Grant Agreement number: 248240
Project acronym: iCARDEA
Project title: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices
Funding Scheme: STREP
Date of latest version of Annex I against which the assessment will be made: December 11, 2009

Period covered: From: February 01, 2011 To: July 31, 2011

Project Coordinator Name: Prof. Dr. Asuman Dogac
Project Coordinator Organization: SRDC Ltd.
06531, Ankara, Turkey
Phone: +90-312-2101393
Fax: +90-312-2101837
Email: asuman@srdc.com.tr

Document History:

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Changes</th>
<th>From</th>
<th>Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>V0.1</td>
<td>June 02, 2011</td>
<td>Draft Created</td>
<td>SRDC</td>
<td>All Partners</td>
</tr>
<tr>
<td>V0.2</td>
<td>July 08, 2011</td>
<td>OFFIS Contribution</td>
<td>OFFIS</td>
<td>SRDC</td>
</tr>
<tr>
<td>V0.3</td>
<td>July 13, 2011</td>
<td>SRFG Contribution</td>
<td>SRFG</td>
<td>SRDC</td>
</tr>
<tr>
<td>V0.4</td>
<td>July 15, 2011</td>
<td>SRDC Contribution</td>
<td>SRDC</td>
<td>SRDC</td>
</tr>
<tr>
<td>V0.5</td>
<td>July 26, 2011</td>
<td>SJM Contribution</td>
<td>SJM</td>
<td>SRDC</td>
</tr>
<tr>
<td>V0.6</td>
<td>July 29, 2011</td>
<td>Medtronic Contribution</td>
<td>Medtronic</td>
<td>SRDC</td>
</tr>
<tr>
<td>V0.7</td>
<td>July 29, 2011</td>
<td>HCPB Contribution</td>
<td>HCPB</td>
<td>SRDC</td>
</tr>
<tr>
<td>V0.8</td>
<td>August 01, 2011</td>
<td>SALK Contribution</td>
<td>SALK</td>
<td>SRDC</td>
</tr>
<tr>
<td>V0.9</td>
<td>August 05, 2011</td>
<td>SRDC Consolidation of inputs</td>
<td>SRDC</td>
<td>All consortium</td>
</tr>
<tr>
<td>V1.0</td>
<td>August 12, 2011</td>
<td>SRFG Contribution regarding PMs spent</td>
<td>SRFG</td>
<td>SRDC</td>
</tr>
<tr>
<td>V1.1</td>
<td>August 14, 2011</td>
<td>FORTH Contribution</td>
<td>FORTH</td>
<td>SRDC</td>
</tr>
</tbody>
</table>

Contributors

SRDC: Prof. Dr. Asuman Dogac, Gokce Banu Laleci Erturkmen, Yildiray Kabak, Elif Eryilmaz
OFFIS: Andreas Thiel, Christian Lupkes
SRFG: Manuela Ploessnig, Bob Mulrenin, Ursula Atzlinger
SJM: Bernhard Pfeifer,
HCPB: Elena Arbelo, Emilce Trucco
SALK: Lynne Hinterbuchner, Erik Vossius
Medtronic: Alejandra Guillen
FORTH: Catherine Chronaki
iCARDEA Consortium Contacts:

<table>
<thead>
<tr>
<th>N°</th>
<th>Organisation</th>
<th>Street name and number</th>
<th>Post Code</th>
<th>Town/ City</th>
<th>Country Code</th>
<th>Family Name</th>
<th>First Name</th>
<th>Phone N°</th>
<th>Fax N°</th>
<th>E-Mail</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SRDC</td>
<td>ODTU Teknokent, Silikon Blok Kat 1 No:14</td>
<td>06531</td>
<td>Ankara</td>
<td>Turkey</td>
<td>Dogac</td>
<td>Asuman</td>
<td>+90-312-2101393</td>
<td>+90(312)2101837</td>
<td><a href="mailto:asuman@srdc.com.tr">asuman@srdc.com.tr</a></td>
</tr>
<tr>
<td>2</td>
<td>OFFIS</td>
<td>Escherweg 2</td>
<td>26121</td>
<td>Oldenburg</td>
<td>Germany</td>
<td>Thoben</td>
<td>Wilfried</td>
<td>+49-441-9722131</td>
<td>+49-441-9722111</td>
<td><a href="mailto:thoben@offis.de">thoben@offis.de</a></td>
</tr>
<tr>
<td>3</td>
<td>SRFG</td>
<td>JAKOB HARINGER Strasse 5/III</td>
<td>5020</td>
<td>Salzburg</td>
<td>Austria</td>
<td>Plößnig</td>
<td>Manuela</td>
<td>+43-662-2288-402</td>
<td>-</td>
<td><a href="mailto:manuela.ploessnig@salzburgresearch.at">manuela.ploessnig@salzburgresearch.at</a></td>
</tr>
<tr>
<td>4</td>
<td>FORTH</td>
<td>PLASTIRA STR 100</td>
<td>70013</td>
<td>Heraklion</td>
<td>Greece</td>
<td>Chronaki</td>
<td>Catherine</td>
<td>+302810391691</td>
<td>+302810391428</td>
<td><a href="mailto:chronaki@ics.forth.gr">chronaki@ics.forth.gr</a></td>
</tr>
<tr>
<td>5</td>
<td>SALK</td>
<td>Mullner Hauptstrasse 48</td>
<td>5020</td>
<td>Salzburg</td>
<td>Austria</td>
<td>Strohmer</td>
<td>Bernhard</td>
<td>+43-6624482-3481</td>
<td>+43-6624482-3486</td>
<td><a href="mailto:b.strohmer@salk.at">b.strohmer@salk.at</a></td>
</tr>
<tr>
<td>6</td>
<td>SJM</td>
<td>Weinerbergstrasse 7</td>
<td>1100</td>
<td>Vienna</td>
<td>Austria</td>
<td>Eberhardt</td>
<td>Karl</td>
<td>+43-16073067</td>
<td>-</td>
<td><a href="mailto:keberhardt@sjm.com">keberhardt@sjm.com</a></td>
</tr>
<tr>
<td>7</td>
<td>Medtronic</td>
<td>Calle Maria De Portugal 11</td>
<td>28050</td>
<td>Madrid</td>
<td>Spain</td>
<td>Colás</td>
<td>Javier</td>
<td>34916250361</td>
<td>34913346453</td>
<td><a href="mailto:javier.colas@medtronic.com">javier.colas@medtronic.com</a></td>
</tr>
<tr>
<td>8</td>
<td>HCPB</td>
<td>Calle Villarroel 170</td>
<td>08036</td>
<td>Barcelona</td>
<td>Spain</td>
<td>Brugada</td>
<td>Josep</td>
<td>+34932275703</td>
<td>+34932275459</td>
<td><a href="mailto:jbrugada@clinic.ub.es">jbrugada@clinic.ub.es</a></td>
</tr>
</tbody>
</table>
Table of contents

1 PUBLISHABLE EXECUTIVE SUMMARY ...........................................................................6
  1.1 Publishable Results ..................................................................................................10
2 PROJECT OBJECTIVES FOR THE PERIOD ..................................................................14
  2.1 Objectives of the reporting period ...........................................................................14
  2.2 Recommendations from the 1st iCARDEA Review Meeting ........................................14
  2.3 Problems encountered in the reporting period ..........................................................26
3 WORKPACKAGE PROGRESS AND ACHIEVEMENTS DURING THE PERIOD .................27
  3.1 WP 2 - Dissemination, Exploitation and Innovation Related Activities .........................27
  3.2 WP 3 - S&T Management and iCARDEA System Architecture .....................................31
  3.3 WP 4 - Personalized Adaptive Care Planner for CIED Recipients .................................31
  3.4 WP 5 - Framework for Patient Empowerment ............................................................32
  3.5 WP 6 - Interoperability Layer ....................................................................................35
  3.6 WP 7 - Context Awareness and Clinically Useful Information Derivation .........................37
  3.7 WP 8 - iCARDEA Testing and Validation Framework ................................................38
  3.8 WP 9 – iCARDEA Pilot Application ..........................................................................40
4 DELIVERABLES AND MILESTONES TABLES .................................................................42
  4.1 Progress Overview per Contractor ............................................................................52
5 PROJECT MANAGEMENT ................................................................................................73
  5.1 Detailed Progress in WP1 ..........................................................................................73
  5.2 Project Timetable and Status ....................................................................................73
  5.3 Deviations from the work plan and their impact to the project ........................................74
  5.4 Co-ordination of the information between partners and communication activities ............74
    5.4.1 Project Meetings Details .....................................................................................74
    5.4.2 Conferences, workshops, demonstration, attended/organized ..................................76
  5.5 Plan and objectives for the next period .......................................................................77
    5.5.1 Plans related with Deliverables Due .....................................................................77
    5.5.1.1 WP1 Project Management .................................................................................77
    5.5.1.2 WP2 Dissemination, Exploitation and Innovation Related Activities ......................77
    5.5.1.3 WP4 Personalized Adaptive Care Planner for CIED Recipients ...............................78
    5.5.1.4 WP5 Framework for Patient Empowerment ..........................................................78
    5.5.1.5 WP6 Interoperability Layer ...............................................................................79
    5.5.1.6 WP7 Context Awareness and Clinically Useful Information Derivation ....................79
    5.5.2 Implementation Plans ...........................................................................................80
    5.5.2.1 WP4 Personalized Adaptive Care Planner for CIED Recipients ...............................80
    5.5.2.2 WP5 Framework for Patient Empowerment ..........................................................81
    5.5.2.3 WP6 Interoperability Layer ...............................................................................82
    5.5.2.4 WP7 Context Awareness and Clinically Useful Information Derivation ....................83
    5.5.2.5 WP8 iCARDEA Testing and Validation Framework ................................................85
    5.5.2.6 WP9 iCARDEA Pilot Application .......................................................................86
    5.5.2.7 Updates regarding D4.1.1 ................................................................................86
6 EXPLANATION OF THE USE OF RESOURCES .................................................................88
  6.1 Resources distribution among the partners: ..................................................................88
  6.2 Summary per partner ...................................................................................................88
7 Appendix 1: Minutes of February 08-09, 2011 Hamburg Technical Meeting ..........................90
  7.1 Participants .................................................................................................................90
  7.2 Agenda .......................................................................................................................90
  7.3 Minutes ......................................................................................................................91
8 Appendix 2: Minutes of March 22-23, 2011 Salzburg Technical Meeting ...............................100
  8.1 Minutes Day 1: March 22, 2011, 15:30-18:30 ..............................................................102
8.1.1 iCARDEA scenario and the EHR interoperability framework ........................................102
8.1.2 Draft Deployment Architecture of EHR-IF: open issues .....................................102
8.1.3 ICD patient follow-up: EHR data – part 1 ..............................................................103
8.1.4 How to convert EHR data from SALK into a standard format: terminologies ........103
8.2 Day 2: May 23, 2011, 7:30-3:30 ...........................................................................104
8.2.1 Technical Discussion: Deployment of the EHR-IF in SALK (8:30-10:00) .....................104
8.2.1.1 Real time data ..................................................................................................104
8.2.1.2 Historical Data ...............................................................................................105
8.2.1.3 Additional issues ............................................................................................105
8.2.2 Patient workflow for outpatient follow-up (8:30-10:00) ..........................................105
8.2.2.1 FOLLOW UP Protocol for ICD Patients .........................................................106
8.2.2.2 Remote Visit via Telemonitoring ....................................................................107
8.2.2.3 Alarms ...........................................................................................................107
8.2.2.4 iCARDEA patient enrollment process .........................................................107
8.2.3 iCARDEA Deployment: Wrap-up & actions: 10:00am-12:00am .........................108
8.2.3.1 Discussion on semi-automated entry of PHR data .......................................108
8.2.4 Discussion of EHR/PHR data interface based on xPHR .......................................109
8.2.5 Integration testing discussion ..............................................................................109
8.2.6 iCARDEA Questionnaire to patients : 12:00pm-15:00pm ..................................109
8.3 Action List ..............................................................................................................111
## 1 PUBLISHABLE EXECUTIVE SUMMARY

<table>
<thead>
<tr>
<th>Contract no</th>
<th>ICT-248240</th>
<th>Reporting period:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contractors</td>
<td>SRDC</td>
<td>OFFIS</td>
</tr>
<tr>
<td>Title</td>
<td>iCARDEA - “An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices”</td>
<td></td>
</tr>
</tbody>
</table>

**Objectives:** According to consensus statement prepared jointly by the Heart Rhythm Society and the European Heart Rhythm Association, more than 800,000 patients in Europe have Cardiovascular Implantable Electronic Devices (CIEDs) 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 device implantation 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 support. iCARDEA project addresses this challenge by:

- Exposing CIED data through standard interfaces
- Developing an intelligent platform to semi-automate follow-up of the CIED patients with context-aware, adaptable computer interpretable clinical guideline models
- Achieving EHR interoperability by exposing legacy EHR systems through standard HL7 CDA Release 2 interfaces so that information about patients’ medical history can be obtained from the patient EHR data and used in the clinical follow-up workflow
- Developing a Patient Empowerment platform providing feedback, education on patient’s health problems and communicating with the care givers

The major objectives of the iCARDEA project are as follows:

- Exposing Data from Remote Monitoring Cardiovascular Implantable Electronic Devices through standard protocols in standard formats: Currently all the major CIED vendors enable remote monitoring capability for their devices. However, patient data is stored in standalone data centers operated by the vendors and presented via secure Web-sites for access to the responsible healthcare professionals. Only in emergency cases, data centers send alerts as email, fax or SMS messages. In order to integrate CIED data into healthcare processes executed by care pathways following computer interpretable clinical guideline models, CIED data needs to be exposed through standard interfaces. The focus of iCARDEA is on using and when necessary contributing to international standards. The interfaces of CIEDs from two major manufacturers, namely, Medtronic and St. Jude Medical are exposed through standard interfaces in iCARDEA Project.
- Providing the Adaptive Care Planner: In iCARDEA, the remote follow-up of CIED patients is coordinated through the Adaptive Care Planner component. The care processes is defined as care pathways using “computer interpretable clinical guideline models”. Clinical guidelines using the information obtained from CIEDs, EHRs and PHRs of the patient interacts with modular
healthcare processes e.g. to invoke a service to assess critical situations for early diagnosis to prevent health complications.

- Providing information continuity by proving the interoperability of heterogeneous data sources, namely the cardiac devices, Electronic Health Records (EHRs) and Personal Health Records (PHRs) of the patients: iCARDEA exposes the CIED interfaces based on HL7, ISO/IEEE 11073 and IHE IDCO standards. Furthermore, the EHR data are generally available from legacy systems and iCARDEA makes legacy EHR data available through interfaces based on HL7 Clinical Document Architecture (CDA) Release 2. Both EHR data and PHR data of the patient are exposed through IHE Care Management profile. In addition to this, the IHE Exchange of Personal Health Record Content (XPHR) Content Profiles are being used in iCARDEA for PHR interoperability.

- Empowering the Patients with a Personal Health Record (PHR) component: iCARDEA project provides feedback and education to the patients through a Personal Health Record (PHR) component so that they can gain the benefits of having their healthcare records and CIED data in a format easily accessible to them. The PHR system also helps preserving privacy of the patient by indicating the type of data collected about herself and the purpose for which they are or will be processed.

- Validation of iCARDEA results: The iCARDEA results will be validated through pilot deployment activities in Austria in the clinical settings involving two groups of patients. One group of ICD patients with ordinary post-surgical control (twice per year) (group 1), one group of ICD patients with iCARDEA-enhanced remote monitoring (group 2), each group between 20-50 persons.

Scientific achievements:
In this reporting period the following scientific achievements performed:

- Within the scope of Task 4.1, the implementation of the first version of iCARDEA Care Plan Definition Tool is finalized in this reporting period. This tool enables the definition of machine processable care plan descriptions and also enables personalization of the care plans to bind the data sources of the variables used in clinical guideline steps to the remotely monitored CIED data, EHRs and PHRs of the patient.

- The implementation of Adaptive Care Plan Engine is continued. A thread mechanism is implemented to enable the execution of multiple care plans. Main GUI of Care Planner is implemented to register patients and care givers of the patients to the system, and to assign care plans to them. Finally the implementation of the alarm mechanism is finalized and tested, which allows patients, medical professionals and care givers to receive feedback about the execution of the care plan through email or SMS.

- Within the scope of Task 5.2 “Patient Education”, HCPB has identified and produced the relevant patient education mechanisms that will be accessible through the PHR portal once it gets operational. Both static and dynamic education materials have already been designed. In order to make them accessible over Web, these education materials are now being uploaded to a “Google Site”.

- In Task 5.1, SRFG has implemented the first prototype of the iCARDEA PHR system (PHRS). This system has user interfaces for patients to report observations of daily living, medications, lifestyle and edit their profile and contact information. These interfaces have been implemented as a JSR-286 based web portal. Health terminology services are integrated to the system to be used by User Interface (UI) controls/widgets.

- Within the scope of Task 5.3, Patient Feedback mechanisms are implemented. These include

---

feedback and communication mechanisms among patients using social software components such as forum and Wiki tools and collaborative portal features for enabling physician to patient communications.

- Within the scope of Task 5.4, SRDC implemented an initial prototype of iCARDEA Consent Management System. It serves a graphical interface to patients to declare their consent policies, and also provides a consent engine that acts as a Policy Decision Point to grant/deny access requests. In this period, we also worked on the requirements of how this consent management tool will be integrated with other components, to secure the privacy of patient related content.

- Within the scope of Task 6.1, in order to realize the effective data integration with various different reports produced by CIED manufactures, a CIED Data Integration Module is built which aims to realize CIED data abstraction, mapping, parsing, validation and exposure processing based on the ISO/IEEE 11073 standard and the IHE Implantable Device Cardiac Observation (IDCO) profile. This tool is being tested with AF and VT guidelines.

- Within the scope of Task 6.2, during this period FORTH worked on the implementation of the EHR-Interoperability Framework (EHR-IF), its integration with iCARDEA components in a general setting and in the context of the iCARDEA deployment in SALK.

- In Task 6.3, initial prototype of the interoperability services and components have been implemented supporting IHE PCC-9 query subscriptions and PCC-10 messaging, and supporting PHRS applications (clients) sharing data via interoperability services. Integration with Care Planner Engine is tested.

- Within the scope of Task 6.4, the Code Mapping API is finalized in conformance to HL7 Common Terminology Services Specifications. As the terminology server UMLS is used. On top of this, mappings of local SALK Lab codes in GLIMPS to LOINC are also added to the terminology server.

- Within the scope of Task 7.1, the first operational prototype of the patient parameter tool is implemented. This tool provides a single interface to access critical clinical parameters to be monitored and analyzed for the personalized evaluation of patients with CIEDs.

- Within the scope of Task 7.2, OFFIS collected the anonymized clinical data of 230 CIED patients. The data analysis processes were modelled and software components were developed to integrate and prepare the data. Online analytical Processes (OLAP) for validation of hypothesis, and also data mining processes for hypothesis creation were used. The resulting data analysis outcomes are presented to the medical professionals at SALK. Besides this, OFFIS made attempts to obtain a broader data base to validate the knowledge or find additional patterns. Communications with HCPB still continues to clarify how the data available in HCPB can be used in data analysis processes. In addition to this, OFFIS examines Physionet MIMIC II Database, as an additional data source for data analysis process.

- Within the scope of Task 8.1 we proceed in accordance to the workplan presented earlier and in the review. Unit and Functional testing of components is being carried out incrementally. In particular testing of the EHR-IF and its interaction to the SALK-HIS is taking place in SALK premises. This allows incremental configuration and fine-tuning of the components in accordance to the needs of induced by personalized adaptive care plans. In parallel to that the testing environment established in SRDC premises is being used for the testing involving multiple components as foreseen in the Task plan.

- Within the scope of Task 8.2, the requirements and the specifications of the iCARDEA Pilot application validation have been defined. For the early validation of the pilot, questionnaires for physicians and patients are prepared. For the final validation of the pilot deployment, test case definitions have been prepared based on the Goal-Question-Metric approach.

- In this reporting period, we have delivered the design of iCARDEA Pilot application. As a part of this design two demonstration scenarios (one for AF and one for VT) and storyboards describing the step-by-step execution of these scenario based on the underlying iCARDEA architecture were
specified. Additionally, an initial specification of the physical deployment architecture is prepared describing how the pilot application will be deployed in a clinical setting by the end-user, SALK located in Austria.

- The protocol for iCARDEA Pilot application and the Case Report Forms have been prepared. Continuous communication with Salzburg Ethical Committee continues to clarify how iCARDEA PHR application can be validated within the ethical and legal limits of European and Austrian regulations.
- Within the scope of Task 9.3, SALK’s IT department has been working closely with FORTH, SRDC and SRFG for enabling deployment of early prototypes. These deployed prototypes will be utilized for early validation of iCARDEA Pilot.
- We have prepared the first Intellectual Property Management Report, there possible licensing strategies have been explored and discussed for iCARDEA components. The decision about the licensing strategy will be discussed during Year 3 of the iCARDEA project and will take into consideration the exploitation plan.
- Two of our journal submissions have been published in this period. On top of this, we have presented five of our conference papers in the respective conferences, and submitted and get acceptance for three more conference papers. Finally iCARDEA Project is disseminated in annual report of OFFIS. These are presented in “Publishable Results” section.

**Socio-economic relevance and policy implications:**

iCARDEA aims to improve the care and follow-up of patients with CIEDs by integrating CIED data to the automated follow up processes through computer interpretable clinical guideline models and adaptable healthcare planners and hence aims to provide improved disease management at the point of need. With its clinical guideline based automated analysis and monitoring platform, iCARDEA aims to reduce the workload of clinical staff in healthcare settings (electrophysiology or other care settings responsible for follow-ups and monitoring) and hence provide economic benefits for health systems using CIEDs.

**Conclusions:**

iCARDEA project is ongoing according to the plans presented in our DoW. The following deliverables have been made available to the Commission in this reporting period:

- D4.1.2 Personalized Adaptive Care Plan Definition Tool (Month 14)
- D6.4.1 Code Mapping API (Month 14)
- D9.2.1 Design of the Implementation of the Pilot Application Scenario (M16)
- D1.1.3 Six Monthly Progress Report (b) (M18)
- D2.3.1 – Reports on Intellectual Property Management (a) (M18)
- D5.3.1 – Patient Feedback Mechanisms for the PHR (M18)
- D6.2.1 – Interoperability Infrastructure for Electronic Healthcare Records (M18)

The following Milestones have been successfully achieved:

- M4 iCARDEA EHR Interoperability and Evaluation Criteria for iCARDEA Pilot Application – Month 18

**Keywords:** Remote Monitoring of Cardiac Patients, Cardiac Implantable Devices, Semantic Interoperability, Patient Empowerment, Care pathways
## 1.1 Publishable Results

<table>
<thead>
<tr>
<th>Authors</th>
<th>Date</th>
<th>Title</th>
<th>Journal</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Authors</td>
<td>Event Date/Location</td>
<td>Title</td>
<td>Location/Conference</td>
<td>Website/Link</td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Navarro, Asuman Dogac, Marco Eichelberg, Andreas Hein</td>
<td>June 2011, accepted Full paper and presentation will be in Sept. 2011</td>
<td>iCARDEA: Practical Data Integration for the Follow-up of Cardiovascular Implantable Electronic Device Patients in Cardiological Departments</td>
<td>Oral Presentation and paper indexed by IEEE &amp; Ei Compendex at Computing in Cardiology 2011, Hangzhou, China</td>
<td><a href="http://www.cinc.org/2011/">http://www.cinc.org/2011/</a></td>
</tr>
<tr>
<td>Maohua Yang, Catherine E. Chronaki, Christian Lüpkes, Andreas Thiel, Manuela Plößnig, Lynne Hinterbuchner, Elena Arbelo, Asuman Dogac, Marco Eichelberg, Andreas Hein</td>
<td></td>
<td></td>
<td><a href="http://www.ehealth2011.at/program/">http://www.ehealth2011.at/program/</a></td>
<td></td>
</tr>
<tr>
<td>---------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>---------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Lynne Hinterbüchner</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2 PROJECT OBJECTIVES FOR THE PERIOD

2.1 Objectives of the reporting period

The objectives of this reporting period can be summarized as follows:

- Delivery of Personalized Adaptive Care Plan Definition Tool
- Delivery of Code Mapping API
- Finalization of the design of the implementation of the pilot application scenario
- Delivery of first version of the Intellectual Property Management Report
- Finalization of the Patient Feedback Mechanisms for the PHR
- Finalization of the Interoperability Infrastructure for Electronic Healthcare Records
- Delivery of Six Monthly Progress Report (b) covering Month 13-18

2.2 Recommendations from the 1st iCARDEA Review Meeting

After receiving the review report of 1st iCARDEA Review meeting, the consortium have discussed and agreed on the following action plan to address the reviewers’ comments in the next periods:

- Recommendation 1

```
Deliverable 1.1.5 (Activity and Management Report full.pdf) should be resubmitted to reflect the current status and the information provided in the answers to the reviewers during the first review meeting, regarding:

• Status of PHR ethical issues as regards to evaluation (wp9, page 341), showing that currently there is no problem obstructing the use of PHR data in the pilot.

• Status of the integration with HIS at SALK (Orbis), clarifying if currently there is any problem to integrate data from iCARDEA into the HIS, including, but not limited to, reimbursement data. If this integration is not possible, the report should include the envisaged impact of this issue in the results, and the potential corrective actions (i.e. doctors will manually type in main information coming from the pilot into the hospital HIS). Feedback of reimbursement data doesn’t imply ethical issues.

• Status of a possible pilot to be set up at Barcelona. This is not included in the work plan, but some tasks reported are related to it (i.e. “Workshop for the analysis of the requirements of the platform to be integrated in the Remote Monitoring Unit in HCPB.” reported by Medtronic). Please clarify the current work plan in the deliverable.
```

Deliverable 1.1.5 has been resubmitted to clarify these issues. Further information about our progress is presented here. As some of the actions have not been finalized yet, we will be reporting the results in the next progress report too.

- Based on our requirement analysis, and pilot deployment design activities, we decided that the information flow will be in one direction: from EHR System of SALK to iCARDEA Components. SALK specifically asked not to update the existing system, in order not to interfere with the ongoing care process in SALK. For this reason the EHR data will be retrieved by EHR Interoperability platform and will be made available to iCARDEA components, mainly the iCARDEA Care Planner. iCARDEA Systems will build standalone graphical interfaces to
provide feedback about remote monitoring of CIED patients to the physicians, for example, the execution of a care plan for Atrial Fibrillation for a specific patient will be presented in a step by step manner through the graphical interfaces of Care Planner Monitoring GUI. Through these interfaces the recommendations will be presented to the medical professionals. In the first iCARDEA Review meeting, our reviewers pointed out the fact that, information may be needed to be sent back to EHR System to facilitate reimbursement of remote monitoring. Although facilitating reimbursement is not directly in the scope of the project, we aim to provide at least the technical infrastructure to feed data back to EHR System to be ready for future exploitation activities. However discussions with SALK after the review meeting confirmed that it is not possible to feed data back to the HIS now, as this is still an observational study and they do not want to update the data available in the existing systems. Apart from that it has been clarified that in SALK reimbursement is paid for outpatient not as per visit basis. SALK receives for all outpatients a fixed budget (like a flat rate), disregarding from the number of patients (or any increase of performance) treated. The budget for outpatients is not allocated to a specific department. The leading Hospital Information System (HIS) is ORBIS from AGFA. SALK is using additionally sub-systems for specific clinical requirements as lab (LIS), cardiac information systems (CIS) and others. These sub-systems are sending the non-valued services to ORBIS and ORBIS handles these over to the accounting system SAP. In the SAP-Systems these services will come to account or will be only counted for statistical reports (outpatients). If iCARDEA would become a subsystem within SALK, this connection ORBIS-SAP would be build. In the pilot deployment, we will be looking at time used and or saved in using the care plan, tele-monitoring vs. normal outpatient care.

- It should be noted that based on our Description of Work, the only pilot site for iCARDEA Deployment activities will be SALK. On the other hand, HCPB being also a medical institute is involved in the pilot deployment activities through their medical expertise in the design of iCARDEA Pilot application, selection and formal representation of iCARDEA Care plans and risk management plans, and finally for preparing the educational material for CIED Patients regarding remote monitoring. However, as it will be described in the upcoming points (Recommendation 5), we are investigating possibility of using historical data of CIED patients in HCPB for WP7 Activities, and also try to elaborate on the requirements for such a system to be deployed in HCPB.

- Issues related with validation of PHR are described in detail in the following points (Recommendation 13).
Recommendation 2:

Requirement: D9.1.1 “Requirement Specifications and Scenario of the Pilot Application” only includes analysis of the current practice in SALK. A similar work for the other clinical partner (Hospital Clinic Barcelona) would improve the result and make it more suitable to a European-wide market. If a full analysis is not possible, a summary of the main differences with the practice at SALK can be useful as well.

......

HCPB should analyze the portability of iCARDEA system to environments other than SALK, as regards to the integration of iCARDEA with existing information systems.

... HCPB should detail, for the next period, the involvement of HCPB HIS / Linkcare SAP in the dissemination of the results eventually via a pilot design.
Possible improvements would be to enhance the requirement analysis with input from HCPB (i.e. adding the results of task “Workshop for the analysis of the requirements of the platform to be integrated in the Remote Monitoring Unit in HCPB.” reported by Medtronic).

......

The quality of the deliverable is good, but the analysis of the current workflows and data has been done only at SALK clinic. A similar work with the other clinical partner (HCPB) would support the European-wide usability of the results.

