

18.02.2025



2CARE4EU

White paper Webinar

Challenges | Lessons learnt | Recommendations

About 2CARE4EU

Who are we?
What is this white paper?

A cluster of PCPs in the health and care domain

2021 - 2025

CareMatrix

eCare

INCAREHEART

ROSIA

White paper

Yes, this is Wikipedia →

“A white paper is a report or guide that informs readers concisely about a complex issue and presents the issuing body's philosophy on the matter. It is meant to help readers understand an issue, solve a problem, or make a decision[...].”

White paper

What to expect today?

- a. Short introduction to each of the 2CARE4EU PCPs
- b. Common challenges – Sofía Moreno (ROSIA)
- c. Lessons learnt per phase – Ulises Pisano (eCare)
- d. Policy recommendations – Klaus Piesche (INCAREHEART)
- e. Questions, answers, discussion
- f. Lunch



Introduction to the PCPs

Four PCPs, many takeaways – let's set the stage

Introduction to the PCPs

Magnus (CareMatrix)

Ulises (eCare)

Åsa (INCAREHEART)

Sofía (ROSIA)

CAREMATRIX

Buyers group

- Region Skåne, Sweden
- Vestre Viken, Norway
- Osakidetza, Spain

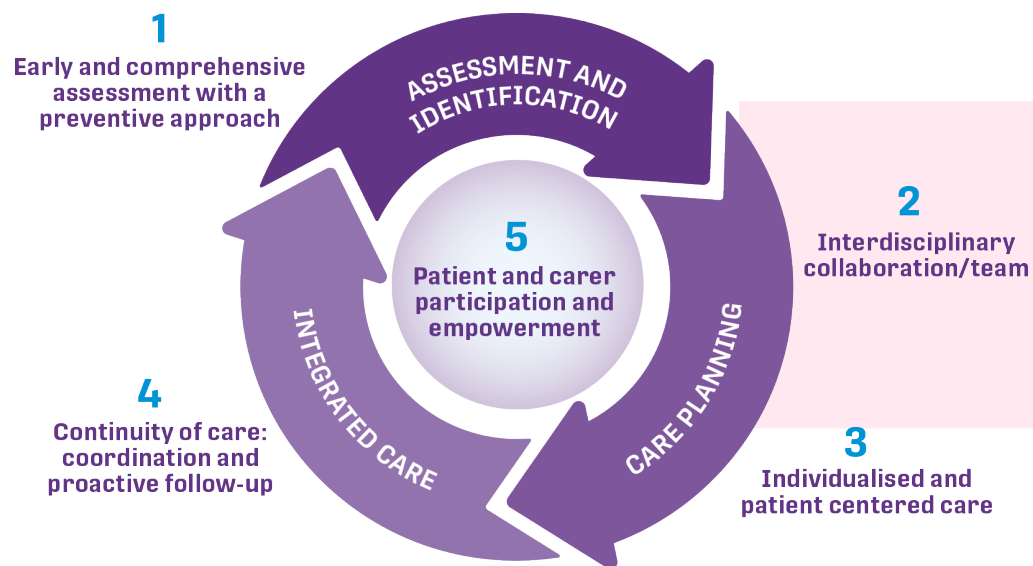
Further consortium members

- Innovation Skåne (Coordinator)
- Norway Heathtech
- BIOEF
- International Foundation for Integrated Care (IFIC)

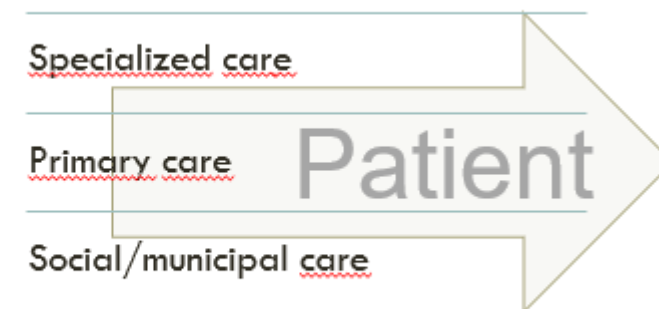
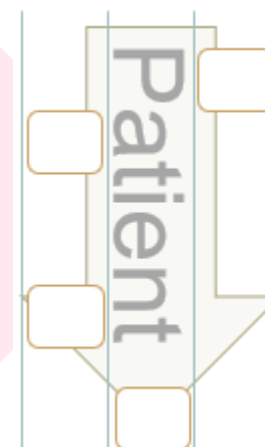


