pedro Gámez Idoate, CEO Geoactio
Alicia Abad Mochales (Manager medical sector, Efronconsulting)
Javier Casero, CEO Asintec
Jochen Grunning (CIO Grupo Hospiten)
María Gálvez Sierra (General Manager Federación Española de Parkinson)
Antonio Guell Sabate (medical Professional)
Gloria Díaz Alvarez (General Manager, CONETIC)
Manuel Pérez Alconchel
5.2.2 Key stakeholders involved in the process

Las acciones de prospección de agentes de interés para la red, se realizan dentro y fuera de España destacando como agentes clave los procedentes del sector público sanitario, las agrupaciones de empresas del sector salud y del sector TIC, las propias empresas, el sector de las aseguradoras de salud, Asociaciones de pacientes y Hospitales y profesionales médicos. Destacamos por su interés:

- Servicio Madrileño de Salud (Autoridad pública de salud)
- Sociedad Pública del Gobierno Vasco dependiente del Departamento de Sanidad, Osatek
- Asociaciones TIC regionales miembros de CONETIC
- Agrupaciones de empresas TIC españolas, el colectivo identificado alcanza el 9% de las empresas asociadas en CONETIC, 119 empresas.
- Clusters de Salud (AraHealth, Cluster Saude, Cluster de Murcia)
- Portugueses Health Cluster
- La Melee, France Clusters
- Bretagne Commerce Internacional
- Federación Española de Parkinson
- Aseguradoras de Salud (Eulen, Sanitas, Novartis)
- Hospitales (Quirón, Grupo Hospiten)
APPENDIX