First of all, HCPB together with Medtronic elaborated the possibility of exploitation of iCARDEA results as follows:

Medtronic and HCPB, together with LinkCare Health Services SL, had a meeting in the HCPB premises in Barcelona with the objective to evaluate the integration of the iCARDEA system with the LinkCare platform. LinkCare Health Services SL is a recently created spin-off of Hospital Clinic of Barcelona that is currently developing a software platform for chronic disease management with different applications for processes and resources administration. This software is modular and will provide services to different units in the hospital. Some of these modules are already working in the center while other modules as the heart failure one are still under design. The objective of this meeting was to evaluate from the clinical and technical point of view the feasibility and willingness of LinkCare and the hospital to integrate some of the features that the iCardea System has developed.

LinkCare system is a data management, care and follow up platform that allows to remote monitoring of patients and multiple therapies. It is connected to the hospital’s SAP system. It also allows connecting several telemetry devices for monitoring and follow up.
Both the hospital and the representative of LinkCare responsible of the service platform, showed interest in the potential exploitation of some of the iCardea applications through the heart failure module of LinkCare. Still, these modules are currently being designed and the adoption of the iCardea system would be a long term project, as it should be included in the production plan of the platform in its future revisions. The interest was focused in the applications related to the therapies for AF/VF as well as the automatic and remote follow up based on clinical guidelines, which could become an accessory service for the heart failure management platform.
A possible structure for the global architecture would be:
Secondly, HCPB and Medtronic presented the administrative requirements of having a prototype implementation in HCPB premises as follows:

The deployment of the iCardea system in HCPB and its usage for the treatment and follow up of patients during a pilot incurs a series of costs and administrative/legal procedures that must be considered prior to studying the viability do it.

The use of a not CE marked device/software with patients in a clinical study implies that two organisms must approve the protocol and plans for the study:
- Medical Ethical Committee (MEC) of the Hospital
- Ministry of Health authorities in Spain

Exhaustive documentation in Spanish related to the technical details of the system (risk analysis, usability tests…) and the study itself (patient informed consent, protocol, materials to be given to the patients, investigators’ brochure, etc…) must be provided to both organisms for their analysis and subsequent approval or denial. Average time of response of these organisms is of 1 month from the Medical Ethical Committee and 60 days from the national authorities.

On top of this, there must be an entity or organization collaborating in the project (one partner) that should sponsor the study and be in charge of the insurance policy.

It is also possible to design the pilot in such a way that it can be purely observational, meaning that there would be no deviation from current clinical practice in the way patients are diagnosed and treated, but the system could be deployed in the center and used for its evaluation by the physicians only. As patients would have no interaction with any non CE Marked devices, there would be no need to present the protocol to the competent authorities and the process to get the
approval would be significantly easier. Still, the MEC approval would be needed and some documentation like the protocol, patient informed consent, investigators brochure, etc. should be prepared and submitted.

The inclusion of a second center besides SALK would require, therefore, the allocation of a specific budget to organize the pilot, prepare the documentation, deploy the system and recruit and follow the patients during the pilot. It would also take extra 4 or 5 months (minimum) of time to set up the study and obtain the corresponding approvals to be able to start the study. As such a study has not been included in the project plan and budget; it will not be possible to conduct such a second pilot study in HCPB within the scope of iCARDEA Project.

The consortium is right now working on the option to enrich the requirement analysis specification to identify what kind of additional technical requirements would be needed to be addressed to have another pilot in a different pilot setting then SALK, and the consortium aims to collaborate with HCPB for this extension. As HCPB reported that they do not have the additional resources in project budget to address this requirement, the coordinator is trying to find an optimal solution that would not require extensive contribution of HCPB, by organizing a bilateral meeting with HCPB.

- **Recommendation 3**

  The review of the state of the art (Deliverable 3.4.1 annex 1) should include a summary with major findings relevant to iCARDEA identified during this review. Being a public deliverable this gives value to potential readers as compared to a list of summaries of initiatives which are already available. A minor comment related to this document: EPSOS project should be considered as it is more relevant to iCARDEA than the Imia initiative on travellers which is mentioned as it has a European scope and uses IHE profiles.

Following suggestion of the reviewers’ iCARDEA will keep the State of the Art component of 3.4.1 open throughout the project providing regular updates as an online document available at the iCARDEA site. In this online document, developments relevant to PanEuropean initiatives relevant to iCARDEA will be provided, including epSOS, renewingHealth, eHealth Governance Initiative, recent publications, as well as developments related to interoperability and standards. FORTH will coordinate the relevant activity. Downloadable versions of the document in PDF will be produced every 6 months.

- **Recommendation 4:**

  Use case specification (Deliverable 3.4.1, annex 3) related to “Data analysis and correlation tool” should be defined in more detail, as current description is not clear enough at this project stage. For example, details on how the decision is divided between iCARDEA and the human doctor are to be provided.

  ......

  The use case specification as regards to data analysis and correlation tool should be enhanced, as very little detail is provided and it is not developed to the same level as the rest of use cases.
We have updated the Deliverable; it will be submitted along with D1.1.3.

**Recommendation 5:**

*The revised version of Del 1.1.5 should include the current scope of WP7 tasks, as well as figures related to the data mining process (number of new CIED patients each year at SALK, number of patients to be included in the database for mining, further details on how the decision is divided between iCARDEA and the human doctor,...) Furthermore, a rationale for the decision of dropping the use of PhysioNET in the project should be provided.*

*The scope of the work under WP7 (Context Awareness and Clinically Useful Information Derivation) has significantly changed from what was anticipated in the proposal. Task 7.2, which aims at developing and establishing a data analysis process is now oriented only to data mining of a database of 250 existing SALK patients. Other objectives such as literature mining or using established biomedical knowledge bases such as PhysioNET (pg 12, Description of work document) have been disregarded. The scope of this task should be enhanced via adding more patient data, to improve the clinician significance of patterns and information extracted, augmenting the number of clinical scenarios to demonstrate the technical validity of the system or going back to the initial approach.*

......

*The scope of Task 7.2 “Correlating Patient Specific data with established knowledge bases” has been significantly modified. OFFIS performed a survey of different available medical knowledge bases, but they report that none of these knowledge bases are suitable for the pattern extraction and correlation in iCARDEA, since the attributes are all different from those available in the iCARDEA pilot scenario. To produce potentially useful patterns, it is proposed to create a database of historical cases of ICD and CIED patients that were treated at the SALK hospital. A legal agreement was achieved between OFFIS and SALK that describes the scope of data analysis and allows the usage of patient data for research purposes of iCARDEA. ([iCARDEAD1.1.5ActivityandManagementReportFULL. pdf page 31]).

This workpackage has achieved all the objectives for the current reporting period. However, the scope of forecoming tasks has been changed. These plans have to be revised to deliver the best results possible according to the original workplan. (see section 1.C, recommendations concerning future work)*

Besides the data analysis on SALK, data attempts were made to obtain a broader data base to validate the knowledge or find additional patterns. Despite publications shows that studies with 192 or 624 patients can produce reliable and good results, OFFIS contacted the second clinical Partner HCPB to clarify, how many ICD and CIED patients they’ve got and what data is available. Also the privacy and security issues were short noticed. A first result was that HCPB has an amount of about 150 patients with remote monitoring. Further discussion will show if the total amount of patients with an ICD or CIED with or without remote monitoring will be higher and if the data is available in a computer interpretable format. Currently OFFIS and HCPB teams are also trying to resolve, whether and how such a data analysis study can be carried out in HCPB. HCPB team identified the requirements of such a study, these will be discussed between OFFIS and HCPB to see if it is possible to carry out data analysis task within HCPB.
Also a dataset of clinical data was found via Computing in Cardiology (CinC). The dataset of the 2009 CinC Challenge referred to the Physionet MIMIC II Database. A first research showed that the data is potentially useful, but is not specialized to ICD or CIED patients. Patterns induced on this data will have no special references to ICD or CIED. Since the ICD-9 coding was used for diagnosis, the temporal data analysis prototype can be “misused” to provide mappings of the found patterns to the ICD-10 Codes of the SALK environment to be potential useful at the iCARDEA pilot. The public database MIMIC II consists of 110 patients. There seems the possibility to obtain up to 20,000 patients but this has to be evaluated especially with respect to the required piracy and security issues. The usefulness of the provided data items will be discussed with the clinical partners.

OFFIS updated the action plan to implement Task 7.2 and 7.3 as follows to reflect these decisions (The actions related with using the available data in HCPB has the pre-requisite of an agreement between HCPB and OFFIS):

- **D7.2.1 Data Analysis and Correlation Tool – due Month 24** and **D7.3.1 Security and Privacy of Context Awareness and Clinically Useful Information Derivation – due Month 20**
  - OFFIS evaluates available data at HCPB for potentially usefulness at pattern extraction process and with respect to the usefulness at the pilot scenario. Month 20 (30. September 2011)
    - OFFIS and HCPB clarify if the data is available in a computer interpretable format and should be used for data analysis (30. September 2011)
  - Old cases data from HCPB HIS are extracted and integrated into the analysis database according to Security and Privacy laws (15. February 2012)
    - HCPB provides extracted old cases data from HCPB HIS according to Security and Privacy laws (15. December 2011)
      - Prerequisite: There was an agreement to use HCPB data and D7.3.1 (OFFIS and HCPB) were able to clarify the needed legal regulations (30. November 2011)
    - OFFIS integrates the data into the analysis database according to Security and Privacy laws (15. February 2012)
  - OFFIS provides patterns based on HCPB data (28. February 2012)
  - OFFIS provides first prototype with research results by Month 19 (31. August 2011) based on SALK data
    - HCPB / SALK will provide input on the obtained results.
  - OFFIS provides the second prototype together with the implanted security and privacy concepts and results from D7.3.1 by Month 21 (31. October 2011)
    - HCPB / SALK will provide last comments on the used data, algorithms and patterns.
  - The final prototype is ready and integrated into the iCARDEA framework at SALK by Month 24 (31. January 2012)
  - Despite the fact that the database in consequence of its origin and kind of patients with high feasibility will not produce analysis results that are usable at the iCARDEA environment OFFIS revaluates the Physionet Datasources with the goal to obtain more patient data from a clinical dataset.
Clinical Database from Physionet were obtained and integrated into the analysis database according to Security and Privacy (30 September 2011)

- Prerequisite: D7.3.1 OFFIS were able to clarify the needed legal regulations with Physionet (31.08.2011)

- D7.3.1 OFFIS and HCPB clarify the needed legal regulations to use the old cases data from HCPB

- D7.3.1 OFFIS and HCPB make a first check of potential regulations (31. August 2011)
- D7.3.1 OFFIS and HCPB clarify the needed legal regulations (30. November 2011)
  - Prerequisite: D7.2.1 OFFIS and HCPB clarify if the data is available in a computer interpretable format and should be used for data analysis (30. September 2011)

- D7.3.1 OFFIS clarify the needed legal regulations to use the clinical databases from Physionet (31. August 2011)
  - Prerequisite: OFFIS found a clinical dataset for data analysis at Physionet (31.07.2011)

- **Recommendation 6:**

  The consortium should work on clarifying how and when feedback from iCARDEA system will be provided to the patient (making impact on behaviour by e.g. sending information in SMS messages). This is expected to be included in the next pilot demonstration, as the technology is available in iCARDEA.

  Similarly, it is not clear whether programmed reporting date/time can be overwritten by patient based on his/her feelings of disturbances (e.g. pushbutton based report).

  ..... 

  A further analysis on the feedback to be provided to patient should be done, taking into account that the technology is already available in iCARDEA (e.g. for feedback to Doctors). Other issue that deserves further attention is the possibility of the patient to override the programmed reporting date/time based on his/her symptoms.

In the VT Storyboard we added steps where patients will also be informed through SMSs. We will demonstrate this. However it is not clear whether such SMS messages will be in line with the study protocol, this will be clarified in the next reporting period. If it will not be possible due to ethical reasons, iCARDEA will have the capability but it will not be utilized in the pilot.

iCARDEA already supports patient to initiate CIED alerts.

Feedback to patients will also be provided through the PHR Portal, through patient forums where patients interact, providing one another support and feedback as response to their questions. Also, the patient’s PHR information will be shared via the PHR system interoperability services with iCARDEA components, such as the iCARDEA Patient Parameter Monitor and iCARDEA Care Planner. With these applications, the medical professionals can monitor and provide feedback to patients.
• **Recommendation 7:**

WP2 (Exploitation) should analyse the different aspects of changing of the current clinical workflow, tasks and responsibilities, for example the potential resistance of the electrophysiologist or the reimbursement aspects.

....

Exploitation plans are adequate for this stage of the project. For the next reporting period, the major CIED vendors involved in the project should play a leading role, a joint exploitation plan has to be produced and the different aspects of changing of the current clinical workflow and the technical variables of the competitors (standards etc.) should be analysed in more depth.

....

Plans for exploitation are defined at an adequate level for this project phase; although no joint exploitation plan is presented (it will be added in subsequent versions of exploitation plan). A leading role of the major vendors involved (Medtronic & SJM) in this joint exploitation plan is expected.

Some products such as the care planner are less well covered in the individual exploitation plans.

SRDC will plan the next revision of the Deliverable (to be delivered by Month 24) to cover these issues with the help of SALK, HCPB, SJM and Medtronic.

• **Recommendation 8:**

WP 6 (Interoperability) should foresee integration with other electronic health care record outside the clinic that is following up the CIED patient, mainly primary care records and records from other clinics (i.e. specialist doctors following a co morbidity of the patient). Furthermore this WP should work on the requirements for installing iCARDEA in other sites besides SALK. To achieve this goal, the following information is expected at the end of the project).

- A list of the parameters needed by the care planning tool, to check compatibility with other than SALK HIS/PHR systems.

- Summary of the major requirements to port iCARDEA from SALK HIS / PHR / workflow to other environments.

- Summary of the major requirements to use CIED platforms other than Medtronic CareLink® and STJude Merlin_net (for example Biotronic)

We are already using standard interfaces such as IHE CM, and IHE IDCO. This will facilitate communicating with external EHR Systems and other ICD vendors. We will identify the list of parameters needed by the care planning tool. The EHR Interoperability framework developed by FORTH can support integration with GP systems, if the latter support the IHE CM integration profile. Relevant security concerns can be addressed by the patient providing authorization for integration with GP systems as well as secure transfer of information. At SALK the relevant
information is already provided to GPs using EDF messages. Currently, integration testing with GP systems is not in scope for iCARDEA but the mechanisms will be available. OFFIS will provide a description of the current state and needs for the data extraction and information transformation from vendors (Minimal needs of the portals / data source / pdfs etc.) Furthermore a description of the current state of the IHE IDCO delivery from the vendors will be provided.

- **Recommendation 9:**

  *To demonstrate the flexibility of the care planning tool other guidelines should be implemented in the next reporting period (for example the guideline for selection of patients for CIED).*

  Action: In the next reporting period implementation of VT Care Plan will be demonstrated. The consortium has already initiated this process by starting the definition of the VT Storyboard.

- **Recommendation 10:**

  *Clinical scenario (WP 9, task 9.2) could be improved with the inclusion of a non compliant patient (frequent situation in real life), as well as with a patient having some comorbidity.*

  Both AF and VT Care Plans include risk assessments where the conditions comorbid diseases are checked especially when recommending a new drug therapy. We will exemplify such situations in our scenarios. Co-morbidity could be addressed by risk factors recorded in the PHR system (diabetes, hypertension, increased cholesterol) or through medical history of the EHR.

  However it is difficult to address the requirement of noncompliant patients.

- **Recommendation 11:**

  * Furthermore, the need of the cardiologists (or nurses) to access to some other data base (like the EHR of a specialist or of the general practitioner that care for the patient) could be reflected in the scenario.*

  Action: This does not seem to be possible in real deployment. However we will investigate whether we can add a step to VT scenario, and have a proof of concept implementation, where data from an external clinic can also be fed to iCARDEA Care Management DB. Yet, based on our initial analysis, this crosses into the policies of SALK in implementing iCARDEA. Even if in principle it is technically possible, it is not consistent with the current care processes that involve telemonitoring in SALK.
Recommendation 12:

The consortium has strong players in health information standards and the work done by the project should influence the standardization work. The project could contact SDOs like IHE and IEEE 11073 and provide requests for updates of the standards according to the project results. Example of results that could be of interest are the mapping of terminology, which can be of interest to the IEEE 11073 Rosetta terminology project, and the results of implementation of the IDCO profile, which are of interest to IHE. Another related task already identified by the consortium is the testing of project results at the IHE connectathon.

Cooperation with HL7 is well established. Other SDOs that might benefit from project results are IHE and IEEE 11073. Project results could be of interest to this organizations and formal interaction is encouraged. Specifically, mapping of terminology can be of interest to the IEEE 11073 Rosetta terminology project, and the results of implementation of the IDCO profile are of interest to IHE. A potential interaction identified by the consortium is the testing of project results at the IHE connectathon.

FORTH is closely following the developments in IEEE 11073 through its participation in the HL7/ISO/CEN TC251 group on Healthcare Devices, the home of the IEEE 11073 Rosetta project. There has been already a presentation of iCARDEA in this group, and additional presentations are planned in the future, as the work to presented in IEEE EMBC in Boston (M. Yang et al: Guideline-Driven Telemonitoring and Follow-up of Cardiovascular Implantable Electronic Devices using ISO/IEEE 11073, HL7 & IHE Profiles). In addition to this, during the implementation of CIED Interoperability System, unclear sections about the HL7 and IEEE 11073 Nomenclature interoperability in IHE IDCO standard were detected and found. To clarify this point feedback is sent to the IHE PCD Technical Committee. The Consortium will further investigate opportunities to provide feedback about implementation of the selected profiles to the Standardization organizations.

Recommendation 13:

The results of this WP5 are good and the prototypes allow for an optimistic assessment of the project progress. As already mentioned measures have to be put in place to ensure these prototypes (e.g. PHR) can be tested with real patients with feedback given to the patients by iCARDEA not only on active patient requests but also on warning signals sensed by ICD. The two major market players (Google Health and Microsoft HealthVault) should be taken into account especially Microsoft as it’s approach is usable in iCARDEA (for it allows connection of medical devices and hospital data).

Initially iCARDEA Pilot study is presented to the Ethics committee as an observational study. However it has been clarified that, involvement of PHR tool would require active involvement of patient to carry out activities that is not included in the normal treatment strategy, and this would require the study to be a Medical Device Study according to European Union Regulations. A Medical Device Study has much stricter requirements, such as inclusion of an Insurance Policy.
for possible adverse events (for example consider a patient reports a life threatening issue through PHR, and the medical professionals do not check the PHR immediately which may cause medical and ethical problems, which would need to be covered through an Insurance Policy supported by the study sponsor). As iCARDEA Pilot was not planned as a Medical Device Study but as an observational study in the proposal phase, we do not have the resources, to address these issues within a Medical Device Study. To remedy this, SRFG with the guidance from SALK, is planning alternative deployment schemes, for possible validation of PHR within the legal and ethical limits provided. Based on these studies, the current plan is as follows: The PHR system will be installed at the patients home if they have computer access by using USB sticks as “ready to go” application. The patient will transfer recorded data (such as medication compliance, blood pressure, weight, possible problems) to SALK on a daily basis via email. The PHR system at the patient’s home only contains those data recorded by the patient but no additional EHR data from SALK. The Pilot Application installed at the SALK additionally includes a PHR system where complementary tests such as the import of EHR data can be evaluated. Currently, this proposal will be verified by the Ethics Committee. A new consent form has been sent for approval to Ethics Committee who will decide whether this alternative deployment plan still can be considered as an observational study and not a medical device study.

**Recommendation 14:**

| D1.2.1 – Quality Assurance (QA) Plan: Good quality assurance plan. The risk assessment should be updated to include issues identified in this review. |

Action: SRDC will provide an update for D1.2.1.

**Recommendation 15:**

| D2.1.1 Exploitation and Dissemination Plan (a): The dissemination strategy is very good, but it should target as well patient organizations and a wider audience of healthcare professionals involved in care for CIED patients (i.e. conferences such as ESC, AHA, etc), as most of the scientific dissemination up to now is to technical audience. |

Dissemination of results to patient organizations is also not covered and of potential interest.

---

The first year of the project was highly focused on the technical aspect of the iCARDEA platform with little results to be used for dissemination in a more clinical field. We have presented early results of the project in 11th Annual Spring Meeting on Cardiovascular Nursing and in Austrian Cardiology Conference and in Europace Meeting (of the European Heart Rhythm Society) 2011. However, now that we are entering a more practical phase, it is expected that more clinically relevant results can be produced and presented in medical conferences.
Recommendation 16:

D9.1.1 – Requirement Specifications and Scenario of the Pilot Application:

According to PilotApplicationScenarioStoryboard,v1.0.doc page 8, the patient has to enter several data regularly in the iCARDEA PHR. The project should assess how this can affect patient compliance and how to deal with not committed patients.

SRFG is aware that patients have different needs, preferences and “eSkills”, in particular related with using new technologies such as web applications. The idea behind Patient Empowerment is offering different approaches such as access to relevant information for improving their decision making competence, supporting the change of behaviour by an Action Plan or offering services for recording observations of daily living in order to foster self-control. Based on the patient’s individual requirements and preferences the patient can choose his preferred services and this will improve patient compliance in principle.

Regarding collecting regularly data for observations of daily living iCARDEA will survey patients’ opinion and feedback at two stages:

- Feedback to an early iCARDEA prototype in August 2011 – this also will include questions about existing behaviour with regard to observations of daily living, Internet usage and barriers for using PHR services. This patient feedback will be an additional input for the PHR implementation phase.
- Feedback to the final iCARDEA prototype – this will include questions with regard to patient well-being, satisfaction, usability and acceptance of PHR services.

2.3 Problems encountered in the reporting period

The major issue we have encountered in this reporting period is the validation of PHR platform within iCARDEA Pilot application. As has been described, the iCARDEA Study Protocol has been designed as an observational study, yet the inclusion of PHR application to the pilot would require active participation of patients which involved tasks that is not included in the current treatment practices. This would require the pilot study to be a Medical Device Study according to EU regulations, which has stricter requirements such as inclusion of an insurance policy. Since this will not be possible during the lifetime of the project, SRFG and SALK teams are working on alternative deployment schemes that may facilitate validation of PHR within the ethical and legal limits enforced. As described in the previous section (Recommendation 13), this alternative deployment plan will also be presented to the Ethical committee to be approved.

Furthermore, the full deployment of the EHR-IF has proved more challenging and time-consuming than originally anticipated. Although iCARDEA is based on widely-accepted health information technology standards and well-established terminologies, achieving semantic interoperability requires detailed testing and mapping of terms among de-jure and de-facto terms. Moreover, the administrative procedures involved in some of the required steps have taken more than anticipated. To achieve the iCARDEA workplan, the decision was reached to following an incremental approach that involves intense on site and of-site testing. At the end of this reporting period the initial version of the EHR-IF has been installed and tested for the first set of HL7 messages and EDF reports. Additional tests and further configuration is foreseen during the following months, and we expect that additional resources from FORTH will be invested.
3 WORKPACKAGE PROGRESS AND ACHIEVEMENTS DURING THE PERIOD

The scientific and technical progress made in different work packages are presented in the following subsections.

3.1 WP 2 –Dissemination, Exploitation and Innovation Related Activities

Regarding dissemination we here forth present the articles published, and the contributions in technical and medical conferences through the lifetime of the project.

- **Project website**: http://www.icardea.eu/ (http://www.srdc.com.tr/icardea alternatively). 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).

- **Project brochures**: The following table summarizes brochures and newsletters produced within the iCARDEA consortium.

<table>
<thead>
<tr>
<th>DESCRIPTION</th>
<th>TITLE</th>
<th>FIRST AUTHOR</th>
<th>REFERENCE ADDITIONAL INFO</th>
</tr>
</thead>
<tbody>
<tr>
<td>iCARDEA Press Release</td>
<td>iCARDEA: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices</td>
<td>iCARDEA Consortium</td>
<td>Press release</td>
</tr>
<tr>
<td>FP7 Booklet</td>
<td>iCARDEA: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices</td>
<td>iCARDEA Consortium</td>
<td>FP7 Booklet</td>
</tr>
<tr>
<td>iCARDEA Press Release</td>
<td>EU-Projekt iCARDEA gestartet</td>
<td>Marco Eichelberg</td>
<td>OFFIS Newsletter Available online at <a href="http://www.offis.de/aktuelles_presse/detai">http://www.offis.de/aktuelles_presse/detai</a>...</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Available online at <a href="http://www.offis.de/aktuelles_presse/detai">http://www.offis.de/aktuelles_presse/detai</a>...</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.offis.de/aktuelles_presse/detai">http://www.offis.de/aktuelles_presse/detai</a>...</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.offis.de/aktuelles_presse/detai">http://www.offis.de/aktuelles_presse/detai</a>...</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.offis.de/aktuelles_presse/detai">http://www.offis.de/aktuelles_presse/detai</a>...</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><a href="http://www.offis.de/aktuelles_presse/detai">http://www.offis.de/aktuelles_presse/detai</a>...</td>
</tr>
</tbody>
</table>

- **Articles published**: The following table summarizes the articles and/or accepted for publication in relation to the iCARDEA project till now.

Page 27 of 112
<table>
<thead>
<tr>
<th>TITLE</th>
<th>FIRST AUTHOR</th>
<th>REFERENCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>iCARDEA – an Approach to Reducing Human Workload in Cardiovascular Implantable Electronic Device Follow-Ups</td>
<td>Maohua Yang</td>
<td>Computing in Cardiology 2010, Volume 37, Page 221-224, Alan Murray, ISSN 0276-6574</td>
</tr>
<tr>
<td>Interoperability Challenges in the Health Management of Patients with Implantable Defibrillators</td>
<td>Catherine Chronaki</td>
<td>Computing in Cardiology 2010, Volume 37, Page 225-228, Alan Murray, ISSN 0276-6574</td>
</tr>
<tr>
<td>Interoperability of Medical Device Information and the Clinical Applications: An HL7 RMIM based on IEEE 11073 DIM</td>
<td>Mustafa Yuksel</td>
<td>IEEE Transactions on Information Technology in BioMedicine</td>
</tr>
<tr>
<td>iCARDEA: EU-Projekt zur optimierten Nachsorge von Herzpatienten</td>
<td>Hans-Jürgen Appelrath</td>
<td>Datawork 2010;48:19</td>
</tr>
<tr>
<td>Patient empowerment for Patients with implantable Defibrillators</td>
<td>Manuela Plößnig</td>
<td>eHealth2011 poster</td>
</tr>
<tr>
<td></td>
<td></td>
<td>eHealth 2011 conference</td>
</tr>
<tr>
<td>Patient Empowerment Framework for Cardiac Patients</td>
<td>Robert Mulrenin</td>
<td>Poster for MIE 2011</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Submitted and accepted for publication; to be published August 2011</td>
</tr>
</tbody>
</table>
Guideline-Driven Telemointoring and Follow-up of Cardiovascular Implantable Electronic Devices using ISO/IEEE 11073, HL7 & IHE Profiles
Maohua Yang
(In print) EMBC 2011

iCARDEA: Practical Data Integration for the Follow-up of Cardiovascular Implantable Electronic Device Patients in Cardiological Departments
Maohua Yang
(In print) Computing in Cardiology 2011

- **Scientific presentations at congresses:** The following table includes every presentation made at a scientific congress in relation to iCARDEA’s results.

<table>
<thead>
<tr>
<th>TITLE</th>
<th>FIRST AUTHOR</th>
<th>CONGRESS</th>
<th>TYPE</th>
<th>SITE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>iCARDEA – an Approach to Reducing Human Workload in Cardiovascular Implantable Electronic Device Follow-Ups</td>
<td>Maohua Yang</td>
<td>Computing in Cardiology 2010</td>
<td>oral presentation</td>
<td>Belfast, Northern Ireland, United Kingdom</td>
<td>26 – 29 September 2010</td>
</tr>
<tr>
<td>Interoperability Challenges in the Health Management of Patients with Implantable Defibrillators</td>
<td>Catherine Chronaki</td>
<td>Computing in Cardiology 2010</td>
<td>oral presentation</td>
<td>Belfast, Northern Ireland, United Kingdom</td>
<td>26 – 29 September 2010</td>
</tr>
<tr>
<td>An Intelligent Platform for Personalized Remote Monitoring of the CIED Patients</td>
<td>Catherine Chronaki</td>
<td>13th World Congress on Medical and Health Informatics (MedInfo2010)</td>
<td>oral presentation</td>
<td>Cape Town, South Africa</td>
<td>12 - 15 September 2010</td>
</tr>
<tr>
<td>iCARDEA – An intelligent platform for personalised remote monitoring of the cardiac patients with electronic implant devices</td>
<td>Lynne Hinterbüchner</td>
<td>11th Annual Spring Meeting on Cardiovascular Nursing</td>
<td>poster</td>
<td>Brussels, Belgium</td>
<td>1 - 2 April 2011</td>
</tr>
</tbody>
</table>
Additionally, the dissemination strategy will target patient organizations as well and a wider audience of healthcare professionals involved in care for CIED patients (i.e. conferences such as ESC, AHA, etc). However, the development of iCARDEA is still mostly in its technical part. The early results have already been presented at the European Heart Rhythm Association Meeting (of the European Society of Cardiology). We are awaiting the deployment of the iCARDEA platform and its implementation in order to have more clinically relevant results to present to the medical and patient communities.