CAREMATRIX Building blocks

Visualising INTEGRATED CARE, along the person-centred continuum



Adressing SILOS, in work flows and data management

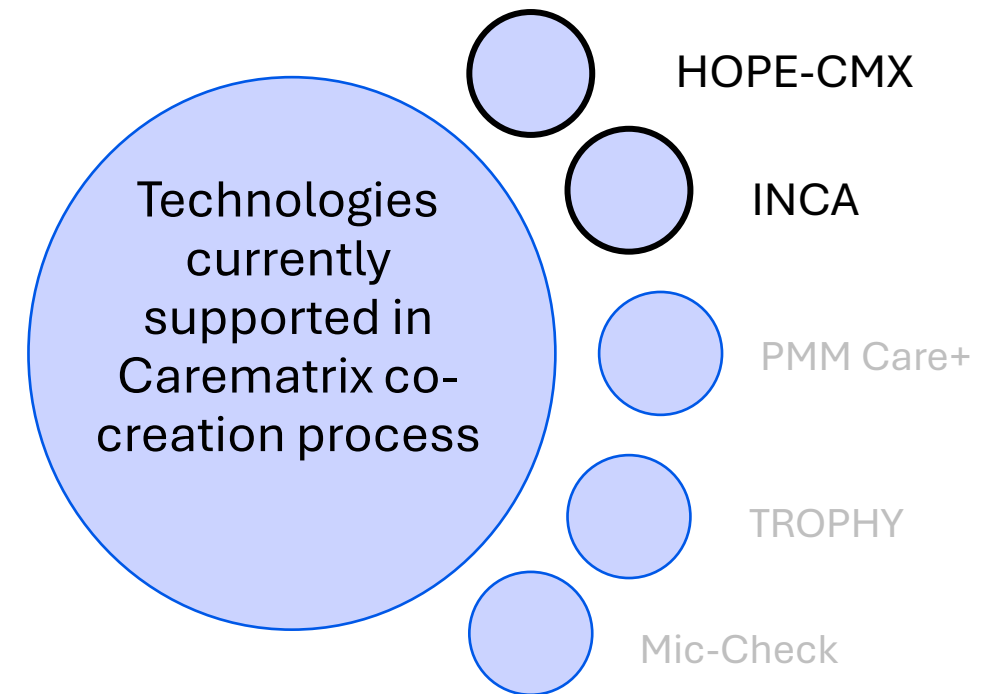


CAREMATRIX Process

We are currently in phase 3

Remember the original Vision and Purpose

Importance of Phase 2 – pilot development phase





Call: [H2020-SC1-DTH-2018-2](#)

Topic: [SC1-DTH-10-2019-2020 - Digital health and care services](#)



8 partners

[4 procurers \(IT, ES, DE\)](#)

[4 supporting organizations \(PT, ES\)](#)



Sep'19 – Jun'24 (58 months duration)

- 48 months
- 4 months (Extension 1-COVID crisis)
- 6 months (Extension 2 - entry of a new coordinator and replacement of a procurer)



€3,920,000
for procurement

eCARE

(S01) Promote **systematic routine screening** for pre-frailty stages

(S02) Prevention and management of **functional and cognitive decline and psychosocial frailty**

(S03) Manage functional decline and frailty through **multidimensional targeted intervention**

(S04) Contribute to integrated pathways of care with **better informed, prepared and trained workforce**

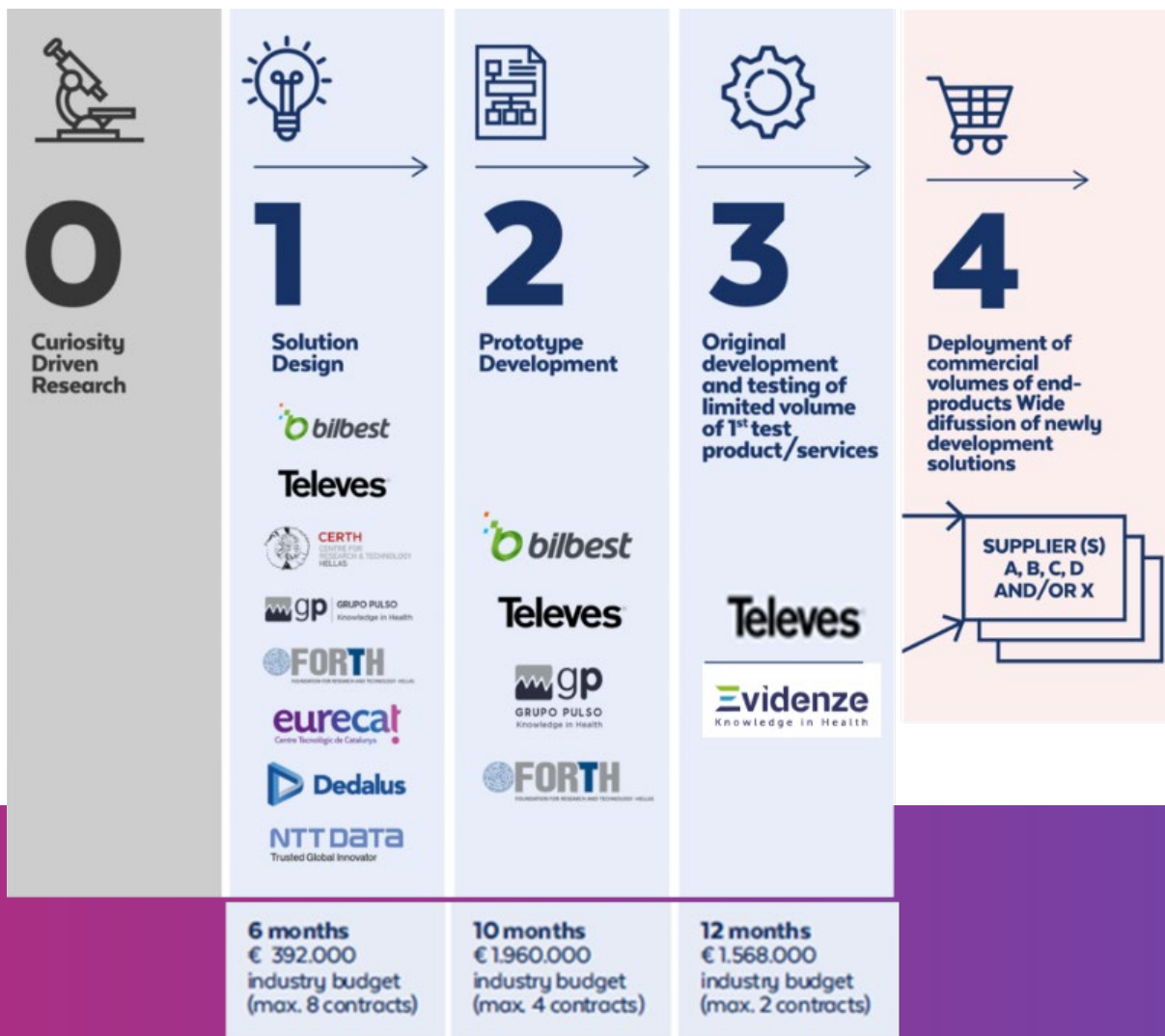
(S05) Convey the shift to **patient-centric intervention strategies** to ensure engagement and technology acceptance

