



## 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 D8.2.1 Functional and Non-functional Evaluation Criteria for iCARDEA Pilot Application

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# 1 Introduction

## 1.1 Purpose

This document 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. 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 first phase based on an early prototype will be based on questionnaires for the end-users (medical experts and CIED patients). For the final prototype test cases for the iCARDEA components will be defined. The test cases are based on categories for evaluation and validation such as possible medical risks, management of symptoms, usability or security issues. The description of the test cases also include criteria that allow to specify if a test case is successful, if a test case failed and how the result of a text case can be measured.

## 1.2 Definitions, acronyms and abbreviations

Abbreviation/Acronym	DEFINITION
AF	Atrial fibrillation
CIED	Cardiovascular Implantable Electronic Device
DACT	Data Analysis and Correlation Tool
HIS	Hospital information System
PHR	Personal Health System
PPM	Patient Parameter Monitor
TC	Test Case
VT	Ventricular tachycardia

**Table 1 List of Abbreviations and Acronyms**

## 2 Overall Description

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

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

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

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<sup>1</sup> US National Guideline Clearinghouse, <http://www.guideline.gov/>

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

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

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

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

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

<sup>7</sup> Terenziani P, Montani S, Bottrighi A et al. The GLARE approach to clinical guidelines: main features. *Studies in Health Technology and Informatics*, 2004. 101, 162-6.

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

Currently the CIED data is available from two different sources. The patient may be at the clinic during an in-clinic follow-up, so the data from the CIED can be directly accessed using the CIED Programmer of the vendor. The CIED Programmer is able to export the data into PDF file(s) stored in a configurable directory. Alternatively, the patient may be at home and the data is transmitted (semi-) automatically into the CIED Data Centre of the vendor for a remote follow-up. The physicians then can access the CIED Portal of the vendor that functions as frontend of the CIED Data Centre. It is also possible to export the CIED Data to the clinic, however right now this export has to be triggered manually in the CIED Portal. The data is then either exported using the IHE IDCO/HL7 v2.5 message or it is exported to a vendor system that has to be installed in the clinic. Currently the v2.5 messages transferred by the CIED Vendors usually contain limited information; however the PDF reports that contain the detailed data are embedded in the message. The vendor system in the clinic then automatically stores the data in a single PDF file using a configurable filename and the filename includes additional information such as the Patient name, Patient ID, and the timestamp.

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

In iCARDEA, a care plan is personalized to a patient by also accessing his medical history from the EHR systems. For example, in executing iCARDEA care plans for monitoring CIED patients with Atrial Fibrillation (AF), the history of the non-cardiac conditions, detailed information about severity of each condition (e.g., record of prior hospitalizations or specifics of therapy for the condition), the medications being taken at the time of spontaneous arrhythmia occurrence or the non-cardiac conditions denoting contraindications to the proposed therapies need to be accessed from the patient EHRs. The major challenge addressed in accessing the EHR systems is the interoperability problem of communicating with very many heterogeneous EHR systems. To be able to avoid routinely monitoring a wide variety of clinical data from disparate systems, and developing ad hoc interfaces to access heterogeneous systems, IHE has specified the “Care Management Profile”<sup>11</sup> and this profile is used in the iCARDEA system.

## 2.1 iCARDEA System Architecture

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<sup>9</sup> IHE Implantable Device - Cardiac - Observation Profile, [http://www.ihe.net/Technical\\_Framework/upload/IHE\\_PCD\\_TF\\_Supplement\\_IDCO\\_2009-08-10.pdf](http://www.ihe.net/Technical_Framework/upload/IHE_PCD_TF_Supplement_IDCO_2009-08-10.pdf)

<sup>10</sup> ISO/IEEE 11073-10101:2004, Point-of-care medical device communication -- Part 10101: Nomenclature, [http://www.iso.org/iso/catalogue\\_detail.htm?csnumber=37890](http://www.iso.org/iso/catalogue_detail.htm?csnumber=37890)

<sup>11</sup> IHE Patient Care Coordination (PCC) Technical Framework Supplement, 2008-2009, Care Management (CM), Draft for Trial Implementation, August 22, 2008

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

1. **Personalized Adaptive Care Planner for the CIED Recipients:** In the iCARDEA project, the personalized follow-up of CIED patients is coordinated through a “care plan” which is an executable definition of computer interpretable clinical guideline models. The care plans are represented in GLIF, and the Care Plan Engine is capable of semi-automatically executing the care plan by processing its machine processable definition. The control flow of the care plan is dynamically adapted based on the patient’s context derived from the data coming from CIEDs and the medical context obtained from the EHRs. Through a graphical monitoring tool, the physicians are allowed to follow the execution of the care plan in detail, and coordinate the flow of actions when consultations to physicians are required.
2. **The CIED Data Exposure Module** uses “IHE Implantable Device Cardiac Observation Profile (IDCO)” to expose the CIED data from different vendors in a machine processable format to be used in the care plan of the patients. For this, it has a component that allows accessing the CIED Portal of the vendor and triggers the CIED data export automatically from the CIED Data Centre (periodically every x hours or each morning at a defined time). The CIED Data Listener Component waits for the exported data. For this it either scans a configurable directory in case of the data is exported directly to a vendor system in the clinic, alternatively it listens a pre-configured port for the exported data using the IHE IDCO/HL7 v2.5 protocol in case of direct network retrieval. In both cases the PDF file(s) need to be processed to extract the CIED data and the Data Translation Service subsystem creates a valid IHE IDCO format (HL7 v2.5 ORU Message) and makes the CIED data available to the iCARDEA Adaptive Care Planner through PCD-09 Send Observation message.
3. **EHR Interoperability Infrastructure:** To execute the clinical guidelines, it is also necessary to have access to medical history of the patients in the EHR systems. Considering that there are very many EHR systems with proprietary interfaces, in iCARDEA, “IHE Care Management (CM) Profile” is used. In our system, the proprietary hospital information systems export “Discharge Summary” and also “Laboratory Report Summary” CDA documents in conformance to IHE CDA Document templates<sup>12</sup> to an EHR Server which is implemented as an IHE XDS Repository<sup>13</sup>. This EHR Server also acts as a “Clinical Data Source” by implementing the IHE CM Profile. In this way, Adaptive Care Manager can subscribe

<sup>12</sup> IHE Care Coordination Framework, Content Modules, [http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1#Medical\\_Documents\\_Specification\\_1.3.6.1.4.1.19376.1.5.3.1.1.1](http://wiki.ihe.net/index.php?title=1.3.6.1.4.1.19376.1.5.3.1.1#Medical_Documents_Specification_1.3.6.1.4.1.19376.1.5.3.1.1.1)

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

to receive update notifications for the clinical data that is necessary to execute the care plans. IHE Care Management Profile specifies standard interfaces to extract this data that is needed by the care plans from the EHR systems. The two standardized transactions used in the iCARDEA system are as follows:

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

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

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

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

4. There is also a Patient Empowerment component that aims to provide active and informed involvement of patients in management of their own health. Through the web based PHR, patients will be able to view their medical history, CIED data, and manage their medication summaries, daily nutrition information.

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

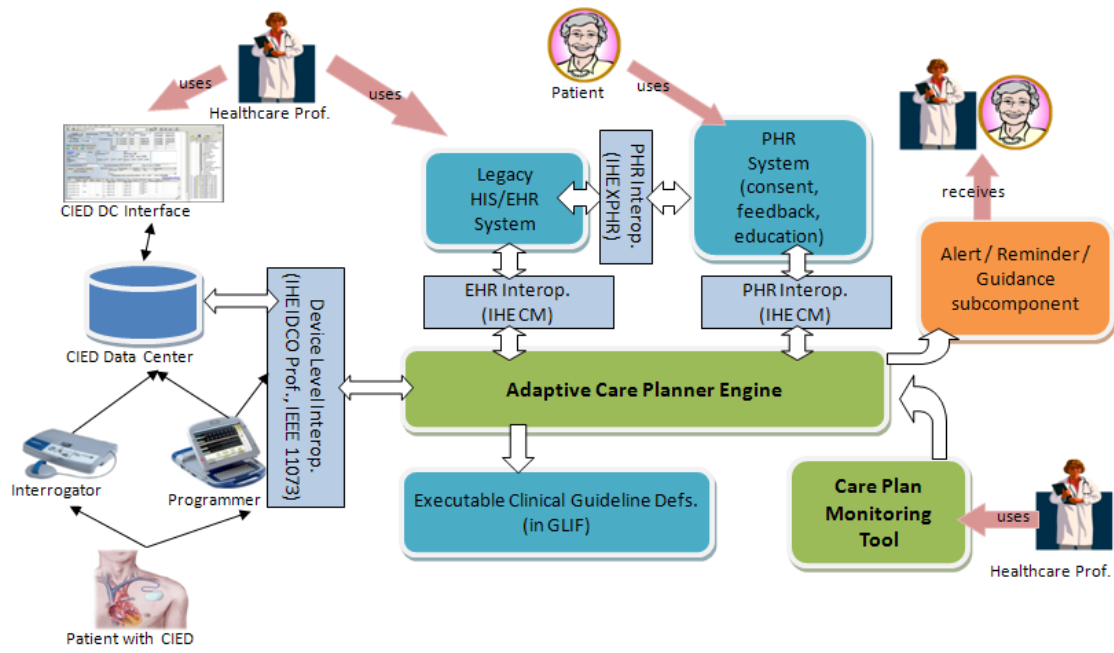


Figure 1 iCARDEA Architecture Overview

### 3 Evaluation of an Early Prototype

Time frame: M17-M19

iCARDEA validation includes test of an early iCARDEA prototype with reduced functionalities. This will be an enhanced version of the prototype developed for the first review meeting in May 2011. 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 prototype may also include paper-based mockups in order to simulate graphical user interfaces for those iCARDEA functions which are not yet implemented. The early prototype aims to receive feedback from the users (medical experts, patients) about basic iCARDEA features, usability and possible barriers.

The evaluation for the early prototype is based on the review story board covering an Atrial Fibrillation Scenario (see deliverable D9.2.1 “Design of the Implementation of the Pilot Application Scenario”) and includes the following aspects:

- Usability and acceptance – refers to patients and medical experts
- Barriers – refers to aspects currently hampering the usage of the iCARDEA system.

The results of this evaluation phase will give additional information for the implementation phase of iCARDEA. For the evaluation of the early prototype no specific test cases are defined. The main instrument will be questionnaires for the end-users covering usability/acceptance and barrier aspects for the following iCARDEA components.