As an Annex of this report, a copy of the dissemination material produced during this period (February-July 2011) is presented.
Task 2.3 focuses on approaches how iCARDEA can cope with innovation produced during the project. The results of this reporting period are summarized in D231 Reports on Intellectual Property Management (a) and comprise the following issues:

- A patent search – aiming to offer valuable clues how innovative iCARDEA assets can be exploited
- Description of background and foreground knowledge for innovative iCARDEA assets – aiming to describe how the project intents to deal with intellectual properties of iCARDEA components. This is defined by each partner and will be updated as needed in the course of the project.

For the time being and based on the discussion about licensing strategies for iCARDEA there seemed to be a preferences of some iCARDEA partners towards open source and a permissive licensing strategy. However, there is no common agreed licensing strategy at the current stage of the iCARDEA project (month 18). The decision about the licensing strategy will be discussed during Year 3 of the iCARDEA project and will take into consideration the exploitation plan.

D2.3.1 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.

3.2 WP 3 -S&T Management and iCARDEA System Architecture

Within the scope of Task 3.1, SRDC coordinated the technical management of iCARDEA Project. Two separate action plans have been prepared covering Month 12-18 (presented as an annex of D1.1.5) and Month 18-24 (presented in Section 5.5).

3.3 WP 4 -Personalized Adaptive Care Planner for CIED Recipients

Within the scope of Task 4.1, the implementation of the first version of iCARDEA Care Plan Definition Tool is finalized in this reporting period. This tool enables the definition of machine processable care plans as clinical guideline definitions. It makes it possible to define and personalize the care plans, and to bind the data sources of the variables used in clinical guideline steps to the remote monitoring CIED data, EHRs and PHRs of the patient. In iCARDEA, we have chosen GLIF as an executable representation of Care Plans. In GLIF, care plans defined as guidelines are represented as an ontology that describes the flow of actions, the clinical concepts and their information resources in detail. It is possible to use an ontology editor like Protégé Tool\(^2\) to create a new clinical guideline instance as an ontology. However this process is cumbersome even for computer specialists; it would be very difficult for the medical professionals to design the care plans through such an Ontology Editor. To ease this process we developed the Care Plan Definition Tool as a graphical environment, through which the care plans can be designed intuitively through drag and drop mechanisms. Medical Domain experts are enabled to graphically design care plan definitions through adding and configuring the selected care plan steps (Eligibility Criteria Step, Start Step, Consult Step, Decision Step, Recommendation Step and Final Step). Care Plan Definition Tool represents these flow of actions through an internal XML model that matches the flowchart representation of Care plans. Then when the care plan definition is finalized, it is possible to export the definition as a GLIF guideline definition ready to be executed by the Care Plan Engine. The details of Care Plan Definition Tool are presented in “D4.1.2 Personalized Adaptive Care Plan Definition Tool” which is delivered by the end of Month 16. In addition to this, an installation and user guide of the

\(^2\) Protégé Ontology Editor and Knowledge Acquisition System, http://protege.stanford.edu/
tool is prepared, and this will be used within the scope of Task 9.3, for the phase 1 validation of iCARDEA architecture by the end users.

Within the scope of Task 4.3, SRDC team continued with the implementation of Care Plan Engine. The initial prototype that is capable of running a care plan definition represented as GLIF definition by processing the data retrieved from CIED, EHR and PHR is extended in this reporting period from the following aspects: First of all, a thread mechanism is implemented to enable the engine to execute multiple care plans of several patients simultaneously. In addition to this, the main GUI of the Care Planner is implemented, where patients and care givers of the patients can be registered to the platform, by selecting their preferences to receive alarms, recommendations to be presented by the care plan engine. Care Plan Engine is extended to send the alarm/recommendation messages to patients/care givers or medical professionals through email and SMS messages based on the Care Plan definition. Finally, the implementation of a Monitoring graphical interface is initiated to be implemented.

Within the scope of Task 4.4, in parallel with Task 6.5, SRDC elaborated the security and privacy requirements of Care Plan Engine and Definition Tool. It is decided that Care Plan Editor, Care Plan Execution & Monitoring Interfaces to be served over a single portal called iCARDEA Physician Portal. A single sign on mechanism will be provided for Physician: once logged in, they will be able to use all these systems. A secure login mechanism will be implemented for this Portal in cooperation with the Identity Provider of SALK system. This will guarantee that access to this portal will only be allowed to authorized SALK users. Role information of the SALK users will also be collected from the Identity Provider. It is also decided that the communication between Care Plan Engine, CIED Information System, EHR Interoperability Framework and PHRs Portal will be secured through the implementation of IHE ATNA Profile. Certificates will be shared among these components, the messages exchanged between them will be secured through these certificates, and each exchange is audited to an Audit repository. Finally, the Consent Manager component will be integrated with the Care Plan Database, to expose only the allowed part of patients’ EHR and PHR data to the requesting parties such as Patient Parameter Monitor Tool based on patient’s consent.

3.4 WP 5 -Framework for Patient Empowerment

Within the scope of Task 5.2 “Patient Education”, HCPB has identified and produced the relevant patient education mechanisms that will be implemented in the PHR once fully developed. Both static and dynamic educative materials have already been designed and are currently being included in a Google Site. Accessing the already existing material is also facilitated through external webpage links and uploaded documents (those available for public use). Through the web, patient will be able to view this material.

These resources will likely decrease the work load on the healthcare professionals since they will not have to spend enormous amount of time informing the patients about the new devices and systems. In addition, it will assist the patient to control their health status by informed decisions.
<table>
<thead>
<tr>
<th>What is a pacemaker?</th>
<th>YES (Medtronic, AHA/ASA, SEC)</th>
<th>YES (Medtronic, US National Heart Lung and Blood Institute, Medicine Plus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>What is an ICD?</td>
<td>YES (Medtronic, AHA/ASA, SEC)</td>
<td>YES (Medtronic)</td>
</tr>
<tr>
<td>What is an ICM (Implantable Cardiac Monitor)?</td>
<td>YES (Medtronic, AHA/ASA, SEC)</td>
<td>YES (Medtronic)</td>
</tr>
<tr>
<td>What is the function of the heart?</td>
<td>YES (Medtronic, AHA/ASA)</td>
<td>YES (Medtronic)</td>
</tr>
<tr>
<td>What is cardiac resynchronization?</td>
<td>YES (Medtronic, SEC)</td>
<td>YES (Medtronic)</td>
</tr>
<tr>
<td>What kind of follow-ups are made and why?</td>
<td>YES (Medtronic, AHA/ASA, SEC)</td>
<td>YES (Medtronic)</td>
</tr>
<tr>
<td>What is remote monitoring?</td>
<td>YES (Medtronic, AHA/ASA, SEC)</td>
<td>YES (Medtronic)</td>
</tr>
<tr>
<td>How does it work?</td>
<td>YES (Medtronic)</td>
<td>YES (Medtronic)</td>
</tr>
<tr>
<td>What is heart failure?</td>
<td>YES (Medtronic, SEC)</td>
<td>YES (Illumistream, Medline Plus, ASKvisualscience)</td>
</tr>
<tr>
<td>What is atrial fibrillation?</td>
<td>YES (Medtronic)</td>
<td>YES (Medtronic, Medline Plus)</td>
</tr>
<tr>
<td>New habits after device implantation</td>
<td>YES (Medtronic, AHA, Circulation, SEC)</td>
<td>YES (Medtronic, AHA)</td>
</tr>
<tr>
<td>Precautions</td>
<td>YES (Medtronic, AHA/ASA, SEC)</td>
<td>YES (Medtronic, AHA)</td>
</tr>
<tr>
<td>Warning signs and symptoms – how to act</td>
<td>YES (Medtronic, Circulation, SEC)</td>
<td>YES (Medtronic, Circulation, SEC)</td>
</tr>
<tr>
<td>Patient forums</td>
<td>YES (Forums)</td>
<td>YES (Links)</td>
</tr>
<tr>
<td>Patient feedback</td>
<td>YES (Links)</td>
<td>YES (Links)</td>
</tr>
</tbody>
</table>

AHA: American Heart Association; SEC: Spanish Society of Cardiology (Sociedad Española de Cardiología)

Table 1 Available Passive education

The following materials for patient education have been developed:

- **Passive information**: The following table summarizes the currently available documents on general information (what is a pacemaker?, what is an ICD?, what is cardiac resynchronization?, what kind of follow-ups are made and why?, what constitutes remote monitoring or home monitoring? How does it work?, what is heart failure?, what is atrial fibrillation?, etc.), new habits after implantation (wound care, movement and physical activity, food and nutrition, physical activity, travelling, driving, etc.), precautions (magnetic fields, electromagnetic fields, alarm detection systems, mobile phones, laser, radiotherapy, etc.), warning signs and symptoms – how to act (what to expect and how to act in case of shock, how to proceed in case of activation of an audible alert, action in case of decompensation, etc.), patient forums and patient feedback (contact addresses and phone numbers, links to other educational material, query section).

- **Dynamic information**: HCPB has developed a Decision Aid on Telemonitoring in order to help patients with a Cardiovascular Implantable Electronic Device (CIED) to decide whether or not...
being included in a telemonitoring system. Further Decision Aids will be developed, including *anticoagulation* and *catheter ablation of arrhythmias*.

Within the scope of Task 5.1, SRFG has implemented the first prototype of the iCARDEA PHR system (PHRS) that includes a PHR user web application and a separate core PHRS applications server that have the following features:

- User interface components relating to observations of daily living, medications, lifestyle, patient profile and patient contact information.
- Client communication with the interoperability services of the core PHRS application server. The client side view models provide data to the interoperability services on the core PHRS application server.
- Core PHRS application server supports services for healthcare applications, such as the PHRS user web application. The core server provides services, such as:
  - Health terminology services that support User Interface (UI) controls/widgets
  - PHR Interoperability services integrated from Task 6.3
- Terminology services to support UI controls/widgets
- A JSR-286\(^3\) based web portal provides social and collaborative software components

The first prototype also conforming to the patient scenario (Atrial Fibrillation) is created for the first review. For specifying the PHRS user interface for the Atrial Fibrillation storyboard, a mock-up tool was used to define PHRS mock-ups. Based on these mock-ups the user interface for the PHRS was implemented. The mock-ups were iterated with our partner medical professionals and presented to partners.

The continued work moves forward towards a second prototype that will include refactoring of web components to support AJAX functionalities. The refactoring of the persistence components will support semantic technologies, thereby providing greater flexibility for PHRS models and interoperability.

Within the scope of Task 5.3, Patient Feedback mechanisms are implemented. Patient feedback mechanisms include features that should either be integrated into the PHR system or made available via PHR interoperability services. We have identified and implemented, or integrated social software components that:

- Support feedback and communication among patients using social software components such as forum and Wiki tools.
- Support external applications to support communications between patients and medical professionals.
- Collaborative portal features for enabling physician to patient communications. Portal features include messaging (chat, mail) and forums.
- Extend patient profile information to include contact information of their healthcare providers.

There are normally existing and established communication services and protocols to ensure patient safety and conform to established policies e.g. hospital, legal policies. The PHR system does not attempt to compete or replace those services, but offers alternatives that might be utilized during the patient-physician relationship. Deliverable, D5.3.1 Patient Feedback mechanisms is one outcome of this task delivered in this reporting period.

Within the scope of Task 5.4, SRDC implemented an initial prototype of iCARDEA Consent Management System. iCARDEA Consent Management System aims to provide a patient centric access control mechanism for patient related data. It is composed of two main components: Consent Editor and the Consent Engine. In this reporting period, first of all, the implementation of the services to be exposed by Consent Engine, which evaluate the requests to access parts of patients’ EHRs and PHRs and returns a response according to defined policies are completed. For this, Web Services have been implemented which accept SAML (Security Assertion Markup Language) request and return SAML responses. Also, the role mechanism supported in Consent Engine has been updated, and support for hierarchical roles is added to the system. Finally, in this reporting period, we realized that Consent Management system will also be used by Patient Parameter Portal, as this tool will be the main interface to be provided to the Medical Professionals to view Patients’ PHR and EHR data. As a response to this requirement, we re-designed the expected flow of actions among the iCARDEA Components: Consent Manager which acts as a Policy decision point will now be integrated to the Care Plan Database, where the patient data feeds are stored. SRDC has initiated the design of a new interface to Care Plan Database to be served to external components such as Patient Parameter Monitoring Tool, this interface will communicate with the Consent Manager Tool to grant/deny access requests. Also we have planned and designed the interaction among the iCARDEA components, to ensure the identity (including roles) of the users who want to access patient data stored in Care Plan Database. Consent Manager will be extended to communicate with an external Identity Provider to ensure the user identities and roles. The implementation of these new features will be completed in the next reporting period by Month 20.

3.5 WP 6- Interoperability Layer

Within the scope of Task 6.1, in order to realize the effective data integration with various CIED manufactures data format, a CIED Data Integration Module is built which aims to realize CIED data abstraction, mapping, parsing, validation and exposure processing based on the ISO/IEEE 11073 standard and the IHE Implantable Device Cardiac Observation (IDCO) profile for vendor specific reports. CIED data supplied by Medtronic and St. Jude Medical in individual formats are stored in the vendors data centered (CareLink by Medtronic and Merlin.Net by St. Jude Medical) and accessed via internet connection. With the assistance from vendors, OFFIS finalized the mapping between Medtronic PDF reports and corresponding items defined by ISO/IEEE 11073 Nomenclature. During this process, unclear sections about the HL7 and IEEE 11073 Nomenclature interoperability in IHE IDCO standard were detected and found. To clarify this point feedback is sent to the IHE PCD Technical Committee. Furthermore, data sent from St. Jude Medical and Medtronic server will be parsed and transmitted as IHE IDCO compliant HL7v2.5 message. These messages also cover required device items in addition to the required clinical concepts in AT/AF and VT/VF guidelines. AF and VF guidelines are based on the care plan flow charts defined by SRDC, SALK and HCPB. For the initial testing, artificial IHE IDCO compliant HL7v2.5 demo message are generated for the both fabricated AT/AF and VT/VF scenarios. For the software programming realization of this task, different public and commercial libraries were evaluated. The following open source libraries where chosen: HAPI as an open source, object-oriented HL7 Application Programming Interface (API) that includes a set of Java tools for HL7 parsing and encoding to support connectivity and message handling, is used for the HL7v2.5 message processing. For the integration of PDF based reports, iText and PDFBox are used for the extraction of EGM figures and textual data.

Within the scope of Task 6.2, during this period FORTH worked on the implementation of the EHR-IF, its integration with iCARDEA components in a general setting and in the context of the iCARDEA deployment in SALK. Although EHR-IF has been designed as a general-purpose standards-based interoperability framework for the integration of care plans to any hospital and/or personal health

---

4 http://www.oasis-open.org/committees/tc_home.php?wg_abbrev=security
information system, actual deployment (in SALK and any healthcare setting) requires significant levels of configuration and fine-tuning. As a result, the last 6-months highlighted intense almost daily collaboration, an on-site meeting in March, and weekly conference calls in June and July among SALK, FORTH, and SRDC to clarify deployment details particularly in relation to security and semantic interoperability. Submitted deliverable 6.2.1 focuses on functionality and deployment of EHR-IF elaborating of procedures followed that can be adapted in other healthcare settings as well. An important lesson learned is the value of following an iterative process to fine-tune integration and effectively support current and future care plans.

The key achievements over this period besides delivery of D6.2.1 have been the deployment of the EHR-IF in SALK including receipt and basic processing HL7 messages (Admission Discharge Transfer/Laboratory Results) and EDF reports (Discharge Letters), establishing communication with and using the semantic mapping services of Code-Mapping API (SRDC).

Having achieved the main milestone for this period, FORTH will continue to work with SALK to further elaborate on the level of semantic interoperability achieved with HL7 messages and EDF files.

Within the scope of Task 6.3, during this period, SRFG implemented the first prototype of the interoperability services and components supporting IHE PCC-9 query subscriptions and PCC-10 messaging, and supporting PHRS applications (clients) sharing data via interoperability services. The PCC transactions can support the iCARDEA care manager and EHR interoperability components. When a data consumer subscribes to the PHR interoperability services, changes to the patient information from the PHRS web client are received and communicated via PCC-10 messages to all subscribers. Drone software was implemented to test, simulate and visually demonstrate the transactions between different actors e.g. PHR user web application, interoperability services (integrated in the PHRS application server), and Care Planner interoperability services. This software helps to demonstrate the PHRS interoperability services during presentations. Extensive work was performed to create appropriate and valid PCC-10 messages, especially using the appropriate IHE profiles and vocabularies. Semantic Interoperability is on the vocabulary and metadata level, where the metadata level is given more emphasis. To support interoperability among components, services were defined and described in WSDL files (Web Service Description language) so that partners and future developers can use to utilize PHRS interoperability services and access PHRS patient information. Continuing work involves refactoring persistence components that include triple store based storage. This will facilitate query and access by current and future healthcare applications. Refactoring work includes additional APIs for use by clients such as the PHRS application server and web client.

Within the scope of Task 6.4, SRDC implemented the first prototype of iCARDEA Code Mapping System. The implementation fully complies with the HL7 Common Terminology Services (HL7 CTS) APIs, in other words we have implemented the relevant methods of the Web Services proposed by CTS. As the terminology server, we are using Unified Medical Language System (UMLS) as proposed in our DoW. For this purpose first of all we have deployed a local installation of UMLS Knowledge Source Server (KSS) by making use of the MetamorphoSys tool provided by UMLS. Currently we have chosen only LOINC, SNOMEDCT, HL7 v2.5, HL7 v3.0, RxNORM, ICD10 and MeSH as the controlled vocabularies and classification systems to be used. Then we have implemented the Web Services proposed by CTS by accessing this local Knowledge Source installation. The following functionalities are provided through these Web Services as outlined as requirements in the requirement engineering phase:

- Get a code translated from one code system to another code system
- Validate a given code

---

7 http://www.ncbi.nlm.nih.gov/books/NBK9683/
Get supported mappings
Get supported code systems

In addition to this initial implementation, in this reporting period, we communicated with SALK team to identify the local codes used in their systems, so that these local code systems can also be supported by iCARDEA Code Mapping API. First of all, we identified the coded elements in our Atrial Fibrillation and Ventricular Tachycardia guidelines, and identified the data sources of these coded elements in SALK Systems together with FORTH Team. We have identified that a local lab coding system is used by SALK, called GLIMPS. The mapping of these codes to LOINC lab codes has been finalized and uploaded to the local knowledge source server of iCARDEA Code Mapping API. In this way, it also supports the mapping of local GLIMPS codes to LOINC codes. Deliverable 6.4.1, Code Mapping API, has been delivered to the Commission by Month 16.

Within the scope of 6.5, FORTH has collected security requirements for iCARDEA components. The next period will focus on the preparation of the relevant deliverable and the implementation of the relevant infrastructure in the EHR-IF to provide the ability for authentication, monitoring, and auditing of all iCARDEA related activities.

3.6 WP 7- Context Awareness and Clinically Useful Information Derivation

Within the scope of Task 7.1, a bilateral meeting of OFFIS with HCPB to refine the data requirements and visualization concepts was held prior the Hamburg Meeting.

The healthcare professionals identified the need for a single tool to display all required parameters instead of accessing multiple different tools. This will be achieved by analyzing patient data from CIEDs, Electronic Healthcare Records and Personal Health Records, such as history of illness, surgeries, medications, and then graphically presenting these data in an intelligent way by combining the fields from separate sources. Furthermore, predefined sets of values to be examined for the treatment of different complications were identified as useful and will be presented in an optimized view. Based on this information OFFIS created further mock-up of the “Patient Parameter Monitor” tool, containing sample data obtained from CIED, PHR and EHR and highlighting possible consistency problems. Several proposed visualization concepts of the data were discussed.

HCPB redefined the requested parameters and provided OFFIS with a list of critical clinical parameters to be monitored and analyzed for the personalized evaluation of patients with CIEDs, including:

- **Entry page**: general information of the patient and device, measured parameters, arrhythmia episodes, programmed parameters.
- **AT/AF episode**: arrhythmia episode information, patient’s relevant information, patient’s objective data.
- **VT/VF episode**: arrhythmia episode information, patient’s relevant information, patient’s objective data.
- **Patient information**: clinical data, device information, healthcare practitioner’s information (doctor, nurse, contact data, etc.).
- **Programmed parameters**: bradycardia, tachycardia.

All these parameters have been properly described including: definition, type of variable, format, information source (CIED, EHR, PHR), time frame and validation rules. Thereafter, other partners such as SJM, Medtronic and SALK have provided their input to better define the nomenclature and accessibility of all these data.
The information source and provider were identified and the integration in the iCARDEA database was prepared. In coordination with SRDC, OFFIS decided on the data interchange and integration of the patient parameter monitor with the other iCARDEA components and the needed Java API. On this base first functional prototypes were designed and implemented. The prototype will be tested and reviewed in the next period.

Task 7.2 aims at developing and establishing a data analysis process. The goal is to obtain statistically valid patterns about the patients and their medical conditions. Therefore the historical cases of 230 patients were obtained from SALK. The 230 patients are all the patients at SALK which have an implanted ICD or CIED. The data provided where the ICD10 Codes together with the year and kind (main, discharge) of diagnosis, the sex and birth year of the patient, the medication of the patient and vendor and type of the implanted aggregate. Also a list of complications where provided. For the medication a mapping of the medicine name to the agent and dose where defined. Also as preparation for the data analysis the ICD10 codes were divided into two classes: Main diagnosis and secondary diagnosis. After developing a first prototype which provides a visualisation of the semantic changes over the time at the data, the data were integrated in a semantically harmonized way.

Based on the requested kind of data analysis of the healthcare professionals at SALK, the data analysis processes were modelled and software components were developed to integrate and prepare the data. Since the found patterns were not useful, additional data analysis processes were defined. Besides the requested Online analytical Processes (OLAP) datacubes, additional cubes about the distribution of treated patients, the distribution of main and secondary diagnosis according to the age and sex were created. Since OLAP is a hypothesis validation data analysis also a data mining process for hypothesis creation was developed. Therefore association rules were induced on the SALK databases after creating software components to prepare the data. Both attempts created knowledge about the treated patients. The OLAP attempt showed that the first treatment of female person at the clinic cardiac unit is independent from their age. For male persons there is a major peak at the age between 60 and 75. From the association analysis a remarkable result was that the age or sex had a low significance on the diagnosis.

Besides the data analysis on SALK data attempts were made to obtain a broader data base to validate the knowledge or find additional patterns. Despite publications show that studies with 192 or 624 patients can produce reliable and good results, OFFIS contacted the second clinical Partner HCPB to clarify, how many ICD and CIED patients they’ve got and what data is available. Also the privacy and security issues were short noticed. A first result was that HCPB has an amount of about 150 patients with remote monitoring. Further discussion will show if the total amount of patients with an ICD or CIED with or without remote monitoring will be higher and if the data is available in a computer interpretable format. Also a dataset of clinical data was found via Computing in Cardiology (CinC). The dataset of the 2009 CinC Challenge referred to the Physionet MIMIC II Database. A first research showed that the data is potentially useful, but is not specialized to ICD or CIED patients. Patterns induced on this data will have no special references to ICD or CIED. Since the ICD-9 coding was used for diagnosis, the temporal data analysis prototype can be “misused” to provide mappings of the found patterns to the ICD-10 Codes of the SALK environment to be potential useful at the iCARDEA pilot. The public database MIMIC II consists of 110 patients. There seems the possibility to obtain up to 25.000 patients but this has to be evaluated especially with respect to the required privacy and security issues. The usefulness of the provided data items will be discussed with the clinical partners.

3.7 WP 8 -iCARDEA Testing and Validation Framework

This period underlined the intense effort to achieve interoperability among iCARDEA components both in the iCARDEA testing environment established at SRDC as well as in the actual hospital setting of SALK. iCARDEA partners proceeded according to the plan and process presented in deliverable 8.1.1 for bilateral and functional tests of iCARDEA components. Further tests were initiated and successfully
completed in SALK as part of the initial deployment. Further tests are planned as further configuration and fine-tuning of interoperability settings are foreseen as dictated by the care plans developed by iCARDEA.

In the course of implementing this task, FORTH coordinating the preparation of a paper submitted and presented in the International HL7 Interoperability conference which focuses on the challenge of testing for interoperability using off-the-shelf tools separately and in the context of integrated business processes. The paper lamented on the limitations of IHE testing, the lack of synthetic workloads to test interoperability and the lack of benchmarks to measure efficiency (time overhead) and effectiveness (level of semantic integration). The main achievements during this period have been the development of the iCARDEA testing environment, integration of iCARDEA components based on the AF scenario (demonstration also in the May review), and the installation of the iCARDEA components in SALK including the basic testing the processing of relevant HL7 and EDF messages.

The iCARDEA pilot application will be deployed in Austria, at the partner SALK. Task 8.2, iCardea Pilot Application Validation specifies test cases that will be performed on the developed pilot application for the thoroughly examination of the system. The realized system for the pilot application scenarios will be tested as a whole in the test environment by the end users. The tests will be in parallel with the deployment of the pilot application.

In this reporting period the testing requirements for the iCARDEA pilot application was specified. The pilot application will be deployed in Austria in two phases – an early prototype aiming to receive early feedback from iCARDEA users and the final prototype which will be validated by physicians and two groups of patients. The validation of the final prototype will include one group of CIED patients with ordinary post-surgical control and one group of CIED patients with iCARDEA-enhanced remote monitoring.

The evaluation of an early iCARDEA prototype aims to test an early iCARDEA prototype with reduced functionalities. This is basically the prototype presented at the review meeting in May 2011. In preparation for this early validation phase questionnaires for physicians and patients were specified and the deployment infrastructure was established. For more details see Task 9.3.

Two approaches will serve as a basis for the validation plan for the final prototype, on the one hand relevant data related to remote monitoring are collected (e.g. number of follow-ups or number of critical events) in order to compare two patient groups. On the other hand the approach of Goal-Question-Metric is used which is a widely accepted approach to validate software. The basic modules are represented by test cases describing the relevant situations to be evaluated and validated for iCARDEA. The test cases comprise several dimensions such as management of symptoms and medical risks, indicators for remote monitoring or usability and acceptance.

Additionally, the protocol for the Pilot Study was specified in accordance with the legal and ethical requirements. The Pilot Study comprises 2 groups of patients (25 for each cohort) with ICD for secondary prophylaxis will be recruited and randomised in a 1:1 manner after a successful implant. They will either

- have outpatient clinic care as normal (Group1 in-office arm) or
- be followed by telemonitoring with iCARDEA assistance (Group 2 remote arm).

The results of this task are summarized in Deliverable D8.2.1 Functional and Non-functional Evaluation Criteria for iCARDEA Pilot Application.
3.8 WP 9 – iCARDEA Pilot Application

Within the scope of Task 9.2, in this reporting period two demonstration scenarios and storyboards describing the step-by-step execution of these scenario based on the underlying iCARDEA architecture were specified.

- for Atrial Fibrillation (AF) – this demonstration scenario has driven the implementation of the first prototype presented at the review meeting in May 2011.
- for Ventricular Tachycardia (VT) – this demonstration scenario covers additional scenarios for iCARDEA

The demonstration scenarios started with a persona description describing two different types of patients. The specification process was performed in several iterations by involving all iCARDEA partners. The development of the demonstration scenarios and the storyboards ensured a detailed discussion of the Pilot Application design.

Additionally, the Pilot Application design included a discussion and the specification of the physical deployment architecture describing how the pilot application will be deployed in a clinical setting by the end-user located at the SALK in Austria. This specification comprises requirements for the physical deployment architecture including privacy and security issues and a description of the components of the iCARDEA Deployment Architecture.

The results of Task 9.2 are summarized and described in Deliverable D9.2.1 Design of the Implementation of the Pilot Application Scenario.

According to the Description of Work the start of Task 9.3 is planned for Month 29 (June 2012) but an early prototype of the iCARDEA Pilot application with reduced functionalities will be deployed earlier in the clinical setting of the partner SALK (timeframe June-August 2011). This early prototype is based on the prototype presented at the review meeting in May 2011 and aims to receive feedback from the users (medical experts, patients) about basic iCARDEA features, usability and possible barriers at an early stage of the project. The main instrument for the evaluation are questionnaires for the end-users. These questions were specified in D821 “Functional and Non-functional Evaluation Criteria for iCARDEA Pilot Application”. The prototype covers the demonstration scenario for Atrial Fibrillation described in deliverable D9.2.1 “Design of the Implementation of the Pilot Application Scenario” and will be tested by physicians and 5-10 persons of group 2 (of CIED patients with iCARDEA-enhanced remote monitoring). The results of this evaluation phase will give additional information for the implementation phase of iCARDEA.

Within the scope of Task 9.3, first of all SALK has developed the Protocol for the pilot application. Currently the Protocol does not involve the validation of PHR Prototype, as it is still a concern for the Ethic Committee that inclusion of PHR validation would require a Medical Device Study, which has stricter requirements. SRFG will be preparing an alternative deployment strategy including instructions to patients about how to use the system in the next period, so that PHR tool can be deployed and validated within the limits of SALK Ethical requirements. This needs to be further presented to the Ethics Commission. If the Ethics Commission does not accept this alternative deployment plan, and still thinks that inclusion of PHR in these conditions would still require a Medical Device Study, the only viable plan is to validate the prototype of PHR with hypothetical data. In addition to this, the CRF (Case Record forms) requested by the ethics commission have also been developed. In this period, a specific meeting is held at SALK with FORTH and SRFG, where the deployment strategy was discussed and developed to provide needed technical requirements. SALK’s IT department has been working closely with FORTH, SRDC and SRFG for enabling deployment of early prototypes. A meeting is also organized with SRFG in
May to discuss integration of the PHR. If it is authorised by the ethics, SALK has provided the necessary IT elements to install the iCARDEA prototype at SALK within the boundaries allowed in SALK and through Ethics. The validation questionnaires are ready and will be filled in by the physicians involved when the prototype is ready. Currently the patient forms about the PHR will not be used until it is authorised by ethics committee that we can use the PHR platform. For early validation of the components, currently iCARDEA components are being deployed to SALK machines, then these will be demonstrated to fill in the prepared questionnaires for validation.

