

Open Market Consultation

June 2021



Follow-up International OMC

September 27, 2021 15:00-17:00 CEST



www.incareheart.eu



Incareheart has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No. 965134.

Housekeeping rules



This session will be entirely recorded and published on the INCAREHEART channels.



All participants **must be muted** when not presenting to avoid noises



Feel free to post your questions in the **zoom Q&A box**

Objectives



- 1 Present the OMC results
- 2 Present final version of the use cases after feedback
- 3 Guide suppliers in the next steps for Call for Tenders

Presenters



Marie Sherman

Strategist
ProjectCentre
Manager
RJH R&D Project
Centre



**Ioannis
Amarantidis**

Horizon Grants
Expert
RJH R&D Project
Centre



Mikael Lilja

Clinical Manager
RJH R&D Project
Centre



Sonja Müller

Researcher and
project manager
EMPIRICA



Elena López

Project Manager
TICBIOMED

+ the buyers group carefully listening

Agenda



Welcome & introduction

INCAREHEART in brief

OMC results

Final use cases

Questions & Answers

INCAREHEART PCP Phases and next steps

Questions & Answers



Marie SHERMAN

Strategist

ProjectCentre Manager

REGION

JÄMTLAND HÄRJEDALEN

R&D / ProjectCentre



INCAREHEART

1 IN BRIEF

Chronic Heart Failure (CHF)



15 million people
living with CHF in Europe

4% to 10%
hospital death rates

\$108 billion p.a.
managing heart failure costs

“

GOAL



To procure R&D services that deliver an ICT-enabled integrated care solution to effectively support the management of a multidisciplinary care and support model for people living with **C**hronic **H**eart **F**ailure



MINISTRY OF HEALTH

Turkey



REGION OF CENTRAL MACEDONIA

Greece



**UNIVERSITÀ DEGLI STUDI DI
NAPOLI FEDERICO II**

Italy



**SANTA CASA DA MISERICORDIA
DA AMADORA**

Portugal



REGION JÄMTLAND HÄRJEDALEN (LEAD PROCURER)

Sweden

5 procurers

1,320,000
people living with heart failure

€4,650,000
for procurement



EMPIRICA



TICBIOMED



**INTERNATIONAL FOUNDATION FOR
INTEGRATED CARE**

3

supporting
organisations

Supported by an Expert Advisory Board



Mikael LILJA

Clinical Manager

REGION
JÄMTLAND HÄRJEDALEN
R&D / ProjectCentre

A buyer's view: Innovativeness of interest



- What is the solution's impact on the care process
 - Technical innovativeness or integration of existing solutions is not enough
- Does the solution provide improvement to known problem areas?
 - Transitions
 - Integration of care
 - Patient participation
 - Integration to existing EHR systems
- Does the solution take present and future restrictions in account?
 - Shortage of staffing
 - Costs
 - Legal aspects
 - Time
- Safety and other use aspects?
 - Manually by care personnel or automated
 - i.e.. do we computerise traditional work or are we buying something new
 - Up-dates of e.g., algorithms
 - Strong ownership



Elena LÓPEZ

Project Manager

TICBIOMED



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2

OMC RESULTS

Why an Open Market Consultation?



The OMC aims to bring the market perspective to a procurement process



It helps the procurers to prepare an effective pro-innovation tendering approach

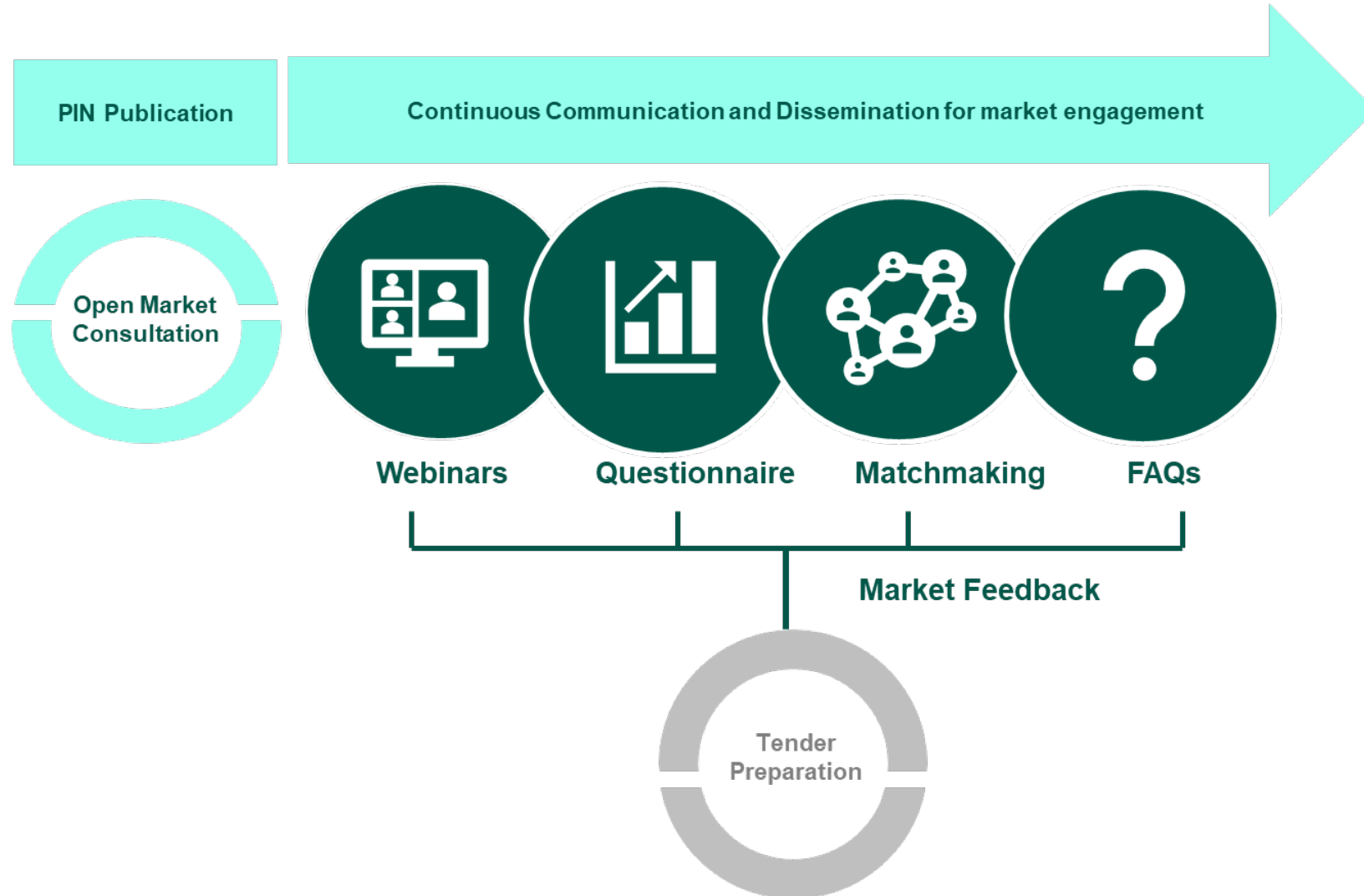


It enables the suppliers to work in advance and prepare competitive offers.



() Participation in the Open Market Consultation is not a prerequisite nor gives any advantage for the Call for Tenders*

OMC in INCAREHEART



Participants so far...



