iCARDEA

Information Society Technologies

iCARDEA

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

SPECIFIC TARGETED RESEARCH PROJECT

PRIORITY Objective ICT-2009.5.1: Personal Health Systems - a) Minimally invasive systems and ICT-enabled artificial organs: a1) Cardiovascular diseases

iCARDEA D2.3.1 Reports on Intellectual Property Management (a)

Due Date:	July 31, 2011
Actual Submission Date:	August 01, 2011
Project Dates:	Project Start Date : February 01, 2010 Project End Date : January 31, 2013 Project Duration : 36 months
Leading Contractor Organization:	SRFG

Project co-funded by the European Commission within the Seventh Framework Programme (2007-2013)		
Dissemination Level		
PU	Public	x
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

Document History:

Version	Date	Changes	From	Review
V0.1	February 21, 2011	Initial Document	SRFG	All partners
V0.4	June 28, 2011	Results of the patent search, iCARDEA assets for IPR management	All partners	All partners
V1.0	July 13, 2011	Finalising D231	SRFG	All partners

Table of contents

1 Introduction

1.1 Purpose

This document provides detailed information how iCARDEA copes with innovation produced during the project within the scope of Task 9.2 “Management of Innovation and Intellectual Property”. The first part of the document includes the results of a patent search offering valuable clues how innovative iCARDEA assets can be exploited.

The second part of the document describes how the project intents to deal with intellectual properties of iCARDEA components. The starting point are the innovative assets in iCARDEA and the pre-existing know-how (background knowledge) updated with new pre-existing know-how (background) and knowledge (foreground) contributions as needed in the project. This is defined by each partner and will be updated as needed in the course of the project.

This document will be updated by D2.3.1 Reports on Intellectual Property Management (b) by the end of the project. The list of iCARDEA assets with specified background and foreground knowledge will be a living document and will be refined during the project.

1.2 Definitions, acronyms and abbreviations

Abbreviation/Acronym	DEFINITION
AF	Atrial fibrillation
CIED	Cardiovascular Implantable Electronic Device
HIS	Hospital information System
VT	Ventricular tachycardia

Table 1 – List of Abbreviations and Acronyms

2 Overall Description

Management of cardiac arrhythmia abnormalities that are not transient or reversible require constant clinical monitoring as a chronic condition. Delays on diagnosis or medical assistance increase risks of adverse outcomes such as heart failure, stroke or sudden cardiac. Therefore, Cardiovascular Implantable Electronic Devices (CIED) have become a part of the standard therapy in patients who are at the risk of life-threatening cardiac arrhythmias.

CIED devices with remote monitoring capabilities can store and transmit cardiac status and device function data. Remote sensor devices are located in patients' homes to transfer stored data from the cardiac implant to a remote monitoring service centre. These remote monitoring service centers, operated by device manufacturers, receive, store, analyze and translate transmitted data into patient-specific reports and allow healthcare professionals to access patient data or to receive alerts in case of unusual persisting data variations. These systems are also capable of providing this valuable information in machine processable form. iCARDEA project has set out to use this information to semi-automate the follow-up of cardiac arrhythmia patients with the care plans based on computer interpretable clinical guideline models by also personalizing the guidelines with the data obtained from patient EHRs.

Clinical guidelines include plans for treatment and aim to reduce inter-practice variations and the cost of the medical services, improve the quality of care and standardize clinical procedures. A variety of government and professional organizations are producing and disseminating clinical guidelines[1],[2]. Several computer interpretable models of Clinical Guidelines have also been proposed such as GLIF[3], ASBRU[4], and ARDEN[5]. Additionally, there are several guideline execution engines processing these models, such as GLEE[6], GLARE[7] and DeGel[8] demonstrating that the guideline definitions can be executed to automate the decision making process. In the iCARDEA system, GLIF is used for the definition of the care plans and an engine is developed to execute them. In this respect, the care plans presented in this deliverable are defined using GLIF Notation.

Currently the CIED data is available from two different sources. The patient may be at the clinic during an in-clinic follow-up, so the data from the CIED can be directly accessed using the CIED Programmer of the vendor. The CIED Programmer is able to export the data into PDF file(s) stored in a configurable directory. Alternatively, the patient may be at home and the data is transmitted (semi-) automatically into the CIED Data Centre of the vendor for a remote follow-up. The physicians then can access the CIED Portal of the vendor that functions as frontend of the CIED Data Centre. It is also possible to export the CIED Data to the clinic, however right now this export has to be triggered manually in the CIED Portal. The data is then either exported using the IHE IDCO/HL7 v2.5 message or it is exported to a vendor system that has to be installed in the clinic. Currently the

[1] US National Guideline Clearinghouse, http://www.guideline.gov/

[2] National Institute for Clinical Excellence- England/Wales (\uppercase{NICE}) Published Guidelines, http://www.nice.org.uk/page.aspx?o=guidelines.completed

[3] Boxwala AA, Peleg M, Tu S et al. GLIF3: a representation format for sharable computer-interpretable clinical practice guidelines. Journal of Biomed Inform., 2004, 37(3), 147-61

[4] Shahar, Y., Miksch, S., and Johnson, P. The Asgaard project: A task-specific framework for the application and critiquing of time-oriented clinical guidelines. Artificial Intelligence in Medicine, 1998, 14: 29-51.