For Task 9.4, Ethical management, SALK has had two meetings with Salzburg Ethics Committee. The main issue discussed in these meetings was the possibility of validating PHR tool in the pilot deployment. Initially iCARDEA Pilot study is presented to the Ethics committee as an observational study. However it has been clarified that, involvement of PHR tool would require active involvement of patient to carry out activities (such as using a new software product) that is not included in the normal treatment strategy, and this would require the study to be a Medical Device Study according to European Union Regulations. A medical Device Study has much stricter requirements, such as inclusion of an Insurance Policy for possible adverse events (for example consider a patient reports a life threatening issue through PHR, and the medical professionals do not check the PHR immediately which may cause medical and ethical problems, which would need to be covered through an Insurance Policy supported by the study Sponsor). As iCARDEA Pilot was not planned as a Medical Device Study but as an observational study in the proposal phase, we do not have the resources, to address these issues within a Medical Device Study. To remedy this, SRFG with the guidance from SALK, is planning alternative deployment schemes, for possible validation of PHR within the legal and ethical limits provided. This will be clarified in the next reporting period.
## 4 DELIVERABLES AND MILESTONES TABLES

<table>
<thead>
<tr>
<th>Del. no.</th>
<th>Deliverable name</th>
<th>WP No</th>
<th>Lead Beneficiary</th>
<th>Nature</th>
<th>Dissemination Level</th>
<th>Delivery date from Annex I (Proj Month)</th>
<th>Delivered Yes/No</th>
<th>Actual / Forecast Delivery Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>D4.1.2</td>
<td>Personalized Adaptive Care Plan Definition Tool</td>
<td>WP4</td>
<td>SRDC</td>
<td>Prototype</td>
<td>Public</td>
<td>M16</td>
<td>Yes</td>
<td>May 31, 2011</td>
<td>-</td>
</tr>
<tr>
<td>D6.4.1</td>
<td>Code Mapping API</td>
<td>WP6</td>
<td>SRDC</td>
<td>Prototype</td>
<td>Public</td>
<td>M16</td>
<td>Yes</td>
<td>May 31, 2011</td>
<td>-</td>
</tr>
<tr>
<td>D9.2.1</td>
<td>Design of the Implementation of the Pilot Application Scenario</td>
<td>WP9</td>
<td>SRFG</td>
<td>Report</td>
<td>Public</td>
<td>M16</td>
<td>Yes</td>
<td>May 31, 2011</td>
<td>-</td>
</tr>
<tr>
<td>D1.1.3</td>
<td>Six Monthly Progress Report (b)</td>
<td>WP1</td>
<td>SRFG</td>
<td>Report</td>
<td>Restricted</td>
<td>M18</td>
<td>Yes</td>
<td>August 18, 2011</td>
<td>-</td>
</tr>
<tr>
<td>D2.3.1</td>
<td>Reports on Intellectual Property Management (a)</td>
<td>WP2</td>
<td>SRFG</td>
<td>Report</td>
<td>Public</td>
<td>M18</td>
<td>Yes</td>
<td>August 01, 2011</td>
<td>-</td>
</tr>
<tr>
<td>D5.3.1</td>
<td>Patient Feedback Mechanisms for the PHR</td>
<td>WP5</td>
<td>SRFG</td>
<td>Prototype</td>
<td>Public</td>
<td>M18</td>
<td>Yes</td>
<td>August 04, 2011</td>
<td>-</td>
</tr>
<tr>
<td>6.2.1</td>
<td>Interoperability Infrastructure for Electronic Healthcare Records</td>
<td>WP6</td>
<td>FORTH</td>
<td>Prototype</td>
<td>Public</td>
<td>M18</td>
<td>Yes</td>
<td>August 12, 2011</td>
<td>-</td>
</tr>
<tr>
<td>8.2.1</td>
<td>Functional and Non-functional Evaluation Criteria for iCARDEA Pilot Application</td>
<td>WP8</td>
<td>SRFG</td>
<td>Report</td>
<td>Public</td>
<td>M18</td>
<td>Yes</td>
<td>August 01, 2011</td>
<td>-</td>
</tr>
</tbody>
</table>
3.4.1 Conceptual Design of the iCARDEA Architecture WP3 SRDC Report Public M18 Yes August 18, 2011 The previously submitted deliverable is updated based on the comments of the Reviewers. The use cases related with Task 7.2 are extended.

<table>
<thead>
<tr>
<th>Milestone no.</th>
<th>Milestone name</th>
<th>Workpackage no.</th>
<th>Lead beneficiary</th>
<th>Delivery date from Annex 1</th>
<th>Achieved Yes/No</th>
<th>Actual/Forecast achievement date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>M4</td>
<td>iCARDEA EHR Interoperability and Evaluation Criteria for iCARDEA Pilot Application</td>
<td>WP6 and WP8</td>
<td>FORTH</td>
<td>Mont 18</td>
<td>Yes</td>
<td>August 12, 2011</td>
<td>-</td>
</tr>
</tbody>
</table>
**DELIVERABLE SUMMARY SHEET**

**Project Number:** ICT-248240  
**Project Acronym:** iCARDEA  
**Title:** An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices

**Deliverable No:** D4.1.2 Personalized Adaptive Care Plan Definition Tool  
**Due date:** M16  
**Delivery date:** May 31, 2011  
**Responsible Partner:** SRDC

**Brief Description of the Deliverable Content**

This document provides detailed information about the requirements, design and implementation of iCARDEA Care plan definition tool developed within the scope of “Task 4.1 Adaptable Computer Interpretable Clinical Guideline Models for Executable Personalized CIED Follow-up”. It introduces the architecture of Care Plan Definition Tool, detailed information about the graphical interfaces it provides, and information about how to edit/update the building blocks of a care plan definition flow.
# DELIVERABLE SUMMARY SHEET

<table>
<thead>
<tr>
<th>Project Number:</th>
<th>ICT-248240</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Acronym:</td>
<td>iCARDEA</td>
</tr>
<tr>
<td>Title:</td>
<td>An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices</td>
</tr>
</tbody>
</table>

**Deliverable No:** D6.4.1 Code Mapping API  
**Due date:** M16  
**Delivery date:** May 31, 2011  
**Responsible Partner:** SRDC

## Brief Description of the Deliverable Content

This document describes the achievements in Task 6.4 “Code Mapping among Healthcare Code Systems”. In Task 6.4, the iCARDEA Code Mapping API is implemented. In the implementation of the iCARDEA Code Mapping API, Unified Medical Language System is used as the terminology server. However, UMLS provides a proprietary API to access its code mappings. Accessing the code mappings that UMLS provided in a standard way would enhance the interoperability. For this purpose, we have used HL7 v3 Common Terminology Services (CTS). In order to access the existing terminology servers using CTS, CTS interfaces must be mapped to the interfaces of the terminology servers. In this respect, we provide the implementation of CTS functions in terms of the Web Service operations. 
In the deliverable, first the UMLS is described in detail. After that the supported code systems is presented. After introducing the HL7 v3 CTS, the implementation of CTS services is described in detail.
DELIVERABLE SUMMARY SHEET

Project Number: ICT-248240
Project Acronym: iCARDEA
Title: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices

Deliverable No: D9.2.1 Design of the Implementation of the Pilot Application Scenario
Due date: M16
Delivery date: May 31, 2011
Responsible Partner: SRFG
Partners contributed: All partners

Brief Description of the Deliverable Content

The design of the Pilot Application was driven from two demonstration scenarios about Atrial Fibrillation (AF) and about Ventricular Tachycardia (VT). Both scenarios are described in detailed storyboards within D921 comprising a step-by-step execution of the scenario based on the underlying iCARDEA architecture. The Atrial Fibrillation storyboard is enriched by screenshots/mockups of the iCARDEA components.

Additionally, this document includes a section about the physical deployment architecture describing how the Pilot Application will be deployed in a clinical setting by the end-user located at the SALK in Austria. This section comprises requirements for the physical deployment architecture including privacy and security issues and a description of the components of the iCARDEA Deployment Architecture.
<table>
<thead>
<tr>
<th>Project Number:</th>
<th>ICT-248240</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Acronym:</td>
<td>iCARDEA</td>
</tr>
<tr>
<td>Title:</td>
<td>An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices</td>
</tr>
</tbody>
</table>

**Deliverable No:** D1.1.3 Six Monthly Progress Report (b)  
**Due date:** M18  
**Delivery date:** August 18, 2011  
**Responsible Partner:** SRDC  
**Partners contributed:** All partners

**Brief Description of the Deliverable Content**

The six monthly progress report includes a detailed description of each partners’ progress in each active work package, the meetings and conferences organized, the publications achieved, the financial data about use of project resources. The progress reports were collected from partners to construct Six Monthly Progress Report of iCARDEA project covering the period M13-M18.
Project Number: ICT-248240
Project Acronym: iCARDEA
Title: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices

Deliverable No: D2.3.1 – Reports on Intellectual Property Management (a)
Due date: M18
Delivery date: August 01, 2011
Responsible Partner: SRFG
Partners contributed: All partners

Brief Description of the Deliverable Content

D231 provides detailed information how iCARDEA copes with innovation produced during the project. 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.
Project Number: ICT-248240
Project Acronym: iCARDEA
Title: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices

Deliverable No: D5.3.1 – Patient Feedback Mechanisms for the PHR
Due date: M18
Delivery date: August 04, 2011
Responsible Partner: SRFG
Partners contributed: SRFG, SRDC

Brief Description of the Deliverable Content

The deliverable describes issues relating to feedback mechanisms and the patient feedback mechanisms used in the PHR system, and how the PHR system and iCARDEA components support the communication between healthcare providers and patients. This comprises:

- Communication between Patients and Physicians
  - Contact information in case of emergency
  - Patient Communication via remote monitoring
    - Communication through Remote Monitoring applications
    - iCARDEA Care Planner Engine Component
    - iCARDEA Patient Parameter Monitor
  - Limitations of patient communications
- Communication with patients sharing similar situations
  - Forums for patients and other health experts
  - Wiki-based resources especially to reference patient communities and forums
<table>
<thead>
<tr>
<th>Project Number: ICT-248240</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Acronym: iCARDEA</td>
</tr>
<tr>
<td>Title: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Deliverable No: D6.2.1 – Interoperability Infrastructure for Electronic Healthcare Records</th>
</tr>
</thead>
<tbody>
<tr>
<td>Due date: July 30, 2011</td>
</tr>
<tr>
<td>Delivery date: August 12, 2011</td>
</tr>
<tr>
<td>Responsible Partner: FORTH</td>
</tr>
<tr>
<td>Partners contributed: FORTH, SRDC, SALK, OFFIS</td>
</tr>
</tbody>
</table>

**Brief Description of the Deliverable Content**

Deliverable D6.2.1 provides an overview of the EHR Interoperability Framework (EHR-IF), its components, installation instructions and configuration requirements. Detailed sections provide information that would guide potentially interested healthcare facilities to review the iCARDEA EHR-IF and decide whether they would like to invest on its deployment at their site. D6.2.1 also provides a snapshot of what is currently operational at the University Hospital of Salzburg and a separate section lays out some of the foreseen areas where effort will be invested in the future.
## DELIVERABLE SUMMARY SHEET

**Project Number:** ICT-248240  
**Project Acronym:** iCARDEA  
**Title:** An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices

<table>
<thead>
<tr>
<th>Deliverable No:</th>
<th>D8.2.1 – Functional and Non-functional Evaluation Criteria for iCARDEA Pilot Application</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Due date:</strong></td>
<td>July 31, 2011</td>
</tr>
<tr>
<td><strong>Delivery date:</strong></td>
<td>July 31, 2011</td>
</tr>
<tr>
<td><strong>Responsible Partner:</strong></td>
<td>SRFG</td>
</tr>
<tr>
<td><strong>Partners contributed:</strong></td>
<td>All partners</td>
</tr>
</tbody>
</table>

### Brief Description of the Deliverable Content

D821 provides detailed information about the testing environment for the iCARDEA pilot application developed within the scope of Task T8.2 “iCARDEA Pilot Application Validation”. The pilot application will be deployed in Austria in two phases – an early prototype aiming to receive early feedback from iCARDEA users and the final prototype which will be validated by two groups of patients. D821 includes:

- Description of the Pilot Study and the clinical protocol
- Evaluation of an Early Prototype – describing the questions for the iCARDEA components
- Evaluation and Validation of the Final Prototype – specifying relevant goals and questions driving the specification of test cases in the next step.
4.1 Progress Overview per Contractor

In this section, the progress in the active tasks is described by summarizing the contributions of the iCARDEA consortium members.

PROGRESS OVERVIEW SHEET

| Contractor name: SRDC |

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Planned Effort(^2)</th>
<th>Planned Date(^3)</th>
<th>Actual Date(^4)</th>
<th>Resources employed(^2)</th>
<th>Cumulative Resources(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Project</td>
<td>Start</td>
<td>End</td>
<td>Start</td>
<td>End</td>
</tr>
<tr>
<td>WP1</td>
<td>13</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP2</td>
<td>2.5</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP3</td>
<td>16</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP4</td>
<td>17</td>
<td>5</td>
<td>26</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>WP5</td>
<td>8.75</td>
<td>9</td>
<td>22</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP6</td>
<td>13</td>
<td>9</td>
<td>22</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP7</td>
<td>2</td>
<td>9</td>
<td>24</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>WP8</td>
<td>5</td>
<td>9</td>
<td>36</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP9</td>
<td>5.5</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>TOTAL</td>
<td>82.75</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

One person month is equal to 140 Person hours

Main contributions during this period

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td></td>
</tr>
<tr>
<td>Task1.1</td>
<td>Within the scope of T1.1, SRDC coordinated the organization of the 1(^{st}) Review of iCARDEA Project. In addition to this, a draft action plan is created by SRDC on how to address the comments we received in the first review meeting, and this draft action plan has been communicated and discussed with partners to have a final version to be executed. SRDC also attended and coordinated Hamburg Technical Meeting.</td>
</tr>
<tr>
<td>Task1.2</td>
<td>Within the scope of this task, SRDC coordinated the review and quality assurance of the deliverables submitted to the Commission.</td>
</tr>
<tr>
<td>WP2</td>
<td></td>
</tr>
<tr>
<td>Task 2.1</td>
<td>In this reporting period, two of the journal publications initiated by SRDC has been published: Mustafa Yuksel and Asuman Dogac, Interoperability of Medical Device Information and the Clinical Applications: An HL7 RMIM based on IEEE 11073 DIM, IEEE Transactions on Information Technology In Biomedicine, Vol. 15, No. 4, July2011:557-66.</td>
</tr>
</tbody>
</table>

In addition to these, SRDC contributed to the EMBC 2011, CinC 2011, MIE2011 and IHIC 2011 submissions.

<table>
<thead>
<tr>
<th>Task 2.3</th>
<th>In this reporting period, SRDC contributed to the first report in Intellectual Property Rights Management, presenting the licensing issues of the SRDC components.</th>
</tr>
</thead>
</table>

**WP3**

**Task 3.1** Within the scope of Task 3.1, SRDC coordinated the technical management of iCARDEA Project. Two separate action plans have been prepared covering Month 12-18 (presented as an annex of D1.1.5) and Month 18-24 (presented in Section 5.5). SRDC has conducted a number of teleconferences with the partners for the technical coordination of project implementation.

**WP4**

**Task 4.1** Within the scope of Task 4.1, SRDC completed the implementation of the first version of iCARDEA Care Plan Definition Tool. This tool enables the definition of machine processable care plans as clinical guideline definitions. It makes it possible to define and personalize the care plans, and to bind the data sources of the variables used in clinical guideline steps to the CIED data, EHRs and PHRs of the patient. The details of Care Plan Definition Tool are presented in “D4.1.2 Personalized Adaptive Care Plan Definition Tool” which is delivered by the end of Month 16.

**Task 4.3** Within the scope of Task 4.3, SRDC team continued with the implementation of Care Plan Engine. First of all, a thread mechanism is implemented to enable the engine to execute multiple care plans of several patients simultaneously. The main GUI of the Care Planner is implemented, where patients and care givers of the patients can be registered to the platform, by selecting their preferences to receive alarms, recommendations to be presented by the care plan engine. Care Plan Engine is extended to send the alarm/recommendation messages to patients/care givers or medical professionals through email and SMS messages based on the Care Plan definition. Finally, the implementation of a Monitoring graphical interface is initiated to be implemented.

**Task 4.4** Within the scope of Task 4.4, in parallel with Task 6.5, SRDC elaborated the security and privacy requirements of Care Plan Engine and Definition Tool.

**WP5**

**Task 5.3** Deliverable 5.3.1 is reviewed and a contribution about the feedback mechanisms provided by Care Planner Engine is provided to SRFG Team.

**Task 5.4** Within the scope of Task 5.4, SRDC implemented an initial prototype of iCARDEA Consent Management System. Finally the integration of Consent Management Tool with Patient Parameter Monitoring tool is planned and designed, which will be implemented in the next reporting period.

**WP6**
| **Task 6.2** | Within the scope of Task 6.2, SRDC actively involved in the discussions related with how EHR Interoperability System will be integrated with SALK Systems. SRDC joined the weekly teleconferences organized between FORTH, SALK and SRDC Teams. Also SRDC prepared the EHR requirements of VT care plan and presented these to FORTH team for testing their system for VT scenario. SRDC also reviewed Deliverable 6.2.1 and provided a section related with the integration of Code Mapping API with EHR Interoperability Framework. |
| **Task 6.4** | Within the scope of Task 6.4, SRDC implemented the first prototype of iCARDEA Code Mapping System. The implementation fully complies with the HL7 Common Terminology Services (HL7 CTS) APIs, and uses UMLS as a terminology server. In addition to this, mappings of local SALK Lab codes in GLIMPS to LOINC are also added to the terminology server. Deliverable 6.4.1, Code Mapping API, has been delivered to the Commission by Month 16. |
| **WP8** | **Task 8.1** Within the scope of Task 8.1, SRDC delivered the unit tests of Care Plan Definition Tool and also Code Mapping API to FORTH.  
**Task 8.2** Within the scope of Task 8.2, as a part of Deliverable 8.2.1, SRDC provided the test case descriptions related with Adaptive Care Planner, Consent Management System and the Code Mapping API. |
| **WP9** | **Task 9.2** SRDC actively contributed to Deliverable 9.2.1. SRDC provided the template and the draft of the story boards for AF and VT care plans, and coordinated the finalization of these storyboards with the input from partners.  
**Task 9.3** Within the scope of Task 9.3, SRDC deployed the Care Plan Editor, Care Plan Engine and Code Mapping API to SALK Servers. In addition to this, installation and user guides of the tools are prepared, and this will be used within the scope of Task 9.3, for the phase 1 validation of iCARDEA architecture by the end users. |

1 Each partner should fill its own Progress Overview Sheet for period in question. The Project Coordinator will check and approve the forms and attach them to the corresponding Progress Report  
2 In person-months (or in person-hours)  
3 Project month when the activity was planned to be started or to be completed  
4 Project month when the activity was actually started or completed  
5 Give a figure use for converting person hours to person months
PROGRESS OVERVIEW SHEET

Contractor name: OFFIS

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Planned Effort²</th>
<th>Planned Date³</th>
<th>Actual Date⁴</th>
<th>Resources employed²</th>
<th>Cumulative Resources²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Project</td>
<td>Start</td>
<td>End</td>
<td>Start</td>
<td>End</td>
</tr>
<tr>
<td>WP1</td>
<td>1.00</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP2</td>
<td>2.50</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP3</td>
<td>18.00</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP4</td>
<td>1.00</td>
<td>5</td>
<td>26</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>WP5</td>
<td>2.50</td>
<td>9</td>
<td>22</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP6</td>
<td>13.00</td>
<td>9</td>
<td>22</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP7</td>
<td>17.00</td>
<td>9</td>
<td>24</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP8</td>
<td>5.00</td>
<td>9</td>
<td>36</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP9</td>
<td>5.50</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>TOTAL</td>
<td>65.50</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>19.53</td>
</tr>
</tbody>
</table>

One person month is equal to 140 Person hours

Main contributions during this period

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Task 1.1</strong></td>
<td>Preparation and Participation to consortium meetings in Hamburg (DE). Contribution to and review of deliverables D1.1.5 “First Activity and Management Reports”. Also contribution to and review of D1.1.3 “Six-Monthly Progress Report”.</td>
</tr>
<tr>
<td><strong>WP2</strong></td>
<td>Submission of paper on iCARDEA for “IEEE at 33rd Annual International Conference of the IEEE Engineering in Medicine and Biology Society” (accepted). Submission of paper on iCARDEA IEEE &amp; Ei Compendex at Computing in Cardiology 2011 (accepted) Brief articles on iCARDEA in the annual report of OFFIS. Presentation of the project on the GI-Workshop &quot;Grundlagen von Datenbanken 2011&quot;</td>
</tr>
<tr>
<td><strong>Task 2.2</strong></td>
<td>Review and contribution to D2.3.1 “Reports on Intellectual Property Management” OFFIS mainly initiated a discussion on the software licences and provided information on fore- and background knowledge of “Data Analysis through Temporal Dimensions Module”, “Privacy-aware Data Analysis Concept” and “CIED Data Interoperability Module”</td>
</tr>
<tr>
<td><strong>WP6</strong></td>
<td>Contributions to D6.1.1 “Interoperability Infrastructure for Electronic Healthcare Records” Through the cooperation with CIED vendors, OFFIS has finished mapping IEEE 11073 Nomenclature items required by Care Plan with real CIED</td>
</tr>
</tbody>
</table>
information in PDF reports.

OFFIS was engaged with software programming and testing for IHE IDCO compliant HL7v2.5 message interoperability with the subtask as below.

1) Software for parsing component to abstract and parsing HL7v2.5 ORU message. 2) Software for PIX client component for the fusion of PID segment with Patient Identity. 3) Software for sending component with alert and error handle mechanism to transmit HL7v2.5 messages to Adaptive Care Planner.

Software for running and management mechanism (moving, deleting and renaming files, generating log file generally). 4) Design for the network topology and DMZ which will be implemented in SALK. 5) Generating and installing standalone executable *.jar file in SALK. 6) User Guidance for the direct user in SALK combined with actual workflow to draw up appropriate implement guideline.

For the software implementation, faking demo CIED Data (as IHE IDCO compliant HL7v2.5 message) that fulfils the requirements of the AT/AF and VT/VF demo scenario provided by SALK to the Care Plan Engine was supplied and tested for demo scenario.

OFFIS provided and showed the first functional prototype in EU-review meeting. And second functional prototype including PIX is revealed by Month 17.

### Task 6.2
Review D6.2.1 “Interoperability Infrastructure for Electronic Healthcare Records”

### Task 6.4
Review and Contributions to D6.4.1 “Code Mapping API”. Especially clarification of the national ICD Coding systems and the needed information for the data analysis.

### WP7

#### Task 7.1
The needs of the Healthcare professionals’ for the Patient Parameter Monitoring Tool were recognized in several meetings and discussions. The needed data attributes were identified. The possible data sources of the information were evaluated; first review of the system design was made using mock-up tools. Decisions on the database layout and storage were made. Interfaces for the patient data access and the access rights management are in discussion. First functional prototype is installed and will be evaluated.

#### Task 7.2
OFFIS obtained the historical cases for CIED patients of SALK. The data was prepared by cleansing and standardisation like creating a mapping from the medicament name to the agent and dose. For the requested OLAP data analysis, analysis metadata was defined (cubes) and software components developed to integrate the patient data into the cubes. A first prototype of the temporal data analysis tool was used to integrate the data of patients without semantic loss.

Also a data mining process was established to produce association rules. The data mining algorithm required also software components to integrate and especially prepare the data.

After this first patterns and statistics about SALK’s historical patients cases were found and sent to the medical experts for validation.

To obtain a broader range of historical cases of CIED patients, first consultations with HCPB were performed with the goal to obtain their patient data.

#### Task 7.3
The process of transmission the patient data secure from SALK to OFFIS
was established. Also first consultations with HCPB were performed to clarify the legal privacy and security needs to obtain HCPB patient data.

WP8

**Task 8.2**
Provided input to D8.2.1 “Functional and Non-functional Evaluation Criteria for iCARDEA Pilot Application” for CIED Data Interoperability Module, Patient Parameter Monitoring Tool and Data Analysis Application. Furthermore provided input to security, privacy measurements, data safety and performance aspects.

WP9

**Task 9.1**
Review (in multiple iterations) of Deliverable D9.1.1 “Requirements of iCARDEA Pilot Application”. Definition of the prerequisites for the access to the CIED Data sources in the SALK Environment. Technical prerequisite for the software and hardware environment. Clarify the CIED data internet access with vendors server in security manners.

**Task 9.2**
Review and Contributions to D9.2.1 “Design of the Implementation of the Pilot Application Scenario”. Provided especially input about integration of the CIED Data Interoperability Module, Patient Parameter Monitoring Tool and Data Analysis Application. Conception of the integration of a demilitarized zone (DMZ) in the workflow. Defining and mapping Care Plan required information with IEEE 11073 Nomenclature items in real CIED PDF report. Formulating needs for the IHE IDCO message for the AT/AF and VT/VF scenarios as testing examples. Building architecture structure for the whole iCARDEA practical environment and defining the interaction relationship between various iCARDEA software components. Draft the procedure to integrate iCARDEA into current work flow for healthcare giver in best way from both technical and management aspects. For example, the data update and administration mechanism.

**Task 9.4**
Provision and training of an ethics contact person in coordination with SALK. Sensitization of all iCARDEA employees to ethic standards agreed at and required by SALK.

---

1 Each partner should fill its own Progress Overview Sheet for period in question. The Project Coordinator will check and approve the forms and attach them to the corresponding Progress Report
2 In person-months (or in person-hours)
3 Project month when the activity was planned to be started or to be completed
4 Project month when the activity was actually started or completed
5 Give a figure use for converting person hours to person months
PROGRESS OVERVIEW SHEET

Contractor name: SRFG

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Planned Effort</th>
<th>Planned Date</th>
<th>Actual Date</th>
<th>Resources employed</th>
<th>Cumulative Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Project</td>
<td>Start</td>
<td>End</td>
<td>This Period</td>
<td>Since Start</td>
</tr>
<tr>
<td>WP1</td>
<td>1</td>
<td>1</td>
<td>36</td>
<td>0,30</td>
<td>0,39</td>
</tr>
<tr>
<td>WP2</td>
<td>2,5</td>
<td>1</td>
<td>36</td>
<td>0,08</td>
<td>1,50</td>
</tr>
<tr>
<td>WP3</td>
<td>8</td>
<td>1</td>
<td>36</td>
<td>-</td>
<td>8,00</td>
</tr>
<tr>
<td>WP4</td>
<td>2,5</td>
<td>5</td>
<td>26</td>
<td>0,25</td>
<td>0,82</td>
</tr>
<tr>
<td>WP5</td>
<td>14</td>
<td>9</td>
<td>22</td>
<td>5,19</td>
<td>7,12</td>
</tr>
<tr>
<td>WP6</td>
<td>6,5</td>
<td>9</td>
<td>22</td>
<td>4,03</td>
<td>6,12</td>
</tr>
<tr>
<td>WP7</td>
<td>1</td>
<td>9</td>
<td>24</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>WP8</td>
<td>11</td>
<td>9</td>
<td>36</td>
<td>1,21</td>
<td>1,47</td>
</tr>
<tr>
<td>WP9</td>
<td>10,1</td>
<td>1</td>
<td>36</td>
<td>1,26</td>
<td>3,10</td>
</tr>
<tr>
<td>TOTAL</td>
<td>56,60</td>
<td>-</td>
<td>-</td>
<td>12,32</td>
<td>28,52</td>
</tr>
</tbody>
</table>

One person month is equal to 140 Person hours

Main contributions during this period

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td></td>
</tr>
<tr>
<td>Task1.1</td>
<td>Contributions to the Progress Report</td>
</tr>
<tr>
<td>WP2</td>
<td></td>
</tr>
<tr>
<td>Task 2.3</td>
<td>This task comprises the following activities in this period:</td>
</tr>
<tr>
<td></td>
<td>- Coordination of D2.3.1 “Reports on Intellectual Property Management (a)”</td>
</tr>
<tr>
<td></td>
<td>- Specification of open source licencing strategies</td>
</tr>
<tr>
<td></td>
<td>- Specification of background and foreground knowledge for SRFG</td>
</tr>
<tr>
<td>WP5</td>
<td></td>
</tr>
<tr>
<td>Task 4.3</td>
<td>Discussions with partners about Care Planer</td>
</tr>
<tr>
<td>WP5</td>
<td></td>
</tr>
<tr>
<td>Task 5.1</td>
<td>Based on the technical use cases specified in Task 3.4 mockups for the PHR user interface were specified as part of the Atrial Fibrillation storyboard. Based on that the demonstration prototype for the PHR system was implemented for the first review in May 2011 comprising the following issues:</td>
</tr>
<tr>
<td></td>
<td>- User interface components relating to observations of daily living, medications, lifestyle, patient profile and patient contact information.</td>
</tr>
<tr>
<td></td>
<td>- Client communication with the interoperability services of the core PHRS application server. The client side view models provide</td>
</tr>
</tbody>
</table>

Page 58 of 112
data to the interoperability services on the core PHRS application server.
- Core PHRS application server supports services for healthcare applications, such as the PHRS user web application. The core server provides services, such as
  - Health terminology services that support User Interface (UI) controls/widgets
  - PHR Interoperability services integrated from Task 6.3
- Terminology services to support UI controls/widgets
- A JSR-286\(^8\) based web portal provides social and collaborative software components

| Task 5.2 | In coordination with the medical partners HCPB and SALK a basic structure for information and education material as part of the PHR portal and a template for decision aids were specified. A Google Site was created allowing the medical partners to create and assemble the web-based content for the PHR portal. |
| Task 5.3 | Based on the technical use cases specified in Task 3.4 and on the Atrial Fibrillation storyboard patient feedback mechanisms were specified and included into the PHR portal. This comprises:  
  - Support feedback and communication among patients using social software components such as forum and Wiki tools.  
  - Support external applications to support communications between patients and medical professionals.  
  - Collaborative portal features for enabling physician to patient communications. Portal features include messaging (chat, mail) and forums.  
  - Extend patient profile information to include contact information of their healthcare providers. |

| WP6 |  |
| Task 6.2 | Activities included the extension and testing of the interoperability services for EHR import based on IHE PCC profiles, and discussion related to EHR interactions with the PHRS. |
| Task 6.3 | During this period, SRFG implemented the first prototype of the interoperability services and components supporting IHE PCC-9 query subscriptions and PCC-10 messaging, and supporting PHRS applications sharing data via interoperability services. |
| Task 6.5 | Activities included:  
  - An initial prototype of the security module, including unit testing, documentation and a light integration of the SRDC component (Consent manager T5.4) with the core PHRS architecture.  
  - Work on the PHRS security requirements for deliverable D6.5.1 Security and Privacy of the interoperability layer |

| WP8 | Refactor and extension to the existing security module, introductions of actors and roles. |
| Task 8.1 | In this period Task 8.1 comprises the following activities  
  - Implementing unit and functional tests for PCC9 and PCC10 messages  
  - Test and preparing the installation PHR system for the review |

### Task 8.2
SRFG leads this task which is dedicated to the validation of the Pilot Application. This period comprises the following activities:
- Specifying and preparing the validation of an early prototype together with all partners. SRFG coordinated together with SALK the testing environment including questionnaires for physicians and patients.
- Together with partners, SRFG coordinated the specification of test cases for the validation of the final Pilot Application.
- In D9.1.1 “Requirements of iCARDEA Pilot Application” the validation phases were updated.