#### 3.1 Personalized Adaptive Care Planer

The tools that will be used by medical experts in the pilot application (i.e. the tools whose graphical user interfaces will be used) are Careplan Definition Tool and Careplan Monitoring Tool. In addition to these tools, SRDC developed a web based GUI that integrates all the tools into one environment. In this environment, patient management and careplan management tasks are also realized. In this respect the following questions will be asked to the medical experts for the evaluation:

**Careplan Definition Tool** (Target users: physicians)

<i>Questions</i>	<i>Scale</i>
How do you rate the user-friendliness of the tool?	low – medium - high
Are the constructs used to define a careplan are familiar to you?	no – possibly - yes

Have you had any difficulty to understand the aim and properties of the careplan constructs (steps)?	no – possibly - yes
Do the error messages contain sufficient detail?	no – possibly - yes
How do you rate the performance of the tool?	low – medium - high
Have you ever seen any deadlock situation?	no – possibly - yes

### Careplan Monitoring Tool (Target users: physicians)

<i>Questions</i>	<i>Scale</i>
How do you rate the user-friendliness of the tool?	low – medium - high
Do the alarm/recommendation messages contain sufficient details?	no – possibly - yes
Do the consult windows contain sufficient details?	no – possibly - yes
Is the tracking of the execution of a careplan user-friendly?	no – possibly - yes
How do you rate the performance of the tool?	low – medium - high
Have you ever seen any deadlock situation?	no – possibly - yes

### Web-based main graphical user interface (Target users: physicians)

<i>Questions</i>	<i>Scale</i>
How do you rate the user-friendliness of the GUI?	low – medium - high
How do you rate the performance of the tool?	low – medium - high
Have you ever seen any deadlock situation?	no – possibly - yes
Is the patient management user-friendly?	no – possibly - yes
Is the careplan management user-friendly?	no – possibly - yes

## 3.2 Context awareness and clinically useful information derivation

The tools that will be used by medical experts in the pilot application (i.e. the tools whose graphical user interfaces will be used) are Patient Parameter Monitor (PPM) and Data Analysis and Correlation Tool (DACT). The medical experts will use these tools for the retrieval of information about the status of the patient and to view and assign the pattern obtained by data analysis. In this respect the following questions will be asked to the medical experts for the evaluation:

### PPM Patient Parameter Monitor (Target users: physicians)

<i>Questions</i>	<i>Scale</i>
How do you rate the information of the PPM?	low – medium - high
How do you rate the presentation of the PPM?	low – medium - high
Is the presentation useful for your daily work?	no – possibly - yes
Would you need additional information?	no – possibly - yes

If yes, which type of information?	open answer (text)
Would you like to have less information? If yes, which information is not needed?	no – possibly – yes open answer (text)
Is the PPM user-friendly?	no – possibly - yes
Where there any barriers for you when looking for information? If no or sometimes – can you describe these barriers?	no – sometimes – yes open answer (text)

### DACT Data Analysis and Correlation Tool (Target users: physicians)

<i>Questions</i>	<i>Scale</i>
Is the presentation of the found patterns easy to understand? If not – are there too many rejected patterns? If not – are the patterns too specialized? If not – other explanations?	no – possibly – yes no – possibly – yes no – possibly – yes open answer (text)
Is the patterns analysis useful for your work?	no – possibly – yes
Is the patterns analysis useful for your research?	no – possibly – yes

### 3.3 CIED Data Interoperability Module

Normally there is no direct access to the CIED Data Interoperability Module for the physicians. In our case we have to use a workaround for the data transfer between the vendor data centers and SALK infrastructure. The data extracted by CIED will be used and presented in Careplan and PPM.

#### Technical Tests – in- /outcoming data (Target users: technical staff)

<i>Questions</i>	<i>Scale</i>
Are you missing parameters? If yes – which ones	no – yes open answer (text)
Are there incomplete input data? If yes – Why: Missing in pdfs? Not extracted from pdf?	no – yes description of failure
How big is the overload for data collection from vendor data center ?	No overload - Tolerable – inadequate
Is the feedback of the CIED Data extraction process appropriate? If no - explain	no – yes open answer (text)

### 3.4 Patient Empowerment Framework

The early prototype of the PHR system to be tested is focused on the management of the user profile, the recording of observations of daily living and information resources.

**PHR system** (Target group: patients)

<i>Questions</i>	<i>Scale</i>
Are you doing any observations of daily living? eg about weight, hypertension, sport activities If yes, what are you recording? If no, would you try it?	no – sometimes – yes no – sometimes – yes open answer (text)
Do you record medication changes? If no, would you ready to try it?	no – sometimes – yes no – sometimes – yes
Is it easy for you to record activities of daily living with the PHR system? If “difficult” – can you explain why is it difficult for you?	Easy – medium – difficult open answer (text)
Is it easy for you to record physical activities? If “difficult” – can you explain why is it difficult for you?	Easy – medium – difficult open answer (text)
Is it easy for you to record problems? If “difficult” – can you explain why is it difficult for you?	Easy – medium – difficult open answer (text)
Is it easy for you to record medication changes? If “difficult” – can you explain why is it difficult for you?	Easy – medium – difficult open answer (text)
How do you rate the user-friendliness of the PHR system?	low – medium - high
Do you use personal health devices at home? BP monitor, Glucose meter, INR, other?	no – sometimes – frequently
Do you have concerns with privacy? If sometimes or frequently, can you explain why?	no – sometimes – frequently open answer (text)

**Information** (Target group: patients)

<i>Questions</i>	<i>Scale</i>
What are your sources of information about your disease? e.g. Doctor, GP, internet, leaflets, pharmacy, other patients, self help groups.	open answer (text)
What is important for you to know about the disease?	open answer (text)
Do you feel that you are well informed about your disease? If no or sometimes – which kind of information are you missing?	no – sometimes – yes open answer (text)
Which topics in relation to your disease are particularly important to you?	open answer (text)
Where there any barriers for you when looking for infor-	no – sometimes – frequently

mation? If yes or sometimes – can you describe these barriers?	open answer (text)
What type of resources/information would you be looking for in relation to your disease? e.g. talks, groups, internet pages, leaflets, asking physicians, asking nurses, videos, other patients, GPs, cardiologists, etc.	open answer (text)
Do you use the Internet?	no – sometimes – frequently

### 3.5 EHR interoperability Framework

The tools that provide user interface to be used by medical experts in the pilot application are CDA Editor and Patient Index (PIX) Manager.

**CDA Editor** (target group: physicians)

<i>Questions</i>	<i>Scale</i>
How do you rate the user-friendliness of the tool?	low – medium - high
Are there all the required medical data types (laboratory exams, findings/problems, medications etc)?	No – Yes
Are there all required medical codes (for laboratory exams, medications, findings etc)?	No – Possibly – Yes open answer (text)
Is it easy to find patient's medical info (e.g. medication, laboratory exam)?	No – Possibly – Yes open answer (text)
Is it easy to add/edit patient's medical info?	No – Possibly – Yes open answer (text)
Is the patient's info stored in CDA complete? Are there any fields missing?	No – Possibly – Yes open answer (text)

**Patient Index Manager** (target group: physicians)

<i>Questions</i>	<i>Scale</i>
How do you rate the user-friendliness of the tool?	low – medium - high
Is it easy to map patients' codes?	No – Possibly – Yes open answer (text)
Is it easy to find patient's demographics info?	No – Possibly – Yes open answer (text)
Is it easy to add/edit patient's info?	No – Possibly – Yes open answer (text)
Is the info stored for each patient complete? Are there any fields missing?	No – Possibly – Yes open answer (text)

## 4 Evaluation and Validation of the Final Prototype

Time frame: M28-M36

The evaluation and validation of the final prototype is based on demonstration scenarios described in the deliverable D9.2.1 “Design of the Implementation of the Pilot Application Scenario”. Basically, two scenarios are specified for the iCARDEA Pilot Application – a scenario for Atrial Fibrillation and a scenario for Ventricular Tachycardia. The evaluation and validation of both scenarios are described by the test cases specified in section 4.4.

The validation of the iCARDEA prototype will be quantitative including physicians and two groups of patients and based on a Pilot Study (see section 4.1) including a Study Protocol (see section 4.5). Hence, the iCARDEA validation of the final prototype will address 3 target groups:

- Physicians – referring to the treating physicians being responsible for the remote monitoring
- Patient Group 1 in-office arm – with ordinary post-surgical control (twice per year). This group will have outpatient clinic care as normal.
- Patient Group 2 remote arm – with iCARDEA-enhanced remote monitoring. They will follow remote monitoring with iCARDEA assistance.

Finally, two approaches serve as a basis for the validation plan, 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 Patient Group 1 and Patient Group 2. 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 (TCs) describing the relevant situations to be evaluated and validated for iCARDEA.

### 4.1 Description of the Pilot Study

The Pilot Study comprises 2 groups of patients (25 for each cohort) with ICD for secondary prophylaxis. They 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).

All patients need to sign a consent form. All alerts that come from the telemonitoring will be evaluated as usual. The medical personnel will then at a later time evaluate the use and functioning of the iCARDEA components.

The protocol for the Pilot Study can be found in section 4.5.

## 4.2 The Goal Question Metric Approach

The Goal-Question-Metric (GQM)<sup>15</sup> method is used to define measurement on the software project, process, and product in such a way that

- Resulting metrics are tailored to the organization and its goal.
- Resulting measurement data play a constructive and instructive role in the organization.
- Metrics and their interpretation reflect the values and the viewpoints of the different groups affected (e.g., developers, users, and operators).

GQM defines a measurement model on three levels:

- Conceptual level (goal): A goal is defined for an object, for a variety of reasons, with respect to various models of quality, from various points of view, and relative to a particular environment.
- Operational level (question): A set of questions is used to define models of the object of study and then focuses on that object to characterize the assessment or achievement of a specific goal.
- Quantitative level (metric): A set of metrics, based on the models, is associated with every question in order to answer it in a measurable way.

Although originally used to define and evaluate a particular project in a particular environment, GQM can also be used for control and improvement of a single project within an organization running several projects.

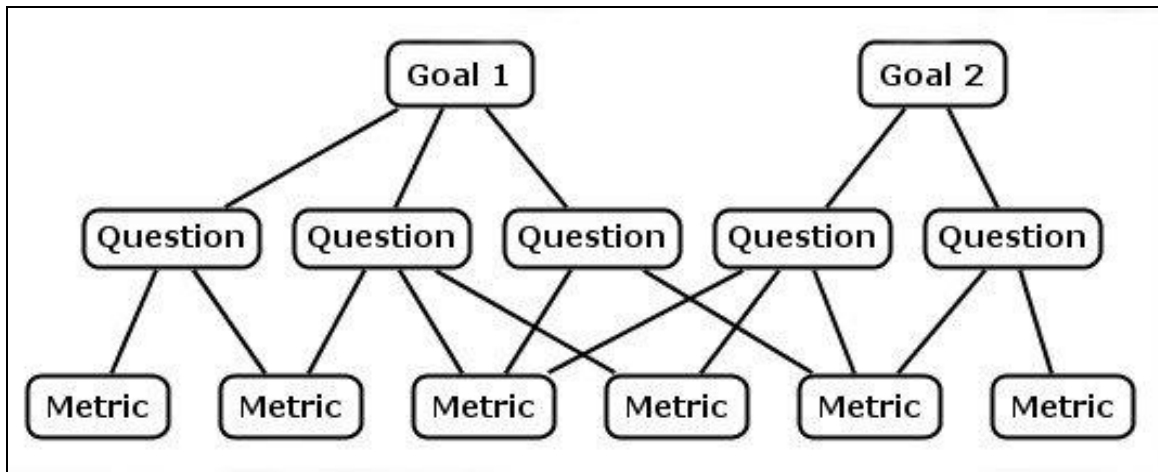


Figure 2 - the GQM paradigm<sup>16</sup>

<sup>15</sup> <ftp://ftp.cs.umd.edu/pub/sel/papers/gqm.pdf>

<sup>16</sup> <ftp://ftp.cs.umd.edu/pub/sel/papers/gqm.pdf>

The GQM paradigm (see Figure 2) represents a practical approach for bounding the measurement problem. It provides an organisation with a great deal of flexibility, allowing it to focus its measurement program on its own particular needs and culture. It is based upon two basic assumptions:

1. that a measurement program should not be ‘metric-based’ but ‘goal-based’ and
2. that the definition of goals and measures need to be tailored to the individual organization

However, these assumptions make the process more difficult than just offering people a ‘collection of metrics’ or a standard predefined set of goals and metrics. It requires that the organization make explicit its own goals and processes.

The GQM method contains four phases:

1. The Planning phase, during which a project for measurement application is selected, defined, characterised, and planned, resulting in a project plan.
2. The Definition phase, in which the measurement programme is defined (goal, questions, metrics, and hypotheses are defined) and documented.
3. The Data Collection phase, where the actual data collection takes place, resulting in collected data.
4. The Interpretation phase, during which collected data is processed with respect to the defined metrics into measurement results that provide answers to the defined questions, after which goal attainment can be evaluated.