(S06) Contribute to **research and methodology on frailty** and active and healthy ageing

(S07) Contribute to managing demand and increasing the sustainability of health and social eCare by **optimising resources, systems and societal costs** associated with ageing

(S08) Support **competitive translational research, development and transfer of innovation** to the market

eCARE



INCAREHEART

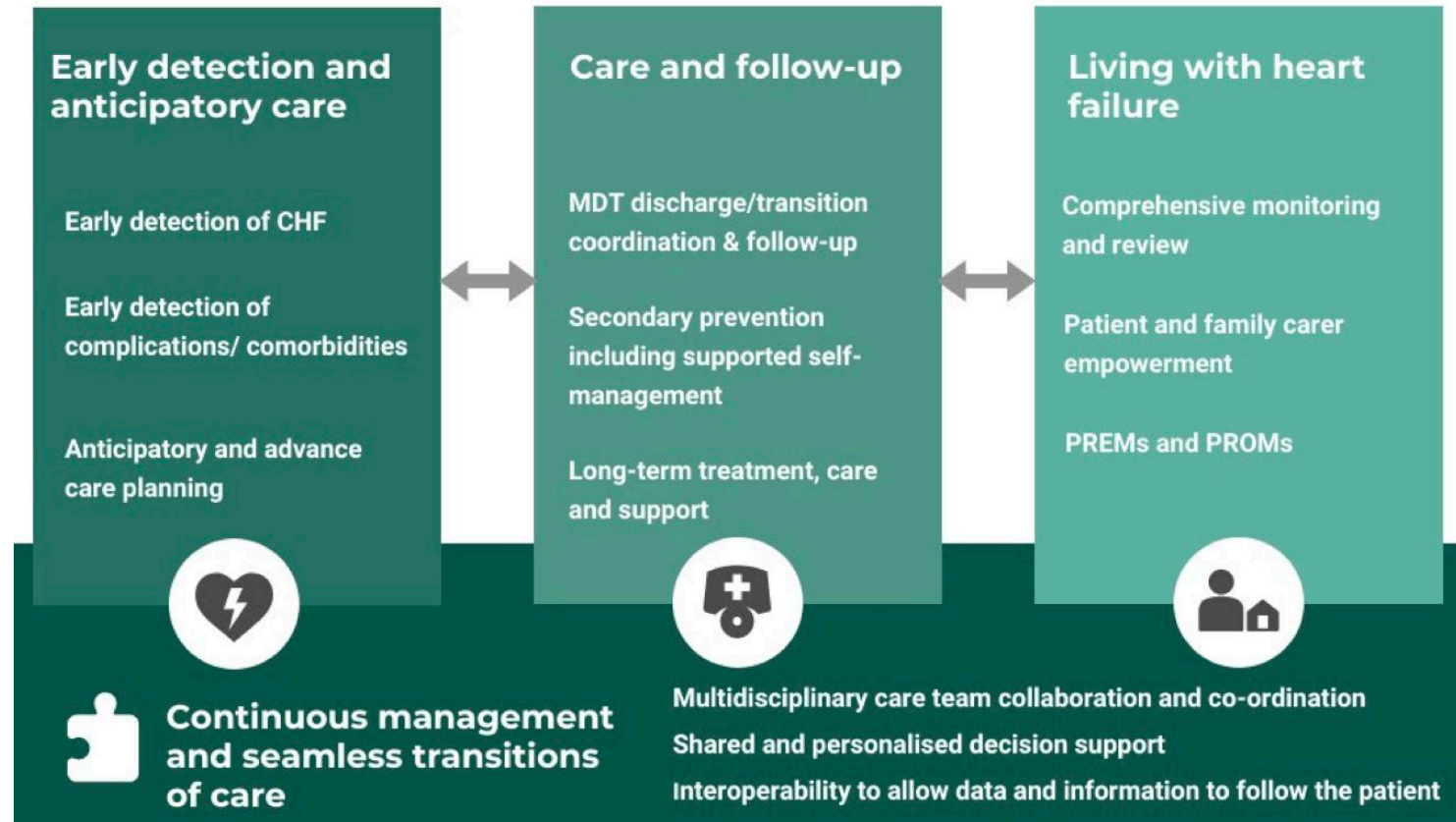
Buyers group

- Ministry of Health – Türkiye
- Region of Central Macedonia – Greece
- Università degli Studi di Napoli Federico II – Italy
- Santa Casa da Misericórdia da Amadora – Portugal
- Region Jämtland Härjedalen – Sweden (Lead procurer)

