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White paper

Challenges, lessons learned
and recommendations for
PCPs implementation.

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Introduction

The 2CARE4EU Cluster is a joint endeavour of four Pre-Commercial Procurement (PCP) projects: **INCAREHEART**, **CareMatrix**, **ROSIA**, and **eCare**. These initiatives share a common goal of advancing innovative ICT-based solutions to address critical challenges in health and care, including improving chronic disease treatment, enabling rehabilitation in remote areas, enhancing predictive analysis for frailty prevention, and advancing integrated care. This collaborative endeavour, spanning from 2021 to 2025, showcases the commitment of diverse stakeholders to advancing healthcare innovation.

Partners from the four initiatives, including public procurers and knowledge organisations, have emphasised that the PCP framework demands a distinctive approach, with phases and objectives specifically tailored to co-creating and testing innovative solutions in real-world environments. This White Paper delves into the challenges encountered, ranging from legal and regulatory barriers to operational and technological constraints.

This document serves a dual purpose: first, to consolidate the key lessons learned from the 2CARE4EU Cluster's implementation of PCPs, and second, to offer actionable recommendations for the European Commission and policymakers based on these insights. The goal is to inform and shape the next generation of PCP instruments, ensuring they are better equipped to drive innovation, address emerging healthcare needs, and promote sustainable collaboration both within and beyond the EU.

By sharing these experiences and proposing strategic improvements, the 2CARE4EU Cluster aims to contribute to a more effective and impactful future for PCPs, enabling transformative advancements in healthcare technology and delivery.



Challenges in PCP implementation

Implementing PCP projects in healthcare and social care presents significant obstacles that can impact their overall success and scalability. These challenges originate from regulatory complexities, legal constraints, and interoperability barriers that hinder seamless integration into existing healthcare systems. Additionally, limited resources, strict timelines, and the need for sustainable market adoption further complicate the process.

This section outlines the critical challenges faced throughout PCP implementation, shedding light on the structural and operational barriers encountered by procurers and suppliers. By identifying these challenges, we emphasize the importance of developing strategic solutions to support innovation, enhance collaboration, and ensure the long-term viability of PCP-driven advancements in the healthcare domain.

Regulatory and legal complexities and fragmentation

- **National and regional regulations.** In some cases, implementing PCPs by multiple procurers in different EU member states and Horizon-associated countries creates a complex and challenging regulatory environment for suppliers. Besides, differences among healthcare systems impede the easy escalation of innovative solutions across different European countries.
- **Impacts on all phases.** Regulatory aspects can affect every stage of solution development, from testing and piloting to development and adoption. Potential restrictions or limitations in these phases must be carefully considered to ensure smooth implementation and compliance.

Operational fit and system integration

- **Interoperability challenges.** Achieving interoperability requires alignment with various IT systems, each with internal rules, including standards, hardware legacy, and data access limitations. This creates significant challenges for procurers and suppliers, adding to the implementation complexity.
- **Integration constraints.** Effective integration between systems requires considerable time and resources. However, the time constraints of the PCP phases often restrict the ability to thoroughly address system integration systems and data interoperability challenges. Furthermore, available resources are typically allocated to the development of innovative solutions, leaving little to support integration between systems and ensure data interoperability.
- **Proprietary legacy systems.** Legacy systems are often proprietary, necessitating close cooperation with suppliers of those systems to achieve compatibility and integration with new solutions, as they possess the technical expertise and access necessary to adapt or upgrade their platforms. However, such cooperation can lead to dependencies, limit flexibility, and increase costs. Ensuring compatibility and integration with new solutions may necessitate

joint efforts to develop APIs, bridge gaps in standards, or negotiate access to proprietary elements, adding further complexity to the procurement and implementation process.

Time and resource demands

- **Accumulated delays.** Work to be carried out between phases often leads to delays, concentrating much of the workload at the end of the project. This severely reduces the available time during phase III, limiting the ability to conduct meaningful pilots.
- **Complex legal and ethical procedures.** Legal and ethical procedures are complex and time-intensive. PCP processes frequently exceed anticipated time and resource demands, with activities such as preparing Tender documentation or securing ethical approval causing delays and hampering the innovation process. Compounding these challenges is the need to account for new and evolving legislation, such as the MDR, AI Act, eIDAS and EHDS which add additional layers of compliance and complexity. These delays are particularly detrimental in rapid technological advancements, where time is critical to capitalise on cutting-edge innovations.

