

iCARDEA

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

SPECIFIC TARGETED RESEARCH PROJECT

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

iCARDEA D1.1.9 Project Presentation

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PU	Public	X
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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Project name: An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices

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



Project Participants:

Benef. Role*	Benef. Number	Beneficiary name	Beneficiary short name	Country
CO	1	Software Research, Development, Consultation Company	SRDC	Turkey
CR	2	OFFIS e.V.	OFFIS	Germany
CR	3	Salzburg Research Forschungsgesellschaft m.b.H	SRFG	Austria
CR	4	Foundation for Research and Technology Hellas – Institute of Computer Science	FORTH-ICS	Greece
CR	5	Salzburger Landeskliniken Betriebsges m.b.H	SALK	Austria
CR	6	St. Jude Medical Medizintechnik Ges m.b.H	SJM	Austria
CR	7	Medtronic Ibérica	MDT	Spain
CR	8	Hospital Clinic I Provincial de Barcelona	HCPB	Spain

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Project Main Goal(s):

Over the last decade, there has been an exponential growth in the number of cardiac implantable devices, in their electronic and software complexity widening their function and application. iCARDEA project will expose CIED data through standard interfaces to develop an intelligent platform to semi-automate the follow-up of the CIED patients with context-aware, adaptable computer interpretable clinical guideline models. EHR interoperability will be achieved by exposing legacy EHR systems through standard HL7 CDA interfaces so that information about patients' medical history such as the non-cardiac conditions denoting contraindications to the proposed therapies can be obtained from the patient EHR data and used in the clinical follow-up workflow. The major objectives of the iCARDEA project are as follows:

1. **Remote monitoring for implantable cardiac devices** - Cardiac arrhythmia abnormalities that are not transient or reversible require constant clinical monitoring. Delays on diagnosis or medical assistance increase risks of adverse outcomes such as heart failure, stroke or sudden cardiac death among people with certain arrhythmias. The situation is more critical for high risk patients who have structural heart diseases or experience such abnormalities or arrests previously. Therefore, Cardiovascular Implantable Electronic Devices (CIED) including pacemakers, implantable cardioverter defibrillators (ICD) and cardiac resynchronisation therapy (CRT) have become part of the standard therapy in patients who are at the risk of life-threatening cardiac arrhythmias. 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 support¹.

The iCARDEA Project will develop an intelligent platform to automate the follow-up of the CIED patients with adaptable computer interpretable clinical guideline models which access data seamlessly in EHR data resources, CIED data and PHRs using standard interfaces. The computer interpretable guideline models to be developed will be adaptable, designed from re-usable building blocks to easily personalize the patient and device follow-up. Then these guideline models will be converted to executable clinical workflows which will perform the follow-up activities and automate the risk assessment via integrative models and hence support medical professionals by automatically assessing the situations and generating alarms.

- 2. Integrating remote cardiac monitoring with EHR Systems** - In the first generation of Cardiovascular Implantable Electronic Devices, the majority of CIED recipients are followed routinely at intervals ranging from three to six months. Additionally, a substantial number of patients require extra non-scheduled visits due to arrhythmic events or system-related complications. The healthcare professionals realized that routine and non-routine CIED follow-up visits, including system integrity check, are time-consuming and should be reduced by proper ICT support.

Therefore, for the second generation of Cardiovascular Implantable Electronic Devices, all the major CIED vendors are upgrading their devices with remote, day-to-day, wireless, automatic monitoring of CIED recipients and devices in order to decrease the number of follow-up visits and automate CIED data transfer from device to data centers. In other words, data coming from the CIEDs are collected, analyzed and stored at the data centers operated by the vendors, and only in case of emergencies, alerts are sent to responsible parties. The complete patient reports are exposed through only Web-pages of the data centers, however they are not available as machine processable data to healthcare processes for further processing. In short, CIED data is neither integrated with the healthcare processes, nor with Electronic Healthcare Records of the healthcare provider, nor with the Personal Health Records of the patient. The iCARDEA project will wrap vendor specific CIED data to expose them through standard interfaces based on the HL7, ISO/IEEE 11073 standards and the IHE IDCO Profile to be used in clinical workflows.