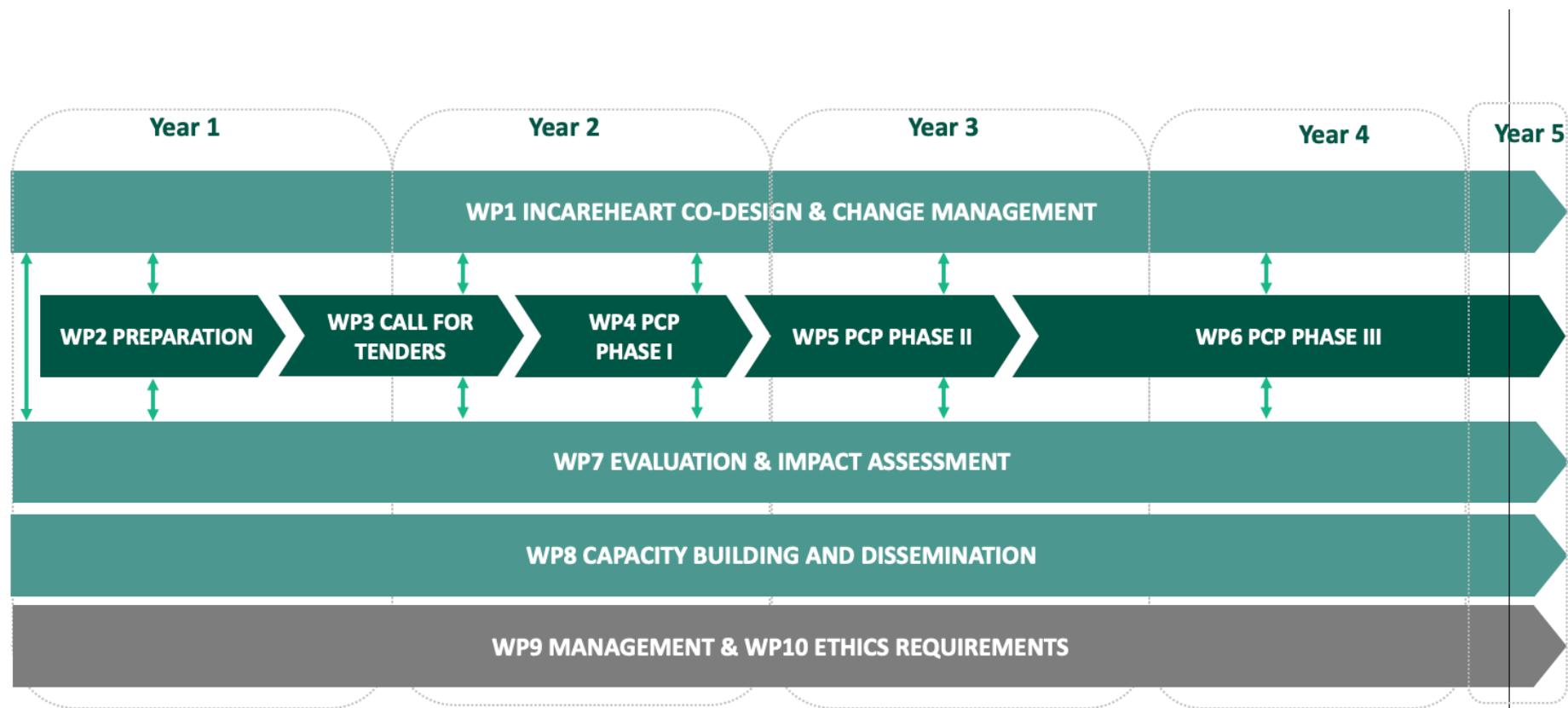
Further consortium members

- empirica
- Ticbiomed
- International foundation for integrated care (IFIC)

INCAREHEART Building blocks



INCAREHEART



ROSIA PCP

What is the problem?

- An aging population and new habits increase the demand for rehabilitation services.
- Resources are not growing at the same pace.
- The issue is more severe in rural areas.
- **Urgent action is needed!**

Inaction is not an option.

At the same time there are many apps and devices using cutting-edge technology and data driven interventions which can support telerehabilitation and self-management

ROSIA PCP

BUT

- Integration: How can digital services connect easily with public healthcare IT systems?
- Data Access & Sharing: How can they share and access personal health data securely?
- Care Pathways: How can they be integrated into new integrate care models?
- Prescription: How can doctors prescribe them?
- Scalability: How can we promote solutions for all rehabilitation needs?