[5] Jenders RA, Corman R, Dasgupta B. Making the standard more standard: a data and query model for knowledge representation in the Arden syntax. Proceedings of AMIA Annual Symp., 2003, 323-30.

[6] Wang D, Shortliffe EH. GLEE - a model-driven execution system for computer-based implementation of clinical practice guidelines. Proceedings of AMIA Symp., 2002, 855-9.

[7] Terenziani P, Montani S, Bottrighi A et al. The GLARE approach to clinical guidelines: main features. Studies in Health Technolohy and Informatics, 2004. 101, 162-6.

[8] Shahar Y, Young O, Shalom E, Mayaffit A, Moskovitch R, Hessing A, and Galperin M. DeGeL: A Hybrid, Multiple-Ontology Framework for Specification and Retrieval of Clinical Guidelines. Proceedings of the 9th Conference on Artificial Intelligence in Medicine, Springer-Verlag Heidelberg, 2003, 122 - 131.

v2.5 messages transferred by the CIED Vendors usually contain limited information; however the PDF reports that contain the detailed data are embedded in the message. The vendor system in the clinic then automatically stores the data in a single PDF file using a configurable filename and the filename includes additional information such as the Patient name, Patient ID, and the timestamp.

iCARDEA uses “IHE Implantable Device Cardiac Observation Profile (IDCO)"[9] to automatically expose the CIED data from different vendors in a machine processable format to be used in the care plan of the patients. There are different CIED vendors each with its own device and data centre interfaces. On the other hand, IHE has defined this profile in order to standardize transferring information from an interrogated implantable cardiac device to the healthcare enterprise information management systems. The implant device is interrogated in clinic or home environment using vendor proprietary equipment and the information is transferred to clinic system as structured HL7 v2.5 ORU message using IEEE 11073 IDC nomenclature[10].

In iCARDEA, a care plan is personalized to a patient by also accessing his medical history from the EHR systems. For example, in executing iCARDEA care plans for monitoring CIED patients with Atrial Fibrillation (AF), the history of the non-cardiac conditions, detailed information about severity of each condition (e.g., record of prior hospitalizations or specifics of therapy for the condition), the medications being taken at the time of spontaneous arrhythmia occurrence or the non-cardiac conditions denoting contraindications to the proposed therapies need to be accessed from the patient EHRs. The major challenge addressed in accessing the EHR systems is the interoperability problem of communicating with very many heterogeneous EHR systems. It should be noted that the care plans in this deliverables are generic in that they are not personalized to a specific patient.

To be able to avoid routinely monitoring a wide variety of clinical data from disparate systems, and developing ad hoc interfaces to access heterogeneous systems, IHE has specified the “Care Management Profile”[11] and this profile is used in the iCARDEA system.

2.1 iCARDEA System Architecture

The iCARDEA system aims to automate and personalize the follow-up of cardiac arrhythmia patients with implanted CIED devices with computer interpretable clinical guideline models using standard device interfaces and integrating patient EHRs. Figure 1 shows the overall architecture and the environment in which iCARDEA needs to provide interoperation services. The major components of the system are as follows:

1. Personalized Adaptive Care Planner for the CIED Recipients: In the iCARDEA project, the personalized follow-up of CIED patients is coordinated through a

[9] IHE Implantable Device - Cardiac – Observation Profile, http://www.ihe.net/Technical_Framework/upload/IHE_PCD_TF_Supplement_IDCO_2009-08-10.pdf

[10] ISO/IEEE 11073-10101:2004, Point-of-care medical device communication -- Part 10101: Nomenclature, http://www.iso.org/iso/catalogue_detail.htm?csnumber=37890

[11] IHE Patient Care Coordination (PCC) Technical Framework Supplement, 2008-2009, Care Management (CM), Draft for Trial Implementation, August 22, 2008

"care plan" which is an executable definition of computer interpretable clinical guideline models. The care plans are represented in GLIF, and the Care Plan Engine is capable of semi-automatically executing the care plan by processing its machine processable definition. The control flow of the care plan is dynamically adapted based on the patient's context derived from the data coming from CIEDs and the medical context obtained from the EHRs. Through a graphical monitoring tool, the physicians are allowed to follow the execution of the care plan in detail, and coordinate the flow of actions when consultations to physicians are required.

2. The CIED Data Exposure Module uses "IHE Implantable Device Cardiac Observation Profile (IDCO)" to expose the CIED data from different vendors in a machine processable format to be used in the care plan of the patients. For this, it has a component that allows accessing the CIED Portal of the vendor and triggers the CIED data export automatically from the CIED Data Centre (periodically every x hours or each morning at a defined time). The CIED Data Listener Component waits for the exported data. For this it either scans a configurable directory in case of the data is exported directly to a vendor system in the clinic, alternatively it listens a pre-configured port for the exported data using the IHE IDCO/HL7 v2.5 protocol in case of direct network retrieval. In both cases the PDF file(s) need to be processed to extract the CIED data and the Data Translation Service subsystem creates a valid IHE IDCO format (HL7 v2.5 ORU Message) and makes the CIED data available to the iCARDEA Adaptive Care Planner through PCD-09 Send Observation message.

