DAPHNE

Data-as-a-service platform for healthy lifestyle and preventive medicine

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610440

D10.6 Ethical monitoring report v3

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Abstract

The main aim of this deliverable is to describe the Ethical Management of the whole DAPHNE project for development of the system, with a focus on the last year of testing cycles. The report addresses a number of ethical concerns, including data management, equipment's safety and accuracy, ethical approval and informed consent. The report describes the measures taken to address each of the ethical concerns and concludes that these are sufficient to meet high standards of ethical integrity. Finally the main innovation of the newest EU regulation has been described and commented for eventual future work of the project.

Executive summary

This report addresses the ethical concerns arising during the DAPHNE project, including data management, equipment's safety and accuracy, ethical approval and informed consent. In each of the areas taken into consideration, the report elaborates the management by an ethical point of view.

In particular the main areas of Ethical monitoring are the following:

- **Privacy and data management**
  This area includes:
  - *data storage:* clinical data has been stored in an on-site repository (Daphne PHR - Personal Health Record) inside the Hospitals facilities. Data coming from the wearable sensors and the mobile applications has been stored in the **self-tracking repository** (data cloud).
  - *data sharing:* Users (patients and well-being individuals) have the right to decide if they want to share their data, decide which data to share and for what research purpose (Not-for-Profit and For-Profit purposes) in an online form in the PHS. In general, patients' data stored inside the Hospital PHR can be sent to the Data Cloud for future researches only after the Ethical Committee approval, and only for Not-For-Profit purposes.

- **Local Ethical Committee approval and informed consent**
  Ethical approval was requested and obtained for all the tests performed in cycle 1, 2 and 3. An informed consent, approved by the local Ethical Committee, has been obtained for all the participants recruited in the three testing cycles. In case of minors both the informed consent and the assent, from parents and patients respectively, have been obtained.

- **Safety and certification of the brand-new DAPHNE wearable sensors**
  Prior to the beginning of the three testing cycles a risk analysis has been performed by the manufacturer (Evalan) and the following documents have been produced: 1) instructions for the sensor's use; 2) sensor's safety information; 3) Risk Management document. Moreover, Evalan obtained the CE certificate for the sensor device prior to the beginning of cycle 3 (tests involving patients).

- **Technological gap**
  The exclusion from the treatment of people without access to technologies (smartphone and PC) was considered as a gap in the third cycle of tests. For future consideration the necessary equipment for making the tests should be provided to the users.

Finally an overview of the reform of EU data protection rules has been added. The report concludes that ethical issues are highly significant in the handling of patient information and in the recruitment of trial participants, and that the procedures and measures that have been taken are sufficient to address these concerns and meet high standards of ethical integrity.

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Abstract (for dissemination)	The main aim of this deliverable is to describe the Ethical Management of the whole DAPHNE project for development of the system, with a focus on the last year of testing cycles. The report addresses a number of ethical concerns, including data management, equipment's safety, ethical approval and informed consent. The report describes the measures taken to address each of the ethical concerns and concludes that these are sufficient to meet high standards of ethical integrity. Finally the main innovation of the newest EU regulation has been described and commented for eventual future work of the project.
Keywords	Ethical approval, ethical management

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Abbreviations

GDPR: The General Data Protection Regulation

IBM: International Business Machines Corporation

MoH: Ministry Of Health

OPBG: *Ospedale Pediatrico Bambino Gesù*

PHR: Personal Health Record

PHS: Personal Health Services

UNIVLDS: University of Leeds

UPM: Universidad Politécnica de Madrid

WP: Work Package

1 Introduction

As previously stated and discussed in the Deliverable D10.2 [1] "fundamental ethical principles, including those reflected in the Charter of Fundamental Rights of the European Union [2], must be respected in any kind of clinical and non-clinical research involving human beings. Moreover, to protect and guarantee people's rights, every kind of study that involves human participants needs to go through a formal process of ethics review".

During the project, the consortium faced several ethical points of different natures to be monitored and managed. Considerable effort has been necessary to build a model set of procedures that could guarantee in every step the protection of participants' rights.

In particular, the main problems the consortium has dealt with are: privacy and data management (data storage and sharing); local Ethical Committee approval and informed consent; safety and certification of the brand-new DAPHNE wearable sensors; technological gap.

Finally an overview of the reform of EU data protection rules has been added to the current deliverable, in order to describe the main innovation of the Regulation, which must be taken into account in case of future work for the project.