ROSIA PCP

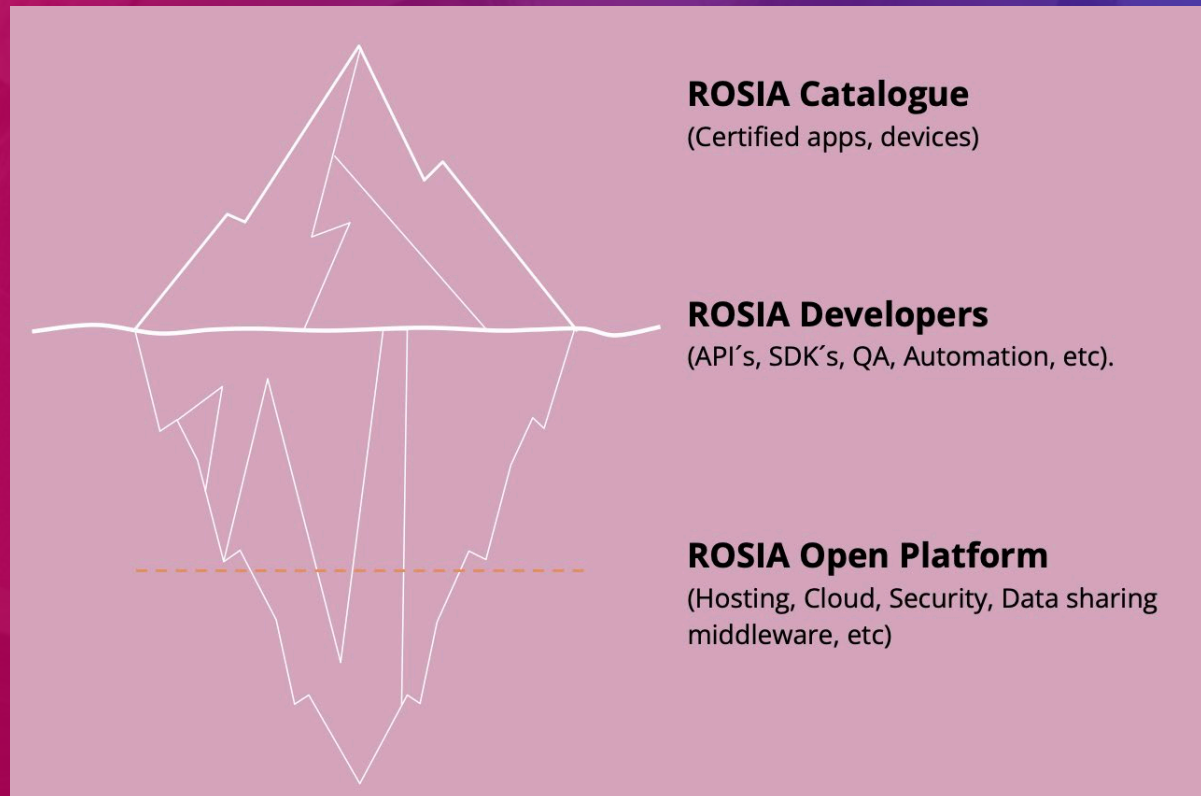
ROSIA Solution

2CARE4EU

Supervised community and self care rehabilitation
at the patient environment.

Flexible and scalable value-based model of care.

Tailored integrated care model.





Common challenges

Different projects, same struggles - Welcome to PCPs.

Common challenges

Sofia (ROSIA)

Sustainability, Impact, and Market Adoption

- Long R&D Timelines

Risk of obsolescence before implementation, but extended co-creation enhances understanding of healthcare needs.

- Measuring Impact Challenges

Few PCP projects reach high TRLs, and pilot phases are often too short for solid decision-making evidence.

- Regulation & Reimbursement Barriers

- Adapting to evolving regulatory frameworks is complex.
- Existing models are not well-suited for digital and preventive innovations.
- Without regulatory evolution, innovations may struggle to integrate into healthcare systems.

Common challenges

Sofia (ROSIA)

Key Constraints in the PCP Process

- **Accumulated Delays:** Workload buildup between phases slows testing and deployment.
- **Limited Pilot Testing:** Insufficient time for real-world validation.
- **Legal & Ethical Complexities:**
 - Lengthy and resource-heavy approval processes.
 - Emerging regulations (MDR, AI Act, EHDS) add unplanned complexity.
- **Interoperability Issues:**
 - Rigid healthcare IT systems and technical barriers.
 - Legacy systems hinder new solution integration.
 - Legal restrictions limit uncertified device data use.
- **Regulatory Adaptation:** Ongoing changes require continuous adjustments, causing delays.

From PCP to PPIs through MDR Certification: A valley of death?

Common challenges

Sofia (ROSIA)

- PCP projects focus on prototypes that cannot achieve MDR certification within project timelines.
- Lack of sufficient evidence makes it difficult to attract investment.
- MDR certification is expensive and can take years.
- This particularly impacts startups and SMEs, making market entry more difficult.



Lessons learnt

Innovation is hard, but at least we took notes.

Lessons learnt

Ulises Pisano (eCare -
INCAREHEART)

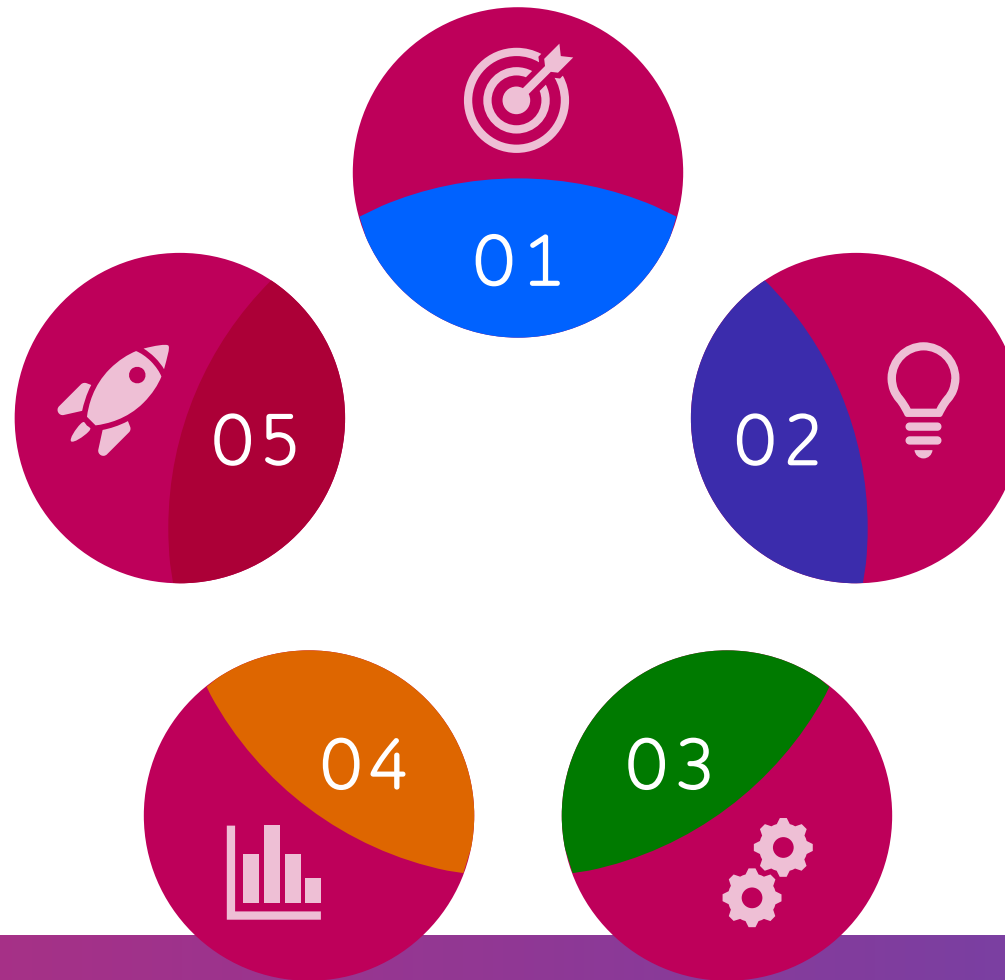
Phase 0

Coordination and tender preparation

- Prioritise supporting suppliers but be aware of budget limitations.
- Set realistic expectations, so long-term mutually beneficial relationships can be maintained.