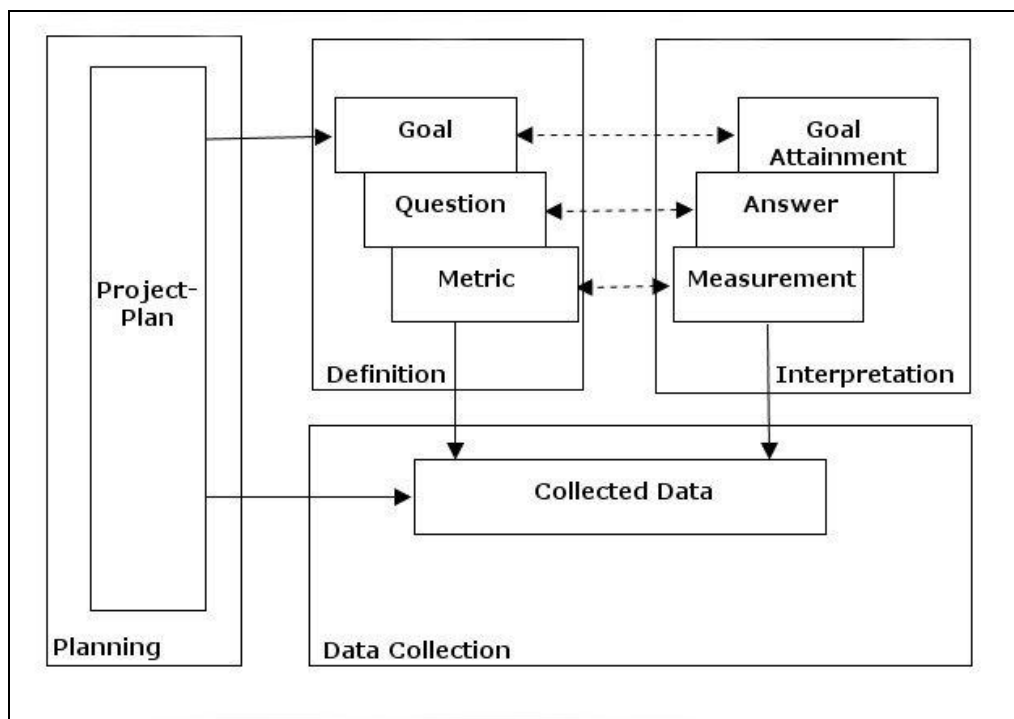


Figure 3 - basic phases of the GQM method

The four phases of the GQM method are illustrated in Figure 3. The GQM paradigm provides a method for top-down metric definition and bottom-up data interpretation.

### 4.3 Overview Test Cases

Based on the GQM approach Table 2 gives an overview of the goals, questions and test cases for the final iCARDEA validation. The goals were specified based on the project objectives and on the quantified specific objectives for iCARDEA system components described in the Description of Work.

Additionally, based on the Description of Work and on the developed storyboards the evaluation and validation for the final prototype will include the following dimensions for the test cases (TCs). These dimensions are being used as an orientation for asking the right questions:

- **Basic criteria** – refers to the basic features that should be measured by the pilot application. If applicable the results of the test cases should be used for comparing behaviours between Patient Group 1 and Patient Group 2.
- **Management of symptoms and medical risks** – time and pathway from patient-record symptoms to clinical decision in response to the symptom and to possible medical risks which could be detected earlier.
- **Indicators for remote monitoring** – refers to remote monitoring management and to the questions how remote monitoring in iCARDEA can reduce risks for the patients (concerning the device and medical risks)
- **Usability and acceptance** – refers to patients and medical experts
- **Security and privacy issues** – evaluates the adequacy of the iCARDEA security and privacy measures
- **Atrial Fibrillation** – addressing additional test cases for Atrial Fibrillation
- **Ventricular Tachycardia** – addressing additional test cases for Ventricular Tachycardia

Goal	Questions	Test Cases <sup>17</sup>
<b>Goal 1: Improving the quality of health care for remote monitoring</b>		
	What are the basic features to be measured?	TC1.1 Number of Patients TC1.3 Latency of iCARDEA Data TC1.4 How stable are the connections between the components TC1.5 Downtime of Servers TC1.6 Response time of failure reports TC1.7 Number of access DACT TC1.8 Time between follow up and PPM Access
	Which indicators for remote monitoring can be measured?	TC1.2 Number of follow-ups TC2.3 Number and type of actions TC3.1 Full transmission (SJM devices) TC3.2 Full transmission (MDT devices)

<sup>17</sup> See chapter 4.4 for the detailed description of Test Cases

		TC3.3 Number of CIED reports TC3.6 Number of errors
	Can medical risks detected earlier?	TC2.5 Number of recommendations received by the patient/care givers TC2.9 Tachycardia under detected TC3.4 Number of alerts TC3.5 Number of critical events TC6.2 Medical risks for AF TC7.2 Medical risks for VT
	How would physicians assess the usability, acceptance and usefulness of iCARDEA?	TC4.1 User satisfaction TC4.2 Usability of DACT TC4.3 Usability of PPM TC4.6 Usability of Care Plan Monitoring Tool TC4.9 Usability of Care Plan Definition Tool TC4.16 Usability of Patient Index Manager
	Does iCARDEA improve the quality of remote monitoring in comparison with the control group?	TC1.9 Patient well-being TC1.10 Burden of in-office follow-up visit TC2.1 Time between event onset and clinical decision TC2.5 Number of recommendations received by the patient/care givers TC2.9 Tachycardia under detected TC3.1 Full transmission (SJM devices) TC3.2 Full transmission (MDT devices) TC3.3 Number of CIED reports TC3.4 Number of alerts TC3.5 Number of critical events TC3.6 Number of errors TC3.7 The time spent for monitoring a CIED Patient TC4.1 User satisfaction TC6.1 Onset of atrial fibrillation TC6.2 Medical risks for AF TC6.3, AF Symptoms TC6.4 Barriers and limits for AF TC7.1 Number and onset of symptoms TC7.2 Medical risks for VT TC7.3 VT symptoms TC7.4 Barriers and limits for VT
	Does the electronic care plans improve the care for Atrial Fibrillation?	TC6.1 Onset of atrial fibrillation TC6.2 Medical risks for AF TC6.3 AF Symptoms TC6.4 Barriers and limits for AF TC6.5 Readability of AF Careplan in the Careplan Definition Tool TC6.6 Readability of AF Careplan in the Careplan Monitoring Tool TC6.7 Clearness of the recommendations for AF Careplan
	Does the electronic care plans improve the care for Ventricular Tachycardia?	TC7.1 Number and onset of symptoms TC7.2 Medical risks for VT TC7.3 VT symptoms TC7.4 Barriers and limits for VT TC7.5 Readability of VT Careplan in the Careplan Definition Tool TC7.6 Readability of VT Careplan in the Careplan Monitoring Tool TC7.7 Clearness of the recommendations for VT Careplan
	Is security and privacy sufficiently ensured?	TC5.1 Wrong Permission TC5.3 Satisfaction with security and privacy
<b>Goal 2: Providing clinical guidelines for Remote Monitoring CIED based on integrated patient data from heterogeneous data sources</b>		

	What are the basic features to be measured?	TC2.2 Number of diagnosis per categories TC4.10 Time Spent to define a new Care Plan
	Are the presented patient data (EHR, CIED, PHR) sufficient and useful for remote monitoring?	TC4.11 Satisfaction with presented patient data from heterogenous data sources TC4.15 Usability of CDA Editor TC4.16 Usability of Patient Index Manager
	How would physicians assess the usefulness of recommendations based on the clinical guidelines?	TC4.4 The number of simultaneously executing careplans TC4.5 The number of correct recommendations by the Care Planner TC4.6 Usability of Care Plan Monitoring Tool TC4.8 Clearness of the Care Planner Recommendations TC4.9 Usability of Care Plan Definition Tool
<b>Goal 3: Increasing the level of Patient Empowerment</b>		
	What are the basic features to be measured from the patients' point of view?	TC2.6 Number of medication changes recorded by the PHR system TC2.7 Number of observations of daily living recorded by the PHR system TC2.8 Number of problems recorded by the PHR system
	How would patients assess the usability, acceptance and usefulness of using iCARDEA?	TC1.9 Patient well-being TC1.10 Burden of in-office follow-up visit TC4.1 User satisfaction TC4.12 Usability of the PHR system TC4.13 Usability of the Action Plan TC4.14 Usability of information material for patients
	Is security and privacy sufficiently ensured from the patients' point of view?	TC4.7 Usability of Consent Management Tool TC5.1 Wrong Permission TC5.2 Authorized access to patient data TC5.3 Satisfaction with security and privacy

Table 2 - GQM for the iCARDEA validation

#### 4.4 Description of Test Cases

This section describes test cases which cover both scenarios – for the Atrial Fibrillation Scenario and for Ventricular Tachycardia Scenario – and represent the third level of the GQM approach. The results of the test cases will be collected based on one of the following methods:

- **Questionnaire** – this could either be a question in a summarizing questionnaire or a dedicated questionnaire such as the EuroQol 5 D<sup>18</sup> for patient well-being. The questionnaire will be used at the end of the validation phase.
- **Manual logfile** – recording additional data during the validation phase which are not possible to record electronically by iCARDEA components, e.g. number of follow-ups
- **Software output** – this could be e.g. a logfile or a history created by an iCARDEA component and aiming to record data (e.g. number of critical events) during the validation phase.

As iCARDEA will not be used by Patient Group 1 this approach has to be replaced by manual logfiles for Patient Group 1.

<sup>18</sup> <http://www.euroqol.org/eq-5d/how-to-obtain-eq-5d.html>

Table 3 gives an overview about the test cases for the validation of the final prototype, the related target groups (physician, patient group 1, patient group 2) and the associated methods to be used to collect and record the required results of the test cases.

No	Test Cases	Physician	Patient Group 1	Patient Group 2	Method for collecting data
<b>Basic Test Cases</b>					
TC 1.1	Number of Patients		x	x	Manual logfile
TC 1.2	Number of follow-ups		x	x	Manual logfile
TC 1.3	Latency of iCARDEA Data	x			Software output (CIED Data Interoperability Module)
TC 1.4	How stable are the connections between the components				Manual logfile
TC 1.5	Downtime of Servers				Manual logfile
TC 1.6	Response time of failure reports				Manual logfile
TC 1.7	Number of access DACT	x			Software output (DACT)
TC 1.8	Time between follow up and PPM Access	x			Manual logfile
TC 1.9	Patient well-being		x	x	Questionnaire
TC 1.10	Burden of in-office follow-up visit		x	x	Questionnaire
<b>Management of symptoms medical risks</b>					
TC 2.1	Time between event onset and clinical decision		x	x	Manual logfile
TC2.2	Number of diagnosis per categories		x	x	Software output (Care Planer)
TC 2.3	Number and type of actions		x	x	Software output (Care Planer)
TC 2.4	Number of Patterns	x			Software output (DACT)
TC 2.5	Number of recommendations received by the patient/care givers	x	x	x	Software output (Care Planer)
TC 2.6	Number of medication changes recorded by the PHR system			x	Software output (PHR Portal)
TC 2.7	Number of observations of daily living recorded by the PHR system			x	Software output (PHR Portal)
TC 2.8	Number of problems recorded by the PHR system			x	Software output (PHR Portal)
TC2.9	Tachycardia under detected		x	x	Manual logfile
<b>Indicators for remote monitoring</b>					
TC 3.1	Full transmission (SJM devices)		x	x	Software output (CIED Data Interoperability Module)
TC 3.2	Full transmission (MDT devices)		x	x	Software output (CIED Data Interoperability Module)
TC 3.3	Number of CIED reports		x	x	Software output (CIED Data Interoperability Module)
TC 3.4	Number of alerts		x	x	Software output (CIED Data Interoperability Module)
TC 3.5	Number of critical events		x	x	Software output (CIED Data Interoperability Module)
TC 3.6	Number of errors			x	Software output (CIED Data Interoperability Module)