### WP9

#### Task 9.2
SRFG leads this task which is dedicated to the design of the iCARDEA Pilot Application. This period comprises the following activities:
- SRFG contributed to the specification of the two storyboards for Atrial Fibrillation and for Ventricular Tachycardia with a particular focus on the PHR portal.
- SRFG coordinated together with SALK the specification of the deployment architecture describing how the Pilot Application will be deployed in a clinical setting by the end-user located at the SALK in Austria.

#### Task 9.3
SRFG activities included:
- Preparation of the early prototype validation and testing.
- Preparation of the PHRS end-user guide, and German translation of the guide and user interface labels.
- Preparation of questionnaires for validation phase 2.

#### Task 9.4
In coordination with SALK open legal issues related to the PHR portal were clarified and the Patient Consent Form was updated for the PHR portal.

---

1. Each partner should fill its own Progress Overview Sheet for period in question. The Project Coordinator will check and approve the forms and attach them to the corresponding Progress Report.
2. In person-months (or in person-hours).
3. Project month when the activity was planned to be started or to be completed.
4. Project month when the activity was actually started or completed.
5. Give a figure use for converting person hours to person months.
## PROGRESS OVERVIEW SHEET

**Contractor name:** FORTH

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Planned Effort&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Planned Date&lt;sup&gt;3&lt;/sup&gt;</th>
<th>Actual Date&lt;sup&gt;4&lt;/sup&gt;</th>
<th>Resources employed&lt;sup&gt;2&lt;/sup&gt;</th>
<th>Cumulative Resources&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Project</td>
<td>Start</td>
<td>End</td>
<td>Start</td>
<td>End</td>
</tr>
<tr>
<td>WP1</td>
<td>1</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP2</td>
<td>2.5</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP3</td>
<td>13</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP4</td>
<td>3</td>
<td>5</td>
<td>26</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>WP5</td>
<td>3.9</td>
<td>9</td>
<td>22</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP6</td>
<td>16</td>
<td>9</td>
<td>22</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP7</td>
<td>2</td>
<td>9</td>
<td>24</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP8</td>
<td>7</td>
<td>9</td>
<td>36</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP9</td>
<td>5.5</td>
<td>9</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>53.9</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

One person month is equal to 140<sup>5</sup> Person hours

### Main contributions during this period

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td></td>
</tr>
<tr>
<td><strong>Task 1.1</strong></td>
<td>Participation in consortium meetings in Hamburg (DE) and Project Review (Brussels). Contribution to relevant management six month, and yearly reports.</td>
</tr>
<tr>
<td>WP2</td>
<td></td>
</tr>
<tr>
<td><strong>Task 2.2.1</strong></td>
<td>Within the scope of 2.1, FORTH contributed to the exploitation part of iCARDEA, refining the exploitable assets.</td>
</tr>
<tr>
<td><strong>Task 2.2.2</strong></td>
<td>During this period, FORTH engaged in significant dissemination activities related to the iCARDEA project. The approach followed with testing was presented in the IHIC2011, gaining quite favourable reviews from the health information standards community. FORTH contributed to the preparation of the paper accepted in EMBC2011 and will be presenting it, and abstracts submitted to Computing in Cardiology 2011 (accepted – to be presented by OFFIS) and ICPES2011 (in collaboration with HCPB). Furthermore the work of iCARDEA was presented as part of a presentation at the Panhellenic Medical Congress in May 2011. In this period, FORTH also contributed to D231 Reports on Intellectual Property Management.</td>
</tr>
<tr>
<td>WP 6</td>
<td></td>
</tr>
<tr>
<td><strong>Task 6.1</strong></td>
<td>FORTH contributed to the work led by OFFIS in 6.1 in view of the</td>
</tr>
</tbody>
</table>
preparation of the paper submitted and to be presented in EMBS2011 (Guideline-Driven Telemonitoring and Follow-up of Cardiovascular Implantable Electronic Devices using IEEE 11073, HL7 & IHE Profiles)

| Task 6.2 | FORTH collaborated intensely with SALK and SRDC in the implementation and initial deployment of the EHR-IF. For the most part of this period weekly meetings were held among FORTH, SALK and SRDC to keep track of the schedule maintaining progress. Deliverable 6.2.1 was prepared with contributions from SRDC as well as discussions and eventual review by OFFIS and SALK. We expect this task to continue with further configuration and refinement over the following period. |
| Task 6.4 | FORTH integrated the Code Mapping System to the EHR-IF. |
| Task 6.5 | FORTH has prepared a template for the relevant deliverable and has requested and received initial contributions from partners as to security requirements associated with components under their responsibility. Initial work on the relevant IHE profiles has started for the EHR-IF |
| WP8 |  |
| Task 8.1 | Progress in 8.1 continues with unit tests of individual components and bilateral tests. A testing platform has been prepared at the premises of SRDC and is used for preliminary testing. At the same times iCARDEA components have been installed at SLAK and testing proceeds in parallel on site. |
| Task 8.2 | FORTH has contributed to deliverable D8.2.1 prepared by SRFG. |

---

1 Each partner should fill its own Progress Overview Sheet for period in question. The Project Coordinator will check and approve the forms and attach them to the corresponding Progress Report
2 In person-months (or in person-hours)
3 Project month when the activity was planned to be started or to be completed
4 Project month when the activity was actually started or completed
5 Give a figure use for converting person hours to person months
## PROGRESS OVERVIEW SHEET

Contractor name: SALK

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Planned Effort</th>
<th>Planned Date</th>
<th>Actual Date</th>
<th>Resources employed</th>
<th>Cumulative Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Project</td>
<td>Start</td>
<td>End</td>
<td>Start</td>
<td>End</td>
</tr>
<tr>
<td>WP1</td>
<td>1,00</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP2</td>
<td>2,00</td>
<td>1</td>
<td>36</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>WP3</td>
<td>1,00</td>
<td>1</td>
<td>36</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>WP4</td>
<td>3,85</td>
<td>5</td>
<td>16</td>
<td>2</td>
<td>-</td>
</tr>
<tr>
<td>WP5</td>
<td>0,75</td>
<td>9</td>
<td>22</td>
<td>10</td>
<td>-</td>
</tr>
<tr>
<td>WP6</td>
<td>0,50</td>
<td>9</td>
<td>22</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP7</td>
<td>1,50</td>
<td>9</td>
<td>24</td>
<td>8</td>
<td>-</td>
</tr>
<tr>
<td>WP8</td>
<td>3,00</td>
<td>9</td>
<td>36</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP9</td>
<td>10,25</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>TOTAL</td>
<td>23,85</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

One person month is equal to 160 hours per month; assumption, has to be calculated by individual basis. Person hours

### Main contributions during this period

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td>Meeting with the EU Commission for the 1st Review of iCARDEA Project</td>
</tr>
<tr>
<td>Task 1.1</td>
<td>Meeting with Partners in Hamburg</td>
</tr>
<tr>
<td>WP2</td>
<td>Poster presentation at CCNAP meeting Brussels March 2011, Moderated</td>
</tr>
<tr>
<td>Task 2.2</td>
<td>poster presentation ÖKG meeting Salzburg May 25th 2011</td>
</tr>
<tr>
<td>WP5</td>
<td>Discussions with hospital Barcelona on concept; discussions with SRFG</td>
</tr>
<tr>
<td>Task 5.1</td>
<td>on concept; concept of PHR deployment</td>
</tr>
<tr>
<td>WP6</td>
<td>Meeting with FORTH, SRFG,SALK March 22 @ SALK Deployment architecture</td>
</tr>
<tr>
<td>WP7</td>
<td>for EHR and PHR Interoperability architectures</td>
</tr>
<tr>
<td>Task 7.1</td>
<td>Meeting, discussion, input and coordination with partners and within</td>
</tr>
<tr>
<td></td>
<td>SALK on patient parameters to be monitored</td>
</tr>
<tr>
<td>WP8</td>
<td>Preparation of validation of pilot application within SALK; coordination,</td>
</tr>
<tr>
<td>Task 8.2</td>
<td>discussion and communication</td>
</tr>
<tr>
<td>WP9</td>
<td>Design of pilot application; development of patient scenario with;</td>
</tr>
<tr>
<td>Task 9.2</td>
<td>collecting input from physicians from SALK; working closely with all</td>
</tr>
<tr>
<td></td>
<td>partners involved</td>
</tr>
</tbody>
</table>
| **Task 9.3** | SALK IT Department coordinated the following activities:  
- Checking required HL7 messages,  
- Support to partners for deployment design,  
- Test interface to Lab Information System,  
- Test Interface to Hospital Information System  
- Prototype support |
| **Task 9.4** | Many discussions with Ethic Commission of Salzburg; clarifying ethical issues of PHR and patient involvement; discussions with SRFG on this topic; input for design of PHR portal, amended consent form developed and sent for admission to Salzburg ethic commission. |

1 Each partner should fill its own Progress Overview Sheet for period in question. The Project Coordinator will check and approve the forms and attach them to the corresponding Progress Report  
2 In person-months (or in person-hours)  
3 Project month when the activity was planned to be started or to be completed  
4 Project month when the activity was actually started or completed  
5 Give a figure use for converting person hours to person months
## PROGRESS OVERVIEW SHEET

**Contractor name: SJM**

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Planned Effort</th>
<th>Planned Date</th>
<th>Actual Date</th>
<th>Resources employed</th>
<th>Cumulative Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Project</td>
<td>Start</td>
<td>End</td>
<td>Start</td>
<td>End</td>
</tr>
<tr>
<td>WP1</td>
<td>1</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP2</td>
<td>3,75</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP3</td>
<td>1</td>
<td>1</td>
<td>36</td>
<td>1</td>
<td>-</td>
</tr>
<tr>
<td>WP4</td>
<td>2</td>
<td>5</td>
<td>26</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>WP5</td>
<td>0.5</td>
<td>9</td>
<td>22</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>WP6</td>
<td>3,85</td>
<td>9</td>
<td>22</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP7</td>
<td>0.5</td>
<td>9</td>
<td>24</td>
<td>9</td>
<td>-</td>
</tr>
<tr>
<td>WP8</td>
<td>1</td>
<td>9</td>
<td>36</td>
<td>12</td>
<td>-</td>
</tr>
<tr>
<td>TOTAL</td>
<td>18,10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

One person month is equal to 155 Person hours

### Main contributions during this period

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td></td>
</tr>
<tr>
<td>Task1.1</td>
<td></td>
</tr>
<tr>
<td>Task 2.2</td>
<td></td>
</tr>
<tr>
<td>WP3</td>
<td></td>
</tr>
<tr>
<td>Task 3.1</td>
<td></td>
</tr>
<tr>
<td>WP4</td>
<td></td>
</tr>
<tr>
<td>Task 4.1</td>
<td></td>
</tr>
<tr>
<td>WP5</td>
<td></td>
</tr>
<tr>
<td>Task 5.1</td>
<td></td>
</tr>
</tbody>
</table>

Preparation and participation to consortium meetings in Hamburg/Germany. Furthermore contribution and review of deliverables First Activity and Management Reports was performed. Also contribution to and review Six-Monthly Progress Report is delivered. Preparation and participation to review meeting in Brussels/Belgium.

Contribution of device specific and home monitoring related information and review to the submitted papers from partners Generation of Intellectual Property and Patent Search Management document and distribution as well as presentation at Hamburg meeting.

Discussion and contribution to the SJM specific interface and the data delivery structure of the Merlin system.

Specification of the care planner and the possibilities of the different defined types. Specification together with Salzburg Research and SALK.

Specification and discussion/contribution of the framework for patient empowerment.
<table>
<thead>
<tr>
<th>Task 8.1</th>
<th>Discussion of different testing scenarios and how to deal with regression tests. Sending of different testing scenarios and protocols to responsible group FORTH.</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP9</td>
<td></td>
</tr>
<tr>
<td>Task 9.1</td>
<td>Review of the Requirements of iCardea Pilot Application. Definition of data and information access for CIED devices and security issues that must be addressed.</td>
</tr>
<tr>
<td>Task 9.2</td>
<td>Review and contributions to Design of Implementation of the Pilot Application Scenario. CIED data interoperability. Interaction interfaces for SJM devices.</td>
</tr>
</tbody>
</table>

1 Each partner should fill its own Progress Overview Sheet for period in question. The Project Coordinator will check and approve the forms and attach them to the corresponding Progress Report.
2 In person-months (or in person-hours)
3 Project month when the activity was planned to be started or to be completed
4 Project month when the activity was actually started or completed
5 Give a figure use for converting person hours to person months
PROGRESS OVERVIEW SHEET

Contractor name: Medtronic

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Planned Effort</th>
<th>Planned Date</th>
<th>Actual Date</th>
<th>Resources employed</th>
<th>Cumulative Resources</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Project</td>
<td>Start</td>
<td>End</td>
<td>Start</td>
<td>End</td>
</tr>
<tr>
<td>WP1</td>
<td>1</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP2</td>
<td>4.75</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP3</td>
<td>1</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP4</td>
<td>2</td>
<td>5</td>
<td>26</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP5</td>
<td>1</td>
<td>9</td>
<td>22</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP6</td>
<td>3.95</td>
<td>9</td>
<td>22</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP7</td>
<td>0.5</td>
<td>9</td>
<td>24</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP8</td>
<td>1</td>
<td>9</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP9</td>
<td>5</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>TOTAL</td>
<td>20.20</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
</tbody>
</table>

One person month is equal to 148.33 Person hours

Main contributions during this period

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td></td>
</tr>
<tr>
<td>Task 1.1</td>
<td>Medtronic's contribution in this task has been devoted to the cooperation and collaboration with the required administrative issues in order to achieve a correct on-going of iCARDEA project. To that end, all the necessary administrative procedures were followed to complete the periodic management reports.</td>
</tr>
<tr>
<td>Task 1.2</td>
<td>Medtronic has participated in the revision of quality assurance plan in order to keep the project stakeholders’ level of confidence high and ensure the technical quality of the documentation together with the consortium.</td>
</tr>
<tr>
<td>WP2</td>
<td></td>
</tr>
<tr>
<td>Task 2.2.1(a)</td>
<td>After providing the market and literature research on the last reporting period regarding to CIED monitoring platform and overview of current processes of care for remote follow-up, Medtronic has further analysed the exploitability of the iCARDEA system within chronic diseases management platforms as a crucial holistic approach to the core of these software platforms. Exploitation plan will be updated on month 24.</td>
</tr>
<tr>
<td>Task 2.2</td>
<td>Medtronic has contributed the papers written within the project prior to be published and has contributed to the article submitted to the EMBC2011 “Guideline-Driven Telemonitoring and Follow-up of Cardiovascular Implantable Electronic Devices using ISO/IEEE 11073, HL7 &amp; IHE Profiles”.</td>
</tr>
<tr>
<td>Task 2.3</td>
<td>Medtronic has performed a literature research on patents to empirically</td>
</tr>
<tr>
<td>WP3</td>
<td>Task 3.3</td>
</tr>
<tr>
<td>WP4</td>
<td>Task 4.3</td>
</tr>
<tr>
<td>WP8</td>
<td>Task 8.2</td>
</tr>
<tr>
<td>WP9</td>
<td>Task 9.1</td>
</tr>
</tbody>
</table>

---

1 Each partner should fill its own Progress Overview Sheet for period in question. The Project Coordinator will check and approve the forms and attach them to the corresponding Progress Report.

2 In person-months (or in person-hours)

3 Project month when the activity was planned to be started or to be completed

4 Project month when the activity was actually started or completed

5 Give a figure use for converting person hours to person months
### PROGRESS OVERVIEW SHEET

Contractor name: HCPB

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Planned Effort(^2)</th>
<th>Planned Date(^3)</th>
<th>Actual Date(^4)</th>
<th>Resources employed(^2)</th>
<th>Cumulative Resources(^2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Whole Project</td>
<td>Start</td>
<td>End</td>
<td>Start</td>
<td>End</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Start</td>
<td>End</td>
<td></td>
<td></td>
</tr>
<tr>
<td>WP1</td>
<td>1</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP2</td>
<td>3.5</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP3</td>
<td>1.5</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP4</td>
<td>8</td>
<td>5</td>
<td>26</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP5</td>
<td>7.5</td>
<td>9</td>
<td>22</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP6</td>
<td>2</td>
<td>9</td>
<td>22</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP7</td>
<td>5</td>
<td>9</td>
<td>24</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP8</td>
<td>2</td>
<td>9</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>WP9</td>
<td>2</td>
<td>1</td>
<td>36</td>
<td>13</td>
<td>-</td>
</tr>
<tr>
<td>TOTAL</td>
<td>32.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

One person month is equal to \(^3\) Person hours

#### Main contributions during this period

<table>
<thead>
<tr>
<th>Workpackage/Task</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td><strong>Task1.1</strong> Within the scope of administrative management, HCPB has attended the consortium meeting in Hamburg (Germany) and the EC Review meeting in Brussels (Belgium), participating in the development of the presentation and defending the project evolution. Additionally, the next iCARDEA consortium meeting is to be held on September 29(^{th})-30(^{th}) in Barcelona (Spain), and it is being organized by HCPB. Finally, HCPB has contributed to the periodic and final activities reports, periodic and final management report and the response to the EC Technical Review Report.</td>
</tr>
<tr>
<td>WP2</td>
<td><strong>Task 2.1</strong> HCPB exploitation strategy is being designed together with Linkcare Health Services SL, a recently created spin-off of Hospital Clinic of Barcelona. Both the hospital and LinkCare are interested 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. These modules are currently being designed and the adoption of the iCardea system would be a long term project, as it should be included in the production plan of the platform in its future</td>
</tr>
</tbody>
</table>
revisions. At this moment in time the priorities of LinkCare remain in the development of other modules of the platform and the deployment of the first ones that are being used (home hospitalization, etc.). In the next stages there will be a revision of the possibility of adopting some of the iCardea features. Several exploratory meetings took place and it was agreed that once the iCARDEA platform was fully designed it may be of interest for the clinical follow-up of chronic patients. Unfortunately, in the current socioeconomic context, until specific resources are put into the project, a more specific requirement analysis and the actual implementation will have to wait.

**Task 2.2**
The “Dissemination Plan” was first issued at month 12. During this year a revision is being performed and will be submitted to the Project Management Board at month 24.

HCBP, as coordinator of the task 2.2, has registered every dissemination activity (publication, presentation in congresses, webpage, brochure, newsletter, etc.) carried out by any partner and the consortium.

On the other hand, the iCARDEA project was presented, at the Europace Meeting (European Heart Rhythm Association of the European Society of Cardiology), that took place in Madrid in June 2011. Several abstracts have been submitted to the European American Cardiology Societies meetings, but unfortunately, due to the more technical stage of the project, they have not been accepted so far. Two additional abstracts for the World Congress on Arrhythmias are under evaluation at the moment.

**Task 2.3**
HCPB contributed in the development of deliverable D2.3.1 “Reports on Intellectual Property Management”

**WP3**

**Task 3.1**
Within the scope of Task 3.1, HCPB has collaborated in the development of the action plan every six months, as prepared by SRDC. At the Hamburg Technical meeting (February 2011) the action plan was discussed and extended to cover months 13 – 18.

**Task 3.3**
For the “Gathering Technical Requirements of iCARDEA Architecture”, HCPB continues to collaborate in the evaluation of the scientific requirements (clinical guidelines models, CIED adaptice care planner, monitoring tool, personal health record, etc.).

**WP4**

**Task 4.1**
HCPB has extensively collaborated with SRDC and SALK teams to define the Clinical Guideline Definitions for the follow-up of CIED Patients as a care plan. The clinical guideline and flowcharts for the management of Atrial Fibrillation, Ventricular Arrhythmias and device follow-up have been reviewed and we have continuously given clinical feedback on the development of the computer interpretable guideless and the personalized adaptive care plan definition tool.

**Task 4.3**
Within the scope of this task, HCPB has contributed by providing the scientific/clinically relevant information/definitions for the adaptive care plan and identifying the necessary context variables. The alternative pathways in the follow-up care process have been defined by HCPB with the aid of SALK (clinical data), Medtronic (CIEDs data) and SJM (CIEDs data). Outcome parameters have also been defined.
### WP5

**Task 5.2**  
Within the scope of Task 5.2 “Patient Education”, HCPB has identified and produced the relevant patient education mechanisms that will be implemented in the PHR once fully developed. Both static and dynamic educative materials have already been designed and are currently being included in a Google Site. Already existing material is also facilitated through external webpage links and uploaded documents (those available for public use).

### WP 6

**Task 6.1**  
Within the scope of task 6.1, the workflows for remote monitoring of CIEDs patients (both the device and the clinical status of the patient) are being supervised, from a clinical perspective, by HCPB.

### WP 7

**Task 7.1**  
Within the scope of task 7.1., HCPB provided OFFIS with a revised list of clinically relevant parameters for the personalized evaluation of patients with CIEDs (general information, AT/AF episode, VT/VF episode, measured and programmed parameters), for its implementation in an assistant. All these parameters were properly described including: definition, information source, type of variable, format, time frame and validation rules.

Additionally, from an end-user (healthcare professionals) perspective, we have evaluated and discussed the system design with OFFIS in several meetings.

**Task 7.2**  
Within the scope of Task 7.2 HCPB has supervised the development of the iCARDEA Data Analysis Correlation Tool. We have overviewed the clinical patterns obtained after the analysis of 230 patients with CIED from SALK premises. Finally, through several meetings with clinical, administrative, legal and ethical representatives of HCPB, the possibility of implementing this tool in our premises was evaluated. However, despite our goodwill, there are some unavoidable requirements for it to be possible:

- Technically it involves two steps: 1) the preparation of an exploitation routine that identifies all the cases that are to be retrieved, the fields that are needed and the format of the resulting file (some restrictions apply in the latter case); and 2) the creation of a one-way only anonymisation function ensuring that data provided will not be traceable back.
- According to our security policy in place, these are activities that can only be carried out by our own personnel, legally bound by contract to keep confidentially with regard to these matters. So, external personnel cannot be involved in it. Once data has been anonymised, then externals can use it (in the context and for the purpose that has been established in a study protocol).
- Also, any exploitation of HCPB’s data should be carried out under the premise that it is purpose oriented. This means that it is done in the context of, for instance, a clinical study. In the case of iCardea, a prerequisite for this is authorization by the Hospital’s Ethical Committee. This requires that a minimum protocol should be
written down, containing the information required for this type of studies. This cannot be replaced by any other type of document (including non-disclosure agreements or alike).

All these requirements will be discussed at the consortium meeting in Barcelona (29\textsuperscript{th} -30\textsuperscript{th} September).

**WP 8**

**Task 8.2**

For the iCARDEA Pilot Application Validation, HCPB has collaborated in the definition of test case scenarios that will later be evaluated in the developed pilot application. As potential end users, we have reviewed and given our comments/expertise on the pilot application scenarios. Finally, we have contributed to and reviewed the deliverable D.8.2.1.

**WP 9**

**Task 9.1**

For task 9.1, the Requirements of iCARDEA Pilot Application, HCPB has contributed by collaborating in their definition. HCPB has provided comments to the deliverable D.9.1.1 and its multiple revisions.

**Task 9.2**

Within the scope of task 9.2, HCPB has reviewed and contributed to the deliverable D.9.2.1 “Design of the implementation of the Pilot Application Scenario”, providing medical/clinical/research expertise. Also all the clinical scenarios have been carefully supervised for them to be relevant and representative of real-world situations. Additional scenarios have been proposed.

Finally, following recommendations of the EC Technical review report, we have held several meetings with clinical, administrative, legal and ethical representatives at HCPB with regards a potential implementation of a Pilot Application of iCARDEA. However, the deployment of the iCardea system in HCPB and its usage for the treatment and follow up of patients during a pilot incurs a series of costs and administrative/legal procedures that must be considered prior to studying the viability to do it.

- The use of a not CE marked device/software with patients in a clinical study implies that the protocol and plans for the study must be approved by the Medical Ethical Committee of HCPB and Ministry of Health authorities in Spain (in any situation that a device/system without CE mark is to be used, the national authorities have to be informed). Exhaustive documentation in Spanish related to the technical details of the system (risk analysis, usability tests...) and the study itself (patient informed consent, protocol, materials to be given to the patients, investigators’ brochure, etc...) must be provided to both organisms for their analysis and subsequent approval or denial.
- In addition, there must be an entity or organization collaborating in the project (one partner) that should sponsor the study and be in charge of the insurance policy.
- This would require, therefore, the allocation of specific budget specific resources to organize the pilot, prepare the documentation, deploy the system and recruit and follow the patients during the pilot.
As deployment of a Pilot Application in HCPB was not contemplated by the iCARDEA project, all these matters will be discussed at the consortium meeting in Barcelona (29th-30th September, 2011).

1 Each partner should fill its own Progress Overview Sheet for period in question. The Project Coordinator will check and approve the forms and attach them to the corresponding Progress Report
2 In person-months (or in person-hours)
3 Project month when the activity was planned to be started or to be completed
4 Project month when the activity was actually started or completed
5 Give a figure use for converting person hours to person months

5 PROJECT MANAGEMENT
5.1 Detailed Progress in WP1

Within the scope of WP1, SRDC has carried out the management tasks to coordinate the iCARDEA project. In order to fulfill management tasks, SRDC endeavoured for on-time accomplishment of tasks and delivery of the project deliverables. In addition to these, SRDC has organized and chaired project meetings with the cooperation of the other consortium members. Based on iCARDEA Quality Assurance Plan, each deliverable sent to SRDC to be submitted to the Commission is checked for quality, and necessary updates and notices are informed to the respective partners.

SRDC Team has prepared detailed action plans for the coordination of the project, presenting the responsibilities and the deadlines for contributions. The action plan covering Month 12-18 is presented as an annex of D1.1.5 and the action plan covering Month 18-24 is presented in Section 5.5.

In addition to this, the comments and recommendations presented in the 1st iCARDEA Review Report are discussed with partners and an action plan has been prepared to present how these comments will be addressed in the next periods. This action plan is presented in Section 2.2.

For the management of iCARDEA Project, following consortium meetings took place in the last six months of the project:
- iCARDEA Technical Meeting, February 08-09, 2011 in Hamburg, Germany, Consortium
- iCARDEA Review Meeting Rehearsal, May 05, 2011, Brussels, Belgium, Consortium

Several other bilateral teleconferences and meetings have been organized to coordinate the activities in individual tasks as presented in Section 5.4.1.

In the next iCARDEA consortium meeting the current status of the implementation activities, and the actions to address the reviewers’ comments will be discussed on September 29-30, 2011 in Barcelona, Spain.

5.2 Project Timetable and Status

The project proceeds as planned with all the deliverables submitted on time. There are a few deviations from the plan which are presented in the next section.
5.3 Deviations from the work plan and their impact to the project

- As summarized in Section 2.3, validation of PHR Platform with real patients as a part of SALK pilot application is still under discussion. Partners are investigating alternative deployment plans that will be presented to the Ethical Committee.
- In order to address the Reviewers’ comments, OFFIS team is examining whether it is possible to conduct the data analysis task also in HCPB Premises, which was not originally in the plan.
- In order to address the Reviewers’ comments, iCARDEA Consortium will investigate the possibility of extending the Requirements Analysis specification for HCPB also, although a pilot deployment in HCPB is not planned in the DoW.
- The effort to be invested in Task 6.2 (EHR-IF) and Task 8.1 by FORTH is expected to be higher than originally anticipated. However, this deviation is not expected to have any impact on the costs or timeline of the project.

