



iCARDEA

“An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices”

SPECIFIC TARGETED RESEARCH PROJECT

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iCARDEA –D2.1.2 Exploitation and Dissemination Plan (b)

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iCARDEA Consortium Contacts:

Organization	Name	Phone	Fax	E-Mail
SRDC	Asuman Dogac	+90-312-2101393	+90(312)2101837	asuman@srdc.com.tr
OFFIS	Wilfried Thoben	+49-441-9722-131	+49-441-9722-111	thoben@offis.de
SRFG	Manuela Plößnig	+43-662-2288-402	-	manuela.ploessnig@salzburgresearch.at
FORTH	Catherine Chronaki	+30-2810391691	+30-2810391428	chronaki@ics.forth.gr
SALK	Bernhard Strohmer	+43-6624482-3481	+43-6624482-3486	b.strohmer@salk.at
SJM	Karl Eberhardt	+43-16073067	-	keberhardt@sjm.com
Medtronic	Alejandra Guillén	+34-916250361	+34-913346453	alejandra.guillen@medtronic.com
HCPB	Josep Brugada	+34-932275703	+34-932275459	jbrugada@clinic.ub.es

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1 SCOPE

Deliverable 2.1.2 addresses the presentation of yearly iCARDEA Exploitation and Dissemination Plans as a result of the activities carried out in Task 2.1 Exploitation and Task 2.2 Dissemination. Section 2 presents the activities carried out to create the strategic Exploitation Plan for iCARDEA Project Results.

1.1 Definitions and Acronyms

A list of all abbreviations and acronyms used in this document is shown in Table 1.

Abbreviation/ Acronym	DEFINITION
CCD	HL7 Continuity of Care Document for exchanging patient medical summaries ¹ ; an HL7 CDA (Clinical Document Architecture) implementation of CCR.
CCR	Continuity of Care Record for exchanging patient medical summaries ²
CIED	Cardiac Implementable Electronic Device
CRM	Cardiac Rhythm Management
CRT-ICD	Cardiac Resynchronization Therapy & Implantable Cardioverter Defibrillator
DoW	Description of Work
EC	European Commission
EHR	Electronic Health Record
ePHR	Electronic Personal Health Record
EU	European Union
FP7	7 th Framework Programme
HIS	Hospital Information System
HIS	Hospital Information System
HMO	Health Maintenance Organisation – a type of MCO
IDCO	Implantable Device Cardiology Observation
IEEE	Institute of Electrical and Electronic Engineers
MCO	Managed Care Organisation
PCHR	Personally Controlled Health Record
PCN	Patient Care Network
PHR	Personal Health Record
PHR-S	PHR systems
PHS	Personal health System
SWOT	Strength, Weakness, Opportunities and Threats
WP	Work Package

Table 1: List of Abbreviations and Acronyms

¹ CCD Continuity of Care Document http://en.wikipedia.org/wiki/Continuity_of_Care_Document

² CCR – Continuity of Care Record http://en.wikipedia.org/wiki/Continuity_of_Care_Record,
<http://www.ccrstandard.com/>

2 ICARDEA EXPLOITATION PLAN

2.1 Introduction

The aim of this document is to provide a strategic Exploitation Plan for the results coming from iCARDEA project. Task 2.1 entails the identification of the business and market opportunities the iCARDEA project will offer to the European Industry. For this purpose the following activities are planned:

- A comprehensive market survey will be carried out in the fields iCARDEA project addresses, such as CIEDs; computer interpretable clinical guidelines for the care and follow up of CIED patients; Personal Health Record Systems, Patient Empowerment architectures; comprehensive security and privacy mechanisms for eHealth; developing interoperability interfaces for CIEDs; EHRs and PHRs based on International Standards and the competencies of the competitors.
- Identification of Project's exploitable assets;
- Strength, Weakness, Opportunities and Threats (SWOT) Analysis for each iCARDEA Exploitable asset to reveal and structure all possible strengths and opportunities, as well as weaknesses and risks that have to be considered for exploitation
- Identification of iCARDEA Exploitation Strategy
 - Identification of the positioning of iCARDEA Solutions in the Open Source Market
 - Identification of Joint Exploitation Strategy
 - Identification of Individual Exploitation Strategy for each Partner
- Elaboration of Business Model and Forecasts for each iCARDEA exploitable Asset
 - Identification of Marketing Models
 - Identification of Cost Models
 - Identification of Revenue Models
 - Identification of Commercialization Policies
 - Identification of Business Plans for Industrial Partners and iCARDEA end user

This deliverable will be reported as yearly; in the first version of the Deliverable (D2.1.1a), we have addressed the initial Market Analysis (which will be updated where necessary in each yearly report), identification of iCARDEA Exploitable Assets, conducting SWOT analysis for each Exploitable Asset, and elaboration of initial individual exploitation plans of each partner. In this version of the document (second version released in the end of the second reporting period, D2.1.2b), we focused on identification of the initial version of the joint iCARDEA Exploitation Strategy. We positioned iCARDEA Solutions in the Open Source Market, defined exploitable iCARDEA services and packages, defined partner roles in joint exploitation activity, analyzed the best strategy for iCARDEA exploitation and iCARDEA deployment flexibility and present an initial analysis of return of investment. Finally we elaborated on possible legal, organisational, and economic barriers for a successful deployment of an

iCARDEA enabled remote monitoring system within a hospital and tried to outline the necessary steps to be taken at organisational and political scale to overcome these. Section 2.2 will give a description of the project and its related modules; exploitation can be provided on the entire project or focused on a part of it, for that an overview of distribution and packaging will be done. Markets analysis section (Section 2.3) will give information about possible identified markets in terms of current situation trends, market status, collaborators and competitors and prospects. In Section 2.4, we have identified initial set of iCARDEA Exploitable assets and present the SWOT analysis for each of them. Exploitation strategy section (Section 2.5.1.3) describes the individual exploitation plans for each partner. In Section 2.5, iCARDEA Joint and individual exploitation strategy is presented.

2.2 Project Overview

The iCARDEA project will develop an intelligent platform to automate and personalize the follow-up of cardiac arrhythmia patients with implanted CIED devices with context-aware, adaptable computer interpretable clinical guideline models using standard device interfaces and integrating patient EHRs and PHRs. One of the important aspects of iCARDEA is the user-centred approach, which focuses the research and development efforts on a user perspective, involving both the patients and healthcare professionals from the beginning of the project. Figure 1 shows the architecture and overall view of the iCARDEA platform itself and the environment in which iCARDEA needs to provide interoperation services. In order to provide a holistic solution, the project has identified the following specific technical objectives:

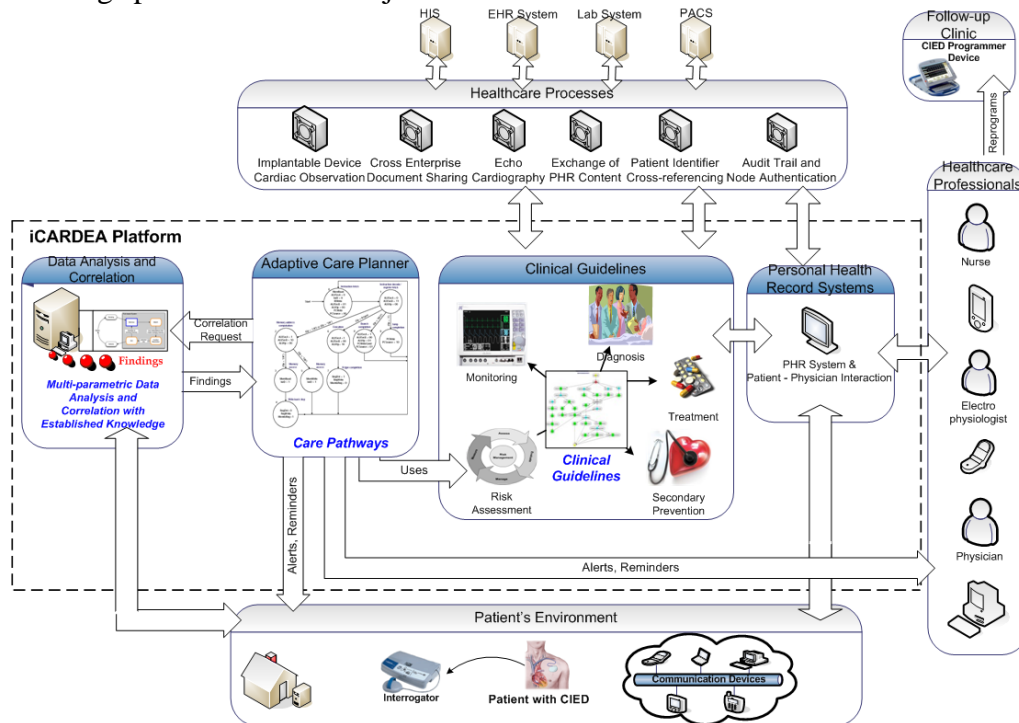


Figure 1 iCARDEA Architecture

CIED Data Exposure Module will be developed to integrate the data gathered from remote monitoring Cardiovascular Implantable Electronic Devices into automated healthcare processes executed by care pathways and the computer interpretable clinical guideline models; thus realize the personalized remote follow-up of CIED patients.

Patient Empowerment Framework will be developed in order to provide active and informed involvement of patients in management of their own health. Through the web based PHR, patients will be able to view their medical history, CIED data, and manage their medication summaries, daily nutrition information. PHR system will be implemented as a user-friendly Web application so that it will accessible from anywhere.

Interoperability Infrastructure for EHRs, PHRs and Code Systems will be developed to realize a comprehensive follow-up of CIED patients, it is necessary to have access to medical history and other clinical information of the patients that are stored in EHR and PHR systems. This information is very critical in shaping and guiding the personalized care pathway. For example, access to patients' medical history such as the non-cardiac conditions denoting contraindications to the proposed therapies can lead to more appropriate therapies/care plans in the clinical workflow. Furthermore, providing the right information to the treating physician at the right time, rather than searching through diverse information systems in different hospital departments or through paper EHRs in large paper archives can certainly help in more effective use of their time.

Data Analysis and Correlation Tool to be developed will provide dynamically updated, personalized alerting mechanisms to the patients and physicians for early detection of further complications such as contraindications and co morbidities. This alerting mechanism will be complementary to built-in alerting mechanism of CIEDs. Unlike built-in alerting mechanism of CIEDs, this tool will not be based solely on data transmitted from CIEDs, but also harmonize it with patient specific data such as medications and the severity of the arrhythmias.

Personalized Adaptive Care Planner for CIED Recipients: In the iCARDEA project the personalized follow-up of CIED patients will be coordinated through a "care plan" which is an executable definition of a care pathway that consists of computer interpretable clinical guideline models. The control flow of the care plan will be dynamically adapted based on the patient's context derived from the data coming from CIEDs and the medical context obtained from the EHRs, and the PHRs. This way, Personalized Adaptive Care Planner for CIED Recipients will realize context-aware multi-parametric monitoring.

2.3 Market Analysis

2.3.1 Cardiac Implantable Electronic Devices

In recent years the rate of ICD implantation has grown substantially, it is estimated that 1 million cardiac devices were implanted, with at least 4 million annual follow-up visits in the U.S. ^{i, ii} In Spain the total number of implanted pace-makers in 2010 was 35.137 whereas defibrillators reached the number of 5.345. ⁱⁱⁱ It is not easy to provide an exact

number of implanting centres in Spain but approximately there are 90 centres implanting ICDs and 100 pacemakers.

In Europe as overall, in a perspective study based on reports from major manufacturers from 2005 to 2010 the number of cardiac devices implanted was increased in all of families showing these results in units per million inhabitants:

Cardiac Device	2005	2010
Pacemakers	829	951
Defibrillators	90	158
CRT-P	23	31
CRT-D	37	100

Table 2 - Cardiac device perspective. Source population data: OECD. Eucomed based on reports from major manufacturers.

At the same time the results of primary and secondary prevention trails have shown significant improvement in mortality and morbidity. However, the increasing number of patients with ICD indication leaves the implanting centres with large logistic problems, especially with the number of follow-up visits. The standard of care for defibrillator follow-up is an in-person evaluation 1 month after implant, again 2 months later, and every 3 to 6 months thereafter.ⁱⁱ This volume of visits adds burden to clinicians and creates the need for a more cost-effective solution for the follow-up of these patients. Logistic problems are an important issue to solve. Usually the introduction of a new technology or data management system entails some changes in the treatment procedures. This involves facing several difficulties in order to achieve a complete adoption. The lack of trained personnel, definition of specific agendas to support the hours devoted to the remote follow-up, physical space to install the hardware, special software requirements that are not foreseen in the hospital network are usually elements to cover and overcome to make an easier adoption of a new system in hospitals.

Therefore new methods of tele-cardiology are currently developed and used in clinical practice. One of the most promising solutions is remote/home monitoring in which the implant sends the messages triggered by an event automatically. By utilizing these event triggered data transfers, the cardiologists are able to guide patients more effectively.

It is important to remark the growth of population on the age range with a CIED. This circumstance due to the current improvement of biomedical and healthcare systems implies the need of a change on the CIED patient's follow-up activities.

2.3.1.1 Market Description

The industry has been developing best-fitted software (web) applications to support the requirements of the home monitoring market. These web-based applications are proprietary systems of the different CIED vendors and are linked only to the proprietary devices of the respective vendors.

After the technology enables the development of remote monitoring devices, all the new released devices in this industry starts to incorporate this capability as an important feature. Nowadays almost all the CIED in the market from the different vendors have the possibility of remote monitoring, however not all of the patients that need CIED follow up are currently using remote monitoring devices. It is expected that when CIED replacements take place new versions of the devices with remote monitoring capabilities will be implanted.

Each company provides a platform to the healthcare professionals to connect to their own CIED in order to coordinate the remote follow up, to monitor devices and/or clinical parameters, and to monitor different alerts.

At this point a healthcare institute using implanted patients from different vendors (such as: Medtronic, St Jude, Boston Medical, etc...) will need a connection to each of these platforms and the know how to use each of these systems. Obviously this is an important handicap for a robust remote follow-up system in practice.

2.3.1.2 Current situation

The main remote monitoring system applications in the market belong to the most known vendors and are used to follow up patients using the particular provider devices. In the following subsections the current situation of these remote monitoring systems are briefly presented. These main vendors are Medtronic, Saint Jude, Boston Scientific and Biotronik.

Merlin.net™ (St Jude Medical):

The main monitoring system of St Jude Medical (SJM) used worldwide is the Merlin.net Patient Care Network (PCN). It is a web-based solution, where physicians are able to see all transmissions, triggered events and useful diagnostic data. The collected data and information stored in a central repository of SJM would be delivered to the iCARDEA system, to be incorporated into the careplan engine and processed by the system.

CareLink Network™ (Medtronic, Inc.):

The Medtronic CareLink® Network is a remote monitoring service, connecting cardiac device patients to their clinic from their homes. As a clinician, it is possible to access 24/7 – via a secure Internet website – to a wide range of trended reports offering information comparable to an in-office visit. These diagnostic reports can be exported to a hospital network or EHR for greater accessibility to the data and clinical documentation. In addition, it is possible to receive Medtronic CareAlert® Notifications which provide alerts to potential issues before they become problems.



Figure 2 - Medtronic's Carelink System

The Medtronic CareLink Monitor plugs into a standard phone line. The monitor gathers the information and sends it to a secure storage site. It is not necessary to use the Internet to transmit.

Patient confidentiality is a priority of the Network. The website is secure, protected by username and password for use by authorized clinic personnel.

The clinic can see a device information by logging on to a computer and pulling up the information when and where they need it by using a special website. The website is secure, protected by username and password for use by authorized clinic personnel.

Latitude Patient Management system™ (Boston Scientific):

The LATITUDE Patient Management system monitors the patient's implanted cardioverter defibrillator (ICD) or cardiac resynchronization therapy defibrillator (CRT-D) by gathering information through the use of the LATITUDE Communicator, a small piece of equipment that resides in the patient's home and connects to a standard phone jack. Some patients may also use the LATITUDE Heart Failure Management system (blood pressure monitor, weight scale with alert capability, device diagnostics and symptom self-report questions), if prescribed by their doctor.

Home Monitoring™ (Biotronik):

Home Monitoring™ is an internet-based, automatic remote monitoring system that uses the cellular phone network to enable physicians to remotely monitor their patients' clinical status and their device status no matter where they happen to be.

The system detects clinically relevant events early and alerts physicians, allowing earlier intervention that increases the level of patient care.



Figure 3 - Biotronik's remote monitoring concept

When a clinically relevant status change occurs, BIOTRONIK Home Monitoring® generates an event alert via email, SMS, or fax to the physician while simultaneously displaying the severity of the patients' status on the secure BIOTRONIK Home Monitoring® website.

2.3.1.3 Target market

The introduction of remote CIED monitoring follow-up in the hospital is a novel service that calls for revision of the traditional appointment-based workflows. Based on remote implant monitoring reports and the presence or lack of alerts, health professionals may choose to reschedule or skip appointments assessing additional information from the health record of patient.

So far, the different web platforms (the main ones are mentioned in the previous chapter) offer information strictly related to the parameters gathered by the devices and the therapies provided (on top of this, there are other services associated like alerts and scheduling of the interrogations, but those are based on the same data). There is no direct integration interface of data with Electronic Health Records (EHRs) nor with Personal Health Records (PHRs), nevertheless export to EHR and PHR is possible and, therefore, all the data analysis functionalities provided by the current remote monitoring systems are linked to the features of the implantable devices. It is not possible to carry our complex data analysis and decision making processes that requires the access to past medical history or the current condition of the patients. iCARDEA Platform will extend these platforms by enabling complex clinical decision making based on the clinical data gathered from CIEDs, EHRs and also PHRs.

These platforms cannot be conceived as stand-alone products as their performance is directly depending on the devices and cannot be used for the follow-up of patients who are not using a particular CIED. This sets the target market of these platforms as the same target market of the implantable devices, as both products co-exist together for the treatment or secondary prevention of cardiac arrhythmias and heart failure.

The current monitoring systems for CIEDs are providing their main services to the medical professionals. While the clinicians have access to all the information and reports available in the different providers' web platforms, the patients do not intervene directly in the data acquisition unless it is strictly necessary and they are not required to check the information or the reports available. The system aims to be transparent to the patient and to be a support tool for those who are involved in the patient device follow-up.

Even if the final users of the devices themselves are the patients suffering the aforementioned conditions, they do not play a significant role in the process of selection and purchase of the products. The decision making processes affect mainly the professional side, involving the physicians, the hospitals and the health administration at different levels, depending on the health care system structure.

iCARDEA, on the other hand, aims to empower the patients to play an active role in their health care. By connecting the manufacturers' web services and integrating them with the EHRs and PHRs, not only the physicians will obtain the benefit that this represents in terms of improving their knowledge for diagnose and treatment, but also the patients will turn into active actors supporting those decisions. This may result in the patients having more influence in the processes of choice and purchase of the products too.

The widening of the data that will be provided to and handled by the medical professionals also opens the possibility to use this system to follow up patients before they are recommended to use a CIED, which also broadens the target market for the platform.

2.3.1.4 Identification of potential customers

iCARDEA project is developing a platform capable to integrate and manage CIED data from different vendors. This platform allows potential users to manage patients with implantable CIED under the same umbrella. Tools for automatic follow-ups based on clinical guidelines are developed and will be used by the system.

From this point of view the potential customers of the system would be the physicians and caregivers that would use the system, however regarding the benefits of iCARDEA the most beneficiated of the system would be patients, because they will receive constant care and probably less on clinic follow up and more remote follow-up. But also the health care providers, the healthcare systems will reduce costs by using such a system which is also an important benefit for the user and also an important added value for the system.

Vendors can also be a potential customer as they win value and attraction when their proprietary systems and services can be accessed by a standardized interface reducing the burden of special equipment and software that a hospital needs.

At the same time, the fact of deploying a complete system does not mean it makes the current caring processes more efficient in terms of saved time and subsequently money. In some occasions doctors keep their patients practising the usual follow-up routine along with the same revisions regardless of whether the patient has already been remotely followed-up by his cardiologist / electrophysiologist. It is not easy to change the current processes in hospital units to make them more efficient as they can be to generate the benefits and cost savings the usage of the data management systems entail.

Enabling the integration of vendor systems with others already existing is also a big opportunity for vendors because at the same time it enables potential changes and enhancements of current processes and it improves the market penetration of vendors

systems. That is another reason why a platform such as iCARDEA could provide added value to a clinical organization.

Another important outcome of the iCARDEA project would be standardization of the clinical follow-up and remote follow-up following electronic health guidelines developed by the project. This would be also an important outcome of the project for the potential customers and users of the system.

2.3.1.5 Collaborators & Competitors

The iCARDEA platform offers a collection of services that include the integration of data coming from different CIED manufacturer platforms, merging them into a single interface for the medical professionals. For this, the collaboration of all the competitor vendors is required, at least, to offer data in a compliant standard of interoperability so that it can be presented through this external interface.

On top of this, the implication of the administration in the different health centers and health care systems is necessary to allow the connection of this platform into the current electronic records already available and under use, so that the adoption of the system and the data exchange is possible in real practice.

There are no direct competitors for iCARDEA in Europe currently, as a single interface for CIED platforms is not available in the market. Still, there is a big potential for partnership with developers of chronic disease follow-up platforms that are currently being adopted by different centers and even local administration following strategies for addressing the burden and problems that chronic diseases represent to the public health care systems.

2.3.1.6 Market Prospect

This project brings together device-related, medical data as well as patient self-entered information that will help enhancing the outcome of the therapy, which could potentially influence the pacemaker and ICD business.

By using remote care technology on a broad basis, usability and practicability of delivered technology and parameters will be further improved and results could influence future designs and developments.

One of the main potential applications of iCARDEA in the industry of the CIEDs is the possibility to use new structured, semi structured and unstructured data in performing analytics by means of using different data mining methodologies, to extract more intelligence that is currently not available, such as the prediction of adverse and critic events or a more accurate evaluation of the health status of the patients.

2.3.2 Clinical Decision Support System: Personalized Adaptive Care Planner and Execution Engine for CIED Recipients

Clinical decision support provides clinicians, staff, patients, or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times to enhance health and health care³. Clinical guidelines provides decision support to the health care practitioners with patient care decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances as they contain a set of directions or principles to assist. Therefore, they can be effective in increasing physician compliance with recommendations. However, dissemination of practice guidelines on paper alone has generally proved to be insufficient. Computerised decision support to individual professionals at the point of care is one of the most effective methods of improving decision making and currently there are some computerised clinical guidelines in screening for cancer, in vaccination, in management of diabetes, for ordering (laboratory) tests, for dosing and prescribing of drugs. Furthermore, integrating them with clinical information systems, electronic health records (EHR) applications and other data providers have the potential to improve care and should be part of any comprehensive approach to improve quality.

For a market analysis of the existing personalized adaptive care planner and execution engines, we mainly investigated journal databases, and proceedings of the most relevant conferences in the domain.

2.3.2.1 Market Description

Although clinical practice guidelines are designed to promote effectiveness and inhibit ineffective treatments, the guidelines are not being widely used in daily practice. The reasons for this can be summarized as “the failure of integration of guideline implementations with clinical workflows”⁴ and “the complexity of fully integrated decision support systems due to the nature of heterogeneous set of clinical applications need to be involved in the decision process”⁵.

There are some international organizations which create and maintain repositories with guidelines in different domains (e.g., oncology, cardiology, paediatrics) such as National Guidelines Clearinghouse⁶ and National Library of Medicine HSTAT⁷. In addition to these, there are some tools for executing personalized care plans in the market as described in Section 2.3.2.2. However, only a few systems progressed beyond the prototype stage and the research laboratory and have commercially strengthened. While

³ Osheroff J, et al. A Roadmap for National Action on Clinical Decision Support, June 2006
<http://www.amia.org/inside/initiatives/cds/cdsroadmap.pdf>.

⁴ M. Fieschi, et al., “Medical decision support systems: Old dilemmas and new paradigms?,” *Methods Inf. Med.*, vol. 42, no. 3, pp. 190–198, 2003

⁵ M. Entwistle and R. N. Shiffman, “Turning guidelines into practice: Making it happen with standards—Part,” in *Healthcare and Informatics Review Online*. Auckland, New Zealand: Enigma, Mar. 2005.

⁶ <http://www.guideline.gov/>

⁷ <http://hstat.nlm.nih.gov/hq/Hquest/screen/HquestHome/s/58442;jsessionid=D08973271C7108DE42B126529FBFA086>

modelling and converting guidelines into computer-interpretable format are currently active research areas, the execution of guidelines is a less developed field. The iCARDEA project is mainly focused on developing a system that allows the automatic (or semi-automatic) execution of guidelines. Within this respect, in next section, the analysis of clinical guideline execution engines is realized. The inspected tools are Arezzo™, SmartCare™, GLARE, GLEE, HeCaSe2, and SAGE, most of which are research oriented and developed by computer science research groups.

2.3.2.2 Current situation

Arezzo™ is a commercial product to create, visualize and enact PROforma guidelines developed at Cancer Research, UK. The Arezzo® clinical decision support technology enables the design, creation, and execution of clinical pathways, guidelines and patient care protocols that present patients and medical professionals with evidence-based advice for each individual patient. Arezzo guides the user through the collection of the data required to assist in making decisions about the clinical actions that should be taken both in simple cases and in highly complex patient care situations. This is especially useful for multi-disciplinary care pathways for patients with a wide range of signs and symptoms.⁸

SmartCare™⁹ is a generic framework built by Dräger Medical for allowing clinical guidelines and protocols to be executed by automatically operated medical devices. The system is said to be extensible theoretically, but currently it was applied for the automated control of a mechanical ventilator. The underlying methodology comprises two sequential phases and seamlessly combines knowledge engineering with expert system techniques, e.g. rule-based forward chaining and temporal reasoning, for clinical guidelines modelling and software engineering techniques for source code generation and for integration to the target platform¹⁰.

GuideLine Acquisition, Representation and Execution (GLARE) is a system to acquire and execute clinical guidelines, developed at the Computer Science Department of the Università del Piemonte Orientale of Alessandria (Italy) in cooperation with Azienda Ospedaliera San Giovanni Battista of Torino (one of the largest hospitals in Italy). GLARE supports the decision-making process of users/physicians faced with various alternatives in the guidelines. Additionally through a "what if" facility, a form of hypothetical reasoning which allows users to gather relevant decision parameters (e.g., costs, resources, times) from selected parts of the guideline in a semi-automatic fashion, may guide healthcare practitioner by presenting not only locally available data but also other relevant data stemming from alternative pathways¹¹.

⁸ <http://www.infermed.com/index.php/arezzo>

⁹ http://www.openclinical.org/aisp_smartcarePS.html

¹⁰ Mersmann S and Dojat M. SmartCare - Automated clinical guidelines in critical care. In: R. Lopez de Mantara and L. Saitta, eds., 16th European Conference on Artificial Intelligence (ECAI'04). IOS press, Valencia (ES) 22-27 Aug, 2004:745-749

¹¹ Supporting physicians in taking decisions in Clinical. Guidelines: the GLARE's "what if" facility, Proc. AMIA. 2002, 772-776, 2002.

GLIF3 Guideline Execution Engine (GLEE)¹² is a tool for executing guidelines encoded in the GLIF3 format. In addition to serving as an interface to the GLIF3 guideline representation model to support the specified functions, GLEE provides defined interfaces to electronic medical records (EMRs) and other clinical applications to facilitate its integration with the clinical information system at a local institution. The execution model of GLEE takes the “system suggests, user controls” approach. According to this approach, GLEE suggests which actions can be performed and decides which actions (whose preconditions are satisfied) can change the state from started to finished. However, the user can control the process, and it can initiate, confirm or decide different transitions between actions¹³.

HeCaSe2 is an agent based clinical guideline engine which let different entities in a healthcare organisation (i.e. medical centres, departments, services, doctors, patients) act as agents with different roles in a dynamic multi-agent system. This system provides services both to patients for booking a visit with a doctor, or looking up the medical record and to doctors for supporting in the application of a guideline to a patient. Guidelines are used to provide a high level supervision of the activities to be carried out to address a specific pathology.

Standards-based Sharable Active Guideline Environment (SAGE)¹⁴ was formed to create a methodology and infrastructure required to demonstrate integration of decision-support technology for guideline-based care in commercial clinical information systems¹⁵. Innovative features of the SAGE guideline model include organization of guideline recommendations, use of a suite of data models and services as interfaces to clinical information systems, and systematic use of standard terminologies. Furthermore, it provides deployment-driven guideline modelling methodology.

2.3.2.3 Target market

Cardiovascular Disease (CVD) is the main cause of death in the European Union (EU) accounting for over 2.0 million deaths each year. 42% of all deaths in the EU, 45% deaths in women and 38% deaths in men, are from CVD as shown in Figure 4 and Figure 5.

¹² http://people.dbmi.columbia.edu/homepages/wandong/homepage20030326_files/GLEE.htm

¹³ D.Isern, M.Millan, A.Moreno, G.Pedone, L.Z.Varga, Home Care Personalisation with Individual Intervention Plans, In Proc. of WS K4HeLP ECAI08, D.Riaño (ed), pp. 50-54, July 2008.