TC 3.7	The time spent for monitoring a CIED Patient		x	x	Manual logfile
<b>Usability and acceptance</b>					
TC 4.1	User satisfaction	x	x	x	Questionnaire
TC 4.2	Usability of DACT	x			Questionnaire
TC 4.3	Usability of PPM	x			Questionnaire
TC 4.4	The number of simultaneously executing careplans	x			Software output (Care Planer)
TC 4.5	The number of correct recommendations by the Care Planner	x			Manual logfile
TC 4.6	Usability of Care Plan Monitoring Tool	x			Questionnaire
TC 4.7	Usability of Consent Management Tool			x	Questionnaire
TC 4.8	Clearness of the Care Planner Recommendations	x			Questionnaire
TC 4.9	Usability of Care Plan Definition Tool	x			Questionnaire
TC 4.10	Time Spent to define a new Care Plan	x			Manual logfile
TC 4.11	Satisfaction with presented patient data from heterogenous data sources	x			Questionnaire
TC 4.12	Usability of the PHR system			x	Questionnaire
TC 4.13	Usability of the Action Plan			x	Questionnaire
TC 4.14	Usability of information material for patients			x	Questionnaire
TC 4.15	Usability of CDA Editor	x			Questionnaire
TC 4.16	Usability of Patient Index Manager	x			Questionnaire
<b>Security and privacy issues</b>					
TC 5.1	Wrong Permission				Software output (Care Planer, PHR Portal, CIED, Patient Consent)
TC 5.2	Authorized access to patient data				Software output (Patient Consent)
TC 5.3	Satisfaction with security and privacy	x	x	x	Questionnaire
<b>Atrial Fibrillation Scenario</b>					
TC 6.1	Onset of atrial fibrillation		x	x	Manual logfile, Software output(Caer Plan Engine)
TC 6.2	Medical risks for AF		x	x	Manual logfile
TC 6.3	AF Symptoms		x	x	Manual logfile, Software output (PHR Portal)
TC 6.4	Barriers and limits for AF		x	x	Manual logfile
TC 6.5	Readability of AF Careplan in the Careplan Definition Tool	x			Questionnaire
TC 6.6	Readability of AF Careplan in the Careplan Monitoring Tool	x			Questionnaire
TC 6.7	Clearness of the recommendations for AF Careplan	x			Manual logfile
<b>Ventricular Tachycardia Scenario</b>					
TC 7.1	Number and onset of symptoms		x	x	Manual logfile, Software output(Caer Plan Engine)
TC 7.2	Medical risks for VT		x	x	Manual logfile, Software output(Caer Plan Engine)
TC 7.3	VT symptoms		x	x	Manual logfile, Software output (PHR Portal)

TC 7.4	Barriers and limits for VT		x	x	Manual logfile
TC 7.5	Readability of VT Careplan in the Careplan Definition Tool	x			Questionnaire
TC 7.6	Readability of VT Careplan in the Careplan Monitoring Tool	x			Questionnaire
TC 7.7	Clearness of the recommendations for VT Careplan	x			Manual logfile

**Table 3 - overview test cases, target groups and validation methods**

The following sections describe the tests cases in detail.

#### 4.4.1 Basic Test Cases

TC 1.1	<b>Number of Patients</b>
Description	Subsumes the number of patients (male & female) and their age for both groups of patients
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Number of patients per patient group
Method	Manual logfile
Remark	

TC 1.2	<b>Number of follow-ups</b>
Description	Subsumes the number of in-person and remote follow-ups classified after the type of follow-up: <ul style="list-style-type: none"> <li>• First regular follow-up</li> <li>• Regular follow-up</li> <li>• Additional follow-up due to technical reasons</li> <li>• Unscheduled follow-up due to critical events</li> <li>• Unscheduled follow-up due to medical intervention</li> </ul>
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Total number of follow-ups classified after the type of follow-up Number of unscheduled follow-ups classified after the type of follow-up
Method	Manual logfile
Remark	Prehospital discharge and CIED activation will not be considered.

TC 1.3	<b>Latency of iCARDEA Data</b>
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Description	Time between creation of report and export to iCARDEA
Target group	Physicians
Successful if	
Not successful if	
Measurement result	Duration in minutes/seconds
Method	Software output (CIED Data Interoperability Module)
Remark	

TC 1.4	<b>How stable are the connections between the components</b>
Description	Wrong, Missing or incomplete datatransfer
Target group	-
Successful if	n/a
Not successful if	n/a
Measurement result	Total number of unstable datatransfer Total number of wrong datatransfer Total number of missing datatransfer Total number of icomplete datatransfer
Method	Manual logfile
Remark	

TC 1.5	<b>Downtime of Servers</b>
Description	Amount of unsuccessful logins due to technical reasons
Target group	-
Successful if	Below 0,1%
Not successful if	$\geq 0,1\%$
Measurement result	Total number unsuccesfully logins Description of the reason for each unsuccesfull login
Method	Manual logfile
Remark	

TC 1.6	<b>Response time of failure reports</b>
Description	Time between failure of a system / server or component and the start of an action of the technical staff
Target group	--
Successful if	<12h
Not successful if	>12h
Measurement result	Minutes between failure an action started
Method	Manual logfile
Remark	

TC 1.7	<b>Number of access DACT</b>
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Description	How often the tools is used
Target group	Physicians
Successful if	n/a
Not successful if	n/a
Measurement result	Total number of DACT accesses
Method	Software output (DACT)
Remark	

TC 1.8	<b>Time between follow up and PPM Access</b>
Description	How often the tool is used without follow up
Target group	Physicians
Successful if	n/a
Not successful if	n/a
Measurement result	Duration in minutes and seconds
Method	Manual logfile
Remark	

TC 1.9	<b>Patient well-being</b>
Description	Measured by the State and Trait Anxiety Index, Short <sup>19</sup> and EuroQol 5D <sup>20</sup>
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Interviews based on questionnaires
Method	Questionnaire
Remark	

TC 1.10	<b>Burden of in-office follow-up visit</b>
Description	Patients will complete a questionnaire to characterize the burden experienced (eg, distanced traveled, time off work) by them and their caregiver as a result of attending an in-office visit
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Interviews based on questionnaires
Method	Questionnaire

<sup>19</sup> Spielberger CD, Gorsuch RL, Lushene PR, Vagg PR, Jacobs AG. 1983. Manual for the State-Trait Anxiety Inventory

<sup>20</sup> <http://www.euroqol.org/eq-5d/how-to-obtain-eq-5d.html>

Remark	
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#### 4.4.2 Management of symptoms and medical risks

TC 2.1	<b>Time between event onset and clinical decision</b>
Description	The time between event onset and clinical decision for each event will be determined. These times will then be averaged for each patient so that each patient has an average time from event onset to clinical decision and will contribute one value to the analysis. The time to clinical decision is defined as the time at which the clinician determines what action, if any, to take in response to an event and occurs shortly after viewing the device information, which could be done remotely or at an in-office visit.
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	average time, min time, max time
Method	Manual logfile
Remark	

TC 2.2	<b>Number of diagnosis per categories</b>
Description	Subsumes the number of diagnosis classified after the following categories <ul style="list-style-type: none"> <li>• atrial fibrillation</li> <li>• ventricular tachyarrhythmias</li> <li>• inappropriate therapies</li> <li>• non-sustained ventricular tachycardia</li> <li>• device malfunction</li> <li>• impending heart failure</li> <li>• Appropriate therapies: sustained ventricular tachycardia and ventricular fibrillation</li> </ul>
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Number of diagnosis classified per diagnosis categories
Method	Software output (Care Planer)
Remark	

TC 2.3	<b>Number and type of actions</b>
Description	Subsumes the number and type of actions based on the following

	categories: <ul style="list-style-type: none"> <li>• drug therapy change</li> <li>• device reprogramming</li> <li>• confirmation of diagnosis without further intervention</li> <li>• diagnostic tests</li> </ul>
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Number and type of actions per action category
Method	Software output (Care Planer)
Remark	

TC 2.4	<b>Number of Patterns</b>
Description	The amount of identified patterns using the Data Analysis Correlation Tool
Target group	Physicians
Successful if	More than one was identified
Not successful if	No pattern could be identified
Measurement result	Integer.
Method	Software output (DACT)
Remark	At this point, patterns refer to patterns that are determined as useful by health care actors for iCARDEA project.

TC 2.5	<b>Number of recommendations received by the patient/care givers</b>
Description	Subsumes the number of recommendations received by the patients and their care givers during remote monitoring of the patient as a result of care plan execution
Target group	Physicians, Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Total number of recommendation messages received Brief description of each alert
Method	Software output (Care Planer)
Remark	

TC 2.6	<b>Number of medication changes recorded by the PHR system</b>
Description	Subsumes the number of medication changes recorded by patients through the PHR system.
Target group	Patient group 2
Successful if	n/a

Not successful if	n/a
Measurement result	<ul style="list-style-type: none"> <li>• Total number of medication changes</li> <li>• Average number of medication changes per patient</li> </ul>
Method	Software output (PHR Portal)
Remark	

TC 2.7	<b>Number of observations of daily living recorded by the PHR system</b>
Description	<p>Subsumes the number of observations of daily living recorded by patients through the PHR system classified after the following categories:</p> <ul style="list-style-type: none"> <li>• hypertension</li> <li>• body weight</li> </ul>
Target group	Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Total and average number of observations of daily living for hypertension and body weight
Method	Software output (PHR Portal)
Remark	

TC 2.8	<b>Number of problems recorded by the PHR system</b>
Description	<p>Subsumes the number of problems recorded by patients through the PHR system. This will be classified after the following symptoms categories</p> <ul style="list-style-type: none"> <li>• Chest pain</li> <li>• Diarrhea</li> <li>• Dyspnea</li> <li>• Extra bruising or bleeding</li> <li>• Extra pillow to sleep at night</li> <li>• Fatigue</li> <li>• Fever</li> <li>• Other symptoms</li> <li>• Palpitations</li> <li>• Rashes</li> <li>• Shortness of breath</li> <li>• Swelling in feet or ankles</li> <li>• Temporary loss of speech</li> <li>• Temporary weakness</li> <li>• Vomit</li> <li>• Weight gain</li> <li>• Wound hematoma</li> </ul>

Target group	Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Total number of problems/symptoms classified after symptoms categories
Method	Software output (PHR Portal)
Remark	

TC 2.9	<b>Tachycardia under detected</b>
Description	Medical risk - Tachycardia under detected. Low ventricular pacing in resynchronization therapy patients. Inappropriate therapies in high frequencies tachycardia other than VF/VT Electrical storm.
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Numbers of events. Percentage of ventricular pacing. Shocks. More than 3 shocks in 24 hours.
Method	Manual logfile
Remark	

#### 4.4.3 Indicators for remote monitoring

TC 3.1	<b>Full transmission (SJM devices)</b>
Description	<p>Depending on the device there are several parameters that initiate a full transmission and are therefore indicators for remote monitoring:</p> <ul style="list-style-type: none"> <li>• VT/VF episode</li> <li>• AT/AF episode</li> <li>• Impedance to low/high (Lead problem)</li> <li>• High output amplitude <math>\geq 5V</math></li> <li>• RV pacing over n% for m days</li> <li>• Tachy-Therapy is deactivated</li> <li>• Device is working in backup mode</li> <li>• Device Capacitor loading time limit exceeded</li> <li>• Possible damage in the electronic circuit</li> <li>• Device Reset</li> <li>• Battery at ERI</li> <li>• Possible problem with the shock electrode</li> <li>• Impedance of the shock electrode out of range</li> <li>• Impedance of the atrial/ventricular pace/sense lead out of range</li> </ul>

Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	A list of parameters for each full transmission
Method	Software output (CIED Data Interoperability Module)
Remark	The home monitoring system from SJM does not need an interaction from the patient as it operates automatically. After the system has been connected to a specific device the monitoring system initiates a link to the device every night. If the system is unable to detect the device the connection will be tried to establish some hours later until connection could be established successfully.