281
attendees



214
**economic
operators**



18
countries



28
**questionnaire
answers**



83
**questions
and answers**



+20
**matchmaking
registrations**





INCAREHEART

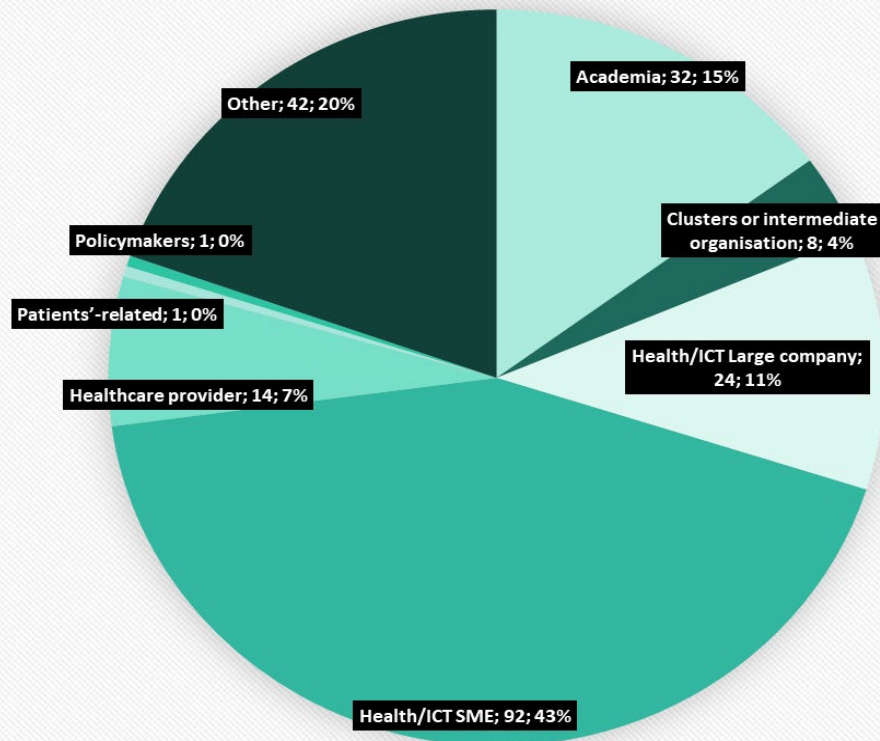
8 key findings from the OMC

#1 High number of economic operators interested in INCAREHEART

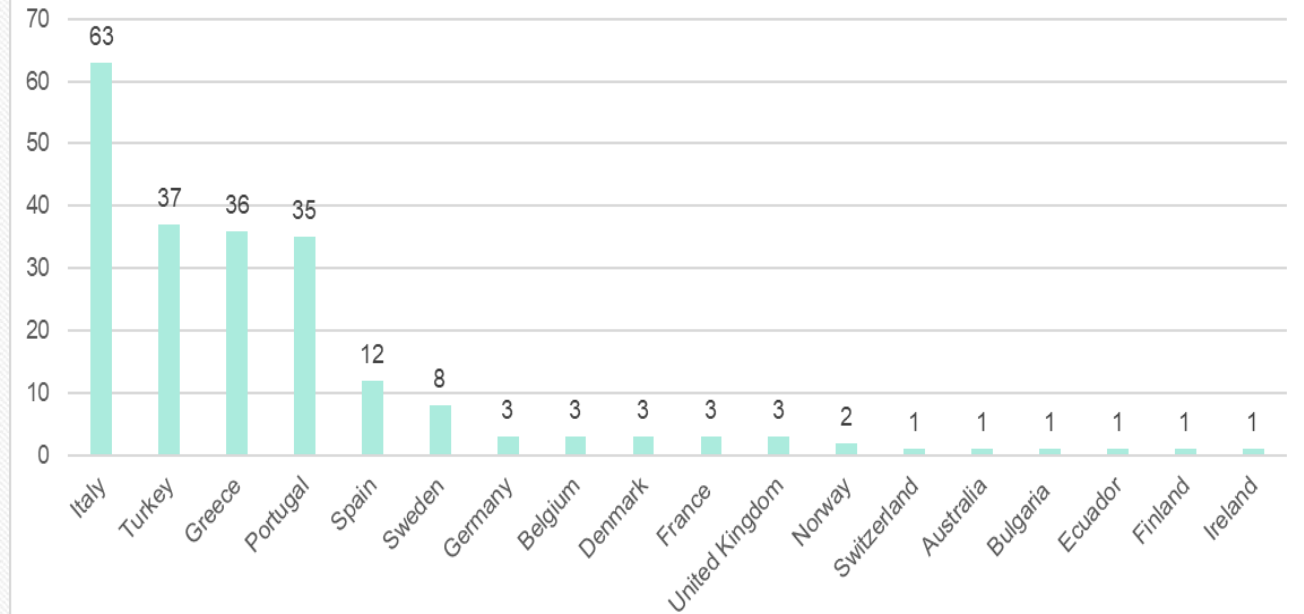


INCAREHEART

Organisation type



Country of organisations participating



#2 Joint tenders are very likely



- ▶ **Both single and joint offers** are welcome
- ▶ But OMC shows it might be difficult to cover all the requirements playing solo, especially for SMEs
- ▶ **INCAREHEART encourages you to search for partners if you cannot cover all the scope**
- ▶ Matchmaking tool available on the website until the call for tenders' closure

humanITcare

Seeking a coordinator

Care and follow-up Continuous management and seamless transition of care Living with heart failure

HumanITcare is an AI-based solution that gathers insightful data and generates smart alarms for health care professionals or caregivers in real-time based on the tailored needs of the patient's chronic condition. The clinical insights of chronic conditions are generated from our Remote Patient Monitoring platform and delivered to the doctor in an interactive clinical dashboard. Medical professionals can also receive smart alarms that report patient's health evolution, so healthcare professionals can make better medical decisions, thus offering an accurate and personalized treatment. Moreover we have wide experience of the integration of EHR standards (HL7 – FHIR). HumanITcare is the first CE Certified software that can easily integrate through an API model that connects medical devices. Backed by clinical evidence, and powered by highly accurate AI.

Value my organisation can add in a joint tender

-Interoperability -Data Integration (API) -Telemedicine -Telerehabilitation -Data management plan -All the languages available -App development -AI development - PROMIS & PREMS

Areas of cooperation sought

Clinical Cooperation / Software / Caregivers

Organisation details

Organisation type:
Health/ICT SME

Organisation size:
Micro (<10 employees and ≤ € 2 m turnover)

Headquarters country:
Spain

Website:
<https://humanitcare.com/>

Contact

Contact person
Nuria Pastor Hernández

Job title
Chief Executive Officer

Email
nuria.pastor@humanitcare.com

<https://incareheart.eu/matchmaking/>

#3 ATTENTION: tenderers need to demonstrate medical capacity in relation to CHF

- ▶ Tenderers will have to demonstrate their capacity to create a solution in the field of CHF management and to judge the quality of medical algorithms and learning material, understand medical procedures, pathophysiology of CHF, its co-morbidities and concomitant diseases.
- ▶ It is NOT JUST technology development – the solution needs innovativeness of interest!

#4 The scope is feasible, relevant and innovative for OMC participants

- ▶ Spot on: Interoperability, patient-centred multidisciplinary care team collaboration, personalised treatments, and adherence monitoring.

OMC participant:

It is challenging but feasible using modular approach, interoperable platform, leveraging as much as possible on reliable device/solutions already in the market/premarket, involving interdisciplinary team and exploiting personalised coaching strategies

OMC participant:

An end-to-end "all-in-on" solution should be the long-term goal

#5 But there are potential challenges



- ▶ Early detection of Chronic Heart Failure (CHF) and comorbidities
- ▶ Compatibility with different legal issues and diverse care policies and processes among the 5 procurers
- ▶ Interoperability and integration with existing systems
- ▶ Behavioural change of the patients and change in how care is organised

#5 But there are potential challenges



▶ **Early detection of Chronic Heart Failure (CHF) and comorbidities**

- Scope modified to decrease complexity: use cases

▶ **Compatibility with different legal issues and diverse care policies and processes among the 5 procurers.**

- Description of the legal and regulatory context in each procurer organization
- Operational, staff and business requirements per site

▶ **Interoperability and integration with existing systems.**

- Description of the existing systems per procurer organisation, including technology used, responsible for maintaining and further developing the system, architecture...