¹⁴ http://www.openclinical.org/gmm_sage.html

¹⁵ Tu SW, Campbell JR, Glasgow J et al. The SAGE Guideline Model: Achievements and Overview. J Am Med Inform Assoc. 2007 September-October;14(5):589-598.

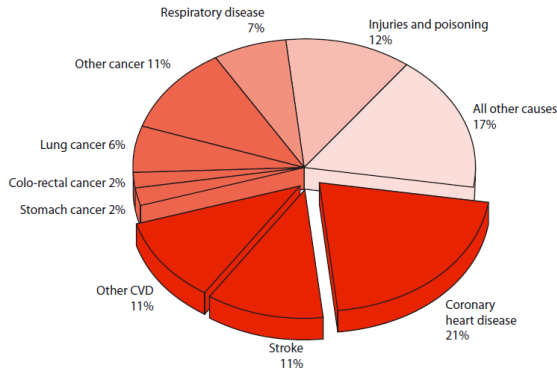


Figure 4 Deaths by cause, men

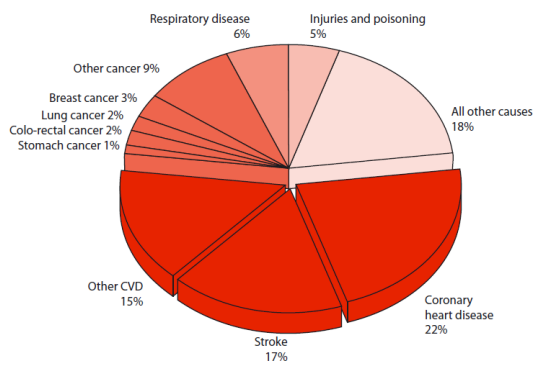


Figure 5 Deaths by cause, woman

According to consensus statement¹⁶ prepared jointly by the Heart Rhythm Society and the European Heart Rhythm Association, more than 800,000 patients in Europe have implanted pacemaker, ICD or CRT devices for the treatment or secondary prevention of cardiac arrhythmias. In addition, the number of follow-up visits for patients with an implanted cardiac device exceeds 5.8 million visits each year, and that number will continue to increase as more devices are implanted.

The exponential growth rate of cardiac devices implantation as shown in Figure 6 calls for new methods of long-term surveillance with a view to optimize patient safety and care, alleviate the burden of caregivers, lower health care cost through ICT support¹⁷.

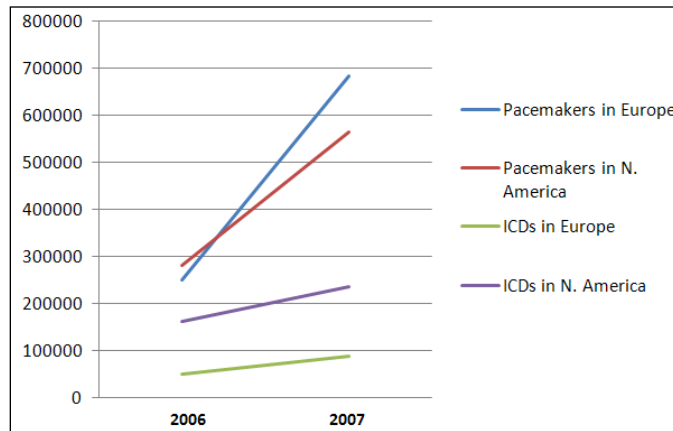


Figure 6 Growth rate of CIEDs in EU and North America¹³

The iCARDEA Project addresses these challenges by developing an integrated intelligent platform for continuous, remote and personalized monitoring the cardiac arrhythmia patients with implanted devices. Indeed, the personalized adaptive care planner and

¹⁶ HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIED): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations

¹⁷ Remote, Wireless, Ambulatory Monitoring of Implantable Pacemakers, Cardioverter Defibrillators, and Cardiac Resynchronization Therapy Systems, A. Lazarus, Pacing and Clinical Electrophysiol. 2007 Jan;30 Suppl 1:S2-S12

execution engine that will be developed within the scope of the iCARDEA project aimed to be generic. However, in the project a more specialized version tailored to cardiac arrhythmia clinical guidelines will be in focus. The iCARDEA personalized adaptive care planner and execution engine as exploitable asset will target market for cardiac arrhythmia patients with implanted devices. Therefore, target market will be healthcare industry specialized in remote monitoring of cardiac patients such as hospitals, rehabilitation centers.

2.3.2.4 Identification of potential customers

Personalized adaptive care planner and execution engine are intended to ensure consistent high quality clinical practice and provide some benefits to both patients and health care managers. Possible customers are health care professionals, doctors and guideline authors. For healthcare professionals the use of clinical guidelines can improve the quality of clinical decisions and activities and, in consequence, also improve the patient outcomes through the knowledge provided and help doctors to use the clinical knowledge about the patient at the appropriate point of his care. For guideline authors, modeling tool encourages to employ rigorous formal techniques, which help to ensure syntactic, logical and medical validity of clinical guideline.

Furthermore, nowadays some treatments need knowledge integration of various team and medical care is often provided not by individual professionals but by multidisciplinary teams. Whereas individual decision making is mainly a cognitive process, decision making in teams is additionally influenced by the social context, such as the interpersonal relationships within the team¹⁸. Therefore, this tool will be a good asset for multidisciplinary teams working on remote monitoring of cardiac patients with implemented devices as guidelines provides a systematic approach to integrate disparate and distributed knowledge. Such functionality is particularly important for healthcare facilities working on a fixed budget that need to optimize the time of their physicians, while at the same time increasing the quality of care provided to increasing number of patients with a CIED implant.

2.3.2.5 Collaborators & Competitors

In order to facilitate adoption and more extensive use of iCARDEA personalized adaptive care planner and execution engine, we need collaboration of national or other payer initiatives that provide incentives for clinical decision support deployment and technological development institutes that use more widespread electronic medical records, patient records or CIED data with clinical decision support capabilities. Currently, there are also some initiatives in insurance companies' incentives to make use of clinical decision support systems more attractive.¹⁹ With collaboration with these insurance companies deployment of personalized adaptive care planner and execution engine can be expanded.

¹⁸ Effect of guideline based computerised decision support on decision making of multidisciplinary teams: cluster randomised trial in cardiac rehabilitation, *BMJ* 2009;338:b1440 27 April 2009, doi:10.1136/bmj.b1440

¹⁹ Medicare Improvements for Patients and Providers Act of 2008, H.R. 6331: 2008.

2.3.2.6 Market Prospect

Homecare is more cost efficient than nursing home or hospital care, and every patient would rather stay at home if possible. Through remote monitoring via the help of (semi)automatically executing clinical guideline healthcare staff can utilize the action recommendations, scheduling notes to alert other staff. Furthermore, the process flow can also provide users with many reminders, including when a CIED is out of order, when a supervisory visit is required, or when a procedure needs to be completed during a visit. Worldwide homecare information systems markets at \$2 billion in 2009 are expected to reach \$4.8 billion by 2016²⁰. An important part of this remote home healthcare system is clinical guideline execution engine which lets the situation of the patient to be kept under control according to medical knowledge embedded in the guidelines and to be monitored.

However, all previously deployed guideline based decision support systems have shown impact and improvement in current clinical practices, the guideline-based clinical decision support systems have not yet achieved to be both accepted widely in current clinical practice and go beyond clinical trials as presented above in the current situation section. To address this problem, in iCARDEA we aim to provide a care plan execution environment as a decision support mechanism enabling remote monitoring of cardiac patients that is already integrated with the underlying clinical information systems and CIED data portals through interoperable interfaces.

2.3.3 Personal Health Record (PHR), PHR Systems and Patient Empowerment

A detailed description about Personal Health Records (PHRs), PHR systems and Patient Empowerment in a more technical way (including functionalities) can be found in the iCARDEA deliverable “D3.2 - State of the Art: Technologies and Architectures”. The following section will complete this description based on a non-technological view. In connection with PHRs, Patient Empowerment often can be seen as an integrated function of PHR systems.

2.3.3.1 Market Description

A PHR is not the same as an Electronic Health Record (EHR). The latter is designed for use by health care providers and is electronic based. Whereas a PHR means different things to different people and can be delivered on different platforms and not only electronically. A PHR can be paper-based, PC-based (desktop-based solutions in general lack the ability to easily exchange information between consumers and healthcare

²⁰ Homecare Information Software and Services Market Shares Strategies, and Forecasts, Worldwide, 2010 to 2016,
http://marketpublishers.com/report/services/other_services/homecare_information_software_n_services_market_shares_strategies_n_forecasts_worldwide_2010_to_2016.html

providers), Internet-based or mobile-based (e.g. accessible via Smart Phones)²¹. Increasingly, a PHR is an electronic repository in which a person can store his or her health-related information securely and privately, and share that information with health care provider.

On this note a Personal Health Record (PHR) is typically an electronic, lifelong record of health information that is initiated and maintained by an individual. These individuals own and manage the information in the PHR, which comes from both their healthcare providers and the individuals themselves²². A PHR allows individuals to become a more active partner in their own healthcare, and gives a person up-to-date information when and where he needs it.

Looking at applications, PHR systems can either be information systems of e.g. provider organisations that integrate or connect a tethered PHR with their systems. Persons who have such a PHR can view e.g. an abstract or parts of their health record and in some cases, patients may have the right to add information e.g. about their health status. Another approach is standalone PHR systems. In these cases, individuals must type in, scan, and insert parts of his medical records by himself, e.g. diagnoses, treatments, medication lists. Typically, this type of PHR system is portable and can be moved to health care providers.²³

PHR system can contain a diverse range of data. Usually they include information about:²⁴

- ◆ allergies and adverse drug reactions
- ◆ medications (including dose and how often taken) including over the counter medications and herbal remedies
- ◆ illnesses and hospitalizations
- ◆ surgeries and other procedures
- ◆ vaccinations
- ◆ laboratory test results
- ◆ family history
- ◆ observations of daily living

In addition to storing an individual's personal health information, some PHRs provide added-value services such as drug-drug interaction checking or electronic messaging between patients and providers.

²¹

http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_027539.hcsp?dDocName=bok1_027539

²² <http://www.hoise.com/vmw/07/articles/vmw/LV-VM-08-07-26.html>

²³ <http://www.chcf.org/~media/Files/PDF/P/PHRPerspectives.pdf>

²⁴ <http://www.medmemory.com/personal-health-record-comparisons.html>

2.3.3.2 Current situation

The earliest English-language article indexed by PubMed that mentions the term "Personal Health Record" is dated June 1978. In early 2000, the number of articles and recorded instances of PHR implementations also began to increase significantly as PHR systems began to proliferate and be implemented by a growing number of healthcare provider organizations. In 2008, Microsoft and Google entered the PHR market place. Since then, interest in PHRs among health care policymakers and experts has intensified, but consumer adoption is slowly growing.^{25,26}

According to a PHR Market Overview in the US market by Frost & Sullivan over the past decade vendors have offered their PHRs solutions directly to customers. The increasing focus on PHR in the health care industry is driving employers, health insurers, and health care providers to offer a PHR solution in their respective constituencies as an essential part of their competitive strategies. Vendors are still offering their PHR solutions directly to consumers but they are increasingly looking to provide their PHR solutions through these alternative distribution channels. Although customer adoption rates are poised for growth, vendors need to raise customer awareness and convince customers of the distinct value of PHR solutions. Despite low awareness, surveys indicate that customers generally prefer electronic access to their personal health information. This, coupled with the fact that the patient's role is gradually shifting from being passive to active, is driving the uptake of PHR solutions.²⁷

In Europe the European Commission organized in 2007 the "Conference on Personal Health Systems - PHS 2007"²⁸. The vision for Personal Health Systems (PHS) to take healthcare out of the hospital, bring it to the home and embed it into people's lives was clearly articulated at the conference. As in the U.S., they are still in the early stages of deployment in Europe. The following are two key points articulated at the conference:²⁹

- ◆ Successful deployment of PHS presupposes the existence of favourable policy and political support. To obtain this support, there is a need to continue to collect large scale clinical evidence which demonstrates how PHR systems contribute to improved patient well-being, patient safety, quality of care, and affordability.
- ◆ Empowerment of patients and their families through use of health IT systems is critical to the future of healthcare. Again, while there are many isolated success stories, there is a need to collect more evidence and clearly document the cost/benefits. Further collaboration between the U.S. and Europe could accelerate progress.

In summary, although significant scientific challenges still remain for Europe, technology is not any more the limiting factor. Several directions must be explored and education has to play a bigger role to improve performance and disseminate the potential of the new

²⁵ http://en.wikipedia.org/wiki/Personal_health_record

²⁶ <http://www.chcf.org/~media/Files/PDF/P/PHRPerspectives.pdf>

²⁷ <http://www.frost.com/prod/servlet/report-brochure.pag?id=N0FF-01-00-00-00>

²⁸ http://ec.europa.eu/information_society/events/phs_2007/index_en.htm

²⁹ <http://www.hoise.com/vmw/07/articles/vmw/LV-VM-08-07-26.html>

technologies. The deployment has to be done within the European States, but this procedure needs time. With regards to technology, this is no longer the key link in the chain. There are still issues like privacy, interoperability, user-friendliness, reliability and dependability, which need to be addressed.³⁰

With regards to cost/benefits, according to a recent AAFP Report published in May 2006³¹, PHR systems offer a number of potential benefits to patients, their physicians and the health care system. These include:

- ◆ Empowerment of patients – PHRs let patients verify the information in their medical record and monitor health data about themselves. This is in particular very useful for chronic disease management. PHR systems also provide scheduling reminders for health maintenance services.
- ◆ Improved patient-provider relationships – PHRs improve communication between patients and clinicians, allow documentation of interactions with patients and convey timely explanations of test results.
- ◆ Increased patient safety – PHR systems provide drug alerts, help identify missed procedures and services, and get important test results to patients rapidly. PHRs also give patients timely access to updated care plans.
- ◆ Improved quality of care – PHR systems enable continuous, comprehensive care with better coordination between patients, physicians and other providers.
- ◆ More efficient delivery of care – PHRs help avoid duplicative testing and unnecessary services. They provide more efficient communication between patients and physicians
- ◆ Better safeguards on health information privacy – by giving patients control of access to their records, PHRs offer more selectivity in sharing of personal health information.
- ◆ Bigger cost savings – improved documentation brought about by PHRs can decrease malpractice costs. PHRs' ability to reduce duplicative tests and services is a factor here, too.

While PHR systems offer many advantages, they also raise at least two concerns:³²

- ◆ Privacy – often patients are concerned about the privacy of their health information. However, when developed in the right way, electronic PHRs offer security features that can provide better protection than paper-based record systems.
- ◆ Accuracy - involving patients not only in viewing and interpreting but also entering their own data raises the issue of data accuracy. Here again, proper development of the PHR can reduce this concern and actually improve data accuracy.

³⁰ Personal Health Systems: Deployment opportunities and ICT research challenges”, conference report, 2007, http://ec.europa.eu/information_society/newsroom/cf/document.cfm?action=display&doc_id=323

³¹ <http://www.aafp.org/fpm/2006/0500/p57.html>

³² <http://www.aafp.org/fpm/2006/0500/p57.html>

2.3.3.3 Target market

There are a number of PHR software and service providers in the market and choosing a personal health record system that fits the consumers' needs is often a challenge. Choosing a PHR system should be based on long-term consideration because the consumer will be tied with it for a long time. Hence, selecting a PHR system should consider some key features³³:

- ◆ The Basics – ability to add/delete/share/correct current and past medical records. Almost all of the providers already provide these basic features. Additionally, PHR systems must have the ability to control and share information with healthcare providers and family members, with the consent of the customer.
- ◆ Ability to pull medical records automatically from healthcare providers – refers to health problems, prescription drugs, allergies, drugs, etc. With the consent of the consumer, some of the PHR providers can pull records from insurance providers, pharmacies and diagnostic labs. Additionally, some PHR systems offer tools available to convert paper based records into online records and then upload to the PHR.
- ◆ Compatibility with other health recording tools and the ability to share information with healthcare providers – a lot of third party tools and mash-up services are now becoming available providing personalized health and wellness tools. For example, Google Health³⁴ can work with several third party tools that can help to import paper records into the PHR, or it can integrate personal data with a heart attack risk calculator tool. However, the consumer may have to pay for those third party tools although some are available for free.
- ◆ PHR as a communication medium – refers to the ability to share information with healthcare provider, e.g. schedule appointments, get prescriptions, obtain prescriptions without visiting doctor's office, etc.
- ◆ Tool Design and ease of use – the consumer should get quickly familiar with the PHR system. Additionally, if the consumer also wants to have his health information in handheld devices, s/he should make sure the PHR system is compatible with those devices.
- ◆ Proactive health monitoring and alert mechanism – universal availability and reliability were primary goals of storing PHRs online. The current second generation of PHR systems provides several advanced features to help a consumer to take control of his health, e.g. alerts on the own health conditions such as diabetes, high blood pressure reaching certain thresholds or the ability to detect risk factors associated with prescription drugs, over-the-counter medications, and herbal supplements. Currently only few PHR service providers offer health monitoring services. Often such features are offered through third party provider and typically they are not for free.
- ◆ Security and control – refers to security features that ensure the medical information stays protected all the time, while the information is still accessible from anywhere. The consumer has to have full control to his own online health

³³ <http://www.phrreviews.com/how-to-choose-a-phr>

³⁴ <https://www.google.com/health>

records. Furthermore, the consumer should be able to grant access to his friends, family or doctors if he wishes.

- ◆ **Cost and reliability of the software** – some PHR systems are offered free and the rest (this is a minority though) charge a small fee. Those companies offering free services need to generate income. Hence, they are e.g. charging for advanced features, charging the consumers employer or in some rare cases de-personalize and sell health information to drugs companies. In fact, major providers such as Google Health and Microsoft Health Vault offer free and reliable services but do not sell your information. If the consumer uses free software services, he should just make sure to understand the revenue model.

The iCARDEA PHR system seeks to address the above features. Additionally, from the beginning supporting interoperability was of great importance in iCARDEA and patients can include information from healthcare provider or share their own information with their treating physician. But the iCARDEA PHR system will go beyond and will primarily address two target groups

- ◆ **Supporting cardiac patients by providing services for patient empowerment** – the basic instrument for these services is the iCARDEA PHR system including Patient Empowerment services such as for changing behaviour, access to specific information and education material for CIED patients. Additionally, in some situations patients prefer face-to-face communication and iCARDEA offers both, online and offline services, depending on the patients needs.
- ◆ **Supporting physicians by offering a service for additional patient information** – physicians can also benefit from the Patient empowerment services. If the patient agrees he can share recorded information (e.g. a food log, logs with recordings about blood pressure or weight) with his physician. This information can be an additional input for the individual health care process.

2.3.3.4 Identification of potential customers

Beyond doubt the primary group of customers is the patient or in a more general way the individual citizen who will manage his personal health data on an electronic basis. An additional group of customers are health professionals. They play an important role in ensuring that PHRs help patients achieve health care goals. Supporting that they need to learn how to incorporate patients' observation and treatment responses into clinical encounter based on data collected with devices at the patients' home. PHR systems or information systems including PHR components can support this with sophisticated interfaces.³⁵ Another group of potential customers are vendors aiming to offer interfaces to PHR system or to include PHR functions in their Personal Health Applications. Finally, governments can also be customers. They may want their citizens to access their own records, e.g. through national health portals.

Currently there are several PHR business models – some charge the consumer directly for a PHR, others charge the consumer's employer, and still others give them to patients or

³⁵ <http://www.chcf.org/~media/Files/PDF/P/PHRPerspectives.pdf>

customer without charge to build loyalty. Those models that generate revenue from PHRs do so through subscriber fees, advertising, or transaction or licensing fees.³⁶

According to a White Paper about PHRs³⁷ PHR systems offer a number of potential benefits for various stakeholders:

Stakeholder	PHR Benefits
Consumers	<ul style="list-style-type: none"> ◆ One of the most important PHR benefits is greater patient access to a wide array of credible health information, data, and knowledge. Patients can leverage that access to improve their health and manage their diseases. ◆ Patients with chronic illnesses will be able to track their diseases in conjunction with their providers, promoting earlier interventions when they encounter a deviation or problem. ◆ Improved communication using a PHR system will make it easier for patients and caregivers to ask questions, to set up appointments, to request refills and referrals, and to report problems. ◆ PHR systems can make it easier for proxy caregivers, such as family members, to better care for patients. ◆ PHR systems can provide an ongoing connection between patient and physician. Patients value being able to readily access test results and better communication with clinicians
Clinicians	<ul style="list-style-type: none"> ◆ Patients entering data into their health records can elect to submit the data into their clinicians' EHRs. Having more data helps clinicians to make better decisions. ◆ The PHR may also become a conduit for improved sharing of medical records. Patients who are more engaged in their health are more active participants in the therapeutic process. ◆ PHR-mediated electronic communication between patients and members of their health care teams can free clinicians from the limitations of telephone and face-to-face communication and improve the efficiency of such personal contacts.
Others	<ul style="list-style-type: none"> ◆ Potential benefits of PHRs to payers and purchasers of health care may include lower chronic disease management costs, lower medication costs and lower wellness program costs.

2.3.3.5 Collaborators & Competitors

In 2007, the Markle Foundation estimates that nearly 200 PHR products were available.³⁸ They vary in terms of architecture, format, features, functions and business models. Many

³⁶ <http://www.chcf.org/~media/Files/PDF/P/PHRPerspectives.pdf>

³⁷ Tang, Paul / Ash, Joan / Bates, David / Overhage, Marc / Sands, Daniel: Personal Health Records: Definitions, Benefits, and Strategies for Overcoming Barriers to Adoption, JAMIA 2006;13:121-126 doi:10.1197/jamia.M2025

early adopters of Web-based PHR systems were people who managed their own chronic conditions or the chronic conditions of relatives or wanted to give care providers access to their medical information in an emergency.³⁹ Although there are already existing PHR systems, not all of them are electronically available for integration into health products. Also, the aggregation of patient data across national borders by Google Health and Microsoft Health Vault are leading to legal and ethical roadblocks, and will prevent uptake of these services. Therefore, to be marketable, PHR Systems should provide components for new health application products offered by various vendors. National systems offering EHR solutions are likely to provide more services to patients and will look to adaptable services and components. Another important criterion is the ability to support interoperability of patient data based on established standards. Applications such as Google Health or Microsoft Health Vault integrate a number of third party applications; however, they do not use IHE PCC profiles for exchanging data among applications and in particular exchanging data with clinical systems. This section will list some relevant examples of PHR systems:

Google Health⁴⁰ – online PHR, free account

Google released its online PHR system in 2008. The service allows Google users to volunteer their health records – either manually or by logging into their accounts at partnered health services providers – into the Google Health system, thereby merging potentially separate health records into one centralized Google Health profile. Google Health is freely available for personal use and can pull medical data from your insurance companies, physicians and hospitals automatically. Additionally, Google has worked with many healthcare providers and application software companies to integrate into their electronic health records platform, e.g. MedNotes with Drugs.com⁴¹ which is a free medication management system. An interesting benefit of Google Health is the ability to pull medical records from primary care providers, insurance companies, pharmacies, laboratories and hospitals. The consumer can link his online personal health records to a number of such health care providers and pull his data instantly. This will save time, centralize health records in one place, and reduce the errors if the data were entered manually. Finally, Google Health is also integrated with few companies that will convert paper records and import into the PHR.⁴² On June 2011 Google announced it is retiring Google Health in January 1, 2012. Data will be available for download through January 1, 2013. The reason of abandoning the project is the lack of widespread adoption.⁴³

Microsoft Health Vault⁴⁴ – online PHR, free account

Microsoft PHR works as a platform and it has numerous third party apps built on top of it. For example, the consumer can use personal health devices such as pedometer to monitor his health and fitness. Microsoft has also released another personal health

³⁸ <http://www.chcf.org/~media/Files/PDF/P/PHRPerspectives.pdf>

³⁹ <http://www.chcf.org/~media/Files/PDF/P/PHRPerspectives.pdf>

⁴⁰ <http://www.google.com/health>

⁴¹ <http://www.drugs.com/>

⁴² <http://www.phrreviews.com/google-health-phr-review>

⁴³ <http://googleblog.blogspot.com/2011/06/update-on-google-health-and-google.html>

⁴⁴ <http://www.healthvault.com/Industry/index.aspx>

services product called My Health Info⁴⁵ which is an interactive and customizable dashboard that allows people to view all their health information: blood pressure, blood glucose, BMI, immunizations, allergies, lab results, medications, steps walked, health articles and more, in a single, organized, and convenient location. It used the HealthVault as a platform so information updated in one product is automatically updated in the other. This service offers tools and widgets to upload, organize and monitor health information stored in their personal HealthVault accounts. The service also allows people to research medical concerns, read the latest health news, gain guidance from medical experts, learn about nutrition, and monitor conditions such as high blood pressure or diabetes.

Indivo X⁴⁶ – standalone PHR, open source, free account

Indivio is a platform for personally controlled health records (PCHR) and enables an individual to own and manage a complete, secure, digital copy of his health and wellness information. This includes e.g. information about medication, family medical history, immunizations, lab results, etc. Furthermore, Indivio integrates several third-party applications, e.g. Dossia, an open source PHR service offered by some of the largest employers in the U.S. (e.g. A.T., Sanofis-aventis).

Tolven⁴⁷ – online, free account

Tolven offers an electronic health record for both - An electronic Personal Health Record (ePHR) for consumers and an electronic Clinician Health Record (eCHR) for healthcare providers. The ePHR allows consumer to create, view, store and share healthcare information about themselves or on behalf of those they look after (e.g., aged relatives, children and those with disabilities) and to communicate with their care providers. Tolven also offers real-time access to healthcare records via smartphones.

WebMD Health Manager⁴⁸ – online, commercial

The WebMD Health Manager is a PHR that enables individuals to better manage their personal health and well-being. It includes a set of health risk assessments, goal-setting and tracking tools for monitoring progress and results, messaging and reminders, lifestyle improvement programs, clinically reviewed health information references for health or medical question and decision support for understanding the risks and benefits of medical procedures and treatment options. One interesting feature is the HealthQuotient™ which is a health assessment service that scores the health status of the user and provides recommendations for improvement and beneficial behaviour changes.

Project HealthDesign⁴⁹ – open source (LGPL)

Launched in 2006, Project HealthDesign is a national program of the Robert Wood Johnson Foundation⁵⁰ created to stimulate innovation in personal health information technology. The first-generation PHRs functioned primarily as data repositories. In the meantime Project HealthDesign views PHRs as springboards for action and improved

⁴⁵ <http://my-health-info.health.msn.com/MSN/Default.aspx>

⁴⁶ <http://indivohealth.org/>

⁴⁷ <http://www.tolven.org/>

⁴⁸ <http://www.webmd.com/health-manager>

⁴⁹ <http://www.projecthealthdesign.org/403826>

⁵⁰ <http://rwjf.org/>

health decision making. Multidisciplinary teams create a range of tools addressed specific and complex self-management tasks, e.g. a cell-phone-enabled medication management system to alert children when to take their medicine or a personal digital assistant that collects and supports self-reported pain and activity data.

myPHR⁵¹ – paper-based, free

The American Health Information Association (AHIMA) is a national nonprofit organization dedicated to the effective management of personal health information. It has put together a Web site with a set of procedures and forms a customer can use to construct his own personal health record. myPHR itself is a paper-based PHR and offers several PHR forms which are available as templates in different languages (e.g. English, Spanish) for different target groups (e.g. adults, children). Additionally, the Web site offers a service for selecting PHR systems based on criteria like format (Web-based / software-based / paper-based) and cost (free / for purchase).

LifeSensor⁵² - online PHR, commercial

LifeSensor is a Web-based personal health record allowing patients electronically manage, control, and coordinate lifelong health. Other health team members whom patient authorize can also access, update or add information when they need it from any location. LifeSensor includes among other features a drug interaction check, vaccination planner and an online fitness trainer. Additionally, in an emergency, when every second counts, potentially harmful treatments can be identified and avoided.

The LifeSensor service has been discontinued effective 2011-12-31, but the provider, ICW, still offers the underlying software as a product, permitting other organizations to set-up and run adapted versions of the LifeSensor PHR.

In Europe the growing interest in PHRs has led to the developments on the national level as well as smaller scale initiatives. The main purposes of introducing PHRs in Europe have been to empower patients with a sense of ownership of their care and to improve communication, between both patients and clinicians, as well as between different clinicians involved in that person's care. Two European examples beyond LifeSensor are:

HealthSpace⁵³ (UK) – HealthSpace is a free, online personal health organiser providing an integrated, secure patient portal for anyone living in England, aged 16 or over. HealthSpace allows users to manage health and lifestyle by keeping track of information such as your weight, blood pressure, cholesterol levels and medications. Additionally, HealthSpace offers an online service for choosing and booking hospital appointments and a calendar to keep track of appointments and events.

akteonline.de⁵⁴ (D) – the aim of this project from the University Hospital Münster was to design and develop a personal electronic health record in order to support patient empowerment and additionally to enhance their communication and information exchange with health professionals. akteonline.de includes among others a forum for

⁵¹ http://www.myphr.com/index.php/start_a_phr/choose_a_phr/

⁵² <http://www.LifeSensor.com/>

⁵³ <https://www.healthspace.nhs.uk/>

⁵⁴ <https://www.akteonline.de/>

experience exchange, medication, preventive medical checkup and a service for importing data.