TC 3.2	<b>Full transmission (MDT devices)</b>
Description	<p>In MEDTRONIC devices, depending on the technical characteristics, a full transmission can be initiated in three several ways. The first case is when a device itself detects an alert; there are defined eighteen alerts which are listed in the following lines. The second case is when the physician has scheduled a complete transmission, then when the date arrives the transmission automatically starts. The last case is when the physician asks the patient to execute a transmission.</p> <p>Alerts:</p> <ul style="list-style-type: none"> <li>• VF Detection Therapy OFF</li> <li>• Low Battery Voltage</li> <li>• Excessive Charge Time</li> <li>• Atrial Pacing</li> <li>• RV Pacing</li> <li>• LV Pacing</li> <li>• Ventricular Defib</li> <li>• SVC (HVZ) Defib</li> <li>• Electrical Reset</li> <li>• Pacing Mode DOO VOO AOO</li> <li>• Active Can Off without SVC</li> <li>• Charge Circuit Timeout</li> <li>• Daily AT/AF Burden &gt; Threshold</li> <li>• Fast Ventricular Rate During AT/AF</li> <li>• Number of Shocks delivered in an Episode</li> <li>• All therapies in a Zone Exhausted</li> <li>• Optivol Fluid Status Monitoring Alert</li> <li>• Lead Integrity Alert - LIA</li> </ul>
Target group	Patient group 1, Patient group 2
Successful if	n/a

Not successful if	n/a
Measurement result	A list of parameters for each full transmission
Method	Software output (CIED Data Interoperability Module)
Remark	If the device could not achieve to complete the transmission it automatically retries after a certain amount of time.

TC 3.3	<b>Number of CIED reports</b>
Description	Total number of CIED Reports for iCARDEA Patients
Target group	Patient group 1, Patient group 2
Successful if	More than 60% CIED-report was obtained from the Data Center
Not successful if	If 25% or less of the CIED reports were exported to iCARDEA
Measurement result	Total number of CIED reports
Method	
Remark	

TC 3.4	<b>Number of alerts</b>
Description	<p>Subsumes the number of alerts received by the medical professionals during remote monitoring of the patient. The programming involves the device and clinical management alerts</p> <ul style="list-style-type: none"> <li>• Patient Group 1 - only those alerts associated with system integrity are enabled</li> <li>• Patient Group 2 - all alerts are enabled. The lead/device integrity alerts are programmed to sound an audible tone as in the in-office arm and are programmed to wirelessly transmit to the home monitor to ensure the greatest chance of a clinician becoming aware of the detected condition. The clinical management alerts are also programmed to transmit wirelessly but not to sound an audible tone</li> </ul> <p>An overview of alert programming for both patient groups is described in Table 4</p>
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Total number of alerts received Brief description of each type of alert
Method	Software output (CIED Data Interoperability Module)
Remark	

	Remote Arm	In-office arm
<b>Home Monitor</b>	Yes	No (not provided)
<b>Clinical management alerts</b>		
AT/AF daily burden	Wireless, 12 h/d	Off

Rapid ventricular rate during AT/AF	Wireless, 120 beat/min for $\geq 6$ h AT/AF per day	Off	Off
No. of shocks delivered	Wireless, 2 shocks	Off	
All therapies exhausted in a zone	Wireless		
<b>Lead/device integrity alerts</b>			
Lead impedance out of range	Wireless and audible, nominal ranges	Audible,	nominal
VF detection/therapy off	Wireless and audible	ranges	
Low battery voltage RRT	Wireless and audible	Audible	
Excessive charge time EOS	Wireless and audible	Audible	Audible
<i>RRT, Recommended replacement time; EOS, end of service.</i>			

**Table 4 - Alert programming**

TC 3.5	<b>Number of critical events</b>
Description	Subsumes the number of critical events based on the following categories: <ul style="list-style-type: none"> <li>• Wounds Problems</li> <li>• Clinicals issues: chest pain, symptoms of heart failure</li> <li>• Appropriate shocks</li> <li>• Inappropriate Shocks.</li> </ul>
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Number of critical events classified after event types
Method	Software output (CIED Data Interoperability Module)
Remark	

TC 3.6	<b>Number of errors</b>
Description	Subsumes the number of errors and describes the type of error such as transmission interruption, device malfunction (e.g. under detected tachycardias) impairment of permanent parameters (e.g. lead dislocation or rupture (e.g. elevated impedance)
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Total number of errors Brief description for each error
Method	Software output (CIED Data Interoperability Module)
Remark	

TC 3.7	<b>The time spent for monitoring a CIED Patient</b>
Description	The time spent for monitoring a patient with and without iCAR-DEA
Target group	Patient group 1, Patient group 2

Successful if	n/a
Not successful if	n/a
Measurement result	average time, min time, max time
Method	Manual logfile
Remark	

#### 4.4.4 Usability and acceptance

TC 4.1	<b>User satisfaction</b>
Description	Indicates the level of satisfaction quantifying the medical expert's/patient's satisfaction with and without iCARDEA. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians, Patient group 1, Patient group 2
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	<ul style="list-style-type: none"> <li>• Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10</li> <li>• Average satisfaction level</li> </ul>
Method	Questionnaire
Remark	

TC 4.2	<b>Usability of DACT</b>
Description	Indicates the overall level of satisfaction quantifying physician's satisfaction in using the DACT. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.3	<b>Usability of PPM</b>
Description	Indicates the overall level of satisfaction quantifying physician's satisfaction in using the PPM. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10

Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.4	<b>The number of simultaneously executing careplans</b>
Description	How many careplans is the Careplan Engine able to execute?
Target group	Physicians
Successful if	n/a
Not successful if	n/a
Measurement result	Number of simultaneously executed careplans per session
Method	Software output (Care Planer)
Remark	

TC 4.5	<b>The number of correct recommendations by the Care Planner</b>
Description	The ratio of the correctness/appropriateness of the recommendations of the care planner to the Medical Professionals
Target group	Physicians
Successful if	n/a
Not successful if	n/a
Measurement result	Number of correct and not correct recommendations per session percentage of correct recommendations per session
Method	Manual logfile
Remark	

TC 4.6	<b>Usability of Care Plan Monitoring Tool</b>
Description	Indicates the level of satisfaction quantifying medical expert's satisfaction in using iCARDEA Care Plan Monitoring Tool. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.7	<b>Usability of Consent Management Tool</b>
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Description	Indicates the level of satisfaction quantifying patients' satisfaction in using iCARDEA Consent Management Tool for defining the consent documents. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Patient group 2
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.8	<b>Clarity of the Care Planner Recommendations</b>
Description	Indicates the level of clarity of the recommendations provided by the Care Planner to Medical Professionals. The clarity can be expressed on a scale between 1 (totally unclear) and 10 (very, clear presenting all the necessary patient medical history, and the flow of actions)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of clarity for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.9	<b>Usability of Care Plan Definition Tool</b>
Description	Indicates the level of satisfaction quantifying medical expert's satisfaction in using iCARDEA Care Plan Definition Tool for defining new Care Plans. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.10	<b>Time Spent to define a new Care Plan</b>
Description	The time spent for defining a new Care Plan using iCARDEA Care Plan Definition Tool

Target group	Physicians
Successful if	n/a
Not successful if	n/a
Measurement result	Duration in minutes
Method	Manual logfile
Remark	

TC 4.11	<b>Satisfaction with presented patient data from heterogenous data sources</b>
Description	The level of satisfaction with the presented patient data (EHR, PHR, CIED) in the Care Planer integrated from different iCARDEA components. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction based on a scale between 1 and 10 for the following type of patient data: EHR, PHR, CIED
Method	Scale between 1 and 4
Remark	Questionnaire

TC 4.12	<b>Usability of the PHR system</b>
Description	Indicates the overall level of satisfaction quantifying patient's satisfaction in using the PHR system. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Patient group 2
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.13	<b>Usability of the Action Plan</b>
Description	Indicates the level of satisfaction quantifying patient's satisfaction in using the Action plan of the PHR system. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Patient group 2
Successful if	Scale between 5 and 10

Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.14	<b>Usability of information material for patients</b>
Description	Indicates the level of satisfaction quantifying patient's satisfaction in using the information material included in the PHR system. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Patient group 2
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.15	<b>Usability of CDA Editor</b>
Description	Indicates the level of satisfaction quantifying medical expert's satisfaction in using CDA Editor. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 4.16	<b>Usability of Patient Index Manager</b>
Description	Indicates the level of satisfaction quantifying medical expert's satisfaction in using Patient Index Manager. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a

	scale between 1 and 10
Method	Questionnaire
Remark	

#### 4.4.5 Security and privacy issues

TC 5.1	<b>Wrong Permission</b>
Description	Amount of unprivileged access to patient's EHR, PHR and CIED data
Target group	-
Successful if	No access will be granted to unauthorized roles to access patient data based on Patient's consent
Not successful if	Access will be granted to unauthorized roles to access patient data based on Patient's consent
Measurement result	Total number of unprivileged access
Method	Software output (Care Planer, PHR Portal, CIED, Patient Consent)
Remark	Amount of unprivileged access to patient's EHR, PHR and CIED data

TC 5.2	<b>Authorized access to patient data</b>
Description	The authorized roles through patient consent can see the data about a patient.
Target group	-
Successful if	If the authorized person can access to patient data as described and authorized through patient consent
Not successful if	If the authorized person cannot access to patient data although he has authorized to see the requested type of patient data through patient consent
Measurement result	Total number authorized access failures
Method	Software output (Patient Consent)
Remark	

TC 5.3	<b>Satisfaction with security and privacy</b>
Description	Indicates the level of satisfaction of the target groups about security and privacy. The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians, Patient group 1, Patient group 2
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction for each iCARDEA end user based on a

	scale between 1 and 10
Method	Questionnaire
Remark	

#### 4.4.6 Atrial Fibrillation

This section describes additional test cases for the demonstration scenario with the focus on atrial fibrillation.

TC 6.1	<b>Onset of atrial fibrillation</b>
Description	Duration and number of episodes. Need of antiarrhythmic drugs. Anticoagulation issues.
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Number of episodes and high atrial frequency. CHASDS score
Method	Manual logfile, Software output (Care Plan Engine)
Remark	

TC 6.2	<b>Medical risks for AF</b>
Description	Thromboembolics events. Tachycardio myopathy. Heart failure.
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Clinical test. Complementary test.
Method	Manual logfile
Remark	

TC 6.3	<b>AF Symptoms</b>
Description	Palpitations. Dyspnea Syncope. Chest pain. Impaired mobility or speech
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Clinical test ECG Device Interrogation
Method	Manual logfile, Software output (PHR Portal)
Remark	

TC 6.4	<b>Barriers and limits for AF</b>
Description	Shorts episodes of atrial fibrillation. Inappropriate detection (noise, other SVT)

Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	EGM. Device interrogation
Method	Manual logfile
Remark	

TC 6.5	<b>Readability of AF Careplan in the Careplan Definition Tool</b>
Description	The AF Careplan is rather long. Is it user-friendly to update/read/find the related part of an executing careplan? The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 6.6	<b>Readability of AF Careplan in the Careplan Monitoring Tool</b>
Description	The AF Careplan is rather long. Is it user-friendly to update/read/find the related part of an executing careplan? The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 6.7	<b>Clearness of the recommendations for AF Careplan</b>
Description	The medical professionals are asked whether the recommendations provided by the Care Planner for AF Care Plan are clear enough, i.e do they include the reasoning of the recommendations, do they contain the necessary relevant patient history, and the flow of actions happened that led to the presentation of this recommendation.
Target group	Physicians
Successful if	n/a
Not successful if	n/a
Measurement result	descriptive

Method	Manual logfile
Remark	

#### 4.4.7 Ventricular Tachycardia

This section describes additional test cases for the demonstration scenario with the focus on ventricular tachycardia.