- 3. Leveraging the potential of CIEDs as widespread, ambient intelligent devices** - It is clear that remote monitoring CIEDs are very complex and successful systems that play a critical role in the management of arrhythmia patients and their use has increased exponentially over the years. Their function and application have widened and their electronic and software complexity has increased. Maintaining the high quality, quantity, efficiency and reliability of healthcare that this group of cardiac arrhythmia patients deserves has put significant pressure on healthcare resources. The systems themselves are capable to provide valuable machine processable clinical information which can be used for automated healthcare processes. However, the full potential of remote monitoring is not exploited effectively at the moment and the high workload of healthcare professionals in this field persists despite the potential afforded by modern cardiac devices.

By using interfaces based on the international standards, iCARDEA project will expose this information to be used to semi-automate the care and follow-up processes based on computer interpretable clinical guidelines. Furthermore, thanks to standard interfaces and interoperability utilities to be provided by iCARDEA, CIEDs from different manufacturers and their future versions will become interoperable.

- 4. Clinical guidelines are under-utilized because of lack of integration into EHR Systems** - Clinical practice guidelines present and formalize medical knowledge required for clinical decision-making and try to standardize the patient care delivery by guiding the healthcare practitioners regarding next actions to be performed. By modelling and converting paper-based follow-up care guidelines into an electronic and executable format, healthcare processes, which need to be achieved as routine follow-ups or remote monitoring of patients

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

with CIEDs, can be automated and hence the workload of healthcare professionals can be decreased by reduced hospitalization and overall efficiency and accuracy of the process can be improved by minimizing costs.

The iCARDEA platform will provide EHR interoperability so that information about patients' medical history such as history of non-cardiac conditions; more detailed information about severity of each condition (e.g., record of prior hospitalizations or specifics of therapy for the condition); the medications being taken at the time of spontaneous arrhythmia occurrence or the non-cardiac conditions denoting contraindications to the proposed therapies can be obtained from the patient EHR data and used in the clinical workflow.

5. **Integration of monitoring with indicators for the quality of service in health care** - Currently, computerized clinical guidelines are mostly modeled at the set-up phase of clinical business process models and cannot be altered according to patient context dynamically at the execution time. By correlating the data coming from CIEDs with the context of the patient obtained from his EHRs, iCARDEA clinical workflows will be capable of proposing proper adjustments in the healthcare processes, pending approval of the clinicians. Furthermore, iCARDEA will introduce "Outcome Indicators" to measure the success of the care process so that it can be automatically combined with expert feedback to achieve a closed-loop system.
6. **Patient specific adaptive care** - CIEDs are capable of analyzing and producing patient specific alerts or warnings in critical conditions, but, the alert thresholds or conditions are static, in other words they are programmed beforehand, and not able to be updated or re-programmed remotely due to current CIED software setups and potential risk of failure. iCARDEA architecture will enhance underlying warning and alerting mechanisms for early diagnosis of further complications without altering CIED programs by providing additional data analysis and correlation mechanism generating patient specific alerts or warnings based on data accumulated in already established knowledge bases.

In addition to EHRs and CIED data, the system will also consume the patient data entered via patients in order to achieve accurate decision making which takes into account user impressions and experience, that may not be detected via CIEDs or embedded in EHRs, into consideration. The Personal Health Record (PHR) system to be developed by iCARDEA will enable patients to access and coordinate their health information to gain the benefits of having their healthcare records and CIED data in a format easily accessible to them. The PHR system will also be used for feedback and the education of the patient.
7. **Validation for effectiveness, privacy, trust and security** - Due to the extremely sensitive nature of patient related information, both medical records and patient's context information cannot be disclosed indiscriminately and different healthcare providers must have different access rights. The patient should be at the center of this process controlling his/her consent. Comprehensive identity management, trust and privacy mechanisms will be provided through the iCARDEA platform based on the EU directives 95/46/EC and 2002/58/EC² which present the general principles of processing of personal data, and in particular Recommendation R(97)5 of the Council of Europe³ discussing legal protection of medical data collected and processed automatically will be taken into account while providing the necessary confidentiality and privacy mechanisms.