5.4 Co-ordination of the information between partners and communication activities

5.4.1 Project Meetings Details

The following is the list of all the project meetings that took place in the last 6 months:

<table>
<thead>
<tr>
<th>Title</th>
<th>Data and Place</th>
<th>Main conclusions</th>
<th>Partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Meeting at Hamburg Meeting</td>
<td>2011-02-07</td>
<td>Discussion of WP7, regarding to the required parameters at PPM and templates for /AF and VT/VF, the database and envisaged results of data analysis and the analysis paths.</td>
<td>OFFIS, HCPB</td>
</tr>
<tr>
<td>Hamburg Technical Meeting</td>
<td>2011-02-08 2011-02-09</td>
<td>Discussion on the progress of each active tasks, dissemination and exploitation plans, preperations for the review meeting, and action plan for M12-M18. Minutes of the meeting is available in Appendix 1.</td>
<td>All the consortium</td>
</tr>
<tr>
<td>Post-Meeting at Hamburg Meeting</td>
<td>2011-02-09</td>
<td>Discussion of WP7, regarding to the available patients at SALK for data analysis and the meaning of Austrian coding system. Also discussion of the function and layout of PPM</td>
<td>OFFIS, SALK</td>
</tr>
<tr>
<td>Teleconference</td>
<td>2011-03-01</td>
<td>Discussion of how and when the process of data extraction at SALK can be done accordingly to the agreements at Task 7.3 Privacy and Security</td>
<td>OFFIS, SALK</td>
</tr>
<tr>
<td>Teleconference on AF Storyboard</td>
<td>2011-03-17</td>
<td>Discussion on finalizing the story board of the AF care plan demonstration for the review meeting</td>
<td>SRDC, OFFIS, SALK, SRFG, SJM, FORTH</td>
</tr>
<tr>
<td>Teleconference on Paper</td>
<td>2011-03-18 2011-03-21 2011-03-24</td>
<td>Preparation, Discussion and Review of the EMBC 2011 Paper (Theme, structure, contents, table and figure in paper and the integrated project results)</td>
<td>OFFIS, FORTH</td>
</tr>
<tr>
<td>Event Description</td>
<td>Date</td>
<td>Details</td>
<td>Participants</td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td>------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------</td>
</tr>
<tr>
<td>Technical meeting</td>
<td>2011-03-22</td>
<td>Partners discussed EHR/PHR interoperability and technical issues regarding to the Pilot Application environment. Minutes of the meeting is available in Appendix 2.</td>
<td>FORTH, SALK, SRFG</td>
</tr>
<tr>
<td>Technical meeting</td>
<td>2011-03-23</td>
<td></td>
<td>FORTH, SALK, SRFG</td>
</tr>
<tr>
<td>Teleconference on Task 7.2</td>
<td>2011-04-14</td>
<td>Technical Discussion about the deliverable of privacy secured historical patient data</td>
<td>OFFIS, SALK</td>
</tr>
<tr>
<td>Teleconference on Paper CinC 2011</td>
<td>2011-04-24</td>
<td>Preparation, Discussion and Review of the CinC 2011 Paper (Theme, structure, contents, table and figure in paper and the integrated project results)</td>
<td>OFFIS FORTH</td>
</tr>
<tr>
<td>Teleconference on Paper CinC 2011</td>
<td>2011-04-28</td>
<td></td>
<td>OFFIS FORTH</td>
</tr>
<tr>
<td>Teleconference on Task 7.2</td>
<td>2011-05-06</td>
<td>Discussion of the amount and scope of historical patient data. Discussion of the kind and meaning of available complications</td>
<td>OFFIS, SALK</td>
</tr>
<tr>
<td>iCardea Rehearsal and Review</td>
<td>2011-05-05</td>
<td>Rehearsal and Review meeting</td>
<td>All the consortium</td>
</tr>
<tr>
<td>iCardea Rehearsal and Review</td>
<td>2011-05-06</td>
<td></td>
<td>All the consortium</td>
</tr>
<tr>
<td>Teleconference on deployment architecture</td>
<td>2011-05-23</td>
<td>Discussion on deployment architecture at SALK</td>
<td>SRDC, OFFIS, SALK</td>
</tr>
<tr>
<td>Meeting related with Deployment of PHR</td>
<td>2011-05-25</td>
<td>Discussion on possible deployment strategies for PHR in SALK Main results include: PHR application will go on a USB stick, data emailed to SALK, no data can be exported to the patient from EHR</td>
<td>SALK, SRFG</td>
</tr>
<tr>
<td>Teleconference on Task 9.2</td>
<td>2011-05-30</td>
<td>Discussion on deployment concept and integration of a DMZ</td>
<td>OFFIS SALK</td>
</tr>
<tr>
<td>Teleconference on Task 6.2, 6.5, 8.1</td>
<td>2011-06-10</td>
<td>Discussion on activity report and workplan</td>
<td>SRDC FORTH</td>
</tr>
<tr>
<td>Teleconference on Task 6.1, 7.1, 7.2</td>
<td>2011-06-11</td>
<td>Discussion on activity report and workplan</td>
<td>OFFIS SRDC</td>
</tr>
<tr>
<td>Teleconference on Task 5.1, 5.3</td>
<td>2011-06-15</td>
<td>Discussion on activity report and workplan</td>
<td>SRDC SRFG</td>
</tr>
<tr>
<td>Teleconference on VT</td>
<td>2011-06-20</td>
<td>Discussion of WP4 and WP9, regarding the clinical scenarios (ventricular arrhythmias)</td>
<td>HCPB, SRDC, SALK,</td>
</tr>
</tbody>
</table>
### Storyboard

| Teleconference for discussing Patient Education | 2011-06-30 | Partners discussed and decided about the next steps for T5.2 Patient Education | SRFG, HCPB, SRDC |
| Teleconference for discussing D821 and D231 | 2011-07-01 | Partners discussed open issues for the deliverables D821 (Functional and Non-functional Evaluation Criteria for iCARDEA Pilot Application) and D231 (Intellectual Property Management) | SRFG, FORTH |

#### 5.4.2 Conferences, workshops, demonstration, attended/organized

**Conferences and Workshops attended by each partner**

<table>
<thead>
<tr>
<th>Date</th>
<th>Type and Title/Scope</th>
<th>Number of persons attended + other information</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011-05-30 to 2011-06-03</td>
<td>Scientific Conference on Databasis and Data analysis “Grundlagen von Datenbanken“. Presentation of the Task 7.2 Data analysis research</td>
<td>1 Person (OFFIS) from 2011-05-29 till 2011-06-03 at Austria</td>
</tr>
<tr>
<td>May, 26-27, 2011</td>
<td>eHealth2011, Vienna</td>
<td>3 persons (SRFG) attended 1 person paper presentation</td>
</tr>
<tr>
<td>March 31—2 April 2011</td>
<td>CCNAP Cardiac nursing meeting for Europe (Poster presentation, Many Cardiologist from Europe also at the meeting)</td>
<td>SALK attended, and presented About 300 attendees</td>
</tr>
<tr>
<td>May 25-28, 2011</td>
<td>ÖKG Austrian cardiology meeting moderated poster in arrhythmia specialty area</td>
<td>SALK attended and presented About 700 attendees</td>
</tr>
<tr>
<td>May 13-14, 2011</td>
<td>International HL7 Interoperability Conference</td>
<td>FORTH attended and presented the iCARDEA testing and evaluation approach in front of ~100 attendees.</td>
</tr>
</tbody>
</table>
May 21, 2011  |  Pan-Hellenic Medical Congress  |  FORTH attended and presented iCARDEA project objectives about 1000 attendees (50 in the room)

5.5  Plan and objectives for the next period

5.5.1  Plans related with Deliverables Due

5.5.1.1  WP1 Project Management

- **D1.1.6 Second Activity and Management Reports** – due Month 24
  - Each Partner will send its contribution for “D1.1.6 Second Activity and Management Reports” **January 20, 2012**
  - SRDC will collect and integrate the inputs for “D1.1.6 Second Activity and Management Reports” and send a consolidated version to the Consortium **January 27, 2012**
  - Each Partner will send its comments on the consolidated “D1.1.6 Second Activity and Management Reports” to SRDC **February 10, 2012**
  - Each Partner will send the financial figures to SRDC as soon as they are ready but no later than **February 10, 2012**
  - SRDC will update “D1.1.6 Second Activity and Management Reports” based on partners comments and financial figures and send it to the Consortium **February 17, 2012**
  - SRDC will send it to the Commission **February 24, 2012**

5.5.1.2  WP2 Dissemination, Exploitation and Innovation Related Activities

- **D2.1.2 “Exploitation and Dissemination Plan (b) – due Month 24**
  - SRDC will provide a template, role distribution and action plan for contributions for the Exploitation Plan by **August 31, 2011**
  - SRDC will prepare an initial version of “Exploitation Plan Report” and present for consortium review by **November 30, 2011**
  - As a result of the consortium review and consolidation, second release of the exploitation report will be ready by **January 13, 2012** to be included in D2.1.2
  - HCPB will prepare the dissemination report for the second year of the project and provide it for consortium review by **January 13, 2012** to be included in D2.1.2
  - Partners will provide comments for the exploitation and dissemination by **January 20, 2012**
As a result of the consortium review and consolidation, final release of D2.1.2 will be ready by January 27, 2012

5.5.1.3 WP4 Personalized Adaptive Care Planner for CIED Recipients

- D4.4.1 “Security and Privacy for Personalized Adaptive Care Planner” – due Month 24
  - SRDC will prepare an initial version of D4.4.1 “Security and Privacy for Personalized Adaptive Care Planner” for consortium review by January 13, 2012
  - All partners will provide comments by January 20, 2012
  - SRDC will update the document with partner’s reviews and provide a final release of D4.4.1 to be send to the Commission by January 27, 2012

5.5.1.4 WP5 Framework for Patient Empowerment

- D5.2.1 Patient Education Mechanisms for the PHR – due Month 20
  - HCPB will prepare D5.2.1 Patient Education Mechanisms for the PHR for consortium review by September 09, 2011
  - All partners will provide comments by September 16, 2011
  - HCPB will update the document with partner’s reviews and provide a final release of D5.2.1 to be send to the Commission by September 30, 2011

- D5.4.1 Patient Consent Management and Security – due Month 20
  - SRDC will prepare D5.4.1 Patient Consent Management and Security for consortium review by September 09, 2011
  - All partners will provide comments by September 16, 2011
  - SRDC will update the document with partner’s reviews and provide a final release of D5.4.1 to be send to the Commission by September 30, 2011

- D5.1.1 Personal Health Record System – due Month 22
  - SRFG will prepare D5.1.1 Personal Health Record System for consortium review by November 11, 2011
  - All partners will provide comments by November 18, 2011
  - SRFG will update the document with partner’s reviews and provide a final release of D5.1.1 to be send to the Commission by November 30, 2011
5.5.1.5 WP6 Interoperability Layer

- D6.1.1 Exposing CIED Data through Standard Interfaces – due Month 20
  - OFFIS will prepare D6.1.1 Exposing CIED Data through Standard Interfaces for consortium review by **September 09, 2011**
  - All partners will provide comments by **September 16, 2011**
  - OFFIS will update the document with partner’s reviews and provide a final release of D6.1.1 to be send to the Commission by **September 30, 2011**

- D6.3.1 Interoperability Infrastructure for Personal Health Records – due Month 22
  - SRFG will prepare D6.3.1 Interoperability Infrastructure for Personal Health Records for consortium review by **November 11, 2011**
  - All partners will provide comments by **November 18, 2011**
  - SRFG will update the document with partner’s reviews and provide a final release of D6.3.1 to be send to the Commission by **November 30, 2011**

- D6.5.1 Security and Privacy of the Interoperability Layer – due Month 20
  - FORTH will prepare D6.5.1 Security and Privacy of the Interoperability Layer for consortium review by **September 09, 2011**
  - All partners will provide comments by **September 16, 2011**
  - FORTH will update the document with partner’s reviews and provide a final release of D6.5.1 to be send to the Commission by **September 30, 2011**

5.5.1.6 WP7 Context Awareness and Clinically Useful Information Derivation

- D7.1.1 Personalized Follow-up Parameter Assistant – due Month 22
  - HCPB will prepare D7.1.1 Personalized Follow-up Parameter Assistant for consortium review by **November 11, 2011**
  - All partners will provide comments by **November 18, 2011**
  - HCPB will update the document with partner’s reviews and provide a final release of D7.1.1 to be send to the Commission by **November 30, 2011**

- D7.3.1 Security and Privacy of Context Awareness and Clinically Useful Information Derivation – due Month 20
  - OFFIS will prepare D7.3.1 Security and Privacy of Context Awareness and Clinically Useful Information Derivation for consortium review by **September 09, 2011**
All partners will provide comments by September 16, 2011
OFFIS will update the document with partner’s reviews and provide a final release of D7.3.1 to be send to the Commission by September 30, 2011

D7.2.1 Data Analysis and Correlation Tool – due Month 24
OFFIS will prepare D7.2.1 Data Analysis and Correlation Tool for consortium review by January 13, 2011
All partners will provide comments by January 20, 2011
OFFIS will update the document with partner’s reviews and provide a final release of D7.2.1 to be send to the Commission by January 27, 2011

5.5.2 Implementation Plans

5.5.2.1 WP4 Personalized Adaptive Care Planner for CIED Recipients

D4.3.1 CIED based Personalized Adaptive Care Planner Engine – due Month 26 and D4.4.1 Security and Privacy for Personalized Adaptive Care Planner – due Month 24
First prototype of Monitoring Tool by the end of August (M19)
Second Prototype of Care Plan Engine will be ready by the end of September (M20)
Integrating Monitoring tool, alarm manager, EHR Interoperability, Code Mapping API

- Alarm Management Interfaces
  - Adding Healthcare Actors
  - Adding their preferences to receive alarm messages
  - Urgent messages through SMS
  - Other messages through emails

- Monitoring GUI
  - Current implementation is not Medical Professional friendly
    - Java based implementation
    - It is designed for remote automatic care plan execution
    - Presents the care plan flow and consult and recommendation windows are implemented as pop-ups
  - We aim to create a wizard based care plan monitoring interface
    - Flex based Web Interface
• It will be possible to hide the care plan flow view, and present the consult and recommendation windows one after another in a consecutive way, that presents

• Brief Patient history (access to EHR documents)

• Brief history of previous care plan steps

• Brief history of the CIED alarm (access to CIED report)

• It will also be possible to see the results of previously executed care plans from a log interface

  Prerequisite: D6.4.1 Interoperability Infrastructure for Electronic Healthcare Records (Month 18)

☐ Third Prototype of Care Plan Engine by the end of November (M22)

  Integrating CIED Information System

  Prerequisite: D6.1.1 Exposing CIED Data through Standard Interfaces (Month 20)

☐ Security and Privacy for Personalized Adaptive Care Planner (Integration of ATNA with Guideline Engine) by the end of January 2012 (M24)

  Prerequisite: D6.5.1 Security and Privacy of the Interoperability Layer (Month 20)

☐ Final Version by the end of April 2012 (M26)

  Integration of PHR Interoperability, Security & Privacy

  Prerequisite: D6.3.1 Interoperability Infrastructure for Personal Health Records (Month 22)

5.5.2.2 WP5 Framework for Patient Empowerment

■ D5.1.1 Personal Health Record System – due Month 22

☐ Barcelona prototype will be ready by September 20, 2011 including

  Action Plan and calendar

  examples for Information material and decision aids

  Prerequisite: HCBP provides the content for these examples

  Authentication integration including PIX and SAML consumer

  Prerequisite: needs to be coordinated with FORTH

☐ Final prototype will be ready by November 30, 2011 including

  Administrative functions including the integration of the Consent Manager

  Final version of information material

  German version of the PHR system
D5.2.1 Patient Education for the PHR – **due Month 20**

- Final prototype will be ready by September 23, 2011
  - Prerequisite: HCPB and SALK will prepare German and English versions of the information and education material by June 30, 2011

D5.4.1 Patient Consent Management and Security – **due Month 20**

- Second prototype of Patient Consent Management and Security will be ready by the end of March (M19)
- Integration with Care Management Database
- Final version of Patient Consent Management and Security will be ready by the end of May (M20)

### 5.5.2.3 WP6 Interoperability Layer

D6.2.1 Interoperability Infrastructure for Electronic Healthcare Records – **due Month 18**

- July 15, 2011: FORTH/EHR-IF components are installed, manual messages are send to the HL7 listener and EDF listener. PIDS is installed and first version of the CDA editor. [Done]
  - Terminology of AF/VT in place
  - Manual testing of HL7 messages
  - Manual testing of EDF messages
  - Medical history and problems in CDA editor
- July 22, 2011: SRDC/Care planner is installed communication with EHR-IF achieved and tested. HL7 listener operotional no filtering.
  - Headings of EDF messages are operational
  - Medication of EDF messages is parsed
  - Option without filtering of HL7 message based on IDs is implemented
- June 29, 2011: FORTH/EHR-IF works with filtering of messages based on ID:
  - Terminologies are collected to the Code API
  - Work with Code API live
- August-September
  - Security components are installed
  - Work on the second version of the listeners which will attempt to recognize larger parts of the document.
- September December:
  - Develop 3rd version of the EDF message to recognize further content.
  - Develop scalable, interoperability solutions that can be transferred to other settings (geographics, national, etc).
  - Further configure, fine tune, and test the EHR-IF components

D6.1.1 Exposing CIED Data through Standard Interfaces – **due Month 20**
- OFFIS provides third functional prototype including test cases and test case documents for integration tests by Month 19 (31. August 2011)
- The final prototype will be ready and integrated into the iCARDEA framework at SALK by Month 20 (30. September 2011)
  - Prerequisite: DMZ Server is available at SALK

- D6.3.1 Interoperability Infrastructure for Personal Health Records – due Month 22
  - Barcelona prototype will be ready by September 20, 2011 including
    - Improvements for the query (user specific queries) and messaging
  - Final prototype will be ready by November 30, 2011 including
    - EHR interoperability for patient documents, e.g. medical reports, based on HL7v3/CDA

- D6.5.1 Security and Privacy of the Interoperability Layer – due Month 20

  - Assemble requirements from iCARDEA components & evaluate the suitability of IHE security infrastructure (e.g. ATNA) [Month 17] [Done]
  - Prepare an initial template with requests for contributions by partners developing iCARDEA components [Month 18]
  - Comments and Contributions by iCARDEA partners [Month 19]
  - Amended version out to partners by Comments [Month 20]
  - Revised version to be submitted to the EC [Month 20.]

5.5.2.4 WP7 Context Awareness and Clinically Useful Information Derivation

- D7.1.1 Personalized Follow-up Parameter Assistant – due Month 22 and D7.3.1 Security and Privacy of Context Awareness and Clinically Useful Information Derivation – due Month 20

  - OFFIS provides first functional prototype by Month 19 (30. August 2011)
    - HCPB / SALK provides input on the usability
    - Prerequisite: The required data interfaces are provided
  - OFFIS provides second prototype together with the implanted security and privacy concepts by Month 20 (30. September 2011)
  - The final prototype is ready and integrated into the iCARDEA framework at SALK by Month 22 (30. November 2011)
  - OFFIS will send the list of inputs that they have been working on with HCPB to whole consortium, and each partner will comment on it by February 28, 2011
    - Then OFFIS and FORTH teams need to make sure that these data are available from the PDF reports of CIED devices and in the HIS of SALK, and these data are sent to the Care Plan Engine through IDCO and CM messages, so that they can be stored in the Care Management DB (15. August 2011)
D7.2.1 Data Analysis and Correlation Tool – *due Month 24* and D7.3.1 Security and Privacy of Context Awareness and Clinically Useful Information Derivation – *due Month 20*

- OFFIS evaluates available data at HCPB for potentially usefulness at pattern extraction process and with respect to the usefulness at the pilot scenario. Month 20 (30. September 2011)
  - OFFIS and HCPB clarify if the data is available in a computer interpretable format and should be used for data analysis (30. September 2011)
- Old cases data from HCPB HIS are extracted and integrated into the analysis database according to Security and Privacy laws (15. February 2012)
  - HCPB provides extracted old cases data from HCPB HIS according to Security and Privacy laws (15. December 2011)
    - Prerequisite: There was an agreement to use HCPB data and D7.3.1 (OFFIS and HCPB) were able to clarify the needed legal regulations (30. November 2011)
  - OFFIS integrates the data into the analysis database according to Security and Privacy laws (15. February 2012)
- OFFIS provides patterns based on HCPB data (28. February 2012)
- OFFIS provides first prototype with research results by Month 19 (31. August 2011) based on SALK data
  - HCPB / SALK will provide input on the obtained results.
- OFFIS provides the second prototype together with the implanted security and privacy concepts and results from D7.3.1 by Month 21 (31. October 2011)
  - HCPB / SALK will provide last comments on the used data, algorithms and patterns.
- The final prototype is ready and integrated into the iCARDEA framework at SALK by Month 24 (31. January 2012)
- Despite the fact that the database in consequence of its origin and kind of patients with high feasibility will not produce analysis results that are usable at the iCARDEA environment OFFIS reevaluates the Physionet Datasources with the goal to obtain more patient data from a clinical dataset.
- Clinical Database from Physionet were obtained and integrated into the analysis database according to Security and Privacy (30 September 2011)
  - Prerequisite: D7.3.1 OFFIS were able to clarify the needed legal regulations with Physionet (31.08.2011)
- D7.3.1 OFFIS and HCPB clarify the needed legal regulations to use the old cases data from HCPB
  - D7.3.1 OFFIS and HCPB make a first check of potential regulations (31. August 2011)
  - D7.3.1 OFFIS and HCPB clarify the needed legal regulations (30. November 2011)
Prerequisite: D7.2.1 OFFIS and HCPB clarify if the data is available in a computer interpretable format and should be used for data analysis (30. September 2011)

D7.3.1 OFFIS clarify the needed legal regulations to use the clinical databases from Physionet (31. August 2011)

Prerequisite: OFFIS found a clinical dataset for data analysis at Physionet (31.07.2011)

5.5.2.5 WP8 iCARDEA Testing and Validation Framework

D81.2 Test and Evaluation Report for iCARDEA Components - due Month 28

General template

- Functional Test cases submitted by partners (M19)
- Bilateral tests 1st phase (initial) (M14)
- Bilateral tests 2nd phase (coding systems, PIX) (M16)
- Unit test reports submitted (M18)
- Reliability tests (M20)
- Maintainability tests (M22)
- Portability tests (M22)
- Efficiency tests (M23)
- Bilateral tests 3rd phase (security & privacy) (M24)
- Usability tests (M24, M26)
- Final report for testing and evaluation of iCARDEA components (M26-M28)

Test and Evaluation Schedule –SRDC-FORTH-SRFG

- SRDC Functional Test cases submitted by SRDC (M19)
- SRFG Unit Test reports (PHRS system: patient feedback mechanisms:) (M19)
- SRDC/FORTH Bilateral tests (Care Plan Engine- Code Mapping API, PIX) (M19)
- SRDC Unit test reports submitted for Code Mapping API and Care Plan Definition Tool (M16) [Delivered]
- FORTH Unit test reports submitted (EHR IF) (M18)
- SRDC/FORTH Bilateral Test (Care Plan Engine – EHR Interoperability) M19
- SRFG Functional & Component tests (PHRS system modules, inter-component tests for patient feedback and education mechanisms) (M20)
- FORTH Reliability tests (EHR IF M20)
- SRFG Unit Test reports (PHRS system: patient education mechanisms) (M20)
- SRDC/OFFIS Bilateral Test (Care Plan Engine – CIED Information System) M20
- SRDC Unit Test report submitted for the Consent Management System (M20)

---

9 This tentative plan will be revised within the evaluation team and with input from OFFIS. Additional information will be added on the preparation of test data/error reports, etc.
- SRDC/SRFG Bilateral Test (Care Plan Engine – PHR Interoperability) M22
- FORTH Maintainability tests (EHR IF M22)
- FORTH Portability tests (EHR IF M22)
- SRFG/FORTH Bilateral tests (PHRS Interoperability - EHR Interoperability) (M22)
- SRFG/SRDC Bilateral tests (PHRS modules – Consent Manager Module) (M22)
- SRFG Functional & Component test reports (PHRS system modules, inter-component tests) (M22)
- SRFG Unit Test reports (PHRS system modules) (M22)
- FORTH Efficiency tests (EHR IF M23)
- FORTH Bilateral tests 3rd phase (security & privacy) (EHR IF et al M24)
- SRDC/FORTH Bilateral tests (Care Plan Engine -Security & privacy of Interoperability Architecture) (M24)
- SRDC Unit Test submitted for the Care Plan Engine (M26)
- SRDC Reliability tests, Maintainability tests, Portability tests, Efficiency tests, Usability tests
  - SRDC Code Mapping API, Care Plan Editor, Consent Management System (M22)
  - SRDC Care Plan Engine (M26)

☐ Test and Evaluation Schedule – OFFIS
- Task 7.1 Patient Parameter Monitor Due Month 22
  - Bilateral test of PPM with caremangementDB Month 19
  - Usability test Month 19
  - Definition of test patterns and patient test cases Month 20
  - Bilateral test of PPM functional Prototype with caremangementDB Month 20
  - Portability tests, Efficiency tests Month 21

- Task 7.2 Data Analysis and Correlation Tool Due Month 24
  - Definition of test patterns and patient test cases Month 20
  - Efficiency tests for data analysis Month 21
  - Bilateral test with caremangementDB Month 21
  - Usability tests for Patient Pattern System Month 22
  - Unit test reports supported for Patient Pattern System Month 22
  - Portability tests for Patient Pattern System Month 23

5.5.2.6 WP9 iCARDEA Pilot Application

- T9.3
  - SALK records feedback from patients and physicians about the iCardea prototype based on the questionnaire by August 31, 2011.

5.5.2.7 Updates regarding D4.1.1
The AF Care Plan will be updated by SRDC, HCPB and SALK based on the information available in D4.2.1, in particular:

- HAS-BLED Score will be added
- Drug Interactions Causing Arrhythmias presented in Table 17 will be integrated to the AF Care Plan
6 EXPLANATION OF THE USE OF RESOURCES

This section presents the resources used in the project. Details of resources spent by each partner are given.