▶ **Behavioural change of the patients and change in how care is organised.**

- It is a priority for the buyers' group too
- A framework will be developed for the conduction of change management and organisational measures for application in the INCAREHEART pilots

#6 Phases duration could be challenging

- ▶ Most OMC participants agree with the proposed budget and phases duration, but some suggest increasing Phase I and Phase II.
- ▶ **Phase I** duration and budget remains unchanged.
- ▶ **Phase II** duration has been extended 1 month. Budget remains unchanged.
- ▶ **Phase III** duration is now 14 months. Budget remains unchanged.

Phase	Start date	End date	Duration	Phase budget	Suppliers to be awarded
Phase 1	June 2022	Aug 2022	3 months	697,500 €	5 suppliers
Phase 2	Sept 2022	May 2023	9 months	1,395,000 €	4 suppliers
Phase 3	June 2023	July 2024	14 months	2,557,500 €	2 suppliers

#7 End-users involvement: a repeated concern

- ▶ End-users have participated in the requirements elicitation process: interviews and focus groups
- ▶ They will participate in the development and testing of the solution
 - Prototype v1 $n > 5$ at each site
 - Prototype v2 $n > 15$ at each site
 - Pilot 100 patients at each site = 500 patients
 - Pilot 25 healthcare professionals at each site = 125 professionals



#8 Future exploitation will be important

- ▶ Suppliers keep ownership of the intellectual property rights attached to the results generated during the PCP implementation

- ▶ Prepare in good time for exploitation!

- ▶ You will need to provide:
 - A business strategy describing the approach for commercializing the solution
 - A report on the measures undertaken to protect the IPRs generated in each phase

THANK YOU
for your involvement in this
phase

See you all in the Call for Tenders!



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3

FINAL USE CASES



Sonja MÜLLER

Researcher

EMPIRICA

Aim of the procurement



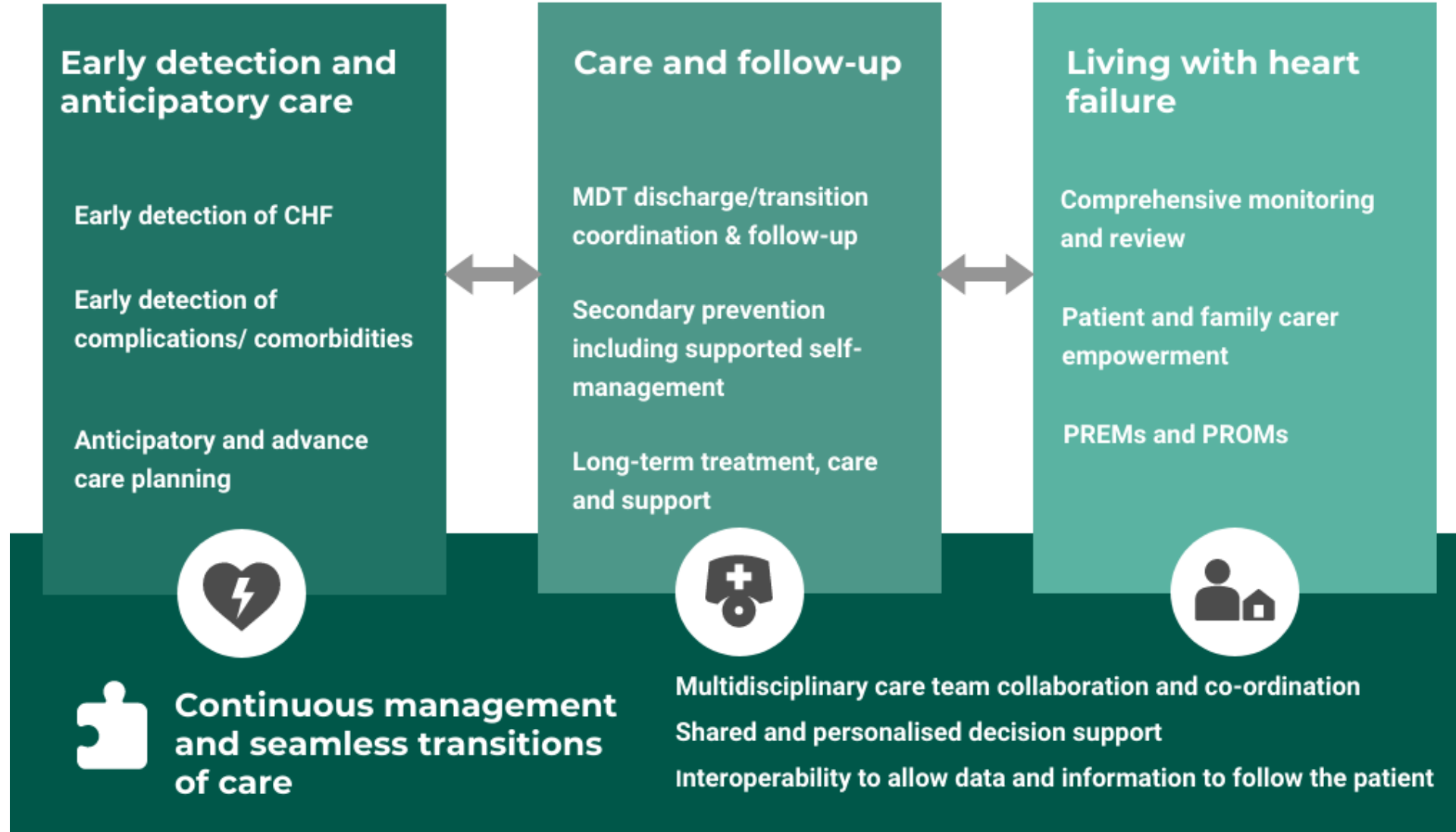
Addressing unmet needs in CHF care

of the procurers relating to different aspects (building blocks) of chronic heart failure