2.3.3.6 Market Prospect

Looking at the current challenges in healthcare (e.g. increasing age of the population, increasing costs, demands for new treatment) it becomes clear that the current healthcare system must evolve from the doctor-centered production system of today to a more holistic, integrated person-centered system of the future. We must better understand that each of us is the primary healthcare provider for ourselves. And we have to recognize that the whole person must be treated: mind, body, and spirit. PHR systems will play a key role in this impending change.⁵⁵

PHRs serve as a hub for information about and for patients. Today PHRs will evolve into a suite of devices and applications enabling consumers not only to acquire, store, manage and interpret health information, but also to take appropriate health actions. And the information will be accessible whenever and wherever a patient needs it. Brennan⁵⁶ forecasts two possible paths for PHRs in the next three to five years. One will involve developing better links between health records containing a patient's observations and the records his clinician keeps. The other will entail a greater proliferation of more clinically useful home-monitoring and alert systems as home electronics mature. Advanced PHRs might typically include:⁵⁷

- ◆ Information about an individual's health status, health practices and use of health services
- ◆ Patient preferences for services
- ◆ Decision logics from a person's health plan that initiate alerts, warnings or recommendations when clinical findings exceed the desired boundaries
- ◆ Observations of individuals about physical and social environments
- ◆ Rules regarding privacy and information access
- ◆ Middleware tools that manage identity, e.g. translate data from different applications

A growing awareness and competence in the use of computers and the Internet will support electronic information management in health care. Additionally, there is also a growing national awareness for safer and better-coordinated health care based on electronic patient records. An example is the European eHealth project epSOS⁵⁸ which include several national institutions from different European countries. The project focuses on electronic patient record system and in particular on medication records. However, future developments may require policy changes. Law and policies must give patients and care providers' confidence about data privacy. Furthermore, there are still challenges (more organisational than technological) for exchanging patient data between the different stakeholder in health care, e.g. health provider or patients.

⁵⁵ <http://www.hoise.com/vmw/07/articles/vmw/LV-VM-08-07-26.html>

⁵⁶ Patricia Brennan in Gearon, Christopher: Perspectives on the Future of Personal Health Records, 2007

⁵⁷ Patricia Brennan in Gearon, Christopher: Perspectives on the Future of Personal Health Records, 2007

⁵⁸ <http://www.epsos.eu/>

Over the next 10-15 years Groen et al⁵⁹ see an extensive use of information system including EHR and PHR, in particular by healthcare organisations. There can be a number of events, not yet predictable, which can influence (accelerate / decelerate) this development, e.g. security problems, complexity, lack of interoperability, high cost, ease of use or rate of change in reengineering medical business practices. However, from the patients' point of view (Groen et al in 2007) the evolution of PHR system in the United States may look like the following vision:

- Crawling** (2007) the PHR on a personal computer – it is linked to application like MS Word and Excel and contains most of a person's medical information. Less than 2% of the population using PHRs.
- Walking** (2010) the PHR is embedded in mobile phones, PDAs or Smartphone – with full-time connection to the Internet, capable of scanning for needed health and medical information programmed into the support system. Less than 10% of the population using PHRs.
- Jogging** (2015) the PHR has evolved into the complete medical record interfaced to EHRs used by their healthcare provider organizations – it may include a digital nurse that continually seeks health and medical information of patients and processes real-time biometric information from implanted biosensors. More than 20% of the population using PHRs.
- and Beyond** (2020) The PHR as a secure interactive Internet-connected service – combined with a portable virtual doctor with artificial intelligence, that provides full access to medical history and all necessary real-time biometric information being collected via intelligent clothing and implanted biosensors. The virtual doctor has arrived for people with the specific medical needs that require such services. Well over 50% of the population using PHRs

Figure 7 Groen's Evolution of the PHR System

From this review, it is clear that there is a great demand for interoperable patient data and for electronic services to manage patient data. Patient empowerment needs patient data and information which are electronically available for the patients. The access to patient information increases the control that patients can have in their healthcare. The iCARDEA Patient Empowerment Framework will facilitate the management of patient data for the patients by several services and hence, improve the compliance. The access to personal health data and disease-related information will support cardiac patients in their personal health management and will enable better decision making.

2.3.4 Interoperability Interfaces for CIEDs

The interoperability of healthcare information systems is a growing need as the systems get more and more complex and feature-rich. Looking at the CIED devices, this is the

⁵⁹ Groen, Peter / Goldstein, Douglas / Nasuti, Jaime: Personal Health Record (PHR) Systems: An Evolving Challenge to EHR Systems, 2007, <http://www.hoise.com/vmw/07/articles/vmw/LV-VM-08-07-26.html>

same. The CIEDs observe the heart and record their own activity. This information is transmitted to the vendors who analyse the data and allow the physicians in the hospitals to check-up their patients before they attend their periodically checkups. The general problem is that each vendor has its own software system that the physician has to interact with and a hospital is working with more than just one vendor of CIEDs. To solve this issue and to optimize the follow-up process the data has to be collected in a central place, to make the work of the physicians easier and more cost efficient.

2.3.4.1 Market Description

More and more CIEDs include remote monitoring features which would allow transferring the status of the device to the vendors. Because the ICD/CRT vendors are in a global competition the global cardiac implants market faces the same problem.

1. Cardiac Implants Market in the US⁶⁰

The US demand for cardiac implants will increase 8.8 percent annually to \$16.4 billion in 2012. Evolving demographic and epidemiological patterns, along with the introduction of new and improved products, will promote growth. Based on aging population trends, the number of persons afflicted with one or more heart conditions is forecast to reach 73 million in 2012, up 1.7 percent per year from 2007. Implants are more effective than pharmaceuticals in treating, managing or preventing such cardiovascular disorders as arrhythmias, congestive heart failure, myocardial infarction, peripheral artery disease, stroke and valvular heart disease. The market for cardiac implants is expected to recover from a sharp decline in coronary drug-eluting stent sales that began in mid-2006 and continued into the fourth quarter of 2007. This decline was due to a number of reports that linked the devices to a slightly greater risk of thrombosis in some post-angioplasty patients. Although the reported risk was only one half of one percent greater than for heart patients who received alternative therapies (i.e., angioplasty with bare-metal stents, coronary bypass surgery, medications), it prompted many physicians to discontinue using drug-eluting stents. This trend will change as new generation drug-eluting stents with smaller struts and a greatly reduced risk of complications reach the market over the next year.

2. Cardiac Implants Market in Europe

Overall the Western European Cardiac Rhythm Management Market earned revenues of \$3.4 Billion in 2008 and is estimated to reach \$7.3 Billion in 2015.⁶¹ According to a consensus statement prepared together by the Heart Rhythm Society and the European Heart Rhythm Association⁶², more than 800,000 patients in Europe have implanted pacemaker, ICD or CRT devices for the

⁶⁰ US Cardiac Implants Market, Freedonia, Jan 2008, <http://www.reportlinker.com/p096399/US-Cardiac-Implants-Market.html?request=news>

⁶¹ "Western European Market for Cardiac Rhythm Management", Frost & Sullivan, Jan 2009, <http://www.researchandmarkets.com/reports/835336/>

⁶² HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIED): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations, Hearst Rhythm Society, San Francisco, May 2008, http://www.theheart.org/documents/sponsorededucation/845119_PressCenter/PDF/HRS_EHRAConsensus.pdf

treatment or secondary prevention of cardiac arrhythmias. In addition, the number of follow-up visits for patients with an implanted cardiac device exceeds 5.8 million visits each year, and the number of cardiac implantable devices has been an exponential growth.

3. **Cardiac Implants Market in China**⁶³

In 2005 China became the 3rd largest national market for medical devices, with a value of \$4.5 billion. In 2006, the overall medical device industry in China saw 15.3% growth – which is expected to continue in the near to mid-term. The market for high end devices, particularly implantable devices such as pacemakers and other cardiac devices grew even more quickly, at about 25%.

Although the industry is seeing rapid growth, the size of the current Chinese market is still relatively small. China accounted for only 2% of 2006 global medical device sales, whereas the U.S. accounted for 40%, EU for 30%, and Japan for 10% of sales. Moreover, on a per capita basis the Chinese market appears even smaller, given that China's population is almost double that of the other three markets combined.

2.3.4.2 Current situation

Currently it is impossible to process CIED data from multiple vendors automatically, if this is possible at all. The problems show themselves as the vendors use proprietary data formats or don't provide export functions that 3rd party developers can use. This prevents healthcare software vendors to implement data interchange protocols between different systems. As more and more CIED vendors are offering products with remote monitoring features, they also offer the clinics and physicians access to their own proprietary web portal or in-clinic gateway servers to the actual CIED vendor system. Physicians are able to access the data of their patients and are informed in case of unusual events or critical errors as those systems also offer notification mechanisms⁶⁴.

The problems are raised by fact that each vendor offers their own web portal that each physician has to log-in to different web portals⁶⁵ utilizing different feature sets and navigation concepts. From the physicians' point of view this will increase the time spent on the follow-up process for each patient. The physician has to look up which CIED has been implanted⁶⁶ on which patient from the hospital information system (HIS), has to log-in to the correct vendor system and so on.

Additional information such as medication or allergies might be needed in the follow-up process. This additional information is normally not available through the HIS but

⁶³ "Implantable Cardiac Devices in China White Paper on Barriers and Inhibitors to Market Growth", Emerging Asia Inc., September 2007, <http://www.emerging-asia.com/en/clientresource/papers/Medical%20Devices%20in%20China%20-%20Growth%20Barriers%20060907.pdf>

⁶⁴ Notifications are send using e-mail or short message service (SMS).

⁶⁵ This also means the user may need to memorize different login credentials.

⁶⁶ Most hospitals work with multiple CIED vendors and over the years the CIEDs will be replaced by newer CIED models. As a result one patient will most likely be implanted with different models from one or more vendors over time.

maintained in (multiple) specialized systems which increase the risk of incomplete and false information in particular over time.

There are ongoing efforts to increase the interoperability of healthcare information systems. This is namely IHE International (<http://www.ihe.net/>), as an international voluntary collaboration of vendors, healthcare providers, regulatory agencies, and independent experts working on improving medical data interoperability in a number of subject areas (domains), which is composed of over 300 member organisations, healthcare IT and consulting companies. IHE promotes the coordinated use of established standards such as DICOM and HL7 to address clinical need in support of optimal patient care.

The IHE domain concerned with electronic medical devices is the Patient Care Devices domain (PCD). As one of IHE PCD domain integration profiles, IDCO has been defined for an intermediary system to send device data from an implantable device such as CIED. The IHE PIX profile has been developed to enable correlation of patient identifiers from different sources, e.g. the hospital information system (HIS), the implant, or the personal health record system. Using established standards makes it easier to implement the interoperability and enable to use information more efficiently.

2.3.4.3 Target market

There are two general options which lead to different potential customers and can be targeted simultaneously:

- 1. CIED data interoperability as a service**

The interoperability functionality can be integrated into a service which offers its functionality to 3rd party applications.

- 2. Application based on the service to integrate additional patient data**

Beside the CIED data interoperability service, an additional application can be developed that supports the data integration and visualisation of additional data sources such as personal health record (PHR) or hospital information systems (HIS). The CIED data is integrated using the CIED data interoperability service described above.

With the interoperability service, the EHR, PHR and HIS software vendors as well as Cardiology software vendors will be targeted. They only need to call the functions provided by the service to integrate it into their products. As the CIED data is returned in a standardized HL7 format, they only need to implement methods to process this format and don't have to write code to query each CRT/ICD vendor system. This will reduce the costs significantly for those software vendors.

The CIED data interoperability service can also be offered to CRT/ICD vendors to enhance their products because it will provide the export functionality that the CRT/ICD vendors might not yet support to their end-users. This will generate an advantage in competition compared to those vendors not yet offering export functionalities. Close collaboration with these vendors is possible and may be required to be able to offer enhanced and specialized functions like raw data exchange (e.g. needed to create charts).

Raw data exchange is currently not offered by the vendors participating in the iCARDEA project but it would allow adding enhanced data analysis functionality.

The main target for an application which features not only the CIED data, but also the data integration of additional sources such as personal health record (PHR) or hospital information systems (HIS) and also visualisation of the data would target the hospitals. The physicians will no longer need to memorize different login credentials for each of the CRT/ICD vendors and no longer have to query e.g. the HIS for the patient data. This will make it easier to prepare follow-up visits and reduces the preparation time for each visit. If data analysis functionality is integrated as well as notification handling for the case of remarkable events (subsection 2.3.4.2), the system directly allows the users to give priority to those patients. Patients with normal data are invited using the general 3 to 6 month time frame. This will help physicians to better manage the important cases and may even help to prevent sudden death if the CIED data already shows abnormality.

2.3.4.4 Identification of potential customers

Based on the products and identified target markets the first customers are the CRT/ICD vendors with international presence. Two of them (Medtronic and St. Jude Medical) are involved in the iCARDEA research project, strengthening their market position.

CRT/ICD vendors (the first three by descending market share in the global ICD market⁶⁷):

1. Medtronic (<http://www.medtronic.com/>)
2. Boston Scientific (<http://www.bostonscientific.com/>)
3. St. Jude Medical (<http://www.sjm.com/>)
4. Biotronik (<http://www.biotronik.de/>)
5. Cameron Health (<http://www.cameronhealth.com/>)
6. ELA Medical – Sorin Group (<http://www.elamedical.com/>)

Beside the CRT/ICD vendors EHR, PHR, HIS software vendors as well as Cardiology software vendors are potential customers.

Cardiology software vendors:

1. Lumedx (<http://www.lumedx.com/>)
For example the product “Apollo Advance” which features e.g. collecting medications of the patients and also reports and analytical tools (<http://lumedx.com/cardiovascular/apollo/index.asp>) could be enhanced by utilizing the CIED data interoperability service.
2. General Electric Healthcare (<http://www.gehealthcare.com/>)
GE Healthcare offers a feature rich tool collection with Centricity Carddas (http://www.gehealthcare.com/euen/iis/products/cardiology/iis_cardiology.html). It support diagnosis and optimized workflow in all areas in cardiology.

⁶⁷ The Implantable Cardioverter Defibrillator (ICD) global market share in 2005: 52% Medtronic, Boston Scientific 26%, St. Jude Medical 20% and others 2% - [http://www.wikinvest.com/stock/St. Jude Medical %28STJ%29#_note-7](http://www.wikinvest.com/stock/St._Jude_Medical_%28STJ%29#_note-7)

3. Schwarzer (<http://www.scharzer.net/>)
The cardioBase evo software from Schwarzer is one solution (<http://www.schwarzer.net/kardio/english/kardiset.htm>) for an integrated data network in cardiology. It supports HL7 based hospital communication as well as pacemaker/ICD clinical modules and device communication with several vendors.

In general all hospitals providing implantation of CIED devices are potential customers of the software suite to help their physicians to handle the patient follow-up process more efficiently.

2.3.4.5 Collaborators & Competitors

Collaborators:

- CRT/ICD vendors
- HIS software vendors because they store general patient data

Competitors:

- CRT/ICD vendors
- EHR, PHR and HIS software vendors
- Cardiology software vendors

The competitors are also collaborators when they have to share information to allow interoperability in their domain. The potential risk of this competition depends on the domain, the vendor position in the market and also the number of competitors. For concrete prospects a thoroughly market analysis including the competitor's overall development is required.

2.3.4.6 Market Prospect

As the numbers of procedures of Cardiovascular Implantable Electronic Devices (CIED) including pacemakers, Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronisation Therapy (CRT) continues to increase constantly, the number of follow-up visits for patients with an implanted cardiac device will increase exponentially. The exponential growth rate calls for new methods of long-term surveillance with a view to optimizing patient safety and care, alleviating the burden of caregivers, and lowering health care costs through ICT support⁶⁸.

To tackle this issue the manufacturers of cardiology devices must invest in research in development to solve these issues. iCARDEA will be helpful lowering the health care costs for the treatment of heart problems like the cardiac arrhythmias and support the expansion on the European Cardiac Rhythm Management.

⁶⁸ Remote, Wireless, Ambulatory Monitoring of Implantable Pacemakers, Cardioverter Defibrillators, and Cardiac Resynchronization Therapy Systems, A. Lazarus, Pacing and Clinical Electrophysiol. 2007 Jan;30 Suppl 1: p. 2-12

2.3.5 Interoperability Interfaces for PHRs

Considering where the potential interoperability interfaces are, at least four are of interest:

1. PHR systems \leftrightarrow EHR systems Data exchange between PHR systems and EHR systems, HIS systems
2. PHR systems \leftrightarrow PHR systems Data exchange between PHR systems
3. PHR systems \leftrightarrow Devices without explicit human interaction. Data exchange between devices without direct human interaction. Implicit feedback, not explicit. Sensors, medical devices, other consumer devices (bathroom scales, blood glucose monitor, blood pressure, cardiology).
4. PHR systems \leftrightarrow Devices with human interaction. Data exchange with explicit and even implicit human interaction Mobile devices; Human device interactivity with mobile devices.

2.3.5.1 Market Description

An important and powerful feature for PHR systems is the ability to exchange patient data with other applications or devices. Interoperability interfaces are clearly marketable for exchanging medical information from applications. As we use more health applications, there will be a clear need to interoperability, and in particular, a common environment for the user/patient to collect, reuse, and analyze data gathered by mobile applications, for example.

The PHR systems \leftrightarrow EHR systems market can be generalized into the following areas:

- Personal Health applications (PHR systems, etc) that include connectivity to EHR systems, devices based on standards or proprietary interfaces
 - Examples: Personal Health Systems - Microsoft HealthVault⁶⁹ (CCR, CCD), Indivo X⁷⁰, many other products provide document exchange using CCR⁷¹.
- Open Source interoperability frameworks that are loosely coupled to a business model or commercial entity(s)
 - Example: Open eHealth IPF Integration Platform Framework⁷²
- Open Source interoperability frameworks that are tightly coupled to a business model or commercial entity(s)
 - Example: Mirth Projects⁷³
- Commercial solutions that build on their framework or other 3rd party frameworks
- Open Source solutions provided to enable national interoperability objectives

⁶⁹ Microsoft HealthVault <http://en.wikipedia.org/wiki/Healthvault>

⁷⁰ Indivo X <http://indivohealth.org/>

⁷¹ CCR implementations/deployments
<http://www.ccrstandard.com/ccrstandardimplementationsanddeployments>

⁷² Open eHealth IPF – Integration Platform Framework <http://www.openehealth.org/gf/project/ipf/>

⁷³ Mirth Project http://en.wikipedia.org/wiki/Mirth_%28software%29

- Example: NHIN⁷⁴ CONNECT⁷⁵ software; supporting the American electronic health network, the Nationwide Health Information Network (NHIN)⁷⁴

PHR systems ↔ PHR systems

Some PHR systems include PHR systems interoperability interfaces to other PHR systems, such as Indivo X. The reason for this is that:

- Consumers will likely have one or more PHR systems in their lifetime
- PHR systems can easily become data silos. Perhaps data can be imported, but not exported or exchanged with competing products

PHR systems ↔ Devices without human interactivity; sensors, implicit feedback by human

Devices record observations and connect either directly or via a compatible router (home based, etc) that transmit observations to a personal health application or data center. Manufacturers provide interoperability interfaces to enable their home or personal products to communicate with Microsoft HealthVault PHR, such bathroom scales, blood pressure monitors. Additionally, sensors included in mobile hardware can provide many opportunities to collect data.

PHR systems ↔ Mobile Devices with human interactivity; including explicit and implicit human feedback

The market for mobile health applications will likely drive the PHR systems market. As new mobile device markets exploit particular device user interfaces, such as iPad/iPhone, we see immediately many medical applications⁷⁶ based on touch interfaces or even basic mobile texting⁷⁷ for disease management⁷⁸. What clearly missing are the interoperability interfaces that would enable the user to store their personal health information in a user's PHR systems.

2.3.5.2 Current situation

The transfer of data from EHRs to PHR systems is fraught with legal, ethical, and political issues, especially regarding patient data security. These issues can't be solved by technical means. Patients can be provided with paper-based documentation or other physical mediums that do not involve digital transfer of data to an electronic storage area controlled by the patient. Technically everything is possible; however, the other non-technical issues must be first addressed.

⁷⁴ Nationwide Health Information Network (NHIN),

<http://healthit.hhs.gov/portal/server.pt?open=512&mode=2&cached=true&objID=1142>

⁷⁵ NHIN CONNECT <http://connectopensource.org/about/what-is-CONNECT>

⁷⁶ iPad medical applications <http://masterofpublichealth.org/2010/25-ipad-apps-revolutionizing-healthcare/>

⁷⁷ Mobile texting <http://edition.cnn.com/2010/HEALTH/05/21/mobile.health.apps/index.html>

⁷⁸ Mobile texting and disease management <http://mobileactive.org/review-text-messaging-tool-behavior-change-disease-prevention-and-management>

Any work regarding interoperability could be based work on IHE profiles, some countries and organisations favour this. The problem is that some IHE profiles are work-in-progress and not yet ready to be accepted by the industry; therefore propriety solutions using established standards are likely more common.

The emergence of National EHR initiatives could help to drive a more personal service – oriented atmosphere for patients in the form of PHR systems. In US markets, Managed Care Organisations (MCO) or Health Maintenance Organisations (HMOs), for example, do provide many services for patients beyond providing insurance, administrative services, and negotiating costs with health care providers. HMOs, acting as the data collection center, can provide personal health content services to their customers; they play an important role for data exchange with hospitals and pharmacy services, therefore interoperability interfaces must play an important role. Online PHR systems for example, Microsoft HealthVault does negotiate with various MCO and pharmacy systems. The American National Health Information Network (NHIN) is also focused on interoperability issues and provides centralized documentation and, most importantly, common software tools for interoperability e.g. NHIN CONNECT, and standardization related documentation such as HL7 standards and IHE profiles.

Mobile health applications are driving users toward singular health applications – there is clearly a market especially for recording ODLs⁷⁹ (Observations of Daily Living), however, a common PHR system could help the user share these applications and data – instead we expect data silos, therefore providing interoperability interfaces to PHRs would be an attractive focus in iCARDEA. We expect that the EHR data exchange will not be so critical for these devices or systems; we can regard the EHR systems \leftrightarrow PHR systems data exchange as just another feature that might be utilized by a medical summary Personal Health Application (PHA). The iCARDEA Patient Empowerment framework, therefore, could be described as a set of PHAs supported by a common framework that includes interoperability interfaces that support data exchange between EHRs, devices/sensors or applications, particularly mobile devices.

Summary of the primary issues regarding interoperability interfaces

As a first approach to the topic, the issues such as the selection of the standards for exchanging data, the process of exchange and the specifications should be considered.

Approaches to exchange personal health record content and medical summaries⁸⁰:

Under the IHE Patient Care Coordination, there are three relevant IHE PCC Integration Profiles that are described in the PCC Technical Framework Volumes 1 & 2, Revision 5.0⁸¹

⁷⁹ Observations of Daily Living ODL <http://www.projecthealthdesign.org/>

⁸⁰ IHE Medical Summaries <http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.2>

⁸¹ PCC Technical Framework Volume 1+2

http://www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_5-0_Vol_1_-2009-08-10.pdf; the following is not directly relevant to XPHR:

http://www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_50_Vol_2_2009-08-10.pdf

1. Cross Enterprise Sharing of Medical Summaries Integration Profile (XDS-MS), including Medical Summary Document Content (MS) specification,
2. Emergency Department Referral (EDR), and
3. Exchange of Personal Health Record Content (XPHR)

In the context of this market study, the XPHR profile which uses the HL7 CCD as the document exchange specification is considered.

- HL7 CCD usage:
 - Some PHR system products do offer both HL7 CCD and CCR interoperability. Although HL7 CCD is an HL7 CDA implementation, some products do consider the original ATSM CCR. There are products that provide connectors and APIs to particular products, such as Google Health that are based on a standard, although there is no mention of general support for CCR or CCD interfaces.
 - When there is mention of the particular document exchange formats, HL7 CCD or CCR, in product or projects descriptions, we do not see mention of an IHE profile, such as XPHR (Exchange of Patient Health Record Content Profile); a profile that uses HL7 CCD, but provides a blueprint on how to implement standards compliant systems. XPHR Update, XPHR Extract, and data transaction related issues help to guide the implementers. The only project, Open eHealth, does mention their intention to address IHE XPHR⁸² profile in their development workshops. Note that HL7 CCD is harmonized with CCR, however, many products have been based on ATSM CCR, an *original* standard.
- Approaches to implement standards based interoperability system:
 - Observe the appropriate IHE profile(s). We expect that most of the solutions for exchanging data between EHR systems and PHR systems (XPHR Extract, XPHR Update) should be based on the IHE XPHR profile. However, neither the Mirth Projects nor NHIN CONNECT projects mention this particular profile, although NHIN does reference the IHE profiles. Only the open eHealth project discusses an intention to work with XPHR profile in their integration framework software (IPF).
 - Be modular, extendable– technically, the solutions should be modular, reusable, extendable
 - Define an appropriate licensing strategy

- PHR update of an EHR:

We have not seen clear discussions of this in the PHR systems or interoperability products. However, particular data might be useful to healthcare actors depending on the type of interactions foreseen between healthcare actors and patients e.g. dietary logs, logs relating to psychological aspects e.g. mood, and other relevant observations of daily

⁸² IHE XPHR Exchange of Personal Health Records
<http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1.5>
http://www.ihe.net/Technical_Framework/index.cfm#PCC

living (ODLs⁸³) for supporting the interactions with patients and healthcare actors. A specific case where a PHR could provide update to the EHR is when the patient carries out a lab exam to an external laboratory, and wishes to notify his/her hospital based EHR.

2.3.5.3 Identification of potential customers

A first overview of potential customers:

- Customers for the iCARDEA CIED Patients and Healthcare Actors (cardiologists, nurses, patient support personnel, etc) who are involved with Patient Empowerment framework or Care Planner
- National initiatives requiring interoperability know-how and tools. European countries building EHR systems require interoperability solutions and PHRs are the next step. Regardless of the political or legal uncertainty, pilot projects would be the first approach. Example: the Austrian ELGA system (National EHR) might provide iCARDEA opportunities to follow-up pilot studies involving PHR systems interoperability interfaces.
- CIED Vendors may be interested to present a complete picture of patient data in their web portals.
- Communities involved in Open Source interoperability frameworks, and their customers or users. Example: Open eHealth Integration Framework
- Health Insurance organisations – Public (National) or private institutions could use interoperability services to support patient access to their administrative and medical summary data.
- Wellness or rehabilitation related organisation – independent or associated with health insurance organizations or managed care organizations. Wellness planning might be one approach to enable PHR systems to create, activate patient wellness plans and collect observations as a means of enhancing patient feedback to health professionals and to support behavioural changes need to achieve a particular wellness plan. Interoperability interfaces would support, for example, the collection of action plans and ODLs (Observations of Daily Living).

2.3.5.4 Collaborators & Competitors

	Product types	Collaborator or Competitor
Open eHealth IPF ⁷²	Interoperability Framework, basic HL7 support, interest in IHE profiles	Collaborators. Work together on IHE profiles especially XPHR, using HL7 CCD standard
Mirth Project ⁷³	Interoperability Framework plus commercial components to support standards such as CCD and connectivity	Competitor. The commercial products are competitors for CCD/CCR doc exchange
NHIN Connect ⁷⁴	Open source interoperability and connectivity	Neither, but open source available for reuse
PHR Systems +	PHR system, PHR system	Collaborators; especially to bring an

⁸³ Observations of Daily Living ODL <http://www.projecthealthdesign.org/>

Interoperability layer and/or Connectors (APIs)	frameworks: Indivo X ⁷⁰ , Project Health Design ⁸⁴	interoperability framework based on, for example, Open eHealth IPF.
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2.3.5.5 Market Prospect

The main issues to address are the legal, ethical and political ones. Likely, it is best to be well situated to promote know-how and technology solutions to European National initiatives. Secondly, a pragmatic approach would be to join an existing open source interoperability project that intends to utilize IHE profiles – the use of these profiles constraining the use of standards like HL7 CCD. It is the preference of institutions, such as the SALK⁸⁵ to observe IHE profiles; therefore, we should follow the usage of standards in context of the IHE profiles. Rather than compete with a well-established project, we should collaborate, share and focus shared objectives regarding exchange of personal health data. However, for the many health applications becoming available, the data exchange standards and XPHR profile might suffice for prototype interoperability interfaces in order to demonstrate the value of PHR systems.

2.3.6 Interoperability Interfaces for EHRs

In iCARDEA, interoperability interfaces to EHRs are a key enabler for the reliable, secure, and cost-effective use of patient data in personalized care plans. This is particularly important as hospitals come to realize that they need to support novel workflows that use health information technology in an optimal way supporting in-patient, out-patient as well remote care.