3. EHR Interoperability Infrastructure: To execute the clinical guidelines, it is also necessary to have access to medical history of the patients in the EHR systems. Considering that there are very many EHR systems with proprietary interfaces, in iCARDEA, "IHE Care Management (CM) Profile" is used. In our system, the proprietary hospital information systems export "Discharge Summary" and also "Laboratory Report Summary" CDA documents in conformance to IHE CDA Document templates[12] to an EHR Server which is implemented as an IHE XDS Repository[13]. Additional specialized applications are used to enter patient identification information (IHE PIX) and medical history data in CDA format. This EHR Server also acts as a "Clinical Data Source" by implementing the IHE CM Profile. In this way, Adaptive Care Manager can subscribe to receive update notifications for the clinical data that is necessary to execute the care plans. IHE Care Management Profile specifies standard interfaces to extract this data that is needed by the care plans from the EHR systems. The two standardized transactions used in the iCARDEA system are as follows:

[12] IHE Care Coordination Framework, Content Modules, http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1#Medical_Documents_Specification_1.3.6.1.4.1.19376.1.5.3.1.1.1

[13] IHE Cross Enterprise Document Sharing (XDS) Profile, http://www.ihe.net/Technical_Framework/index.cfm#IT

- "PCC-09 Care Management Data Query" allows querying the clinical data sources such as the EHR systems for the data required to execute the care plan.
- "PCC-10-V3 Care Management Update" allows the clinical data sources (EHR systems) to send the updated clinical data to the subscribed Care management systems as an HL7 V3 messages.

Additionally, IHE has specified "Content Modules" to be used as the payloads of these transactions to transfer clinical data in terms of CDA Sections and Entries. The HL7 Clinical Document Architecture (CDA)[14] is a document mark-up standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange and each CDA document is made up of CDA Sections and each Section is made up of CDA Entries.

Different content module templates for CDA Documents such as Discharge Summary, Referral Summary; CDA Sections such as History of Present Illness, Medications, and CDA Entries such as Problem Entry, Vital Signs Observation have been specified.

While a Care manager queries a clinical data source, it specifies the type of the clinical data required through a code specified in the "careProvisionCode" field, such as "LABCAT", meaning all lab results. For each code specified in this controlled code list, the IHE content module template (for example "Simple Observations" template is specified for reporting lab results) is also specified through which the clinical data update is sent. The clinical data sources send the updated clinical data to the iCARDEA care plan engine by conforming to these content module templates. In this way the interoperability of the transactions among clinical data sources and care managers is guaranteed.

4. There is also a Patient Empowerment component that aims 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.

[14] HL7 Clinical Document Architecture (CDA), http://hl7.org/library/ Committees/structure/CDA.ReleaseTwo.CommitteeBallot03.Aug.2004.zip

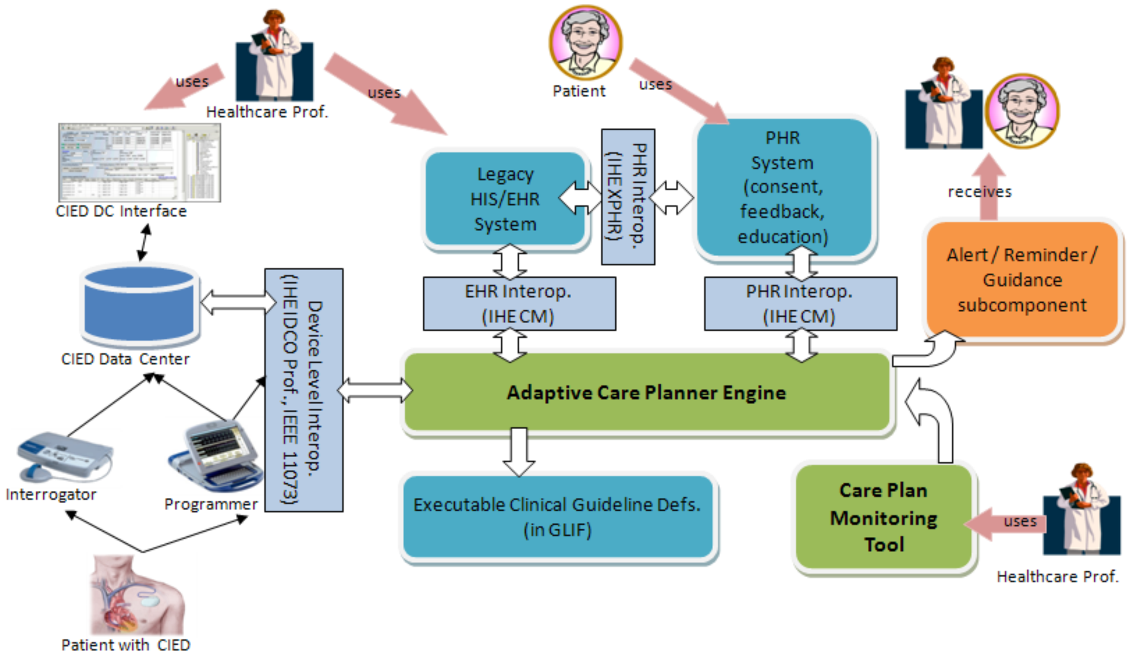

Figure 1 iCARDEA Architecture Overview

3 Patent Search with regard to the iCARDEA project

This section gives an overview of patent search results relevant for the iCARDEA project.