6.1 Resources distribution among the partners:

<table>
<thead>
<tr>
<th>Partner</th>
<th>Allocated Share in Advance Payment</th>
<th>Allocated Share in First Payment</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRDC</td>
<td>€ 292,697.25</td>
<td>€ 196,072.04</td>
</tr>
<tr>
<td>OFFIS</td>
<td>€ 217,645.19</td>
<td>€ 145,796.16</td>
</tr>
<tr>
<td>SRFG</td>
<td>€ 218,413.69</td>
<td>€ 146,310.96</td>
</tr>
<tr>
<td>FORTH</td>
<td>€ 171,495.51</td>
<td>€ 114,881.42</td>
</tr>
<tr>
<td>SALK</td>
<td>€ 88,508.08</td>
<td>€ 59,289.79</td>
</tr>
<tr>
<td>SJM</td>
<td>€ 66,431.81</td>
<td>€ 44,501.34</td>
</tr>
<tr>
<td>Medtronic</td>
<td>€ 66,352.06</td>
<td>€ 44,447.92</td>
</tr>
<tr>
<td>HCPB</td>
<td>€ 106,043.42</td>
<td>€ 71,036.37</td>
</tr>
<tr>
<td>Total</td>
<td>€ 1,227,587.00</td>
<td>€ 822,336.00</td>
</tr>
</tbody>
</table>

Table 2 Payment allocation for the Contractors

6.2 Summary per partner

<table>
<thead>
<tr>
<th>Partner</th>
<th>Person-month spent</th>
<th>Total person-month in budget</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRDC</td>
<td>6.936</td>
<td>82.750</td>
</tr>
<tr>
<td>OFFIS</td>
<td>19.53</td>
<td>65.5</td>
</tr>
<tr>
<td>SRFG</td>
<td>12.32</td>
<td>56.6</td>
</tr>
<tr>
<td>FORTH</td>
<td>13.175</td>
<td>53.6</td>
</tr>
<tr>
<td>SALK</td>
<td>1.40</td>
<td>23.85</td>
</tr>
<tr>
<td>SJM</td>
<td>2.5</td>
<td>18.1</td>
</tr>
<tr>
<td>Medtronic</td>
<td>4.68</td>
<td>20.2</td>
</tr>
<tr>
<td>HCPB</td>
<td>8.7</td>
<td>32.5</td>
</tr>
<tr>
<td>Total</td>
<td>69.241</td>
<td>353.4</td>
</tr>
</tbody>
</table>

Table 3 Summary of the efforts spent in the last six months
<table>
<thead>
<tr>
<th>WP</th>
<th>SRDC</th>
<th>OFFIS</th>
<th>SRFG</th>
<th>FORTH</th>
<th>SALK</th>
<th>SJM</th>
<th>Medtronic</th>
<th>HCPB</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>WP1</td>
<td>1.714</td>
<td>0.00</td>
<td>0.3</td>
<td>0.015</td>
<td>0.30</td>
<td>0.2</td>
<td>0.14</td>
<td>0</td>
<td>2.669</td>
</tr>
<tr>
<td>WP2</td>
<td>0</td>
<td>1.00</td>
<td>0.08</td>
<td>0.5</td>
<td>0.00</td>
<td>0.3</td>
<td>0.86</td>
<td>0.5</td>
<td>3.24</td>
</tr>
<tr>
<td>WP3</td>
<td>0</td>
<td>0.00</td>
<td>0</td>
<td>0</td>
<td>0.20</td>
<td>0.1</td>
<td>0.05</td>
<td>0.2</td>
<td>0.55</td>
</tr>
<tr>
<td>WP4</td>
<td>0.822</td>
<td>0.00</td>
<td>0.25</td>
<td>0</td>
<td>0.00</td>
<td>0.5</td>
<td>0.31</td>
<td>2</td>
<td>3.882</td>
</tr>
<tr>
<td>WP5</td>
<td>2.182</td>
<td>0.00</td>
<td>5.19</td>
<td>0</td>
<td>0.10</td>
<td>0.1</td>
<td>0.42</td>
<td>3</td>
<td>10.992</td>
</tr>
<tr>
<td>WP6</td>
<td>1.789</td>
<td>7.50</td>
<td>4.03</td>
<td>8</td>
<td>0.00</td>
<td>0</td>
<td>1.69</td>
<td>0.5</td>
<td>23.509</td>
</tr>
<tr>
<td>WP7</td>
<td>0</td>
<td>9.53</td>
<td>0</td>
<td>0</td>
<td>0.30</td>
<td>0</td>
<td>0.20</td>
<td>1.5</td>
<td>11.53</td>
</tr>
<tr>
<td>WP8</td>
<td>0</td>
<td>1.00</td>
<td>1.21</td>
<td>4.36</td>
<td>0.20</td>
<td>0.3</td>
<td>0.22</td>
<td>0.5</td>
<td>7.79</td>
</tr>
<tr>
<td>WP9</td>
<td>0.429</td>
<td>0.50</td>
<td>1.26</td>
<td>0.3</td>
<td>0.30</td>
<td>1.0</td>
<td>0.79</td>
<td>0.5</td>
<td>5.079</td>
</tr>
<tr>
<td>TOTAL</td>
<td>6.936</td>
<td>19.53</td>
<td>12.32</td>
<td>13.175</td>
<td>1.40</td>
<td>2.5</td>
<td>4.68</td>
<td>8.7</td>
<td>69.241</td>
</tr>
</tbody>
</table>

Table 4 Person Month Values Spent for this period
7 Appendix 1: Minutes of February 08-09, 2011 Hamburg Technical Meeting

7.1 PARTICIPANTS

- Gokce Banu Laleci Erturkmen (SRDC)
- Yildiray Kabağ (SRDC)
- Elena Arbelo (HCPB)
- Maohua Yang (OFFIS)
- Christian Lüpkes (OFFIS)
- Marco Eichelberg (OFFIS)
- Catherine Chronaki (FORTH)
- Ioannis Petrakis (FORTH)
- Erik Vossius Irshaid (SALK)
- Lynne Hinterbuchner (SALK)
- Manuela Plößing (SRFG)
- Bob Mulrenin (SRFG)
- Mihai Radulescu-Kobler (SRFG)
- Bernhard Pfeifer (SJM)
- Duarte Fernandez (Medtronic)

7.2 AGENDA

February 08, 2011, Tuesday

<table>
<thead>
<tr>
<th>Time</th>
<th>Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>09:00</td>
<td>Welcome - Opening Remarks (SRDC)</td>
</tr>
<tr>
<td>09:15</td>
<td>Pilot Application Scenario description (SALK)</td>
</tr>
<tr>
<td></td>
<td>Current Status and action plan for the “Design of Pilot application deployment” (SRFG)</td>
</tr>
<tr>
<td>09:45</td>
<td>Discussion of the Implementation interfaces of first iCARDEA Prototype</td>
</tr>
<tr>
<td></td>
<td>- Going over the guideline flow for pilot application scenario (SRDC)</td>
</tr>
<tr>
<td></td>
<td>- EHR Interoperability architecture required for this pilot (CDA document prepared)</td>
</tr>
<tr>
<td></td>
<td>- CIED Interoperability architecture required for this pilot (Sample PDF reports and/or DB structure for storing CIED data)</td>
</tr>
<tr>
<td>10:40</td>
<td>Coffee Break</td>
</tr>
<tr>
<td>11:00</td>
<td>Status of Personalized Adaptive Care Plan Definition Tool, demonstration of first prototype (SRDC)</td>
</tr>
<tr>
<td>11:20</td>
<td>Status of Task 4.3 CIED based Personalized Adaptive Care Planner Engine, demonstration of first prototype</td>
</tr>
<tr>
<td>11:40</td>
<td>Results of Task 4.2.1 Integrative Risk Assessment Model (HCPB)</td>
</tr>
<tr>
<td>12:00</td>
<td>Lunch Break</td>
</tr>
<tr>
<td>13:00</td>
<td>Status of Task 5.1 Personal Health Record System, demonstration of first prototype (SRFG)</td>
</tr>
<tr>
<td>13:20</td>
<td>Status of Task 5.3 Patient Feedback, demonstration of first prototype (SRFG)</td>
</tr>
<tr>
<td>13:40</td>
<td>Status of Task 5.2 “Patient Education for the PHR”, demonstration of first prototype (HCPB &amp; SALK &amp; SRFG)</td>
</tr>
<tr>
<td>14:00</td>
<td>Status of Task 5.4 Patient Consent Management and Security, demonstration of first prototype (SRDC)</td>
</tr>
<tr>
<td>14:20</td>
<td>Status of Task 6.1 Exposing CIED Data through Standard Interfaces, demonstration of first prototype (OFFIS)</td>
</tr>
</tbody>
</table>
### 7.3 MINUTES

Gokce (SRDC) opened the project meeting, welcomed the participants to the meeting and explained the agenda. The main aim of the first day of the meeting was to review the progress in each WP and on the second day parallel sessions on various technical topics will take place.

**Current Status and action plan for the “Design of Pilot application deployment” (SRFG)**

#### 14:40
Coffee Break

#### 15:00
<table>
<thead>
<tr>
<th>Time</th>
<th>Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:00</td>
<td>Status of Task 6.2 Providing interoperability with EHRs, demonstration of first prototype (FORTH)</td>
</tr>
<tr>
<td>15:20</td>
<td>Status of Task 6.3 Providing interoperability with PHRs, demonstration of first prototype (SRFG)</td>
</tr>
<tr>
<td>15:40</td>
<td>Status of Task 6.4 Code Mapping among Healthcare Code Systems, demonstration of first prototype (SRDC)</td>
</tr>
<tr>
<td>16:00</td>
<td>Status of Task 6.5 Security and Privacy of the Interoperability Layer demonstration of first prototype (FORTH)</td>
</tr>
<tr>
<td>16:20</td>
<td>Status of Task 7.1 Determining on Patient Parameters to be Monitored for Personalized Follow-up (HCPB, OFFIS)</td>
</tr>
<tr>
<td>16:40</td>
<td>Status of Task 7.2 Correlating Patient Specific Data with Established Knowledge Bases (OFFIS)</td>
</tr>
<tr>
<td>17:00</td>
<td>Dissemination Activities (HCPB)</td>
</tr>
<tr>
<td>17:15</td>
<td>IPR Issues (Medtronic &amp; St.Jude)</td>
</tr>
<tr>
<td>17:30</td>
<td>Adjourn</td>
</tr>
</tbody>
</table>

February 09, 2011, Wednesday

#### Time | Issue
--- | ---
09:30 | Ethical Issues Training (SALK)
10:30 | Status of Task 8.1 Functional Tests and End-User Validation of iCARDEA Components (FORTH)
10:45 | Coffee Break
11:00 | Action Plan, Plans for iCARDEA Review Meeting and Exploitation Plan next steps (SRDC)
11:45 | Remaining Issues and Open Discussion
12:15 | Lunch Break
13:00 | Parallel Sessions:
   - Hand-on Integration of Adaptive Care Planner, EHR Interoperability and CIED Interoperability Prototypes, PHR Interoperability Prototypes (SRDC, OFFIS, FORTH, SRFG)
   - WP7 Meeting (OFFIS & SALK)
   - Discussion on open issues for Pilot deployment (All partners except coders)
14:40 | Coffee break
17:30 | Adjourn
After that Manuela (SRFG) presented the current status and the action plan for the design of the pilot application deployment in the scope of Task 9.2. She emphasized the need for including all the components of iCARDEA to the pilot application scenario and described the components to be included which are mainly PHR, EHR and Care Planner. She stated that one demonstration scenario is not sufficient and an additional demonstration scenario is necessary where e.g. a female patient with moderate sport activities exists. The careplan to be applied will be VT careplan and data analysis should also be applied in the scenario. Catherine stated that the “sport” keyword should be detailed (e.g. what kind of sport the patient does). Catherine also expressed the need for the social properties such as the family, friend and home situations of the patient. It is agreed to replace the term "sports" by "physical activity" or "fitness". Gokce stated that the code mapping should also be included to the scenario, because the systems may use different code systems. It is also discussed whether the brand names of the drugs or the active ingredient of the drugs should be presented in the scenario. At this point Gokce presented that to execute the scenario they also need to access the classes of each drug. It is agreed that such tables will be available in care management database, and we can concentrate only on the mappings of local names/codes of a subset of drugs relevant to our care plans to standardised coded representations of drugs and drug classes. She also stated that the epSOS project is currently working on an extensive mapping of the various national drug databases using coding schemes. iCARDEA can make use of the outcomes of the epSOS project.

Lynne, Manuela, Catherine and Gokce will prepare a draft of this additional scenario that will be circulated to the partners. Christian asked the due date for the scenario. Gokce told that the scenario will be delivered as a part of D9.2.1 at the end of May 2011. For this purpose, at the end of February 2011 SRFG will provide a template to the consortium for D9.2.1. In this respect, Manuela presented the action plan for the deliverable. Gokce, at this point, stated that the deliverable should include all the deployment (setup) details (which system will be used, will there be a firewall?) in the SALK premises. For this purpose, Eric and Axel from SALK will provide necessary details. Manuela and Gokce said that if there is a change in the requirements deliverable (or any other deliverables) it should be informed as soon as possible, the deliverable should be finalized latest at the end of May 2011.

Discussion of the Implementation interfaces of first iCARDEA Prototype

After Manuela’s presentation, Gokce presented the pilot application scenario and the careplan flow. The demonstration scenario is about a cardiac patient who experienced a sudden death and was resuscitated. The patient is implanted a CIED device and the AF careplan is applied with the help of iCARDEA system. At this point, Lynne (SALK) discussed where the iCARDEA system should exist in a hospital. Erik stated that the iCARDEA can be a part of Hospital Information System. Catherine asked the information content concerning the medication list that should be exchanged between the EHR, PHR and HIS of SALK. Gokce presented that in the care plan the requirement of retrieving the active medication list from the HIS through the EHR System is identified; on top of this, it is also necessary to keep track of the medication compliance through the PHR system. For this reason, PHR system needs to retrieve the currently active medication list from the HIS through the EHR Interoperability system and should allow the patient to update it (such as dose change, medication change). PHR System is going to use free text while specifying the name of a new medication. Gokce, stated that FORTH needs to communicate with SALK to resolve how medications are actually stored in SALK HIS. Lynne said that all countries have their own medication lists. Catherine also asked whether it is in the scope of the careplan to for example schedule a dentist (medical professional). Gokce presented that in the AF careplan, such an interaction is added to demonstrate the capabilities of PHR system. After that Gokce presented all the possible dynamic graphical user interfaces (GUI) within the execution of the AF careplan. It is also decided that the AF careplan is rather long and may be difficult to follow by
the reviewers. Therefore, one page of manual/summary showing the flow would be beneficial and the consortium will prepare such a manual. Furthermore, different possible flows (paths) in the AF careplan will be prepared by the consortium. Finally, it is decided that further information will be provided how the AF careplan is executed within a hospital if iCARDEA does not exist.

Status of Task 6.1 Exposing CIED Data through Standard Interfaces, demonstration of first prototype (OFFIS)

After the coffee break, Maohua Yang (OFFIS) presented the CIED information requirements. He also presented the PDF document from where the information items can be acquired. The process he applied is as follows: He first mapped the information items identified in Deliverable 4.1.1 to the PDF files from Medtronic (St.Jude is already able to generate IHE IDCO messages). After that he generated the HL7 messages for the PDF reports. He said that he achieved some preliminary PDF data extraction. Concerning the images, they are extracted from the PDFs as bitmap images. He stated that there are some problematic cases and Gokce recommended that he prepares a list of them and email to Medtronic. Furthermore, Maohua stated that the impedance (in ohms) should be included somewhere in the report, and this can be used to determine what the problem with the lead is. Time in AT/AF should be also available for each AT/AF episode. In addition, SJM will check if an export of an XPDF containing more meta-data in the form could be possible, because this will make parsing the PDF easier. Finally, concerning the patient id reconciliation, the IHE PIX will be used and it will be the responsibility of FORTH. The consortium decided to create an application where the patients, including HIS Patient ID, protocol ID, and ICD serial number would be added manually. Behind that will be a PIX manager that can be queried e.g. by the CIED data exposure component. OFFIS will take the CIED serial number and perform a PIX lookup based on this number, and receive the HIS patient ID and the iCARDEA protocol ID, which then need to be placed into the HL7 IDCO message.

Results of Task 4.2.1 Integrative Risk Assessment Model (HCPB)

After Maohua’s presentation, Elena Arbelo (HCPB) presented the results of Task 4.2.1 integrative risk assessment model for each of the careplans developed within the scope of iCARDEA (AF, VT and technical). Gokce stated that most of the risks are already integrated in the careplans. In other words, they are handled in the careplans. Elena mentioned that it would be better to include HAS-BLED bleeding score to the AF careplan. For this purpose, she will provide necessary flow and description. Furthermore, considering the use of Beta Blocker, the medical professional should be alerted. For example, before prescribing Digoxin, whether the patient receives Sotalol or not should be checked. Elena will provide necessary flow and information for this. Finally it is decided that the drug Interactions causing Arrhythmias presented in Table 17 of D4.2.1 will be integrated to the AF Care Plan. SRDC will try to integrate this and ask the unclear points to Elena.

Dissemination Activities (HCPB)

Elena presented the dissemination activities and provided the upcoming cardiac related conferences to the consortium. Lynne presented that she will submit an abstract to 2011 Annual Spring Meeting on Cardiovascular Nursing. It is discussed that Elena and Lynne will submit abstracts to ESC 2011. They advised that it is also possible to submit a technical abstract to this conference (Track 9.12 "internet and telemedicine"), Catherine will check this option. Gokce presented that they plan to submit an abstract to eChallenges 2011 related with the Consent Editor Tool. Catherine presented that they are planning to submit a paper to IHIC 2011.
Status of Task 5.2 “Patient Education for the PHR”, demonstration of first prototype (HCPB & SALK & SRFG)
After the lunch Elena presented the kinds of education material that can be added to PHR for patient education. It is mentioned that besides documents and videos and links to external material or social websites, there will be also decision aids for specific decision situations in the PHR. Lynne will provide German version of the material. It is decided that SIM and Medtronic will check whether we can use the already existing education material of SJM and Medtronic for the patients in PHR.

Status of Personalized Adaptive Care Plan Definition Tool, demonstration of first prototype (SRDC) and Status of Task 4.3 CIED based Personalized Adaptive Care Planner Engine, demonstration of first prototype
Gokce presented the current version of the Adaptive Care Plan Definition Tool, whose due date is at the end of May 2011. She demonstrated the current implementation. After the presentation, Gokce demonstrated the Care Plan Engine with AF careplan. Duarte asked whether the care plan is working automatically. Gokce presented that in Istanbul meeting, it is decided that in each decision point the care plan needs to consult the medical professional by presenting the available information and possible options, leaving the decision to the medical professionals. It is clarified that after getting an alert message from the CIED System, the medical professional will initiate the execution of the care plan.

Status of Task 5.1 Personal Health Record System and Task 5.3 Patient Feedback, demonstration of first prototype (SRFG)
Afterwards, Manuela, Bob and Mihai presented the current version of the Personal Health Record which is in the scope of Task 5.1. Bob mentioned that they will implement their system based on portal and portlet technology. For this purpose, they will use WSRP (Web Services for Remote Portals) standards. Bob demonstrated the current version of the PHR implementation as a Web Portal. Mihai presented that they decided to store their codes in a GIT system. Yildiray asked him to upload their stable versions to iCARDEA’s SVN repository. Mihai also presented that the PHRS Security Module needs to be integrated with the Consent Editor and Consent Manager developed by SRDC.

Status of Task 6.4 Code Mapping among Healthcare Code Systems, demonstration of first prototype (SRDC)
After Mihai’s presentation, Gokce presented the Consent Editor. In her presentation, she demonstrated the current version of the tool as well. In the demo, she created a sample consent rule and generated XACML document of the rule. Marco stated that the user should not need to download the XACML document manually. Yildiray explained that SRDC already defined the mechanisms to integrate the Consent Editor to PHR system and the entire grant of accesses will be transparent to the patient.

Status of Task 6.2 Providing interoperability with EHRs, demonstration of first prototype (FORTH)
Yannis presented the status of task 6.2 which is providing interoperability with EHR and demonstrated the current version of their implementation. He stated that the EHR implementation will finish at the end of July 2011. He presented that the PIX Manager, the XDS Registry and Repository and Subscribe/Update Services are almost completed. Future actions are noted as the implementation of CDA Converter, and XPHR protocol. Gokce had a remark at this point. The FORTH team should work closely with SALK team considering their interoperability tool needs to be communicating with the SALK HIS
System. Catherine presented that they are planning a meeting with SALK in March 2011, after this they may have a second one if needed. Christian stated that for their Patient Parameter Monitor component they will use SRDC’s Care Management DB. Considering the PID reconciliation, PID Feed transaction will not be used. It is also discussed that the PIDs will be entered manually through a Web Form and OFFIS will implement a PIX client only.

**Status of Task 6.3 Providing interoperability with PHRs, demonstration of first prototype (SRFG)**

Mihai presented the current achievements in the task 6.3 providing interoperability with PHRs and demonstrate the current implementation. Bob stated that there are some vague points in PCC9 and PCC10 queries. Catherine and Marco said that it would be very beneficial if iCARDEA provides a best practice document to IHE with identified problems using the IHE profiles. This will also improve the dissemination of the project. Marco presented that a good way to realize this is through the open mailing list. Mihai will start a resource page on this.

**Status of Task 6.4 Code Mapping among Healthcare Code Systems, demonstration of first prototype (SRDC)**

Gokce presented the current version of the Code Mapping System and the achievements for Task 6.4. The system is based on UMLS system and HL7 Common Terminology Services. In other words, the system exposes the UMLS data in a standard (HL7) format. Catherine asked whether the GLIMSS coding system (used in SALK) is included. Gokce replied that the local coding systems are not included but they can be inserted to the system manually. Christian asked whether it is possible to translate the codes to different languages. Marco said that ICD10 and SNOMED may have but not all of terminologies provide codes for different languages. SRDC will check whether German-language versions of the UMLS terminologies are available in SRDC local installation. Marco asked whether the web services provided by the UMLS project on the Internet are used, Gokce clarified that the UMLS resources are installed locally on a machine of SRDC.

**Status of Task 6.5 Security and Privacy of the Interoperability Layer demonstration of first prototype (FORTH)**

Catherine presented the status of Task 6.5 Security and Privacy of the Interoperability Layer demonstration of the first prototype. This task will end at the end of Month 20 and Catherine provided the corresponding time table to achieve this goal. She outlined that the first action will be identification of the requirements for the Security and Privacy of the Interoperability Layer. Partners will need to provide FORTH with their security requirements for their components and the overall application. FORTH will provide the necessary templates and instructions for this action in March 2011.

**Status of Task 7.1 Determining on Patient Parameters to be Monitored for Personalized Follow-up (HCPB, OFFIS) and Task 7.2 Correlating Patient Specific Data with Established Knowledge Bases (OFFIS)**

After that Christian explained the status of Task 7.1 which is on determining on patient parameters to be monitored for personalized follow-up. Christian presented the updated list of patient parameters to be monitored and will provide the patient parameters to the consortium as well and the consortium will send back their comments. Gokce presented that OFFIS and FORTH teams need to make sure that these data are available from the PDF reports of CIED devices and in the HIS of SALK, and these data are sent to the Care Plan Engine through IDCO and CM messages, so that they can be stored in the Care Management DB.
Catherine questioned how and when this Patient Parameter Monitoring Tool can be used. It has been clarified, it could be used during regular in clinic monitoring sessions, and also Care Plan Engine can use this tool as a part of Monitoring Tool to present a coherent view of patient parameters when necessary.

Regarding Task 7.2 and 7.3, Christian presented that finally an agreement between SALK and OFFIS is established about the use of anonymized patient data for data analysis. Also mock-ups for the Data Analysis tool are presented by Christian and the identified patient values and questions to be answered by data analysis. Christian also explained the steps of needed quality assurance and the research on problems of analysis spanning a longer time period.

**IPR Issues (Medtronic & St.Jude)**
In the second day of the meeting, Duarte (Medtronic) and Bernhard (St.Jude) presented on Task 2.3.1 Intellectual Property Rights Issues. It is clarified that when publications are disseminated, it is not possible to get the results patented. Marco stated that in Europe the algorithms cannot be patented. However, Bernhard mentioned that the algorithm to be developed in the data mining part of iCARDEA or the careplans (AF, VT, technical) can be patented because they are used in a workflow. Mihai asked what about the open source community because most of the iCARDEA components will be shared as open source libraries. Bernhard said that if iCARDEA uses its own SVN and do not publish it then in any case the results can be patented. Gokce stated that the consortium should identify each patentable feature of iCARDEA case-by-case basis. Marco said that the European patents are very expensive (20,000-30,000 EU). Erik stated that maybe protection by utility patent (Gebrauchsmusterschutz), which is common in Germany, can be used and these types of patents are about 1000 Euro.

It is agreed that if a topic is of interest to everybody iCARDEA mailing lists will be used. Otherwise bilateral communications will be preferred. SRDC requested to be copied to these bilateral discussions to keep track of project developments.

**Ethical Issues Training (SALK)**
Lynne presented the Ethical Issues by presenting Good Clinical Practice guidelines to the consortium. Gokce asked the status of the Ethical Approval of iCARDEA Pilot application. Lynne presented that they have already presented the pilot application to the Ethical Committee and initial approval is taken; now Lynne is preparing the protocol which will be ready by next week to be presented to the Ethical Committee. Catherine asked about the inclusion of patient representative groups. Duarte and Lynne said that these groups only provide patients to studies and they are not directly involved in such clinical studies.

**Status of Task 8.1 Functional Tests and End-User Validation of iCARDEA Components (FORTH)**
Yannis (FORTH) presented the status of Task 8.1: Functional Tests and End-User Validation of iCARDEA Components. He presented the evaluation strategy and the steps to be executed by the consortium. Gokce stated that by Month 16 some of the components will not be completed. Therefore the unit test phase may not be completed, but the consortium should do their unit tests on the already implemented version of the components. Marco stated that reliability test, portability tests, usability tests are too much for a research prototype, but not unit tests. This would increase the development effort by a factor of, perhaps, 5 (20% development, 80% testing), which the consortium cannot afford. Therefore iCARDEA may not require efficiency, portability and maintainability tests because the iCARDEA develops a prototype. Gokce stated that actually the unit tests and functionality tests can be performed fully and the rest of the tests can be realized not in a very detailed manner. Bernhard also supported the idea and will send an email detailing the test procedure. Marco presented the cmake tool that is used for monitoring the
testing of C++ based projects and stated that it would be better to use such a tool. **SRDC and FORTH will collaborate on this topic and provide a continuous integration server.** The consortium will provide a time table for the testing of their components and also will provide sample messages to be used in the tests. Mihai mentioned about two tools Test Unit and Test Engine. He stated that he will used junit for unit testing and Test Engine for integration testing. **He will provide an email detailing his ideas.** Catherine requested to form testing groups and also the vendor partners (Medtronic and St.Jude) to join to these groups. **The consortium will build these evaluation groups until February 15th.** Marco will contact IHE to request the relevant test cases/data that are used in Connectathons, to be used as a starting point for iCARDEA integration testing, the relevant profiles are IDCO, XDS, CM, XPHR, with the understanding that any further tests produced will be shared with the relevant IHE committees. SRDC, OFFIS, SRFG will provide the testing schedule for their components (Feb 18), to be consolidated in a unified testing plan, by FORTH (March 15).

**Action Plan, Plans for iCARDEA Review Meeting and Exploitation Plan next steps (SRDC)**

After Yannis’ presentation Gokce presented the action plan for the next six months. The Action Plan is presented as an Annex to this document. Marco recommended adding a couple of IPR related slides to the slides to be prepared for the review meeting. Manuela requested to add PHR feedback mechanisms slides. Gokce recommended adding a couple of backup slides for Patient Education as well. OFFIS will prepare backup slides for CIED interoperability and SRFG will prepare PHR Interoperability backup slides. FORTH will prepare backup slides for EHR Interoperability, Security of Interoperability and OFFIS will prepare backup slides for Patient Parameter Monitoring. SRFG will prepare slides for Pilot Application Design. Medtronic will prepare the IPR slide. SRFG will decide whether they can demonstrate a PHR prototype. **SRDC will lead the storyboarding activity and preparation of the leaflet and it will be ready by the beginning of April 2011. For the review meeting demonstration, virtual machines (may be in different machines) will be installed. SRDC will coordinate this task.**

Next meeting can be together with ESC and MIE events on 28-31 August 2011. Alternatively a meeting to be hosted by HCPB in early September is discussed as a possibility. A **doodle poll will be opened.**

A copy of the action plan discussed is attached.

**SRDC-OFFIS Bilateral Meeting:**

Two issues were identified in the messages provided by Maohua:

1. One deprecated MDC_IDC element is identified. The element belongs to the prior versions of the nomenclature. It is informed to St.Jude as well.
2. For the Observation Sub IDs, integer (incrementing) will be used.

**Maohua will send the CIED messages based on the demonstration scenario till 17th of March.** These messages will reflect the CIED information to be used in the scenario and it will contain EGM data and PDF report too. SRDC will provide a number of additional scripts to run the components (e.g. for observation processor).

Additionally, Gokce, Yildiray and Christian held a meeting on Patient Parameter Monitor (PPM) and Data Analysis Component of iCARDEA. The following decisions are taken.

- OFFIS will provide API to SRDC for getting html patient values. Therefore the Patient Parameter Monitor engine will be used to generate HTML code for careplan engine
- Single sign on should be done and commonly used at the iCARDEA platform
The big vision is, one big iCARDEA System so that the user don't have to log on to all different iCARDEA tools.

- OFFIS can use their caremanagementDB and access it directly and create their own relations.
- SRDC create a new Database Scheme as VPP and will provide it to OFFIS.
- OFFIS is not expecting them to do all the work on extending the Database for PPM.
- OFFIS can use the DB directly for comments and logging of access.
- OFFIS: PCC Subscribe and Update is not suitable for Patient Parameter Monitor, since WP7 needs a query protocol; therefore the CaremangementDB via Java Api will be used.
- PHR (Has to be under control of Consent Editor) (available over java API if allowed) Data is always stored, but access controlled. SRDC will not delete the PHR data at the caremenagement DB.
- OFFIS suggested that at the iCARDEA platform a single configuration environment file should be used. This would be good for the portability of the iCARDEA System and there could be only one defined directory for logs, making maintenance easier.
- It was decided to use MySQL and the idea of migration to PostgreSQL will not take part.
- PPM could be used at the first review to show the patient data at a follow up. The data would be shown at a mock up of the tool.

SRDC-FORTH Bilateral Meeting:
Yannis sent the messages prepared by SRDC to FORTH EHR Interoperability Infrastructure. These messages reflect the EHR messages to be sent from EHR Interoperability Infrastructure to Adaptive Care Planner. There are five categories of message:
1. Lab Results
2. Medications
3. Problems
4. Vital Signs
5. Procedures

The Lab Results and Problem messages are successfully entered to Care Management DB. There were some points to be resolved in Medications in terms of the message format. For example, SRDC used single effectiveTime value for medications; whereas FORTH uses two values (low, high) for the same information item. These conflicts will be reported to SRDC by FORTH till February 18th, 2011. The Vital Signs and Procedures messages will be tested till February 18th, too.

SRDC-SRFG Bilateral Meeting:
Mihai merged the overlapping HL7 classes into a single library. SRDC will integrate this library. SRDC will send a permanent URL for the PCC10 endpoint (with port 80 for firewall). SRDC and SRFG agreed on ACK codes and cancel messages. Furthermore, the current version of the implementation does not use WS-Addressing. Mihai will improve the PCC 9 Web Service in that it will obtain the PCC10 return address from the SOAP header of the PCC9 query till the end of February 2011.

SRFG-FORTH Bilateral Meeting:
SRFG and FORTH discussed the option of implementing the xPHR content profile, as the means to populate the PHR on first use. FORTH will prepare a first draft of the data by February 28 that
can be provided to be commended upon by SRFG by March 15. The use of xPHR over PCC-9/PCC-10 will be investigated. If successful this capability will be demonstrated in the review.