1.1 Scope

The main aim of the current deliverable is to describe the ethical management of the DAPHNE project during the three years of the project, with a focus on the last year and the three different cycles of test. Each of the following sections is describing a single ethical point of monitoring and its management.

2 Ethical points of monitoring in the DAPHNE project

2.1 Privacy and data management

The main critical points linked to privacy protection and data management for the end-users are the following:

- Lack of information for the users about the management and use of the data (eg. where the data will be stored, who is the data controller, who can manage the data, for what purposes the data can be shared, which data can be shared etc.);
- Lack of information about the possibility of consent withdrawal/data deleting;
- Lack of information about the risk of being identified if anonymization is not properly guaranteed;
- Lack of information about the risk of third parties accessing to the data and the possibility of selling the data for profit-purposes.

In order to address all these points, one important prerequisite is the so-called "privacy by design". This expression means that privacy issues should be considered during the development of the system, for example, by limiting the access to the data to specific users, by controlling who can access the data, by defining the data actually useful for the system, or by limiting the data sharing. This requirement is in line with the Directive 95/46/EU [3]: "the controller must implement appropriate technical and organizational measures to protect personal data against accidental or unlawful destruction or accidental loss, alteration , unauthorized disclosure or access, in particular where the processing involves the transmission of data over a network, and against all other unlawful forms of processing." and the Proposal for the Regulation on data protection (see section 2.5, [4]) "the controller shall implement appropriate technical and organizational measures and procedures in such a way that the processing will (…) ensure the protection of the rights of the data subject",

The concept of "privacy by design" has been at the bottom of the design and the development of the entire DAPHNE platform. The different requirements have been achieved and fully explained in the deliverables D2.2 *Privacy and Security Legal Isuues* [5] and D2.3 *Privacy and Security Analysis* [6].

In addition, during the "35th International Conference of Data Protection and Privacy Commissioners Privacy: A Compass in Turbulent World" (September 2013) [7], with the aim of ensuring the consent is only given after the data subject has been properly informed, the use the so-called "granular consent" was proposed[8]:

- Granular consent means that "individuals can finely (specifically) control which personal data processing functions [are] offered by the app they want to activate". Granular consent echoes the notion that consent to data processing ought to be 'specific', that is, users must give consent for each type of data the app intends to access" [9];

This solution has critical points:

1) Digital information are with small font
2) Often there is no choice for "not-sharing" the data or "withdrawal the consent"
3) The fact that the consents are digital and multiple could lead the users o opt-in automatically, without be effectively aware of their choice.

In the DAPHNE project users have been fully informed about anonymisation, storage, sharing and management of their data, by using detailed informed consents, approved by the different Ethical Committees, signed by participants prior to the beginning of the different tests (see section 2.2.2). Moreover, a detailed granular online consent form relating to the **data sharing** has been developed in the Personal Health Servie (PHS) (see section 2.1.2). The critical points listed above have been taken into consideration in

the development of the consent (see section 2.1.2). The following paragraphs will focus on data storage, sharing and management.

2.1.1 Data storage

The storage of data obtained from patients and from well-being individuals has been one of the major issues and challenges raised during the development of the DAPHNE system. Specifically, for the testing cycles different types of participants have been enrolled: healthy volunteers for cycles 1 and 2, and patients for cycle 3 [10]. At the beginning, the idea was to have the same model to store all the different data derived from the cycles. Later, it was clear that it would not be possible to treat the data coming from patients in the same way as the data from healthy individuals (the well-being subjects), and two separate procedures were suggested. Finally it was proposed to divide the storage of information into two different components: (i) the Data Cloud, containing data from volunteers that could be accessible for the Big Data Users (if volunteers accepted) and (ii) an on-site storage (Daphne PHR - Personal Health Record) representing the data that, due to security restrictions, were not allowed to leave the Hospital facilities (see section 2.1 of the deliverable *D10.4 Ethical monitoring report V2* [11] and the data dictionary of the deliverable *D2.7 Daphne System Architecture final design and development*) [12].

According to this model the data collected during cycle 1 and 2 from healthy volunteers has been wholly stored inside the Data Cloud (**Data Cloud's PHR** and **self-tracking repository**). On the contrary, the data from patients collected in cycle 3 were divided in two different classes, as fully explained in the data dictionary of the deliverable D2.7 [12] and summarized in the deliverable D10.4 [11]:

1. Clinical data (anthropometrics, health markers, psychological assessment, aggregated data and automatic and physician recommendations) has been stored inside the **Hospital's PHR**.
2. Data coming from the wearable sensors and the mobile applications (psychological questionnaires items results, processed data from the sensors, food intake from the nutrition application) has be stored in the **self-tracking repository** (data cloud), in a secure anonymised way. The raw data stored inside the data cloud has not be processed or analysed, except to assess its successful transfer and potential for later analysis.

