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D.8.3 Exploitation and Sustainability Plan

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Executive Summary

The Exploitation Plan is intended to provide an effective strategy and framework for the adoption and exploitation of the CARRE project results to ensure their sustainability.

The exploitation plan approach is designed to generate value and return from the knowledge, technology and commercial potential of the project's intermediate and final outcomes in multiple contexts: industry, research community, policy makers and society.

About CARRE

CARRE is a project, funded by the FP7 Programme of the European Commission, which will provide an innovative means for managing comorbidities (multiple co-occurring medical conditions), with an immediate focus on chronic cardiac and renal disease patients or persons with an increased risk of such conditions.

Sources of medical and other knowledge will be semantically linked with outputs from sensors to provide clinical information, personalised to the individual patient that can help to support the tracking of the progression and interactions of comorbid conditions. Visual analytics will be employed so that patients and clinicians will be able to visualise, understand and interact with this linked knowledge and take advantage of personalised empowerment services supported by a dedicated decision-support system.

The ultimate goal is to provide, via an integrative approach, a means by which patients with comorbidities are helped to take an active role in care processes, including self-care and shared decision-making, and medical professionals are supported in understanding and treating comorbidities.

Terms and Definitions

The following are definitions of terms, abbreviations and acronyms used in this document.

Term	Definition
ACM	Association of Computing Machinery - International scientific and educational organization dedicated to advancing the arts, sciences, and applications of information technology
AF	Atrial fibrillation
CKD	chronic kidney disease
DG	Directorates General – term to describe European Commission departments
DoW	Description of work
ECG	Electrocardiogram
EDF	European data format
EMBL	The European Molecular Biology Laboratory
FP7	7th framework programme
GALEN	A project to bridge the gap between different terminology systems through the construction of a terminology server
ICD-10	10th revision of the International Statistical Classification of Diseases and Related Health Problems
ICT	Information and communication technologies
LOINC	Logical Observation Identifiers Names and Codes
MedDRA	Medical Dictionary for Regulatory Activities
MeSH	Medical Subject Headings
NCBO	National Center for Biomedical Ontology
NHS	National health system
NICE	National Institute for Health and Care Excellence, UK
OWL	Web Ontology Language
RDF	Resource description framework
ROI	Return on investment
RxNORM	a name of a terminology in medicine that contains all medications available on US market
SNOMED-CT	Systematized Nomenclature of Medicine--Clinical Terms
SPARQL	a semantic query language for databases
SROI	Social return on investment
UMLS	Unified Modelling Language System
WHO-ART	Adverse Reaction Terminology

1. Introduction

The issue of value creation by eHealth systems has been explored in several EU-funded projects. An initial consolidated attempt was undertaken by the European eHealth IMPACT study[1]. The study concluded that identifying the economic and financial benefits of eHealth needs to take into consideration the overall operational context within which these applications and services lie. More importantly, it indicated the need to go beyond non-financial elements, by considering issues such as change management and organisational adaptation within the healthcare delivery organisation for developing a specific eHealth system or application. Therefore, it concluded that future investors should not expect miracles and 'Big Bang'-type faultiness from complete eHealth applications, especially in more complex cases where large amounts of data and organisational effort are required.

The following section present an overall approach towards an analysis of value creation by the CARRE project. The overall project social return on investment can be discussed along a number of different axes:

- the expected impacts for the particular call as laid out in the call and addressed in the DoW;
- the impact of CARRE as an FP7 project;
- the impact of CARRE as an eHealth intervention
- the project performance indicators as led out in DoW;
- the project scientific and technological exploitable outcomes and the individual exploitation and sustainability plans;
- the project contribution to standards; and
- the overall benefit for the society.

The subsequent sections of this deliverable discuss each of the above axes.

2. Project Impact as in the call (FP7-ICT-WP2013.5.1)

The following paragraphs discuss how CARRE project addresses the expected impacts as listed in the call description (FP7-ICT-WP2013.5.1).

Strengthened evidence base on health outcomes, quality of life, care efficiency gains and economic benefits from the use of ICT in new care models.

Cardiorenal disease is a common, serious and costly condition. In a recent USA study the incremental health care costs associated with a diagnosis of chronic kidney disease (CKD) in patients with diabetes and/or hypertension for the managed care database for approximately 30 million people during 2000-2006 showed that in the post-CKD period, costs directly related to treatment of CKD accounted for 9%-19% of all-cause medical service costs[2]. Managing cardiorenal patients is however complicated as comorbidities require care provision by different medical specialties administering often contradicting and interacting treatment regiments. Also the chronic nature of the condition requires a great deal of self-management and caregivers' involvement at home.

CARRE aims at strengthening the cardiorenal patient, mainly by reinforcing the patient understanding of the disease and its comorbidities complex interdependencies as they are personalized to the specific patient. CARRE thus implements the "*patients getting up off their knees*" mandate of current patient empowerment initiatives[3]. By improving the patient's ability to understand and manage his/her own complex disease in the presence of comorbidities, patients can better negotiate with different teams of health professionals and navigate the complexities of health systems for comorbid management; literature suggest that this is crucial to achieving

[1] Stroetmann, K.A., Jones, T. Dobrev, A. and Veli, N.O. 'eHealth is worth it: the economic benefits of implemented eHealth solutions at ten European sites', final report prepared for the European Commission, 2006.

[2] Laliberté F, et al. Direct all-cause health care costs associated with chronic kidney disease in patients with Diabetes and hypertension: a managed care perspective J Manag Care Pharm, 15:312-22, 2009

[3] The WHO, Empowering Patients, 17-4-2012 http://www.euro.who.int/en/what-we-do/health-topics/noncommunicable-diseases/sections/news/2012/4/empowering-patients (last visit: 10/12/2012).

better health outcomes[4].

The CARRE clinical investigational protocol[5] is designed to measure via a randomized control trial the impact of the CARRE intervention to (a) health literacy, (b) patient empowerment, (c) quality of life and (d) health condition (including risk reduction and prevention, disease progression, reduction in necessary medication, and lifestyle improvement). The clinical investigation is planned to extend beyond the duration of the project so as to be able to draw statistically significant solutions after longer study periods, as planned in the evaluation plan presented in D.7.1.

Reinforced medical knowledge with respect to efficient management of comorbidities.

A recent thorough treatment of comorbidity management[6] suggests that one way to improve care in such cases is to cross reference evidence, knowledge and guidelines for each condition. This practice is not currently implemented, and clinicians and patients alike are required to read separate documents on evidence and guidelines for each condition (with a notable exception of NICE[7] guidelines for depression). As it has already been argued in literature[8], simple cross referencing of existing medical evidence and guidelines for all possible combinations of conditions would quickly make it unreadable and thus inefficient.

CARRE project significantly contributes towards this goal by the already developed risk factor database and respective interactive system. This database summarizes current medical evidence on risk factors in cardiorenal disease and comorbidities and presents respective information in a systematic tabular form. This is greatly enhanced by the rich, interactive, state-of-the-art graphical representations of risk factors and their complex relationships and pathways. Overall the system offers an innovative and intuitive approach of visualizing essential medical evidence data, thus providing a reinforced way of presenting complex scientific knowledge to clinical practioners. This is expected to reinforce the understanding and the use of state-of-art medical evidence by clinical practitioners and thus make evidence based medicine easier to apply.

Involvement of care authorities in development of personalised care solutions, with increased commitment in the deployment of innovative services after the R&D phase.

In a very recent publication Nigel Crisp[9], former UK NHS chief executive states that "*it is striking that no country has yet been successful in giving its citizens a truly central role in improving health and healthcare, preferring instead to rely almost exclusively on economic and professional levers*". People are defined in terms of economic and professional frameworks and are reduced to being mere consumers in need of satisfying, or passive patients in need of treatment or education. In any case, they are not seen as active participants in their own right.

CARRE follows an approach of "*first understand, then conquer, then decide*" which targets both the patient and the medical professional. As such it is designed to steer the active involvement of patients and health authorities in the management of comorbidities. CARRE service brings evidence based medicine to the patient via an intuitive interactive interface. This enables the patient to understand their health risks and set their own personalized lifestyle goals in order to reduce risks and prevent health deterioration and disease progression.

This service can be employed in different business models for the deployment of innovative services after the R&D phase:

- The CARRE service can be adopted by primary health care practices or regional and community practices to empower citizens to understand the effect of lifestyle choices in chronic lifestyle related

4 Editorial, Patient Empowerment – who empowers whom? The Lancet 379(9827): 1677, 2012

5 The CARRE clinical investigational plan is part of D.7.4 (due together with the evaluation results in the end of the project); its first draft has already been produced as Annex 4 in this document. The final detailed investigational plan will be submitted for approval to the respective bioethics authorities of the two pilot sites and is expected to be approved and available by mid-March 2016 at the latest.

6 Guthrie B., Payne K., Alderson P., McMurdo M.E.T., Mercer S.M., Adapting clinical guidelines to take account of multimorbidity, BMJ, vol. 345, e6341, 2012 (Published 4 October 2012)

7 The NICE Guidelines, NHS, UK http://www.nice.org.uk/ (Last visit: 2/12/2012)

8 Guthrie B., Payne K., Alderson P., McMurdo M.E.T., Mercer S.M., Adapting clinical guidelines to take account of multimorbidity, BMJ, vol. 345, e6341, 2012 (Published 4 October 2012)

9 Crisp N., Patient power needs to be built on strong intellectual foundations, BMJ 2012;345:e6177(Published 21 September 2012)

disease. The project discusses the potential for such deployment with local regional communities (municipal health and social security services in Greece).

- The CARRE service can be adopted by healthcare systems to help monitor patient with or at risk of cardiorenal disease and help increase their awareness on disease and its management, with the aim to increase quality of life, reduce necessary medication and delay disease progression and health deterioration. The two CARRE pilot centers (university hospitals in Greece and Lithuania) plan to sustain the service and prolong evaluation after the end of the project to derive more statistically significant evidence on the above.
- The CARRE service can be adopted by private health care institutions and health insurance companies to (a) increase support and empowerment of their clients and (b) construct personalized health plans based on medical evidence. The consortium plans targeted communication to respective stakeholders, including health international insurance companies and national telecommunications industry offering telemedicine services.

Increased level of education and acceptance by patients and care givers of ICT solutions for personalised care.

One of the most important aspects of cardiorenal disease diagnosis and treatment is early detection and aggressive management of underlying causes. Prevention of the disease includes: lifestyle modification (controlling obesity, diabetes and hypertension), public-health education for reduction of excessive bodyweight, regular exercise, and dietary approaches, control of hypertension, dietary protein restriction and blood-pressure control, proteinuria management, dyslipidaemia management and smoking cessation. Delaying disease progression is crucial and must include patient education and aggressive treatment and management of CKD and its comorbidities [11,10]. Effective implementation of such strategies will only come when both the general public and the cardiorenal community work together towards public awareness and lifestyle management on a personal basis, which is the central issue in CARRE.

However, in order to engage effectively the public (including patients and caregivers) ICT technology providers have to somehow address the intellectual gap that usually exists when interventions unavoidably designed and developed by technocrats are offered to be used by the layman. CARRE addresses effectively at least one aspect of this gap, which relates to the often long distance between medical and layman terms involved in the description of disease and treatment plans. In specific, CARRE will address this via semantic coupling either via Linked Data Cloud or dedicated semantic tools, e.g. MedlinePlus Health Topics[11] which provides end users with relevant information in layman's terms but also scientific literature allowing more advanced knowledge extraction.

Moreover, the project has developed advanced interactive visual representations of scientific knowledge on medical risk factors; these turn difficult to grasp scientific concepts (e.g. of risk ratio) into intuitive and interactive graphics which can eventually help citizens and medical experts alike to understand, interact with and use in their everyday life complex scientific concepts.

Improved interaction between patients, their relatives and carers, facilitating more active participation of patients and relatives in care processes.

CARRE solution aims to enhance the patients' and caregivers' understanding of the complex interrelations of treatments, adverse events, lifestyle management and disease projections in the case of cardiorenal comorbidities is the basic common ground for understanding each other, and clarifying roles and dispositions, thus enhancing eventually collaboration and participation in the care process. This is supported in particular of the interactive visual model of personalized health risk factors developed by the project, which can be used as a basis for patient-doctor collaboration and patient-carer/relative collaboration to understand implied health risks and efficiently plan lifestyle changes to improve or prevent them.

[10] Khwaja A, et al The management of CKD: a look into the future. Kidney Int, 72:1316-23, 2007

[11] The MedLinePlus Health Topics, http://www.nlm.nih.gov/medlineplus/healthtopics.html (last visit: 3/12/2012).

Improved cooperation between the providers of health, social and informal care and increased confidence in decision support systems for disease/patient management

CARRE has developed novel technology to describe and visualize disease projections and trajectories based on state-of-the-art medical evidence on risk factors.

The generic risk factor data and visual model can be used by health providers to design overall policies, and by medical experts to better understand quantitatively the nature of interdependencies of different comorbidities and causing factors in cardiorenal disease. When the risk model is personalized to a particular patient it can serve as a common bridge between the patient and the medical expert to help collaboratively set personalized goals and interactively plan lifestyle and treatment interventions, dynamically set monitoring and self-monitoring regimes and thus increase cooperation in disease management and decision support.

3. Return on investment as an FP7 project

Studies in the mid-1990s based upon firm-level data from thousands of companies suggest that there is a significant payoff from IT investments[12]. These results suggest that investing in IT is on average a positive return on investement (ROI) activity, but the benefits of IT investments are difficult to measure and risk factors can significantly impact the actual ROI realized.

Social return on investment (SROI) is a method for measuring values that are not traditionally reflected in financial statements, including social, economic and environmental factors, which can identify how effectively an organization uses its capital and other resources to create value for the community[13]. While a traditional cost-benefit analysis is used to compare different investments or projects, SROI is used more to evaluate the general progress of certain developments, showing both the financial and social impact of the corporation.