3.1 Homogenization of different Vendor Systems

System and Method for Managing Locally-Initiated Medical Device Interrogation[15] - this patent relates in general to automated patient management and, specifically, to a system and method for managing locally-initiated medical device interrogation. This includes a patient management device that interfaces to one or more medical devices, including implantable and external medical devices and monitors. A caregiver-specified schedule defines the frequency of autonomous patient data retrieval from the medical devices. Caregiver-specified criteria define the permissibility, conditionality, and maximum permissible occurrences of patient-initiated medical device interrogation. The schedule and criteria define mutually exclusive controls over the operation of the patient management device under which the scheduled autonomous medical device interrogations proceed independently of patient-initiated interrogation.

15 http://v3.espacenet.com/publicationDetails/description?CC=US&NR=2011004277A1&KC=A1&FT=D&date=20110106&DB=EPODOC&locale=en_V3

3.2 Implantable CIED and Interfaces for Bridging the Technologies with HIS

EHR management method and system[16] **-** the invention aims at providing a system and method for creating, maintaining and utilising a consolidated and structured electronic record of patient health information. The EHR system comprising: a communication module to receive patient medical encounter files from at least one third party database server; a protocol module which stores and maintains a predefined rule set determining data fields for a generated patient record; a record building module to parse the received patient medical encounter files to obtain patient data and associated medical encounter data from the medical encounter files in accordance with the rule set and to store the obtained data associated with a particular patient in the predetermined fields for the patient record, thereby to create a current patient database with multiple patient records, each patient record to comprise information on multiple medical encounters of the patient. Preferably the data is stored in the predetermined fields in accordance with universal standards relating to the practice area of a third party responsible for the third party database server. For example, the universal standard may be Logical Observation Identifiers Names and Codes (LOINC) used for identifying laboratory observations or Digital Imaging and Communications in Medicine (DICOM) used for handling, storing, printing, and transmitting information in medical imaging. By using the universal standard, the patient records are stored in a form which is unrelated to the format of the patient medical encounter files.

EHR management system would allow storing the reports coming from the Patient's CIED in a database linked to the patient's profile. The transmission and collection of the reports is independent to their content so it would allow to profile-linking and storing reports coming from different vendor systems. The invention suggests a methodology and architecture to implement a EHR system within a HIS.

3.3 Medical information transactions

Electronic Health Record Transaction Monitoring[17] – A computer-readable storage medium including a program, which when executed on a processor performs a method for providing individuals with notifications pertaining to use of heath records, comprising: generating a report describing accesses to health records of respective individuals of a plurality of individuals whose respective health records are accessed in a network-accessible storage repository configured to store a plurality of electronic health records

16 http://v3.espacenet.com/publicationDetails/description?CC=WO&NR=2010052638A1&KC=A1&FT=D&date=20100514&DB=EPODOC&locale=en_V3

17 Richard D. Dettinger et al, , http://www.google.com/patents/about?id=ekGXAAAAEBAJ

for the plurality of individuals; wherein the network-accessible storage repository is configured to allow research organizations access to the health records and wherein each of the accesses described in the report are related to a one or more research projects; and providing the reports to the respective individuals, whereby each report is specific to the health records of the respective individual being provided the report.

Method, system and message structure for electronically exchanging medical information[18] - The present invention relates to a message structure for electronically exchanging medical information between applications utilizing disparate medical coding systems and record architectures, the message structure comprising an optional storyline keyword that sets the context for one or more subsequent statements, each of which statements comprise a genre selected from a set of genre keywords representing message categories, a subject, comprising either a natural language string of one or more words or a nested statement, and, optionally, one or more parametrized predicates comprising a context joiner selected from a set of context joiner keywords, and a parameter comprising a natural language string of one or more words or a nested statement.

3.4 Workflow Engine Patent and Software Search

This section includes discussions about the findings of existing software solutions enabling workflow enabled process execution and bridging mechanisms for binary decision trees with patient records accessible via web technology.

Weka[19] - Weka stands for Waikato (New Zealand, University) Environment for Knowledge Analysis and is a popular suite of machine learning software and data mining algorithms written using the programming language Java. Weka is free software available under the GNU General Public License. Weka has a workflow management engine, which enabled to design and execute defined workflows as well as performing analytical tasks. Weka is one of the mostly used data mining framework and lot of new developed data mining approaches do have a Weka interface due to its interface variety.

YAWL[20] - stands for Yet Another Workflow Language and is a BPM/Workflow system. Due to its design YAWL is able to handles complex data, transformations, integration with organizational resources and also Web Service integration and qualifies therefore for many tasks. It is also built using the programming language Java. It uses XML Schema and XQuery natively, which are important for development.