Table 1 summarizes the data storage process in hospitals.

Table 1 Data storage in hospitals for the pilot studies

Hospital's PHR	Self-tracking repository
•Anthropometrics •Health markers •Psychological questionnaires' assessment (scale results) •Aggregated data from the back-end servers •Automatic recommendations •Physician recommendations	•Psychological questionnaires' single answers (items results) •Processed data from the sensors/aggregator/WP4 •Food intake

2.1.2 Data sharing

To implement data sharing, the following decisions have been taken (as reported in deliverable D10.4 [11]), and followed for the three different cycles of tests:

1) According to the architecture described in D10.4 (see figure 1 of D10.4), no data stored inside the hospital's PHR for the pilot study has been shared and sent to the Data Cloud.
   In fact, in the future, in order to share the data it will be mandatory to submit a proposal to the competent local Ethical Committee (OPBG or Nevet). The proposals could be only for Not-For-Profit purposes. Data will be sent to the Data Cloud in an anonymous way only if the Ethics Board approves the request, and it will be available for specific Big Data Users who ask for the data. Moreover, only the data of patients' who give their consent will be shared.

2) Patients, and parents in case of minors, have been able to decide whether to share or not their data, which data to share and for what research purpose in a "granular" online consent form in the PHS Portal. The critical points listed above have been taken into consideration in the development of the consent.
   - First of all, it was necessary to complete the consent during the first access, otherwise no data could have been stored and collected;
   - Patients had the possibility to share or not their data *a priori* by choosing "consent all" or "disconsent all", respectively (see Figure 1). Otherwise, they could specify their consent;
   - For what concerns the clinical data stored inside the Hospital's PHR, patients/parents had three possible options: "public health planning", "public scientific research" (consent for non-profit activities) or "not sharing data" (see Figure 2);
   - For what concerns the data stored in the Self-repository in the Data Cloud, patients/parents had in addition two options for sharing their data for profit activities: "Health marketing", "Pharmaceutical research" (see Figure 3).
   - Users (patients and well-being individuals) had the possibility to opt-in and opt-out at any time. All the information has been fully explained in the written Informed Consent (see section 2.2.2).

The data flagged as "not sharing data" in the PHS consent form, have been uploaded to the Self-track repository to be stored and used by hospitals but cannot be shared with any type of organization (Not-For-Profit and For-Profit).