While the approach varies depending on the program that is being evaluated, there are four main elements that are needed to measure SROI:

- Inputs – resources investment in the activity (such as the costs of running a job readiness program)
- Outputs – the direct and tangible products from the activity (for example, the number of people trained)
- Outcomes – the changes to people resulting from the activity (i.e., new jobs, better income, improved quality of life for the individuals; increased taxes and reduced support for the government)
- Impact – the outcome less an estimate of what would have happened anyways (for example, if 20 people got new jobs but 5 of them would have anyways, the impact is based on the 15 people who got jobs as a result of the job readiness program)

The Ex-post evaluation[14] of the 7th EU Framework Programme (2007-2013) published on November 2015 identified major areas of achievement of FP7 framework programme. The following paragraphs address the contribution of CARRE towards each area.

1. **FP7 encouraged scientific excellence on individual and institutional level.** CARRE contributes novel interdisciplinary research in a number of scientific fields. This is demonstrated by the number of scientific publications produced by the project during the first two years: 7 journal papers, 26 papers in conference proceedings, 9 invited presentations. More scientific publications are currently being submitted.
2. **FP7 engaged industry and SMEs strategically.** At the contract phase, CARRE was set up as an academic consortium consisting of 4 Universities, 1 University Hospital and 1 Research Institute. However, during the course of the project, CARRE managed to draw attention and to engage

[12] M. Jeffery, Return on Investment Analysis for e-Business Projects, The Internet Encyclopedia, John Wiley & Sons, Inc, 2004 DOI: 10.1002/047148296X.tie154 http://onlinelibrary.wiley.com/doi/10.1002/047148296X.tie154/abstract

[13] Millar & Hall (2012) Social Return on Investment (SROI) and Performance Measurement. In Public Management Review, DOI:10.1080/14719037.2012.698857

[14] I.O. Fresco, A. Martinuzzi, A. Wiman and the Members of the High Level Expert Group, Ex-Post-Evaluation of the 7th EU Framework Programme: (2007-2013) COMMITMENT and COHERENCE essential ingredients for success in science and innovation, November 2015, accessed on Feb 1, 2016, https://ec.europa.eu/research/evaluations/pdf/fp7_final_evaluation_expert_group_report.pdf

successfully industrial partners, in particular 4 SMEs with activities in the area of sensors and medical IT solutions, and 1 large telecommunications enterprise. Also, other associated partners include 1 non-profit medical research organization on lifestyle medicine, 1 technical university and 3 healthcare providers (as presented in D.8.4). Now, the project is engaging into discussions for the exploitation of research results with the SMEs in the areas of electronic devices, production of control devices and machine vision systems, visual mobile tools and sports medicine, and machine learning and big data analytics.

3. **FP7 reinforced a new mode of collaboration and an open innovation framework**. CARRE involves collaboration of a highly interdisciplinary team, including medical experts, semantic technology scientists, medical device developers, visual analytics scientists and decision support and security experts. Also, all project outcomes are offered as open source software and results and, where appropriate, uploaded onto open innovation portals and frameworks for wide public use.
4. **FP7 strengthened the European Research Area by catalysing a culture of cooperation and constructing comprehensive networks fit to address thematic challenges.** CARRE is a cross-border and cross-sector consortium with a geographical impact covering all corners of the European continent.
5. **FP7 addressed certain societal challenges through research, technology and innovation.** CARRE addresses the societal challenge of personalized health, and in particular the sensitive area of increasing awareness on health risks and managing health risk prediction and prevention. As such, it is a natural predecessor to H2020 calls under the Health Societal challenge. Furthermore, the project exhibits a particular task on gender balances awareness in science and technology, and has demonstrated activities towards a balanced team which have also been communicated as success stories to corresponding bodies such as the IFMBE Committee on Women in Medical and Biological Engineering.
6. **FP7 encouraged harmonisation of national research and innovation systems and policies.** CARRE has clustered with a number of European and national projects with cross-fertilization and results uptake activities.
7. **Stimulated mobility of researchers across Europe.** CARRE team from 4 different countries spanning different European areas (west, north-east and Mediterranean) collaborate actively with a number of working project meetings thus exposing researchers to other European working environments and practices.
8. **FP7 reached a critical mass of research across the European landscape and worldwide and put research on the public agenda**. CARRE research is placed on the sensitive arear of health risk awareness, improvement and prevention. Part of the project outcomes aim at transforming highly scientific information for intuitive use by the general public.

4. CARRE as an eHealth intervention

A comprehensive discussion on return on investment for eHelath is included in the Office of Health Affairs, University College Dublin, “Health Policy Documents: eHealth Strategy for Ireland”[15]. We have used the five main areas of eHealth benefit identified in this Policy Document to draft expected benefits of CARRE:

1. **Increase efficiency of legacy healthcare systems – lower cost of operations, reduce demand on resources.** CARRE solution employs and promotes self-monitoring of chronic patients and people at risk of chronic disease in the area of cardiorenal syndrome and comorbidities. Also, develops and shows solutions to assist personal planning of lifestyle changes. Thus, the project expects to improve quality of life and empowerment and to reduce health risks or at least improve health factors leading to increased health risks.
2. **Increase efficiency of new healthcare investments: enable new health services/policies, and open up new services.** CARRE has developed a prototype of a health risk reference database and a

[15] Office of Health Affairs, University College Dublin, “Health Policy Documents: eHealth Strategy for Ireland”[15], 2013 http://healthaffairs.ucd.ie/wp-content/uploads/2015/09/eHealth_Strategy_2013.pdf Retrieved 2 Feb 2016

number of related technologies that enable the use and re-use of this outcome for building new ehealth services. Also, the project is expected to contribute evidence on employing health risk awareness policies and services to improve health risks and/or factors leading to increased health risks.

3. **Open up new markets.** CARRE technological breakthroughs include two new marketable personal sensors and also a number and variety of software components that can be used and re-used in other products.
4. **Open up export markets.** CARRE technological breakthroughs include two new marketable personal sensors that once turned into commercial products can open up export markets.
5. **Increase well-being and better patient outcomes.** CARRE service is expected to increase awareness on health risks, enhance patient empowerment, improve quality of life and reduce health risks and/or factors leading to health risks, thus improving health status and deterring disease progression.

Furthermore, CARRE project addresses several of the recommendations led out for the ICT for Health Unit, DG Information Society and Media, European Commission towards value-creating and sustainable business models for ehealth[16]. Namely, the project addresses the policy recommendation laid out in the Reoprt's executive summary (page viii-ix) as follows:

1. the project launces a pilot action of a novel personalized ehealth service;
2. a final project report includes a best practices and implications report – also a separate report on privacy-by-design best practices is being prepared for publication;
3. the cognitive model of patient empowerment (published) and the privacy-by-design best practices (under development) are the project's contributions towards the definition of benchmarking parameters for seamless monitoring and comparing ehealth models across Europe;
4. the projects contributed a generic modelling of data exchanged and privacy requirements for personal ehealth systems thus providing the technical background for required legal clarification of accessing personal health data;
5. the project is a working paradigm of standards adoption at all levels of development, including standards for systems interoperability and medical terminologies – all project results are offered as open access via appropriate standardized interfaces (even the system components communicate via standardized technologies), while part of the project results contribute to medical terminologies.

[16] L. Valeri, D. Giesen, P. Jansen, K. Klokgieters, Business Models for eHealth, Final Report, Prepared for ICT for Health Unit, DG Information Society and Media, European Commission, 28 February, 2010

5. CARRE direct outputs as performance indicators

Table 1. Key performance indicators during the project (cumulative)

No.	**Indicator description**	**Achieved number**
1.	Number of PhD students trained within the project	4
2.	Number of MSc students trained within the project	6
3.	Number of peer-reviewed publications in scientific journals	7
4.	Number of peer-reviewed publications in scientific conference proceedings	26
5.	Working prototype of new method and technology	20
6.	Number of healthcare professionals engaged	250
7.	Number of patients engaged	600
8.	Number of other stakeholders engaged	16
9.	Number of clustering events attended	36
10.	Number of clustering events organized	11
11.	Number of projects with which communication and interaction has been established	6
12.	Number of invitation as keynote speakers at international events	8
13.	Number of invitation as keynote speakers at national events	2

6. Exploitation approach

6.1. Exploitation strategy

Exploitation of the project results requires the development of an appropriate marketing and manu-facture mechanism to ensure the project's sustainability. Therefore, as preparatory steps towards designing the strategy, we have to address the following five basic questions:

1. What? What are the project results that can be exploited? To which sector do they belong (academic, technology, education, institutions etc)?
2. To whom? Identify target market(s), main target groups or end users suitable for the exploita-tion of project deliverables
3. How? Which mechanisms and strategies are to be used for each type of project outcome and according to which user needs?
4. Why? What is the aim of each partner's individual exploitation plan?
5. By whom? Which product(s) /project outcomes can be best exploited by the Consortium as a whole, if any? Which product(s) /project outcomes can be best exploited by each consortium partner?

6.2. CARRE Exploitable Outcomes

Table 2. CARRE exploitable outcomes

Exploitable Outcome					**Background**	**Foreground**
Exploitable Asset		**Category**	**Exploitation type**	**TRL level***	**IPR Owners & Contributors**	**Interest in Shared Exploitation**
1.	Risk factor ontology	model & software	non-commercial	6	OU, DUTH, VULSK	OU, DUTH, VULSK
2.	Measurements ontology	model & software	non-commercial	6	OU, KTU, DUTH, VULSK	OU, KTU, DUTH, VULSK
3.	Web lifestyle ontology	model & software	non-commercial	5	DUTH, OU	DUTH, OU
4.	RDF importer tool	software	non-commercial	6	DUTH	
5.	Risk factor reference data base	repository	non-commercial & commercial	4	DUTH, VULSK, OU	DUTH, VULSK, OU
6.	Risk factor management system	software system & repository	non-commercial & commercial	6	DUTH, OU, BED, VULSK	DUTH, OU, BED, VULSK
7.	Medical evidence aggregators	software	non-commercial	3	BED, DUTH, VULSK	BED, DUTH, VULSK
8.	Educational resource aggregator	software	non-commercial	6	DUTH	DUTH
9.	Personal sensor data aggregators & management system	software	non-commercial & commercial	6	OU, KTU, DUTH	OU, KTU, DUTH
10.	Web lifestyle aggregator	software	non-commercial	4	DUTH	DUTH
11.	PHR aggregator & entry system	software	commercial	6	VULSK, OU	VULSK, OU
12.	Wrist worn device	hardware & software	commercial	5	KTU	KTU

13.	Multiparametric scales	hardware & software	commercial	5	KTU	KTU
14.	Multiparametric scales data analyzer	software	commercial	4	KTU	KTU
15.	ECG signal analyser	software	commercial	5	KTU	KTU
16.	Decision support alerts system	model & software	commercial	6	PIAP, DUTH, VULSK	PIAP, DUTH, VULSK
17.	Visual analytics	model & software	non-commercial	6	BED, DUTH, OU	BED, DUTH, OU, KTU
18.	Empowerment model as a cognitive process	model	non-commercial	2	DUTH	DUTH, VULSK
19.	Privacy-by-design argument	model & best practices	non-commercial	3	DUTH, OU, BED, VULSK, KTU, PIAP	DUTH, OU, BED, VULSK, KTU, PIAP
20.	CARRE integrated system & service	software system	non-commercial & commercial	6	DUTH, OU, BED, VULSK, KTU, PIAP	DUTH, OU, BED, VULSK, KTU, PIAP

* Technology Readiness Levels

TRL 1 – basic principles observed

TRL 2 – technology concept formulated

TRL 3 – experimental proof of concept

TRL 4 – technology validated in lab

TRL 5 – technology validated in relevant environment (industrially relevant environment in the case of key enabling technologies)

TRL 6 – technology demonstrated in relevant environment (industrially relevant environment in the case of key enabling technologies)

TRL 7 – system prototype demonstration in operational environment

TRL 8 – system complete and qualified

TRL 9 – actual system proven in operational environment (competitive manufacturing in the case of key enabling technologies; or in space)

6.3. Exploitation & sustainability plans for individual outcomes

6.3.1. Risk factor ontology

6.3.1.1. Short description and key differentiators

The risk factor ontology is a novel ontology to describe risk factors in the medical domain. To the best of our knowledge there is no other ontology to describe the area of risk factors (in medicine and in general). As such, the CARRE ontology is expected to be uptaken and used in a variety of cases to describe and treat risk factors in medicine and in general. Currently the ontology is being extended to describe risk factor minimization and mitigation (within T6.2 and T6.3), which will ensure a comprehensive treatment of the entire process of risk management, thus increasing largely the visibility and potential of this work.

The ontology was presented in the well established international conference by ACM (one of the world's largest educational and scientific computing society) K-CAP2015: 8th International Conference on Knowledge Capture, ACM, Palisades, NY, USA, Oct. 7-10, 2015, which gathers computer scientists, engineers and other scientistis from all over the world to discuss state or the art advances on computational approaches to digitally capture, describe and manage knowledge. The ontology got very good reviews during the peer review process of the conference and was vividly discussed during the presentation. The ontology was also summarised in a presentation to ISWC 2016 the 15th International Semantic Web Conference, Kobe, Japan, Oct. 17-21, 2016, which is the premier global event for Semantic Web research, where it was very well-reviewed, particularly with regard to the novelty of its application, and attracted a great deal of interest during the conference.

The ontology is also published in the NCBO Bioportal (http://bioportal.bioontology.org/) which is the world's most comprehensive repository of biomedical ontologies. The repository provides a uniform access interface (for humans and programs alike) for more than Currently, the repository hosts more than 500 ontologies and controlled vocabularies in the area of medical and biological sciences withinmore that 5.8 million classes, 39 million indexed records and more that 95 trillion direct annotations. Prominent examples of well known ontologies hosted in NCBO Bioportal include UMLS, ICD-10, SNOMED-CT, MeSH, LOINC, MedDRA, RxNORM, WHO-ART, GALEN, etc. These ontologies are also interconnected and provided as RDF triples via a SPARQL end point at http://sparql.bioontology.org. Bioportal has a high rank Google pagerank and receives about 1.8 thousands daily visitors with about 2.6 thousands daily page views[17].

The CARRE ontologies (http://bioportal.bioontology.org/ontologies/CARRE) are provided open access and according to the site's statistics have received more than 200 visits so far. Also, CARRE is listed as one of the 292 contributing projects[18] (http://bioportal.bioontology.org/projects).