EHR data residing in hospital information systems, clinical information systems (i.e. cardiology), medical data management systems (e.g. ECG) as well as in outpatient offices or primary care centers, are all sources of legal documents providing medically certified patient data that need to be retrieved on the basis of emerging care plans that are specific to the patients' diagnosis and the actual message received from the cardiac implant through remote monitoring. Their gradual integration to a unified information space that picks up the relevant key information through the adaptive care planner, will be an asset to the SALK and other specialized cardiology hospitals: it will reduce the burden of information that specialized cardiologists have to cope with as the number of CIED patients that need regular follow-up increases.

In iCARDEA, a general EHR interoperability framework has been designed and is currently being implemented that enables different means of interoperating with various EHR/PHR systems based on standards. If necessary the information is converted and stored into a standard format. Then the information is available either actively through subscriptions (e.g. IHE CM profile) or passively through the IHE-XDS interface.

⁸⁴ <http://www.projecthealthdesign.org/>

⁸⁵ SALK – Salzburger Landeslliniken (Hospital system of Salzburg) - <http://www.salk.at/>

2.3.6.1 Market Description

Despite the economic crises, as reported earlier, the healthcare information technology market is estimated to be \$53.8 billion by 2014, growing at a compound annual growth of 16.1% as reported by a recent Frost & Sullivan report. Main driving force for this is the need to contain health care costs. In particular, the European EHR market is expected to more than double over the next 5 years⁸⁶. By helping to record, store, retrieve and manage patient details and a lifetime of patients' contacts with healthcare providers, EHRs can be instrumental in reducing patient waiting time and improving scheduling of follow-up visits. The growth potential is expected to be higher in large and medium hospitals where currently EHR adoption rates are lower.

In Europe in particular, where there is a strong political backing for the Digital Agenda which will provide each European Citizen with EHR, the prospects for Health Information technology are quite good. Health Information Technology includes besides different type of EHRs, a multitude of systems from Hospital Information Systems, to laboratory systems, medical devices, remote monitoring, diagnostic systems, data mining and clinical decision support. Additionally, there are several services which involve multiple healthcare facilities, insurance companies, pharmacies such as e-prescription, claims management, e-referral, etc.

Integrating all these diverse sources of information is the only way to harness the value of patient data, using information more efficiently to reduce medical errors, compile quality indicators and most importantly use all the available patient data to reach effective diagnosis and treatment in a timely manner for the best possible patient outcome.

2.3.6.2 Current situation

The European hospital information systems market is quite fragmented and established vendors maintain strong relationships with provider groups that use their legacy systems and are reluctant to upgrade their systems with more advanced ones.

Give the high cost of upgrades it might be preferable to offer integrated healthcare IT solutions that allow planning and incremental integration of advanced functionality over a longer timeline.

The availability of health information standards supported by integration engines creates a favourable environment for the provision, acceptance and adoption of low cost integration solutions that facilitate effective use of information.

IHE integration and content profiles using standards such as HL7 in an interoperable way create a favourable environment for success stories and best practices that will lower the barriers to full market adoption and defragmentation of the eHealth market.

2.3.6.3 Target market

The target market includes the hospitals and the patients who wish to use integrated remote monitoring of CIEDs by also accessing the EHRs of the patient in the healthcare

⁸⁶ Frost & Sullivan, European Electronic Health Record Market, M440-48, May 2010.

facility they interact with. This market will potentially include all future implantations of CIEDs which will be equipped with an antenna, but also possibly patients that opt for traditional remote health monitoring with external body sensors. The market will also be affected by reimbursement of the basic service which will create additional market incentives.

US IMPLANTABLE MEDICAL DEVICES DEMAND (million dollars)					
Item	% Annual Growth				
	2004	2009	2014	2004-2009	2009-2014
Implantable Medical Devices Demand	19870	32860	49050	10.6	8.3
Orthopedic Implants	10290	16900	25800	10.4	8.8
Cardiac Implants	7460	12280	17600	10.5	7.5
Other Implantable Medical Devices	2120	3680	5650	11.7	9.0

Table 3: Potential demand for cardiac implants⁸⁷

2.3.6.4 Identification of potential customers

Potential Customers is large hospitals that manage cardiac patients with a CIED, typically on a fixed budget, have decided to adopt remote monitoring of CIED as a service. Such hospitals are typically hospitals that implant more than 100 CIEDs per year. The EHRA white book⁸⁸ provides a list of such centers in Europe. Further study is required to investigate the reimbursement model of such large centers. They would like to provide an integrated solution to optimise the time of physicians and organize better the information available on CIED patients.

Hospitals are likely to pay and support EHR interoperability interfaces if convinced that they can defend the quality and cost-effectiveness of the healthcare processes established for CIED patient remote or in person follow-up or following a reported event.

However, the market driver is more likely to be clinicians who embrace integrated solution having been convinced that it would save them time, and help them do a better job providing the information they need at their fingertips.

Finally, potential customers may be national or regional or even community healthcare systems that need to adopt a sustainable approach to integrated EHR supporting remote monitoring, incentives, quality assurance, and reimbursement.

2.3.6.5 Collaborators & Competitors

Competitors may be vendors of integration services or providers of integration technology. These companies are typically established in US and collaborate with smaller SME's in Europe e.g. InterfaceWare, Accenx, Tolven, Orion, etc. Another competitor may be implementers of customized solutions that do not conform to standards. Besides

⁸⁷ Report: Implantable Medical Devices (US industry forecasts for 2014 & 2019), Freedonia Group, 2010

⁸⁸ <http://www.escardio.org/communities/EHRA/publications/Documents/ehra-white-book-2010.pdf>

integrators being competitors, large HIS software vendors may be competitors as they are the first point of contact when extensions to HIS is requested. In that sense, Agfa, IBM, etc. may be considered competitors, but could turn into collaborators per below.

However, competitors may turn to collaborators given the extensive expertise of the iCARDEA consortium in implementing integrated solutions based on IHE and HL7 standards. Additional competitors are large vendors providing turn-key solutions.

2.3.6.6 Market Prospect

The reduction in the number of hospitals and healthcare professionals combined with the increase in the number of CIED implantations in an aging population facing cardiovascular diseases that affect their ability to live and work independently creates a viable market prospect for supported innovative clinical pathways based on integrated EHR, PHR, and tele-monitoring data. Integrated EHR solutions affect their confidence in working and travelling leading to a more efficient interaction with health care systems.

Healthcare systems at different levels national, regional, community need to prove their efficiency and effectiveness. Interoperability interfaces with EHRs that assure security and privacy provide the means to accomplish this goal with residing to hugely expensive and sometimes inefficient all-in-one information systems.

Moreover, the introduction of the remote monitoring service to the hospital is a new process that creates the opportunity to influence the reengineering of the workflow taking an evidence-based approach as directed by guidelines.

Recent guidelines stress the value of reviewing and comparing ECGs as part of the care provision. Thus the need serially compare and evaluate ECGs may reinvigorate the use of interoperable formats that can be supported as part of the EHR interoperability framework.

Finally, emerging functionality profiles and certification criteria for EHR such as those provided for cardiology information systems by CCHIT and more general ones provided by EuroREC can help solidify functionality as well as interoperability expectations from EHR vendors.

2.3.7 Data Analysis Applications in eHealth

Data Analysis is used at very different fields of the Health sector. Data analysis is used at the German public health sector for fraud detection by the health insurances to identify illegal kinds of accounting by the medical service providers. This analysis uses billing data and has a saving potential of up to 1.5 billion Euro in Germany⁸⁹⁹⁰. Also data analysis is done on hospital data together with demographic and geographical data to help hospitals to get a better strategic focus on the needs of the future⁹¹⁹²⁹³. Another common

⁸⁹ http://www.versicherungsbetriebe.de/data/beitrag/Artikel-Licht-ins-Dunkel_5679636.html

⁹⁰ <http://www.tagesschau.de/inland/krankenhausrechnungen100.html>

⁹¹ <http://www-is.informatik.uni-oldenburg.de/knobi/>

⁹² <http://www.info-analytics.com/krankenhaus>

⁹³ <http://www.gebera.com/download/SWOT-Routinedaten.pdf>

field for data analysis are medical research institutes using especially collected data, like cancer registries⁹⁴.

The iCARDEA Data Analysis components support healthcare professionals at hospitals. This aim is addressed by making it easier to access the patient data in a structured and harmonized way and by using long-time-harmonized data acquired over longer periods to generate patient-specific warnings and suggestions based on statistically valid patterns extracted using state-of-the-art data analysis techniques applied to long-time reference case knowledge bases. The attempt and usage of data analysis is not limited to the hospital market and could also be used in areas where health data is obtained over longer time periods with the purpose to obtain new knowledge over the data. This could be the case in eHealth projects with connected and collected patient data like prospeGKT, EPA Rhein/Ruhr or Asklepios-EMR⁹⁵⁹⁶.

2.3.7.1 Market Description

The market of data analysis at the health sector is divided mainly into two groups, public health sector who pays for the health system and commercial health provider, receiving spending. At the first group, data analysis is done at the health reporting system, like “Informationssystem der Gesundheitsberichterstattung des Bundes” at Germany⁹⁷, “Plattform Gesundheitsberichterstattung” at Austria⁹⁸ or the “World Health Report” of the WHO⁹⁹. Other participants are the already mentioned fraud detection and registries, but also the health insurance funds who have own Institutes for data analysis¹⁰⁰¹⁰¹. Also founded research is at this group.

The other group consists of the health care providers who uses data analysis to improve their products, to optimize their workflows with the aim to gain competitive advantages, or to produce scientific results for the reputation or also participating on research founding.

Healthcare professionals with access to structured information as required for data analysis tasks are mainly located in hospitals, due to the required technical and personal infrastructure or in the mentioned specialized reporting centres. But the reporting centres have to our experience their own specialized data analysis tools and strategies.

GEO/TIME	2003	2004	2005	2006	2007
Belgium	:	:	31112,61	31774,38	34031,29
Bulgaria	1392,97	1491,04	1699,26	1825,19	2031,64
Czech Republic	6019,94	6340,80	7254,90	7918,04	8603,52
Denmark	17528,98	18624,04	19680,88	21009,10	22116,34

⁹⁴ <http://www.krebsregister-niedersachsen.de/registerstelle/>

⁹⁵ <http://www.ehealthurope.net/Features/item.cfm?docId=190>

⁹⁶ <http://www.gematik.de/c>

⁹⁷ <http://www.gbe-bund.de/>

⁹⁸ <http://www.oebig.org/>

⁹⁹ <http://www.who.int/whr/en/index.html>

¹⁰⁰ <http://www.wido.de/> Wissenschaftliches Institut der AOK

¹⁰¹ <http://www.tk.de/tk/wineg/118306>

GEO/TIME	2003	2004	2005	2006	2007
Germany (including ex-GDR from 1991)	233778,0	233543,0	239361,0	244917,0	252751,0
Estonia	435,38	497,40	561,62	671,80	830,17
Spain	63791,06	68868,60	75270,95	82063,65	88827,34
France	173705,8	182707,0	191609,6	199227,5	208440,7
Cyprus	796,03	808,41	866,08	921,03	1001,41
Latvia	:	:	826,57	1085,49	:
Lithuania	:	1035,11	1223,40	1490,58	1768,20
Luxembourg (Grand-Duché)	:	:	2316,18	:	:
Hungary	6179,13	6615,97	7379,63	7248,94	7485,54
Netherlands	46611,06	48962,82	50461,61	52521,86	55220,70
Austria	:	24230,32	25340,09	26328,83	:
Poland	:	12670,67	15187,62	16871,72	19982,73
Portugal	13447,68	14376,82	15162,55	15436,67	:
Romania	2618,57	3038,39	4112,90	4396,53	5812,20
Slovenia	2228,74	2283,90	2431,20	2564,75	2714,01
Slovakia	:	:	2711,50	3269,85	:
Finland	11872,02	12529,89	13278,15	13891,02	14706,29
Sweden	25930,82	26454,41	26984,87	28418,91	30048,22
SUM of Helthcare Cost (without approx) in Million Euro	606336,18	665078,59	734833,17	763852,84	756371,30
SUM of comparable Healthcare Costs with approx in Million Euro	677586,18	701358,59	734833,17	766252,84	805821,30

Table 4: Overall healthcare costs at some countries of the European Union

GEO/TIME	2003	2004	2005	2006	2007
Bulgaria	496,20	544,52	:	:	:
Czech Republic	2858,41	2988,46	3337,71	3710,69	4018,61
Germany (including ex-GDR from 1991)	66868,00	67995,00	69429,00	71303,00	72376,00
Estonia	:	:	262,07	294,88	384,43
Spain	24295,35	26711,32	29555,12	32689,80	35579,70
France	63489,92	66993,35	70684,16	73526,10	76617,51
Cyprus	302,23	301,18	322,57	362,16	386,24
Latvia	:	:	336,38	467,91	:
Lithuania	:	365,71	447,55	597,65	694,24
Luxembourg (Grand-Duché)	:	:	763,68	:	:
Romania	1331,28	1402,96	1847,30	1929,18	2727,14
Slovenia	889,36	918,30	980,71	1045,79	1087,46
Slovakia	:	:	776,76	875,85	:
Finland	4420,33	4532,65	4804,80	5146,06	5414,04
Sweden	11471,58	11677,06	11928,96	12708,44	13450,88

GEO/TIME	2003	2004	2005	2006	2007
SUM of Hospital related Healthcare Cost (without approx) in Million Euro	176422,66	184430,51	195476,77	204657,51	212736,25

Table 5: Hospital related healthcare costs at some countries of the European Union

Table 3 shows the overall healthcare costs at some countries of the European Union¹⁰². The values of Table 4 are from the same source and represent the Hospital related costs. Only the countries where data was available are shown and “.” indicates not available values. The values show, that the rate hospital market grows faster than the healthcare costs.

2.3.7.2 Current situation

The money spent in the hospital market in Europe evolved over the last years. Due to increase of the hospital treatments, older people and limited funding it is important to make the treatments more efficient and cost effective.

2.3.7.3 Target market

The target markets of the data analysis components are medium and large hospitals / healthcare providers. Depending on the different national healthcare systems these are either one or a few nation-wide healthcare providers or otherwise a very fragmented market of commercial and statutory healthcare providers. Commercial providers can use data analysis to reduce their cost in treatment and enlarge their profit. Statutory providers can benefit from cost savings in the treatment and the patients benefit by receiving a more specialized treatment.

2.3.7.4 Identification of potential customers

Potential customers are healthcare providers who want to obtain knowledge advantage about their medical treatment process and by that reduce the workload / costs. Normally, this is the case if there are enough patients who are treated in the same way to reach the return of investment.

The following healthcare providers are of high interest, because of their size:

- Capio AB with 100 hospitals in Sweden, Norway, Denmark, Finland, France, England and Spain.
- Asklepios AG with 90 hospitals in Germany, 8 Hospitals in Greece, 6 hospitals in USA and activities in Portugal, Poland, Russia and Romania.¹⁰³
- Fresenius with 62 hospitals in Germany operated by Fresenius Helios and worldwide hospital management, consulting and its solutions by Fresenius Vamed and Netcare.¹⁰⁴

¹⁰² http://epp.eurostat.ec.europa.eu/portal/page/portal/health/public_health/database, Last updated: 13.04.2010

¹⁰³ http://de.wikipedia.org/wiki/Asklepios_Kliniken

¹⁰⁴ http://de.wikipedia.org/wiki/Fresenius_SE

The long-time data analysis capabilities are also relevant for epidemiology and statistics:

- Eurostat as the statistics division of the European commission at the theme of public health
- Robert Koch Institute in Germany as the German federal institution responsible for disease control and prevention.

2.3.7.5 Collaborators & Competitors

Collaborators are all vendors of medical systems, which provide structured data about the patient and / or the treatment. Potential competitors could be other vendors of data analysis software like SPSS, SAS, SAP or Cognos, which are already used in hospitals for controlling purposes.

2.3.7.6 Market Prospect

Due to the cost pressure at the health market it is important for every healthcare provider (regardless whether commercial or statutory) to optimize the treatments of the patient. By using state of the art data analysis techniques to create knowledge from past cases and use this knowledge advantage for the future, treatment costs can be reduced either for the benefit of the commercial company or the national budget.

For the IT Sector of the health market there is a grow estimated. It is estimated that *the Western European healthcare sector will generate a growth of IT investment from \$12 billion in 2009 to \$14.4 billion in 2012. In the various recovery plans outlined by Western European governments, the modernization and the rationalization of the healthcare systems is seen as hub for growth and a condition for the long term sustainability of public health systems. IT investments are hailed as a fundamental part of these modernization strategies: Health Industry Insights expect a significant growth in IT spending in the coming years but projects and implementations will be increasingly under scrutiny.*¹⁰⁵

For the German health market, as the biggest in Europe, it is assumed that the spendings rise up to 8% of the Healthcare system in 2020 compared to 1% in 2005.¹⁰⁶

We assume that with the IT Health sector, also Data Analysis in eHealth to rise.

2.4 Exploitable Assets

2.4.1 Personalized Adaptive Care Planner Environment

iCARDEA Project develops a Personalized Adaptive Care Planner Environment for coordinating the remote follow-up of CIED Patients. This Personalized Adaptive Care Planner Environment is based on computer interpretable clinical guideline models. The Care Planner Environment has three main components:

¹⁰⁵

http://www.reportbuyer.com/pharma_healthcare/finance_investment/business_strategy_western_european_healthcare_sector_spending_2008n2012_special_update.html "Business Strategy: Western European, Healthcare Sector Spending 2008–2012 Special Update" Last updated: 18.08.2011

¹⁰⁶ <http://www.ehealthurope.net/features/germany/>

- Care Plan Definition Tool: A graphical interface is provided for defining care pathways based on evidence based guidelines. It is possible to import clinical guidelines represented in Guideline Interchange Format (GLIF). These care pathways are enabled to be personalized for individual patients, where necessary the thresholds can be adjusted according to the patient specific conditions.
- Care Plan Engine: The personalized care pathway definitions are executed by the Care Plan Engine. The Care Plan Engine seamlessly accesses data in EHR data resources, CIED data and PHRs using standard interfaces, and care pathway becomes adaptive based on these personalized data collected
- Care Plan Monitoring Tool: A graphical monitoring environment is provided to present the results of the executing and previously executed care pathways.

iCARDEA Personalized Adaptive Care Plan Environment is implemented based on standard interfaces: IHE Care Management Profile is implemented to access the data from Electronic Healthcare Records and Personal Health Records of the patient; IHE Implantable Device Cardiac Observation Profile (IDCO) is used for accessing the observations from Cardiac Implantable Devices. For the definition of clinical guidelines the “Guideline Interchange Format (GLIF)” is used. Through such standard interfaces, we aim to exploit the Adaptive Care Plan Engine for enabling Care Management for various different clinical conditions as a Chronic Disease Management System.

The economic impact of chronic and preventable diseases is measured in hundreds of billions of dollars worldwide^{107,108}. A significant percentage of emergency department visits are the result of poor management of chronic conditions, with one study citing almost 30% of ambulatory visits being a result of preventable chronic disease¹⁰⁹. In some areas, chronic disease patients account for almost 80% of healthcare costs, and over 90% of prescriptions filled.¹¹⁰ Controlling chronic disease will result in a diversion of patients from costly acute care, resulting in significant savings. For these reasons we believe that iCARDEA Adaptive Care Plane Environment will have a high chance of exploitation as a Chronic Disease Management System. Although the clinical pathways to be defined and implemented in iCARDEA project will be for remote monitoring of CIED patients, the developed Care Plan Engine will be generic to be exploited for various different clinical domains.

2.4.1.1 SWOT Analysis

Strengths

- The definition and validation of the clinical guidelines becomes easier with the Careplan Definition Tool.
- The execution/implementation of the guidelines will be computerized.

¹⁰⁷ Preventing Chronic Diseases: a vital investment, 2008, World Health Organization

¹⁰⁸ IHE Patient Care Coordination (PCC) Technical Framework Supplement

¹⁰⁹ Ambulatory Medical Care Utilization Estimates for 2005, 2007, The Centers for Disease Control and Prevention

¹¹⁰ Prescription for Pennsylvania: Right State, Right Plan, Right Now, 2008, Chronic Care Management, Reimbursement and Cost Reduction Commission

- The Web-based monitoring of the execution of the clinical guidelines will enable the healthcare professionals to intervene to the guideline execution in anytime/anywhere manner
- The guideline execution/definition will benefit from the already existing medical data in the Hospital Information Systems. This will be achieved with the standard-based interfaces of the Adaptive Care Planner. As a result, treatment/monitoring of the CIED patients will be improved.
- The usage of clinical guidelines in the hospital settings will be increased with a robust Adaptive Careplanner Engine.
- The healthcare professionals will be allowed to see the results of the previous execution of the guidelines.
- The healthcare professionals will be allowed to personalize a clinical guideline to a specific patient so that the treatment will become more effective.

Weaknesses

- Although clinical practice guidelines are designed to promote effectiveness and inhibit ineffective treatments, the guidelines are not being widely used in daily practice.

Opportunities

- There is no graphical guideline definition tool in the market.
- All the guideline execution engines are research oriented. There is no guideline execution engine with high quality-of-service parameters in the market.
- The current guideline execution engine cannot interact with the already existing ICT Infrastructure of the Medical Institutes.
- The current guideline engines are generic and do not specialize on CIED patient needs.
- There is no tool in the market that can provide web-based monitoring of guideline executions.

Threats

- The research-oriented guideline execution engine providers could develop competing products (although no such development is known at this time).
- Healthcare professionals may resist using the software.

2.4.1.2 PEST Analysis

Political/Legislation Factors

- There are no regulations/directives considering the use of clinical guidelines in the treatment of the cardiac patients. Furthermore, the clinical guidelines are recommendation in nature. The final decisions are up to clinical experts. Therefore, the existence of legislation against the use of guidelines is not probable.

Economic Factors

- The use of clinical guidelines supports the decisions of the clinical experts. As there are no commercial clinical guideline engines/tools to be demonstrated to the doctors, they are not aware of the benefits of the guidelines. Therefore, up to now,

the medical institutes have not allocated much budget on them. However, our experiences show that with the demonstration of a robust guideline definition and execution platform, the doctors show sufficient willingness for their adoption. In the future, we expect budget allocations by the medical institutes towards the use of medical careplans.

Socio-cultural Factors

- It is evident that the population is aging in the EU. And the number of patients assigned to a doctor increases over time. On the other hand, the use of guidelines with a software tool will help the doctors in their daily jobs.

Technological Factors

- The Adaptive Careplanner Engine is a new technology to the medical experts, as they need to get used to consult to the software before giving their final decisions.

2.4.2 Data Analysis through Temporal OLAP Dimensions Module

The Temporal OLAP Dimensions can enhance standard Online Analytical Processing (OLAP) with support for changing dimensions. Unlike existing concepts, the Temporal OLAP Dimensions Module enables users to select the appropriate encoding for the respective analysis and prepare the data on the fly. This has the effect that at the data integration there is no need to decide which encoding to use for all data and to then convert the data in advance. Conversation would cause a loss of detail information, which is prevented by the Temporal OLAP Dimensions Module. Although the knowledge of how to map data from one encoding to another one is not used at the data integration, this knowledge is stored to be later used by the Temporal OLAP Dimensions Module. The planned software and underlying concepts will be part of a PhD thesis.

2.4.2.1 SWOT Analysis

Strengths

- Enables more powerful analyses compared to existing OLAP tools
- Data integration becomes easier
- No loss of information due to data integration

Weaknesses

- User needs to choose among multiple “truths”, which makes use of the system more complex
- New approach, “unknown territory” to current OLAP users

Opportunities

- No other OLAP tool supports this concept yet
- Perceived as real user need
- Applicable to many types of medical data that use an encoding that changes over time (e.g. ICD-10)
- Also applicable to non-medical data that use an encoding changing over time (e.g. product catalogues, country codes)

Threats

- Commercial OLAP providers could develop competing product (although no such development is known at this time).
- Users might be afraid of the complexity of the approach

2.4.2.2 PEST Analysis**Political/Legislation Factors**

- The data analysis technological innovation is not underlying legal or political restrictions. There could be stronger or weaker legal regulations on collecting and using data, but at the moment there are no such attempts known. Often access of external experts access to the needed data is not legally allowed, especially if the patient consent is not clearly defining this use case.
-

Economic Factors

- The use of OLAP data analysis is a well established process at the economy. For the temporal OLAP there is the benefit of more accurate analysis. The problem can be that the customers don't see the benefit or return of investment for the special data analysis. But since this is an additional analysis feature without causing higher cost, there seems no economic threat.

Socio-cultural Factors

- A problem could be, that data analysis on personal (especially patient) data is seen as unethical by the population or the customers. But people can also see the benefits form data analysis leading to better or cheaper treatments if data analysis is used at the health-domain. But since temporal OLAP can also be used on other kind of data then human centered, where socio-cultural factors are not applicable.

Technological Factors

- Since OLAP is well established for more than a decade and became industrial standard, it is unlikely, that Data Warehouses are replaced in the next time. Since Temporal Data Warehousing and Temporal OLAP is an R&D field, Competitors could develop the same functionality.

2.4.3 Privacy-aware Data Analysis Concept

A concept together with the required software components ensuring privacy-aware data analysis of medical data and presentation to the end user is developed. The developed prototype is compliant with Austrian data protection law.

The prototype is specialized for the requirements of the European laws concerning processing of medical data, but the underlying concepts can be used for other types of privacy-aware data analysis as well.

2.4.3.1 SWOT Analysis**Strengths**

- Enhanced knowledge on privacy aware data analysis

- Enhanced tool support for privacy aware data analysis
- Offering more and new powerful data analysis tools compared to competitors.

Weaknesses

- Only few specialists need privacy aware medical data analysis

Opportunities

- The generic concept can be used also at Germany, where OFFIS is already active at the privacy aware medical data analysis market.
- Worldwide discussion on Privacy and Security concerns which could result in new domains for usage of privacy aware data analysis.

Threats

- EU changes the concept of privacy law for medical data analysis.
- Commercial data analysis providers could develop competing concepts with tool support.

2.4.3.2 PEST Analysis

Political/Legislation Factors

- Since the privacy and security standards are mandated by country specific laws, stronger or weaker legal privacy regulation on data collection, storage and analysis will have direct effects. Especially in the field of sensitive patient data there are already strict regulations on usage of patient data.

Economic Factors

- The data analysis of clinical data becomes more important for clinics due to the larger amount of treatments at hospitals and stagnant treatment costs. By using data analysis at clinics, which needs high privacy and security standards and is targeted by the concept, the treatment can be more efficient and the analysis costs per patient decreases.

Socio-cultural Factors

- By using a high security and privacy concept, possible concerns of the patients or clinicians to data safety can be reduced and so strengthen their positive confidence in data analysis.

Technological Factors

- If encryption is used to ensure the privacy and security of the data, there is the technological problem of new more powerful CPUs which can break encryptions faster than assumed. Since also new technologies or improvements of encryption can arise, these have to be adapted to fulfil the safety and privacy concerns.

2.4.4 CIED Data Interoperability Module

Currently, CIED read-outs for clinical studies or patient follow-up must often be redundantly collected or the same type of data must be collected using different methods and formats depending on CIED vendors, since there is no standard format and interchange protocol supported by all vendors.

The CIED Data Interoperability Module enables the act of combining sources of CIED data residing in multiple, distributed locations to present a single, central collection of the data. For this purpose, the CIED data from various individual CIED vendors would be received, converted into a standard format and forwarded through a standard interface, which is defined by HL7, ISO/IEEE 11073 and the IHE IDCO Profile. The CIED Data Interoperability Module is composed of three main components:

- CIED Data Receiver: Through various vendor-specific interfaces, CIED data is captured. This enables a regular receipt of up-to-date information.
- CIED Data Processor: The data provided by the CIED vendor's message will be abstracted according to the requirements of the clinical guidelines used in iCARDEA. The CIED data is encapsulated with IEEE 11073 Nomenclature into an HL7v2 message.
- CIED Data Sender: Transmits the final IHE IDCO compliant HL7v2 message to the central receiver, in the case of iCARDEA to the Care Plan Engine.

Many health care organizations or teams have invested significant effort in the Data Interoperability. Data Interoperability is facing the challenge of accessing, aggregating and integrating data among its multiple systems or external facilities. Unfortunately, most CIED data is made available today a non-standard, non-structured or even non-coded form, resulting in a lack of interoperability. Interoperability is a property of a product or system, whose interfaces are completely understood, to work with other products or systems, present or future, without any restricted access or implementation¹¹¹. The CIED Data Interoperability Module allows CIED data to be used in further applications (including but not limited to the iCARDEA Care Plan Engine) and processing regardless of origin, and to be aggregated and compared across location and time.

2.4.4.1 SWOT Analysis

Strengths

- Enables automatic real-time data updating, thus improving consistency and correctness of patient information.
- Improves the efficiency of healthcare delivery while reducing the administrative costs and time associated with accessing and analyzing CIED information.
- Streamlined compliance with international electronic data standards such as HL7, IEEE 11073. Accordingly, the performance and efficiency for data collecting and processing will be improved.

Weaknesses

- Data diversity because of the differences between various CIED vendors requires significant adaptation effort for each vendor, product and version.
- Not all data delivered by vendors in a proprietary format (e. g. bitmap graphics in a PDF document) can be converted to an IHE IDCO compliant standard format.