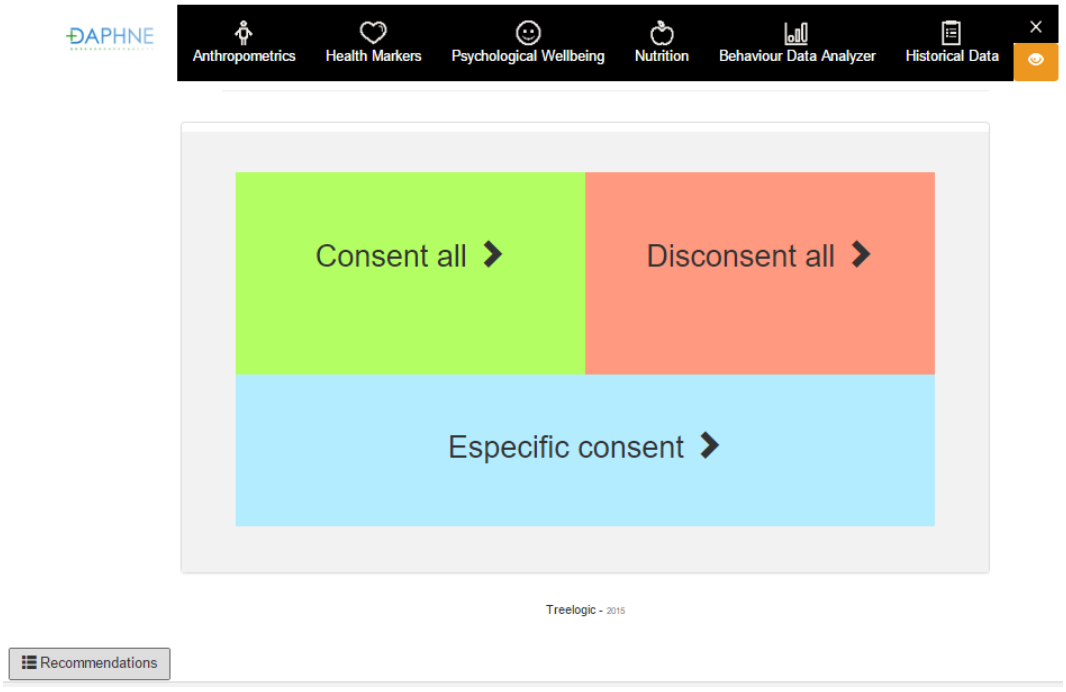

Figure 1 First screen of the online consent form in the PHS

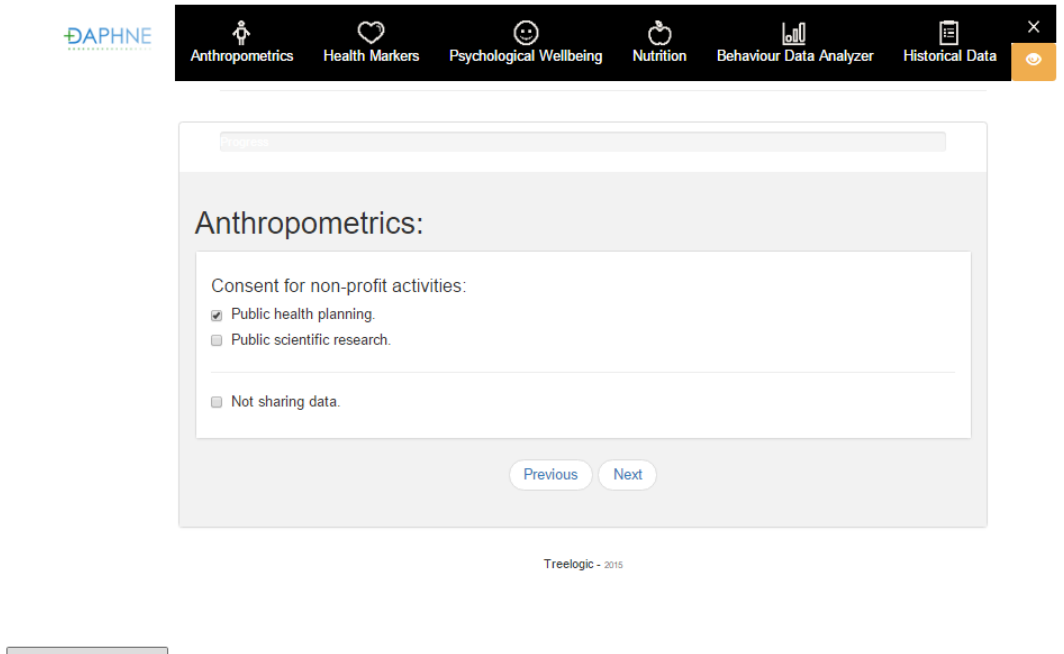

Figure 2 Different options of sharing data stored inside the Hospital's PHR

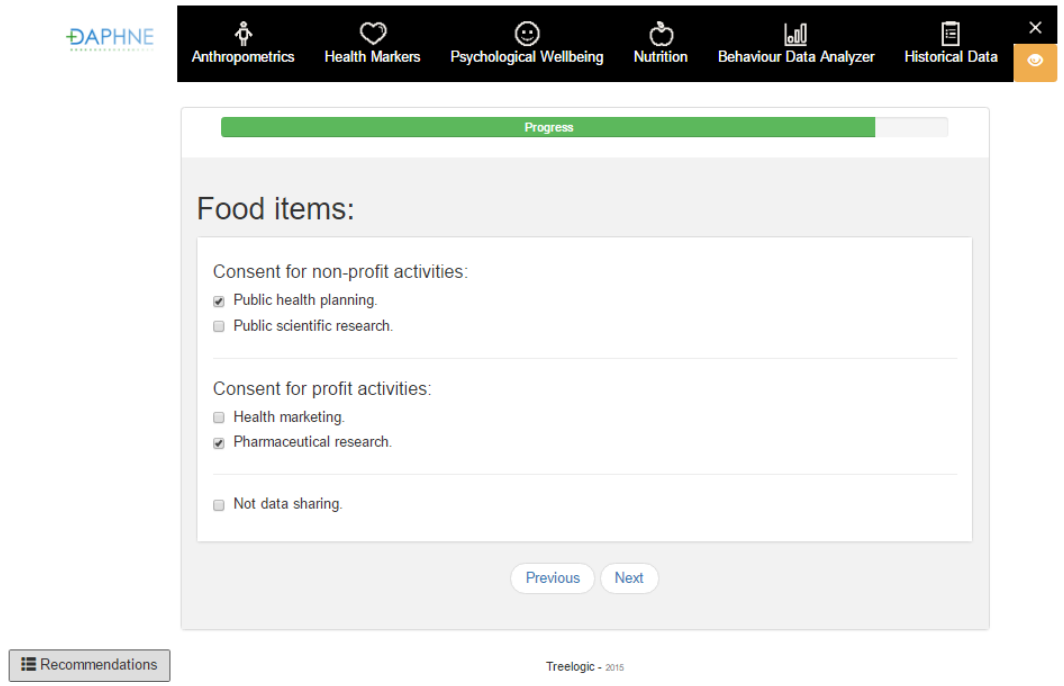

Figure 3 Different options of sharing data stored inside the Self-tracking repository in the data cloud

The PHS Portal is the tool where patients and informal caregivers (parents) had the possibility to check their health information, sensor analysis and receive personalized recommendations (fully explained in the deliverable *D5.2 Personal Health Services design* [13]).

By default, no data can be used for research without the user´s previous opt-in consent (as configurable in the online application).

The consent about "clinical data" has been stored in the PHR (inside the Hospitals in case "of patients and inside the Data Cloud in case of volunteers) while the consent about the "Data coming from the wearable sensors and the mobile applications" has been stored in the Self-tracking data store in the Data Cloud.

In the future, in case the Hospital will decide to export the data from the private PHR to the public PHR (upon the approval of the Ethical Committee), the consent will be exported with the data and based on that the Data-as-a-Service API will retrieve the anonymized data.

Moreover, as deeply explained in the deliverable *D6.4 Data cloud final prototype* [14]:

- In case of consent revocation, once researcher requests a query for certain fields, system verifies that consent of each subject permits sharing these fields for current purposes and this permission is up-to-date. This consent management mechanism also supports consent-revocation – once subject revokes his consent, system will address his data fields as data without permission. As a result, the query output always contains data only for subjects with valid consent. Unfortunately, no mechanism can be implemented for revoking data queried prior to consent revocation.
- DAPHNE Data Cloud provides an interface for deletion of any type of personal detail, including submitted data, consent and awareness log. Such data deletion can be triggered by the patient, the clinical data owner or automatically by the Data Cloud according to preconfigured data storage policy.