Embedding care integration in the challenge brief

- Care integration needs should be operationalised and included in the challenge brief.
- Adapt the standard PCP model to local and regional contexts



Open Market Consultation optimisation

- Discuss questions posed in the OMC.
- Implement a thorough and analytical OMC.
- Support the OMC with a targeted marketing campaign.
- Identify relevant R&D teams and innovative companies.

Stakeholder engagement

- Involve procurers' internal teams as early as possible.
- Establish connections with other PCP projects
- Involve other procuring organisations.

Analysis tools and instruments

- Develop standard templates for tender evaluation and monitoring.
- Ensure transparency and equal treatment of suppliers.

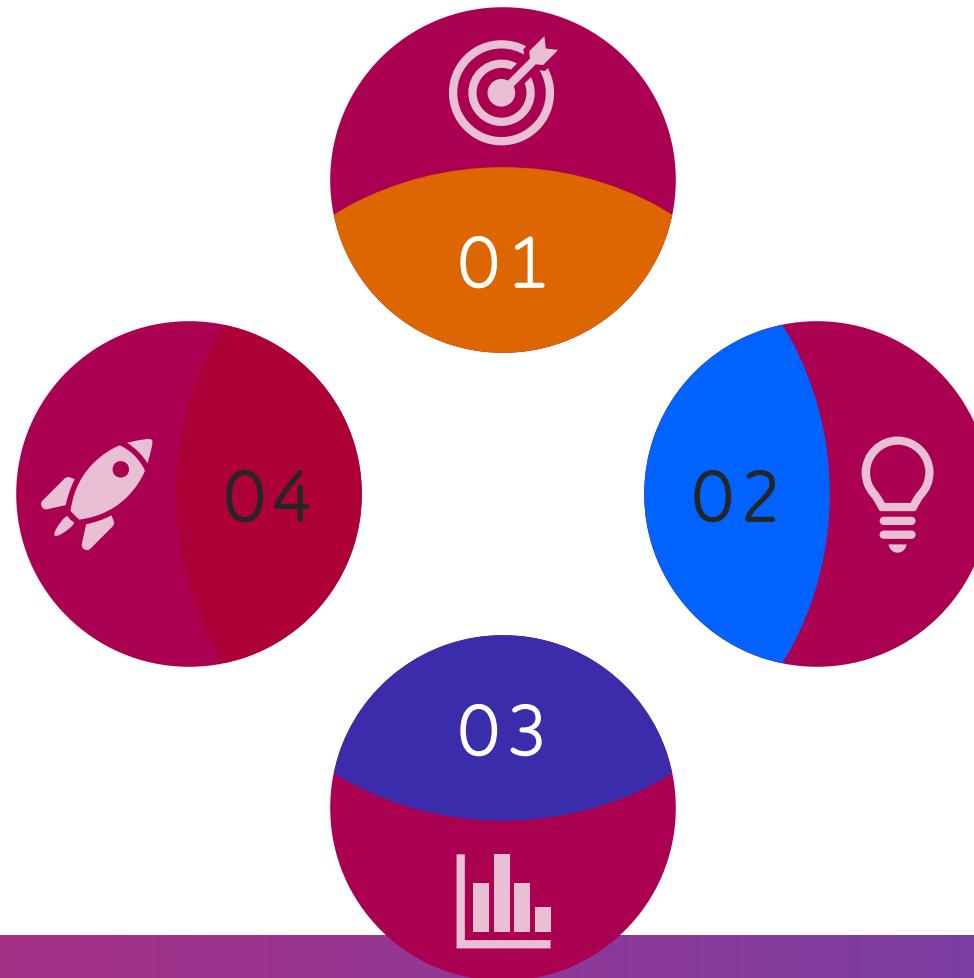
Phase I

Supplier support and engagement

- Tailored support to suppliers (structured guidance).
- Actively engage with suppliers to co-design the technologies
- Provide clear expectations and feedback.

Internal stakeholders' involvement

- Mobilise procurers' internal support teams early in the process.
- Promote cross-departmental collaboration and knowledge-sharing.
- Ensure management buy-in and organisational commitment.



Guidelines and expectations management

- Encourage continued supplier engagement by setting achievable milestones.
- Offer guidance on regulatory and compliance requirements.

Monitoring

- Supplier monitoring requires substantial time and resources.
- Facilitate continuous communication and feedback loops with suppliers.