6.3.1.2. Exploitation strategy

The primary exploitable value in an ontology lies in its use to represent and analyse data in its particular domain of application. The representation of medical risk factors and risk mitigation/minimisation strategies is a crucial component in the use of eHealth techniques to translate cutting-edge research into common practice in a timely and safe manner. Our exploitation strategy is to engage with key players in the research dissemination and standardisation area to encourage the use of the CARRE risk factor ontology to model relevant data for publication. Among others, we plan to contact scientific publishers and research bodies currently involved in the curation of scientific reference databases such as the Cochrane Collaboration[19] and regulatory bodies (e.g., NICE[20]), the Digital Physiological Human Institute[21] and the EMBL European Bioinformatics Institute[22].

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17 Web analytics for bioportal.bioontology.org on Feb 2016 by http://www.easycounter.com/report/bioportal.bioontology.org

18 This number reflects the status of the Bioportal as on Feb 10, 2016

19 Cochrane Collaboration, http://www.cochrane.org

20 NICE, https://www.nice.org.uk

21 Digital Physiological Human Institute http://www.vph-institute.org/

22 EMBL European Bioinformatics Institute, http://www.ebi.ac.uk/

We will continue to demonstrate the added-value of the CARRE risk factor ontology in future scientific work for the automated analysis of the "big picture" of state-of-the-art medical knowledge, something which is impractical without it, and by doing so emphasise the benefits of its reuse across medical (and perhaps non-medical) fields.

6.3.1.3. Sustainability plan

The ongoing costs of hosting a comparatively small ontology are negligible. Updates and modifications to the ontology may be required due to two different factors: a) a change in the technological standards for ontology representation, or b) new insights into the domain of risk factors arising either from future scientific discovery or application in practice. Updates of the first type are likely also to have a negligible cost: any significant change to a standard as widely used as the OWL language will inevitably be accompanied by tools to perform the conversions. Updates of the second type may be more involved, and will be funded by the research or application scenario which leads to the new insights. At a first stage, the medical partners DUTH and VULSK are committed to research on updates of the second type, especially via PhD research. To this end, a PhD is currently being initiated in DUTH to look into the issue of maintainance and curation of risk data – extend the ontology to account for versioning of risk factor information due to evolution of medical evidence.

6.3.1.4. Return on investment

As such, the CARRE ontology is expected to be uptaken and used in a variety of cases to describe and treat risk factors in medicine and in general. Currently the ontology is being extended to describe risk factor minimization and mitigation (within T6.2 and T6.3), which will ensure a comprehensive treatment of the entire process of risk management, thus increasing largely the visibility and potential of this work.

6.3.2. Measurements Ontology

6.3.2.1. Short description and key differentiators

The measurements ontology is a novel ontology to describe measurements in the healthcare and Quantified Self domain. Its novelty in relation to other ontologies and vocabularies related to measurements lies in its annotation of measurements with terms from standard external vocabularies to represent the semantic (and specifically, clinical) types and units of measurement, and in its application to Quantified Self data. This annotation enables data represented using this ontology to be interlinked with other forms of data from the wider Linked Open Data cloud, which dramatically increases the reuse potential of this data. Even over the course of the project, we have repeatedly identified new areas to which this ontology could be meaningfully applied beyond direct physical measurements of the patient; for example, it has proven useful for representing the recommendations of the decision support systems. The ontology was presented at ISWC 2016 the 15th International Semantic Web Conference, Kobe, Japan, Oct. 17-21, 2016, alongside a summary of the risk factor ontology. The novelty of its application to bridge Quantified Self data with Linked Open Data relating to clinical uses was very well reviewed.

As with the risk factor ontology, the measurements ontology is also published in the NCBO Bioportal (http://bioportal.bioontology.org/) which is the world's most comprehensive repository of biomedical ontologies, as described above in Section 6.3.1.

The CARRE ontologies (http://bioportal.bioontology.org/ontologies/CARRE) are provided open access and according to the site's statistics have received more than 200 visits so far. Also, CARRE is listed as one of the 550 contributing projects[23] (http://bioportal.bioontology.org/projects).

6.3.2.2. Exploitation strategy

As with the risk factor ontology, the value of the measurements ontology lies in its use to represent data. All of the CARRE partners have ongoing use cases which require the representation of observational data which would benefit from semantic annotation; we will continue to use the measurements ontology for this purpose in increasingly wide domains. The OU in particular has plans to provide data aggregation and analysis tools for use by students across a wide range of courses, from health and fitness, to sustainable energy. As a result, a

[23] This number reflects the status of the Bioportal as in October 2016

potentially large number of students will learn to work with semantic measurement data using the CARRE measurements ontology, thus increasing the reach and visibility of our work.

6.3.2.3. Sustainability plan

The ongoing costs of hosting a comparatively small ontology are negligible. Updates and modifications to the ontology may be required due to two different factors: a) a change in the technological standards for ontology representation, or b) new insights into the domain of risk factors arising either from future scientific discovery or application in practice. Updates of the first type are likely also to have a negligible cost: any significant change to a standard as widely used as the OWL language will inevitably be accompanied by tools to perform the conversions. Updates of the second type may be more involved, and will be funded by the research or application scenario which leads to the new insights. The medical partners DUTH and VULSK as multicenter healthcare service providers offer an environment for extensive ontology testing in clinical settings.

6.3.2.4. Return on investment

By providing a common model for measurement data representation connecting to the Linked Open Data cloud, aggregation, visualization, analysis and educational tools can be developed in common and applied across the full range of domains for which measurements can be gathered, with significant cost and effort savings.

6.3.3. Web Lifestyle Ontology

6.3.3.1. Short description and key differentiators

The Web Lifestyle Ontology was designed and developed in order to represent the detected intentions from the Web Lifestyle Data Aggregator, which presented in Deliverable 3.3, in the private RDF repository of user. In particular, it seeks to represent what is involved in the gathering of data from the web and social lifestyle of user on the Internet. We decided, therefore, to develop the ontology using the Protégé v5.0, a free, open-source ontology editor from the Stanford University.

CARRE Web Lifestyle Ontology is generic and can support different type of providers (e.g. web searches, Facebook, Twitter etc.). Additionally, the predefined intentions are also generic supporting the majority of intentions in the Web. In the context of CARRE, we utilize, as a first attempt, the web searches as provider and we only upload the relevant intentions (health and travel) to CARRE in the private RDF repository.

6.3.3.2. Exploitation strategy

This ontology is at an early stage of development and covers only a limited area of information on lifestyle that can be extracted from the on-line activities of a person. As such, it can be exploited and further extended in research work, before it can be widely exploitable for generic use. At the moment DUTH and OU are committed to further research on this ontology to extend it to cover a better part of the area of lifestyle from on-line activities.

6.3.3.3. Sustainability plan

This ontology will be sustained and developed as it is a state-of-the-art research topic within the research interests of partners DUTH and OU. Especially, DUTH is interested to investigate the merging of this ontology with concepts and notions on privacy, so as to describe privacy options, requirements and measures on particular bits of lifestyle information as extracted from on-line personal activity.

6.3.3.4. Return on investment

In its full developed version, this ontology is expected to be able to support the emerging research area of modelling on-life personal activities, including also important notions and concepts of privacy.

6.3.4. RDF Importer Tool

6.3.4.1. Short description and key differentiators

The RDF Importer was developed to address implementation and intergration issues related to batch update and data migration of the RDF graphs. Its initial concept was a simple command line based tool that is responsible for converting excel-formatted data into RDF datastores.

The software component is integrated with a CSV schema that is based on CARRE ontologies and its functionality is to parse tabular data into triples for the purpose of later importing them into RDF databases.

After extensive use within CARRE integration activities, the RDF importer tool was updated to handle multiple graphs and multiple deployments as well as queued imports. More specific it consists of:

- a command line tool, which is responsible for importing an excel file to specific rdf graph in a specific rdf database;
- a web based graphical user interface, which is available at https://importer.carre-project.eu ,using CARRE credentials; and
- an application programming interface (API) server, which implements a custom pipeline (queue) for concurrently handling multiple jobs. It is also responsible for sending email reports for each job upon completion.

6.3.4.2. Exploitation strategy

The RDF Importer is currently hosted in CARRE infrastructure and the deployment guidelines are documented in the repository. Its software and hardware requirements are minimal so that it can be installed within the RDF database server without much of an effort. As a result it could be reused by any other project that interacts with RDF databases and performs RF data manipulation in a frequent basis. DUTH is offering this tool as an open source to help fellow researchers and developers to migrate more easily conventional data to RDF triples, thus contributing to the uptake of semantic technologies. DUTH plans to routinely use the tool for conversion of conventional data into RDF.

6.3.4.3. Sustainability plan

RDF importer tool has been developed from the start as an opensource project to attract external collaborators and thus ensure its further development without restrictions.

6.3.4.4. Return on investment

The source code of this project is properly documented and available in a public repository at Github (https://github.com/carre-project/rdf-importer). Furthermore to promote the reusability of this tool, we have included different presets or templates (config.json files) that can be customized and easily adapted to other projects. Although the development of this component has not been cumbersome and time/resource consuming, its functionality allows for a great savings in time and effort to convert conventional data to RDF triples for the non-expert in semantic technologies.

6.3.5. Risk factor reference data base and system

6.3.5.1. Short description and key differentiators

The project has developed and is continually improving and enhancing a reference database of systematically described risk factors in the area of cardiorenal disease and comorbidities. The reference database can be viewed, edited, reviewed and overall managed via an intuitive web based interface. Also, the risk factor descriptions can be exploited by 3rd party systems via an open access standards based programming interface.

6.3.5.2. Exploitation strategy

The database is expected to form the basis for a reference database on health risk factors. Actions toward this end require to build in the database rigorous curation mechanisms and create a critical mass of risk factor descriptions from different medical areas. The consortium is currently looking for sources to fund these activities beyond the activities of this project. Amongst else, we are currently contacting scientific publishers and research bodies currnelty involved in the curation of scientific reference databases such as the Cochrane Collaboration[24] and regulatory bodies (e.g., NICE[25]), the Digital Physiological Human Institute[26] and the EMBL European Bioinformatics Institute[27]. Also, the data base and system will be exploited in the clinical practice and undergraduate education. In particular, DUTH has already incorporated the use of the system in the 5th year undergraduate course “Critical Appraisal of Medical Literature”.

6.3.5.3. Sustainability plan

DUTH and VULSK are committeed to contiune thorough analysis and timely update of current risk factor database related to cardiorenal syndrome, and expansion of similar ontology to specific medical conditions, e.g. cardiovascular diseases, kidney diseases, diabetes or other medical fields related to cardiorenal syndrome. Both being multicenter healthcare service provider in their countries and involved in teaching of medical university students, post-graduate or post-doctoral medical specialists, they intent to maintain and extend the risk factor reference data base, for use in their medical practice and especially to train new medical students and doctors in the area of evidence based medicine and health risk prediction and management.

6.3.5.4. Return on investment

The risk factor reference database and its management system is a novel approach to risk prediction based on multiple high level state-of-the-art evidence which can be dynamically updated. As such it can be considered a breakthrough in the way health risks are calculated, especially as it provides open access to the data. It can be considered as the seed of a scientific reference database.

6.3.6. Medical evidence aggregators

6.3.6.1. Short description and key differentiators

On-going research work on identifying relevant scientific articles from PubMed contributes significantly towards natural text processing in sciences, an area of high scientific interest at the moment. The work performed in CARRE is in synergy with related activities of other EU funded projects, such as DrInventor FP7-ICT (http://drinventor.eu/). The project has developed an online search machiam that semi-automatically find new evidences for the exisiting risk associations and new risk associations. The task had been accomplished and functioning. The research in this area is still showing strong interests from natural language mining community. In fact, here at BED, a PhD student is working on the area and investigating deep learning algorithms to improve the quality of the search. CARRE scenario can be a test case for the research, and the outcome may in turn help to increase the accuracy of this task in aggregator.

6.3.6.2. Exploitation strategy

This data aggregation task is in at an early stage, and in CARRE it is particlly used to demo the overall concept. The function itself is particularly targeted at the CARRE scenario that is the cardiorenal diseases. Therefore, limits its opportunity to be exploitaed as a product. To make it ready for expoitation, as mentioned before, firstly it needs to be more accurate, and more importantly, it needs to be expand to work for a wider range of medical areas. Never the less, we will continue to conduct research in this area.

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[24] Cochrane Collaboration, http://www.cochrane.org

[25] NICE, https://www.nice.org.uk

[26] Digital Physiological Human Institute http://www.vph-institute.org/

[27] EMBL European Bioinformatics Institute, http://www.ebi.ac.uk/

6.3.6.3. Sustainability plan

The aggregator by design does not save the searched results (to respect copyright policies). As a result, the aggregator is not required to store a large amount data, and maintaing the code is easily achieveable. A code update will be required to achieve further research in data mining medical literature. This is a hot research topic and as mentioned, it is currently pursued by a PhD candidate in BED and also (independenty) a PhD candidate in DUTH (see related early publications in D.8.2.2). In addition, this further research is expected to open new opportunities with partners for future funding applications, especially under Marie-Curie programs ITN networks.

6.3.6.4. Return on investment

The medical evidence aggregator is an important part of the CARRE concept, and itself supports the sustainability of the CARRE risk factor reference data base. That is, it supports the medical expert in literature searching for new risk evidences and new risk factors. Additionally, it contributes novel scientific results in the hot research area of medical literature data mining.

6.3.7. Educational resource aggregator

6.3.7.1. Short description and key differentiators

The aim of the educational resource aggregator is to harvest educational resources from 3rd party repositories, present these to the medical expert for annotation and rating, and output the results of the annotation (together with resource metadata) to the CARRE public RDF repository.

The main parts of this aggregator are:

- the Resource Retriever, which accepts CARRE concept terms from the CARRE public RDF repository and uses them to formulate queries to external 3rd party educational resource repositories.
- the Resource Rating, which presents the retrieved results and metadata to the expert user for rating and annotation
- the Resource Metadata Processing, which involves metadata enrichment via semantic web sources (such as NCBO BioPortal medical ontologies and DBpedia)
- the Web GUI, the front end part in which all the user interactions happen

The innovation of the aggregator relies on the concept of Linked Open Data which they promote the notion of resubility by sharing common language and frameworks.