² EU Directive 95/46/EC (http://europa.eu.int/com-m/internal_market/privacy/law_en.htm), Supplementary Directive 2002/58/EC http://europa.eu.int/information_society/topics/ecom/useful_information/library/legislation/index_en.htm

³ Council Of Europe – Committee of Ministers, Recommendation No. R(97)5 of The Committee Of Ministers to Member States on the Protection Of Medical Data, Council of Europe Publishing, Strasbourg, 12 February 1997

Technical approach:

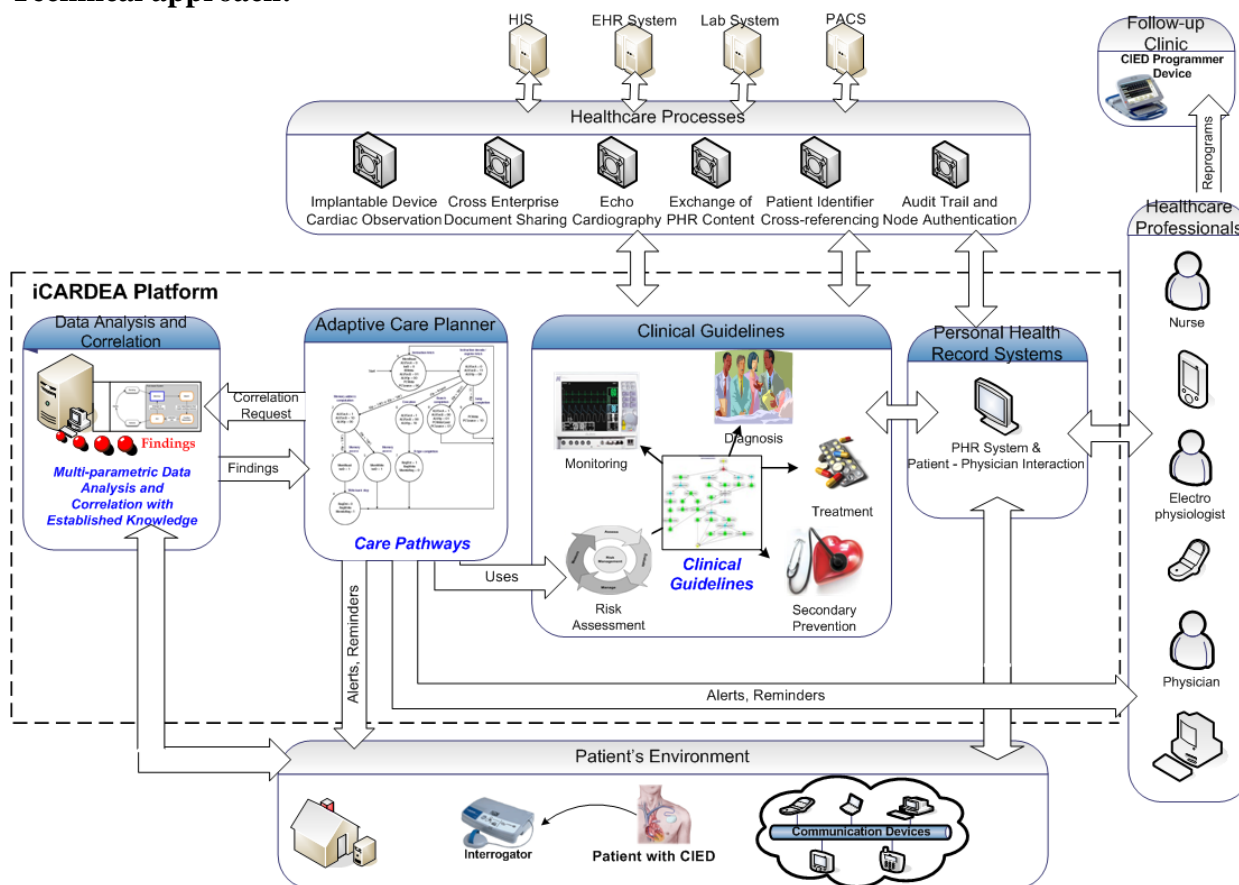


Figure 1 iCARDEA Architecture

The iCARDEA project will develop an intelligent platform to automate and personalize the follow-up of cardiac arrhythmia patients with implanted CIED devices with context-aware, adaptable computer interpretable clinical guideline models using standard device interfaces and integrating patient EHRs and PHRs. One of the important aspects of iCARDEA is the user-centered approach, which focuses the research and development efforts on a user perspective, involving both the patients and healthcare professionals from the beginning of the project. **Error! Reference source not found.** shows the architecture and overall view of the iCARDEA platform itself and the environment in which iCARDEA needs to provide interoperation services. In order to provide a holistic solution, the project has identified the following specific technical objectives:

1. **CIED Data Exposure Module** will be developed to integrate the data gathered from remote monitoring Cardiovascular Implantable Electronic Devices into automated healthcare processes executed by care pathways and the computer interpretable clinical guideline models; thus realize the personalized remote follow-up of CIED patients.
2. **Patient Empowerment Framework** will be developed in order to provide active and informed involvement of patients in management of their own health. Through the web based PHR, patients will be able to view their medical history, CIED data, and manage their medication summaries, daily nutrition information. PHR system will be implemented as a user-friendly Web application so that it will accessible from anywhere.