TC 7.1	<b>Number and onset of symptoms</b>
Description	Number and onset of symptoms. Circumstances of episodes. Relation with other diseases and medications. Appropriate and Inappropriate shocks
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Number of shocks
Method	Manual logfile, Software output (Care Plan Engine)
Remark	

TC 7.2	<b>Medical risks for VT</b>
Description	Electrical storm. Syncope. Need of change medications. Need of ablation.
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Number of shocks
Method	Manual logfile, Software output (Care Plan Engine)
Remark	

TC 7.3	<b>VT symptoms</b>
Description	Dyspnea. Chest pain. Syncope. Palpitations. Heart failure.
Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	Clinical assessment. PHR
Method	Manual logfile, Software output (PHR Portal)
Remark	

TC 7.4	<b>Barriers and limits for VT</b>
Description	Inappropriate shocks (noise, other arrhythmias) Unsuccessful therapies.

Target group	Patient group 1, Patient group 2
Successful if	n/a
Not successful if	n/a
Measurement result	EGM. Device interrogation
Method	Manual logfile
Remark	

TC 7.5	<b>Readability of VT Careplan in the Careplan Definition Tool</b>
Description	The VT Careplan is rather long. Is it user-friendly to update/read/find a related part of the careplan? The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 7.6	<b>Readability of VT Careplan in the Careplan Monitoring Tool</b>
Description	The VT Careplan is rather long. Is it user-friendly to update/read/find the related part of an executing careplan? The satisfaction can be expressed on a scale between 1 (totally unsatisfied) and 10 (highly satisfied)
Target group	Physicians
Successful if	Scale between 5 and 10
Not successful if	Scale between 1 and 4
Measurement result	Level of satisfaction based on a scale between 1 and 10
Method	Questionnaire
Remark	

TC 7.7	<b>Clearness of the recommendations for VT Careplan</b>
Description	The medical professionals are asked whether the recommendations provided by the Care Planner for VT Care Plan are clear enough, i.e do they include the reasoning of the recommendations, do they contain the necessary relevant patient history, and the flow of actions happened that led to the presentation of this recommendation.
Target group	Physicians
Successful if	n/a
Not successful if	n/a
Measurement result	descriptive

Method	Manual logfile
Remark	

## Appendices

### 4.5 Study Protocol

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The present pilot study will be conducted according to this protocol, and in compliance with good clinical practices, the Declaration Helsinki and the local laws and regulations and the applicable regulatory requirements.

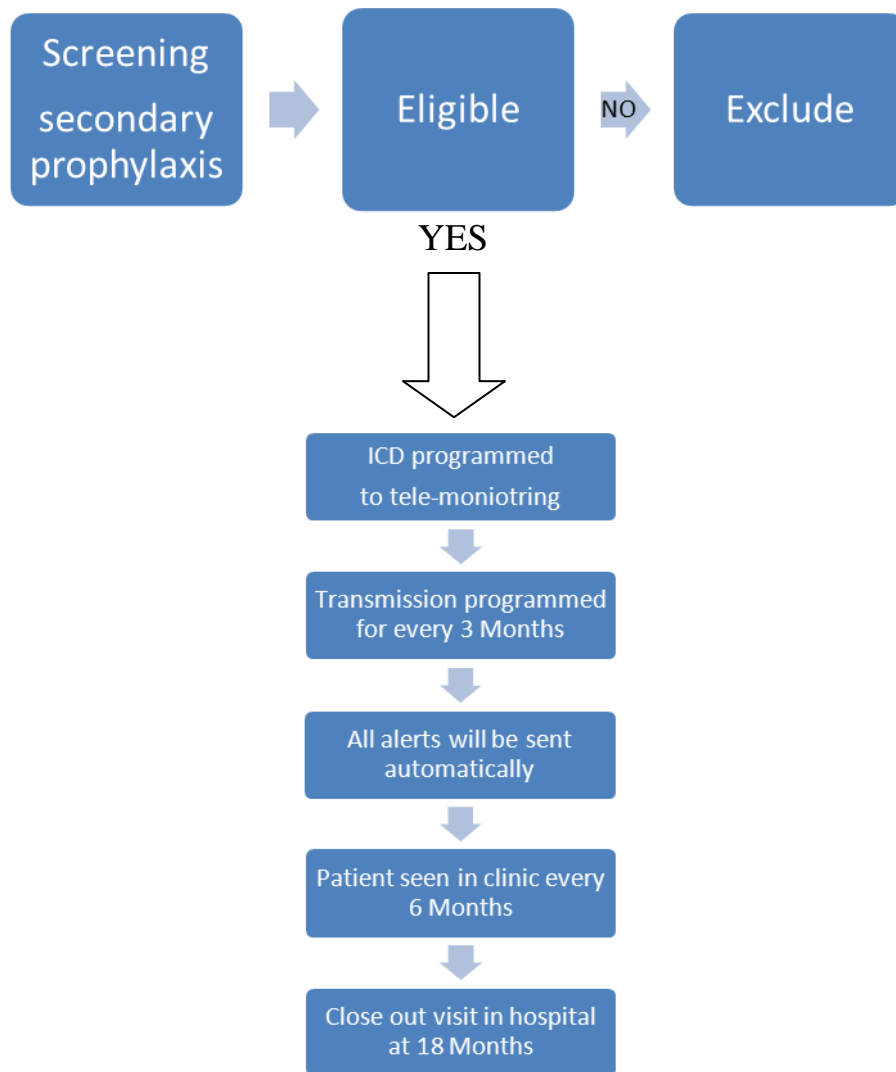
### Investigational Plan

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

#### Design of the pilot study

Objective	To assess the functionality of the iCARDEA care planning/ risk assessment abilities, in assisting the medical professional with decision making in the care of the ICD patient
Design	The pilot study is a prospective, randomised evaluation of remote monitoring to evaluate the iCARDEA platform, and telemetry alert notification system and their impact on how quickly clinicians become aware and can act on device issues or a clinical event.
Hypothesis	Remote monitoring / in conjunction with iCARDEA with alert notification reduces the time from a clinical event to a clinical decision in response to arrhythmias, and device issues compared to patients receiving in office care only
Sample Size	Approximately 50 adult patients implanted with an ICD from either St Jude or Medtronic's for secondary prevention of ventricular arrhythmias
Study Centre	Salzburg Universitätsklinikum

STUDY FLOW CHART



## Introduction

### Background

#### Cardiac Implantable Electronic Devices (CIED) Medical Devices

Cardiac arrhythmia abnormalities that are not transient or reversible require constant clinical monitoring. Delays in diagnosis or medical assistance increase risk 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 disease, other health conditions or have suffered from a previous cardiac arrest. Therefore, CIEDs including pacemakers, implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy (CRT) have become part of the standard therapy in patients who are at risk of life-threatening cardiac arrhythmias.

CIEDs are used to treat a number of conditions for patients with cardiac arrhythmia abnormalities. The normal heart rhythm is coordinated by cardiac electrical impulses which are generated by the sinus node in the right atrium and synchronize the contractions of the heart's chambers. Cardiac arrhythmia occurs when this regular heart beat is disrupted in a number of ways.

The internal mechanisms of the CIEDs (pacemakers, ICDs, CRTs) are similar. They are composed of pulse generator with battery, capacitors, microprocessor and electronic circuits and leads which are insulated wires connected directly to the heart. In terms of functionality, they have different capabilities:

- Pacemakers transmit electrical impulses to regulate the heart rhythm and are used for the treatment of bradycardia and tachycardia
- ICDs additionally provide interventions for both bradycardia and tachycardia. An ICD constantly checks electrical activity to detect abnormal rhythms in which case it delivers a shock called defibrillation, to restore its normal rhythm as in a case of VF.
- Cardiac resynchronization therapy (CRT) devices are similar to a pacemaker and ICD, or a combination of both and delivers electrical current to both ventricles and the right atrium to induce synchronous contractions.

CIEDs require patients to follow regular scheduled hospital visits to monitor the adverse events, anomalous device behaviour, and troublesome interaction between devices and their recipients. The success of the CIEDs led to exponentially increasing number of CIED patients which make the follow up visits a burden on the health care institutions and professionals.

Since the late 1990s to enhance patient safety between follow-up visits some ICD/CRT – Ds have provided audible alarms when device and / or lead integrity issues were detected. The effectiveness of these alarms relies on the patients' recognition of the audible alarm, as well as the patient notifying the clinician of the alert in a timely manner. Until recently, only device and / or lead integrity issues have had the capability to generate a patient alert, and as a result, detected changes in disease state such as increased or decreased T/AF burden or rapid ventricular response during AT/AF went unnoticed until

the patients regularly scheduled visit every 3 months or until patient reported symptoms. Newly expanded disease monitoring and alerting capabilities present opportunities to improve the clinicians' ability to more accurately monitor and provide more timely management of their patients.

All current CIEDs provide clinicians access to device- collected diagnostic information. Clinicians become aware of potential issues by reviewing these diagnostics at scheduled clinic visits, when patients come to the clinic reporting symptoms, or over the internet as a result of remote device transmission. Clinicians typically review a comprehensive suite of diagnostic data containing information on the status of the device( ie, device and lead integrity information) as well as information regarding the patients disease state (i.e., AT/AF duration and frequency, rapid ventricular response during AT/AF , patients activity, changes in intrathoracic impedance and calculated fluid index (not all devices have this capability ) for monitoring of pulmonary congestion / oedema , percent ventricular pacing , heart rate variability, etc) during routine patient visits.

According to the American College of Cardiology/American Heart Association 2008 device guidelines<sup>1</sup> (ACC/AHA) and the HRS/E2008 device guidelines HRA 2008 expert consensus <sup>2</sup>, ICDs should be followed at 3 to 6 month intervals depending on the device model and the patient's clinical status. Additionally a substantial number of patients require extra non scheduled visits due to arrhythmic events or system related complications. With the growing number of patients having CIED, follow ups there is a large demand on the human resources in the health care institutions.<sup>3</sup>

### **The latest generation of ICD**

This burden triggered the development of remote monitoring capabilities for the CIEDs in the beginning of 2000s. In recent years, all major CIED manufacturers have introduced their own remote monitoring systems such as CareLink ® network (Medtronic Inc., USA)<sup>4</sup> Home monitoring (Biotronic, Germany)<sup>5</sup>, Latitude® Patient management system (Boston Scientific , USA)<sup>6</sup> and Merlin.net™ (St. Jude Medical, USA)<sup>7</sup>. This newer generation of CIEDs is equipped with a micro antenna to communicate with a small external device located close to the patient, usually known as a transmitter or interrogator. This transmitter device can be totally mobile, such as in the form of a cellular phone or more stationary such as a desk top telephone. The transmitters are able to interrogate programmed parameters and diagnostic data stored in the CIED memory either with active participation of the patient (via a wand) or automatically (wand less). In the CIEDs that require active participation of the patient, usually an audible signal or vibration from the device itself reminds the patient to initiate a data transfer.

The transmitter device then forwards the data after an encryption process to the data centre operated by the manufacturer via standard telephone lines or cellular facilities. The data centre receives, stores, analyzes and translates transmitted data into patient specific reports. Remote monitoring systems also incorporate means for physicians to access patient data or to receive alerts. While critical alerts are forwarded via e-mail, fax, or short message service (SMS) , the physicians are able to access complete patient reports and history through secure web sites served by remote monitoring service centres or vendors. Depending on the type of CIED, remote monitoring covers device functions and several

clinical elements, including Atrial Fibrillation (AF), heart failure, sense and pace measurements, high – definition intra cardiac electrogram (IEGM) and therapies delivered.

In addition to device and/or lead integrity alerts, the new devices have expanded the notification capabilities to include disease management alerts, such as AT/AF daily burden and rapid ventricular response during AT/AF. Some of these CIEDs also contain wireless telemetry, which can automatically transmit information from the patient's implanted device to a monitor in the patient's home, and then to the office using standard telephone lines. Because no direct patient interaction is required, this reduces potential patient adherence issues. Along with the automatic alerting capacities, clinicians can also schedule when they would like the device to transmit for routine device checks via a secure Web site. Both the scheduled and alert-driven device transmissions contain the entire set of device diagnostic information available during an office visit such as intrathoracic impedance and calculated fluid index monitoring, etc, thus allowing the clinician to better manage the patient's device and disease by having critical disease information immediately available.