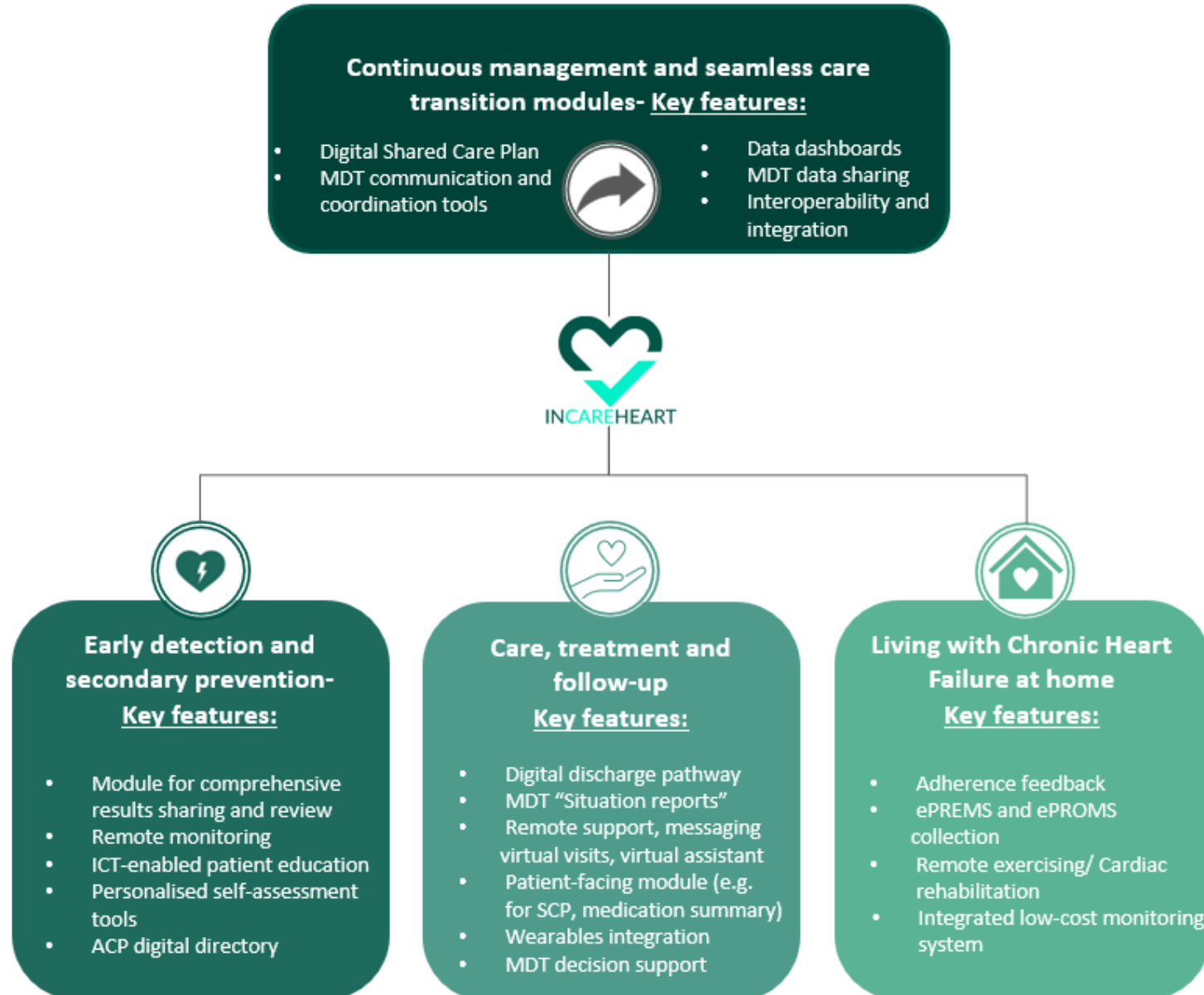
Integrated Solutions needed

there are individual solutions for some of these blocks, but **there is no solution currently available on the market that integrates seamlessly all blocks** and is interoperable with the procurers' existing systems

INCAREHEART building blocks



INCAREHEART solution: key features



Solution target users



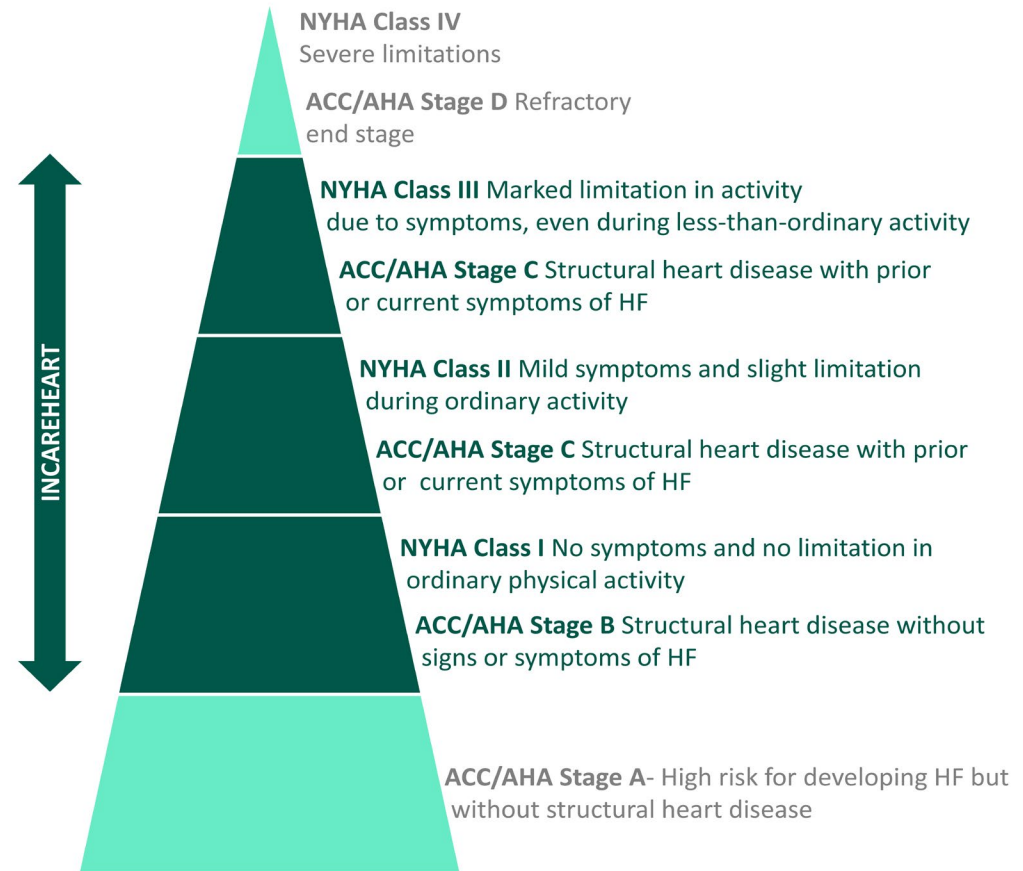
Stratification of the heart failure population
(according to NYHA classification and ACC/AHA)

PATIENTS

FAMILY CARERS

HEALTH & SOCIAL
CARE
PROFESSIONALS

DECISION MAKERS



Requirements and use cases available online soon



UC1: CHF early detection



UC2: Enrolling people with CHF, the MDT care team and carers/family members



UC3: Supporting empowerment & self-management of the person living with CHF and their family carers