3. **Interoperability Infrastructure** for EHRs, PHRs and Code Systems will be developed to realize a comprehensive follow-up of CIED patients, it is necessary to have access to medical history and other clinical information of the patients that are stored in EHR and PHR systems. This information is very critical in shaping and guiding the personalized care pathway. For example,

access to patients' medical history such as the non-cardiac conditions denoting contraindications to the proposed therapies can lead to new therapies in the clinical workflow.

4. **Data Analysis and Correlation Tool** to be developed will provide dynamically updated, personalized alerting mechanisms to the patients and physicians for early detection of further complications such as contraindications and co morbidities. This alerting mechanism will be complementary to built-in alerting mechanism of CIEDs. Unlike built-in alerting mechanism of CIEDs, this tool will not be based solely on data transmitted from CIEDs, but also harmonize it with patient specific data such as medications and the severity of the arrhythmias.
5. **Personalized Adaptive Care Planner for CIED Recipients:** In the iCARDEA project the personalized follow-up of CIED patients will be coordinated through a "care plan" which is an executable definition of a care pathway that consists of computer interpretable clinical guideline models. The control flow of the care plan will be dynamically adapted based on the patient's context derived from the data coming from CIEDs and the medical context obtained from the EHRs, and the PHRs. This way, Personalized Adaptive Care Planner for CIED Recipients will realize context-aware multi-parametric monitoring.

Expected achievements/impact:

Cardiovascular Disease (CVD) is the main cause of death in the European Union (EU) accounting for over 2.0 million deaths each year. 42% of all deaths in the EU, 45% deaths in women and 38% deaths in men, are from CVD as shown in Figure 2a and Figure b.