[18] Inventor: Yeong Kuang Oon
http://www.google.com/patents/about?id=_uTRAAAAEBAJ&dq=%22electronic+health+record%22+layer

[19] http://www.cs.waikato.ac.nz/ml/weka/
[20] http://www.yawlfoundation.org/

3.5 Data Integration and Interconnection

Talend[21] – Data management encompasses all measures implemented to support the use of data as a resource. The purpose of data management is to manage and supply accurate and timely data to business processes. Major disciplines in Data Management include data integration, data quality, Master Data Management, etc.
Talend provides with: Data Integration Solutions, Data Quality Solutions, Master Data Management Solutions, Data Synchronization, ETL for Analytics, Application Integration Summarizing one can say that the Talend solution could be seen and used as one key application for building up biomedical data warehouse systems consisting of different data sources. Talend is also implemented using Java and with its module concept new ones can be easily be integrated. Furthermore, the Talend solution package has proven to be sucessful in the biomedical research and application area.

Pentaho Data Integration[22] - Kettle (K.E.T.T.L.E - Kettle ETTL Environment) has been recently acquired by the Pentaho group and renamed to Pentaho Data Integration. Kettle is a leading open source ETL application on the market. It also focuses on business intelligence which is used for analytical tasks.

3.6 Decision Making and Data Analysis

KNIME[23] – stands for Konstanz Information Miner. It is a user-friendly and comprehensive open-source data integration, processing, analysis, and exploration platform. This software package is currently used in industry and academia due to its modern software engineering practices. Univ.-Prof. Dr. Michael Berthold and his group is responsible for further development of KNIME.

KDD Designer[24] – stands for Knowledge Discovery in Database Designer and is abbreviated by KD3. This software package is relatively new (has been developing since 2007) and focuses on easy creation of interfaces, data integration and execution of complex workflows for statistical analysis and data miming. Assoc. Prof. Dr. Bernhard Pfeifer and his research group developed this Java based parallel workflow and data mining execution pipeline and is responsible for further development. Its design enables to easily integrate other existing software modules by a modern software engineering approach, and, furthermore, algorithms from WEKA can directly be used by the KD3 tool. Each defined workflow can be automatically packed to a compact executable JAR file, and then be integrated into other existing execution pipelines or system.

[21] http://www.talend.com/index.php
[22] http://kettle.pentaho.com/
[23] http://www.knime.org/
[24] http://www.umit.at/page.cfm?pageid=2672

3.7 Conclusions for iCARDEA

After performing the patent search, some difficulties have been found for iCARDEA:

- Software as a standalone application cannot be patented. Only an algorithm or a piece of software incorporated in a workflow or designed for a specialized working field can be patented.
- As several pieces of the iCARDEA platform and structure is already published it must be noticed here that in case the piece could have been patented this is not possible anymore, because already published knowledge is impossible to be protected by patents.

Against that background and in line with the consortium partners the focus in iCARDEA will be on open source components. This will be described in detail in the next chapter.

4 Intellectual Property Management of iCARDEA Assets

This section describes how the iCARDEA consortium intends to manage intellectual properties in the project based on identified innovative assets. The subsequently described list of iCARDEA assets is a living IPR management database and will be updated during the execution of the project and with new pre-existing know-how (background) and knowledge (foreground) contributions as needed.

4.1 Identified Innovative Assets

iCARDEA comprises several, basically independent software modules which communicate with each other based on HL7 interoperability standards. These software modules represent the key categories for the innovative iCARDEA assets:

- Personalized Adaptive Care Planner Environment
- Data Analysis through Temporal Dimensions Module
- Privacy-aware Data Analysis Concept
- CIED Data Interoperability Module
- Framework for Patient Empowerment
- EHR Interoperability Framework

Depending on the preferred usage of the iCARDEA assets they can be described by the following intellectual properties criteria:

- **Type of asset** – Product / Service / Method
- **IPR type** – Patent / Open source/ Copyright

Table 2 gives an overview how each iCARDEA consortium partner intends to manage the intellectual properties of each iCARDEA asset based on the previously mentioned intellectual properties criteria.

iCARDEA Assests	Type	SRDC	OFFIS	SRFG	FORTH	SALK	SJM	Medtronic	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 Framework	Asset	Service		Service	Product/Method				Product/Method
	IPR	Open source		Open Source	Open Source / Free for non commercial use				Open source

Table 2 - Overview iCARDEA Assets

4.1.1 Open source licensing strategies

Looking at Table 2 most of the assets will be open source. At the current stage of the project it is not yet clear which type of open source licensing agreement will be appropriate. Basically, two open sources licensing strategies for commercial use are possible:

- **Permissive** – such as BSD or Apache licenses

- **Copyleft** – for a commercially restrictive use. Copyleft removes the right to add further license restrictions upon redistribution. An examples for Copyleft is GPL

In the following three possible open sources licensing strategies for iCARDEA assets are briefly described[25]:

- **BSD License** – are permissive free software licenses and give a complete freedom to copy, distribute and modify work for any purpose, provided that the original license and copyright notice are included. Derivative work can be released under another license or as proprietary software. Two variants of the license, the New BSD License/Modified BSD License, and the Simplified BSD License/FreeBSD License have been verified as GPL-compatible free software licenses by the Free Software Foundation[26], and have been accepted as open source licenses by the Open Source Initiative[27].
- **Apache License** – is a free software license. The code under the license can be used in open, free and proprietary software (like the BSD licenses). It imposes the conditions that in any licensed file, all original copyright, attribution and trademark notices must be preserved. Additionally, with any modified work, a notice of change must be included. Any existing notices of change must also be kept. All of these notices must be distributed in a text file and in the source code or documentation. In comparison Apache license also includes many more legal terms and conditions that (among other purposes) dissolves any liability of the original copyright owner. The Apache license (version 2) is said to be GPL-compatible, meaning that a project containing code licensed under both must also be licensed under GPL version 3.
- **GNU General Public License (GPL)** – is the most widely used free software license. The GPL is the first copyleft license for general use, which means that derived works can only be distributed under the same license terms. GPL code can be sold**,** but no proprietary software can be derived from it. If any derivative work is distributed, then the source code must be made available under the same license. Essentially, once a work is released under the GPL, it remains GPL and no further restrictions can be applied. A compromise between the strong-copyleft GPL and permissive licenses such as the BSD licenses is code licensed under LGPL (GNU Lesser General Public License). LGPL can be linked with any other code no matter what license that code has.[28]