6.3.7.2. Exploitation strategy

The educational resource aggregator is developed as an open source project with two main goals. Its primary goal is to provide medical experts a mean of rating and annotating educational resources and serve them to patients through any 3rd party software. Secondary it can serve as a comparison tool of both authoritative and non-authoritative educational data sources such as Wikipedia and MedlinePlus. DUTH plans to further exploit this aggregator for educational purposes in the medical curriculum, to allow undergraduate students assess patient related educational material on the web, evaluate and rate it and further on translate it into Greek (as part of course mini-projects) in order to increase the corpus of patient related educational material available in greek language (e.g. on Wikipedia).

6.3.7.3. Sustainability plan

From the beginning of this project a great effort was made to attract medical experts to assist in the improvement and extension of the educational data provided by different data sources. The rating of educational data is expected to be sustained via use of the educational aggregator in the undergraduate and residents educational programmes in DUTH and VULSK.

6.3.7.4. Return on investment

This aggregator's main output is the annotated and rated educational resources that are accessible through the CARRE SPARQL endpoint. More specific the annotation methodology and rating process are described in the MERA ontology which is available at bioportal (https://bioportal.bioontology.org/ontologies/MERA). In addition to the annotation dataset and the concise MERA ontology, this aggregator is a working demonstration of the process of rating and annotating patient related educational material in order to validate its value and relevancy in a crowd sourcing approach.

6.3.8. Personal sensor data aggregators & management system

6.3.8.1. Short description and key differentiators

The project has developed a variety of software aggregators to harvest personal data from proprietary cloud a number of 3rd party vendors of personal monitoring devices. All these aggregators are developed using technological standards, and they are offered as open access software via the project site, thus they can be readily used by non-expert technologists to harvest and aggregate data from 3rd party vendor clouds, following privacy friendly approaches.

A CARRE Life-style and ECG aggregator is Java software for analysis of data ECG files recorded by Emotion Faros or similar devices, developed within the CARRE project. Description of the Life-style and ECG aggregator is provided in the update of the deliverable D3.2 "Sensors and Aggregators for Personal Sensor Data: UPDATE". The accepted data format is European data format, EDF. The CARRE Life-style and ECG aggregator performs ECG analysis, atrial fibrillation (AF) detection, parametrization (AF episode start time, duration and average heart rate in AF), and parameter uploading to the personal CARRE RDF repository as well as analysis report generation in .PDF format.

The aggregators are novel in representing data in a semantic machine-readable format (RDF) compatible with the Linked Open Data cloud, enabling the integration of personal sensor data with a wide range of other data sources, while maintaining privacy-by-design. At the time of writing, there are no known sensor data aggregation tools which make use of Semantic Web approaches.

6.3.8.2. Exploitation strategy

The combination of flexible and easily-extensible sensor data aggregation with Semantic Web technologies offers significant opportunities for new and unforeseen use cases to emerge, and we will seek to pursue these. For example, the OU intends to deploy versions of the aggregators internally to support the teaching of data analysis skills to students on its health and fitness-related courses, and to support ongoing research integrating Quantified Self data with Open Data relating to, for example, academic work patterns.

6.3.8.3. Sustainability plan

Different use cases for the sensor data aggregators will have different requirements in terms of hardware, storage, etc., and these will be implemented using separate deployments of the CARRE sensor data aggregator software. Running costs for these deployments will therefore be sourced from the resources funding the individual use cases. The OU will maintain a central open-source repository (via free publicly available services such as Github[28]) with a master copy of the software. Improvements and modifications to the software arising from different exploitation scenarios will be fed back in to the central repository, thus spreading the sustainability requirements of the software across multiple sources.

6.3.8.4. Return on investment

The availability of an easy to deploy, and easy to use, system for collecting personal sensor data and providing semantic annotations will save both cost and effort, to a significant degree, across the envisioned exploitation strategies.

[28] http://www.github.com

6.3.9. Web lifestyle aggregator

6.3.9.1. Short description and key differentiators

The Web lifestyle data aggregator harvests patients' web searches in order to extract their intentions. Patients intentions can be useful information because the can help the doctor or a decision support system to adjust the pharmaceutical and nutritional treatment of patient. Overall its architecture was built by taking into consideration (as much as is possible) the protection of the patient's privacy. The main parts of this aggregator are the Query Detector and the User Intention Extractor. The Query Detector constitutes a browser extension (Firefox add-on and Chrome extension) that is responsible to detect the user's queries in the web search engines (e.g. Google, Bing and Yahoo). Accordigly, the User Intention Extractor is a Java standalone application that is responsible to store (only) locally the incoming queries, categorize them in specific categories (e.g. traveling, health diseases, etc.) in order to extract the patient's intentions and to visualize the detected intentions in a user-friendly way. Furthermore, the extracted intentions that are relevant to CARRE is possible to be uploaded to .PDF format in patient's private RDF repository.

The novelty of Web lifestyle data aggregator is its privacy-by-design architecture and its functionality to send in a semantic machine-readable format (RDF) to a remote repository (throw a SPARQL Endpoint) only the intentions that are allowed by her owner. All these are achieved using a tiny and compact implementation that only runs at user-side.

6.3.9.2. Exploitation strategy

The Web lifestyle data aggregator will be exploited as a starting point for further data mining techniques to aggregate personal information and intention by a user's on-line activities to serve as input in personal decision support systems. The main characteristic to be exploited is the privacy-friendly architecture. Already, in the context of CARRE project, the ECG aggregator exploits its architecture in order to perform ECG analysis, atrial fibrillation (AF) detection and upload only the AF events (and not the raw data) in patient's RDF repository. A secondary outcome of this aggregator is its functionality to work as a personal search query logger with many applications in Information Retrieval, such as to create collaborative anonymized query datasets. The aggregator will also be exploited as a testbed for privacy on the sensor, also extend for other lifestyle related information aggregation from social media for research towards a digital healthy lifestyle coach.

6.3.9.3. Sustainability plan

The aggregator will also be exploited as a testbed by KTU in the collection of sensors' data. Additionally, DUTH will extend the current implementation using other lifestyle related information from social media for research towards a digital healthy lifestyle coach. At the same time, another reaserch group in the department of Electrical and Computer Engineering at DUTH has used the same approach in order to peform privacy-enhanced personalized contextual suggestion for tourism.

6.3.9.4. Return on investment

Developments implemented in CARRE web lifestyle aggregator are expected to support the emerging research area of personalization and privacy and serve as an implemented privacy-by-design working example in personal ehealth applications.

6.3.10. PHR aggregator and entry system

6.3.10.1. Short description and key differentiators

The project has developed an entry system for personal health records (PHR). PHR manual data entry system allows user to enter and safe public health records to RDF using a web interface. The system is intended to be used to enter such personal health records that cannot be normally entered using automatic aggregators and in cases, when there is no possibility of using cloud based wearables, that can gather health related data.

PHR manual data entry system is developed in such way, that it can easily expanded using data about observables from public RDF. It is achieved by automatically generating observable inputs by using data

received about the observable from RDF. Only specifiying which observable goes to which form is needed, all the other generation of form is handled automatically.

6.3.10.2. Exploitation strategy

The PHR entry system can exploited as an input tool for personal health record data and their conversion into RDF triples. Apart from the current RDF format, PHR can be adapted to use any other source of metadata input to dynamically generate the forms. VULSK plans to exploit this tool to add functionality to the already operational VIVAport software (health record system) deployed in Vilnius and other hospitals. Also, the modular architecture used in the PHR aggregator can be used as a best practice to develop applications that are based on dynamically generated forms.

6.3.10.3. Sustainability plan

Once the PHR entry system is set up to be used with the health record data repository, no additional human should be needed for it to operate. Input from a person is only needed when there is a need to change the RDF it is using or to change layout of forms. VULSK is planning to sustain the PHR aggregator as an input to CARRE service and also as an RDF converter for personal health data.

6.3.10.4. Return on investment

The PHR aggregator is a fine example of converting personal health data into RDF triples. This forms a best practices example for extending the emerging semantic technologies and triple graph databases into the area of personal health records.

6.3.11. Wrist Worn Device

6.3.11.1. Short description and key differentiators

The wrist worn device is intended to be used for unobtrusive and continuous monitoring of atrial fibrillation arhytmia. It uses biooptical signal, i.e., photoplethysmogram for this purpose. Biopotential signal, i.e., electrocardiogram is acquired synchroneously and is used as a reference. The reference channel can be detached from the device in unobtrusive usage scenario. This is in contrast with other commercial devices (e.g., Fitbit Surge, MioAlpha) that are not able to record the reference data. Morover, there is no commercial biooptical signal based wrist worn device for arrhythmia monitoring currently on the market. There are two scenarios in which CARRE Wrist worn device can be used: real-time atrial fibrillation arrhythmia monitoring, e.g., during hemodialysis procedure, and long-term, offline atrial fibrillation arrhythmia monitoring, e.g., in rehabilitation settings or at user home.

6.3.11.2. Exploitation strategy

Curently, the device is able to perform continuous acquisition of high resolution signals for at least 24 h. Such working time is adequate for some applications, e.g., 3-5h long hemodyalisis procedure. However, it must be increased for other applications, e.g., continuos monitoring at rehabilitation setings or at home. Accelerometry based physical activity detection may help to detect movement free signal episodes suitable for analysis. This screening strategy is being explored for saving energy in the device. The continuos unobtrusive screening can be successfully applied not only for monitoring cardiorenal patients, but also to other high-risk patient groups (i.e., older than 65 years, patients with comorbidities such as ischemic stroke, myocardial infarction, heart failure, hypertension, sleep apnea, etc.). The main threat to successful exploitation - not adequate signal quality for arhytmia detection in biooptical signal. However, our preliminary results from cardiovascular rehabilitation clinics showed that more than 65% of signal duration during 24h monitoring was suitable for analysis.

6.3.11.3. Sustainability plan

The developed device is constantly being updated by including variuos improvements in the hardware and new algorithms. New method to increase the quality of the biooptical signal by application of adaptive filter with capacitative reference sensor for detection of subtle movements of the device against the wrist is being explored.

The device will be used as a scientific instrument for registration of biosignal databases. Currently, it is being used in the project supported by the Research Council of Lithuania “Automatic algorithms for atrial fibrillation risk prediction after acute myocardial infarction”, 2015-2017, (No. MIP-088/15).

Comercialisation of the device will be sought with the help of companies that expressed an interest (e.g., Associated partners Graina, InPeak, and discussions with another SME UAB Quantas).

6.3.11.4. Return on investment

The developed wrist worn device for continuous arrhytmia monitoring is expected to be used in many applications, which requires atrial fibrillation detection, for example, in high risk patient groups, i.e., patients after cryptogenic stroke, with heart failure and all elderly patients >65 years old. The possibility to continuously monitor atrial fibrillation episodes together with physical ativity parameters may stimulate research in arrhythmia provokative factors and new commercial developments.

6.3.12. Multiparametric Scale

6.3.12.1. Short description and key differentiators

Weighing scales are actively investigated now as an operator-less device for unobtrusive, intermittent cardiovascular monitoring [29, 30]. We developed a multiparametric scale which is able to acquire 3 lead electrocardiogram (Einthoven’s triangle) and bioimpedance spectroscopy parameters at 5 frequencies. Bioimpedance is measured between the subject’s feet (lower extremities impedance) and arms (thorax impedance). A graphical display helps to implement a guided breathing test. Raw multisignal data files are recorded in a standard format for biomedical signals – General Data Format (GDF). Therefore the files can be opened in standard GDF viewers (e.g., SigViewer) or CARRE Multiparametric Scales Data Analyzer. The data files are stored locally and also automatically transferred to the computing server via the embedded WiFi module. Currently, CARRE Multiparametric scale is being used as a scientific instrument for unobtrusive registration of biosignal databases. More details about the device and measured parameters can be found in CARRE project deliverable D3.2 “Sensors and Aggregators for Personal Sensor Data: UPDATE”.

6.3.12.2. Exploitation strategy

Currently, CARRE multiparametric scale is being used as a scientific instrument for unobtrusive registration of biosignal databases. Its main strengths: multiple signals and parameters can be registred, operator-less, short registration time (~1.2 min), WiFi wireless capability for autonomous data transfer to remote server (no need for additional smartphone and App). The existing and associate CARRE partners (Lithuanian Health Science University Kaunas Clinics, Department of nephrology) will be invited for testing of the developed technology.

Fitness and self-control of health is very important applications. Commercial companies working in athletes’ management and big data analytics expressed their interest in the technology.

6.3.12.3. Sustainability plan

There are many other opportunities to continue developement of the device. One direction for developments is integration of additional sensors in the scales, e.g., pulse oximeter sensor. The second direction for developments is integration of scales with other sources of information (Internet of things IoT paradigma), e.g., calendars could be connected for reminding the user to consume medication or perform certain activities. An

[29] J.-P. Couderc, C. Beshaw, X. Niu, E. Serrano-Finetti, O. Casas, R. Pallas-Areny, S. Rosero, and W. Zareba, “The QT Scale: A Weight Scale Measuring the QTc Interval,” Ann. Noninvasive Electrocardiol., Jul. 2016.

[30] B. Paliakaite, S. Daukantas, V. Marozas, Assessment of pulse arrival time for arterial stiffness monitoring on body composition scales, Computers in Biology and Medicine, available online April 22, 2016, http://dx.doi.org/10.1016/j.compbiomed.2016.04.012

important issue left as a future work – embedding in the device the proposed .GDF file standard modification with data encryption capability.

Comercialisation of the device will be sought with the help of companies that expressed an interest (e.g., UAB Graina, UAB InPeak, UAB Quantas).

6.3.12.4. Return on investment

The developed multiparametric scale is expected to be used as comprehensive device for self monitoring of health (quantified self). It has been shown that a single device via short testing time, without any additional operator can acquire multiple biosignals and extract relevant cardiovascular parameters. Tracking these parameters over time can provide insights into the fitness of the user and prevention of disease. The device has a potential to be comercialised as a scientific instrument for acquisition of biosignal databases and licensed to commercial companies for consumer product development.