**OFFIS – HCPB Bilateral Meeting (Monday)**

- Elena provided updated Excel Sheets with values for AT/AF and VT/VF.
- Christian clarified that these values / attributes are targeted Dataset. Not all of them may be provided. Which of them are available have to be determined in the future. There are three ways to deal with missing attributes that are not available:
  1. Delete the attributes,
  2. Keep the attributes and insert demo data,
  3. Redefine the template
- Elena stated that this is the data available at their clinic and she wants to see them.
- Elena provided a drawing for VT / AF values she have in mind. This would be like an excel sheet with numbered episodes, together with date, type, additional data (zone) and at last the image of ECG
- Christian again stated that OFFIS will try this, but OFFIS cannot guarantee this. It depends of the CIED-PDF-reports and the requested graphs. In the first step OFFIS have to realise an interface with the generalized dataset of all data sources.
- Further Doing:
  - OFFIS will clarify with SRDC which of the data is available and present this to Elena. Based on that, Elena can refine the excel sheets and provide them to OFFIS.
  - OFFIS will update the Mock Up PPM with the attributes and then discussion it with Elena and SALK. Based on the discussion OFFIS implements the PPM and no further adaption will be done.

- Christian and Elena discussed the usage of PHR Data. Elena stated that PHR has more data about the patient then normally is available to the healthcare professional and this is sometimes trustworthy. Especially medication is important and the well being of the patient interesting. Christian will clarify with SRFG, if there is a possibility for healthcare professional to log on to the PHR portal. OFFIS will not provide a tool to watch all PHR Data, but maybe we can provide PHR Data like medication from the CaremanagementDB.
- Christian then presented Elena the idea of Task 7.2. Elena had objections since the patterns seemed to her unproved. Christian explained that the patterns are validated before the usage by a healthcare professional. Patterns will be created based on old cases from the hospital, validated by experts and then used at iCARDEA. Elena liked the idea and provided input to the layout of analysis paths.

**OFFIS – SALK Bilateral Meeting**

- Lynne can provide a list of all SALK patients with an ICD and CIED device. This is required by SALK IT for preparation of the old cases database- She also provides terms for the identification of the patients and typical complications.
- Lynne describes her view of the PPM and sees it as an ICD follow up tool for the healthcare professional.

**OFFIS – SRFG Bilateral Meeting**

- Christian asked if it is possible that healthcare actors can use the PHR system to view the patient data.
- Bob explained that this is technically possible, but would require a complex registration of the healthcare professional. Due to this, at iCARDEA it is not intended to provide this functionality.
Christian stated, that from a data analysis point of view, the update of values can be caused by different types like correction of an error or a real change of the value. For data analysis this would be interesting to know.

Also the representation of patient’s medication was discussed. Christian would prefer a list of drugs to be chosen of, but Bob stated that free text will be used. Also it is not quite sure, if the medication of the PHR can be provided to the iCARDEA platform since the IHE CM isn’t designed to transport medications that are not coded.

8 Appendix 2: Minutes of March 22-23, 2011 Salzburg Technical Meeting

Date: March 22-23 2011
Place: SALK
Participants: FORTH – Catherine Chronaki, Stelios Sfakianakis, Yannis Petrakis
SALK – Erik Vossius Irshaid, Lynne Hinterbuchner, Axel Schett, Marcus Welch, SALK-IT
SRFG - Manuela Plößnig, Robert Mulrenin, Mihai Radulescu
St Jude - Bernhard Pfeifer,

March 22, 2011, Location SALK, 15:00-18:00

<table>
<thead>
<tr>
<th>Time</th>
<th>Partner</th>
<th>Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>15:00</td>
<td>FORTH: Catherine Chronaki</td>
<td>Presentation of the iCARDEA Sample Demonstration Scenario: revised implementation architecture &lt;br&gt;&lt;b&gt;Objective&lt;/b&gt;: familiarize with the immediate goal of the review</td>
</tr>
<tr>
<td>15:30</td>
<td>FORTH: Stelios Sfakianakis</td>
<td>Deployment Architecture &lt;br&gt;Presentation draft deployment of iCARDEA in SALK &lt;br&gt;Use of iCARDEA &lt;br&gt;Security requirements &lt;br&gt;Administration roles &lt;br&gt;Auditing system use &lt;br&gt;&lt;b&gt;Objective 1&lt;/b&gt;: Decide on security requirements – administration roles &lt;br&gt;&lt;b&gt;Objective 2&lt;/b&gt;: Clarify Deployment Architecture in SALK compile list of open issues and actions.</td>
</tr>
<tr>
<td>16:00</td>
<td>SALK: Lynne Hinterbuchner</td>
<td>Presentation of case for CIED patient: data and workflow &lt;br&gt;&lt;b&gt;Objective&lt;/b&gt;: understand contents of EHR for CIED patients</td>
</tr>
<tr>
<td>16:30</td>
<td>SALK-IT (TBA)</td>
<td>Discuss preliminary list of EHR data &lt;br&gt;Medical history &lt;br&gt;- Admission reports &lt;br&gt;- ECG reports &lt;br&gt;- Coronary Angiography reports &lt;br&gt;- Operation reports &lt;br&gt;- Medical history &lt;br&gt;- Medication at discharge &lt;br&gt;- Discharge report &lt;br&gt;- Lab Findings &lt;br&gt;- Transfer Report &lt;br&gt;&lt;b&gt;Objective 1&lt;/b&gt;: Decide how retrieve EHR data from SALK &lt;br&gt;((suggested src: HL7 listener or Orbis export)) &lt;br&gt;&lt;b&gt;Objective 2&lt;/b&gt;: identify EHR data needed available only in paper.</td>
</tr>
</tbody>
</table>
FORTH with the EHR Interoperability framework (EHR-IF) aims to convert EHR data into a standard format. Terminologies/used GLIMS. Discuss Medication lists use Entry of additional data Security requirements Administration Roles Requirements

**Objective 1:** Decide on a process to map those into a standard terminology using CTS (AF/VT constraint?)

**Objective 2:** Decide on medication lists and ways to map it into a standard terminology using CTS (AF/VT constraint?)

**Objective 3:** Decide on Configuration parameters of the architecture in SALK for AF/VT support

Terminologies  Medication  Data export  EHR listener (HL7 messages)

**17:30**  FORTH SFRG  SALK  Discuss questionnaires for CIED patients and their informal caregivers

**18:00**  Closing

---

**March 23, 2011, Location SALK**

<table>
<thead>
<tr>
<th>Time</th>
<th>Partner</th>
<th>Issue</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>08:00</strong></td>
<td>SALK (Medical Team) FORTH-SFRG  Dr. Hainzer Lynne Hinterbuchner</td>
<td>Clarify iCARDEA workflow and use in the hospital: along phases  Talk to the medical team, follow workflow of CIED patients in SALK  Interaction with CIED patients – education  Questionnaire for CIED patients/ family members  Discussion of telemonitoring process  Review Sample scenario documents  <strong>Objective 1:</strong> Understand the care process of CIED patients, share views of how this will work under the iCARDEA protocol  <strong>Objective 2:</strong> Specify data that need to be maintained electronically to support the iCARDEA protocol</td>
</tr>
<tr>
<td><strong>09:00</strong></td>
<td>SALK-IT/FORTH/ SFRG</td>
<td><strong>Deployment architecture</strong>  <strong>Objective:</strong> Wrap-up &amp; Set up action list</td>
</tr>
<tr>
<td><strong>09:30</strong></td>
<td>FORTH/ SFRG</td>
<td>Discussion of EHR/PHR data interface based on xPHR: test data for the review story board – discussion.  Clarify which type of clinical data is PHR interested in?  Specify initial set up of PHR framework on enrolment  Initial data (coming from the EHR)  Assessment questionnaires  Import data from PHR  <strong>Objective 1:</strong> Clarify interaction between EHR IF and PHR  <strong>Objective 2:</strong> Set up next actions</td>
</tr>
<tr>
<td><strong>10:00</strong></td>
<td>FORTH SFRG</td>
<td>Integration Testing discussion  <strong>Objective:</strong> Work on how to proceed with Integration Testing</td>
</tr>
<tr>
<td><strong>10:30</strong></td>
<td>Break</td>
<td></td>
</tr>
</tbody>
</table>

---

Page 101 of 112
8.1 MINUTES DAY 1: MARCH 22, 2011, 15:30-18:30

Participants: FORTH – Catherine Chronaki, Stelios Sfakianakis, Yannis Petrakis
SALK – Lynne Hinterbuchner,
SALK-IT - Axel Schett, Marcus Welch
SRFG - Manuela Plößnig, Robert Mulrenin, Mihai Radulescu
St Jude - Bernhard Pfeifer and colleague

Apologies: Erik Vossius Irshaid

8.1.1 iCARDEA scenario and the EHR interoperability framework

The meeting started shortly after 3pm with Catherine Chronaki presented the working scenario to the meeting participants, in the frame of the iCARDEA architecture. (presentation attached as iCARDEAscenario_Salzburg_chronaki_20110322.pptx).

Objective: familiarize with the immediate goal of the review.

Everything was clear except for the communication of the CIED exposure service with St. Jude, in which case a database interface to the St Jude back end was described. The idea of applying data mining techniques at the level of a patient’s unstructured EHR data was proposed.

8.1.2 Draft Deployment Architecture of EHR-IF: open issues

Stelios Sfakianakis presented on the draft Deployment Architecture (presentation attached as deployment_arch_FORTH_salzburg_ssfak_20110322.pptx). The issues of Security requirements, Administration Roles, and Auditing were preliminary discussed as the relevant deliverable is due next September.

The meeting participants gained better understanding on the expectations from SALK and SALK-IT.

Objective 1: Decide on security requirements – administration roles

The preliminary assessment on security is that the iCARDEA system will be accessible to a well-known subset of the SALK users, within the hospital. SALK uses active directory. The idea of connecting iCARDEA to the active directory was proposed but deemed infeasible.

The requirement for iCARDEA to be able to support a user list and single sign on were noted.

Action: (FORTH) Propose components that would allow the definition of health users with the right to use iCARDEA

Objective 2: Clarify Deplmt Architecture in SALK compile list of open issues and actions.
Several issues in the deployment architecture were noted particularly in relation to (a) where in SALK is the information we need; (b) how could we get it reliably.

It became clear that most of the information is in unstructured form within ORBIS reports. That EDIFACT messages set to GPs following an out-patient visit of an iCARDEA patient can be a good source of information for the EHR-IF and the Adaptive care planner. It was decided to resume this thread in a meeting early next morning between SALK-IT, FORTH, SFRG.

8.1.3 ICD patient follow-up: EHR data – part 1

The next topic was revisiting the ICD patient workflow, wrt. the process of telemonitoring a implemented in SALK. Lynne explained the way that remote visits of ICD patients will be implemented at SALK:

1. each patient will have their reports extracted and printed during the weekend prior to Monday (the day on which outpatient visits are scheduled).
2. After all patients that are present are examined, the doctor will look at the reports and also log into the vendor portal to review the report online
3. the nurse call the patient to check how he/she is doing
4. the doctor will author a report that will be entered into orbis as if it was a walk in visit.

FORTH EHR listener should be able pick up all ADT messages that refer to iCARDEA patients based on patient id.

Lynne provide all the typical docs of reports and exams made during an outpatient ICD visit to SALK. It became clear that the ECG a typical examination take in a f2f visit will not be carried out in this case.

**Objective 1**: Decide how retrieve EHR data from SALK (e.g.: HL7 listener or Orbis export)

Some clarity was achieved in regards to the value of the ADT HL7 messages, lab results, EDIFACT messages send to GPs, and the actual reports in PDF that can be exported from Orbis.

**Objective 2**: identify EHR data needed available only in paper.

Lynne explained that some of the medical history data that are typically acquired in the context of clinical trials once are dispersed in different reports. Thus, it was deemed necessary that Lynne creates a form that is filed manually with the identification data when the patient is enrolled in iCARDEA.

**Action**: (SALK-Lynne): To provide a paper form describing the contents of this medical history/risk factors/etc form. (April 2011)

**Action (FORTH)**: To implement this form as an extraction to the Patient ID service. 2-weeks after action above is implemented.

The objectives was somewhat achieved, although some of the technical details were left for the following day.

8.1.4 How to convert EHR data from SALK into a standard format: terminologies

Due to the late of the time, this topic was not adequately addressed and was postponed for the next day.
We briefly reviewed EDIFACT messages and terminologies from the lab system. Attached to these minutes as GLIMS.zip.

The meeting adjourned at 18:30

8.2 DAY 2: MAY 23, 2011, 7:30-3:30

Participants: FORTH – Catherine Chronaki, Stelios Sfakianakis, Yannis Petrakis
SALK – Lynne Hinterbuchner, Erik Vossius Irshaid
SALK-IT - Axel Schett, Marcus Welch
SRFG - Manuela Plößnig, Robert Mulrenin, Mihai Radulescu

A change in agenda was decided, based on the results of the previous day. The group was split in 2, with Group 1 focusing on the deployment of EHR-IF in SALK and Group 2 revisiting the patient workflow for outpatient follow-up. The groups met again at 10am to discuss iCARDEA deployment in SALK.

8.2.1 Technical Discussion: Deployment of the EHR-IF in SALK (8:30-10:00)

Participants:
- SALK: Axel Schett, Markus Welch
- SRFG: Robert Mulrenin, Mihai Radulescu
- FORTH: Stelios Sfakianakis, Yiannis Petrakis

Notes: Stelios Sfakianakis

The main issue discussed was the integration of the FORTH's iCARDEA "Gateway" with the SALK's communication system. There are two cases where such integration is used:

- The so-called "real time" or active case is when the Gateway is receiving data at the time it is generated (e.g. by the current visit of a patient or an outpatient).
- The 2nd case refers to the retrieval of "historical" data i.e. data that was stored during the past visits of the patient.

8.2.1.1 Real time data

In the first case (the "real time" one) the integration will be performed through the use of the HL7 Messaging that's already employed in SALK. In particular:

- FORTH will implement an HL7 "Listener" that accepts HL7 (version 2) messages and on the fly generate the appropriate clinical documents that subsequently submits to the iCARDEA Document Repository (also developed by FORTH). The communication will be based on Minimal Lower Layer Message Transport protocol (MLLP) (i.e. TCP sockets) on a single channel/"tcp port".
- SALK will adjust their communication system to send the messages also to the HL7 Listener. The most relevant messages are the ADT and the Laboratory (ORU --
Observation Result) so the communication system will be configured to direct only these messages to the Listener.

The information that can be extracted from these messages is:

- From the ADT messages, when Admit or Transfer is the case we don't get (more or less) nothing except the patient demographic information. But when the patient is discharged the corresponding ADT message contains the diagnosis coded in ICD-10.

- From the ORU messages we get the lab (e.g. blood) results. The only caveat here is the mapping of the local ("GLIMS") codes to some standard coding scheme (e.g. LOINC). This was not further discussed but Markus promised to approach some people from the Laboratory department to try to get more information. When such mapping is agreed on the HL7 Listener will be configured to use it so that the rest of the iCARDEA uses only standard codes in the documents.

Another issue that was discussed is that of course the data transmitted to the iCARDEA systems should be only for the enrolled patients and therefore some filtering for these patients should be performed "somewhere". This filtering can be done in the HL7 Listener but it was agreed that for performance reasons (and also for security?) it will be better for the SALK communication system to filter out messages of non-registered patients before they are sent to the Listener. This of course requires the list of the iCARDEA registered patients (with their SALK/Orbis ids) to be available in the Comm. System's side and kept up-to-date. FORTH's PIX manager can produce such a patient list and update it whenever a new patient is enrolled.

8.2.1.2 Historical Data

For the 2nd case above, i.e. the retrieval of the historical data for the initial "bootstrapping" of the iCARDEA when a new patient enrolls, we briefly discussed the Edifact reports produced by ORBIS and sent to the GPs (e.g. as a referral, after patient's discharge, etc.) These reports have information about the diagnosis and the (Active) medication. The problem is that these reports contain mostly free text and most of this information is uncoded.

Axel considered the task of extracting historical information to be "impossible" because this data is usually stored in free text, PDF files, etc. Instead he proposed such data be entered manually during the patient registration in the iCARDEA system(s). That decision of course needs to be taken by the consortium at large or at least by the actual users (Lynne ?) who will perform the registration.

8.2.1.3 Additional issues

There will be the need to have a single sign on facility in the iCARDEA platform that hopefully integrates seamlessly with SALK's authentication/authorisation systems (MS Active Directory). In the meantime we can have a static list of users and their roles shared among the iCARDEA components, e.g. in an XML file.

8.2.2 Patient workflow for outpatient follow-up (8:30-10:00)

Participants: FORTH – Catherine Chronaki
SALK – Lynne Hinterbuchner, Erik Vossius Irshaid
SRFG - Manuela Plößnig
Notes: Catherine Chronaki

We revisited again the follow-up workflow for (a) outpatient visits (b) remote followup (c) alarms. We collected anonymised samples of the patient folder collected in case of a ICD patient outpatient visit.

8.2.2.1 FOLLOW UP Protocol for ICD Patients

According to Lynne, following implantation (2-3 days) a week later (stitches or by GP) visit 1 month scheduled (verification insurance paper is quarterly) Jan-March, April-June, July-Aug, Sep-Dec. contact GP or cardiologist for referral: by post (request by telephone) or in person. A schedule of 3-6 months is established, unless emergency and entered in the vendor portal.

Upon arrival to the Arrhythmia clinic, the patient needs to check-in. Thus, he/she visits the Secretary of the outpatient department first. The secretary enters the patient data and hands to the patient a one page sheet, recording details for the visit to the outpatient clinic. The visit paper includes the name of the General Practitioner as reported by the patient (GP). At this point the visit is created in Orbis (as a results examinations e.g. lab results may be ordered):

Change in the patient data need to be reported as well as changes in medication instructed by the GP. Some interesting points follow:

1. In between appointments patients frequently visit external GPs/cardiologist who writes medications
2. Some patients have a printed medication list. Others are not aware of their medication: what, frequency, changes, etc.
3. Suggestions to the GP and patient on labwork, medication, directions (e.g. INR), etc. are included in discharge letters. These discharge letters can be configured to be sent via EDIFACT to the GP, and are handed out in printed form to the patient.¹⁰
4. ECG taken right after check in, also weight, blood pressure and noted on the printed paper.
5. Patient has the ICD reading – manufacturers’s rep, doctor, and nurse in the room
   a. Reading taken rep/doctor: full report is printed by the programmer; only the important staff (quick page), saved to disk
   b. Doctor writes discharge letter – stores letter in Orbis under arrhythmia ambulance (outpatient), there is also an ICD report template sometimes used only sometimes.
   c. Letter is stored in folder also in ORBIS
   d. Nurse makes next appointment
   e. Patient gets copy of the letter and paper together with next appointment reminder.
   f. GP gets copy of the letter by Fax or Internet or mail or via Edifact depending on the GP (on the discharger letter has the GP or health professional in control of the patient)

¹⁰ It was noted that presumable a configuration in the communication gateway could allow them to be forwarded to the HL7 EHR listener for iCARDEA patients.
6. At the end of the day, the doctor or nurse sends all the patient folders to the cath lab where the secretary scans them. The visit number (ambulatory or stationary) unique active on the visit. The secretary will be advised to store it a folder\textsuperscript{11}.

7. ADT HL7 messages are generated on visit registration by the secretary at the outpatient clinic: check data, save it with specific convention to this folder. Thus, the EHR-IF may be alerted when a certain patient is admitted to the outpatient clinic.

8. EDIFACT messages associated with a certain patient/visit id may also be intercepted.

9. For a typical Monday: 13 patients, 8-11, 15 min, until 1 pm.

8.2.2.2 Remote Visit via Telemonitoring

3-6 schedule: mark out telemonitoring: manufacturer reps will check and print full CIED reports to be reviewed by the doctor at the end of the session. Nurse will contact patient by phone. Doctor will author letter (as in outpatient visit) to be stored as usual in ORBIS. The regular code will be used for outpatient visits.

8.2.2.3 Alarms

Lynne is checking every day the portal on a daily basis. IF there are alerts they will be printed and placed in a folder to be read by the Cardiologist responsible for the day. Lynne may evaluate especially emergency cases. If a patient needs to be brought it, nurse Lynne will take immediate action. The PDFs with the alerts will receive a stamp with the possible actions to be taken (documented) in the ORBIS system. (Only Biotronik allows documentation of action taken on alert – the other portals do not have that capability).

At the end of the day the folder with the alerts following processing will be given to the secretary to scan and enter to ORBIS, stamped with times\textsuperscript{12}.

Objective 1: Understand the care process of CIED patients, share views of how this will work under the iCARDEA protocol

Objective was achieved. Significant additional clarity was reached regarding the workflows in place and newly defined ones.

Objective 2: Specify data that need to be maintained electronically to support the iCARDEA protocol

This will be covered in part by Lynne’s action to define the form history and risk to be filled out on a patient’s registration with iCARDEA.

8.2.2.4 iCARDEA patient enrollment process

The following process was presented as the one:

Outline iCARDEA enrollment process

1. Lynne new patient

\textsuperscript{11} If the EHR-IF is notified of the admission, an alert may be sent to the nurse to remind him/her of their task to extract relevant data in well-known folder. However, it was noted that this is an error prone walk-around and a solution involving Agfa might be preferable.

\textsuperscript{12} There is no way for the EHR-IF to receive alert on alarms
2. Fill in the patient ids
3. Fill in the admission page
4. Add to the HL7 communication gateway filter (white list) page

8.2.3  iCARDEA Deployment: Wrap-up & actions: 10:00am-12:00am

Participants:  
FORTH – Catherine Chronaki, Stelios Sfakianakis, Yannis Petrakis  
SALK – Lynne Hinterbuchner, Erik Vossius Irshaid  
SALK-IT - Axel Schett, Marcus Welch  
SRFG - Manuela Plößnig, Robert Mulrenin, Mihai Radulescu

Notes: Catherine Chronaki

Objective: Wrap-up & Set up action list

The group met again to discuss the deployment architecture. SALK presented a schematic in visio with 3 parts: EHR-IF/Adaptive care planner, CIED Exposure Service, PHR. There was discussion regarding the number of servers needs and weather specific components are accessed by users outside SALK. The preliminary discussion was that the CIED exposure service and the PHR are accessible outside and as a result are in different security zones. Some discussion followed whether patients should provide input in paper or not. One feasible solution would be to plan 3 different computers, at different levels of security. No final decision was made.

Objective 1: Decide on a process to map those into a standard terminology using CTS (AF/VT constraint?)

Objective 2: Decide on medication lists and ways to map it into a standard terminology using CTS (AF/VT constraint?)

Objective 3: Decide on Configuration parameters of the architecture in SALK for AF/VT support

The terminology issues were discussed extensively throughout the 2-day meeting, and although no final solution was achieved, a number of intermediate actions were suggested. Lynne and Catherine revisited the terminology excell, but due to time restrictions no significant progress was achieved.

Regarding the EHR-IF and its interaction with SALK-IT the following points were noted:

Action- Catherine (FORTH): Write requirement for (a) Agfa to provide all documents in ORBIS associated with a given visit. That would include ECGs, discharge reports, etc. (b) agfa provide in XML the contents of reports associated with a given patient visit. (March 30)

Action – Axel (SALK): Write requirements for SALK IT to support the EHR-IF in relation to HL7 communication platform and Edifact (March 30)

Action Axel: Analyse via OCR PDFs exported from Orbis and report results (April 30)

Action – Marcus (SALK): Catherine to revisit terminology excell with laboratory doctors (April 15)

Action- Catherine/Lynne: To revisit the medication list based on web resources on active substances. Lynne will confirm (April 30)
8.2.3.1 Discussion on semi-automated entry of PHR data

A plan for data entry of PHR data within SALK was discussed to meet the security concerns of SALK. The plan is recorded here for future reference. At the end of the meeting it was not clear whether it was to be adopted.

Context: Different patients have different abilities and preferences and alternative means need to be supported by the patient empowerment framework.

Points:

1. Patients should be able to fill in paper forms
2. No patient name from iCARDEA to PHRS (only Protocol ID)
3. Patient needs to know that PHR is just for testing (and must be clear with the patient)
4. Patient should know that SALK is not looking at the PHR and it’s for test purposes
5. Consent form needs to be revised. The portal needs to be described in detail for group 2 (Manuela)
6. For those patients with no access to the Internet: provide charts of progress towards goals.

Action: Manuela-Lynne: Revisit the consent management and revise protocol (April 2011)

8.2.4 Discussion of EHR/PHR data interface based on xPHR

This item was not addressed due to time limitations and the higher priority of the deployment discussion.

8.2.5 Integration testing discussion

This item was not discussed separately.

Objective: Work on how to proceed with Integration Testing

However Axel took a relevant action regarding testing integration of the EHR-IF to the SALK-IT systems.

Action – Axel (SALK): Set up implementation/testing plan for EHR-IF (April 30).

8.2.6 iCARDEA Questionnaire to patients: 12:00pm-15:00pm

Manuela introduced the topic mentioning different aspects: Effort, scope, responsible person, possible ethical issues.

She also said that these questionnaires fit within: (a) evaluation of the iCARDEA application (b) market study [Part of evaluation (8.1): Austria part of evaluation; Part of exploitation (2.1): Greece, Spain]

Action (Manuela/Catherine): Contact other partners e.g. Spain to see if they are interested in being engaged in survey instrument, April 2011

Lynne presented the questions she has already prepared to ask to CIED patients.

They were along the following lines:

- Know about telemetry
- Stressful
- ICT – education with
- Sock what they expect
- Telemonitoring visits
- Use of the internet

**Action** – Lynne: Share the questionnaire she has prepared. April 2011

The discussion proceeded with brainstorming.

The participants thought that the questionnaire might address the following aspects:

- Do you do medical management, medical information, follow your doctors instructions
- Do you follow instructions in the discharge letter
- Did you receive the brochure given to you with ICD
- What resources do you use to get information about your ICD
- (GP questions)
- What is important for you to know about the disease?
- Do you feel that you are well informed about your diseases?
- What are your sources of information? Doctor, GP, internet, leaflets, pharmacy, other patients, self help groups.
- Which topics in relation to your disease are particularly important to you? Sex, driving, shocks, other
- Where there any barriers for you when looking for information? Lack of internet, no resources,
- What type of resources/information would you be looking for: talks, groups, internet pages, leaflets, asking physicians, asking nurses, videos, other patients, GPs, cardiologists, etc.
- Internet use, frequency, reasons, search for health information
- What causes them most stress about their disease: shock while driving, death, fear of sports, loneliness, lack of knowledge of can do? Need to visit a sports..
- Self Management Medical (patient data, medication, physical/vital data, self control (observation of daily living), preference on recording, shocks, alarms/roles (change of lifestyle: sports, gardening, social)/emotional (fear, depression, anger)
- Do you do home monitoring?
- Would you do it?
- What kind of devices do you use? Blood pressure monitor, weight
- Do you have scheduled visits with your GP?
- How many times did you visit him last 6 months?
- Do you keep track of your medication changes?
- Do you have a list of your current medication?
- Who manages this list?
- Do you use medication tracking tools (e.g. smart boxes?)
- Do you use personal health devices at home? BP monitor, Glucose meter, INR, other?
- Who takes care of you?
- Do you use medication reminders? Online, mobile phone, calendar
- Do you have a calendar for recording medication for monitoring your disease?
- Do you a daily or weekly medical box?
- Concerns with privacy?

From her extensive experience with questionnaires, Lynne explained that questionnaires should be (a) Plain Stupid Questions (b) max 40 questions/categorized questions.

(pilot the questionnaire 3 or 4 patients). According to Lynne we can start asking patients once they sign the consent form.

**Action**: Catherine/Manuela/Lynne: To review above list and prepare concrete plain questions.

### 8.3 ACTION LIST

<table>
<thead>
<tr>
<th>Action</th>
<th>Organization/Person</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>To review above list and prepare concrete plain questions</td>
<td>Catherine/Manuela/Lynne</td>
<td>July 2011</td>
</tr>
<tr>
<td>Email the questionnaire she has prepared</td>
<td>Lynne</td>
<td>April 2011</td>
</tr>
<tr>
<td>Contact other partners e.g. Spain to see if they are interested in being engaged in survey instrument</td>
<td>Manuela/Catherine</td>
<td>April 2011</td>
</tr>
<tr>
<td>Set up implementation/testing plan for EHR-IF</td>
<td>Axel</td>
<td>April 2011</td>
</tr>
<tr>
<td>Revisit the consent management and revise protocol</td>
<td>Manuela/Lynne</td>
<td>April 2011</td>
</tr>
<tr>
<td>To revisit the medication list based on web resources on active substances. Lynne will confirm</td>
<td>Catherine/Lynne</td>
<td>April 2011</td>
</tr>
<tr>
<td>Revisit terminology issues with laboratory doctors</td>
<td>Marcus</td>
<td>April 2011</td>
</tr>
<tr>
<td>Analyse via OCR PDFs exported from Orbis</td>
<td>Axel</td>
<td>April 2011</td>
</tr>
<tr>
<td>Write requirements for SALK IT to support the EHR-IF in relation to HL7 communication platform and Edifact</td>
<td>Axel</td>
<td>March 30</td>
</tr>
<tr>
<td>Write requirement for (a) Agfa to provide all documents in ORBIS associated with a given visit. That would include ECGs, discharge reports, etc. (b) agfa provide in XML the contents of reports associated with a given patient visit. (March 30)</td>
<td>Catherine</td>
<td>March 30</td>
</tr>
<tr>
<td>To provide a paper form describing the contents of this medical history/risk factors/etc form. (April 2011)</td>
<td>Lynne</td>
<td>April 30</td>
</tr>
<tr>
<td>To implement this form as an extraction to the Patient ID service. 2-weeks after action above is implemented.</td>
<td>Yannis</td>
<td>May 30</td>
</tr>
</tbody>
</table>
Propose components that would allow the definition of health users with the right to use iCARDEA

\[\text{April 30}\]

\[\text{Stelios}\]

---

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