Sustainability, impact and market introduction

- **Sustainability over time due to several factors.** Suppliers face challenges tailoring solutions to meet different procurers' needs and expectations. Additionally, the rigid implementation of public procurement processes can stifle innovation, as it may impede the rapid development and market introduction of new technologies before they become obsolete.
- **Real, tangible, and measurable impacts from PCP projects are hard to find.** Suppliers develop solutions that hardly move toward the last stages of TRL, neither being introduced in the market nor implemented by the project procurer organizations. Follow-up strategies for the solutions are pretty unlikely to be rolled out.
- The **large-scale adoption of innovative solutions** depends on their maturity/reliability and the compatibility of the proposed solutions with the organizational models of the structures involved. Without tangible and sound-evidence results, decision-makers allocating resources for investments in new technologies prefer acquiring traditional healthcare services solutions.
- Given the **very long validation processes** and the low starting TRL level, often only some components of the (final) solutions were adopted/acquired after the PCP process, directly from the suppliers who assigned the PCP, and further customization was necessary before use.
- **Adapt reimbursement policies.** Organisations that reimburse healthcare are very often not open to innovation, implement top-down financing frameworks, and are not able to prove the impact of digital health and remote care delivery solutions.

Medical device regulation

- As PCPs focus on prototyping and testing innovative solutions that are not yet market-ready, the **solutions cannot possibly be MDR-certified within the PCP's lifetime**. This means you can test them in your pilot sites to evaluate performance, usability, and other non-clinical aspects – anything not constituting a use as a "medical device", as defined in the MDR's Article 2 (1).
- If existing products, like smart scales or smart watches, are used within the PCP, **MDR and CE-certified devices should be requested as a requirement**. This is not necessarily for the sake of the veracity of the collected data (which also depends on the person using the item) but for compliance reasons.
- Getting all the **certificates required in the MDR is time-consuming and quite expensive**, especially for start-ups or small enterprises, which we often see in PCPs. Besides, the approval process by ethical committees for IT solutions needs this approval, resulting in the need to involve national authorities or complex processes alike.
- **Within a PCP, the suppliers can only lay the groundwork for the certification process**—i.e., a clinical trial with the HSMonitor project's solution as part of it is nothing more than a happy accident, financed outside of the project—and before the MDR took full effect.
- In early 2025, the ramifications for PCPs developing anything that could be considered a medical device under the MDR are pretty clear-cut: The procurers most possibly will not be able to buy the solution once the PCP is over, the supplier has to invest additional time and money. On the positive side, the suppliers may potentially use existing connections with the suppliers to ease up the process.





Lessons learned

- Phase 0: Pre-procurement. Preparation and Open Market consultation
- Phase 1: Solution design
- Phase 2: Prototype development & testing
- Phase 3: Pilot deployment
- Cross-cutting lessons

Lessons learned

The execution of PCP projects, particularly in the healthcare and social care sectors, brings forth both challenges and opportunities that shape future procurement and innovation strategies. As these projects progress through distinct phases—ranging from pre-procurement to pilot deployment—valuable insights emerge regarding best practices, potential pitfalls, and effective adaptation strategies.

This section summarises key lessons learned, offering a structured approach to understanding supplier collaboration, stakeholder engagement, and the operational difficulties of implementing digital health solutions across diverse environments. By sharing these findings, we aim to equip future PCP initiatives with practical guidance, helping them navigate regulatory landscapes, optimize resource allocation, and foster sustainable innovation within the European healthcare ecosystem.

Phase 0

Pre-procurement. Preparation & Open Market Consultation

Coordination and tender preparation

- **Prioritise supporting suppliers** but be aware of budget limitations to manage their demands and expectations. It is important to actively support suppliers by providing clear guidance, timely responses, and fair engagement opportunities. However, this must be balanced with budget limitations to ensure responsible financial management. Setting realistic expectations with suppliers is crucial, so clearly communicate any constraints on funding and operational capacities. By managing supplier demands in alignment with available resources, a sustainable and transparent procurement process can be maintained while strengthening long-term, mutually beneficial relationships.

