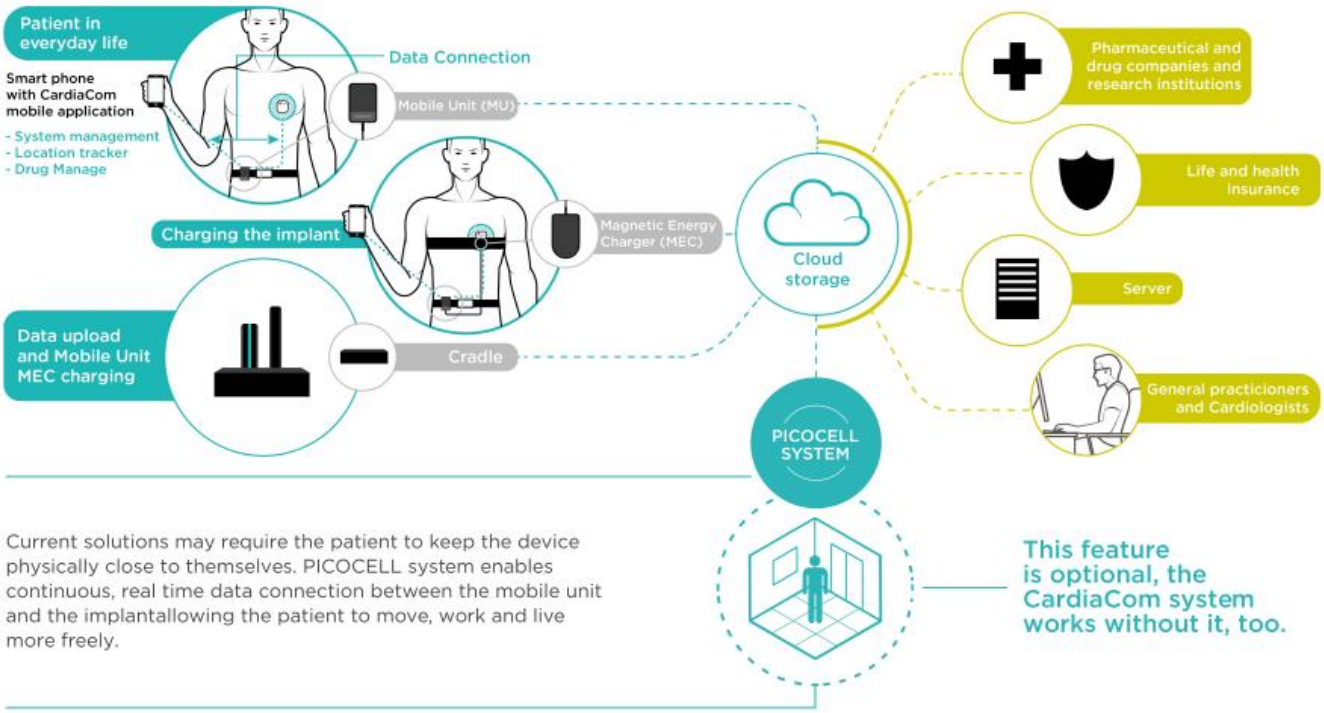
Project CardiaCom PHARMA

1. CardiaCom system



System architecture

CardiaCom system elements

How the system works
The basis of the technology is a smart implant that can be recharged through the skin even by the patient himself. The implant has radio connection to the Mobile Unit device that provides an interface to the implant for the outside world. (The server, the doctors and other users registered in the server, and the patient.) The patient has a convenient user interface through the smartphone application installed on his/her phone. The measurement data stored in the implant is downloaded on the Mobile Unit while the battery charges the implant. When the Mobile Unit is placed into the cradle device, the measurement data will be uploaded to the server automatically. The patient's specialist doctors can carry out diagnostic screening and assessment procedures on the collected data.

A CardiaCom technology indications

- Cardiovascular diseases - long-term monitoring of the patient's condition, continuous automated status surveillance
- Stressful therapeutic treatments - Any drug application/therapy for cardiovascular with side effects that can be expected (e.g. cardiovascular diseases and cancer)
- Sport diagnostic applications - for life with high physical strain. Other unique opportunity for athletes to optimize training, training management support and real time physiological condition supervision during exercise.

2. Project CardiaCom PHARMA

2.1 Proposal data

Consortium leader: Atractor Ltd

Proposal type: Any suitable H2020 project proposal. E.g. Fast Track to Innovation

Project title: CardiaCom PHARMA

Project budget: It depends on the type of the call selected, and the commitment of the partners. Maximum grant request can be around EUR 3M.