Opportunities

¹¹¹ <http://en.wikipedia.org/wiki/Interoperability>

- Building block in the iCARDEA system, which serves a quickly increasing world-market
- May simplify standards compliance for CIED vendors

Threats

- Version changes of vendors' proprietary interfaces may render the system interoperable or, at least, require adaptation (see weaknesses).
- System may become obsolete once all major vendors support IHE IDCO as part of their own product offering.

2.4.4.2 PEST Analysis

Political/Legislation Factors

- Since medical devices are an important treatment for public health, there could be laws to regulate the usage of standards. This could lead to higher interest for CIED Data Interoperability Module by vendors who need a fast way to achieve the standard regulations. A legal concern could be, that the standard is changed too fast or discontinued by the IHE, so that the adaption of CIED Data Interoperability Module isn't feasible anymore.

Economic Factors

- If CIED comes cheaper and are implemented more often or the market for standard devices increases there is a greater market for CIED Data Interoperability Module. This is also the fact, if more hospitals want to have a complete electronic flow of data.

Socio-cultural Factors

- Since the amount of patients with CIED increases, there is a greater market. Also as the new patients are more familiar with modern techniques, the acceptance could increase and also strengthening the market.

Technological Factors

- From a technological view new devices could be already equipped with standard protocols that don't need the adaption anymore. There could be also new CIED technologies which lead to new standards.

2.4.5 Framework for Patient Empowerment

Currently, Patient Empowerment includes a number of different approaches at different levels. Some patients simply want to be given information about their conditions whilst others want to have full control over all medical decision-making issues. The heart of the Patient Empowerment Framework in iCARDEA is the Personal Health Record (PHR) System which enables patients to take an active role in the management of their own healthcare based on the ability to access and to manage their own healthcare data.

The Patient Empowerment Framework

- ◆ offers different approaches to support patient empowerment and to foster self-management, e.g. online services like information material or an action plan and offline services like self-help groups

- ◆ provides a core components platform in order to integrate or create personal health applications
- ◆ the architecture of the PHR system will be flexible in order to integrate or be integrated by other health applications or systems, e.g. reuse services from existing health applications

Furthermore the PHR system will offer services for personal health applications, e.g.

- ◆ A calendar – will support patients to manage their tasks (reminder for medication) and appointments (e.g. appointments for follow-up visits).
- ◆ Observations of Daily Living (ODLs) – the patient will be able to insert ODLs as part of his health data. This refers to general observations like e.g. food logs, mood or exceptional events of daily life that can be included in a diary or in particular to patients with cardiac insufficiency who should e.g. daily control their weight, blood pressure.
- ◆ Action plans – allows patients to organize actions in reasonable steps in order to help the patients to learn how they can change their behaviours in an adoptable and realistic manner. Typically an action plan covers a period of 1-2 weeks. The Action Plan is coupled with the calendar and includes a state option indicating whether a e.g. physical action is currently ”planned” or already ”executed”.
- ◆ Social web-related services – supports both the exchange of information and experience between patients and groups based on an online self-help group (e.g. chat room, group with regular personal meetings) and tagging resp. sharing of information.
- ◆ Education and information material for CIED patients – covering disease related topics. The online material is organised in a wiki and can be easily modified and expanded.

The PHR system will be implemented based on standard interfaces like HL7 and IHE profiles (e.g. IHE Care Management Profile) in order to ensure interoperability.

2.4.5.1 SWOT Analysis

Strengths

- Patient data are electronically available for patients.
- Patients can make remarks or put questions on their data, e.g. by annotations.
- Patients can collect interesting data by their own, e.g. weight for heart failure patients.
- Physicians can look at additional patient data collected by patients
- Patients can organize actions which aim to change their behaviour.

Weaknesses

- Physicians must be aware that data collected by patients might be from different quality and sometimes incomplete.
- Currently, electronic PHR systems are not well-known and not widely used by patients.

Opportunities

- Family members can manage PHR data e.g. in case the patient is no longer able to do it.
- PHR services might be used as plug-in services by 3rd party health applications.
- The PHR portal might exchange patient data and/or services with other EHR or PHR systems.

Threats

- Users might be afraid of privacy issues.
- Physicians would maybe have to less or no time to look at additional patient data at the PHR system.
- Insufficient electronic skills may restrain patients to use an electronic PHR.

2.4.5.2 PEST Analysis

Political/Legislation Factors

- Patient empowerment applications allow managing and storing personal health data. From a legal and ethical point of view using patient data requires to consider special laws and regulation.

Economic Factors

- From the perspective of health care policy patient empowerment is a topic with growing importance. Involving patients in their health care processes in a more active way helps to reduce the increasing costs for health care. Chronic diseases such as heart diseases or diabetes are of special interest in this context because chronic diseases are basically lifelong diseases.

Socio-cultural Factors

- It is well known that the role of patients is changing. Several studies¹¹² demonstrated that patients are using the Internet searching for health related information and that patients want to be more involved in their health care process and in their medical decision making situations. Patient empowerment aims to support these trends.

Technological Factors

- The Patient Empowerment Framework is a new approach based on putting focus on patient empowerment strategies and on established interoperability standards for exchanging patient data with other Personal Health Applications.

¹¹² Such as Coulter, Angela, and Helen Magee (eds.). The European Patient of the Future. Open University Press: Maidenhead, Philadelphia 2003 or <http://www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/P/PDF%20PHRPerspectives.pdf>

2.4.6 EHR interoperability Framework

One of the exploitable assets of iCARDEA is the EHR interoperability Framework which provides the clinician evaluating a specific patient with CIED implant, through the Care plan engine with all pertinent patient data as suggested by his/her personalized medical care plan in a standard format as dictated by the IHE-Care Management (CM), IHE-Cross Document Sharing, and IHE-PHR profiles.

Equipped with a toolbox of converters and adaptors able to be configured to the healthcare information systems supporting specific hospitals/clinics/outpatient offices all relevant patient data of enrolled patients will be processed as they become available.

Patient data are converted to HL7 CDA and registered to its XDS registry, while all relevant subscriptions to the specific patient/data pairs are serviced through IHE CM. From that point on the data are available in a standard format to qualified individuals and systems according the security policy of the healthcare facility. Additionally, data from external laboratories or even primary care facilities can be imported to further enrich the information provided, directly or through the PHR interface. Other possibilities envisioned include interoperability with epSOS to receive and process updated patient summaries, as well as interoperability with primary care systems and national infrastructures such as ELGA in Austria. The toolbox will be continually updated as new adaptors or converters are implemented based on legacy formats or different/older versions standards.

2.4.6.1 SWOT Analysis

Strengths

- The **strength** of the EHR interoperability Framework lays in its ability to act as a buffer independent to specific implementations of hospital/clinical information systems.
- Its reconfigurability combined with the ability to incrementally integrated different subsystems within the hospital is another plus, linked to its flexible design.
- An additional strength is its conformance to the latest profiles from IHE that allows systems to be tested in connectathons confirming conformance to integration profiles.

Weakness

- The main **weakness** of the system is that it is an external system to that of the HIS and thus in the long run may need separate maintenance.

Opportunity

- The **opportunity** lies with the potential reduction in costs and the benefit on the patient through the enablement of efficient novel workflows. The limited funds available for the acquisition of new systems, combined with the lower cost of incremental solutions.

Threat

- The **threat** is with slow adoption of remote monitoring and these workflows in the hospital, late availability of data, etc. Slow adoption of reimbursement and remote monitoring due to security and privacy concerns, limited health and eHealth literacy and patient empowerment are also some threats to the wide adoption of iCARDEA and its components.

2.4.6.2 PEST Analysis**Political/Legislation Factors**

An important political/legislation factor at level of large hospital is related to the acceptance/endorsement of integration partners following the EC medical device mandate.

The medical device mandate hinders innovative integration effort as in many places integration software is considered as a medical device.

Usually large hospitals have framework contracts to software providers and are reluctant to establish parallel business relations with integrators. On the other hand vendors do not typically offer standard interfaces/ profiles beyond connectathons which are primarily marketing events and charge significant amounts for any extensions requested.

Privacy concerns are also strong in many countries prohibiting access to patient data outside the hospital. Future visions of the Future hospital without walls are sadly very far from reality.

A positive political/factor may come from the health care professional associations and advocacy groups that will promote the use of guidelines as the means to improve care particularly in the context of CIED telemonitoring.

Economic Factors

Several economic factors affect the wide exploitation of iCARDEA these relate to:

- (a) wide adoption of reimbursement for telemonitoring and remote followup of CIED patients
- (b) mandate for nationally/EU integrated health records for CIED patients
- (c) quality indicators being enforced along with performance criteria at the hospital level providing incentives to healthcare professionals
- (d) entry of new players in the CIED telemonitoring market e.g. insurance companies
- (e) cost of CIED devices with remote management may be prohibitive due to the financial crisis, calling for attractive bundling models including telemonitoring by CIED vendors.

Socio-cultural Factors

Currently, health telemonitoring and specifically CIED telemonitoring is not widely accepted not only among health care professionals, but also among patients and their next of kin, who in many cases perceive telemonitoring as an attempt to evade responsibility, decrease outpatient visits, and decrease quality of follow-up. Privacy issues also come into play when telemonitoring is brought up. In this setting education can play an important role, particularly if the positive innovative aspects of iCARDEA are highlighted.

Nevertheless this is expected to be a long process as political/legislation issues are mounting. Many pilots and best practice stories need to be compiled and socialized before informed telemonitoring as provided by iCARDEA is realized.

Technological Factors

Technological factors are quite favourable. In the US, advanced cardiology clinics with extensive engagement in telemonitoring are experimenting with remote management of CIEDs. However, it will be quite a long time (est. 5-10 in private discussions) before these developments reach mainstream in the US and even longer in Europe, which so far is more traditional in health care provision.

Personal devices emerge as an important driving force as iPhones allow the physician to receive the alert directly on their smart phone. Delivering iCARDEA on a smart phone could be an interesting development to be explored, which however needs to overcome significant legislation barriers in several EU countries.

2.5 iCARDEA Exploitation Strategy

2.5.1 Joint Exploitation Strategy

Almost all of iCARDEA components will be distributed as open source. In iCARDEA Deliverable 2.3.1a, an overview how each iCARDEA consortium partner intends to manage the intellectual properties of each iCARDEA asset is presented as depicted in Table 6.

iCARDEA Assests	Type	SRDC	OFFIS	SRFG	FORTH	SALK	SJM	Med-tronic	HCPB
Personalized Adaptive Care Planner Environment	Asset	Product				Method			Method
	IPR	Open Source				Open source			Open source
Data Analysis through Temporal Dimensions Module	Asset		Method / Product						
	IPR		Copyright						
Privacy-aware Data Analysis Concept	Asset		Method / Service						
	IPR		Trade secret						
CIED Data Interoperability Module	Asset	Method	Product						Method
	IPR	Open source	Copyright or Open source						Open source
Framework for Patient Empowerment	Asset	Service		Product		Method			Service/ Method
	IPR	Open Source		Open Source		Open source			Open source
EHR Interoperability	Asset	Service		Service	Product/Method				Product /Method

Framework	IPR	Open source		Open Source	Open Source / Free for non commercial use				Open source
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Table 6 Overview iCARDEA Assets (Taken from iCARDEA Deliverable 2.3.1a)

For this reason as a consortium we have investigated possible exploitation opportunities allowed in Open Source Paradigm. In Section 2.5.1.1, we will review the Open Source paradigm. In the light of this review, in Section 2.5.1.2 we try to position iCARDEA Exploitation strategy in the open source market.

We decided that iCARDEA Components can be exploited either as separate open source modules, or as integrated packages providing more extended functionalities. We analyzed the functionalities of these iCARDEA modules and packages. The presented features of these packages will lead to the identification of users of interest and a specific approach to its individual or joint exploitation. In Section 2.5.1.3, we have elaborated on these possible different exploitation packages, and tried to identify the target of the exploitation of the specific package, i.e. **users of interest**, possible services that can be provided for that specific exploitation package, and the **partners** able to potentially perform the **exploitation** defining the role they would play. In Section 2.5.1.4, we present partner roles in the joint iCARDEA Exploitation Strategy.

2.5.1.1 Open Source Paradigm¹¹³

2.5.1.1.1 Open source definition

Open source describes computer software that complies with the following criteria:

1. Free Redistribution: The license shall not restrict any party from selling or giving away the software as a component of an aggregate software distribution containing programs from several different sources. The license shall not require a royalty or other fee for such sale.
2. Source Code: The program must include source code, and must allow distribution in source code as well as compiled form. Where some form of a product is not distributed with source code, there must be a well-publicized means of obtaining the source code for no more than a reasonable reproduction cost preferably, downloading via the Internet without charge. The source code must be the preferred form in which a programmer would modify the program. Deliberately obfuscated source code is not allowed. Intermediate forms such as the output of a preprocessor or translator are not allowed.
3. Derived Works: The license must allow modifications and derived works, and must allow them to be distributed under the same terms as the license of the original software.

¹¹³ Open Source Initiative: www.opensource.org, JISC <http://www.jiscinfonet.ac.uk>, OMII: www.omii.ac.uk, Globus Alliance: www.globus.org, Apache: www.apache.org

4. Integrity of The Author's Source Code: The license may restrict source-code from being distributed in modified form *only* if the license allows the distribution of "patch files" with the source code for the purpose of modifying the program at build time. The license must explicitly permit distribution of software built from modified source code. The license may require derived works to carry a different name or version number from the original software.
5. No Discrimination against Persons or Groups: The license must not discriminate against any person or group of persons.
6. No Discrimination against Fields of Endeavour: The license must not restrict anyone from making use of the program in a specific field of endeavour. For example, it may not restrict the program from being used in a business, or from being used for genetic research.
7. Distribution of License: The rights attached to the program must apply to all to whom the program is redistributed without the need for execution of an additional license by those parties.
8. License Must Not Be Specific to a Product: The rights attached to the program must not depend on the program's being part of a particular software distribution. If the program is extracted from that distribution and used or distributed within the terms of the program's license, all parties to whom the program is redistributed should have the same rights as those that are granted in conjunction with the original software distribution.
9. License Must Not Restrict Other Software: The license must not place restrictions on other software that is distributed along with the licensed software. For example, the license must not insist that all other programs distributed on the same medium must be open-source software.
10. License Must Be Technology-Neutral: No provision of the license may be predicated on any individual technology or style of interface.

There are several other features which many, but not all, open source software products have in common:

- The cost of immediate acquisition to the end-user is usually minimal; this is because the right to freely redistribute the software makes selling licences for copies of open source software an unlikely business proposition
- The development methodology of open source projects shares many characteristics with Agile programming, in that releases are frequent, features are added quickly after customer feedback, developers are often distributed geographically, and formal management structures are limited
- Many, but by no means all, open source projects are created and sustained by informal communities of developers, users and evangelists, rather than commercial companies
- Open source projects often serve as apprentice opportunities for junior developers to rapidly learn their trade by engaging in real-world development

2.5.1.1.2 Open source licences

At the moment there are more than 50 OSI certified open source licenses. The following ones are perhaps the most commonly used:

- Apache License, 2.0
- New and Simplified BSD licenses
- GNU General Public License (GPL)
- GNU Library or "Lesser" General Public License (LGPL)
- MIT license
- Mozilla Public License 1.1 (MPL)
- Common Development and Distribution License
- Common Public License 1.0
- Eclipse Public License

There are some common features among licenses:

- Allow anyone to distribute the software for a fee (or give it away) without royalty to the licensor
- Allow modified versions of the software to be distributed by licensees (under varying terms depending on which licence is chosen)
- Try to exclude liabilities to the extent possible under local laws
- Copyright law prevents the copying, distribution and/or modification of copyright works (subject to certain exceptions)
- The licence allows anyone to perform these activities under certain conditions
- A licensee who disclaims knowledge of the terms of the licence is acknowledging that they had no permission.
- There is no other route by which the software can be lawfully used.

The decision as to which open source licence to use on a new software project should not be taken lightly. In many ways it expresses and shapes the development goals of the project. At the current stage of the iCARDEA project the consortium partners tend towards a permissive licensing strategy as presented in Table 7, either based on MIT or Apache Licenses. The final decision will be agreed on the third year of the project.

iCARDEA Assests	Licensing Strategy
Personalized Adaptive Care Planner Environment	Apache License 2.0
Data Analysis through Temporal Dimensions Module	Closed Source, commercial service offering.
CIED Data Interoperability Module	The license depends on the incoming data: currently some Modules based on: - iText: GNU AFFERO GENERAL PUBLIC LICENSE Version 3, 19 November 2007 - icePDF: Mozilla Public License 1.1 (MPL)

Framework for Patient Empowerment	Apache License 2.0, and with dependencies on Open Source licensed libraries including the (AGPL) GNU AFFERO GENERAL PUBLIC LICENSE
EHR Interoperability Framework	MIT ("Expat") License ^{114,115} will be used since: - It is very simple and short - It is permissive - It is GPL Compatible

Table 7 Licensing Strategy for iCARDEA exploitable assets

2.5.1.1.3 Open source as an exploitation model

Common models are:

- The **community model**: the costs of sustaining the product or service are covered by building a community of users and industry partners who agree to cooperate on development work and maintenance because of their shared interest in an extended life for the product. Products maintained in this way tend to have a wide applicability, such as Apache.
- The **subscription model**: users pay subscription costs to an external body in order to support central maintenance and support. SAKAI and Linux Red Hat software are supported in this fashion.
- The **commercial model**: users choose to adopt and pay for a 'commercialised' version of a piece of software, normally to gain guaranteed support, maintenance and service models.
- The **central support model**: a central body provides robust releases and support for open source products that are of strategic importance to its community. This is often an interim solution, whilst other sustainability models are under development. The UK OMII and the Globus Alliance are example of this model.

2.5.1.2 iCARDEA positioning in the open source context

iCARDEA Project delivers the components produced throughout the project life-time under open source distribution.

Open source solution adoption is driven by multiple sources: for example in Europe governments lead the adoption of open-source software and enterprises may prefer open source solutions in order to lower costs and maximize innovation. Nowadays, open source solution adoption has been increasing very rapidly. According to Golden notes¹¹⁶, who prepares the O'Reilly Radar Report "Open Source in the Enterprise 2008", the number of projects hosted on SourceForge¹¹⁷ (a [source code repository](http://sourceforge.net/) and acts as a centralized location for software developers to control and manage open source software

¹¹⁴ <http://www.opensource.org/licenses/MIT>

¹¹⁵ <http://www.gnu.org/licenses/license-list.html#Expat>

¹¹⁶ <http://www.opensolutionsalliance.org/Portal.do?command=Default&siteId=2&tabId=32&pageId=130>

¹¹⁷ <http://sourceforge.net/index.php>

development.¹¹⁸) has grown at a compound rate of 55%, rising from 12,500 in 2000 to nearly 200,000 by the end of 2007. In that same time period, SourceForge downloads have increased by 7,000 percent.

Five key drivers which may give why open source adoption is very promising and the reasons behind it can be listed as follows:

- **Agility and Scale:** The ability to quickly grow and modify software systems to respond to rapidly changing business conditions is one of the most important reasons. In contrast, given that the source is closed, you are vendor-dependent to fix things. Sometimes they may be responsive, and sometimes they are not in a timely manner. But in open-source products, many of the well known solutions have practically unlimited access to developers.
- **Quality and Security:** Open source solutions' bugs are fixed at high speed and vulnerabilities are patched very quickly. Coverity study states that overall error rates in open source code are 1/100 that of proprietary software on average.
- **Lower costs:** For vendor-solutions you pay not only initial fees for the system, but also additional fees for upgrades. However, open source has been practically free or at least lower initial cost, and the users don't have to pay addition money for major upgrades.
- **Better extensibility:** The open source project is open to be extended out of the box by presenting plenty of plug-ins.
- **Innovation:** The future of innovation appears poised to occur through collaborations, and open source's liberal licensing significantly reduces collaboration friction.

On the other hand, as iCARDEA consortium, by using the open source technology model, we may create a superior product, which immediately has a competitive advantage, and which can be extended by the community while being freely available. Furthermore, by adopting open source business model, we intend to seek first, to maximise use value by gaining input of many users, and second, to extract economic benefit from that increased use value.

As almost all of the components that comprise the iCARDEA architecture will be open source, it is obvious that selling licenses for copies of open source software is an unlikely business proposition; however the provision of services for training, consultancy, and customization is contemplated. An exception is the Data Analysis and Correlation Tool (DACT), which is deeply interwoven with external commercial Data Analysis tools like Mustang, a closed-source software tool provided by OFFIS as background to the project, for which commercial service offerings already exist and will be extended based on the additional capabilities provided by DACT. The concept of an open interface to iCARDEA allows us easily to integrate other (commercial) data analysis tools.

¹¹⁸ <http://en.wikipedia.org/wiki/Sourceforge>

iCARDEA products can be packaged and distributed using three different approaches, as separate iCARDEA Open Modules, as an open platform comprising a set of open modules or as a platform integrated with Proprietary Systems:

- **iCARDEA Open Platform comprising a set of Open Modules**
The modules are described in the next subchapter, and in most cases developed on the basis of state of the art technology and standards and planned to be available as open source modules; Customer can choose the modules needed; either separate modules can be used individually, or all iCARDEA Modules can be used as an Open Platform.
- **iCARDEA Platform integrated with Proprietary Systems**
The iCARDEA Platform is the result of integrating iCARDEA modules on the basis of the customization of the Open Specification for the needs of the addressed customers.

2.5.1.3 iCARDEA Products & Services

This chapter describes the results of iCARDEA research and development project in terms of software modules to be used in developing iCARDEA industrial solutions for the commercial exploitation. The description identifies all the principal modules along with their functionalities.

- Personalized Adaptive Care Planner and Execution Engine (PACP-EXE)
 - o Support for the execution of Clinical Guidelines in GLIF Format and monitoring them
 - o Supports the definition of Clinical Guidelines graphically
 - o Supports sending alarms through Email, SMS and Instant Messaging
 - o Support for retrieving CIED device information conforming to IHE IDCO Profile and storing this information in persistent relational databases
 - o Providing corresponding APIs to access the CIED information in persistent relational database through Hibernate Java Persistent Objects.
 - o Support for retrieving EHR and PHR health information conforming to IHE CM Profile and storing this information in persistent relational databases
 - o Providing corresponding APIs to access the EHR&PHR information in persistent relational database through Hibernate Java Persistent Objects.
- CIED Data Exposure Module (CIED-DEM)
 - o Support for sending CIED information conforming to IHE IDCO Profile
 - o Processing proprietary CIED PDF Reports and generating IHE IDCO Profile conformant messages
- Patient Empowerment Framework (PEF)
 - o Provides Personal Health Record System
 - o Support for receiving queries and sending PHR information based on the IHE PCC Profile
 - o Support for sending queries and receiving EHR information based on IHE PCC Profile
 - o Education Material for CIED patients and a user manual for the PHR systems

- EHR Interoperability Infrastructure (EII)
 - Support for sending EHR information in IHE CM Profile
 - Support for sending EHR information in IHE XPHR Profile
 - Support for converting HL7 v3 CDA R2 documents to IHE CM Profile conformant messages
 - Support for IHE PIX Profile
 - Support for IHE XDS Profile
 - Support for generating HL7 v3 CDA documents from proprietary databases
 - Support for HL7 v2 messages
- Data Analysis and Correlation Tool (DACT)
 - Presents the critical EHR, PHR and CIED information in a single Web portal
 - Support for retrieving information from IHE CM compliant persistent relational databases
 - Support for retrieving information from IHE IDCO compliant persistent relational databases
 - Presents potential useful patterns derived from data analysis, that could be suitable for the patient.

iCARDEA is a framework of software that can be installed in small packages of software or in an integrated platform. The high modularity of the solution gives to industrial partners the possibility to sell iCARDEA in different ways.

- Package 1: Personalized Adaptive Care Planner and Execution Engine (PACP-EXE)
- Package 2: CIED Data Exposure Module (CIED-DEM)
- Package 3: Patient Empowerment Framework (PEF)
- Package 4: EHR Interoperability Infrastructure (EII)
- Package 5: Data Analysis and Correlation Tool (DACT)
- Package 6: PACP-EXE, CIED-DEM, PEF
- Package 7: PACP-EXE, CIED-DEM, EII
- Package 8: All modules

2.5.1.3.1 Package 1: Personalized Adaptive Care Planner and Execution Engine (PACP-EXE)

The PACP-EXE tool allows the medical experts to generate medical care plans graphically. The tool also provides mechanisms to execute and monitor the execution of medical care plans personalized to a specific patient.

Who can benefit from the package?

- **Medical Institutes:** The medical institutes can deploy the PACP-EXE solution to support their daily practices for the follow-up of CIED implanted patients.
- **CIED Vendors:** The CIED Vendors can put additional decision support on top of their raw data from the CIED devices.
- **Existing PHR Systems:** The PHR Systems can put additional decision support on top of their existing data.

- **Existing EHR Systems:** Like in the PHR Systems, the EHR Systems can put decision support mechanism.

Involved Partners and Associated Services

SRDC can provide associated services in terms of **consultancy services** e.g Guidance of medical institutes into the definition and execution of medical guidelines. **Training service** can be served to communities for detailed presentation of the tool's capabilities and serving hands-on experience. **Customization service** can be provided for the specialization of the tool to the specific needs of the current practices of a particular hospital.

2.5.1.3.2 Package 2: CIED Data Exposure Module (CIED-DEM)

Who can benefit from the package?

- **CIED Vendors:** They can use the toolkit to produce IHE IDCO compliant messages out of the box
- **Hospitals:** If they want to get a complete data supply chain it can be used to integrate existing CIEDs
- **Vendors of Cardiology Software:** If they want to integrate existing devices into their software via standard interchange formats.

Involved Partners and Associated Services

OFFIS can provide consulting services and organize workshops on IHE IDCO Profile. It can also provide consulting, workshop services on how to use the package and offer individually adapted software versions.

2.5.1.3.3 Package 3: Patient Empowerment Framework (PEF)

The Patient Empowerment Framework (PEF) allows CIED patients to manage and store patient data that are in particular of interest in relation with their disease.

Who can benefit from the package?

- **CIED patients and their relatives:** The PEF allows patients to import existing patient data, to add and modify disease-relevant observations and to export these data, e.g. for the treating physician.
- **Medical Institutes:** Medical Institutes can add disease-relevant observations of patients to their patient data. This could be in particular of interest for organisations supporting chronic disease management solutions.
- **CIED Vendors:** CIED Vendors can add disease-relevant observations of patients to their patient data.
- **Personal Health Applications:** Existing PHR, EHR or other Personal Health Applications can integrate additional patient data or functions from the PEF
- **National efforts to offer citizens PHR based services:** As national EHR systems become developed and deployed, the patients, patient advocates and medical professions all interested in accessing patient information. These discussions will

eventually lead to rights for the patients to access their data and more opportunity for communication between patients and medical physicians. There will be much opportunity for PHR systems that offer services for interoperability and adaptable components.

- **Health application providers:** Vendors offering health applications on desktop or mobile systems could use PHR system interoperability services or adaptable components. Using the interoperability services, health information might be shared with clinical systems.

Involved Partners and Associated Services

SRFG can provide a **customization service**; this means for example the PEF can be individualized to the needs of other chronic diseases such as diabetes.

2.5.1.3.4 Package 4: EHR Interoperability Infrastructure (EII)

Who can benefit from the package?

The users of interest of this package could be: **Health application providers** such as vendors who can provide interfaces to their applications to share clinical information with the selected partners through well accepted standards and profiles (Such as HL7, IHE CM Profiles).

Involved partners and Associated Services

FORTH can provide installation and maintenance services especially for the customization of EII to the specific needs of the Healthcare application provider, and the healthcare institute. **FORTYH** can also provide services for the upgrade of this interoperability service by updating the interoperability layer of the system with future new standards and rules.

2.5.1.3.5 Package 5: Data Analysis and Correlation Tool (DACT)

Who can benefit from the package?

- **Physicians at clinics:** They can use a single tool to have an overview about all electronic available patients data at a glance via the PPM component without training for multiple different systems
- **Physicians and controllers:** They can also benefit from data analysis by better understanding their patients leading to more effective and / or cheaper treatments.
- **Patients:** They can also benefit due to better treatments based on new knowledge obtained from data analysis which is automatically brought to the attention of the physician if it is potential useful for the patient.
- **Data Analysts:** They can benefit from the temporal data analysis attempt due to more powerful analysis, especially for fine granular medical analysis.

Involved Partners and Associated Services

OFFIS provides consulting and implementation of data analysis processes, especially where privacy and security concerns are important. OFFIS can also provide data analysis services where the temporal evolution of data is important. The DACT package as such will remain closed source software and will be exploited as part of the data analysis service offerings as outlined above. But due to the open interface to iCARDEA it will be able to integrate other data analysis tools into iCARDEA. OFFIS provides also consulting for this.

2.5.1.3.6 Package 6: PACP-EXE, CIED-DEM, PEF

This multiple package presents improved characteristics than the products on its own at the same time it broadens its interest and applications. This package is composed of PACP-EXE, CIED-DEM, PEF modules.

Who can benefit from the package?