UC4: Optimising cardiac rehabilitation and treatment adherence



UC5: Ensuring seamless transitions of care and support



UC6: Early exacerbation detection and treatment adjustment



UC7: Slow or no internet connection



UC8: Regular MDT assessment



UC9: Multidisciplinary team decision support



UC10: Early detection of co-morbidities

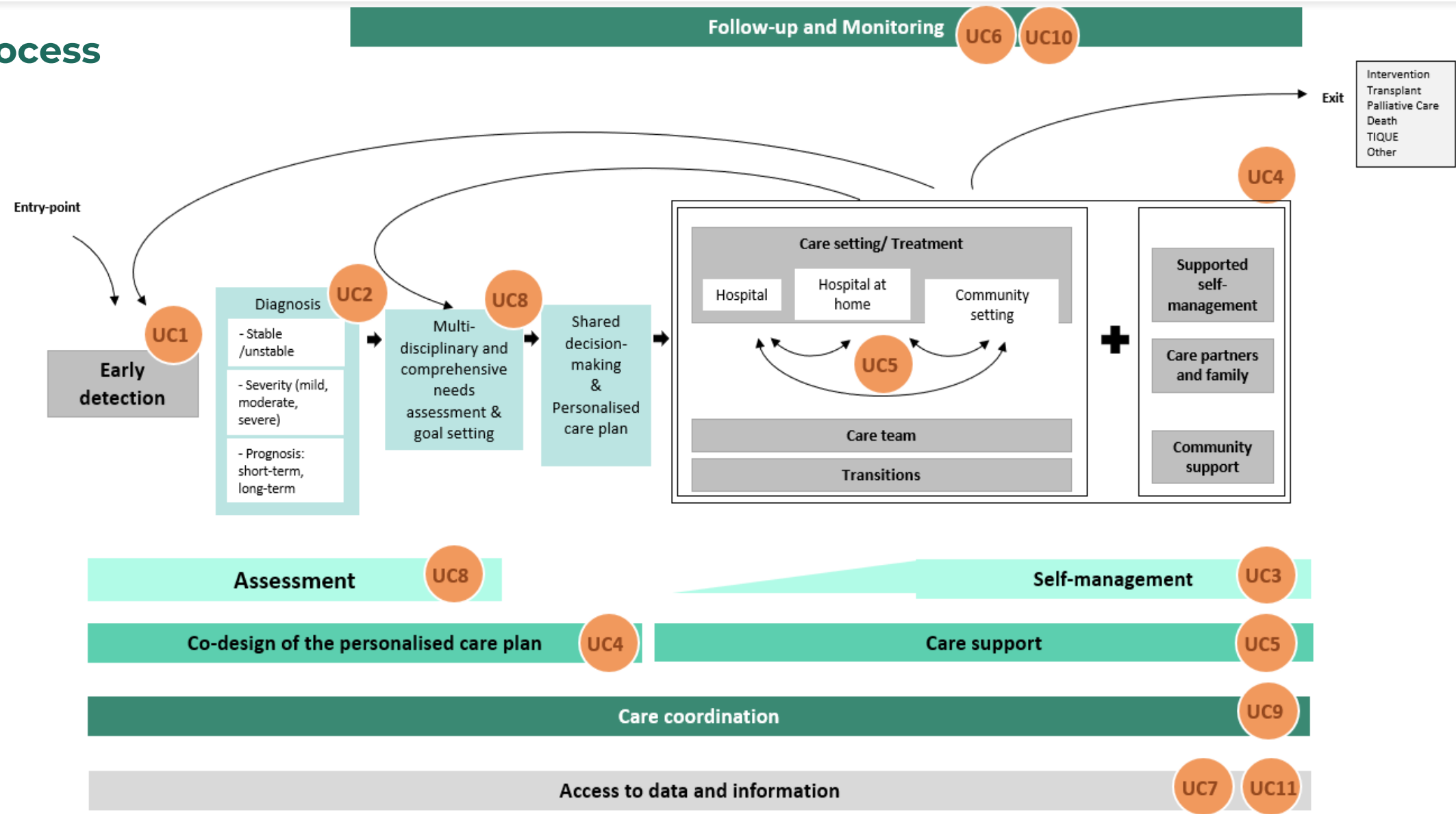


UC11: Interoperability and integration

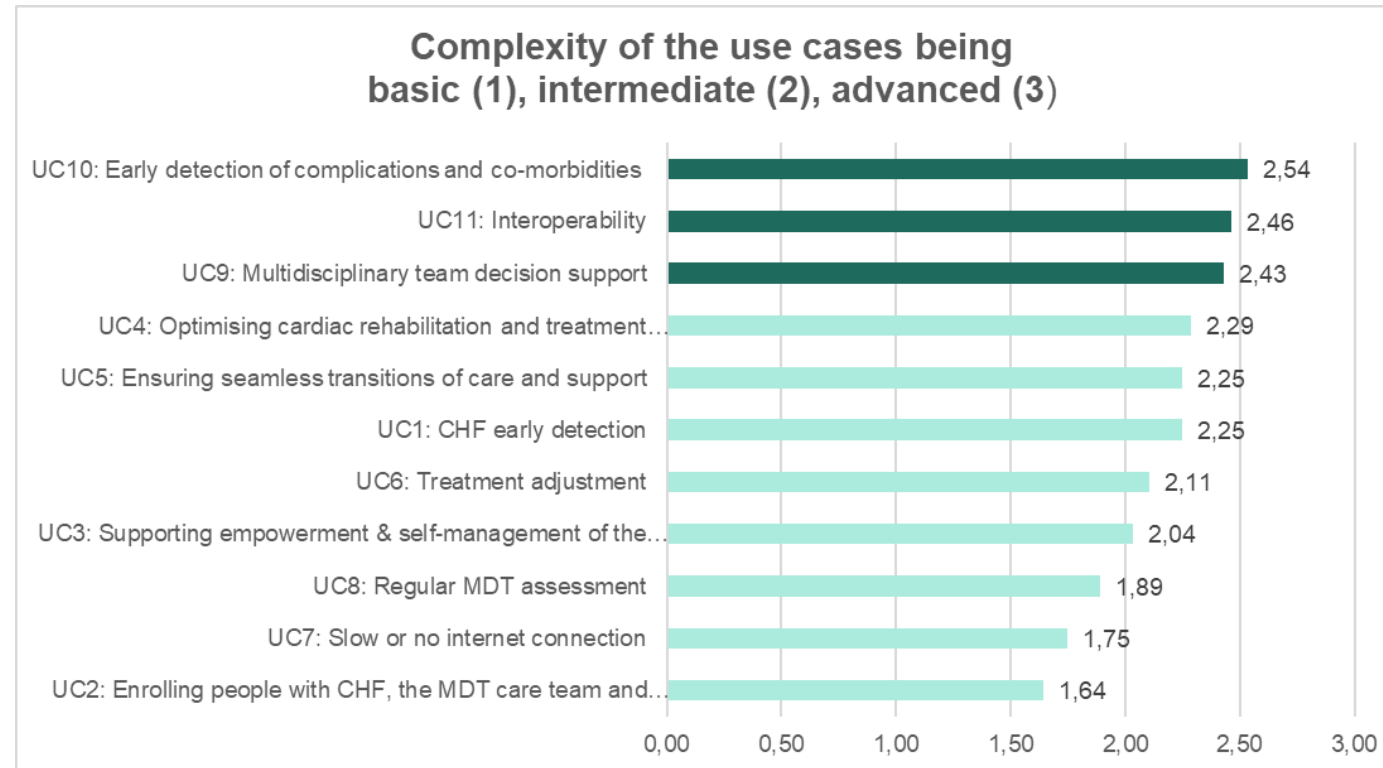


Tender documents will be published at the beginning of December 2021!!

Mapping Use Cases to the INCAREHEART Integrated Process Pathway



Complexity of use cases



► On average, most complex use cases:

- UC10: Early detection of complications and co-morbidities
- UC11: Interoperability
- UC9: Multidisciplinary team decision support
- UC4: Optimising cardiac rehabilitation and treatment adherence

► On average, the simplest:

- UC2: Enrolling people with heart failure

After OMC: Use cases in focus



UC1: CHF early detection



UC9: Multidisciplinary team decision support



UC11: Interoperability and integration



Use case 1 Early detection



- *“Suggest to reduce the scope to manage patients already diagnosed with CHF since they carry most of the existing costs, as a way to reduce the scope”.*
 - Main focus is on **patients diagnosed**, use case and requirements are updated to make this clearer
 - UC 1 now focuses on:
 - a) **Early detection** rather than diagnosis
 - b) Providing educational, interactive (playful?) material about CHF to general population
 - c) Providing digitally-enabled risk assessment tools integrated with symptoms tracker or devices measuring walking distances, other handheld-device data.
- *“The creation of technologies (AI, mobile, device integration etc.) to be used in the block of early detection of CHF can be classified as a major challenge”*
 - The INCAREHEART test will unlikely have the number of patient registrations needed to derive AI algorithms, but tested AI algorithms or standard non-AI algorithms are of course welcome.

Use case 1 Early detection



Summary

INCAREHEART will support health and care systems and responsible professionals in the **earl(ier) identification of CHF patients**.

There must be an approach for earl(ier) detection of CHF/case **self-assessment tools and questionnaires (preferably validated ones)** and proper follow-up must be ensured.