6.3.13. Multiparametric Scales Data Analyzer

6.3.13.1. Short description and key differentiators

CARRE Multiparametric Scales Data Analyzer is a MATLAB GUI software for analysis of data files recorded by the multiparametric scales, developed within the CARRE project. Description of the multiparametric scale is provided in the deliverable D3.2 “Sensors and Aggregators for Personal Sensor Data: Upadate”. The data files are recorded using a standard format (general data format, GDF), therefore they can be opened and viewed by the standard GDF viewers, such as SigViewer. The CARRE Multiparametric Scales Data Analyzer offers additional interactive functionality: processing (filtering) of the recorded biosignals (multi-lead ECG, bioimpedance spectroscopy, and waveforms), estimation of a variety of physiological parameters, including pulse arrival time (i.e, arterial stiffness), heart rate variability (i.e., autonomic balance), and body composition (i.e., hydration). Moreover, the software is capable of detecting the presence of atrial fibrillation arrhythmia.

Until very recently, market analysis showed complete absence of devices in a form-factor of scale for cardiovascular monitoring. The first cardiovascular self-monitoring commercial device was put on the market only recently (August, 2016) by the company Withings[31]. A pulse wave velocity can be monitored during time by this scale. However, CARRE Multiparametric scale together with Data Analyzer offer much more (e.g., atrial fibrillation detection, heart rate variability analysis, guided breathing test) and have greater potential for future developments as raw data (signals) are kept and stored.

6.3.13.2. Exploitation strategy

The software is developed in Matlab language and can be used as a standalone application on a PC. Matlab application is fully adequate for a scientific instrument. However, modern product requires to move stand alone application to the WEB environment. Therefore, porting to Python language and movement of the application to WEB environment is envisioned in the future. There are many other opportunities for new developments. New oportunities arise with integration of additional algoritms. For example, algorithms for other arrhythmias such as atrial and ventricular premature contractions detection could be integrated. The main threat (and oportunity) is growing interest and competition in research society and industry for self monitoring, internet connected Quantified Self devices.

6.3.13.3. Sustainability plan

The existing and associate CARRE partners (Lithuanian Health Science University Kaunas Clinics, Department of nephrology) will be invited for testing of the developed technology. Comercialisation of the device will be sought with the help of companies that expressed an interest (e.g., UAB Graina, UAB InPeak, UAB Quantas.

[31] Body Cardio, https://www.withings.com/us/en/products/body-cardio

6.3.13.4. Return on investment

The Multiparametric Scales Data Analyzer GUI together with multiparametric scale are expected to be used as comprehensive scientific device for colecting and analysis of biosignal databases, development of self monitoring (quantified self) devices. It has been shown that a single device via short testing time, without any additional operator can acquire multiple biosignals and extract relevant cardiovascular parameters. Tracking these parameters over time can provide insights into the fitness of the user and prevention of disease. The device has a potential to be comercialised as a scientific instrument for acquisition of biosignal databases and licensed to commercial companies for consumer product development.

6.3.14. ECG signal analyser

6.3.14.1. Short description and key differentiators

Matlab GUI for paroxysmal atrial fibrillation (AF) detection, parametrization and visualization was developed specifically for AF analysis therefore many AF related features are provided for a user. This is in contrast to commercially available software (e.g., VivaQuant AE-1000), which is dedicated to the detection of wide spectrum of heart arrhythmias, thus no specific emphasis is put on the comprehensive analysis of AF. The software developed in CARRE relies on a high performing AF detector, capable of detecting paroxysmal AF episodes. The developed software provides several state-of-the-art-features: detection of brief AF episodes (< 30 beats), quantification of temporal distribution of AF episodes, characterization of atrial fibrillatory activity (i.e., f-wave frequency). In addition to analysis of AF profile, instantaneous physical activity is given as an additional source of information on AF behavior during increased (or reduced) physical activity. This information has potential to be applied as a biomarker for prediction of therapeutic success and spontaneous AF behavior

6.3.14.2. Exploitation strategy

By combining the algorithms for AF detection, atrial fibrillatory activity analysis and quantification of temporal distribution of AF episodes into a unified tool the user is provided with a comprehensive analysis of AF profile. Therefore, the developed software can be successfully applied not only for monitoring cardiorenal patients, but also to other high-risk patient groups (i.e., older than 65 years, patients with comorbidities such as ischemic stroke, myocardial infarction, heart failure, hypertension, sleep apnea, etc.). Currently, the developed software is being used in the project supported by the Research Council of Lithuania “Automatic algorithms for atrial fibrillation risk prediction after acute myocardial infarction” (No. MIP-088/15).

6.3.14.3. Sustainability plan

The developed software is constantly being updated by including variuos improvements of the algorithms (i.e., false alarm rate reduction during other types of arrhythmia, detection and exclusion of noisy episodes, etc.). In addition to AF detection and atrial fibrillatory activity characterization, it is expected to develop an additional tool for a time-frequency analysis of AF, including an algorithm for AF risk prediction after major cardiovascular events.

6.3.14.4. Return on investment

The developed GUI is expected to be used in many applications, which requires AF detection, for example, in high risk patient groups, i.e., after cryptogenic ischemic stroke or acute myocardial infarction. The possibility to detect brief AF episodes and analyze temporal distribution of AF episodes may stimulate research on whether the episode length and temporal distribution of the episodes have influence on formation of blood clots.

6.3.15. Decision support alerts system

6.3.15.1. Short description and key differentiators

The evaluation of the currently under development decision support services is expected to address the potential of shared decision support based on personalized risk factor status and knowledge to improve personalized health risks, improve quality of life and health status.

6.3.15.2. Exploitation strategy

PIAP will promote the results of CARRE towards Polish ICT services at national and regional level to support their implementation. PIAP will use the technological results gained as a baseline for further research and will increase the specific knowledge for Patients empowerment, to be exploited in cooperation with Biomedical Engineering Institute (Warsaw University of Technology at Mechatronics Faculty) in following joint research projects.

The exploitation type differs on the achieved research result and on the exploitation activity. Some of activities could use direct technical improvements and usually have a direct impact within a short time frame, while others influence research results with a long term impact on the further research directions and networking community to derive strategic guidelines.

PIAP focusing its exploitation activities on improving their current operation and position in existing markets, and on the creation of and preparation for new markets, with the intention to obtain a leadership position..

6.3.15.3. Sustainability plan

PIAP will be responsible for maintaining and supporting Decision Support alerts system, at least the following:

- DSS will be maintained on PIAP servers for continued usage by the interested universities.
- Usage of DSS development rules in massive open online courses (MOOC) is one possible direction of evolution, but it needs to be evaluated in the future.
- Installation and configuration in customer's infrastructure in case of purchasing of specific DSS software.
- Customer support at customization the DSS to customer needs and further administration.
- as a healthcare service provider with its own specialized IT centre working in developing various healh-related IT solutions may contribute in establishing specific decision support system triggers and alerts, offer IT support and basis for clinical testing

VULSK as a healthcare service provider with its own specialized IT centre working in developing various healh-related IT solutions may contribute in establishing specific decision support system triggers and alerts, offer IT support and basis for clinical testing.

6.3.15.4. Return on investment

PIAP is an industrial partner, hence it exploits technical improvements internally. A company uses the acquired know-how to shorten turn-around times from the project results to produce new version, for example to reduce time–to-market and improve its business position or to outperform competitors through the quality of immediately forthcoming new products.

6.3.16. Visual analytics

6.3.16.1. Short description and key differentiators

The project developed novel visual analytics methods for showing scientific health information to the general public. The functions have been evaluated during the pilot demonstration phase of the project for their acceptance by patients and medical professionals. The evaluation has highlighted the efficiency of different visualization approaches followed and gave insights as to the best practice approach towards showing risk factor data to the general public. As a result of the initial tests, some functions had been changed to adapt to user feedback.

6.3.16.2. Exploitation strategy

The final visual interface is a functional prototype and it has shown potential benefit in the initial test. The novel visual interface modules (healthlines and the various diagrams employed for personal and generic risk factor model) will be further exploited for presenting health data to patients and experts in ehealth applications developed by BED and partners in related projects. BED is committed to re-fine this initial work with more user validation in different medical settings. For example, demos and validation is currently being extended outside

the project to include General Practioners and their needs for showing health data to patients in order to explain and guide them through personal management instructions commonly given. BED also plans to closely work with CARRE medical partners, DUTH and VULSK, for the future exploitation of these analytics in other ehealth applications.

6.3.16.3. Sustainability plan

The CARRE visual analytics interface is easy to maintain code wise as it employs generic tools and technologies for its development and deployment and will be maintained and provided for the CARRE service pilot deployments. Any further updates and code maintance will be carried out as part of further research work to advance ehealth visual analytics, which is a main research activity in BED.

6.3.16.4. Return on investment

The visual interface is THE interface that users see, and CARRE has showed to the patients how technology can help them in understanding the progress of their care. So, the educational materials are no longer present to them as texts, the materials are reflected and inline with the risk modelling. The idea of combining the theory and reality is an important and highly useful attempt in helping patients to get an in-sight of the disease. Exploring the technical functions is also a contribution to the visual analytic research community.

6.3.17. Empowerment model

6.3.17.1. Short description and key differentiators

The consortium has devised and proposed a novel model of patient empowerment as a cognitive process. The model was accepted for publication in the esteemed international conference of BIOTEC 2015, 8th International Conference on Biomedical Engineering Systems and Technologies (acceptance ratio of 41%) and, based on the discussions during the conference, is expected to inform the understanding and the systematic design, development and evaluation of patient empowerment services.

6.3.17.2. Exploitation strategy

DUTH research team has already refined and extended the model based on its application to inform the CARRE evaluation procedure. A journal paper publication has been developed and is targeted to cognitive psychology and ehealth technology audiences.

6.3.17.3. Sustainability plan

DUTH is actively working in the area of ehealth modeling and as such this model will be used to inform respective research and its evaluation.

6.3.17.4. Return on investment

A systematic approach to empowerment is expected to support the evaluation of empowerment applications and guide research to pick the appropriate approach for both the design and the evaluation of an empowerment application. The model helps researchers take into account and appropriately address the various incremental parts of the empowerment process. Also, allows for an informative design of an assessment procedure of each individual system component based on the level of its empowerment function according to the model.

6.3.18. Privacy-by-design argument

6.3.18.1. Short description and key differentiators

Following reviewers recommendations, the consortium has liaised with external experts and embarked on a study of privacy by design in personal ehealth systems. The consortium has outlined a generic model of the domain of personal ehealth systems and their major requirements for privacy by design. This work was accepted

for publication and presentation in the esteemed international conference of BIOTEC 2016, 9th International Conference on Biomedical Engineering Systems and Technologies (last year acceptance ratio of 41%). The reviewers commented very favorably for this work and the consortium is now working towards the next step. i.e. deriving best technological practices for embedding privacy during the design of personal ehealth applications. An example of such design and development has already been demonstrated in the CARRE aggregator for lifestyle related information from personal web searches. This privacy by design approach was presented in the highest scientific meeting of its field, the World Congress on Medical Physics and Biomedical Engineering in 2015.

6.3.18.2. Exploitation strategy

All exploitation described above of any CARRE results involving individual sensor data will be based on the privacy-by-design strategy developed in the project, which will be applied throughout and extended where necessary. In addition, all partners will adopt this strategy in other areas of work where relevant, and to promote the use of designed-in privacy measures in general. The OU, for example, will incorporate CARRE privacy results into ongoing research into privacy in the Linked Data world.

The exploitation strategy includes plans to perfom a systematic review in the area of privacy-enhancing technologies in eHealth and to propose a methodology and best practices publication targeted to software engineers in onder to provide guidelines for future developments in the research area of eHealth. As DUTH, we have already started this effort with privacy experts from the department of Electrical and Computer Engineering in DUTH, the department of Politics, Philosophy and Religion in Lancaster University and the School of Computer Science & Informatics in Cardiff University. Our final goal is a main journal publication in a high ranking international journal in the area of eHealth and a series of publications that apply our propose methodology in realistic scenarios.

6.3.18.3. Sustainability plan

This research is currently supported by DUTH matching funds while DUTH is initiating relevant proposals submitted for funding in national and EC calls on privacy for big data.

6.3.18.4. Return on investment

The impact of this research in privacy-enhancing technologies is fundamental not only for the research community but also for the entire society by giving to the individuals the technologies to support their right to information self-determination in the digital health era.

6.3.19. CARRE integrated system and service

6.3.19.1. Short description and key differentiators

CARRE uses commonly available personal sensors, such as activity trackers, scales and personal health records, to collect information about the person, which is then projected against current medical knowledge. This produces a personalized risk prediction model. The patient can interact with the graph to understand health risks and plan lifestyle changes. This personal risk is also used to alert the patient for self-monitoring and everyday lifestyle related activities.

CARRE has also developed a novel system to describe current medical evidence on risk factors in a comprehensive and intuitive way, including concise tabular and interactive graphical views. New evidence on risk factors can be incorporated in this dynamic reference database via a simple to use interface and following a transparent rigorous peer review process. Additionally, experts can use the personalized patient models to explain complex health conditions to the patients and collaborate towards informed co-design of personalized care plans.

One major novelty of CARRE service lies in the fact that it depends on a complex risk prediction system which sums up most of the currently available medical evidence in the area of cardiorenal medical research. Other

currently available risk calculators are only based on data from single studies. e.g. Framingham equation[32], the Joint British Societies (JBS) formula[33] and the ASSIGN score[34]. These take account of a limited set of risk factors and possible outcomes, as these have been produced by specific clinical studies – thus can be limited in application. For example, the ASSIGN score is specialized for Scottish populations, and, while Framingham includes diabetes as a risk factor, it is omitted from the JBS formula (diabetic patients are always high-risk). The Framingham equation takes account of 9 different patient observables and predicts the risk of only one outcome. More fundamentally, each of these hardcode the scientific knowledge about risk into the prediction formula itself, thus requiring new versions to be created to accommodate new scientific knowledge.

6.3.19.2. Exploitation strategy

At a first stage, the consortium plans to exploit the CARRE service for patients by sustaining the pilot deployments in the two medical partners and extending them to include more health care providers. A number of external to the project healthcare providers have expressed their interest in uptaking the service for their practices. To facilitate this, they have been introduced as Associated Partners to the project (see D. 8.4) so that they can freely participate in an extended pilot deployment. This extended pilot deployment is expected to yield more concrete evaluation results. Based on these, a business exploitation plan will be constructed to target the commercial exploitation of the service, especially as a product addressed to private health insurance companies and private health service providers for them to empower and support their clients.