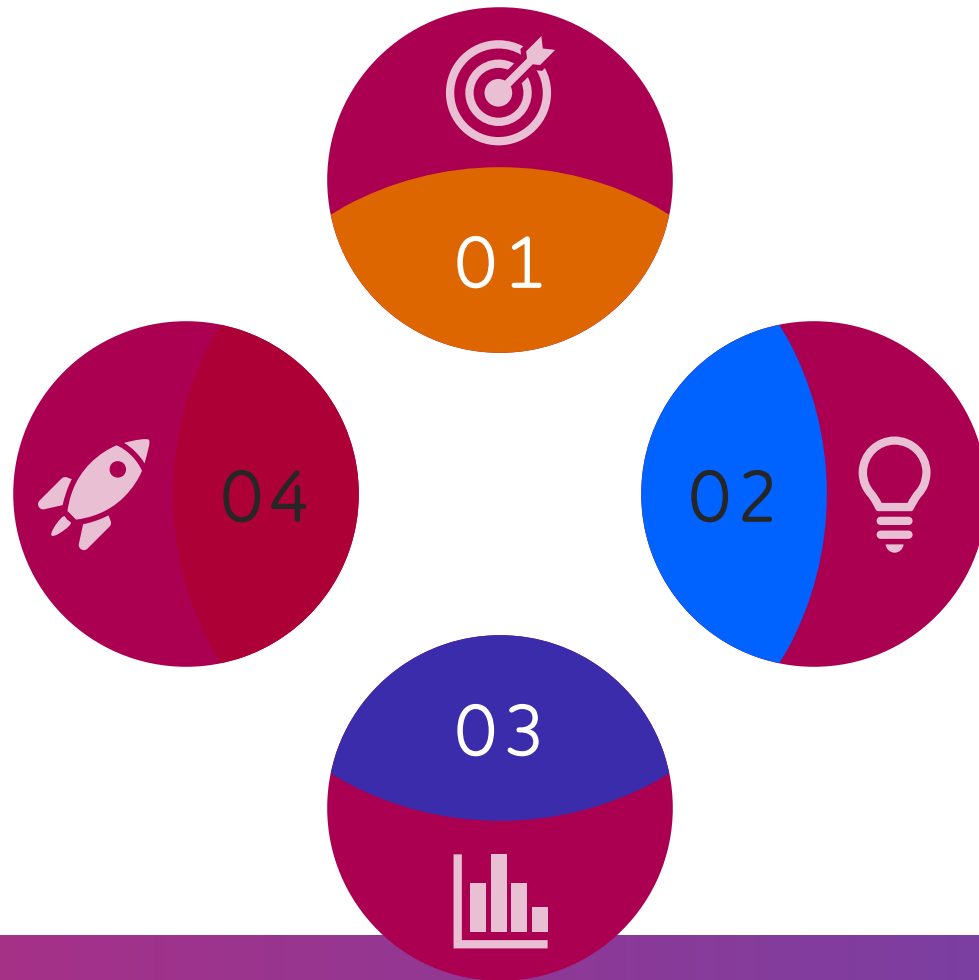
Phase II

Planning and adaptation

- Develop a comprehensive implementation roadmap integrating Phase III planning into Phase II.
- Design the pilot to minimise care professionals' additional workload.

Research protocols

- Ensure research protocols facilitate real-world applicability and scalability.
- Integrate ethical clearance planning into early project timelines.
- Balance standardisation with local flexibility.



Cooperation and development

- Create a collaborative, comfortable environment for suppliers.
- Provide feedback to suppliers and enable their improvement.

Phase coordination

- When planning the timeline, allow suppliers to make adjustments.
- Synchronise procurement and administrative processes
- Facilitate suppliers' work by providing a clear roadmap.

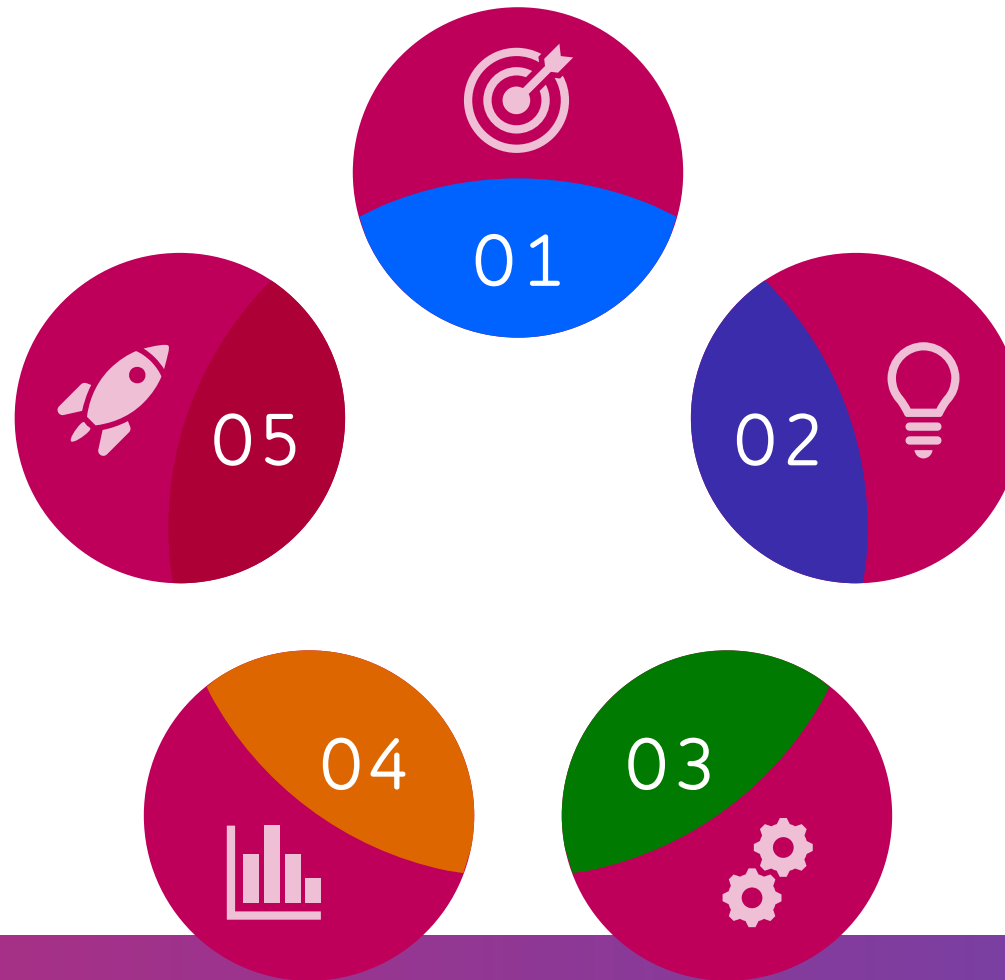
Phase III

Data and interoperability

- Ensure data availability and interoperability.
- Adapt the digital solutions to the different procurers' legislations, IT systems, and healthcare provision pathways.