This package can be used by the following targets:

- **Software Vendors** that have access to a summary of electronic health records through PHR, and who want to use Care Plan Engine for remote patient monitoring through accessing EHR, PHR and CIED data.
- **CIED Vendors** that have access to a summary of electronic health records through PHR, and who want to use Care Plan Engine for more complex decision support through accessing EHR, PHR data besides CIED data

Involved partners and Associated Services:

For this package, we envision the delivery of services to be provided jointly by **SRDC, OFFIS and SRFG**. These services would include consultancy, training and customization services.

2.5.1.3.7 Package 7: PACP-EXE, CIED-DEM, EII

As in Package 6, this multiple package presents improved characteristics than the products on its own at the same time it broadens its interest and applications. This package contains PACP-EXE, CIED-DEM, EII.

Who can benefit from the package?

This package can be used by the following targets:

- Medical institutes that do not have (or do not want to) access to PHR systems, and want to use Care Plan Engine for remote patient monitoring through accessing EHR and CIED data
- Software Vendors that do not have access to PHR systems and want to use Care Plan Engine for remote patient monitoring through accessing EHR and CIED data
- CIED Vendors that do not have access to PHR systems , and who want to use Care Plan Engine for more complex decision support through accessing HER data besides CIED data

Involved partners and Associated Services:

For this package, we envision the delivery of services to be provided jointly by **SRDC, OFFIS and FORTH**. These services would include consultancy, training and customization services.

2.5.1.3.8 Package 8: All modules

This completes the offer of packages by providing the whole iCARDEA solution. This package comprises all the benefits described in each of the mentioned packages.

Who can benefit from the package?

In a general sense and as stated in previous sections of this document, the **users of interest of this package would be: Public and Private Medical institutes, Software Vendors and CIED Vendors.**

Involved partners and Associated Services:

SRDC, OFFIS, SRFG and FORTH that would provide consultancy, training and customization services.

2.5.1.4 Roles in the Joint iCARDEA Exploitation Strategy

As the coordinator, SRDC would act as the contact point for possible iCARDEA Exploitation opportunities.

- The company would provide pre-sales services such as coordination of a detailed presentation of the iCARDEA vision to interested parties/possible exploitation targets identified by the members of the consortium.
- It would assess the requirements of potential customers and present alternative and focused exploitation opportunities/packages by presenting the services provided for the identified solution.
- It would direct potential customers to their respective partners for exploitation of Packages 1-5 (separate iCARDEA Modules) and would conduct a proof of concept validation support (with the help of the respective partners). SRDC would play a major role on the negotiation with potential customers on behalf of the consortium.

Here is depicted the role distribution among the respective partner for joint exploitation (Packages 6-8)

	SRDC	OFFIS	FORTH	SRFG
PACP-EXE	√			
CIED-DEM		√		
PEF				√
EII			√	
DACT		√		
PACP-EXE, CIED-DEM, PEF	√	√		√
PACP-EXE, CIED-DEM, EII	√	√	√	
All	√	√	√	√

Partners would play a specific role in the joint exploitation. **SRDC, OFFIS, FORTH and SRFG** would provide training services for using the modules as they are; they would also provide consultancy services for integration with existing systems as well as customization services based on specific requirements and needs.

St. Jude & Medtronic would extend their own portal for additional decision support mechanisms enabled by execution of care plans. As industry partners they probe to be the best position for finding potential customers using their already existing customer database. In this sense these partners could present iCARDEA Remote Monitoring capabilities as an add-on service to the hospitals or service integrator firms where they are providing Cardiac Implantable Devices. The coordination of exploitation activities would go in collaboration with SRDC.

SALK and HCPB, as Clinical partners, would provide medical consultancy that would help in the care plan definition process. They would exploit iCARDEA AF and VT Care Plans as well as the execution of iCARDEA enabled Care Plans for remote monitoring from a medical perspective. In this sense SALK would be the direct end user of iCARDEA results.

2.5.1.5 Choosing the best strategy for iCARDEA exploitation and iCARDEA deployment flexibility

As previously described, iCARDEA defined packages provide a series of useful features mostly aiming at the improvement of clinical practice and patient empowerment. Regarding the choices of the exploitation of the system, we present two different approaches a) getting in contact with final users directly for a possible exploitation; b) exploiting the system by a Service Integrator firm.

To decide on the best possible strategy, we analyzed the general tendency of procurement of health services by hospitals. Starting after the outsourcing trend in manufacturing industry (Roberts, 2001)¹¹⁹, healthcare sector is pointed as one of top three sectors (along with Finance and Legal) having a higher outsourcing growth (Brown and Wilson, 2005)¹²⁰.

Yang and Huang (2000)¹²¹ identified four imperatives for outsourcing growth in healthcare sector:

- (1) Organizational – iCARDEA aims to generate organizational changes by providing solutions to guide the physician into a more personalised and holistic treatment as well as empowering the patient.

¹¹⁹ Roberts, V. (2001), Managing Strategic Outsourcing in the Healthcare Industry, Journal of Healthcare Management, Vol.46, No.4, pp. 239-249.

¹²⁰ Brown, D. and S. Wilson (2005), The Black Book of Outsourcing: How to Manage The Changes, Challenges and Opportunities, April 2005 Wiley, John & Sons, Incorporated.

¹²¹ Yang, C. and J. Huang (2000), A decision Model for IS Outsourcing, International Journal of Information Management, Vol. 20, pp. 225-239.

- (2) Technological – iCARDEA bases its solutions on a technological platform, modular and oriented to services.
- (3) Strategic.
- (4) Regulatory.

In this environment, healthcare organizations adopt outsourcing solutions for the same reasons as in other sectors (Quinn and Hilmer, 1994), looking for efficiency, quality and profitability gains. In addition to this, in healthcare sector outsourcing is also part of volume flexible strategies¹²² trying to respond to demand fluctuations, increasing care complexity, and to the linkage between clinical performance and act volume (Jack and Powers, 2006)¹²³.

According to (Atun, 2006)¹²⁴, even in some European countries which are more politically reluctant to privatizations (such as United Kingdom, Sweden, Spain and Portugal), outsourcing of clinical services is chosen as a response to reducing the waiting lists for healthcare services. Through contracting agreements with public and private providers (including public-private partnerships (PPPs)), healthcare institutes aim to gain access, quality, equity and efficiency advantages (Abramsom, 2001; Liu et al, 2004).

The activities outsourced in Healthcare sector are quite heterogeneous and varied. They are usually distinguished between non clinical services and clinical services.

In the first group, **Non-Clinical Services**, hospitals tend to outsource Information Technology and services; procurement; purchasing and delivery; payment collection; facility management; non-emergency patient transport; security; maintenance; meals; waste management; sterilization and laboratories.

Regarding outsourcing activities more oriented to **clinical services** there is a tendency to outsource laboratory (pathology, microbiology); pharmacy; radiology; imaging; nuclear medicine; physiotherapy; occupational therapy; speech and language therapy; home delivered high-tech Healthcare (total parenteral nutrition, intravenous chemotherapy, continuous ambulatory peritoneal dialysis).

The **main drivers** that support these activities are: cost and health service quality standardization; partnership policy; cost reduction in auxiliary activities; business process redesign and IT updating; access to expertise; flexibility; focus on critical activities to achieve strategic advantages and patient satisfaction.

This “outsourcing” entails a series of associated benefits such as cost reduction, service standardizations, equipment improvement, access to best practices and top class

¹²² Volume flexible strategies represent a variety of methods where organizations use their portfolio of resources and capabilities to meet fluctuating customer demand while improving organizational performance.

¹²³ Jack, E. P. and T. L. Powers (2006), Managerial perceptions on volume flexible strategies and performance in health care services, *Management Research News*, Vol.29, No.5, pp. 228-241.

¹²⁴ Atun, R. A. (2006), Privatization as decentralization strategy, Report to the World Health Organization Regional Office for Europe Cap 14, 246-71 www.wpro.who.int (visited 12 September, 2008).

technology and, in general, service quality improvement. But its deployment could go together with risks, e.g. adapting problems, high hidden costs of IT outsourcing, difficulty in monitoring results, low impact on costs or vendor difficulty to understand internal processes.

Why iCARDEA fits in this business model?

From reviewing the literature, the most pointed drivers to outsource in healthcare units are (Alper, 2004; Bhattacharya et al, 2003)¹²⁵⁻¹²⁶:

- (1) cost reduction
- (2) risk mitigation
- (3) adapting to quick changes without jeopardize internal resources
- (4) value stream redefining

iCARDEA remote CIED monitoring system, is a high tech home-delivered healthcare service, which is among the listed kind of healthcare services usually tend to be outsourced by hospitals, in order to provide the best possible care to their patients while reducing the cost of auxiliary activities and mitigating the risk of serving this high-tech solution. As will be explained in Section 2.5.1.6 presenting **Return of the investment**, iCARDEA can additionally potentially reduce costs based on the evidence of **reduced number of in-clinic follow-up visit** and **time savings for medical personnel** as well as the value stream that its usage redefines. For these reasons, we believe that iCARDEA solutions can be a good candidate that could be outsourced to Service Integrator Firms.

Yet, the risks of outsourcing healthcare services by hospitals should also be assessed in this context. In general the fact of dealing with medical records entails a series of constraints. Normally that information cannot go outside the hospital's network without consent. Moreover, its management and processing is usually made in the HIS secure and legally accepted environment. iCARDEA modules are developed to be working overcoming these circumstances.

The nature of the data manipulated by the system influences customers perception of the appropriate deployment architecture, i.e. whether to outsource hosting of services and data or not. Hospital payroll data, may not be viewed as sensitively as patient records. As a result, the hospital may opt for a managed service solution for payroll processing but license patient record management from a reputable vendor and run it internally. Depending on the application, it can be more cost-effective to place the application at an ASP/MSP whose equipment or communication bandwidth can handle peak loads that are not cost-effective to handle with the hospital's own dedicated equipment.

Despite of the risks mentioned above, iCARDEA's solutions would gain value if it could be included in a services integrator firm that provides solutions to a hospital. By outsourcing IT to a service integrator, the hospital can focus internal resources to core

¹²⁵ Alper, M. (2004), New Trends in Healthcare Outsourcing, Employee Benefit Plan Review, Feb, Vol. 58, No.8, pp. 14-16.

¹²⁶ Bhattacharya, S., R.S. Behara and D.E. Gundersen (2003), Business Risk Perspective on Information System Outsourcing, International Journal of Accounting Information Systems Vol.4, pp.75-93.

competencies and avoid complexity. So our exploitation strategy will be approaching to service integrator firms rather than hospitals directly.

There is another issue that needs to be assessed for healthcare services to be suitable to be outsourced: The more service oriented the architecture is, the better iCARDEA solutions can be integrated by external systems and external firms. In the following section, we will assess the flexibility and state of maturity the iCARDEA system and therefore it would point out the feasibility of being adopted by a service integrator firm.

2.5.1.5.1 Suitability of iCARDEA solutions to be outsourced by a Service Integrator firm: Decoupling and flexibility of iCARDEA solutions

In this section we analyze the maturity of iCARDEA solutions for being integrated to the services provided by a service integrator firm to ensure an open path for a more feasible adoption. The approach is based on the **Service Integration Maturity Model (SIMM)**¹²⁷ which is composed of seven levels and provides an assessment of the level of de-coupling and amount of flexibility achievable at each stage.

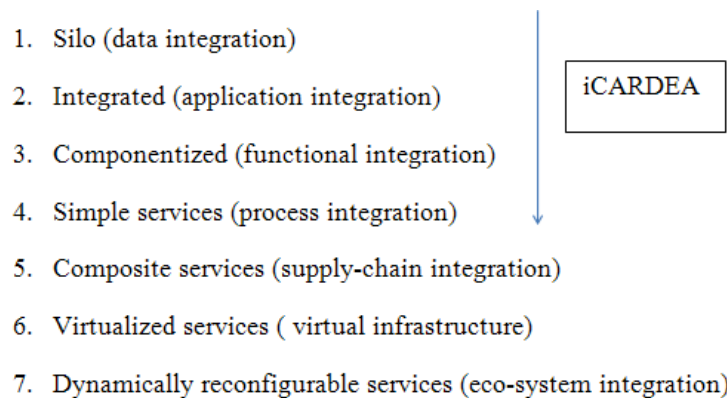


Figure 8 Service Integration Maturity Model (SIMM) and how iCARDEA fulfils the listed maturity levels

Level One: Silo. The system starts from proprietary and quite ad-hoc integration, rendering the architecture brittle in the face of change.

iCARDEA specifically tries to avoid such ad-hoc, brittle integration. For this, it supports “service” based interfaces based on well-defined international standards to the legacy systems used in the hospitals. For example, The PACP-EXE opens up services based on IHE-CM profile to collect patient summary from EHR and PHR systems. If the Hospital Information System within that hospital does not implement this standard service specification, iCARDEA provides further support with EHR Interoperability Infrastructure (EII). Here EII again supports a number of “service” based interfaces based on well-defined international standards to the legacy systems used in the hospitals to collect patient summary. For example, it opens up an IHE XDS based EHR repository interface: If the hospital information system already implements IHE XDS profile, i.e. implements the standardized transaction to store patient summaries as HL7 CDA

¹²⁷ <http://www.ibm.com/developerworks/webservices/library/ws-soa-simm/>

documents (ITI:41 Provide & Register Document Transaction) to the EHR repository implementation provided, there is no need for an ad-hoc integration. If this is not the case, custom adapters need to be developed.

However the integration of CIED Information System with the current Medtronic and SJM Portals to collect the PDF reports and process them can be analyzed as Level 1. Yet, it has to be noted that iCARDEA (through PACP-EXE which is the core of remote monitoring process), opens up “service” based interfaces based on well-defined IHE-IDCO profile to collect CIED data. If CIED vendors implement this industry standard, there would be no need for such brittle integrations.

iCARDEA System cannot be assessed as Level 1, it is the legacy EHR systems and CIED Portals that do not open up such service based interfaces based on well-defined standards, nevertheless vendor manufacturers are working to provide opened and standard communication protocols. Even in this case, iCARDEA provides additional support to overcome this, the EII, and CIED-DEM can be thought as intermediaries that are developed to overcome the deficiency of these legacy systems (not implementing international standards to share patient and CIED data).

Level Two: Integrated. The system moves toward some form of EAI (Enterprise Application Integration), albeit with proprietary connections and integration points. The approaches it uses are tailored to use legacy systems and attempt to dissect and re-factor through data integration.

iCARDEA also fulfils this level as it is comprised of different modules that could be integrated by specialists in hospital’s legacy systems such as:

- *Personalised Adaptive Care Planner and Execution Engine (PACP-EXE) which among other features described in the previous section, it gives support for retrieving CIED device information (from Saint Jude’s Medical and Medtronic’s CIED’s portals) and provides APIs to store it and recover it from a relational database*
- *CIED Data Exposure Module (CIED-DEM) that Hospitals could use to obtain a complete data supply chain that can be used to integrate existing CIEDs (Package 2)*
- *Patient empowerment framework (PEF), which provides a Personal Health Records System that supports the reception of queries based on the IHE PCC Profile (Package 3)*

If the legacy HIS implements the industry standards used to share patient summaries between a Care Manager and a Data Source (IHE –CM Profile) iCARDEA is over Level 2. Yet if HIS does not support this, iCARDEA also serves the ability to achieve this kind of “Integration” through the EII. An HL7 and EDF listener is implemented as custom adopters to collect patient summaries from HIS, and feed them to the PACP-EXE through IHE CM transactions.

Level Three: Componentized. At this level, the system is componentized and major or critical parts of its application portfolio are modularized. It uses legacy transformation and renovation methods to re-factor legacy J2EE or .NET-based systems with clear component boundaries and scope, exposing functionality in a more modular fashion. The integration between components is through their interfaces and the contracts between them.

iCARDEA Platform itself is highly modularized and composed of loosely coupled systems that interact with well defined “service” based interface based on standards. When it comes to communication with the legacy systems within a hospital, it also provides service based interface based on standards, yet, if the legacy systems do not implement these services, it offers “integration” options that can be assessed as “level 1 and 2” as already explained.

Level Four: Simple services. The system embarks on the early phases of SOA by defining and exposing services for consumption internally or externally for end users -- not quite on a large scale -- but it acts as a service provider.

iCARDEA system is built from loosely coupled modules that communicate within themselves through well defined service based interfaces, hence can be assessed as Level 4.

Level Five: Composite Services. Now the system extends its influence into the value chain and into the service eco-system. Services form a contract among suppliers and end users who can build their own eco-system for on-demand interaction.

In order to achieve this level iCARDEA would need to provide deployment architecture completely oriented to services. Privacy and data management contracts among CIED vendors, hospitals and iCARDEA external system would be necessary. This means the final users would allow the external company that holds the system’s services could enter to the hospital’s patient’s databases(both CIED vendor’s proprietary and EHR) from the outside then use, modify, translate, work with that information and finally provide it and represent it to the final user.

iCARDEA does not support on demand interaction through composite business processes. For achieving the current objective “achieving remote monitoring for CIED patients through a Care Plan Engine”, such a business process creation and execution is not needed. However if the Service Integrator wants to make use of iCARDEA components, such as EII, CIED-DEM , for constructing other application logic, then this level of maturity may be needed.

Level Six: Virtualized Services. The system achieves the infrastructure of a virtualized environment to run applications. It achieves this level after decoupling the application, its services, components, and flows. Now the infrastructure is more finely tuned, and the notions of the grid and the grid service render it more agile. It externalizes its monitoring, management, and events (common event infrastructure).

iCARDEA was not built to work in a virtualized architecture. In that case it would require further necessities than those foreseen in Levels 5 and 4. E.g. If we try to sell an application / system as an ASP/MSP it may have to be installed in multiple locations around the world and guarantee such things as performance and availability. In favour of iCARDEA, communication networks are fast and increasing in speed every day, but for the most part locally maintained applications and data are faster.

Level Seven: Dynamically Re-Configurable Services. The system now has dynamically re-configurable software architecture. It can compose services at run-time using externalized policy descriptions, management, and monitoring. *Such a dynamic re-configuration environment is not foreseen in iCARDEA architecture.*

This study has proved what is the iCARDEA system's service integration maturity and the current amount of flexibility the system portrays. For each level it has been pointed what the system provides to make their solutions adoptable as services for their exploitation by a Service Provider firm.

An external provider that has extensive experience with the selected software can plan and deploy iCARDEA solutions while utilizing best practices learned from other implementations, especially when configuring software around existing clinical processes. In addition, external deployment providers can diagnose and resolve critical issues quickly and effectively. All these reasons, along with those mentioned in the sections above, support the claim that best way of leading iCARDEA's exploitation is by means of outsourcing the system to a Health Care service provider.

2.5.1.6 Return of Investment ¹²⁸

Cardiovascular implantable electronic devices are widely used for the treatment of bradycardia, tachycardia, heart failure (HF) and for arrhythmia monitoring¹²⁹. They include: cardiac pacemakers (PM), implantable cardioverter-defibrillators (ICD), cardiac resynchronisation therapy (CRT)* devices, implantable cardiovascular monitors (ICM) and implantable loop recorders (ILR). Monitoring patients, diseases and devices is essential to detect any clinical or device-related problems.

The rate of implantation is expected to rise sharply in Europe. This is due to the progressively ageing trend of Western European populations and the associated increase in age-related health conditions, coupled with an expansion in indications for implantable devices. The European Medical Technology Industry Association (Eucomed) has measured an implantation growth rate of approximately 6% per year between 2003 and 2009.

Estimate costs for CIED monitoring

The healthcare system is burdened in terms of capacity, time and the economic cost of care. Routine follow-up visits, including system interrogations and verification of clinical

¹²⁸ The value of remote monitoring in patients with cardiovascular implantable electronic devices. UC201006251 EE © Medtronic 2009. All Rights Reserved [*Most of the information contained in the Return of Investment*] section is extracted from this Medtronic Inc. publication. Please do not redistribute without consent]

¹²⁹ Adapted from Wilkoff BL et al. (2008)

* Includes CRT-P (for patients who are candidates for CRT, but who are not indicated for an implantable defibrillator) and CRT-D (CRT device and defibrillator).

events, are time-consuming¹³⁰. Additionally, a substantial proportion of recipients require unscheduled visits due to clinical events or system-related complications¹³¹

The majority of cardiac device recipients are routinely followed up at intervals ranging from 3 to 6 months, and the increase in implants will impose a further level of burden on already resource-constrained cardiology services.

In-clinic device follow-up is associated with a considerable burden to healthcare systems and patients. Telemedicine can replace scheduled and unscheduled in-clinic follow-up using remote transmission.

Personnel costs: A French study of ICD patients estimated medical services cost of \$45.73/visit for physician's fees and electrocardiogram and \$48/visit for implantable device surveillance. The cost of transportation in a sitting position, in a medical vehicle without physician attendance, was estimated at \$10.75 for a distance less than 5km between a patient's home and medical facility – for each additional km, \$0.75 was added¹³². For each visit, **a mean overall cost of \$215 was calculated, comprising \$121 for transportation and \$94 for medical services.**¹³³

Maintenance costs will depend on the business model applied for commercializing iCARDEA system; the maintenance fee will depend on the contract and commercial agreement between hospital and the service provider firm.

Cost saving criteria

Reduced number of in-clinic follow-up visit: International recommendations developed in partnership with the European Heart Rhythm Association and Heart Rhythm Society state that patients with a PM should be followed up every 3–12 months and those with an ICD every 3–6 months. Intensified (monthly) monitoring should be considered when a device nears its elective replacement indicator. Within these recommendations, follow-up may be carried out in a clinical setting or remotely, however it is also recommended that any patient should be assessed in-clinic at least once a year¹²⁹.

Crossley GH (2010) reported that replacing routine in-clinic visits with remote follow-up reduces the number of scheduled and unscheduled hospital visits per patient. In-clinic follow-up is quantified in **6.27** annual visits per patient vs. **3.92** corresponding to remote follow-up.

Studies have shown that remote follow-up can be used to replace 50–63% of in-clinic visits without impacting on patient outcomes, such as CV hospitalisations, ER visits and mortality.¹³⁴

¹³¹ Theuns DAMJ et al. PACE 2009;32(suppl. 1):63–5

¹³³ Fauchier et al. PACE 2005; 28:s255-9

¹³⁴ Adapted from Elsner CH et al. (2006)12.

A study by Raatikainen et al., (2008) reported a 41% saving associated with replacing a portion of in-clinic visits with remote monitoring. In addition, an average of €100 per patient was saved because all unscheduled data transmissions during the study period were resolved remotely and patients did not need to be evaluated or reassured at their local hospital. The total annual saving associated with online monitoring was reported to be €524–749 per patient, and applying remote monitoring to all new ICD patients with in Western Europe was estimated to save the healthcare system an estimated €16–23 million annually¹³⁵.

According to this information it seems realistic that using a system as iCARDEA as a service that complements vendors remote monitoring systems would add value to those platforms and therefore portray its inherent benefits in the decrease of the number of in clinic visits per patient and consequently its associated costs.

Time savings for medical personnel: In addition to reducing the number of visits, remote follow-up requires less physician time than in-clinic follow-up. Raatikainen et al. (2008) reported that remote follow-up required 8.4 minutes compared with 25.8 minutes for in-clinic follow-up, (see fig 10). It was also found to be more time consuming for the additional hospital staff to complete an in-clinic visit than remote follow-up (45.3 vs. 9.3 min)¹³⁶. The Italian study by Masella et al. (2008) also found remote follow-up to be more time efficient than in-clinic follow-up, both for physicians (4.7 vs. 15 min) and patients (6.6 vs. 116.3 min).

iCARDEA – benefits aside remote monitoring

Remote follow-up has value: when a patient's medical condition is stable; when device programming is not required; during the maintenance phase of follow-up (in stable device function); during accelerated follow-up to plan elective device replacement; in the event of a field safety corrective action/safety alert where accelerated monitoring may detect a device malfunction. iCARDEA has the possibility to guide the clinician in the VT –AF scenarios and provide value in the remote monitoring process as it integrates CIED data with existing health processes (clinical pathways, guidelines, workflows) and data (HER, PHR).

The usage of iCARDEA potentially entails that healthcare resources are utilised more effectively. On the one side the number of scheduled and unscheduled in clinic visits can be reduced (remote monitoring systems over which iCARDEA deploys part of its services entail this effect), on the other hand when a patient requires an in clinic visit, the decision about its care plan is also suggested which would potentially result in savings in terms of hospital capacity, physician time and transportation costs. Another benefit is the reduction in hardware/software adhoc solutions as iCARDEA system centralises the monitoring in a single access point. (The state of integration with vendors SW is currently under Medtronic's CareLink Network and Saint Jude's Merlin.net, but it is opened to allow future integrations by means of interoperability standards and HL7 message capabilities).

¹³⁵ Raatikainen M.J.P., et al. 2008. Remote monitoring of implantable cardioverter defibrillator patients: A safe, time-saving, and cost-effective means for follow-up. *Europace*, 10(10):1145–51

¹³⁶ Raatikainen MJP et al. *Europace* 2008;10(10):1145–51

2.5.1.7 Other legal/organisational/economical barriers that may hamper exploitation of iCARDEA solutions within an hospital

In previous sections, we tried to present the benefits that remote monitoring of CIED patients can introduce including possible cost and time savings. Despite of these benefits, successful exploitation of iCARDEA results could be hampered by a number of legal, organisational, and economic issues. In this section we will try to elaborate on possible barriers for a successful deployment of an iCARDEA enabled remote monitoring system within a hospital and will try to outline the necessary steps to be taken at organisational and political scale to overcome these.

Adopting the iCARDEA enabled remote monitoring feature for CIED patients will first of all change the current treatment workflow within a hospital, introducing additional responsibilities for a number of actors, while relieving them from some routine treatment steps, like some of the in-clinic ICD follow-ups. For example according to iCARDEA pilot application protocol, qualified personnel should be available to check the alerts received from iCARDEA care planner, and follow the execution of the care plan in such situation as an additional task that is not currently exists in their daily routines. On the other hand, iCARDEA care planner enabled remote monitoring will eliminate quarterly regular in-clinic follow-ups (in clinic visits to be organized on M3, M9, M15 will be replaced with remote visits), hence saving time both for them and patients. This change in the clinical treatment workflow within a hospital should be managed very carefully:

- It should be ensured that clear role and responsibility distribution is established for the new treatment workflow within the healthcare institute. It is advised that this is achieved through an in-hospital protocol for remote CIED monitoring to describe the tasks and responsibilities of the cardiologist, allied professional and hospital management¹³⁷. As will be explained in the following paragraphs, a prerequisite for this is the availability of the suitable billing and documentation system within the hospital to report these activities as treatments to be reimbursed. This necessitates exhaustive safety studies to prove the effectiveness, safety and efficiency of the newly proposed treatment strategy. In addition to this, in most of the clinics, first of all a normal telemonitoring work flow will be needed to be established first, before they will use iCARDEA; care givers will need reassurance that the new technology Telemonitoring functions before they move onto even more technology.
- This role and responsibility distribution should take the existing workload of medical professionals into account and should reserve the required amount of time for the new tasks added to the daily routine of the medical professionals. Currently in some countries, the outpatient clinics do not take these kinds of telemonitoring services into consideration, although they are needed to be taken care of by in house professionals; which is definitely a huge problem for the adoption of telemonitoring.

¹³⁷ Remote monitoring and follow-up of cardiovascular implantable electronic devices in the Netherlands
An expert consensus report of the Netherlands Society of Cardiology, 19.07.2011

This new treatment workplan involving change of responsibilities clearly introduces major impact on time, technical facilities and personnel of the healthcare institute. Hence it should be ensured that the necessary reimbursement mechanisms are put in place. This will depend on the available reimbursement policies in that healthcare institute and more specifically within that country. In the USA, Medicare and Medicaid have expanded reimbursement for remote device monitoring for all states since 2006. Reimbursement rates vary from state to state, and in some instances are the same as an in-office visit without device programming. In the UK, Germany, and Portugal, reimbursement for remote monitoring is similar to that offered for standard follow-up visits¹³⁸. For a successful adoption of remote ICD monitoring within a country, if appropriate reimbursement policies are not available within a country, the necessary policy studies should be activated. The necessary directives, regulations, laws and juridical interpretations that direct and manage the lifecycle of remote health monitoring including the reimbursement policy and the integration of tele-monitoring into the conventional healthcare system should be available¹³⁹. This may necessitate¹⁴⁰:

- Short term pilot studies to evaluate the frequency and reasons of remote CIED monitoring currently done to define without delay the degree and level of reimbursement
- Cost effectiveness studies of remote CIED monitoring should be initiated to evaluate the efficiency of various indications for remote monitoring in the national health setting. The results should be used for fine-tuning of the current reimbursement structure.

Our pilot application is being deployed in Salzburg Austria. Currently, the judicial , insurance and ethical process is still being negotiated in Austria and will probably take some time.

As a result, physician remuneration for tele-health services should be possible. In some countries, there are incentives for the physicians only for the number physical patient visits, such incentives should also be available for remote monitoring activities. In some jurisdictions, the healthcare institutes are funded based on volume of services delivered¹⁴¹, clearly these reimbursement policies should be adjusted to include remote management of CIED patient's care as a service provided by the healthcare providers.