2.2 Ethical Approval and Informed consents for the testing cycles

2.2.1 Ethical Approval

Ethical approval was requested and obtained prior to the beginning of all the tests/studies performed in cycles 1, 2 and 3. In particular:

- For the studies conducted at UPM (cycle 1 and 2), ethical approval was required and obtained from Comité de Ética de la Universidad Politécnica de Madrid (see annexes D in the resubmitted version of D7.1 *Selection of target prototypes and evaluation methodology* [10]);
- For the studies conducted at the University of Leeds (cycle 1 and 2), ethical approval was required and obtained from the School of Psychology Ethics Committee (see annexes G and H in the resubmitted version of D7.1 [10]);
- For the studies conducted at OPBG (cycle 3), ethical approval was required and obtained from the Ethical Committee at the *Bambino Gesù* Children's Hospital (see annexes K in the resubmitted version of D7.1). In particular, an amendment to the original protocol has been asked by the end of March 2016 (Month 29) (annex A) including the CE certificate for the DAPHNE sensor (see annex V in the resubmitted version of D7.1) and the approval has been obtained (see annex L in the resubmitted version of D7.1) [10];
- For the studies conducted at Maccabi's (cycle 3), ethical approval was required and obtained from the Ethical Committee in Maccabi (annex B).

2.2.2 Informed consent

As discussed in depth in deliverable *D10.2 Ethical monitoring report V1* [1]: *"Informed consent is required for every kind of research in which participants are involved. It is a tool through which volunteers are fully informed about: the study purposes and procedures; the way they are involved in; the risks and the benefits derived from it; the data collection, privacy and protection, accessibility and disclosure. Participants has the right to decide what kind of data they want to share and to know they are free to take back their consent and*

opt-out of the trial at any time. Informed consent must be written in a way that participants understand and must be obtained before the starting of the study."

All the informed consent have been approved the local Ethical Committee and collected for each subjects involved in cycle 1, 2 and 3 cycles prior to the beginning of the tests (see annexes B, C, E, F, I, J, M in the resubmitted version of D7.1) [10].