Although there is a preference of some iCARDEA partners towards open source (see Table 2) and a permissive licensing strategy there is no common agreed licensing strategy at the current stage of the iCARDEA project (month 18 of month 36). The decision about the licensing strategy will be discussed during Year 3 of the iCARDEA project and will take into consideration the exploitation plan.

[25] http://www.smashingmagazine.com/2011/06/14/understanding-copyright-and-licenses/#software-licenses
[26] http://www.fsf.org/
[27] http://opensource.org/
[28] http://en.wikipedia.org/wiki/GNU_General_Public_License

4.2 Background and Foreground Knowledge for iCARDEA Assests

In this section each partner present his background and foreground knowledge in relation to the identified iCARDEA assets.

4.2.1 Personalized Adaptive Care Planner Environment

SRDC

- Background Knowledge
    - In the FP6 SAPHIRE Project, SRDC has developed an Intelligent Clinical Decision Support System. For this system, SRDC has extended the Guideline Interchange Format (GLIF) for being executed by computers. This model is being used and further developed within iCARDEA Project. A guideline execution engine has been developed as well which was based on software agents; with the expertise gained from this implementation, CIED based adaptive care planner of iCARDEA is being developed.
- Foreground Knowledge
    - The GLIF enactment engine developed within the scope of SAPHIRE Project was neither IHE Implantable Device Cardiac Observation Profile (IDCO)[29] nor IHE Care Management (CM) Profile[30] compliant. Hence only the core of the engine that parses and processes GLIF definition is used; the components that accesses EHR and wireless medical sensor data have been rewritten to be able to access EHR and CIED data through these standard based interfaces. First of all we have implemented IHE IDCO Observation Processor Component which listens and receives HL7 v2.5 ORU messages. Then we have implemented the IHE CM Care Manager Role, which is composed of a CareManager class that is responsible to send "PCC-9 Care Management Data Query" messages to subscribe to receive medical data through PCC-10 messages, and a CareManagerWS Web Service, which accepts PCC-10 messages. We have designed a Care Management Database to store these IDCO and CM data feeds that are further to be used by the Care Plan Engine while the care plan is being executed.

OFFIS

- Background Knowledge – none

[29] IHE Implantable Device - Cardiac – Observation Profile, http://www.ihe.net/Technical_Framework/upload/IHE_PCD_TF_Supplement_IDCO_2009-08-10.pdf. Last accessed October 15, 2010.

[30] IHE Patient Care Coordination (PCC) Technical Framework Supplement, 2008-2009, Care Management (CM), Draft for Trial Implementation, August 22, 2008

- Foreground Knowledge – none

SRFG

- Background Knowledge – none
- Foreground Knowledge – within the scope of iCARDEA project SRFG gained expertise in IHE Care Management Profile and implemented this profile for achieving interoperability between PHR System and Care Planer.

FORTH

- Background Knowledge – FORTH has extensive knowledge of HL7 CDA technologies gained in the context of previous European projects.
- Foreground Knowledge – The design Adaptive Care Planner environment required the adoption of the IHE Care Management (CM) Profile in order to get almost real time notifications for new clinical data for the iCARDEA patients. FORTH implemented the Clinical Data Source actor of the CM Profile as additional functionality of its XDS server. This component accepts the “PCC-9 Care Management Data Query” subscription messages sent by the Adaptive Care Planner and whenever new clinical information is inserted in the Document Repository that matches some of the subscriptions, it sends back “PCC-10 Care Management Update” messages.

SALK

- Background Knowledge – Medical knowledge and experience in cardiovascular medicine; specific knowledge in electro-physiology;
- Foreground Knowledge – The creation of Care Plans for AF and VT. Expertise gained through the deployment of iCARDEA care planner for remote patient monitoring.

SJM

- Background Knowledge – none
- Foreground Knowledge – none

Medtronic

- Background Knowledge – none
- Foreground Knowledge – none

HCPB

- Background Knowledge – HCPB, working together with the different providers that operate in this district, has pursued the creation of an integrated care model of service integration aiming at maximizing cooperation among professionals, levels of care and institutions. As a result, since year 2000 research lines have been created to explore, develop, validate and implement information and communication technologies to support these new models of care provision. The research lines have been supported by a number of different grants, both at regional, national and European level. At present HCB is participating in the following projects: Nexes (coordinator), Care-man and HomeCare. Additionally, the Arrhythmia Unit of the HCPB is known worldwide, with a vast experience in the management of patients with cardiac arrhythmias, implanted devices and any cardiovascular disease, in general.