Continuous monitoring and timely alerting of changes in device status are crucial to ensure life-saving therapy is always available. Similarly, having real-time information about a patient's disease state is essential for treating the patient effectively and reducing avoidable medical complications.

Early notification of AT/AF and rapid ventricular response during AT/AF can be beneficial due to the numerous medical complications associated with each, such as embolic events, inappropriate shocks, or worsening of heart failure<sup>9-11</sup>. More timely AT/AF information could aid patient management, alter disease progression, or impact the type and frequency of health care utilization. One example would be early notification of a new-onset of AT/AF. If a clinician could be notified that a patient, without a history of AT/AF, had just experienced their first cumulative duration of 12 hours of AT/AF, there would be an opportunity to cardiovert the patient within 48 hours from onset, which could eliminate the need to perform a transesophageal echocardiogram (TEE), and avoid anticoagulation<sup>12,13</sup>. In addition to the alert and clinician notification for a new onset of AT/AF, the clinician also receives the entire set of device-collected diagnostic information available during an office visit for purposes of validating the alert and assessing treatment options.

Leveraging the remote management capabilities available in the latest generation of ICD/CRT-Ds may heighten clinician awareness of device status and disease progression, allowing more timely and effective treatment for the patient, while also reducing the burden of in-office device follow-up visits.

## **Project Rational**

It is clear that 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.

According to consensus statement<sup>13</sup> 2008, device guidelines prepared jointly by the Heart Rhythm Society and the European Heart Rhythm Association, more than 800,000 patients in Europe have implanted pacemaker, ICD or CRT devices for the treatment or secondary prevention of cardiac arrhythmias.

In addition, the number of follow-up visits for patients with an implanted cardiac device exceeds 5.8 million visits each year, and that number will continue to increase as more devices are implanted.

The exponential growth rate of cardiac 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<sup>14</sup>. Health care professionals are being challenged to meet the needs of an increasing volume of complex patients, and as a result, there is a strong desire to streamline device follow-up to allow more time for patient management.

This project will develop a platform to semi-automate the follow-up of the CIED patients using data from the hospitals' electronic health records (EHR), from patient maintained personal health records (PHR) and the CIED device data, provided by the remote monitoring services. These data will be collected and correlated by adaptable computer interpretable clinical guideline models

### **iCARDEA Care planner**

- Exposes CIED data through standard interfaces, IEEE11073 specifications and IHE profiles
- Developing an intelligent platform to semi-automate the 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 and IHE profiles so that information about patients' medical history can be obtained from the patient EHR data and used in the clinical follow-up workflow
- Patient Empowerment platform providing feedback on lifestyle matters, educating patients for better living, while communicating important trends to care givers

### **Randomization**

Patients will be randomised in a 1:1 manner to remote monitoring or in office care. Randomization will be performed after successful implant of a study eligible device, and the patient has signed a consent form.

## **Objective**

### **Primary Objective**

To assess the functionality of the iCARDEA care planning/ risk assessment abilities, in assisting the medical professional with decision making in the care of the ICD patient.

### **Secondary objective**

1. To compare time to clinical decision making between patients managed remotely and patients receiving routine clinic care.
2. To evaluate the use of PHR in assisting patients in the management of their health.
3. To assess the impact of remote monitoring and early notification has on health care utilization compared to routine in-office care (cardiovascular hospitalizations, emergency department and extra clinic visits)

### **Objectives rational**

The primary objective is to demonstrate the functionality of the iCARDEA platform in conjunction with the feasibility of remote management systems working in the real world. Before remote management can change patient outcomes, it is necessary to achieve the goal of getting information to the clinicians in a timelier manner so that they can intervene in the patient health care management. To improve patient outcomes, such as reduction of hospitalizations or improved quality of life, the information must be meaningful and be received in a timely fashion.

### **Study Design**

The pilot study is a prospective, randomised evaluation of remote monitoring in a population of approximately 50 adult patients implanted with an ICD from either St Jude or Medtronic's for secondary prevention of ventricular arrhythmias . The study is designed to evaluate the iCARDEA platform, and telemetry alert notification system and their impact on how quickly clinicians become aware and can act on device issues or a clinical event.

The Pilot application will run for a period of 18 months, yet patients will continued to be monitored for 1 year after pilot testing. The effect of remote monitoring will be compared directly with standard in clinic follow-up. Regardless of whether the patient is followed in clinic or remotely clinicians will have access to the entire set of device collected diagnostics. For patients that are being followed in the outpatient clinic arm of the study the iCARDEA care planner risk assessment will not be used.

### **Study visits**

All patients will have a baseline assessment at day one.

A pre discharge visit will be performed before the patient goes home after implant.

All patients will have in clinic visits at 1, 3,6,9,12,15 and 18 months post implant. Patients randomised to the remote arm will receive a home monitor and will have their visits 3, 9, 15, month visits replaced with remote visits, which will include a device transmission and phone contact. In addition, these patients will have all wireless alerts programmed on. All patients will attend a 12 month in person clinic visit and close out visit.

### Visit Schedule Table 1

The patients in the clinic arm will always be seen in clinic, every 3 months

	V1	3M	6M	9m	12M	15M	18M	closeout	
Alerts	X	X	X	X	X	X	X	X	
Clinic	X		X		X		X	X	
Remote	X*	X		X		X			
ECG	X				X				
Interview	X				X				
Questionnaire	X				X				
PHR	X**	X	X	X	X	X	X	X	

\* day after discharge for test transmission

\*\* PHR portal will be checked weekly, yet no intervention will be given

The PHR portal will be checked on a weekly basis, even though data will be added by the patient more often. There will be no feed back to the patient in regards to what they have been entering into the PHR.

### Programming

The only programming controlled for this study involves the device and clinical management alerts. Tachycardia and bradycardia therapy and detection programming are at the clinician's discretion. A conservative approach will be taken for the selection of the alert thresholds for this study, to limit the number of wireless device transmissions sent to clinicians, in that they only represent values that warrant clinician attention and possible intervention. Specifically, the AT/AF burden as well as the rapid ventricular rate during AT/AF alert is programmed long enough to limit the number of notifications that may not be clinically meaningful, while being short enough to enable clinical action in time to avoid more intense medical interventions.

- **In-office arm:** For the in-office group, only those alerts associated with system integrity are enabled (Table 1).
- **Remote arm:** For patients in the remote group, all alerts are enabled. The lead/device integrity alerts are programmed to sound an audible tone as in the in-office arm and are programmed to wirelessly transmit to the home monitor to ensure the greatest chance of a clinician becoming aware of the detected condition. The clinical management alerts are also programmed to transmit wirelessly but not to sound an audible tone (Table 2).

<b>Table 2. Alert programming</b>		
	<b>Remote Arm</b>	<b>In-office arm</b>
<b>Home Monitor</b>	Yes	No (not provided)
<b>Clinical management alerts</b>		
AT/AF daily burden	Wireless, 12 h/d	Off
Rapid ventricular rate during AT/AF	Wireless, 120 beat/min for $\geq 6$ h AT/AF per day	Off
No. of shocks delivered	Wireless, 2 shocks	Off
All therapies exhausted in a zone	Wireless	
<b>Lead/device integrity alerts</b>		
Lead impedance out of range	Wireless and audible, nominal ranges	Audible, nominal ranges
VF detection/therapy off	Wireless and audible	Audible
Low battery voltage RRT	Wireless and audible	Audible
Excessive charge time EOS	Wireless and audible	Audible

*RRT, Recommended replacement time; EOS, end of service.*

### **Rationale for clinical management alert programming**

The AT/AF daily burden alert threshold is programmed to 12 hours per day. Because the AT/AF daily burden alert evaluates AT/AF duration within a midnight-to-midnight (24-hour) window, 12 hours of cumulative AT/AF burden was selected because it represents a clinically meaningful time spent in AT/AF. In addition, by selecting 12 hours of AT/AF burden it allows for clinicians to bring patients in quickly to evaluate newly detected episode(s) of AT/AF and possibly attempt a cardioversion without prior anticoagulation or TEE, both of which are recommended in the AT/AF guidelines for episodes of AF over 48 hours<sup>1</sup>.

The rapid ventricular rate during AT/AF alert has 2 programmable parameters, AT/AF duration and average ventricular rate within that AT/AF duration. Together, these 2 values represent the threshold for rate control. Current ACC/AHA/ESC (European Society of Cardiology) AF guidelines define adequate rate control as maintaining ventricular rate response between 60 and 80 beat/min at rest and between 90 and 115 beat/min during moderate exercise<sup>15</sup>. Similarly, prior studies have defined rate control as ventricular rates below 80 to 100 beat/min at rest, or  $\leq 110$  beat/min during exercise<sup>16,17</sup>. In this study, the rapid ventricular rate during AT/AF alert is to be programmed conservatively to 120 beat/min for 6 hours per 24-hour day (midnight to midnight) because these values clearly represent poor rate control and medical attention is likely warranted.

Individual physician preferences govern the management of device-delivered shocks. Not all physicians require patients to be seen in the office after receiving only one shock. It is assumed that episodes requiring  $\geq 2$  shocks to convert an arrhythmia constituted a clinically significant event warranting clinician investigation (eg, remote transmission or office visit). As a result, the multiple shock alert in the CONNECT study is programmed to trigger when 2 shocks are delivered during a single detected episode of VT/VF.

### **Variables evaluated for each objective**

The **primary objective** of the study is to assess the functionality of the iCARDEA care planning/ risk assessment abilities, in assisting the medical professional with decision making in the care of the ICD patient, demonstrating that remote monitoring with notification reduces the time from a clinical event to a clinical decision in response to arrhythmias, cardiovascular disease progression, and device issues compared to patients receiving in-office care only.

An **event** is defined in both arms of the study by the alert conditions in [Table I](#) (regardless of whether or not the alert condition was programmed on). The **time to clinical decision** is defined as the time at which the clinician determines what action, if any, to take in response to an event and occurs shortly after viewing the device information, which could be done remotely or at an in-office visit. For example, once a patient experiences 12 hours of AT/AF in a single day, this will begin the time measurement. As soon as the clinician is aware and makes a decision on how to respond to this AT/AF event, the time measurement ends. The clinician's decision in response to an event may be to implement a treatment, or to wait and monitor the patient's progress; the objective measures the time until a decision is made, not when the action is fully implemented.

The study will also be evaluating **secondary objectives**:

- Management of symptoms: time from patient-reported symptoms to clinical decision in response to the symptoms
- Patient well-being: measured by the State and Trait Anxiety Index, Short- Form 12, and EuroQol 5D
- Burden of in-office follow-up visit: patients will complete a questionnaire to characterize the burden experienced (eg, distanced traveled, time off work) by them and their caregiver as a result of attending an in-office visit

### Statistical analysis

The analysis of the **primary objective** will include all randomized patients who experience at least one alert event (for patients randomized to the in-office arm, event onset is defined as the time at which the criteria for triggering an alert are met, as all of the clinical management alerts are turned off in these patients). The time between event onset and clinical decision for each event will be determined. These times will then be averaged for each patient so that each patient has an average time from event onset to clinical decision and will contribute one value to the analysis. A z test will be used to compare the mean time from event onset to clinical decision between the 2 treatment arms.

For the secondary objectives a t test analysis will be used.

### Patient withdrawal

1. The patient does not show up for clinic appointments and /or does not send transmissions as planned.

2. The patient is not willing to continue the study

## **Patient Identification**

All patients enrolled must be identifiable throughout the study. The investigator will maintain a personal and separate list of patient's identification numbers and patient's names to enable records to be found at a later date.