Furthermore, the OU is interested in applying Semantic Web techniques to concrete problems and demonstrating added value from doing so, and will seek to use the CARRE system in a variety of use cases in data literacy education and future Semantic Web research. DUTH and VULSK are also interested in using the pilot system for education purposes in their undergraduate and residency curricula to guide students in the process of explaining and encouraging self-management and health literacy in chronic patients.

6.3.19.3. Sustainability plan

VULSK (one of the biggest university hospitals in Lithuania) and DUTH (with its regional university hospital that also acts as reference center for neighbouring regions of Bulgaria and Turkey) belong to a wide network of healthcare providers in the respective countries. Both partners are in close long-term professional collaboration with other health care providers, some of them have joined CARRE project as associated partners (see D.8.4). Thus a wide network may widely share knowledge and services which CARRE platform brings to end-users, ensuring the interest and resources for sustainability.

6.3.19.4. Return on investment

The return on investment as an ehealth intervention is described in Section 4. As also discussed in detail in D.7.4, the CARRE intervention can increase health literacy and empowerment of cardiorenal patients and thus increase awareness and support prevention and disease progression, thus lowering demand on resources and improving patient outcomes and well-being.

7. Partner Individual Exploitation & Sustainability Plans

7.1. DUTH

DUTH has led the development and thus is primarily interested in exploiting the following outcomes:

[32] Sheridan, S., Pignone, M., Mulrow, C.: Framingham-based tools to calculate the global risk of coronary heart disease. J. Gen. Intern. Med. 18(12), 1039–1052 (2003)

[33] Boon, N., Boyle, R., Bradbury, K., Buckley, J., Connolly, S., Craig, S., Wood, D.: Joint British Societies' consensus recommendations for the prevention of cardiovascular disease (JBS3). Heart 100(Suppl. 2), ii1–ii67 (2014)

[34] Woodward, M., Brindle, P., Tunstall-Pedoe, H.: Adding social deprivation and family history to cardiovascular risk assessment: the ASSIGN score from the Scottish Heart Health Extended Cohort (SHHEC). Heart 93(2), 172–176 (2007)

- Web lifestyle ontology
- RDF importer tool:
- Risk factor reference data base & system
- Educational resource aggregator
- Web lifestyle aggregator
- Empowerment model as a cognitive process
- Privacy-by-design argument
- CARRE integrated system & service

Also, DUTH had significant contribution to and thus is interested in exploiting the following outcomes:

- Risk factor ontology
- Measurements ontology
- Medical evidence aggregators
- Personal sensor data aggregators & management system: testbed for privacy on the sensor
- Decision support alerts system:

DUTH team is a multidisciplinary team with continuing research interests in data and knowledge modeling in medicine, literature data mining and privacy technologies. Thus, DUTH aims to directly exploit the ontologies developed in this project for further research and data modeling in health and medicine. Also, DUTH continues the research on literature data mining with a new PhD research where CARRE research on data mining is extende towards a service for trends analysis of medical literature using a topic modeling approach.

Additionally, DUTH aims to exploit the work in privacy-by-desing of the web lifestyle aggregator to investigate the possibility for privacy preservation by design on the sensor - initial research involves collaboration with KTU and their novel sensors developed within CARRE. This work will also be exploited in collaboration with the local SME PRISMA, who has a long experience and placement in the sensor market and has expressed their interest as a CARRE Associated Partner.

DUTH is committed to further research in order to extend the risk factor database to include more evidence on risk factors related to lifestyle, physical activity and inactivity, surgical interventions and medication adverse effects. Also, DUTH is interested in research on curation of the risk factor data, updates and versioning. The exploitation of the risk factor reference database involves communication with medical literature publishers and evidence based medicine organizations, such as Cochrane Collaboration or NICE for the collaborative development of the risk factor database and its curation as a scientific reference database.

The current risk factor database is also exploited as an educational resource in undergraduate and residency medical curricula of the university and the university hospital. An evaluation of the value of the risk factor database and management system as an educational resource is under way.

Finally, DUTH aims to exploit the CARRE service for patient empowerment and use it to investigate empowerment patterns and impact on different patient groups, also including empowerment of healthy citizens to attain and sustain a healthy lifestyle, and improve heatlh literacy and well-being. This exploitation is in collaboration with the CARRE Associated partner European Lifestyle Medicine Organization. Finally, DUTH is currently discussing the extension of the pilot deployment to cover interested parties to uptake the service nationally, namely Municipality of Peristeri, Attiki, Greece and Association of Hellenic Military Navy Veteran Officers, Coast Guard Officers and Friends with Heart Disease, Athens, Greece who expressed preliminary interest during a recent dissemination event.

Funding of the exploitation plans and preliminary activities was secured by national matching funds for one year after the project end.

7.2. OU

OU has led the development and thus is primarily interested in exploiting the following outcomes:

- Risk factor ontology
- Measurements ontology
- Personal sensor data aggregators & management system:

Also, OU had significant contribution to and thus is interested in exploiting the following outcomes:

- Web lifestyle ontology
- Risk factor reference data base
- Risk factor management system
- PHR aggregator & entry system
- Privacy-by-design argument
- CARRE integrated system & service

The CARRE ontologies will be exploited by the OU for data representation and analysis in ongoing and future scientific and commercial educational contexts, taking advantage of and promoting the cost and efficacy benefits of standardised modelling, particularly of risk and observational data. For example, the CARRE ontologies will be used with undergraduate courses in health and fitness as part of a broad approach to data literacy education.

The risk factor database and reference system will also be exploited in the same contexts, as well as in ongoing work with other CARRE partners in establishing it as a standard reference database for clinical risk.

The aggregators will be exploited as a general easily-redeployed platform for automated collection of observational data in both ongoing and future scientific work (e.g., analysis of activity and health consequences of the 'academic lifestyle') and in a commercial educational context. As well as the health and fitness courses mentioned above, we have applications in progress for sustainable energy education and also medical teaching. For example, the OU and KTU are collaborating on the use of sensor data with virtual and augmented reality tools for the teaching of human physiology using interactive animated healthy and unhealthy heart behaviours.

The CARRE privacy model is an important aspect of all use cases involving private data, and will be used wherever relevant in all our exploitation of CARRE components, and will be extended where necessary. The original bulk of Linked Data research and applications have focused on Linked *Open* Data; CARRE provides an important demonstrator of the need for Linked *Closed* Data, and we will make use of it in future research and applications in the Linked Data arena.

The overall concept of the CARRE integrated system is a strong example of the power of applying Semantic Web techniques, as well as a useful practical system covering the uses of Linked Data – data collection, analysis, integration (of observational and predictive data), visualisation and decision making. The whole system will therefore, with suitable minor customisations, be usable for a variety of use cases in data literacy education, and we intend to exploit it in this fashion.

There are two elements of sustainability to be considered: the maintenance costs of software and data models, and the resource costs of deployed applications. In the case of CARRE components, the first of these is minimal: such costs can be spread across all exploitation use cases and can therefore be sustained with minimal demands on the funding sources of each use case; certainly, lower costs than would be necessary to create or acquire equivalent systems from other sources. The resource costs are proportional, in the case of data aggregation, to the volume of data/number of users in each case; these costs will be incorporated into the relevant funding bids or commercial budgets as appropriate. The Knowledge Media Institute at the OU already has a capable Big Data infrastructure in place to provide the flexibility required.

Income for exploitation plans will be sourced from future research funding bids and commercial income from student fees, as appropriate.

7.3. BED

BED has led the development and thus is primarily interested in exploiting the following outcomes:

- Visual analytics

- Medical evidence aggregators

Also, BED had significant contribution to and thus is interested in exploiting the following outcomes:

- Risk factor management system
- Privacy-by-design argument
- CARRE integrated system & service

The medical data aggregator will be exploitated by BED, mainly as part of the risk modelling. Our part of work is to maintain the sustainability of the concept of the risk modelling. Therefore, the work is part of the CARRE system calloborating with on-going work of other partners. However, medical data mining itself is also possible to be exploited as a standalone system.

The aggregator will be exploited by BED and target medical researcher and professional as users, to help to reduce time when they conducting literature survey in the area of risks related to cardiorenal disease. As mentioned, the relevant research will carry on, and the system is likely to be improved, and that is a necessary part of the exploitation, since we need to increase the quality of the search. Given the time allocated, we are not able to conduct further research in CARRE in improving the accuracy of the search, in which case it may give us some difficulties in commericially exploite the work at it stands. In a short term, we are considering use of it with the research community.

The visual analytics interface is strongly related to other partners in CARRE, and we will collaborate with partners, especially medical partners in order to exploit it.

Similar as the other sub-systems that there is maintenance costs of software and resource costs of deploying and further developing the applications. We also only consider the further developing cost. In terms of the medical evidence aggregator, we are contributing to the overall exploitation plan of CARRE with partners, and will explore the possibility of exploiting it on its own, likely to be as open source. Both tasks are possible since the research is continued in the group. In addition, exploitation will be linked to furure funding applications.

7.4. VULSK

VULSK has led the development and thus is primarily interested in exploiting the following outcomes:

- PHR aggregator & entry system:

Also, VULSK had significant contribution to and thus is interested in exploiting the following outcomes:

- Risk factor ontology
- Measurements ontology
- Risk factor reference data base
- Risk factor management system
- Medical evidence aggregators
- Decision support alerts system
- Empowerment model as a cognitive process
- Privacy-by-design argument
- CARRE integrated system & service

Risk factor system – the use and development of its important for hospital's research plans and clinical use. Extend to cover other areas of medicine, also, medication adverse effects.

Collecting and aggregating of personal medical data, including data from devices as well as data entered manually into the system, is the big interest of the healthcare provider. It's important for both purposes: patient empowerment and continuous patient care, particularly patient monitoring. VULSK is going to use CARRE aggregation tools and further develop Vivaport PHR system integrated with other personal devices aggregators.

As VULSK belongs to a wide network of healthcare providers in Lithuania and some of the outpatient clinics and commercial institutions already expressed official interest become associated partners of the project, we suggest CARRE platform or at least CARRE developed tools and technologies to become part of national or regional solution for aggregating personal medical data and clinical decision support.

7.5. KTU

KTU has led the development and thus is primarily interested in exploiting the following outcomes:

- Wrist worn device
- Body composition scale
- Multiparametric scales data analyzer
- ECG signal analyser

Also, KTU had significant contribution to and thus is interested in exploiting the following outcomes:

- Measurements ontology
- Personal sensor data aggregators & management system
- Visual analytics
- Privacy-by-design argument
- CARRE integrated system & service

The wrist worn device will be used as a scientific instrument for registration of biosignal databases in ongoing educational (batchelor and master thesis related) and future research projects. Currently, it is succsefully being used in the project supported by the Research Council of Lithuania “Automatic algorithms for atrial fibrillation risk prediction after acute myocardial infarction”, 2015-2017, (No. MIP-088/15). Interested project partners associate partners (clinical and SMEs) will be involved in the exploatation as well.

Measurements ontology was enriched in project CARRE by development of trained operator-less physiological measurement methods and data analysis algoritms. The continuous and intermittent measurement parameters describing health status are contribution of the project and will be exploited in future research projects.

Multiparametric scale together with the multiparametric scale data analyzer will be further developed and exploited as a scientific instrument in research projects for acquisition of biosignal databases. Interested project partners and associate partners (clinical and SMEs) will be involved in the exploatation as well.

ECG signal analyser is a state-of-the-art software for comprehensive atrial fibrillation (AF) arrhythmia anlysis. Its unique features: detection of brief AF episodes (< 30 beats), quantification of temporal distribution of AF episodes, characterization of atrial fibrillatory activity. It will be exploited in future research projects, e.g., in a virtual heart project by OU.

Visual analytics component is an important integral part of modern data driven system. Visual analytics functionality is a strong feature of both types of instruments: scientific or consumer. CARRE multiparametric scales and wrist worn device are able to produce multiple types of data and parameters. Therefore, we will collaborate with technical and medical partners in exploitation and adaptation of visual analytics solutions to CARRE new devices. Visual analytics methods and applications will be integrated in the curriculum of biomedical engineering program at KTU.

Privacy and data security technologies are important aspects in prototyping of health monitoring devices. Privacy-by-design paradigm helps to lower the vulnerability riscs and ensures a stronger trust of the users to the personal health devices. The developed model of GDF file encryption will be embedded in CARRE multiparametric scales.

The CARRE integrated system & service is a succesfull example of what is possible to achieve by integration of medical informatics and personal health monitoring devices. The example will be exploited for inspiration of other reseach projects in other medical domains and in biomedical engineering education at KTU.

7.6. PIAP

PIAP has led the development and thus is primarily interested in exploiting the following outcomes:

- Decision support alerts system

Also, PIAP had significant contribution to and thus is interested in exploiting the following outcomes:

- Privacy-by-design argument
- CARRE integrated system & servic

Complementary to activities written in section 5.16 PIAP will exploit project results among the scientific community through different curriculum programmes namely:

Warsaw University of Technology (WUT) at Mechatronics Faculty – by performing student's evaluation of the system capabilities and engaging them in contribution in testing the developed system. This will be done under "Intelligent Measurement Devices" – a new course in the Electronic Measurement Systems specialization on engineering degree. During this course students will gain comprehensive skills: knowledge about the measurements devices used for data acquisition in the project and CARRE services operation rules, putting the most emphasize on the DSS design rules.

Results of CARRE project in academic community will continue to gain increased visibility and improve research of teaching processes. This academic exploitation of strategic guidelines, naturally, has a longer time horizon. The future research agenda will be prepared based on the results achieved by CARRE, and potential problems that have to be solved will be identified, in order to strengthen the project impact. The long run result of the efforts of the academic partners will be to promote the approaches project results in the mainstream of teaching in areas of electronic measurements and innovative ICT solution in higher education environment.

8. Contributions to Standards and Regulations

Mobile health or mHealth is an emerging field of research and technology[35] influencing an approach to health care in general and a strategy of implementations[36].[37]. Wearable eHealth systems for personalized health management (also defined as mHealth) is an issue of particular support of EU programs and many successful projects[38].