- Foreground Knowledge – The development of the careplans for the management of atrial and ventricular arrhythmias within the scope of iCARDEA as well as the identification and production of patient education material (passive information, decision aids, etc.), has facilitated a more organized distribution of tasks and actions for our already existing CIED remote monitoring of patients. On the other hand, HCPB exploitation strategy of iCARDEA is being designed in close relation with Linkcare Health Services SL, a recently created spin-off of HCPB whose main aim is to channel into the market the knowledge and ICT products developed in the HCPB, notably those related to the management of chronic patients. The integration of iCARDEA with Linkcare within the HCPB has a great potential:

  - 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 Catalonian 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 patient 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.

4.2.2 Data Analysis through Temporal Dimensions Module

SRDC

- Background Knowledge – none
- Foreground Knowledge – none

OFFIS

- Background Knowledge – MUSTANG, a multi-dimensional statistical data analysis engine enabling the development of specialized analytical information systems. MUSTANG is defined as Background Knowledge in the consortium agreement.
- Foreground Knowledge – The enhancement of OLAP and underlying DWH technologies by using temporal concepts leading to a new MUSTANG module able to cope with temporally changing data.

SRFG

- Background Knowledge – none
- Foreground Knowledge – none

FORTH

- Background Knowledge –
- Foreground Knowledge –

SALK

- Background Knowledge – none
- Foreground Knowledge – none

SJM

- Background Knowledge – none
- Foreground Knowledge – none

Medtronic

- Background Knowledge – MDT provided to the developers examples of patient's reports that are generated by the CareLink™ system which follow proprietary data structures.
- Foreground Knowledge –

HCPB

- Background Knowledge – none
- Foreground Knowledge – none

4.2.3 Privacy-aware Data Analysis Concept

SRDC

- Background Knowledge – none
- Foreground Knowledge – none

OFFIS

- Background Knowledge –
- Foreground Knowledge – Method and services for privacy aware data analysis applicable to the Austrian health market.

SRFG

- Background Knowledge – none
- Foreground Knowledge – none

FORTH

- Background Knowledge – FORTH has experience from EU projects and in the standards arena in the application of privacy enhancing techniques and related standards.
- Foreground Knowledge – Methods and services for privacy protection in the processing of EHR data from the HIS, in the context of the EHR-IF.

SALK

- Background Knowledge – none
- Foreground Knowledge – none

SJM

- Background Knowledge – none
- Foreground Knowledge – none

Medtronic

- Background Knowledge – Medtronic implements in its devices a series of contracts that assure the privacy and security of the patient's information. The information is encrypted, anonymised and only accessible through Medtronic's proprietary software.
- Foreground Knowledge – Consultancy and information relevant to the development of security management.

HCPB

- Background Knowledge – Legislative framework of data protection (both at a local and EU level) and ethical principles, based on patient autonomy, and working through consent and confidentiality.
- Foreground Knowledge – Patient data security and privacy mechanisms and services have been identified by close cooperation of technical partners, clinicians, patients and decision makers, with special emphasis on the examination of all ethical and legal issues. The issues of appropriate ethical and legal processes that fully respect patient autonomy have been observed, also allowing patients to become more involved in their care, will be examined, and recommendations made for change.

4.2.4 CIED Data Interoperability Module

SRDC

- Background Knowledge

  - SRDC Team had knowledge about IHE IDCO Standard, and IEEE 11073 Nomenclature. Previously SRDC developed a tool that semi-automatically converts proprietary medical sensor device readings to conform to IEEE 11073 nomenclature.
- Foreground Knowledge
  - Within the scope of iCARDEA Project, SRDC investigated the interoperability of ICD Devices by proposing a methodology to achieve mediation through the definition of an HL7 RMIM model based on IEEE 11073 Domain Information Model. This makes it possible to trace the medical device data back to a standard common denominator, that is, HL7 RIM from which all the other medical domains under HL7 are derived. Hence, once the medical device data is obtained in the RMIM format, it can easily be transformed into HL7 based standard interfaces through XML transformations because these interfaces all have their building blocks from the same RIM[31].
  - Also, within the scope of iCARDEA project SRDC gained expertise in IHE IDCO Profile and implemented this profile.

OFFIS

- Background Knowledge –
- Foreground Knowledge – Module for CIED Data Integration as defined in Task 6.1 of the Description of Work.

SRFG

- Background Knowledge – none
- Foreground Knowledge – none

FORTH

- Background Knowledge – Followup of relevant developments inIHE, HL7 and IEEE11073. Particular experience in the acquisition and processing of Waveform data such as ECGs.
- Foreground Knowledge – Methods and services for the Waveform data.

SALK

- Background Knowledge – none
- Foreground Knowledge – none

SJM

- Background Knowledge – none
- Foreground Knowledge – none

Medtronic

---

[31] Yuksel M., Dogac A. Interoperability of Medical Device Information and the Clinical Applications: An HL7 RMIM based on ISO/IEEE 11073 DIM IEEE Transactions on Information Technology in Biomedicine, to appear.