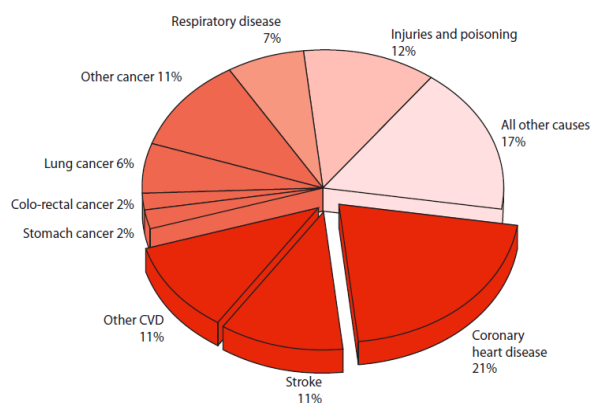


Figure 2a Deaths by cause, men

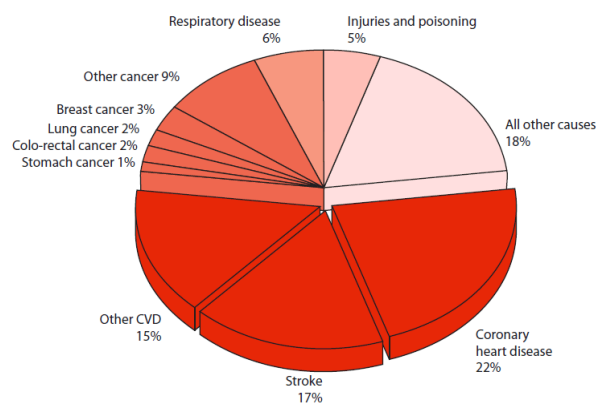


Figure 2b Deaths by cause, woman

Among these causes of death and morbidity, sudden cardiac arrest (SCA) is the major cause in developed countries. Figure 3 presents the major causes of death in USA in 1999⁴. The situation is similar in Europe. Sudden Cardiac Death (SCD) occurs in approximately 50,000–70,000 people annually in the UK and represents the largest proportion of the deaths attributable to coronary heart disease. In about 90% to 95% of cases, SCD occurs in the existence of coronary artery disease or congestive heart failure which makes secondary prevention crucial for life saving.

⁴ National Vital Statistics Report, Vol 49 (11), Oct. 12, 2001

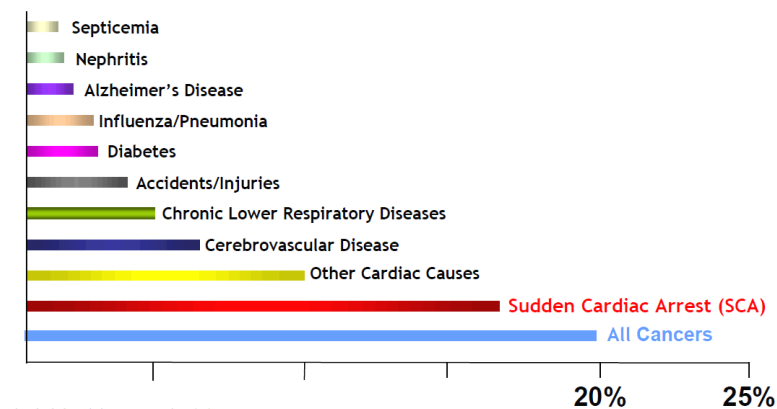


Figure 3 Leading Causes of Death

According to the consensus statement⁵ prepared jointly by the Heart Rhythm Society and the European Heart Rhythm Association, more than 800,000 patients in Europe have implanted pacemaker, ICD or CRT devices for the treatment or secondary prevention of cardiac arrhythmias. In addition, the number of follow-up visits for patients with an implanted cardiac device exceeds 5.8 million visits each year, and that number will continue to increase as more devices are implanted. The iCARDEA Project addresses these challenges by developing an integrated intelligent platform for continuous, remote and personalized monitoring the cardiac arrhythmia patients with implanted devices. The following outcomes are expected as a result of iCARDEA project:

- 1. Reduced visits:** CIED patients are usually scheduled to visit healthcare centers twice a year, which is a routine procedure even though the situation of the patient does not require it. Unfortunately, these unnecessary visits put significant pressure on healthcare sources. With intelligent remote monitoring, patients will only be required to visit healthcare centers if there are any unexpected developments. Consequently, minimized number of visit will reduce the both the burden on healthcare centers, and provide better independent living for the patients.
- 2. Better care quality:** The intermittent monitoring of cardiac rhythm is not enough to detect most of the remediable adverse events either because they are asymptomatic, or become apparent only after persisting long enough. Therefore continuous monitoring of patients with CIEDs is necessary. However, continuous monitoring of cardiac arrhythmia patients put significant pressure on healthcare sources. With remote monitoring, CIED patients will be monitored continuously and no significant developments will be overlooked.
- 3. Improved disease management:** Although the systems themselves are capable enough to provide valuable machine processable clinical information to be input in the automated healthcare processes, full potential of remote monitoring is not exploited effectively at the moment. The data coming from the CIEDs are collected, analyzed and stored at the data centers operated by the vendors, and only in case of emergencies, alerts are sent to responsible parties. The complete patient reports are exposed only through Web-pages of the data centers. iCARDEA will provide and 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 will provide improved disease management at the point of need.
- 4. Reducing Cost Without Compromising Quality of Care:** By shifting the healthcare monitoring to the preferred environments of the patients, and by integrating healthcare processes and information, the iCARDEA will improve the quality of healthcare and will reduce its cost. Studies of the cost-effectiveness of home tele-care are most compelling for chronic conditions. A US study of patients with chronic disease demonstrated savings of over \$8000 per patient, arising from a reduction of costs from \$100 for conventional visits to \$15-

⁵ HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIED): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations

\$40 for tele-care services⁶. In another study, on cardiac rehabilitation for congestive heart failure in the home, a 74% reduction in readmission rates was demonstrated at 90 days⁷. As seen in Figure 4, this is also pictured by Continua Health Alliance⁸ that remote monitoring significantly reduces the cost of care.

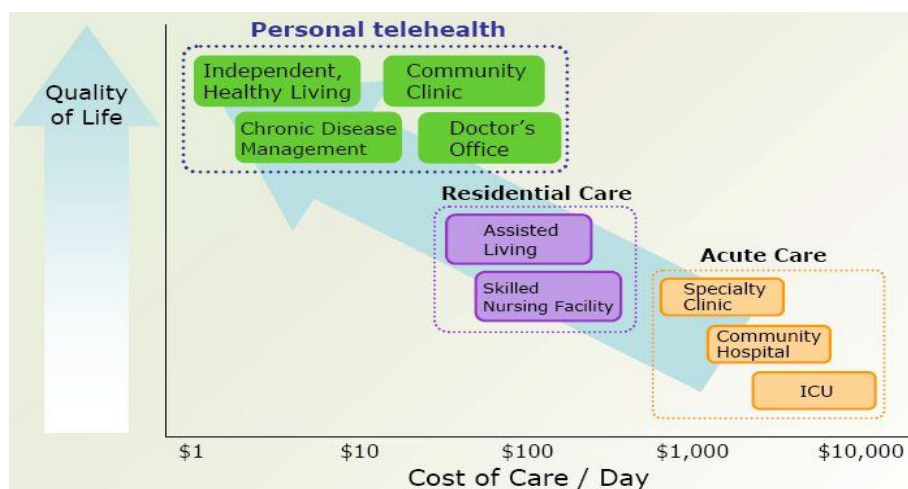


Figure 4 Cost / Quality of Life Diagram of Healthcare Methods by Continua Health Alliance.

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⁶ Schiller AE, Bondmass M, Avital B. Technology based home care for disease management. Remington Report 1997; September/October: 10-12.

⁷ Roglieri JL, Futterman R, McDonough KL, et al. Disease management interventions to improve outcomes in congestive heart failure. Am J Manag Care 1997; 3: 1831-1839.

⁸ <http://www.continuaalliance.org>