Embedding care integration in the challenge brief

- **Care integration needs to be operationalised and included in the challenge brief.** Given its multidimensional nature, all relevant aspects must be adequately represented in the PCP challenge. Operationalising digitally enabled integrated care involves including concrete digital functionalities and tools to support care integration. Additionally, the challenge should emphasise the importance of end-user education and empowerment, ensuring that patients and caregivers can fully engage with integrated care solutions. Strengthening communication channels is also critical to enhancing multidisciplinary collaboration and improving care outcomes.
- **Adapting the standard PCP model to local and regional contexts.** Differences across procurers' sites—whether in healthcare infrastructure, regulatory frameworks, or technological readiness—must be acknowledged and integrated into the project implementation. By acknowledging adaptability, the project can achieve more effective and sustainable outcomes across diverse procurement.

Open Market Consultation optimisation

- **Internally discuss questions posed in OMC** before responding. One unique common position should be achieved before responding to suppliers' questions. This approach ensures consistency and fairness in communication. Respond to all the questions in writing and post them on your website. This ensures that all suppliers receive the same information, preventing any unfair advantage and promoting a level playing field.
- **Implement a thorough and analytical OMC.** Engage with suppliers, actively listen to and adapt your challenge according to the dialogue established with suppliers. Use the OMC to refine the challenges, ensuring they are practical and achievable. Additionally, lessons learned from previous projects should be integrated.
- **Support the OMC with a targeted marketing campaign.** Leverage website tools to facilitate supplier matchmaking and use dedicated channels and messaging to engage potential suppliers.
- **Identify relevant R&D teams and innovative companies.** As part of the OMC preparation, identify research and development (R&D) groups and companies actively working on or with expertise in relevant (technology) fields. Creating a list of potential participants ensures that the OMC reaches the right audience—those capable of contributing valuable insights and offering innovative solutions. Engaging these groups early fosters a collaborative environment, encouraging participation and increasing the likelihood of high-quality tender applications.
- **State of the Art** Conduct an initial market analysis to map the latest advancements in relevant technologies and solutions. This provides a baseline understanding of existing capabilities and identifies gaps the PCP could address, ensuring that the project stays aligned with current market and technology trends. The SotA also helps to identify relevant stakeholders, R&D teams and innovative companies, to participate in the OMC.

Stakeholder engagement

- **Involve procurers' internal teams as early as possible**, especially critical stakeholders who may either facilitate or hinder the process. For instance, IT professionals working in procurers' organisations play a crucial role. Ensure collaboration with multidisciplinary teams, including technology, communication, and legal experts. Involving legal professionals from the outset helps navigate regulatory complexities, ensure compliance, and streamline the procurement process.
- **Establish connections with other PCP projects** and/or initiatives looking for synergies and mutual support. The complexity of PCPs makes it valuable to cluster with similar projects for mutual support.
- **Involve other procuring organisations** to become part of the procurers' networks in the role of observers to gain experience on PCPs for further potential participation and/or acquisition/implementation of the developed solutions

Analysis tools and instruments

- **Develop standard templates for tender evaluation and monitoring.** Provide clear and concise assessment guidelines and documents to ensure transparency and efficiency across all procurement processes.
- **Ensure transparency and equal treatment of suppliers.** Use an accessible platform to share tender-related updates, evaluation criteria, and responses to supplier questions. Establish clear communication protocols to prevent information asymmetry and ensure that all suppliers have equal access to critical details throughout the procurement process

Phase 1 Solution design

Supplier support and engagement

- **Provide tailored support to suppliers** while ensuring transparency and equal treatment. Provide structured guidance and resources that accommodate different supplier needs while maintaining fairness, openness, and compliance with procurement principles.
- **Actively engage with suppliers to co-design the technologies.** Ensure that co-creation takes place well ahead of actual pilots and support suppliers by providing them with comprehensive information on the differential social and healthcare provision in each procurers' system.
- **Provide clear expectations and feedback.** Ensure that suppliers receive timely feedback at each phase of the procurement process.