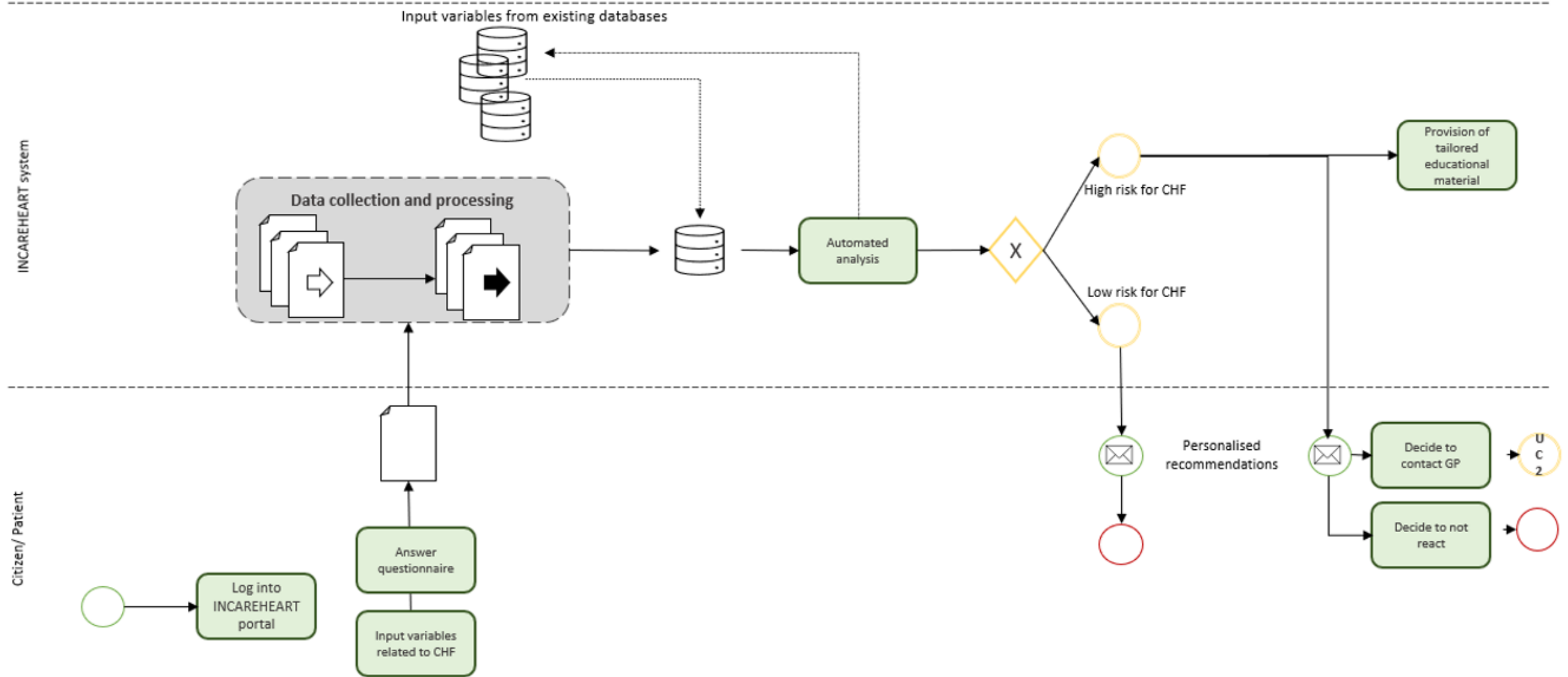
The INCAREHEART solution will also provide a **patient-facing web portal**, to be integrated into the procurers' own portals, but also be available remotely (as a mobile app), which is capable of empowering patients to e.g., measure blood pressure and upload data to the portal and to access tailored information about CHF.

Steps involved

- Patient logs onto the INCAREHEART portal from their mobile phone (or from a computer at home) to **upload data from e.g., mobile blood pressure measurement device or a fitness app/device**,
- INCAREHEART system asks several questions relevant for early detection of CHF
- **Patients answers questionnaire/self-assessment tool**
- System makes recommendations based on entered data (and measurement results) and provides educational material.
- For at-risk patients, a follow-up process is recommended to the patient involving health professionals (doctors and/or nurses)
- GP enrolls patient into INCAREHEART (Cf. use case 2)

Service process model 1

Early detection



UC9: Multidisciplinary team decision support



- *“Individualised Decision Support System (DSS): unclear definition (could range from simple visualisation and decision rules to AI (could range from simple visualisation and decision rules to AI prediction), unclear whether feasible (i.e. enough knowledge available for decision rules, enough training data, needed parameters for DSS known and available)”*
 - **Description of DSS improved**: Some pilot sites can not make datasets of sufficient size available to train AI algorithms, but inclusion and integration of tested AI algorithms or standard non-AI algorithms welcome. Also, including data from monitoring wearables and data entered by the patients/informal caregivers (patients’ treatment preferences).
 - DSS are not to replace healthcare professionals (responsible for the actual decision making) but to offer reliable, timely information in the right format to support their decision-making and preventing increasing their burden.

Use case 9 Multidisciplinary team decision support



Summary

The approach to decision support in INCAREHEART centres on a care plan shared between health and social care professionals and patients, as well as a **data dashboard accessible based on defined roles**.

The INCAREHEART solution will provide a Decision Support System (DSS) to be **used by both patients and professionals** that establishes the personalised care plan based on patient preferences, clinical parameters, and other relevant determinants avoiding fragmented decision-making.

Decision support systems should be envisaged that **integrate a combination of various outcomes to facilitate the treatment decision**, predict exacerbations and to share information between patients, primary care specialists.

The INCAREHEART solution will include processing data available from the Electronic Health Record and other sources.

The DSS will **incorporate patients' treatment preferences** into the clinical decision-making process.