The rapid rise in the wide use of mobile devices, such as smartphones, tablet personal computers, and wireless medical devices, as well as the wireless networks and internet capacity that enable their use, has raised new challenges for standardization, data security and integrity. For example, standardized Health Insurance Portability and Accountability Act approved in USA in 1996 (HIPAA) – needs a revision to be compliant with electronic data security that will allow ubiquitous use of mobile health technologies. The lack of standardized data security to assure privacy, to allow interoperability, and to maximize the full capabilities of mobile devices presents a significant barrier to care internationally[39]. Continua alliance and other organizations are active in promoting greater interoperability of personal health systems[40]. Data protection and security is of particular attention of European data protection supervisor[41].

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35 Robert S.H. Istepanian, Swamy Laxminarayan, and Constantinos S. Pattichis Eds. M-Health: Emerging Mobile Health Systems. Springer 2006, 650 p.

36 A.C.Norris, R.S. Stockdale mand Shara A Strategic approach to m-Health. Health Informatics Journal 2009 vol. 15(3), 244-253. http://jhi.sagepub.com/content/15/3/244.full.pdf+html

37 Digital Agenda for Europe – mHealth https://ec.europa.eu/digital-agenda/en/mhealth

38 A. Lymberis, D.de Rossi Eds. Wearable eHealth systems for personalized health management – state of the art and future challenges. IOS press 2004. 369p.

39 mHealth Data Security: The Need for HIPAA-Compliant Standardization Telemedicine and eHealth Volume: 18 Issue 4: May 7, 2012 p.284-288

40 Enabling smart integrated care: Recommendations for fostering greater interoperability of personal health systems http://www.continuaalliance.org/sites/default/files/SmartPersonalHealth_publication_web_1.pdf

41 European data protection supervisor Mobile Health Opinion 1/2015, Reconciling technological innovation with data protection.

The CARRE project is fully based on technological standards for all its activities and development, including standards for data presentation and communications, semantics, medical terminologies, security and privacy, even for evaluation and presentation. These standards are used for all external project interfaces, but also for the internal interfaces of the components developed by the project, thus ensuring extensibility, use and re-use of the work developed by the project.

Project results are uploaded in and offered via appropriate reference databases and portals. Also, some of the ontologies and external vocabularies used by CARRE are missing certain terms which are necessary for the project. For example, the Clinical Measurements Ontology [42] contains terms relating to physical activity measured in a controlled hospital setting, but no terms relating to physical activity in everyday life (as measured by some of the sensors used by CARRE). The maintainers of such ontologies will be contacted with proposed additions, in order to promote interoperability and avoid vocabulary fragmentation.

8.1. Survey of standardisation bodies and activities

This section presents a general view on standardization bodies and activities in Europe and worldwide which are related to medical devices and mHealth solutions. Since mHealth is inseparable from eHealth and Health Informatics, appropriate bodies related to standardization are also included.

mHealth is a component of eHealth. To date, no standardized definition of mHealth has been established. For the purposes of professional communication, the Global Observatory for eHealth (GOe) defined mHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices. mHealth involves the use and capitalization on a mobile phone's core utility of voice and short messaging service (SMS) as well as more complex functionalities and applications including general packet radio service (GPRS), third and fourth generation mobile telecommunications (3G and 4G systems), global positioning system (GPS), and Bluetooth technology[43]. Data security and citizen privacy are areas that require legal and policy attention to ensure that mHealth users' data are properly protected and appropriate standards are in place.

Main European body is CEN Technical Committee TC 251 'Health informatics' which is specifically dedicated to the development and provision of European Standards ensuring interoperability of health information systems throughout Europe, systematic harmonization of standards with the international environment[44].

Other main institutions working to develop standards in the capacious area of eHealth and mHealth are HL7, ISO/TC 215, ISO/IEEE11073. Organizations such as WHO, ITU, GS1, CONTINUA and others also contribute to the development and promoting of mHealth standards. Important impact also is by EU projects, such as epSOS which covers 23 European countries and promotes a cross boarder sharing of medical data, especially of main (vital) information on citizen's health (health summary). CARRE project have been using an experience of epSOS project in setting the health summary structure and integration of portal Vivaport[45] into CARRE system. Apart from the previous standardization bodies[46] that are directly related with eHealth and mHealth, there are also bodies, such as IHTSDO, IHE, CELENEC, ETSI and W3C, indirectly related with meaning that their standards are utilized in eHealth systems and applications.

Table 3 shows a more comprehensive list of standardization bodies and activities directly or indirectly related with eHealth and mHealth.

Table 3. Standardization bodies directly or indirectly related with eHealth and mHealth.

Name	Role and activity	Web page

https://secure.edps.europa.eu/EDPSWEB/webdav/site/mySite/shared/Documents/Consultation/Opinions/2015/15-05-21_Mhealth_EN.pdf

42 http://bioportal.bioontology.org/ontologies/CMO

43 http://www.who.int/goe/publications/goe_mhealth_web.pdf

44 http://www.cencenelec.eu/standards/Sectors/healthcare/Pages/default.aspx

45 https://vivaport.eu/Default.aspx?ReturnUrl=%2f

46 https://www.itu.int/dms_pub/itu-t/oth/23/01/T23010000170001PDFE.pdf

CEN/TC251 Health Informatics	Main European body for Health Informatics and eHealth standards	http://standards.cen.eu/dyn/www/f?p=204:7:0::::FSP_ORG_ID:6232&cs=18CA078392807EDD402B798AAEF1644E1
CONTINUA Health Alliance	Not-for-profit international industry group convening standards to develop end-to-end, plug-and-play connectivity for personal connected health	http://www.continuaalliance.org/
epSOS: European Patients Smart Open Services	Big project aimed to design, build and evaluate a service infrastructure that demonstrates cross-border interoperability between electronic health record systems in Europe	www.epsos.eu/
GS1 Healthcare	A global non-profit standards association comprised of member institutions from a host of countries. The focus of GS1's standardization effort is primarily supply and demand chains	www.gs1.org/healthcare
ISO/TC215: Health Informatics	The International Organization for Standardization (ISO) establishes eHealth standards and has a wide scope which includes standardization in the field of information for health, and Health Information and Communications Technology (ICT) to promote interoperability between independent systems	www.iso.org/iso/iso_technical_committee?commid=54960
HL7: Electronic Health Information Systems	Health Level Seven International (HL7) is a standards organization specifically devoted to the practice of developing standards related to the exchange, storage, and use of electronic health information such as clinical data and administrative information	www.hl7.org/
ISO/IEEE 11073: Medical / Health Device Communication Standards	International Standard Organization for standardization of data communication and compatibility of medical devices	See ISO/TC 215
ITU-T Q28/16: Multimedia Framework for eHealth Applications	A study group of International Telecommunication Unit (ITU) with the aim to develop a multimedia framework for eHealth applications (and telemedicine in particular); to develop a roadmap for eHealth standards; to construct a general architecture and requirements for e-health applications	http://itu.int/ITU-T/studygroups/com16/sg16-q28.html
WHO Global Observatory for eHealth	An initiative of World Health Organization (WHO) dedicated to the study of eHealth—its evolution and impact on health in countries. The Observatory model combines WHO coordination regionally and at headquarters to monitor the development of eHealth worldwide, with an emphasis on individual countries	www.who.int/goe/en/
DICOM: Digital Imaging and Communications in Medicine	Is a set of specifications dedicated to the standardization of medical images. The U.S. National Electrical Manufacturers Association (NEMA) is responsible for the DICOM standards which specify image file formats, storage protocols, processing and transmission of medical images. Lately also used for signals, e.g. ECG	http://medical.nema.org/
IHTSDO: International Health Terminology Standards Development Organisation	The IHTSDO determines global standards for health terms, an essential part of improving the health of humankind. It is committed to maintain and grow its leadership as the global experts in healthcare terminology, ensuring that SNOMED CT, its world-leading product, is accepted as the global common language for health terms	http://www.ihtsdo.org/
IHE:	IHE is an initiative by healthcare professionals and industry to improve the way computer systems in	http://www.ihe.net/

Integrating the Healthcare Enterprise	healthcare share information. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical need in support of optimal patient care	
CENELEC: European Committee for Electrotechnical Standardisation	CENELEC is the European Committee for Electrotechnical Standardization and is responsible for standardization in the electrotechnical engineering field. Its main goals are to support the electrotechnical industry by removing barriers to trade; ensuring quality, safety and health for citizens; and stimulating innovation	http://www.cenelec.eu/
ETSI: European Telecommunications Standards Institute	ETSI produces globally-applicable standards for Information and Communications Technologies (ICT), including fixed, mobile, radio, converged, broadcast and internet technologies	http://www.etsi.org/
W3C: World Wide Web Consortium	The W3C is the international standards body for Web standards. Its purpose is to develop open standards so that the Web evolves in a single direction rather than being splintered among competing factions. The W3C is the chief standards body for HTTP, HTML and XML.	https://www.w3.org/

8.2. Standards related to CARRE

This section presents the exact standards related to CARRE in terms of included commercial devices, new devices development, software implementations and evaluation procedures within the project.

8.2.1. Commercial devices

Table 4 below presents selected in CARRE commercial devices and their related standards.

Table 4. Selected commercial devices and related standards.

Device	Compliant with Standards	Note
Fitbit Aria Weight scale	EU R&TTE Directive 1999/5/EC EN 60950-1:2006 + A12: 2011.	Declarations in the user manual: ▪ Do not use if you have a pacemaker or any other internal medical device. ▪ Do not use if you are pregnant. ▪ Not intended for use by children under the age of 10. ▪ Aria should not be used to diagnose or treat any medical condition. ▪ Always consult your physician to determine what is ideal for you.
Withings Smart Body Analyser WS-50	EU R&TTE Directive 1999/5/EC EN 60950-1:2006 + A11:2009 + A1:2010 + A12:2011 EN 301 489-1 v1.9.2 (2011), EN 301 489-17 v2.1.1 (2009-05) EN 55022: 2010 (Class B), EN 55024: 2010 EN 61000-4-2:2009, EN61000-4-3-2006 + A1:2008 EN 300 328 v1.8.1	Declarations in the user manual: ▪ This product is not suitable for people wearing a pacemaker or any other internal medical device. ▪ The Withings scale data must be considered purely as reference and not as a medical opinion.
Medisana BS-440 weight scale	EU R&TTE Directive 1999/5/EC	Declarations in the user manual:

			▪ This device is not suitable for pregnant women ▪ Weighing only is no problem, but body fat analysis should be avoided for children because of the current impulse. This impulse is flowing through the body during the body fat measurement process. ▪ These scales are not suitable for people with pacemakers or other medical implants. The body fat information may be inaccurate in people with diabetes or other medical/physical limitations. The same also applies to very highly trained athletes.
Fitbit One			EU R&TTE Directive 1999/5/EC
Medisana Glucometer	Meditouch	2	Electromagnetic compatibility: EN 60601-1-2 EU guidelines 98/79 for in vitro diagnostic devices.
eMotion Faros 180			eMotion Faros product series is both medical CE and FDA cleared.
Medisana BU-575			EU R&TTE Directive 1999/5/EC EN 1060-1 EN 1060-3 EU Guideline “93/42/EEC of the Council Directive dated 14 June 1993 concerning medical devices”
Withings BP-801			Quality Management System Certificate: No. 93878-2011-CE-RGC-NA 3.0 EN 60601-1: 2006 + AC (2010) EN 60601-1-11: 2010 EN 1060-3: 1997 A1:2005 EN 80601-2-30: 2010 EN 301 489-1 v1.9.2: 2011 EN 301 489-17 v2.2.1: 2012 EN 60601-1-2: 2007/ AC:2010 EN 300 328 v1.8.1:2012 EN 1060-4: 2004 EN ISO 13485:2003 / AC: 2009 EN ISO 9001:2008 / AC: 2009 EN ISO 14971: 2012

8.2.2. New devices development

This subsection presents standards and regulations related to new devices development within CARRE and the possibility to adapt them.

8.2.2.1. Wrist worn device

The developed wrist worn monitoring device should be treated as a medical device. Therefore, it should be compliant with “Council Directive 93/42/EEC on Medical Devices (MDD) (1993)”[47], similarly to Medisana BU-

[47] Online: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A31993L0042

575 blood pressure monitor. Moreover, the device is intended to transmit data wirelessly. Such device should also be compliant with "EU R&TTE Directive 1999/5/EC"[48], as most of the selected commercial products discussed in Table 4.

Regarding the specific standards, we can consider some of the standards applied by Withings for the blood pressure monitor, for example, as the following:

- Electromagnetic compatibility and Radio Spectrum Matters: EN 301 489
- Safety of information technology equipment: EN 60950-1
- Medical electrical equipment, General requirements for basic safety and essential performance: EN 60601-1

8.2.2.2. Multiparametric scale

The developed multiparametric scale should be treated as intermittent personal monitoring device. Because it has electrodes and for measurement needs a direct contact with human body it should be compliant with "EU R&TTE Directive 1999/5/EC"[13] as other commercial scales products discussed in Table 4. Device has Bluetooth Low Energy (BLE) and WiFi wireless data transfer technologies so it should conform at least to EN 60950-1:2006 + A12: 2011[49].

Exceptions on device use should be similar to commercial products:

- This device is not suitable for people wearing a pacemaker or any other internal medical device.
- Body fat analysis should be avoided for children and pregnant women because of the current impulses flowing through the body during the body fat measurement process.
- People with disabilities, or who are physically frail, should always be assisted by another person when using this unit. Use a handrail or so when stepping on the unit.

8.2.3. Software implementations

This subsection presents standards related to software implementations within CARRE. In the majority of our implementation processing, we follow all appropriate standards in order to be compatible with internal CARRE components and other external systems. These standards can be separated into five different categories: semantic standards, data and messaging standards, system and programming standards, communication standards and security standards. In the following subsections, we discuss each one of these categories.

8.2.3.1. Semantic standards

The focus of semantic standards is to provide inter-organizational interoperability and solving data exchange problems among different systems and organizations. There are many semantic standards[50],[51] to different domains and some of them in health domain. Some indicative standards in health domain are:

- SNOMED-CT, a comprehensive reference terminology allowing healthcare providers to record medical data accurately and unambiguously[52].
- Electronic Health Record Communication (EN 13606), defines a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient)[53].