Internal stakeholders' involvement

- **Mobilise procurers' internal support teams early in the process.** A successful PCP implementation requires the collaboration of various internal organisational stakeholders, including procurement officers, IT specialists, legal experts, financial controllers, and healthcare professionals.
- **Promote cross-departmental collaboration and knowledge-sharing.** Encourage internal teams to work together by organising regular coordination meetings, training sessions, and interdisciplinary workshops. This contributes to a shared understanding of PCP objectives and helps to identify and solve problems early.
- **Ensure management buy-in and organisational commitment.** Engage decision-makers early to secure organisational support, mitigate resistance to change, and ensure sustainability.

Guidelines and expectation management

- **Encourage continued supplier engagement by setting achievable milestones.** Structure the project timeline with well-defined phases, ensuring that suppliers can realistically meet deadlines. Avoid overly rigid requirements that may hinder

innovation while maintaining the project's necessary quality and compliance standards.

- **Offer guidance on regulatory and compliance requirements.** Given the complexity of sector-specific regulations (e.g., MDR), provide suppliers with early-stage legal and technical support to ensure compliance throughout the PCP process.

Monitoring

- **Supplier monitoring requires substantial time and resources.** Tracking supplier progress, ensuring compliance with contractual obligations, and assessing deliverables often take longer than anticipated. Adequate time and personnel should be allocated to oversee supplier performance effectively throughout all PCP phases.
- **Facilitate continuous communication and feedback loops with suppliers.** Establish regular progress monitoring meetings and establish a trustful and open communication environment,

Phase 2

Prototype development and testing

Planning and adaptation

- **Develop a comprehensive implementation roadmap integrating Phase III planning into Phase II.** Establish a detailed plan early in the process to help both procurers and suppliers anticipate resource needs and operational requirements. Incorporate change management strategies into planning and reporting to ensure a seamless transition between project phases.
- **Design the pilot to minimise care professionals' additional workload:** When designing a pilot in social and healthcare settings, it is crucial to structure the pilot activities and data collection to avoid unnecessary workload or redundant tasks for care professionals. By designing the pilot with minimal duplication and workflow disruption, the project will be more likely to gain the support of health professionals, improve data quality, and foster smoother implementation.

Research protocols

- **Ensure research protocols facilitate real-world applicability and scalability.** Develop protocols that enable comparisons across procurers' sites and consider the long-term applicability of findings in actual health and care environments and systems. This includes defining meaningful outcome measures, ensuring usability testing, and planning for potential regulatory pathways beyond the pilot phase.
- **Integrate ethical clearance planning into early project timelines.** Ethical clearance can take significantly longer than expected, often delaying project time planning and impacting pilot implementation. Engage ethics committees

and regulatory bodies as early as possible, prepare documentation well in advance, and allocate sufficient time for potential iterations or additional requirements.

- **Balance standardisation with local flexibility.** While a standard research protocol is essential for comparability, ensure it allows for local adaptations where necessary.

Cooperation and development

- **Cultivate open collaboration:** Create a collaborative environment where suppliers feel comfortable sharing their ideas and seeking feedback. Encouraging open communication and mutual trust fosters innovation, strengthens partnerships, and leads to more solutions.
- **Support supplier development:** Provide constructive feedback and opportunities for improvement to support suppliers' development. This enhances their capabilities and ensures that the solutions provided are of the highest quality.

Phase coordination

- **Manage phase overlap properly.** When planning the timeline for the call-offs for tenders for Phases 2 and 3 of the PCP, allow for an overlap with the end of the previous phase. This approach gives bidders sufficient time to incorporate feedback, refine their offers, and adjust their solutions based on lessons learned from the preceding Phase.
- **Synchronise procurement and administrative processes:** Ensure that procurement timelines align with internal administrative processes such as deliverable approvals, budget allocations, and legal compliance. Misalignment can lead to unnecessary delays and inefficiencies.
- **Facilitate early supplier engagement for upcoming phases:** Provide suppliers with a clear roadmap, including anticipated requirements, evaluation criteria, and expected deliverables. This helps them prepare proactively and identify risks early.