Another risk for the successful deployment of iCARDEA enabled remote monitoring feature for CIED patients could be physician resistance. Remote CIED monitoring delivers a substantial amount of data to be handled by the cardiologist and allied professional, who may be reluctant to analyse the huge amount of data to detect potential problems. iCARDEA already addresses this risk and rather than purely presenting the

¹³⁸ Remote monitoring and follow-up of pacemakers and implantable cardioverter defibrillators, Haran Burri and David Senouf, *Europace*. 2009 June; 11(6): 701–709.

¹³⁹ Changes in Healthcare: towards a “patient-centric” approach, Silvio Bonfiglio

¹⁴⁰ Remote monitoring and follow-up of cardiovascular implantable electronic devices in the Netherlands An expert consensus report of the Netherlands Society of Cardiology, 19.07.2011

¹⁴¹ Healthcare Unwired, New business models delivering care anywhere, Health Research Institute, Price Waterhouse and Coopers

raw data collected from CIEDs, EHRs and PHRs, provides an assessment of the most recent data in the light of pre-defined clinical guidelines. Another factor that may result in physician reluctance to use the systems could be about legal liability and possible malpractice issues. The lack of the legal framework would also hinder the deployment of such pilot applications in the first place for ethical reasons. For example, in our pilot application, the deployment of PHR application is not accepted by the Salzburg Ethical Committee, due to the patient privacy issues, and the lack of responsibility and liability definitions of physicians for checking the PHR record in the legal framework. To avoid these problems, the legal framework should be put in place by the government that clearly defines the clinical responsibilities and liabilities of medical professionals with respect to remote CIED monitoring¹³⁹, also clear procedure definitions to document alerts and treatments for telemedicine applications should be available.

In an environment like the USA where the insurances reimburse and the work flow is standardized and there are no more issues open is definitely a place where iCARDEA can be exploited. It is standard practice in many hospitals in the USA to put every ICD patient on Telemonitoring as they have proven it is a better way to follow patients. In many European countries there are so many issues being worked out for telemedicine in general it creates a problem for direct use of iCARDEA .

As a summary several barriers have to be removed and often they are not linked to the shortage of suitable and advanced technologies but – preponderantly – they are related to political, legal and cultural issues¹³⁹. We believe that, R&D studies like iCARDEA, combined with pilot results that demonstrate economic and clinical benefit, will drive all the stakeholders to establish the legal framework and required reimbursement policies so that the promise of better and more efficient healthcare management by remote monitoring facilities can be achieved.

2.5.2 Exploitation Strategy by Individual Partners

2.5.2.1 SRDC

SRDC already has a customer base in Turkey including the Ministry of Health (MoH), Turkey thanks to its extensive RTD work on the various aspects of eHealth including semantically enriched Web services for eHealth interoperability, a message exchange framework for providing the interoperability of HL7 v2.x messages with HL7 v3 messages, tools for providing clinical statement interoperability in Electronic Healthcare Records (EHRs) and semi-automated deployment of clinical guidelines.

SRDC contributed to the development of National Health Information Systems (NHIS) of Turkey as a consultant to the MoH, Turkey. NHIS, Turkey is based on the HL7 CDA R2 standard and uses HL7 Web services profile to communicate the EHRs. Currently, through NHIS all the EHRs in Turkey are being collected to the MoH centralized servers but for this information to be shared among the healthcare organizations, comprehensive patient privacy, security and consent management mechanisms are needed. SRDC plans to adapt the related components of iCARDEA for this purpose.

iCARDEA Project will also give SRDC the prospect to enhance its technology base by developing adaptive care planning tools to be integrated into the solutions that the company has and is currently developing. SRDC currently develops a personal health system that enables patients to manage their own care and well being together with their physicians. SRDC is currently in communication with Ministry of health to open this system to whole Turkish citizens as an extension of National Health Information System of Turkey. The adaptive care planner will be a part of this Personal Health System as a decision support system to be used in the shared decision making process involving both the physician and the patient.

In addition to this, iCARDEA automated clinical follow-up workflows offer a good opportunity to remotely monitor the patients at the rural areas in Turkey.

SRDC has also developed a simple code mapping API for the Ministry of Health, Turkey based on UMLS/KS to expose the proprietary interfaces of their Health Coding Reference Server. In the iCARDEA Project this simple API will be extended to develop the iCARDEA code mapping API based on the HL7 Common Terminology Services (CTS) standard interfaces. This component will also be adapted to the Turkish market.

The successful implementations to be realized in iCARDEA will be the basis of the expansion of the company into many other areas including personal health systems. In fact, the positive results of iCARDEA and possibly with other parallel research results like those coming from SRDC R&D programs may provide sustainable advantage to SRDC with respect to other competitors on the eHealth market and the market positioning of SRDC products could be much improved and possibly placed in areas where SRDC can be on the leading edge.

2.5.2.2 OFFIS

As a non-profit research institute with a special focus on technology transfer in the information technology sector OFFIS considers iCARDEA project as an excellent opportunity to improve the already well-established scientific profile of the Data Analysis Technologies research group within the OFFIS Health R&D division. This will be helpful for the acquisition of further 3rd party- funded R&D projects on national and regional level and will provide research topics for M.Sc. and PhD thesis. The research in the area of temporal OLAP dimensions has already led to a related PhD work that is in progress.

Furthermore, we expect opportunities in consultancy and co-operation with commercial partners on the iCARDEA technology applied to healthcare information systems. In our experience, complex explorative data analysis systems are often marketed as hybrid products comprised of the analysis system as such, plus services providing the expertise needed for operating the system, i.e. for converting the customers' questions into executable queries or considering legal regulations like privacy and security issues. As such, it is planned that the temporal OLAP dimension related results of iCARDEA flow into our ongoing MUSTANG project¹⁴² which is a platform for the development of specialised analytical information systems for healthcare and provides the technical basis for a number of further projects.

The results of the privacy-aware data analysis concept will also strengthen the advisory capacity especially in the field of data analysis task in the health area, where privacy and security are always of great significance. The privacy and security concept should be considered as services provided as part of the MUSTANG environment and by that also improving the acquisition of industrial research projects together with commercial partners from the healthcare sector.

In addition to the data analysis related work, the CIED data interoperability module has been identified as an exploitable asset. It may be a useful addition to the clinical department information system for cardiology called Go-Kard, which is being maintained by ICSMED, an OFFIS spin-off. In particular, it could become part of the GO-ICD/SM module, which is used to document clinical CIED tests. Furthermore, the module may be of interest for CIED vendors not yet supporting the IHE IDCO integration profile natively, although the requirements of the medical device directive need to be taken into account here. With the publication of the module under an open source licence, business generated by consultancy related to this module is envisaged.

Finally, with national and international publications and presentations of the research results the visibility and reputation of OFFIS will be increased which should lead to more consultancies.

¹⁴² http://www.offis.de/en/offis_in_portrait/structure/projects/detail/status/mustang.html

2.5.2.3 SRFG

Looking at current eHealth publications and strategic requirements patient empowerment is a topic with growing importance. However, patient empowerment is often a new approach for patients and a new way for them to deal with their diseases. Against that background patient empowerment can be seen as a learning process for both patients and health care actors where useful services of e.g. a PHR system can facilitate this process.

The Patient Empowerment Framework developed in iCARDEA represents the core of an open source framework which is capable of being extended by additional services. The Patient Empowerment Framework is an essential component in iCARDEA. Even though there is only a restricted set of services which can be implemented within iCARDEA, these services are mainly focused on the needs and requirements for cardiac patients with remote monitoring services. For future exploitation the Patient Empowerment Framework can be adjusted to the needs for e.g. other chronic diseases like diabetes or cancer. In these cases the Patient Empowerment Framework is open to include new services, e.g. ODLs like an automatic transfer of daily blood sugar measurement for diabetes patients.

Additionally, Salzburg Research is currently the coordinator of a national project in the area of electronic medication and adverse drug events. Medication is seen as an essential aspect of electronic patient records, not only for the EHR and health care actors but also for patients using a PHR. Therefore, medication services can be useful, additional services for a Patient Empowerment Framework.

Furthermore, the Patient Empowerment Framework in iCARDEA is designed on common established interoperability standards (e.g. HL7, IHE profiles) and is used to exchange patient data with the EHR system as part of the iCARDEA pilot application. This interoperability approach can in principle be used to exchange patient data with any other EHR and PHR systems which is based on the previously mentioned interoperability standards. It is very likely that patients in the future will obtain and exchange their data with several EHR systems and maybe share services which are offered by another PHR system.

2.5.2.4 FORTH

FORTH will investigate potential exploitation of the EHR interoperability framework within the regional health systems of Greece, and possible in collaboration with other partners. There is particular interest in extending this work to primary care as the role of general practitioners in supporting CIED patients is enforced. Additional opportunities for exploitation are possible in the management of emergencies that engage CIED patients.

Finally, FORTH is interested in exploring the role/value of Ambient Intelligence environments for CIED patients, again possibly with other iCARDEA partners.

2.5.2.5 SALK

In the past few years the amount of ICD implants has increased at SALK. The institution, currently has one electro physiologist, one cardiologist specialised in arrhythmias

(currently out on maternity leave) available and one fellow in training. It takes at least a year of working closely in the clinic with the manufacturer and cardiologist to learn how to interpret and understand ICD patients' diagnostic data. In SALK, only one day is reserved during the week to provide an outpatient clinic for ICD follow up. In order to decrease the load of the electro physiologists and cardiologists, tele-monitoring is intended to be initiated; however it has not been realized yet due to high costs. The billing system for outpatient visits would not cover these costs.

Another important deficiency of the outpatient clinic appointments is the overall costs and burden for patients: They may miss a day at work, they may have to travel long distances to come to the clinic, and wait long hours waiting at the clinic.

For SALK, iCARDEA is an opportunity to address these challenges, and to provide proof that tele-monitoring for ICD patients could be cost effective and certainly help decrease the burden of the number of patients coming to outpatient clinic for follow ups, even giving better satisfaction to the patients in their care.

At the beginning of the project, it was not possible to use the CIED data web site to review the patients' data at SALK. The clinicians now have two computer portals where they are able to retrieve CIED data. A standard of procedure to monitor the patients at the times designated as "tele-clinic hours" is developed for this purpose. In the few months of monitoring up to date, it is realized that the most important thing is having dedicated health personnel responsible for looking daily at the transmissions. When alerts are transmitted and if it is not a physician readily available to open the alert, a staff member needs to find one of the cardiologist involved to review the alert. The iCARDEA Care Planner will help the person opening the alerts to assess which actions should be taken through the automated decision making capabilities it serves. On top of this, currently it is not very easy to find the relevant EHRs of the patient to assess the situation, and the clinicians at SALK are looking forward to testing the iCARDEA: the patient parameter monitoring tool together with iCARDEA Care Planner will make the evaluation process of EHR and CIED data quicker and more efficient.

During the initial telemonitoring study carried out through the Web Portals supported by the CIED manufacturers, SALK has found that (even though many alerts do not require action some do) if the patient had not been tele-monitored, their arrhythmia would not have been picked up, as patients often do not notice them. There have been patients that come into the hospital due to alerts and either changed their medications or fine tuned the programming on their ICD. Although a high number of calls from some patients can be a burden in the beginning, it is experienced that they do decrease over time. Even though the patients are told that they are not being monitored 7/24 and that the clinicians at SALK only receive alerts 09:00-15:00 M-F, these patients often felt reassurance in the tele-monitoring. A large population of ICD patients has had no problems or shocks given to them over a long period, yet still need to come for their ICD control in the outpatient clinic. These patients are often young and still in the work force. These patients are happy not to have to come to clinic and be tele-monitored from home.

As presented though this small study, although the initial set up of tele-monitoring in the health care facility can be a financial and strategic challenge, it will improve the monitoring process for the outpatient clinic, the physicians and also for the patients. The use of iCARDEA Care Planner which will enable more automated clinical decision making processes through accessing all the available EHRs and PHRs will be a major breakthrough for remote monitoring of patients. As a tool to speed up the process and provide guidelines for the medical personnel involved in the care of these patients during follow up, iCARDEA Care Planner will help to decrease the burden on all parties involved and provide the patients a good alternative to current outpatient care.

2.5.2.6 SJM

The world wide main monitoring system of St Jude Medical is the Merlin.net PCN Patient Care Network. It is a web-based solution, where physicians are able to see all transmissions, triggered events and useful diagnostic data. The collected data and information stored in a central repository of SJM can be retrieved by iCARDEA system, to be incorporated into the care plan engine and processed by the system.

In recent years the rate of ICD implantation has grown substantially after the results of primary and secondary prevention trails have shown significant improvement in mortality and morbidity. However, the increasing number of patients with ICD indication leaves the implanting centers with large logistic problems, especially with the number of follow-up visits. Therefore new methods of tele-cardiology are currently developed and used in clinical practice. One of the most promising solution is home monitoring in which the implant sends automatically messages triggered by an event. By utilizing this cardiologists are able to guide patients more effectively. Therefore, the industry has been developing best-fitted software usually as Web applications to support the needs of the remote monitoring market.

Currently a follow up (without Merlin.net PCN Patient Care Network) for an ICD patient is done periodically. Usually there is a post implant follow up, then a three month follow up and then the ICD system is technically checked every three or six month if no event occurred. As the battery of an ICD system has a defined life period the follow ups, when the device comes near to the elective replacement indicator, are done in a shorter period although the system has an integrated patient notification mechanism. During the follow-ups the system is checked and all parameters are controlled. During such a follow up it is also possible for the cardiologist to react to special circumstances e.g. atrial fibrillation. When using the remote care system Merlin.net PCN Patient Care Network the cardiologist can react on events even faster, because an event triggers a transmission of the status of the ICD as well as recorded intracardial electrocardiograms, which then helps to react in a faster and more efficient way. Additionally the iCARDEA project could help to enable pattern detection by using its data mining approaches, which may help to reduce occurring events, and improving medication strategy and quality of life.

One important circumstance of the iCARDEA system could be that the physicians do have one homogeneous platform, which could help to reduce the teaching phase of the different existing platforms. But it has to be clearly stated that it is important that features and technology of SJM has to be visible and manageable using the iCARDEA application

in order to support the attending cardiologist. In case this is valid the iCARDEA system could be seen as an add-on to the main remote tele-monitoring solution.

This project will bring device-related, medical data as well as patient self-entered information together to be analyzed within the scope of well defined care plans to support automated decision making and in this way will help enhancing the outcome of the therapy, which could influence the pacemaker and ICD business. A very interesting effect of the iCARDEA solution could be that these well integrated structured (device data) as well as semi structured and unstructured data could be exploited performing analytics and data mining approaches.

As the overall iCARDEA system has an interface to the patient record in the clinics it could also be interesting for the SJM central repository to use the interface for integrating the data and information sources using this approach.

Finally, using remote care technology on a broad basis, usability and practicability of delivered technology and parameters will be further improved and results could influence future designs and developments.

As mentioned above the processes as well as data mining approaches do have the potential to reduce patient risk, and we will incorporate these findings into discussions regarding future product developments and enhancement of existing products and systems. Those findings probably do have a positive impact to further pacemaker as well as AICD developments and are not only focused on remote care technologies.

One of our major findings within iCardea is the lack of a homogeneous platform for patient treatment. As a consequence we will integrate these research results into current and further strategies of product development to make patients life safer and physicians life more convenient. All under the tagline: LESS RISK, MORE CONTROL.

2.5.2.7 MEDTRONIC

Currently the use of ICDs and pace makers has vastly increased. This has a series of associated benefits from a clinical perspective but also the increase in numbers and rate of implementation drive the development of a strong and adequate management system a necessity. This complex management system is constantly being developed and upgraded by the different manufacturers as long as their products are improved and optimized. But it has the consequence that each manufacturer has its own vision of management; as a result the capabilities supported are quite closed to the manufacturer standards and needs. Also the use and adoption of remote patient management needs further development, involving pro-active hospital organization, team creation and interdisciplinary units.

Healthcare providers face difficulties when retrieving data from more than one system in the follow-ups. Access to follow-up information often requires clinicians to use multiple vendor specific systems and interfaces, complicating efficiency and quality of workflows

For each patient follow-up information that is stored in the implantable device is electronically collected by an “interrogating” device. Depending on the location the

interrogation will be performed whether in-clinic by a programmer or remotely by a communicator / data collector (home healthcare environment).

Usually each “interrogating” device is vendor proprietary. Which entails the software, processing and post-processing are shaped to internal standards.

Besides, aggregation of data into a central EMR or device clinic management systems requires manual and paper processes.

According to this point of view, iCARDEA system incorporates capabilities to help the management and organization of data coming from a constantly growing patient environment with more specific needs enabling more routine follow ups, making the link between devices databases, EHR in hospitals and PHRs, as a big step towards remote patient management. In terms of Medtronic systems, iCARDEA would provide the possibility of complementing the treatment management, by optimizing in an efficient way the information received. Especially the use of the diversified and layered iCARDEA modules would be a great addition to the system in terms of the analysis of severity and progression, events notification and monitoring of the disease.

iCARDEA has the potential to improve the efficiency and quality of related clinical processes in terms of having a single point of access for information, standardization of workflow processes, automation of current manual processes for data, collection, aggregation and analysis.

Medtronic already provides its own platform for the management and diagnosis of implanted devices called Carelink. This platform simplifies the management of several diseases. Patients remotely send their biological signs along with their device’s current state so it can be monitored and managed remotely by physicians. From a patient’s perspective, it also gives the possibility to send and visualize their current state through a cross services web platform as well as get informed about their need to require a follow up decided either by the doctor or suggested by the system. iCARDEA System would contribute to Medtronic’s Carelink platform by extending its internal capabilities to manage data and stratify diseases through the capability of accessing and processing patients’ health record information. It also has the associated benefit of making a more attractive management platform as it can manage and show information from different manufacturer’s devices as well as PHR information.

At the same time intellectual property rights should be taken into account because different patients with different ICDs and different treatments are being exposed. The fact that iCARDEA has been built using current standards in medical device practice, management of information and open data management introduces an added value in terms of compatibility and ease of utilization.

2.5.2.8 HCPB

HCPB exploitation strategy is being designed in close relation with Linkcare Health Services SL, a recently created spin-off of Hospital Clinic of Barcelona, and supported by the Fundació Clinic per a la Recerca Biomèdica. Linkcare's main aim is to channel into the market the knowledge and ICT products developed in the Hospital Clinic of Barcelona (HCPB), notably those related to the management of chronic patients. Linkcare core product is a modular platform that supports the design and implementation of any integrated care programme targeting groups of chronic patients and their individualization to specific sub groups (in the case of patients facing co morbidities) while allowing their remote monitoring by health care team pertaining to one or several health care organizations. The platform builds on current standards so that it can be interoperable:

- with legacy Health Electronic Records / Personal Health Records.
- with devices / or specific modules/applications that would be needed for the management and monitoring of specific patients. In other words, Linkcare platform can easily be integrated with additional programs and subprograms. In particular, the integration of Linkcare with iCARDEA is technologically feasible in the very short term.

The integration of iCARDEA with Linkcare within the HCPB has quite a great potential in terms of exploitation since:

- HCPB and Linkcare consolidated experience on how to design and carry out programmes targeting chronic patient's is easily transferable to the specifics of iCARDEA. Actually the Linkcare platform is already used in the HCPB for programmes with chronic patients (including cardiac patient's but without ICD).
- In particular, while including an "iCARDEA patient" into an "iCARDEA programme" run from the Linkcare platform, a professional would get instant access to the patient's Health Electronic Record (namely SAP) of the Hospital since the integration of Linkcare platform and Hospital's SAP is already completed. Inversely, health professionals operating in routine care setting would be able to view on the SAP patient's follow up and discharge reports generated by the iCARDEA programme.
- HCPB and Linkcare are currently integrating the platform with a large PHR regional project promoted by the Catalan Health Regional Ministry. Already, the Linkcare platform allows a patient included in a programme to share documents with the programmes' professionals of his/her choice,
- The platform allows customization of the programmes for patients that suffer from several chronic conditions. In other words, it is possible that a cardiac patients with additional chronic condition(s) is not excluded from the iCARDEA programme: potentially his/her care plan could include specific additional interventions (such as for instance additional biometric measurements, questionnaires, etc) pertaining to a programme related to his/her additional conditions. The possibility of including patient's with co morbidity might

- contribute to increase the external validity of the iCARDEA pilots run in Barcelona
- HCPB/LinkCare can participate in the potential exploitation of some of the iCardea applications (i.e. AF and VT/VF care plans and automatic and remote follow-up based on guidelines) through the heart failure module of LinkCare. Additionally it can be a distributor and provide local support for the other products. However, in terms of time scale we see some initial challenges to move on more actively in this direction: 1) Some of the iCardea modules are still in a prototype phase which implies that there is still a long way till adoption of the iCardea system in a commercial perspective; and 2) the current socioeconomic context makes it a bit more difficult to decide on starting new business lines, unless specific resources are committed.
 - Finally, another potential application of the resources developed within iCARDEA includes the implementation of the patient education material developed within the WP5 into our current clinical practice in the management of patients with CIEDs. There is a compromise of the team to continuously review and update the material (in Spanish and Catalan) to promote to increase the general knowledge of the population and the CIED patients, relatives and healthcare providers.

2.6 Conclusion and future work

In this document, a strategic Exploitation Plan for the results obtained from iCARDEA project is described. In this respect the following activities were achieved in the first reporting period of iCARDEA:

- A comprehensive market survey in the fields that iCARDEA project addresses and the competencies of the competitors.
- Identification of Project's exploitable assets;
- Strength, Weakness, Opportunities and Threats (SWOT) Analysis for each iCARDEA Exploitable asset to reveal and structure all possible strengths and opportunities, as well as weaknesses and risks that have to be considered for exploitation
- Identification of Individual Exploitation Strategy for each Partner

In this reposting period, we focused on identification of the initial iCARDEA Joint Exploitation Strategy. The following activities have been carried out:

- Identification of the positioning of iCARDEA Solutions in the Open Source Market
- Identification of Joint Exploitation Strategy
 - Defining exploitable iCARDEA services and packages
 - Defining partner roles in joint exploitation activity
 - Analyzing the best strategy for iCARDEA exploitation and iCARDEA deployment flexibility
- An initial analysis of return of investment

Finally we elaborated on possible legal, organisational, and economic barriers for a successful deployment of an iCARDEA enabled remote monitoring system within a hospital and will try to outline the necessary steps to be taken at organisational and political scale to overcome these.

In the subsequent versions of the Exploitation Plan, the following activities will be realized:

- Elaboration of Business Model and Forecasts for iCARDEA exploitable assets
 - Identification of Scenarios for exploitation
 - Identification of Cost Models
 - Identification of Revenue Models
 - Identification of Commercialization Policies
 - Identification of Business Plans for Industrial Partners and iCARDEA end user

3 ICARDEA DISSEMINATION PLAN

3.1 Introduction

The goal of the Dissemination Plan is to raise awareness about the approach and the results of the project, to prepare the ground for the exploitation of the iCARDEA results and to seek synergies with other initiatives and will establish cooperation links with them. The following Dissemination Report provides a view of the dissemination activities provided by iCARDEA project, describes the target group to be reached.

The applied strategy is constituted by a process that requires a close relation between:

- the target markets and audiences
- the content, media, formats and language to be used

The results of the project are to be published and presented within the scientific and industry community. In this respect, in-depth knowledge of the various stakeholders to be targeted is strategically important.

Now we are entering a more clinical phase, it is expected that more clinically relevant results can be produced and presented in medical conferences and target as well patient organizations and a wider audience of healthcare professionals involved in care for CIED patients. As an instance, the iCARDEA platform was already presented at the Europace Meeting, the Annual Spring Meeting on Cardiovascular Nursing and ICPES World Society of Arrhythmias.

Furthermore, additional dissemination opportunities have been explored, including the set-up of an exhibition stand at healthcare and technical international congresses. This provides an outstanding chance for the demonstration of the iCARDEA platform and disseminate the results of the project to potential exploitation assets. In this sense, actions have been taken to evaluate the exhibition at the Cardioslim Meeting (Nice, France – June 2012), the MIE 2012, and at the European Society of Cardiology Meeting (Munich, Germany – August 2012).

3.2 Dissemination Strategy

The dissemination strategy must be a cyclic process where all the achievements, progress and publications of the project must be periodically evaluated in order to be communicated to the rest of the consortium and outside of it. In iCARDEA Consortium agreement, the partners have agreed on the rules regulating the dissemination process as presented in the next section.

3.2.1 Consortium agreement Articles regulating the dissemination activities

3.2.1.1 Publication (Article 8.3.1)

Dissemination activities including but not restricted to publications and presentations shall be governed by Article II.30 of the Grant Agreement(GA) subject to the following provisions.

Prior notice of any planned publication shall be made 30 days before the publication. Any objection to the planned publication shall be made in accordance with the GA in writing to the Coordinator and to any Party concerned within 7 days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

An objection is justified if

- (a) the objecting Party's legitimate academic or commercial interests are compromised by the publication; or
- (b) the protection of the objecting Party's Foreground or Background is adversely affected.

The objection has to include a precise request for necessary modifications.

If an objection has been raised the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate actions are performed following the discussion.

The Parties are encouraged to publish the material related with the public deliverables of the project. It is understood that any publication or communication made pursuant to this Article is required to indicate the contribution made by each of the Parties.

3.2.1.2 Publication of another Party's Foreground or Background

For the avoidance of doubt, a Party may **not** publish Foreground or Background of another Party, even if such Foreground or Background is amalgamated with the Party's Foreground, without the other Party's prior written approval. For the avoidance of doubt, the mere absence of an objection according to Article 8.3.1 of iCARDEA Consortium Agreement is not considered as an approval.

3.2.1.3 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense of any dissertation or thesis for a degree which includes their

Foreground or Background. However, confidentiality and publication clauses have to be respected.

3.2.1.4 Use of names, logos or trademarks

Nothing in iCARDEA Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

3.2.2 Communication and dissemination strategy.

The aim of this strategy was to identify the main target groups that are to be addressed in different moments in time during the life of the project to obtain different degrees of impact in each of them depending of the iCARDEA interests.

iCARDEA project dissemination strategy included:

1. Promotion of the iCARDEA project in related standards and research communities, such as Integrating Healthcare Enterprise (IHE), demonstrating the use of their profiles, especially the one on Implantable Device Cardiac Observation Profile (IDCO) and the related IHE Profiles including, PIX and ATNA; HL7 community through the use of Clinical Document Architecture (CDA), Common Terminology Services (CTS) and HL7 Web services Profile; Standards development efforts for ICDs under the auspices of HL7, IEEE 11073 and IHE: <http://www.idcstandards.com/>.
2. Involvement of technology transfer centres, healthcare associations, healthcare IT standard bodies, etc. for additional dissemination/demonstration activities to reach a wider client base. This activity also involves setting-up of user groups and organisation of public workshops and targeted seminars and workshops both for training purposes and for disseminating the project results. There will also be a pro-active outreach network of activity.
3. iCARDEA Web Site: In iCARDEA Web Site the iCARDEA concepts are disseminated through regularly updated iCARDEA White paper and iCARDEA pilot application scenarios will be presented through videos. The project Web site is kept updated with news, public deliverables, articles and material from participation at events (e.g., slides of presentations, keynote speeches, articles in journals and conference proceedings). See section 3.3.2.
4. Electronic advertising of project results through Internet such as distribution of Newsletter and other information through the Web.
5. Dissemination towards patient groups and forums with emphasis on those related to cardiac patients, at the national and European level.
6. Contribution to best practice in standardization efforts, such as ShowMeYourCDA! And OpenECG, and other eHealth forums that promote best practice in interoperability and integrated care.
7. Participation in concertation activities with relevant collaborative projects and horizontal activities in ICT for Health but also with other relevant projects in European Commission programs such as the Competitiveness and

Innovation/Policy Support Program and the Ambient Assisted Living Program. Dissemination and travel resources allocated to the iCARDEA consortium ensure participation to these activities.

8. Publications at commercial and scientific conferences and exhibitions.
 - a. The following conferences and workshops to disseminate the results of the project have been identified:
 - i. EUROPACE: it is the official congress of the European Heart Rhythm Association (EHRA), and the foremost European meeting on cardiac arrhythmias and pacing.
 - ii. Computers in Cardiology: it mainly addresses IT infrastructures and computerization of healthcare processes related with Cardiology.
 - iii. Annual International Conference of the IEEE Engineering in Medicine and Biology Society particularly in relation to the theme "HealthCare information systems and Telemedicine". It is organized annually in September.
 - iv. ESC Congress: the official scientific congress of the European Society of Cardiology. These congresses are very inline with the planned outcomes of the iCARDEA project as they address advancements in remote monitoring.
 - v. Annual Conferences of the Medical Informatics.
 - vi. Annual Scientific Sessions of the Heart Rhythm Society (HRS).
 - vii. World Congress of Cardiac Pacing and Electrophysiology.
 - viii. World Congress on Medical and Health Informatics (MedInfo).
 - ix. EuroPrevent: it is the main scientific meeting place in Europe for all who are engaged in the prevention of cardiovascular diseases such as heart attacks and stroke.
 - x. International HL7 Interoperability Conference.
 - xi. Annual Symposia of the American Medical Informatics Association (AMIA).
 - xii. European Conference on Knowledge Management: research work related with knowledge management, intellectual capital and organisational learning can be submitted to this conference. Algorithms and application results of detection of trends and alarm conditions from established knowledge bases are planned to be presented in this conference.
 - xiii. Annual Conference of the Association for the Advancement of Assistive Technologies in Europe (AAATE): AAATE, as the interdisciplinary pan-European association devoted to all aspects of assistive technology, such as use, research, development, manufacture, supply, provision and policy, provides to the iCARDEA project a natural "channel" for bringing the project results closer to market of potential deployment and uptake parties, which also gives input to affect the iCARDEA product positioning. iCARDEA final results will be presented in this conference.