Ethical and logistical barriers

- Proactively navigate ethical clearance, recruitment, and research pilots.
- Engage multidisciplinary expertise to streamline pilot implementation.



Planning and adaptation

- The roadmap to implementation is uncertain.
- Design carefully the digital solutions evaluation tools.
- Manage device logistics efficiently to prevent pilot delays.
- Ensure flexibility in recruitment and pilot implementation.

Patient engagement

- Maximise patient adherence in pilot studies.

Medical Device Regulation (MDR) certification

- Ensure compliance with MDR requirements to prevent data integration restrictions.
- Strive to incorporate relevant aspects of the certification process into the PCP framework where feasible.

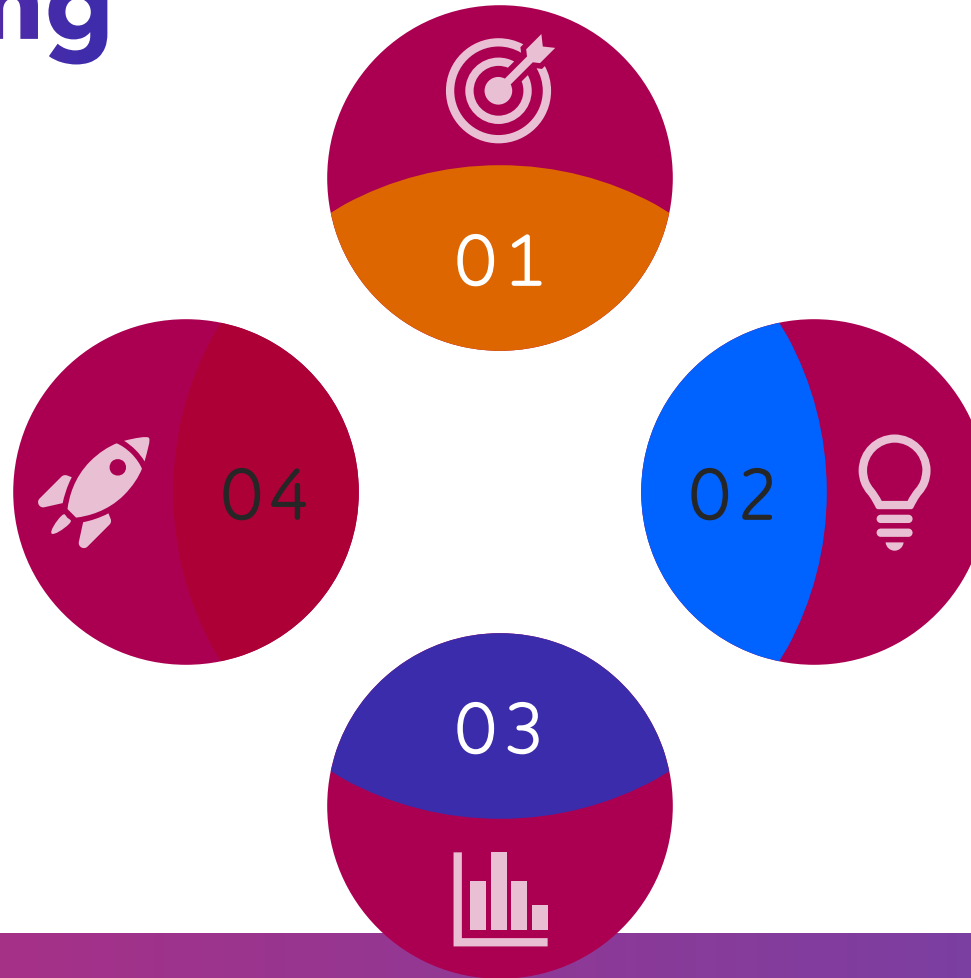
Cross-cutting

Commitment and team composition

- Ensure procurers' genuine interest in the solution through commitment.
- Integrate legal expertise in the coordination team to mitigate risks.

Effective communication

- Ensure clear and agile communication with suppliers.
- Acknowledge and manage high demands on partners.



Strategic planning and adaptability

- Start pilot design, protocol preparation and KPI alignment early.
- Plan enough time to develop the research protocol and get the ethical committee approval.

Time and resource management

- Mitigate the impact of institutional and political changes.



Policy recommendations

Good policy – the secret ingredient to innovation success

Policy recommendations

Klaus Piesche (INCAREHEART)

- Policy and process improvements
- Enhancing PCP impact
- Strategic Vision for the future of PCP

Policy and process improvements

Push PCP beyond their current structure – adaptable, dynamic

- a. A centralised regulatory helpdesk for legal, compliance, and procurement issues
- b. More flexible procurement models – iterative development, dynamic phase funding mechanisms, adaptability to emerging technology
- c. Streamline ethical clearance and MDR compliance to prevent the usual logjams – coordinating with national regulatory bodies to align approval process

Enhancing PCP impact

Funding shouldn't stop when things get interesting

- a. Ensure timely allocation of funding for sustainability actions beyond project timelines
- b. Expand support for clinical trials, MDR certification, and early-stage pilot design
- c. Encourage PPPs for co-financing PCP innovations

Strategic vision for the future of PCPs

Measure what matters to build on success

- a. Enhance monitoring and impact assessment of PCP-funded solutions
- b. Align PCPs with broader EU Health and Data Strategies



Questions and answers

Got questions? We've definitely got opinions.



Thank you!

Now go forth and innovate!