2.3 DAPHNE sensor

2.3.1 DAPHNE sensor's safety

After having conducted all the tests required, the brand-new DAPHNE sensors, developed by Evalan, obtained the CE certification on the 29th of March 2016 (Month 29) (see annex V in the resubmitted version of D7.1 [10]);.

The DAPHNE sensor has been classified as a Class I (low-risk) medical device. The CE certification, together with: (i) the instructions for the sensor's use (see Annex C of D10.4); (ii) the sensor's safety information (see Annex D of D10.4); (iii) the Risk Management document (see Annex M of D10.4) was necessary in order to use the sensor in Hospitals for Cycle 3 [11].

This certification was sent to the Ethical Committee in OPBG and Maccabi's and was approved (see annex L in the resubmitted version of D7.1) [10].

In Italy, in case of clinical investigations with medical devices CE-marked (post-market), a free notification to the Ministry of Health (MoH) was required [10, 15] .

Unfortunately it was not possible for the Hospital to send the above-mentioned notification. Due to a modification of the legislation in Italy to limit the number of Ethical Committees, in the different regions it has been necessary to put together different ECs. The OPBG EC does not belong to none of the 11 ECs currently operating in our region. In fact, the OPBG EC has been re-established (according to the D.M. 08/02/2013 "Criteri per la composizione e il funzionamento dei comitati etici"- GU n.96 del 24-4-2013) on the 31st of July 2013, it took office in the 23rd of October 2013 and it has been acknowledged as National Ethical Commitee ("Delibera della Regione Lazio" n.301 (3/10/13) that modify the DGR n.146 of the "Giunta della Regione Lazio"). Despite the fact that OPBG EC is valid for all legal purposes and works as National Ethical Committee, it has not been validated yet to work for the Italian National Monitoring Centre on Clinical Research (*Osservatorio Nazionale delle Sperimentazioni Cliniche*- OsSC) of the Italian Medicine Agency (*Agenzia Italiana del Farmaco* – AIFA). Since this issue has not been sorted out yet, at present the OPBG EC works according to the OsSC del 30/04/2013, that means by paper.

For all the reasons explained above, since the notification to the MOH could be done exclusively online, it was not possible for us to send it. The MoH has been properly informed about the issue.

2.3.2 DAPHNE sensor's accuracy

One of the critical points of the systems and applications for health monitoring is their accuracy and validation according to scientific guidelines. In fact, users usually choose their applications taking into consideration the approval and comments of other users, and judge them reliable according to the number of downloads. Data about health and well-being must be accurate and reliable, due to the fact that such data will be used to take important decision about clinical treatment. For this reason, since the DAPHNE system is addressed to the treatment of obesity condition, it has been designed and developed considering a user-centric approach but, above all, taking into account the medical and clinical requirements. The interdisciplinary research between designers, computer technicians and clinician has been one of the key points of the three-year work of the DAPHNE project.

2.4 Technological gap

Finally, one of the emerging issue about the ICTH (Information and Communication Technologies in Healthcare) is about the exclusion from the treatment of all those people who do not have access to technologies. This issue is about the gap between who has the knowledge and the skills, and who don't, or again because of different socio-economical status of patients (mobiles/tablets/internet connection costs).
During the DAPHNE project this "technological gap" and consequently the unfeasibility of providing the same level/type of service to every patient has been detected due to:

- Limited Operative System (only Android 5.0) (see section 3.5.10 of D7.4) [16];
- Complexity of the system, above all for parents (see section 3.5.10 of D7.4) [16];
- Costs of internet connection (lots of mobile internet data necessary for the use of the system).

It is important, for the future of the project, to reflect about the fair and equal distribution of the resources and the broadening of the right of access to the new technologies to everyone, including disadvantaged groups:

1. By providing citizen education to the use of the new ICTH;
2. By assuring the same level of service/treatment to those who will not be able to access to these ICT services.

2.5 Reform of EU data protection rules

In January 2012, the European Commission proposed a comprehensive reform of data protection rules in order to strengthen online privacy rights and boost Europe's digital economy. Technological progress and globalisation have profoundly changed the way our data is collected, accessed and used. In addition, the 27 EU Member States have implemented the 1995 rules differently, resulting in divergences in enforcement. The proposal of a single law had the objectives to:

- do away with the current fragmentation and costly administrative burdens, leading to savings for businesses of around €2.3 billion a year;
- to help to reinforce consumer confidence in online services, providing a much needed boost to growth, jobs and innovation in Europe.