- xiv. Annual Conference of the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA): Presenting iCARDEA in this conference will facilitate part of the communications with end user communities.
 - xv. International Workshop on Information Fusion and Dissemination in Wireless Sensor Networks (SensorFusion): Results of the multi-parametric analysis of data coming from CIEDs and CIED in iCARDEA will be submitted to this workshop.
9. Publications in International Journals. The research partners of the project will pursue journal publications since the topic being highly innovative. Once the iCARDEA project results become mature for archival journals we plan to publish them targeting the following journals:
- a. Europace Journal: The European Journal of Pacing, Arrhythmias and Cardiac Electrophysiology of the European Heart Rhythm Association and the Working Group on Cardiac Cellular Electrophysiology of the European Society of Cardiology aims to provide an avenue of communication of top quality European and international original scientific work and reviews in the fields of Arrhythmias, Pacing and Cellular Electrophysiology.
 - b. European Heart Journal: This journal focuses on all types of cardiovascular disease with special emphasis on recent developments such as preventive medicine. A paper describing secondary prevention mechanism built-upon iCARDEA Adaptive Care Planner is aimed to be submitted to this journal.
 - c. European Journal of Heart Failure: This international journal is dedicated to the advancement of knowledge in the field of heart failure. iCARDEA project plans to submit a paper describing overall architecture of the system to show how the project automates routine follow-ups of patients with CIEDs, and hence decrease the workload of healthcare professionals by minimizing heart failures and costs.
 - d. The IEEE Transactions on Information Technology in Biomedicine: This journal focuses on global information technology advances in medicine and biology and will further address the implementation and management of the broad spectrum of health care innovations.
 - e. International Journal of Ad Hoc and Ubiquitous Computing publishes papers that address networking or computing problems in the context of mobile and wireless ad hoc networks, wireless sensor networks, ad hoc computing systems, and ubiquitous computing systems.
 - f. Artificial Intelligence in Medicine: This journal focuses on research activities mainly on subjects which relate the theory and practice of artificial intelligence (AI) with medicine and healthcare such as clinical decision making, intelligent medical information systems. We plan to submit a paper describing the adaptive care planner that will be developed in iCARDEA project to this journal.
 - g. European Journal of Cardiovascular Prevention and Rehabilitation.
 - h. Annual Conference of Integrated Care Pathways.

i. The Journal of Integrated Care Pathways.

10. Representation of the European Commission at the international events when requested by the EC.

11. Other activities:

- a. Conducting successful pilots with players of the eHealth industry.
- b. Participation in concerted activities with other ICT funded projects related to the area of iCARDEA and organised by the European Commission.
- c. Presentation to local and state authorities.
- d. Supporting interested developers by publicizing the availability of open source tools and documentation.
- e. Support of international standards development in support of results.
- f. Support for European interest and recognition of European standards.
- g. Active participation in the closely norm-related committees and meetings specifically CEN TC251 WGs, ISO TC215 WGs, IEEE 11073, HL7, IHE.
- h. Press releases at project start and at major milestones.

In this regard, the following key aspects have been identified for the dissemination of iCARDEA:

3.2.2.1 Target audiences:

- Political Level:
 - EU Commission Services
 - National eHealth Organizations
- Related Projects
- Research Community
 - Interoperability
 - Guideline execution
- Companies
 - CIED Vendors
 - Cardio SW Vendors
- Other
 - Standardisation

3.2.2.2 Channels of Communications:

- Website: see section 3.3.2.
- Presentations at conferences: The following future scientific congresses within the next 12 months, have been identified for the dissemination of iCARDEA's results:

Table 8 Future scientific congresses

CONGRESS	VENUE	DATES	WEBSITE
Congresses on Cardiology			
12th Annual Spring Meeting on Cardiovascular Nursing	Copenhagen - Denmark	16-17 March 2012	http://www.escardio.org/congresses/cardio-nursing-2012/Pages/welcome.aspx
World Congress on Cardiology	Dubai, United Arab Emirates	18-21 April 2012	http://www.world-heart-federation.org/congress-and-events/world-congress-of-cardiology-scientific-sessions-2012
Heart Rhythm Congress	Boston, MA.	09-12 May 2012	http://www.hrsonline.org/Sessions/
EuroPREvent	Dublin - Ireland	03-05 May 2012	http://www.escardio.org/congresses/europrevent-2012/Pages/welcome.aspx
Heart Failure Congress 2012	Belgrade - Serbia	19-22 May 2012	http://www.escardio.org/congresses/hf2012/Pages/welcome.aspx
Cardiostim 2012 18 th World Congress	Nice - France	13-16 June 2012	http://www.cardiostim.com/
ACC Meeting	Chicago- USA	24-27 March 2012	http://www.accscientificsession.org/Pages/home.aspx
ESC Congress	Munich - Germany	25-29 August 2012	http://www.escardio.org/congresses/esc-2009/Pages/ESC-future-congresses.aspx
Congresses on Computer Science			
Computing in Cardiology 2012	Krakow, Poland	9-12 September 2012	http://www.cinc.org/conferences.shtml
MIE 2012	Pisa, Italy	26-29 August 2012	http://www.mie2012.it/
GMDS / Informatik 2012	Braunschweig, Germany	16-21 September 2012	http://www.informatik2012.de/

- Journal/gazette publications.
- Press releases.
- Online newsletter
- Personal contacts

3.2.2.3 Messages to be transmitted to specific audiences:

- Political Level:
 - EU- Funding interoperability saves money in the healthcare sector without lowering healthcare quality
 - Vendors from EU will be more competitive than others
- Research Community:

- Medical Data Analysis isn't easy but we developed tools that make it easier and more powerful

3.2.2.4 Measures-Matrix (What Audience is contacted by which communication channel)

- General Public is informed by Website, press releases and online newsletter
- Research is informed by Website, Conferences, and Papers.

3.3 Dissemination activities

In this section we present the static and dynamic dissemination elements associated to the iCARDEA project. Beside the project website, -where all dissemination material for the general public as well as the internal documents are regularly uploaded- , a total of 13 articles have been published and 14 communications in scientific congresses have been presented. These, as well as the iCARDEA website and the project brochures and press releases will be presented in the following pages.

3.3.1 Project Logo

This is the official iCARDEA Logo:



3.3.2 Project Website

The iCARDEA portal can be accessed using following URL: <http://www.icardea.eu/> (<http://www.srdc.com.tr/icardea> alternatively). It is designed according the needs of the iCARDEA Project. It has specific features designed for the participants of the project such as managing publications and deliverables, as well as providing generic capabilities such as the iCARDEA forum.

The project website is kept updated with news, public deliverables, articles and material from participation at events (e.g., slides of presentations, keynote speeches, articles in journals and conference proceedings).

HOME NEWS WORK PROGRESS CONTACT US

Search...

iCARDEA
An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices

Home

Main Menu

- Home
- News
- Work Progress
- Partners
- All Documents
- Publications
- Deliverables
- Contact Us

Login Form

Username

Password

Remember Me

Login

- Forgot your password?
- Forgot your username?

Welcome to iCARDEA Project Web Site

Contract Number: 248240
Project Acronym: iCARDEA
Project Name: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices
Priority: Objective ICT-2009.5.1: Personal Health Systems
Total Cost (€): 3,613,448
Commission Funding (€): 2,539,833

List of Partners

Partner no	Partner name	Partner org. short name
1 (coordinator)	Software Research and Development and Consultancy Ltd.	SRDC, Turkey
2	OFFIS e.V. (OFFIS)	OFFIS, Germany
3	Salzburg Research Forschungsgesellschaft m.b.H	SRFG, Austria
4	Foundation for Research and Technology Hellas – Institute of Computer Science	FORTH, Greece
5	Salzburger Landeskliniken BetriebsgesmbH	SALK, Austria
6	St. Jude Medical Medizintechnik Ges.m.b.H	SJM, Austria
9	Medtronic Ibérica S.A.	Medtronic, Spain
10	Hospital Clinic I Provincial de Barcelona	HCPB, Spain

Who's Online
We have 7 guests online

Figure 9 Homepage of the iCARDEA Portal

As shown in Figure 9, the **homepage of the portal** contains two menus for easy access, one at the left and the other at the top. The menu on the left is more detailed and is expanded with new functions when the user logs in. The menu on the top provides easy access to vital pages.

The rest of the page is used for viewing the contents or the modules. All the information in the portal is divided into sections, and every section is divided into categories, in other words every piece of content belongs to a category which belongs to a section.

The portal represents an overview of the project, participants and coordinator details. Recent news may also be displayed at the homepage. By using the links at the left and at the top of this page, more detailed information about the project can be reached.

3.3.2.1 Contents and Modules

In the **menus** at the left and at the top of each page there are links to specific content, categories and sections of the website. These links are expanded when a user logs in the Portal.

By default the following links appear on the left menu:

- Home: Entry page of the portal
- News: Lists the news.
- Work Progress: Shows the current state of the progress of the project.
- Partners: Participants' details.
- All Documents: Lists all document categories including Meetings, Publications, Deliverables and Internal Documents (which are private to the project consortium).
- Publications: Lists the Publications of the Project.
- Deliverables: Deliverable coloring schema is shown at the top of the page followed by the deliverables list.
- Contact Us: Easily contact the coordinator.

When a user logs in, this menu expands with a user menu having the links:

- Your Details
- Submit an Article
- Logout

A search box exists on every page, at the right of the top menu. When this search button is clicked, a more detailed search module is shown on the page.

The Login Form is only shown on the Homepage, in the left-bottom part.

3.3.3 Project Brochures

The following table summarizes brochures and newsletters produced within the iCARDEA consortium.

Table 9 Project Brochures

DESCRIPTION	TITLE	FIRST AUTHOR	REFERENCE ADDITIONAL INFO
iCARDEA ID Card	iCARDEA: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices	iCARDEA Consortium	eHealth Monthly Focus (August, 2010) - European Commission: Information Society and Media
iCARDEA Press Release	iCARDEA: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices	iCARDEA Consortium	Press release
FP7 Booklet	iCARDEA: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices	iCARDEA Consortium	FP7 Booklet
iCARDEA Press Release	EU-Projekt iCARDEA gestartet	Marco Eichelberg	OFFIS Newsletter Available online at http://www.offis.de/aktuelles_presse/detailansicht/article/eu-projekt-icardea-gestartet.html

3.2.4 Articles published

The followings tables summarize the articles and/or accepted conference papers for publication in relation to the iCARDEA project during the first (table 10) and second (table 11) reporting period. A copy of these articles is available in the Annex 1.

Table 10 Articles and/or accepted conference publications for publication during the first reporting period.

TITLE	FIRST AUTHOR	REFERENCE
iCARDEA – an Approach to Reducing Human Workload in Cardiovascular Implantable Electronic Device Follow-Ups	Maohua Yang	Computing in Cardiology 2010, Volume 37, Page 221- 224, Alan Murray, ISSN 0276-6574
Interoperability Challenges in the Health Management of Patients with Implantable Defibrillators	Catherine Chronaki	Computing in Cardiology 2010, Volume 37, Page 225- 228, Alan Murray, ISSN 0276-6574
Interoperability of Medical Device Information and the Clinical Applications: An HL7 RMIM based on IEEE 11073 DIM	Mustafa Yuksel	IEEE Transactions on Information Technology In Biomedicine, Vol. 15, No. 4, July2011:557-66.
The Personalized Remote Monitoring of the Atrial Fibrillation Patients with Electronic Implant Devices	Gokce B. Laleci	Journal of Healthcare Engineering Vol. 2, No. 2, 2011 Page 183–196 (June 2011)
iCARDEA: EU-Projekt zur optimierten Nachsorge von Herzpatienten	Hans-Jürgen Appelrath	Datawork 2010;48:19
Intelligent Guideline-driven Approach in Remote Monitoring of Cardiac Implants	Asuman Dogac	ERCIM News 84, page 44 Available online at: http://ercim-news.ercim.eu/images/stories/EN84/EN84-web.pdf

Table 11 Articles and/or accepted for publication during the second reporting period.

TITLE	FIRST AUTHOR	REFERENCE
Patient empowerment for Patients with implantable Defibrillators	Manuela Plößnig	Paper at the eHealth2011 (conference), Vienna
iCARDEA: a Practical Approach to Facilitate Data Integration of Implantable Cardioverter Defibrillator Patients in Cardiological Treatment	Maohua Yang	Oral Presentation and paper indexed by IEEE & Ei Compendex at Computing in Cardiology 2011, Hangzhou, China.
Patient Empowerment Framework for Cardiac Patients	Robert Mulrenin	Poster at MIE2011, Oslo
Guideline-Driven Telemonitoring and Follow-up of Cardiovascular Implantable Electronic Devices using ISO/IEEE 11073, HL7 & IHE Profiles	Maohua Yang	Conf Proc IEEE Eng Med Biol Soc. 2011 Aug;2011:3192-6

Tomorrow's Integrated Care: Integration Testing in Guideline-driven Cardiac Telemonitoring	Catherine Chronaki	IHIC 2011, http://www.srdc.com.tr/icardea/index.php/component/docman/doc_download/187-paper--ihic-2011 , http://www.hl7.org/events/ihic2011/papers/friday/F_Q3_3_IHIC2011-chronaki_v1.pdf
Ad-hoc Datentransformationen für Analytische Informationssysteme	Christian Lüpkes	Grundlagen von Datenbanken 2011, http://ceur-ws.org/Vol-733/paper_luepkes.pdf
iCARDEA - An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices	OFFIS e.V.	OFFIS Jahresbericht 2010 (Published in April 2011)

A more detailed description of each article is described in Annex 1.

3.2.5 Presentations at scientific congresses

The followings tables include every presentation made at a scientific congress in relation to iCARDEA's results during the first (table 12) and the second (table 13) reporting period.

Table 12 Presentations at scientific congress during the first reporting period.

TITLE	FIRST AUTHOR	CONGRESS	TYPE	SITE	DATE
iCARDEA – an Approach to Reducing Human Workload in Cardiovascular Implantable Electronic Device Follow-Ups	Maohua Yang	Computing in Cardiology 2010	oral presentation	Belfast, United Kingdom	26 – 29 September 2010
Interoperability Challenges in the Health Management of Patients with Implantable Defibrillators	Catherine Chronaki	Computing in Cardiology 2010	oral presentation	Belfast, United Kingdom	26 – 29 September 2010
An Intelligent Platform for Personalized Remote Monitoring of the CIED Patients	Asuman Dogac	13 th World Congress on Medical and Health Informatics (MedInfo2010)	oral presentation	Cape Town, South Africa	12 - 15 September 2010

Table 13 Presentations at scientific congress during the second reporting period

TITLE	FIRST AUTHOR	CONGRESS	TYPE	SITE	DATE
Nurse -led Telemonitoring Clinic using iCARDEA An Intelligent Platform for Personalized Remote Monitoring of CIED Patients	Lynne Hinterbüchner	11th Annual Spring Meeting on Cardiovascular Nursing	poster	Brussels, Belgium	1 - 2 April 2011
iCARDEA: an intelligent platform for personalized remote monitoring of the cardiac patients with electronic implantable devices	Elena Arbelo	Europace 2011	poster	Madrid, Spain	26-29 June 2011
Patient empowerment for Patients with implantable Defibrillators	Manuela Plößnig	eHealth2011	oral presentation	Vienna	26- 27 May 2011
Patient Empowerment Framework for Cardiac Patients	Robert Mulrenin	MIE2011	poster	Oslo	29-31 August 2011
Nurse-led Telemonitoring Clinic using iCARDEA An Intelligent Platform for Personalized Remote Monitoring of CIED Patients	Lynne Hinterbüchner	ÖKG (Austrian Cardiology Society)	poster	Salzburg, Austria	25-28 May 2011
Ad-hoc Datentransformationen für Analytische Informationssysteme	Christian Lüpkes	Grundlagen von Datenbanken 2011	oral presentation	Obergurgl, Tirol, Austria	30 May – 3 June 2011
Guideline-Driven Telemonitoring and Follow-up of Cardiovascular Implantable Electronic Devices using ISO/IEEE 11073, HL7 & IHE Profiles	Maohua Yang	EMBC 2011	oral presentation	Boston, USA	30 August-3 September 2011
iCARDEA: Practical Data Integration for the Follow-up of Cardiovascular Implantable Electronic Device Patients in Cardiological Departments	Maohua Yang	Computing in Cardiology 2011	oral presentation	Hangzhou, China	19-21 September 2011

Integrating Out-Patient and Remote Follow-Up of Cardiovascular Implantable Electronic Device Patients	Catherine Chonaki	ICPES 2011 – World Society of Arrhythmias	Oral presentation	Athens, Greece	7th-9th December, 2011
Personalized Remote Monitoring of Atrial Fibrillation in Patients with Electronic Implant Devices	Emilce Trucco	ICPES 2011 – World Society of Arrhythmias	Poster	Athens, Greece	7th-9th December, 2011
iCARDEA: Personalized Remote Monitoring of Patients with Electronic Implanted Devices	Elena Arbelo	ICPES 2011 – World Society of Arrhythmias	Poster	Athens, Greece	7th-9th December, 2011

Table 14 Abstract accepted in the second reporting period to be presented next year

TITLE	FIRST AUTHOR	CONGRESS	TYPE	SITE	DATE
iCARDEA: Personalized Remote Monitoring of Patients with Electronic Implanted Devices	Elena Arbelo	World Congress of Cardiology	poster	Dubai, United Arab Emirates	18 - 21 April 2012
Personalized Remote Monitoring of Atrial Fibrillation and Ventricular Arrhythmias in Patients with Electronic Implant Devices	Elena Arbelo	World Congress of Cardiology	poster	Dubai, United Arab Emirates	18 - 21 April 2012

3.3.6 Clustering activities

A list of the clustering activities within the life of the project should be included here and the relation with the contacted institution (company, specialists, etc.) should be detailed.

Table 15 Clustering activities

Date	Type and Title/Scope	Number of attendants + other information
15-19 January 2010	HL7 January Working Group Meeting, Standards Meeting, Phoenix, Arizona	1 person, Attended Technical Committee meetings relevant to iCARDEA, Presented iCARDEA to the healthcare devices WG
20-22 March 2010	European Heart Rhythm Association (EHRA) summit (http://www.escardio.org/communities/EHRA/organisations-partners/summits/Pages/summit-2010.aspx)	1 person, invited presentation: Interoperability Standards for remote Health Monitoring Mentioned iCARDEA

14-19 May 2010	HL7 Spring Working Group Meeting	1 person, Attended Technical Committee meetings relevant to iCARDEA
28 September 2010	Patient empowerment supported by semantic social media and assistive health services (http://ec.europa.eu/information_society/events/cf/ict2010/item-display.cfm?id=3206)	1 person SRFG was invited to organize a Networking Session at the ICT2010, Brussels: the Patient Empowerment Framework of iCARDEA was presented
4 March 2010	Discussion of iCARDEA-related topics of data analysis and medical knowledge databases with members of Fraunhofer ISST, the German Research Center for Artificial Intelligence (DFKI) and the Federal Ministry of Education and Research (BMBF) during the CeBIT 2010 trade show.	5 People. 1 of OFFIS, 2 of Fraunhofer ISST, 1 of DFKI, 1 of BMBF

ANNEX 1 - DISSEMINATION MATERIAL

Annex 1.1.

Authors: Maohua Yang¹, Christian Lüpkes¹, Asuman Dogac², Mustafa Yuksel², Fulya Tunçer², Tuncay Namlı², Manuela Plöbñig³, Jürgen Ulbs¹, Marco Eichelberg¹.

¹ OFFIS – Institute for Information Technology, Oldenburg, Germany, ² Software Research, Development and Consultation Ltd., Ankara, Turkey, ³ Salzburg Research Forschungsgesellschaft, Salzburg, Austria

Title: iCARDEA – an Approach to Reducing Human Workload in Cardiovascular Implantable Electronic Device Follow-Ups.

Journal: Computing in Cardiology 2010

Reference: Computing in Cardiology 2010, Volume 37, Page 221- 224, Alan Murray, ISSN 0276-6574

Annex 1.2.

Authors: Catherine Chronaki¹, Manuela Plöbñig², Fulya Tuncer³, Mustafa Yuksel³, Gökçe Banu Laleci Ertürkmen³, Christian Lüpkes⁴, Marco Eichelberg⁴, Xavier Navarro⁵, Wolfgang Pecho⁶, Asuman Dogac³

¹FORTH-ICS, Heraklion, Crete, Greece, ²Salzburg Research, Salzburg Austria, ³SRDC, Ankara, Turkey, ⁴OFFIS, Oldenburg, Germany, ⁵Medtronic, Barcelona, Spain, ⁶St Jude, Vienna, Austria

Title: Interoperability Challenges in the Health Management of Patients with Implantable Defibrillators.

Journal: Computing in Cardiology 2010

Reference: Computing in Cardiology 2010, Volume 37, Page 225- 228, Alan Murray, ISSN 0276-6574

Annex 1.3.

Authors: Mustafa Yuksel¹, Asuman Dogac¹

¹SRDC - Software Research and Development and Consultancy Ltd., Ankara, Turkey

Title: Interoperability of Medical Device Information and the Clinical Applications: An HL7 RMIM based on ISO/IEEE 11073 DIM.

Journal: IEEE Transactions on Information Technology in BioMedicine

Reference: IEEE Transactions on Information Technology In Biomedicine, Vol. 15, No. 4, July2011:557-66.

Annex 1.4.

Authors: Gokce B. Laleci¹, Asuman Dogac^{1,2}, Mustafa Yuksel^{1,2}, Yildiray Kabak¹, Elena Arbelo³, Franz Danmayr⁴, Lynne Hinterbuchner⁴, Catherine Chronaki⁵, Marco Eichelberg⁶, Christian Lüpkes⁶

¹Software Research and Development and Consultancy Ltd., Ankara, Turkey, ²Dept. of Computer Eng., Middle East Technical University, Ankara, Turkey, ³Hospital Clinic i Provincial de Barcelona, Barcelona, Spain, ⁴Salzburger Landeskliniken BetriebsgesmbH, Salzburg, Austria, ⁵Foundation for Research and Technology Hellas – Institute of Computer Science, Institute of Computer Science, Crete, Greece, ⁶OFFIS e. V., Institute for Information Technology, Oldenburg, Germany.

Title: The Personalized Remote Monitoring of the Atrial Fibrillation Patients with Electronic Implant Devices.

Journal: Journal of Healthcare Engineering

Reference: Journal of Healthcare Engineering Vol. 2 , No. 2 , 2011 Page 183–196 (June 2011)

Annex 1.5.

Authors: Prof. Dr. Hans-Jürgen Appelrath, Dr. Wilfried Thoben¹.

¹OFFIS e.V., Institute for Information Technology, Oldenburg, Germany.

Title: iCARDEA: EU-Projekt zur optimierten Nachsorge von Herzpatienten

Journal: Datawork

Reference: Datawork 2010;48:19

Annex 1.6.

Authors: Manuela Plößnig 1

³ Salzburg Research Forschungsgesellschaft, Salzburg, Austria

Title: Patient empowerment for Patients with implantable Defibrillators

Journal: Proceedings of eHealth2011

Reference: eHealth2011, page 39-44, ISBN 978-3-85403-279-3, May 2011

Annex 1.7.

Authors: Maohua Yang, Christian Lüpkes¹, Asuman Dogac², Manuela Plößnig³, Marco Eichelberg¹

1 OFFIS – Institute for Information Technology, Oldenburg, Germany

2 Software Research, Development and Consultation Ltd., Ankara, Turkey

3 Salzburg Research Forschungsgesellschaft, Salzburg, Austria¹ OFFIS – Institute for Information Technology, Oldenburg, Germany, ² Software Research, Development and Consultation Ltd., Ankara, Turkey, ³ Salzburg Research Forschungsgesellschaft, Salzburg, Austria

Title: iCARDEA: a Practical Approach to Facilitate Data Integration of Implantable Cardioverter Defibrillator Patients in Cardiological Treatment

Journal: Proceedings of Computing in Cardiology 2011

Reference: Proceedings of Computing in Cardiology 2011, Volume 38, Hangzhou, China <http://cinc.org/archives/2011/pdf/0589.pdf>

Annex 1.8.

Authors: Robert Mulrenin¹, Mihai Radulescu^a, Manuela Plößnig¹, Gökçe Banu Lalecib², Catherine Chronaki³ and Yildiray Kabakb².

1 Salzburg Research Forschungsgesellschaft, Salzburg, Austria

2 Software Research, Development and Consultation Ltd., Ankara, Turkey

3 FORTH-ICS, Heraklion, Greece

Title: Patient Empowerment Framework for Cardiac Patients

Journal: Proceedings of MIE2011

Reference: 23rd International Conference of the European Federation for Medical Informatics, MIE 2011 / CD / Posters

Annex 1.9.

Authors: Maohua Yang¹

¹ OFFIS – Institute for Information Technology, Oldenburg, Germany, ² Software Research, Development and Consultation Ltd., Ankara, Turkey, ³ Salzburg Research Forschungsgesellschaft, Salzburg, Austria

Title: Guideline-Driven Telemonitoring and Follow-up of Cardiovascular Implantable Electronic Devices using ISO/IEEE 11073, HL7 & IHE Profiles

Journal: Proceedings of IEEE Engineering in Medicine and Biology Society (EMBC '11)

Reference: Conf Proc IEEE Eng Med Biol Soc. 2011 Aug;2011:3192-6

Annex 1.10.

Authors: Catherine Chronaki

¹FORTH-ICS, Heraklion, Crete, Greece

Title: Tomorrow's Integrated Care: Integration Testing in Guideline-driven Cardiac Telemonitoring

Journal: Proceedings of 12th INTERNATIONAL HL7 INTEROPERABILITY CONFERENCE

Reference: http://www.hl7.org/events/ihic2011/papers/friday/F_Q3_3_IHIC2011-chronaki_v1.pdf

Annex 1.11.

Authors: Christian Lüpkes¹

1 OFFIS – Institute for Information Technology, Oldenburg, Germany, ² Software Research, Development and Consultation Ltd., Ankara, Turkey, ³ Salzburg Research Forschungsgesellschaft, Salzburg, Austria

Title: **Ad-hoc Datentransformationen für Analytische Informationssysteme**

Journal: Grundlagen von Datenbanken 2011

Reference: http://ceur-ws.org/Vol-733/paper_luepkes.pdf

ANNEX 2 – ABSTRACTS UNDER EVALUATION AT THE TIME OF SUBMISSION OF THE DISSEMINATION REPORT

TITLE	FIRST AUTHOR	CONGRESS	SITE	DATE
Integrated Care in Guideline-driven Telemonitoring of Patients with Electronic Implant Devices. iCARDEA: a European Project.	Elena Arbelo	Heart Rhythm 2012	Boston, USA	9-12 May 2012
Patient Empowerment Mechanisms in Personalized Remote Monitoring of Patients with Electronic Implanted Devices. iCARDEA: a European Project.	Elena Arbelo	Heart Rhythm 2012	Boston, USA	9-12 May 2012
iCARDEA: Patient Education Mechanisms in Personalized Remote Monitoring of Patients with Cardiac Electronic Implanted Devices	Emilce Trucco	Heart Rhythm 2012	Boston, USA	9-12 May 2012
Integrated Care in Guideline-driven Telemonitoring of Patients with Electronic Implant Devices. iCARDEA: a European Project.	Elena Arbelo	Cardiostim 2012	Nice, France	13-16 June 2012
Patient Empowerment Mechanisms in Personalized Remote Monitoring of Patients with Electronic Implanted Devices. iCARDEA: a European Project.	Elena Arbelo	Cardiostim 2012	Nice, France	13-16 June 2012
iCARDEA: Patient Education Mechanisms in Personalized Remote Monitoring of Patients with Cardiac Electronic Implanted Devices	Emilce Trucco	Cardiostim 2012	Nice, France	13-16 June 2012

ⁱ Santini M, Ricci RP, Lunati M, et al. Remote monitoring of patients with biventricular defibrillators through the CareLink system improves clinical management of arrhythmias and heart failure episodes. *J Interv Cardiac Electrophysiol* 2009;24:53– 61.

ⁱⁱ Wilkoff BL, Auricchio A, Brugada J, et al. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. *Heart Rhythm* 2008;5:907–25.

ⁱⁱⁱ Eucomed: Eucomed registry (www.eucomed.org). Eucomed (the European Medical Device Trade Organization). Eucomed represents directly and indirectly 4500 designers, manufacturers, and suppliers of medical technology used in the diagnosis, prevention, treatment, and amelioration of disease and disability.