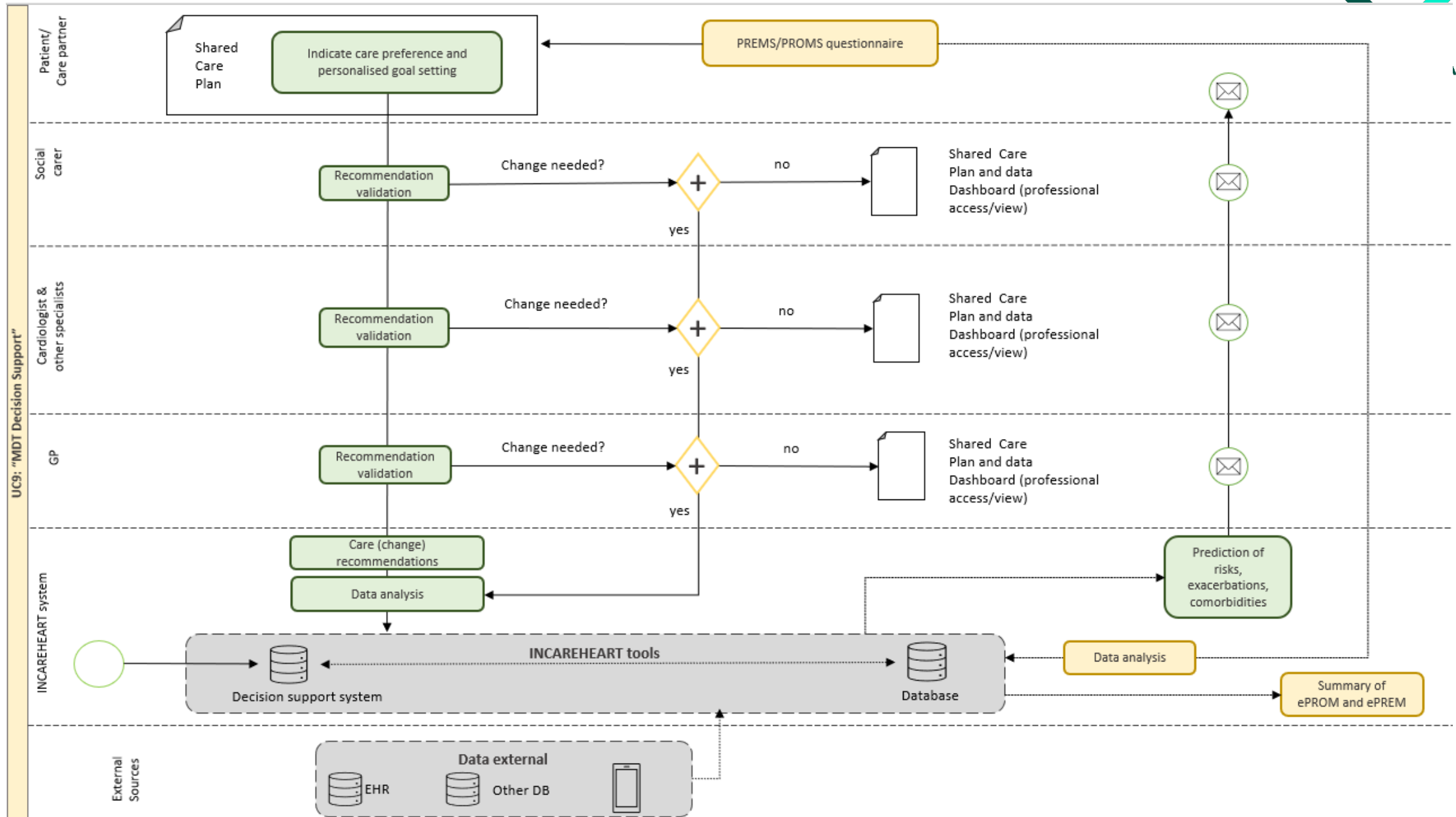
Steps involved

- DSS for patient and professionals: Incorporate patients' treatment preferences into the clinical decision-making process
- Shared Care Plan with personalised goals, treatment, and lifestyle changes
- The Decision Support System integrates a combination of various outcomes such as monitoring devices
 - DSS will facilitate treatment decisions, predict exacerbations and other risks or comorbidities
 - DSS shares information between the patient, all the care team members
- The solution supports decision-making, communication, and self-management
- **ePROMS and ePREMS data are collected and integrated**
- The INCAREHEART solution creates analysis and summaries of ePROMS and ePREMS. These data will support:
 - the analysis of organisational quality to the providers
 - the assessment of the efficiency of care across care transitions as well as patient experience

Service process model 9



ART

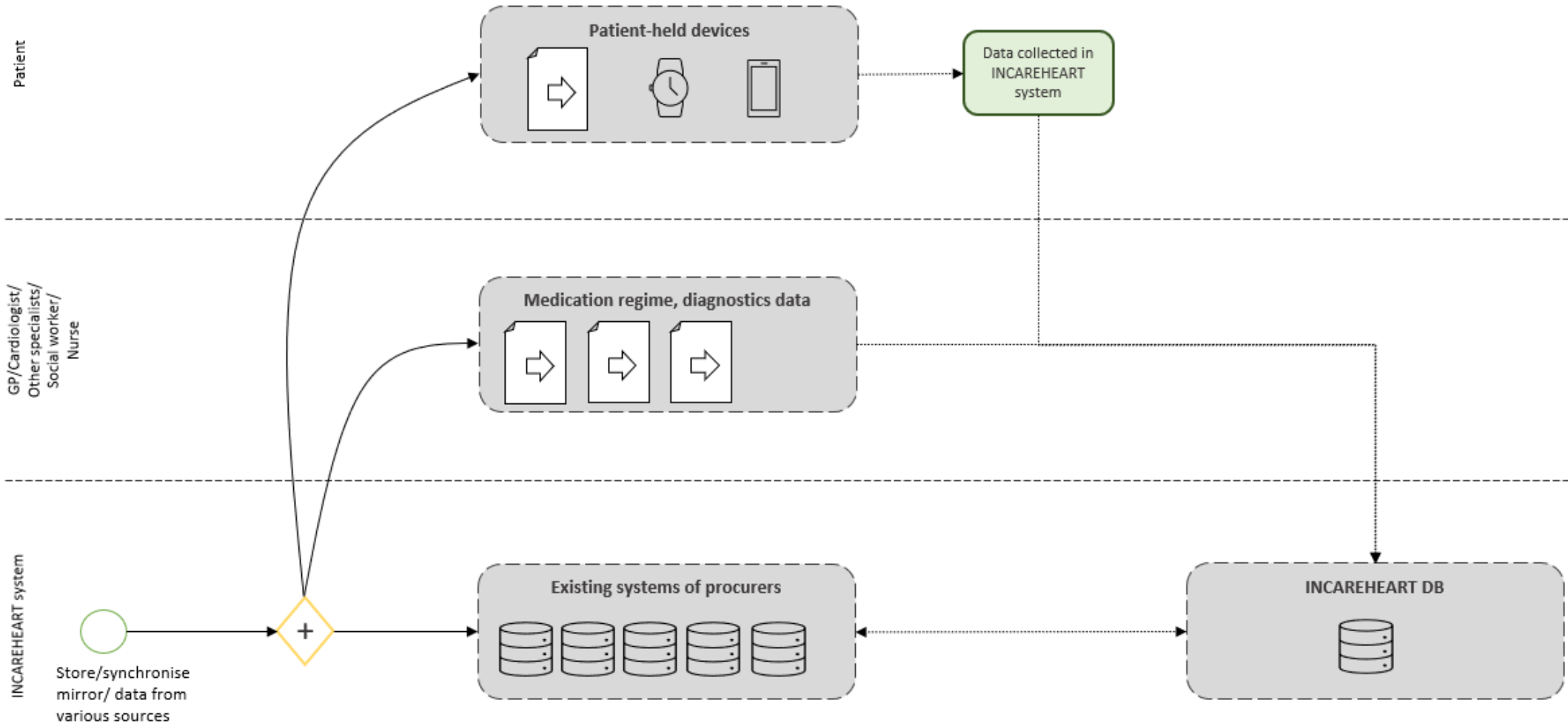


Use case 11 Interoperability and integration



- **“Integration” was added to highlight** it as a INCAREHEART priority
- *“That a PCP tend to have too high ambitions and too many ambitions to solve in one singular product that must be implemented in widely different organisation settings that highly likely don't have established cross regional buyer interoperability framework themselves.”*
 - The nature of a PCP is to boost innovation and to bring together demand and supply side to address societal challenges that are otherwise not addressed timely. Since integration is at the heart of INCAREHEART, we cannot adapt the requirements in that regard
- Clear guidance on **technical and logical requirements and existing IT systems.** Consider dedicating resources to support providers with understanding and interfacing of data / digital infrastructures, as well as updating their systems interface to facilitate interoperability.
 - Will be provided in the Challenge Brief
 - Data processing agreements can be concluded

Service process model 11





DO YOU HAVE ANY
QUESTIONS?