During the extraction of data from the CIED vendor and the EHR the patient data will be identified with the patient's study number, not a name to keep the patient anonymous. The patients PHR data will also be identified by their iCARDEA study number.

## **Assessments of key study parameters**

The amount of non scheduled visits will be counted, and separated into medical or technical visits.

The amount of time needed from becoming aware of an event and time it took until clinical decision

Patient's satisfaction will be measured through an interview, which will assess satisfaction in the PHR and usefulness in decision making and empowerment.

The ease of use, the help in decision making and satisfaction of the iCARDEA care planner will be assessed by the medical personnel through questioning.

To evaluate the costs to the patient in time lost from work, travel to the hospital, and wait in the clinic data will be obtained and documented at each in hospital visit .

The patients will also be interviewed to evaluate their feelings in regards to the ease of use of the monitor, the lack of /or increased stress from the remote monitoring, and whether they feel they have had enough teaching in regards to their ICD, disease process and risk factors

## **Data Collection**

All required data will be recorded on case report forms (CRFs). The CRFs will be collected and stored at the Salzburg Landeskrankenhaus (SALK)

## **Ethical, legal**

### **Good clinical practice**

The Procedures set out in this pilot study protocol are designed to ensure that all the partners abide by the principles of the ICH guidelines and the declaration of Helsinki concerning the conduct, evaluation and documentation of the study. All study partners will assign one person responsible for monitoring that the GCP is followed. All partners will be trained in GCP .The study will also be performed adhering the local legal conditions and requirements

### **Informed consent**

Before a patient can be admitted to the study his/ her informed consent will be obtained. The investigator or an authorized delegate will explain the nature, purpose, significance and scope of the study, including potential risks, to the patient. The patient will also receive a copy of his signed consent form. Sufficient time will be allowed to discuss and answer any questions raised. The consent form needs to be signed and dated from the patient and the investigator. A signed copy of the consent form must be retained as part of the study records. No investigation can be started for the study until after the consent formed is signed.

### **Confidentiality**

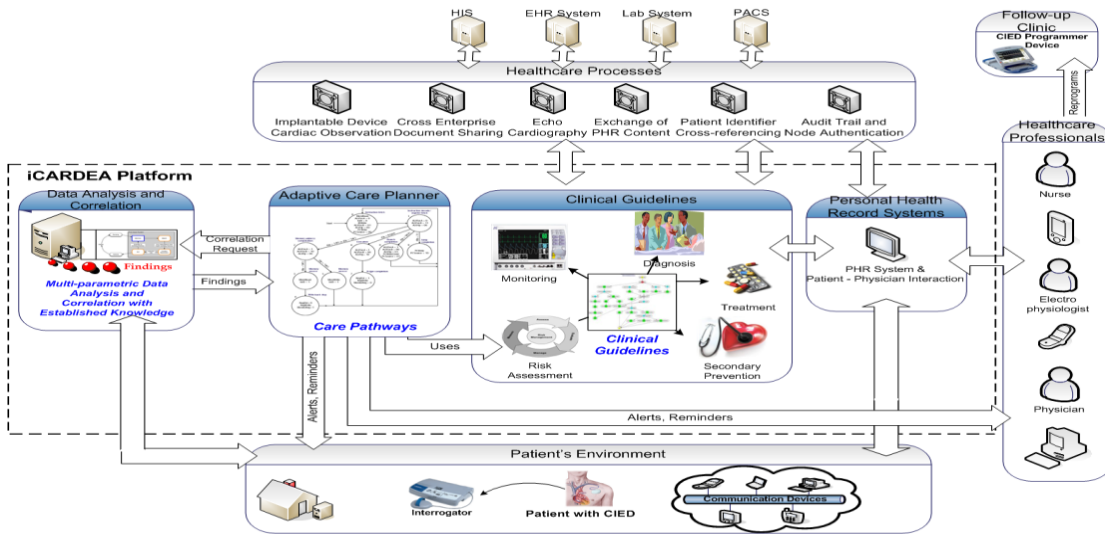
All local requirements regarding data protection will be adhered to. All study findings and documents will be regarded as confidential. The pseudonymity of the patients participating must be maintained. Throughout documentation and evaluation of patients will be recognized on CRFs and other documents by age and identification number. Documents that identify the patient personally (e.g. the signed informed consent) must be maintained in confidence by the investigator.

**REFERENCES**

1. Epstein AE, DiMarco JP, Ellenbogen KA, Estes NAM, III, Freedman RA, Gettes LS, Gillinov AM, Gregoratos G, Hammill SC, Hayes DL, Hlatky MA, Newby LK, Page RL, Schoenfeld MH, Silka MJ, Stevenson LW, Sweeney MO. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities. A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices). *Circulation*. 2008;117(e350-e408).
2. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM, Hayes DL, Howlett JG, Kautzner J, Love CJ, Morgan JM, Priori SG, Reynolds DW, Schoenfeld MH, Vardas PE. HRS/EHRA Expert Consensus on the Monitoring of Cardiovascular Implantable Electronic Devices (CIEDs): Description of Techniques, Indications, Personnel, Frequency and Ethical Considerations. *Europace*. 2008;10(6):707-725.
3. Wilkoff BL, Auricchio A, Brugada J, Cowie M, Ellenbogen KA, Gillis AM, Hayes DL, Howlett JG, Kautzner J, Love CJ, Morgan JM, Priori SG, Reynolds DW, Schoenfeld MH, Vardas PE. HRS/EHRA expert consensus on the monitoring of cardiovascular implantable electronic devices (CIEDs): description of techniques, indications, personnel, frequency and ethical considerations. *Heart Rhythm*. 2008;5(6):907-925.
4. Medtronic. Available at: <http://www.medtronic.com/physician/carelink/index.html>.
5. Biotronik. Available at: <http://www.biotronik-healthservices.com>
6. Boston Scientific. Available at: <http://www.aboutlatitude.com/how-latitude-works/patient-management.html>
7. St.JudeMedical. Available at: <http://www.sjmprofessional.com/Products/Intl/CRT-Systems/Merlin-net-Patient-Care-Network.aspx>
8. Jung W, Rillig A, Birkemeyer R, Miljak T, Meyerfeldt U. Advances in remote monitoring of implantable pacemakers, cardioverter defibrillators and cardiac resynchronization therapy systems. *Journal of Interventional Cardiac Electrophysiology*. 2008;23(1):73-85.
9. Capucci A, Santini M, Padeletti L, Gulizia M, Botto GL, Boriani G, Ricci R, Favale S, Zolezzi F, Di Belardina N, Molon G, Drago F, Villani GQ, Mazzini E, Vimercati M, Grammatico A, Italian ATRI. Monitored atrial fibrillation duration predicts arterial embolic events in patients suffering from bradycardia and atrial fibrillation implanted with antitachycardia pacemakers. *Journal of the American College of Cardiology*. 2005;46:1913 - 1920.
10. Wang TJ, Larson MG, Levy D, Vasan RS, Leip EP, Wolf PA, D'Agostino RB, Murabito JM, Kannel WB, Benjamin EJ. Temporal Relations of Atrial Fibrillation and Congestive Heart Failure and Their Joint Influence on Mortality: The Framingham Heart Study. *Circulation*. 2003;107(23):2920-2925.
11. Bala R, Callans DJ. The management of atrial fibrillation in heart failure. *Curr Treat Options Cardiovasc Med*. 2006;8(4):325-333.

12. Singer DE, Albers GW, Dalen JE, Fang MC, Go AS, Halperin JL, Lip GYH, Manning WJ. Antithrombotic Therapy in Atrial Fibrillation - American College of Chest Physicians Evidence-Based Clinical Practice Guidelines (8th Edition). *Chest*. 2008;133(6 Suppl):546S-592S.
13. Fuster V, Ryden LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Halperin JL, Le Heuzey JY, Kay GN, Lowe JE, Olsson SB, Prystowsky EN, Tamargo JL, Wann S, Smith SC, Jr., Jacobs AK, Adams CD, Anderson JL, Antman EM, Hunt SA, Nishimura R, Ornato JP, Page RL, Riegel B, Priori SG, Blanc JJ, Budaj A, Camm AJ, Dean V, Deckers JW, Despres C, Dickstein K, Lekakis J, McGregor K, Metra M, Morais J, Osterspey A, Zamorano JL. ACC/AHA/ESC 2006 guidelines for the management of patients with atrial fibrillation--executive summary: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation). *Journal of the American College of Cardiology*. 2006;48(4):854-906.
14. Lazarus A. Remote, Wireless, Ambulatory Monitoring of Implantable Pacemakers, Cardioverter Defibrillators, and Cardiac Resynchronization Therapy Systems: Analysis of a Worldwide Database. *Pacing and Clinical Electrophysiology*. 2007;30(s1):S2-S12.
15. Fuster V, Ryden LE, Cannom DS, Crijns HJ, Curtis AB, Ellenbogen KA, Halperin JL, Le Heuzey JY, Kay GN, Lowe JE, Olsson SB, Prystowsky EN, Tamargo JL, Wann S, Smith SC, Jr., Jacobs AK, Adams CD, Anderson JL, Antman EM, Hunt SA, Nishimura R, Ornato JP, Page RL, Riegel B, Priori SG, Blanc JJ, Budaj A, Camm AJ, Dean V, Deckers JW, Despres C, Dickstein K, Lekakis J, McGregor K, Metra M, Morais J, Osterspey A, Zamorano JL. ACC/AHA/ESC 2006 Guidelines for the Management of Patients with Atrial Fibrillation: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Revise the 2001 Guidelines for the Management of Patients With Atrial Fibrillation): developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. *Circulation*. 2006;114(7):e257-354.
16. The Atrial Fibrillation Follow-up Investigation of Rhythm Management I. A Comparison of Rate Control and Rhythm Control in Patients with Atrial Fibrillation. *New England Journal of Medicine*. 2002;347(23):1825-1833.
17. Van Gelder IC, Hagens VE, Bosker HA, Kingma JH, Kamp O, Kingma T, Said SA, Darmanata JI, Timmermans AJM, Tijssen JGP, Crijns HJGM, the Rate Control versus Electrical Cardioversion for Persistent Atrial Fibrillation Study G. A Comparison of Rate Control and Rhythm Control in Patients with Recurrent Persistent Atrial Fibrillation. *New England Journal of Medicine*. 2002;347(23):1834-1840.

# iCARDEA Platform



## Example - iCARDEA careplan for atrial fibrillation

**Patient Name:** Gokce Laleci  
**Patient ID:** 1687600  
**Initial Diagnosis:** [Cardiomyopathy \(Access to EHR\)](#)  
**Implanted Device:** Consulta CRT-D  
**Last Follow-up Date:** February 02, 2010 [\(Access to previous Remote follow-up results\)](#)

**Triggering Event**

Alert Received: May 17, 2010, 15:47  
 Alarms Detected: 21 Seconds in AF Since Last Session  
[\(Access to Report Exported and EGM\)](#)

**Care Plan Execution Summary:** [\(Visualize the Care Plan\)](#)

- AF Daily Burden has exceeded the specified threshold. [\(See CIED Report\)](#)
- VT, Artifact/Noise/Dysfunction, SVT, Sinus Tachycardia or Inappropriate Discharge has not been detected. [\(See CIED Report\)](#)
- The Patient's CHADS2 score is greater than 1 [\(Check Medical History\)](#)
- The patient has no contraindications with Anticoagulation Drugs. [\(Check Medical History, recent Lab results and active medications. Check decision points\)](#)

[Check the Full Execution History](#)

The care plan recommends to prescribe Coumadin 5mg, orally. Shall the HIS be updated?

Yes, I confirm, Please update the HIS

Yes, I confirm, But I would like to update the prescription details

Yes, I confirm, But I will update the HIS

No, Continue with Rate Control

## Tele-monitoring units

St Jude Merlin @ home monitor



Medtronic CareLink monitor