Planned consortium composition

- **Atractor Ltd** – Consortium leader. Its task is work management and technological task implementation.
- **Pharmaceutical research – research institute:** Responsible for carrying out tasks related to pharmaceutical research services, and professional counselling for Atractor Ltd.
- **Pharmaceutical factory**: Its task is to adapt CardiaCom pharmaceutical services to its own business system.

2.2 The new technology services

The implantable product is capable of 24/7 heart rate monitoring with live data analysis and storage. Moreover, it records and manages the schedule of taking drugs. Therefore, it has the capability to observe and evaluate the effectiveness of drug therapies during pre-clinical, clinical trials and can be an objective source of data regarding even post-marketed drugs.

PHARMACEUTICAL SUBSTANCE RESEARCH PHASE

- Monitoring and evaluation of the physiological effects of drug substance during pre-clinical experiments using CardiaCom pre-clinical testing technology
- Monitoring and evaluation of the physiological effects of drug substance in a clinical drug trial

FOLLOWING THE INTRODUCTION TO THE PHARMACEUTICAL MARKET

- Medium- and long-term monitoring and evaluation of physiological effects of active pharmaceutical ingredients (post-marketed drugs)
- Optimization of dosing protocols related to drug substance/drugs
- Proposals to each patient's specialist doctors to fine tune their patients' drug doses

2.3 Project subtasks

Screening and managing of drug intake events
The aim of the procedure is to track the patient's behaviour, and exploration of the possible hostile/wrong behaviour patterns.

Customized drug dosage optimization
The patients' physicians have access to the system and can monitor the physiological effects of the drugs (see section 2.2). They may change the dosage of medicines for their patients based on their professional judgment.

Customized drug resistance testing
The patients' physicians have access to the system and can monitor the physiological effects of the drugs. If the patient's drug dose is unchanged, but the quality of the expected physiological effects of the medication is reduced, the event indicates drug resistance.

Pharmaceutical dosage optimization strategy
All medicine includes instructions supplied by the manufacturer. The system filters the patients who take the medicine to the general proposal. The overall efficiency of the general proposal is calculated by observing this set of patients and monitoring the physiological effects of active pharmaceutical ingredients.

Free drug research
The Pharma partners can make queries relating to medicines produced by them as often as they want. The queries are predefined for the time being. The patient physiology, medication information and evaluation information will be anonymous for these partners.

	THEME	TASK	SUBTASK	PERFORMS
1.1	Enter pharmaceutical protocol data	Proposal on how the database is regularly updated		Research Institute
		Proposal of the database content elements		Research Institute, Pharmaceutical factory
		Development of regular database update	Technical implementation	Atractor
			Updating strategy	Atractor Research Institute
		Handling manual data entry errors		Atractor Research Institute
		Developing Drug Database		Atractor
1.2	Non-compatible medication screening	Finding and processing databases of conflict of existing drugs		Research Institute
		Development of Pharma user interface	Technical implementation	Atractor
			Consultancy	Research Institute
			Consultancy (Research Institute unique needs)	Pharmaceutical factory
		Development of pharmaceutical conflict database server	Technical implementation	Atractor
2.1	Screening and management of drug intake events	Filtering system	Technical implementation	Atractor
		Modelling of possible drug intake events	Modelling	Research Institute
		Development of filtering methods (e.g. physiological and statistical based)	Technical implementation	Atractor
			Consultancy	Research Institute
			Statistical analysis system	Statistician
		Development of event handling procedures	Technical implementation	Atractor
			Procedure development	Atractor, Research Institute
2.2	CardiaCom physiological data analysis	User interface for parameterizing the ECG diagnose algorithm	Technical implementation	Atractor
		Development of server side ECG diagnose algorithm	Technical implementation	Atractor
		Developing ECG based physiological statistics system	Technical implementation	Atractor
			Modelling evaluation system	Research Institute
			Statistical evaluation system	Statistician
		Proposal on new physiological markers to be monitored	Research, modelling	Atractor, Research Institute
2.3	Optimizing patient dosing	1.2 and 2.2 complete it.		

2.4	Optimizing drug dosing strategy	Development of Pharma user interface (entering standard drug dosing)	Technical implementation	Atractor
			Modelling, Consultancy	Research Institute
			Consultancy (Pharmaceutical factory unique needs)	Pharmaceutical factory
		Evaluation system	Technical implementation	Atractor
			Modelling the evaluation system	Research Institute
			Statistical evaluation system	Statistician
2.5	Free drug research	Implementation of Pharma query interface	Technical implementation	Atractor
		Modelling queries	Consultancy	Research Institute, Pharmaceutical factory
		Implementation of queries	Technical implementation	Atractor

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