In order to achieve the goals set, two legislative proposals were planned:

1. a Regulation setting out a general EU framework for data protection;
2. a Directive on protecting personal data processed for the purposes of prevention, detection, investigation or prosecution of criminal offences and related judicial activities.

After over four years of discussion, on 4 May 2016, the official texts of the Regulation and the Directive have been published in the EU Official Journal in all the official languages:

1. Regulation (EU) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL 2016/679 of 27 April 2016) on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (The General Data Protection Regulation - GDPR) [4];
2. Directive (EU) 2016/680 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA [17].

The GDPR will replace the current directive 95/46/EC and will be directly applicable in all Member States without the need for implementing national legislation. It entered into force on 24 May 2016, but it will not apply until 25 May 2018.

On the contrary the Directive enters into force on 5 May 2016 and EU Member States have to transpose it into their national law by 6 May 2018 [18, 19].

The DAPHNE security module has been developed following the **Data Protection Directive** (DPD) 95/46/EC which regulated at that time the processing of personal data within the European Union and covers the protection of individuals with regard to the processing of personal data and on the free movement of such data [5, 6].

In the future the new Regulation must be taken into account. The key changes in the reform include:

- A single set of rules on data protection, valid across the EU. Unnecessary administrative requirements, such as notification requirements for companies, will be removed. This will save businesses around €2.3 billion a year.
- Instead of the current obligation of all companies to notify all data protection activities to data protection supervisors – a requirement that has led to unnecessary paperwork and costs businesses €130 million per year, the Regulation provides for increased responsibility and accountability for those processing personal data.
- For example, companies and organisations must notify the national supervisory authority of serious data breaches as soon as possible (if feasible within 24 hours).
- Organisations will only have to deal with a single national data protection authority in the EU country where they have their main establishment. Likewise, people can refer to the data protection authority in their country, even when their data is processed by a company based outside the EU. Wherever consent is required for data to be processed, it is clarified that it has to be given explicitly, rather than assumed.
- People will have easier access to their own data and be able to transfer personal data from one service provider to another more easily (right to data portability). This will improve competition among services.
- A 'right to be forgotten' will help people better manage data protection risks online: people will be able to delete their data if there are no legitimate grounds for retaining it.
- EU rules must apply if personal data is handled abroad by companies that are active in the EU market and offer their services to EU citizens.
- Independent national data protection authorities will be strengthened so they can better enforce the EU rules at home. They will be empowered to fine companies that violate EU data protection rules. This can lead to penalties of up to €1 million or up to 2% of the global annual turnover of a company.
- A new Directive will apply general data protection principles and rules for police and judicial cooperation in criminal matters. The rules will apply to both domestic and cross-border transfers of data. [20].

3 Conclusions

This document describes in depth the Ethical Monitoring of the entire DAPHNE project, with a focus on the main Ethical concerns arising during the development of the whole DAPHNE system.

In particular the main areas of Ethical monitoring were the following:

- Privacy and data management
- Local Ethical Committee approval and informed consent
- Safety and certification of the brand-new DAPHNE wearable sensors
- Technological gap

Finally an overview of the reform of EU data protection rules has been added. The report concludes that ethical issues are highly significant in the handling of patient information and that the procedures and measure that have been taken are sufficient to address these concerns and meet high standards of ethical integrity.

From an ethical point of view the main positive key points are the following:

- The DAPHNE system has been designed and developed with the help of health care professional, who took into account the updated guidelines available in medicine;
- The development has been user-centric. Users feedback have been collected and considered during the different phases of the project;
- The "privacy by design" concept has been considered for the development of the DAPHNE platform;
- The DAPHNE sensor obtained the CE certification as I class medical device;
- Two different developments have been considered for adults and minors;
- The informed consents fully explained the project and data management;
- Users had the possibility to withdrawal or change their consent in any moment of the tests.

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[16] *Deliverable D7.4. Report on third cycle of validation. OPBG. DAPHNE*

[17] *http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2016.119.01.0089.01.ENG&toc=OJ:L:2016:119:TOC*

[18] *http://ec.europa.eu/justice/data-protection/reform/index_en.htm*

[19] *http://www.allenovery.com/SiteCollectionDocuments/Radical%20changes%20to%20European%20data%20protection%20legislation.pdf*

[20] *http://europa.eu/rapid/press-release_IP-12-46_en.htm?locale=en*

Annex A Request of amendment to the OPBG Ethical Committee

Bambino Gesù
OSPEDALE PEDIATRICO

Research Unit for Multifactorial Diseases, Obesity and Diabetes

Dott.ssa Melania Manco
Malattie Multifattoriali A.R.