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48 Online: http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A31999L0005

49 Online: http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1454920782361&uri=CELEX:32012D0029

50 https://sites.google.com/site/erwinfolmeronsemanticstandards/list-of-semantic-standards

51 Folmer, E.J.A. (2012) Quality of semantic standards. PhD thesis, University of Twente.

52 Lee D, Lau F, Hue Q.A method for encoding clinical datasets with SNOMED CT. BMC Medical Informatics & Decision Making [serial online]. January 2010;10(1):53-64. Available from: Academic Search Complete, Ipswich, MA. (Last accessed: 08/07/2014)

53 http://www.en13606.org/

- International standard developing organization Health Level Seven International (HL7), active since 1987, has developed a large number of standards and standard practices spanning various aspects of EHRs, ranging from recommended best practices to access control[54].

Apart from the explicitly defined semantic health standards, there are also control vocabularies, such as ICD 9 & 10, UMLS and MeSH, that are followed by international communities (e.g. PubMed). In Table 6, it is shown the followed semantic standards in CARRE accordingly with the deliverables in which appear. More specifically, the diseases, medical specialties and in general all the medical terminology are classified with ICD codes, CUIs of UMLS and MeSH terms.

8.2.3.2. Data and messaging standards

Data and messaging standards provide consistent meaning to data shared among different information systems, programs, and agencies. These include representation, format, definition, structuring, tagging, transmission, manipulation, use, and management of data. In health, there are a big number of data standards[55] and some others in more specific domains in health (e.g. clinical research[56]). Some examples of these data standards are:

- GLIF, supports sharing of computer-interpretable clinical guidelines across different medical institutions and system platforms[57].
- RDF, a standard model for data interchange on the Web defined by W3C. RDF has features that facilitate data merging even if the underlying schemas differ, and it specifically supports the evolution of schemas over time without requiring all the data consumers to be changed[58].
- XML, a simple, very flexible text format derived from SGML (ISO 8879). Originally designed to meet the challenges of large-scale electronic publishing, XML is also playing an increasingly important role in the exchange of a wide variety of data on the Web and elsewhere[59].

In CARRE, we utilize more general data standards, such as JSON and XML, for data exchange among our components, RDF standard for the storage of our data and URI standard, as identifiers, for each record in RDF repositories (more details in Table 6).

8.2.3.3. System and programming standards

System and programming standards are methods of programming that have been declared acceptable and allow programmers to use a common ground when writing code. These standards are used in all software implementations and there are for all the well-known programming languages[60,61,62]. Some examples of this category of standards are:

- C#, ISO/IEC 23270:2006, specifies the form and establishes the interpretation of programs written in the C# programming language[63].
- Ruby, ISO/IEC 30170:2012, specifies the syntax and semantics of the computer programming language Ruby, and the requirements for conforming Ruby processors, strictly conforming Ruby programs, and conforming Ruby programs[64].

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54 http://www.hl7.org/implement/standards/product_matrix.cfm?ref=nav (Last accessed: 07/07/2014)

55 Hammond, W. E. (2005). The making and adoption of health data standards. Health affairs, 24(5), 1205-1213.

56 Richesson, R. L., & Krischer, J. (2007). Data standards in clinical research: gaps, overlaps, challenges and future directions. Journal of the American Medical Informatics Association, 14(6), 687-696.

57 Boxwala, A. A., Peleg, M., Tu, S., Ogunyemi, O., Zeng, Q. T., Wang, D., ... & Shortliffe, E. H. (2004). GLIF3: a representation format for sharable computer-interpretable clinical practice guidelines. Journal of biomedical informatics, 37(3), 147-161.

58 https://www.w3.org/RDF/

59 https://www.w3.org/XML/

60 http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_tc_browse.htm?commid=45202

61 Nirmal, B. K. (1986). Programming standards and guidelines. Scott, Foresman & Co.

62 Wooldridge, S. (1977). Systems and programming standards. Petrocelli/Charter.

63 http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=42926

64 http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=59579

On the other hand, very well-known and high-end programming languages, such as JavaScript and Python, do not have formal standards but are acceptable by de facto. In CARRE, we especially use programming standards, such as C#, Java, Python and JavaScript, as backbone of our implementations, HTML5 for all the web interfaces, OWL2 for the implemented ontologies and SPARQL as script language for retrieving triples from RDF repositories (more details in Table 6).

8.2.3.4. Communication standards

Communication standards[65] provide reference models to make sure products, systems or software applications of different vendors can work together in an interconnected environment. These communication standards can also separated into five layer according Table 5 (based on[66]).

In CARRE, we focus as regards our software implementations to the application layer of communication standards. Thus, we use HTTP (and especially HTTPS) as communication protocol among all our components and the WWW, and RESTfull API and SPARQL Endpoint for internal usage and in order to make available our medical knowledge (Risk Factors database) to other external of CARRE applications (more details in Table 6).

Table 5. Layers of communications standards.

Layer	Examples of Standards
5th layer: Application	HTTP, TLS, SMTP, APIs
4th layer: Transport	TCP, UDP
3rd layer: Network	IPv4 or v6, IPsec
2nd layer: Data link	Ethernet, Wi-fi, Bluetooth
1st layer: Physical	Cat 5 cable (LAN), DSL, USB

8.2.3.5. Security standards

Security standards are techniques generally set forth in published materials (e.g. policies, guidelines, best practices etc.) that attempt to protect the cyber environment (e.g. devices, software, services and systems that are connected on the Internet) of a user or organization[67,68]. The main principal objective is to reduce the risks, including prevention or mitigation of possible attacks. Some indicative examples of security standards are:

- OAuth, is an open standard for authorization, commonly used as a way for Internet users to log into third party websites using an existing account for another service[69].
- ISO/IEC 27002:2013, gives guidelines for organizational information security standards and information security management practices including the selection, implementation and management of controls taking into consideration the organization's information security risk environments[70].

In CARRE, we follow ISO/IEC 27002:2013 as security management practices for our implementations, ISO/IEC 27018:2014 for the protection of personal identifiable information (PII) and OAuth as authorization mechanism among our components (more details in Table 6).

65 Ganz, A., Ganz, Z., & Wongthavarawat, K. (2003). Multimedia Wireless Networks: Technologies, Standards and QoS. Pearson Education.

66 https://www.ischool.utexas.edu/~l38613dw/readings/NotesOnInterconnection.html

67 http://www.itu.int/ITU-T/recommendations/rec.aspx?rec=9136

68 Guttman, B., & Roback, E. A. (1995). An introduction to computer security: the NIST handbook. DIANE Publishing.

69 http://oauth.net/

70 http://www.iso.org/iso/catalogue_detail?csnumber=54533

Table 6. Software standards utilized in CARRE software components.

Standard	Category of Standard	URL of standardization body	Deliverables
ICD 9 & 10	Semantic	http://www.who.int/classifications/icd/	D.2.4, D.3.4
UMLS	Semantic	https://www.nlm.nih.gov/research/umls/	D.2.4, D.3.4
SNOMED CT	Semantic	http://www.ihtsdo.org/snomed-ct	D.2.4
MeSH	Semantic	https://www.nlm.nih.gov/mesh/	D.2.4
JSON: RFC 7159	Data/Messaging	http://www.json.org/	D.3.2
XML: ISO 8879	Data/Messaging	http://www.w3.org/XML/	D.3.3
URI: RFC 3305	Data/Messaging	http://www.w3.org/Addressing/	D.2.4, D.3.2, D.4.1
RDF 1.1	Data/Messaging	http://www.w3.org/RDF/	D.2.4, D.3.2, D.3.3, D.3.4, D.4.1
C#: ISO/IEC 23270:2006	System/Programming	http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=42926	D.3.3, D.6.1
Java	System/Programming	http://www.java.com	D.3.3, D.3.4
Python	System/Programming	https://www.python.org/	D.3.2, D.4.2
JavaScript	System/Programming		D.3.4, D.4.1, D.5.1
HTML5	System/Programming	https://www.w3.org/html/	D.3.3, D.3.4, D.4.1, D.5.1, D.6.1
OWL 2	System/Programming	https://www.w3.org/TR/owl2-syntax/	D.2.4
SPARQL 1.1	System/Programming	https://www.w3.org/TR/sparql11-overview/	D.2.4, D.3.2
RESTful API	Communication	https://openapis.org/	D.4.1, D.7.2
SPARQL Endpoint	Communication	https://www.w3.org/TR/sparql11-protocol/	D.4.1, D.7.2
HTTP/1.1: RFC 2616	Communication	http://www.w3.org/Protocols/	D.3.2, D.3.3, D.3.4, D.5.1
OAuth 1.0a & 2.0: RFC 6749	Security	http://oauth.net/	D.2.4, D.3.2, D.3.3
ISO/IEC 27002:2013 (information security control and risk management)	Security	http://www.iso.org/iso/catalogue_detail?csnumber=54533	D.4.1
ISO/IEC 27018:2014 (protection of PII)	Security	http://www.iso.org/iso/catalogue_detail.htm?csnumber=61498	D.4.1

8.2.4. CARRE evaluation procedures

In 2004 and during the HISEVAL workshop in Innsbruck, prominent researchers in the field of medical informatics raised the idea for developing a Statement on the Reporting of Evaluation Studies in Medical Informatics (STARE-HI)[71]. As a consequence STARE-HI guidelines were developed and recently published[72]. The STARE-HI guidelines include a comprehensive list of principles relevant for properly describing health Informatics evaluations, and they recommend a structured list of items that should be included in Health Informatics evaluation reports. These items are organized in various categories: (1) title; (2) abstract; (3) keywords; (4) introduction; (5) study context; (6) methods; (7) results; (8) discussion; (9) conclusion; (10) authors' contribution; (11) competing interests; (12) acknowledgments; (13) references; and (14) appendices. These primary categories include more detailed items.

A more detailed standard involves reporting randomised controlled trials: CONSORT [73][74] (Consolidated Standards of Reporting Trials). This has recently been extended to CONSORT-EHEALTH evaluation standard and checklist to cover of specific requirements of randomized control trials of ehealth interventions[75]. The standard has quickly gained popularity and is now adopted by the *Journal of Medical Internet Research* (JMIR) and authors of eHealth RCTs are required to submit an electronic checklist explaining how they addressed each sub-item.

CARRE project will follow the overall STARE-HI recommendation to report the findings of the pilot evaluation and will also prepare the CONSORT-EHEALTH checklist to describe in detail the randomized control trial which is currently being designed.

9. Benefit for the Society

A comprehensive discussion on return on investment for eHealth interventions is included in the Office of Health Affairs, University College Dublin, "Health Policy Documents: eHealth Strategy for Ireland"[76]. We have used the five main areas of eHealth benefit identified in this Policy Document to draft expected benefits of CARRE:

1. **Increase efficiency of legacy healthcare systems – lower cost of operations, reduce demand on resources.** CARRE solution employs and promotes self-monitoring of chronic patients and people at risk of chronic disease in the area of cardiorenal syndrome and comorbidities. Also, develops and shows solutions to assist personal planning of lifestyle changes. Thus, the project expects to improve quality of life and empowerment and to reduce health risks or at least improve health factors leading to increased health risks.
2. **Increase efficiency of new healthcare investments: enable new health services/policies, and open up new services.** CARRE has developed a prototype of a health risk reference database and a number of related technologies that enable the use and re-use of this outcome for building new ehealth services. Also, the project is expected to contribute evidence on employing health risk awareness policies and services to improve health risks and/or factors leading to increased health risks.
3. **Open up new markets.** CARRE technological breakthroughs include two new marketable personal sensors and also a number and variety of software components that can be used and re-used in other products.

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[71] Ammenwerth, E., Brender, J., Nykanen, P., Prokosch, H.U., Rigby, M., Talmon, J. (2004). Visions and strategies to improve evaluation of health information systems. Reflections and lessons based on the HIS-EVAL workshop in Innsbruck, International Journal of Medical Informatics, 73(6), 479–491

[72] Talmon, J., Ammenwerth, E., Brender, J., Keizer, N. de, Nykanen, P., Rigby, M., STARE-HI – Statement on reporting of evaluation studies in Health Informatics, *International Journal of Medical Informatics*, vol. 78, pp. 1-9, 2009

[73] Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the quality of reporting of randomised controlled trials. The CONSORT statement. JAMA 1996; 276: 637–9

[74] Campbell MK, Elbourne DR, Altman DG, CONSORT group. CONSORT statement: extension to cluster randomised trials. BMJ 2004 Mar 20;328(7441):702-708

[75] Eysenbach G, CONSORT-EHEALTH Group, CONSORT-EHEALTH: Improving and Standardizing Evaluation Reports of Web-based and Mobile Health Interventions, J Med Internet Res 2011;13(4):e126, DOI: 10.2196/jmir.1923

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4. **Open up export markets.** CARRE technological breakthroughs include two new marketable personal sensors that once turned into commercial products can open up export markets.
5. **Increase well-being and better patient outcomes.** CARRE service is expected to increase awareness on health risks, enhance patient empowerment, improve quality of life and reduce health risks and/or factors leading to health risks, thus improving health status and deterring disease progression.

Furthermore, CARRE project addresses several of the recommendations led out for the ICT for Health Unit, DG Information Society and Media, European Commission towards value-creating and sustainable business models for ehealth[77]. Namely, the project addresses the policy recommendation laid out in the Report's executive summary (page viii-ix) as follows:

1. the project launces a pilot action of a novel personalized ehealth service;
2. a final project report includes a best practices and implications report – also a separate report on privacy-by-design best practices is being prepared for publication;
3. the cognitive model of patient empowerment (published) and the privacy-by-design best practices (under development) are the project's contributions towards the definition of benchmarking parameters for seamless monitoring and comparing ehealth models across Europe;
4. the projects contributed a generic modelling of data exchanged and privacy requirements for personal ehealth systems thus providing the technical background for required legal clarification of accessing personal health data;
5. the project is a working paradigm of standards adoption at all levels of development, including standards for systems interoperability and medical terminologies – all project results are offered as open access via appropriate standardized interfaces (even the system components communicate via standardized technologies), while part of the project results contribute to medical terminologies.

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