- Background Knowledge – Medtronic provided knowledge and reports coming from their own proprietary systems: CareLink™, PaceHeart, and Mainspring. Those proprietary systems belong to Medtronic and cannot be used without expressed authorisation of the company. MDT also provided several examples of CIED reports generated with CaleLink™.
- Foreground Knowledge – Medtronic participated on the definition of an architecture that allows integrating the information coming from the reports of CareLink in the iCARDEA system by analysing the PDFs.

HCPB

- Background Knowledge – none
- Foreground Knowledge – none

4.2.5 Framework for Patient Empowerment

SRDC

- Background Knowledge
    - SRDC had developed a personal health platform maintaining and managing users' personal information, medical information like allergies, vital signs, medications, test results, managing users' diet or exercise program, or monitoring a specific disease like diabetes through the help of wireless medical sensor devices. In Turkey, platform is also integrated with the National Family Medicine Information of Turkey.
- Foreground Knowledge
    - SRDC gained expertise in the field of remotely monitoring ICD patients. SRDC aims to extend its PHR tool to include a disease management platform for ICD patients also.
    - Within the scope of iCARDEA project SRDC gained expertise in IHE care Management Profile and implemented this profile for achieving interoperability with PHR System of iCARDEA.

OFFIS

- Background Knowledge – none
- Foreground Knowledge – none

SRFG

- Background Knowledge – SRFG team had knowledge in Patient Empowerment strategies
- Foreground Knowledge – Concept and implementation of the Patient Empowerment Framework as described in WP5 of the iCARDEA DoW. The Patient Empowerment Framework is a Personal Health Record (PHR) system including specific services which support Patient Empowerment concepts.

FORTH

- Background Knowledge – Studies in the citizen's perceptions of eHealth
- Foreground Knowledge – none

SALK

- Background Knowledge – none
- Foreground Knowledge – Educational material provided by SALK

SJM

- Background Knowledge – none
- Foreground Knowledge – none

Medtronic

- Background Knowledge – none
- Foreground Knowledge – none

HCPB

- Background Knowledge – HCPB has decades of experience in the management of patients with implanted cardiac devices providing them with the necessary information and resources for a better management of their own disease. In the past few years, CIEDs with home monitoring capabilities have been implanted at HCPB and thus, we have gained experience in the remote follow-up of patients with devices of the different manufacturers (Medtronic, Boston Scientific, Saint Jude Medical, Biotronik, Sorin).
- Foreground Knowledge – By coordinating the Task 5.2, and in general, being strongly involved in WP5, HCPB has identified the key passive and active information/documentation for patient education as well as the empowerment in the management of their disease. Additionally, in close collaboration with LinkCare (previously described), the PHR currently available in the region of Catalonia is being implemented into an intelligent platform where the patient will be able to get continuous feedback on their status as well as actively participate in the decision making process and management of their disease.

4.2.6 EHR Interoperability Framework

SRDC

- Background Knowledge
  - SRDC has extensive knowledge in HL7 RIM, CDA standards, and also in implementation of IHE profiles. The team previously implemented ATNA and PIX profiles.
- Foreground Knowledge
  - Within the scope of iCARDEA project SRDC gained expertise in IHE Care Management Profile and implemented this profile.

OFFIS

- Background Knowledge – none
- Foreground Knowledge – none

SRFG

- Background Knowledge – none
- Foreground Knowledge – within the scope of iCARDEA project SRFG gained expertise in IHE Care Management Profile and implemented this profile for achieving interoperability between PHR System and EHR Interoperability Framework.

FORTH

- Background Knowledge – FORTH has worked extensively in the past for the design, implementation and deployment of EHR solutions in regional and national settings using international standards like HL7 CDA, ISO TC 215, CEN EN 13606 and open specifications like the ones provided by openEHR[32] and Object Management Group (OMG)[33] .
- Foreground Knowledge – In the context of the iCARDEA project FORTH implemented the “backbone” of the EHR Interoperability Framework, that is the Cross Document Sharing (XDS) and the Patient Identifier Cross-referencing (PIX)/ Patient Demographics Query(PDQ) services of IHE. Therefore FORTH gained expertise in the internals of these components and also in their use by the implementation of custom bridges with the SALK Hospital Information System for the translation of HL7v2 and Edifact messages to CDA.

SALK

- Background Knowledge – none
- Foreground Knowledge – none

SJM

- Background Knowledge – none
- Foreground Knowledge – none

Medtronic

- Background Knowledge – Medtronic provided their knowledge and means to access the information stored in the CareLink DB. To achieve the transfer of CIED reports from Carelink DB to a folder in the hospital system, Medtronic’s Mainspring software was provided.
- Foreground Knowledge –

HCPB

- Background Knowledge – HCPB currently has EHR that provides all clinical information including reports, clinical notes, treatment, laboratory results, imaging

[32] http://www.openehr.org/
[33] http://healthcare.omg.org/

techniques, etc. Additionnally, HCPB and Linkcare have consolidated experience on how to design and carry out programmes targeting chronic patients: the Link-care platform is already used in the HCPB for programmes with chronic patients (also including patients with heart disease -but without CIEDs).

- Foreground Knowledge – Through the experience acquired within the iCARDEA project, HCPB and LinkCare are working on the conversion and implementation of the data obtained of each manufacturer’s telemonitoring system, in order to provide a wholesome evaluation of the CIED patient. The careplans developed for the management of alerts and arrhythmias are also being implemented.