Spett.le Prof Pierpaolo Mastroiacovo
Presidente del Comitato Etico dell'IRRCS
Ospedale Pediatrico Bambino Gesù

Oggetto: Lettera di amendment per il protocollo di studio "Pilot study (cycle 3) for the evaluation of DAPHNE system's functionality in obese adolescents' treatment".
Protocollo: 997_OPBG_2015; approvato in data 09/12/15.

Ch.mo Prof. Mastroiacovo,
Si richiede di emendare il protocollo di studio in oggetto.
L'emendamento si rende necessario per aderire alle richieste formulate dai revisori della Commissione Europea, Ente finanziatore del progetto, durante l'ultima revisione semestrale.
I revisori hanno chiesto la semplificazione del disegno sperimentale e l'aumento del numero dei sensori.
In particolare:

- Il numero dei sensori ActiGraph Link aumenta da 6 a 9.
- Il numero di sensori DAPHNE (prodotti da Evalan) aumenta da 4 a 8.
- Verrà utilizzato un unico sensore da portare in vita invece di due per registrare l'attività fisica e sedentaria. Non saranno più registrate informazioni sul attività cardiaca e sulla risposta allo stress.
- I pazienti verranno suddivisi in due gruppi paralleli, non più in 4:
  - **Gruppo 1**: educazione terapeutica per obesità, sistema DAPHNE completo (sensori, portale PHS sul web, applicazioni DAPHNE per il telefono) – 17 pazienti
  - **Gruppo 2**: educazione terapeutica per obesità, applicazioni DAPHNE (portale PHS sul web, applicazioni DAPHNE per il telefono) – 15 pazienti
- Tutti i pazienti verranno seguiti per 10 settimane e saranno effettuate 4 visite mediche in questo arco temporale.
- Il numero finale di pazienti da arruolare diminuisce da 40 a 32. A corredo della presente lettera si allega il protocollo di studio modificato. Tutte le modifiche sono state apportate utilizzando il comando "Revisione" di Microsoft Word.

Roma 30/03/2015 Dr. Melania Manco

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Joint Commission International

Annex B Ethical approval for cycle 3 in Maccabi

בית חולים
אסותא
סטנדרט של בריאות
בית חולים אסותא תל אביב רחוב הברזל 20, רמת החי"ל ת"א 6997801, טל': 03-7644000, פקס: 03-7645008 www.assuta.co.il

שם הנוהל: נוהל לניסויים רפואיים בבני-אדם	תאריך: מאי 2014
טופס 6	
אישור ועדת הלסינקי לביצוע ניסוי רפואי	

תאריך: 26/01/2016

לכבוד
ד"ר יוסף עזורי, החוקר הראשי
מחלקה: נ.ב.ט
מכבי שירותי בריאות

חוקר נכבד,

הנדון: **<u>אישור ועדת הלסינקי</u>**

שוכנענו שהניסוי הרפואי, אשר פרטיו מופיעים להלן, אינו נוגד את עקרונות הצהרת הלסינקי, תקנות בריאות העם (ניסויים רפואיים בבני-אדם) תשמ"א-1980 ונוהל לניסויים רפואים בבני-אדם 2014.
אישור זה הנו שלב ביניים בהליך אישור הניסוי הרפואי. החוקר יוכל להתחיל בביצוע הניסוי רק לאחר קבלת אישור המנהל (טופס 7).

פרטי הניסוי

מספר בקשה בוועדה מוסדית: 2015093	סוג הניסוי: אמ"ר.
נושא הניסוי (בעברית): הערכת השימוש במערכת Data-as-a Service platform for Healthy lifestyle and preventive medicine	
ניסוי רב-מרכזי בארץ: ☒ כן ☐ לא	

מסמכי הניסוי

פרוטוקול הניסוי- שם/מספר: -2015 001	גרסה: 01	תאריך: 06/09/2015
טופס הסכמה- שם/מספר:	גרסה: 02	תאריך: 15/01/2016
חוברת לחוקר- שם/מספר:	גרסה: 01	תאריך: 22/12/2015

הניסוי הרפואי הנו

☒ ניסוי רפואי מיוחד, שבסמכות מנהל המוסד הרפואי לאשרו ללא אישור נוסף של משרד הבריאות.

☐ ניסוי רפואי שאינו מיוחד, ולכן נדרש גם לאישור נוסף של משרד הבריאות.