INCAREHEART

4 INCAREHEART PCP PHASES & NEXT STEPS

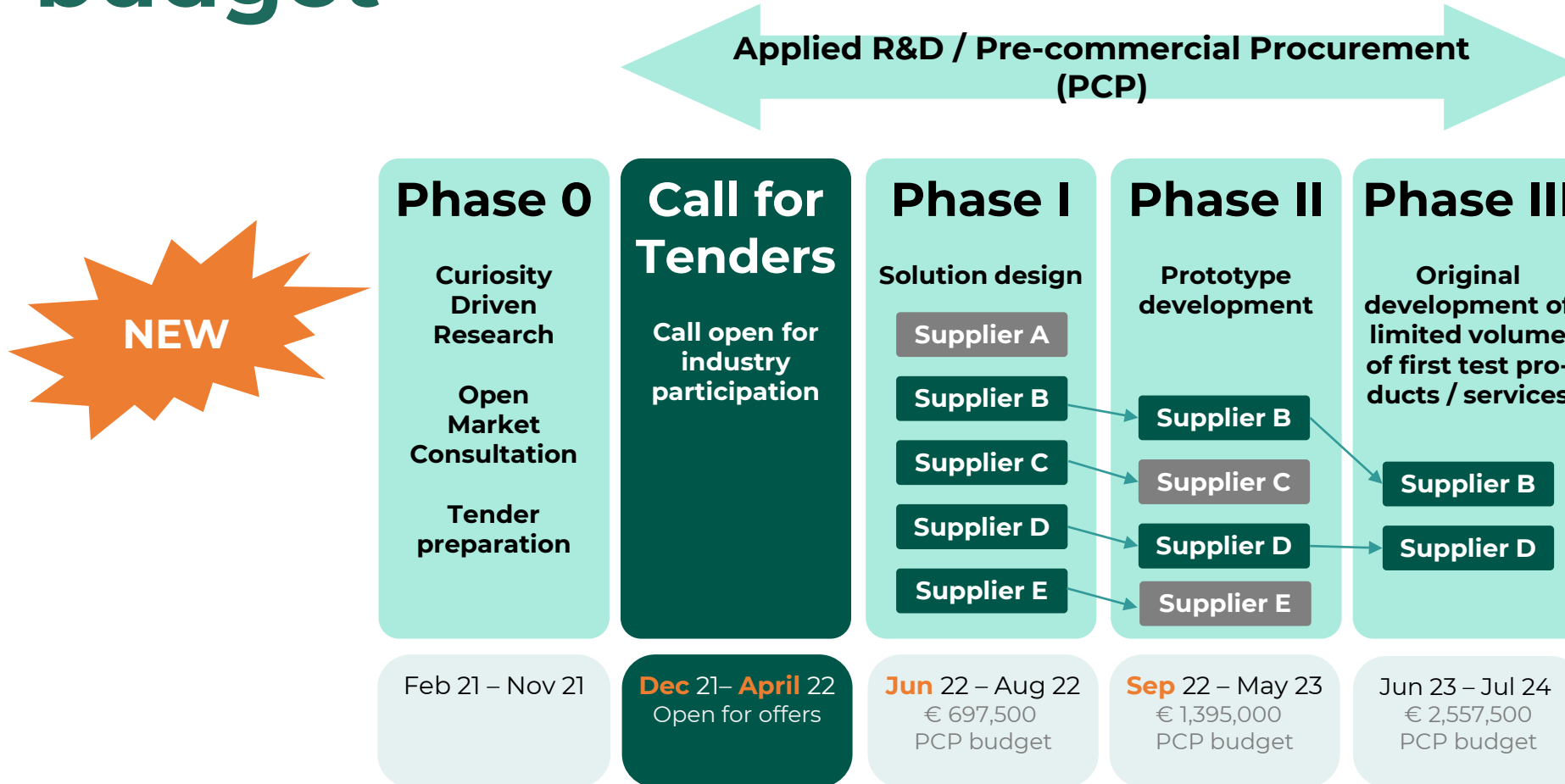


Ioannis AMARANTIDIS

Horizon Grants Expert

REGION
JÄMTLAND HÄRJEDALEN
R&D / ProjectCentre

Overview – phases, timeline, budget



- ▶ Lead Procurer: RJH, overall co-ordination of the procurers, acting on their behalf vis-à-vis the suppliers
- ▶ Procurers (also Buyers Group: RJH, UNINA, SCMA, RCM, MOH)
- ▶ Suppliers (later Contractors) = organisations or consortia competing in the PCP process

NEW

Phase I

Concept design, solution architecture and technical specifications based on procurers' requirements, use cases and process models

Phase I

Solution design

Supplier A

Supplier B

Supplier C

Supplier D

Supplier E

Jun '22 – Aug '22
€ 697,500
PCP budget

- ▶ **5** suppliers expected to be awarded [minimum of 3]
- ▶ **Expected output:**
 - Detailed **report** describing the solution and a detailed plan for the prototyping and testing activities in Phases II & III.
- ▶ **3 months**
- ▶ Maximum phase total budget: **€697,500**
- ▶ The offers are ranked according to **quality – price ratio**
- ▶ Contracts are awarded **until the remaining budget for that phase is insufficient** to contract the next best tender

NEW

Phase II

Development of prototype systems in two iterations

Phase II

Prototype
development

Supplier B

Supplier C

Supplier D

Supplier E

Sep 22 – May 23

€ 1,395,000
PCP budget

- ▶ **4** suppliers expected to be awarded [minimum of 3]
- ▶ **Expected output:**
 - Prototype specification (v1)
 - Prototype demonstration (v2)
 - Plan for development of a limited volume of solutions for field-testing
 - Updated cost/benefits forecast including a preliminary business plan
- ~~8 months~~ **9 months**
- Maximum phase total budget: **€1,395,000**
- The offers are ranked according to **quality – price ratio**
- Contracts are awarded **until the remaining budget for that phase is insufficient** to contract the next best tender

NEW

Phase III

Final development and testing of a limited volume of services in real world conditions

Phase III

Original development of limited volume of first test products / services

Supplier B

Supplier D

Jun 23 – Jul 24
€ 2,557,500
PCP budget

- ▶ **2** suppliers expected to be awarded [minimum of 2]
- ▶ **Expected output:**
 - Implementation in 5 testing sites
 - Overall assessment and success verification
 - Updated cost/benefits forecast, including a preliminary business plan
- ~~16 months~~ **14 months**
- Maximum phase total budget: **€2,557,500**
- The offers are ranked according to **quality – price ratio**
- Contracts are awarded **until the remaining budget for that phase is insufficient** to contract the next best tender

Tendering process



Submission of tenders

NEW

SUBMISSION
(**UNDER
DISCUSSION**)

**DIFFERENT
SECTIONS**
ADMINISTRATIVE
TECHNICAL
FINANCIAL

4 MONTHS
TO SUBMIT
OFFERS
(TBC)

OFFICIAL
LANGUAGE
IS **ENGLISH**

Eligibility and evaluation criteria



- Open **to all types of operators**
(companies or other type of legal entities) regardless of their size or governance structure
- **Single** entity or **joint tender offer**
If the proposal covers all the requirements
- OMC participation is **voluntary**
Participation in the open market consultation is not a condition for submitting a tender
- Quality-price ratio will put a focus on **quality**



Quality / price ratio example

A weight of 80/20 is given to quality and price, respectively

**Score
for
tender**



Cheapest
Price /
Price of
tender X



100



Price
weighting
(20%)



Total quality
score (out of
100) for all
award
criteria of
tender x



Quality
criteria
weighting
(80 %)

The tender ranked first after applying the formula will be awarded the contract

Contract, monitoring and payments



CONTRACTING

framework agreement
with specific contracts
in each phase

MONITORING

During each phase,
contract implementation
**will be monitored
periodically and
reviewed against the
expected outcomes**
(milestones, deliverables
and output or results) for
the phases

COMPLETION CRITERIA

**Satisfactory
completion** of
milestones and
deliverables:
Requirement for
payment

**Successful
completion:**
Prerequisite for passing
from one phase to the
next

Intellectual property rights

SUPPLIERS KEEP OWNERSHIP OF THE INTELLECTUAL PROPERTY RIGHTS

attached to the results
generated during the PCP
implementation

A FINANCIAL COMPENSATION

is to be calculated in the
financial section of the
tender. The **actual price** is
the price quoted by the
supplier.

The **market price** is the
price that the supplier
would have quoted

VAT

- The procurement budget is centralised with the Lead Procurer (RJH). RJH is entitled to a deduction for input VAT. **Suppliers from Sweden** uses national VAT procedures
- **Suppliers from EU member states:** Invoicing without VAT using the reverse charge procedure. RJHs full data and VAT number must be included. Suppliers VAT number must appear.
- **Suppliers from third countries:** VAT is calculated and reported by RJH. If the supplier upon import is obliged to report VAT according to the rules of the home country and the invoice contains VAT, that VAT is non-deductible in Sweden. Instead, VAT amount is to be considered as a cost of the service
- Tenderers to calculate if their net amount + VAT is still under or equal to the ceiling amount, and not higher. Example: Budget procured 120, suppliers VAT 20 %, max. value of the service without VAT is 100.



DO YOU HAVE ANY
QUESTIONS?





THANKS

www.incareheart.eu
[@incareheart](https://twitter.com/incareheart)

#ChronicHeartFailure
#digitalhealth
#Horizon2020