Phase 3 Pilot deployment

Data and interoperability

- **Ensure data availability and interoperability.** Suppliers require access to high-quality health data to (train and) test the digital solutions. However, legal restrictions, privacy regulations and technical barriers often hinder data sharing. These issues are particularly complex for AI-driven digital solutions, which rely on large, standardized datasets to ensure accuracy and efficiency.

- **Adapt the digital solutions to the different procurers' legislations, IT systems, and healthcare provision pathways.** Each supplier's solution must comply not only with the general PCP challenge but also with the legal and organisational particularities of each procurer organisation. Ensuring compliance with these diverse frameworks is essential for seamless integration, regulatory approval, and long-term adoption within procurer organisations.

Ethical and logistical barriers

- **Proactively navigate ethical clearance, recruitment, and research pilots.** The final testing phase, where solutions are trialled with real users, is one of the most complex and challenging stages of PCP implementation. Secure ethical approval early by engaging with regulatory bodies in advance, preparing comprehensive documentation, and anticipating potential compliance challenges. Structure participant recruitment carefully, ensuring adherence to data protection laws, informed consent requirements, and diversity considerations to achieve reliable and representative pilot results.
- **Engage multidisciplinary expertise to streamline pilot implementation.** Involve clinical, technical, and business experts throughout the process. Define clear roles, responsibilities, and timelines, enabling structured coordination and effective conduction of pilot activities.

Planning and adaptation

- **The roadmap to implementation is uncertain.** The alliances required to start a PCP involve different internal actors than the alliance to implement it. Additionally, securing sufficient funding to continue implementing beyond the PCP remains challenging. The lack of standardised Health Technology Assessment (HTA) procedures for digital tools further complicates market adoption, requiring tailored strategies to navigate regulatory and reimbursement frameworks.
- **Design carefully the digital solutions evaluation tools** for adequate comparability of testing results. This design process should be closely aligned with the research protocol and articulated with the PCP Key Performance Indicators (KPIs). By ensuring alignment, the evaluation tools will capture data relevant to project goals, facilitating a clear assessment of each solution's effectiveness and overall impact. Consistency in these evaluation tools enables fair comparison across digital solutions, supports accurate, KPI-driven analysis, and generates meaningful insights for informed decision-making.
- **Manage device logistics efficiently to prevent pilot delays.** The transportation and deployment of digital solutions and the necessary equipment and devices to pilot sites can introduce logistical challenges and potential delays. To mitigate this risk, suppliers should be encouraged to initiate procurement and delivery preparations immediately after the Phase 2 evaluation, ensuring devices are ready for deployment at the start of Phase 3.
- **Ensure flexibility in recruitment and pilot implementation.** Suppliers must provide the necessary training to participants, considering their varying backgrounds and skills. Do not solely rely on the technologies under

development to collect evaluation data- direct engagement with real users, including patients, healthcare professionals, managers, and carers, is essential for refining and optimising digital solutions.

- **Ensure efficient device installation and training to avoid/ minimise delays.** While time for installation and training is typically planned from the outset, ensuring early, structured, well-coordinated, and guided implementation is important for avoiding or at least minimising delays. Personalised training will be key for obtaining accurate evaluation results.
- **Start developing an impact and exploitation strategy early in the PCP process,** ensuring suppliers and contractors are involved in its definition. Engage suppliers and contractors in co-creating the exploitation plan, incorporating insights into their commercialisation, scalability, and regulatory pathways.

Patient engagement

- **Maximise patient adherence in pilot studies.** High adherence among recruited patients is essential for obtaining reliable and representative data. Key strategies to promote patient adherence are clear communication of expectations, user-friendly solution design, regular follow-ups, reminders, and support. Continuously monitor adherence and address barriers early to ensure sustained patient involvement.

Reducing the burden of Medical Device Regulation (MDR) certification

- **Ensure compliance with MDR requirements to prevent data integration restrictions.** Due to reliability reasons, importing data from devices lacking Medical Device Regulation (MDR) certification to, for example, the EHR will often not be permitted. This limitation poses a significant challenge for seamless system integration and data interoperability.
- **Strive to incorporate relevant aspects of the certification process into the PCP framework where feasible.** While achieving full MDR certification within the PCP timeline is likely unfeasible, integrating specific aspects of the certification process could enhance regulatory readiness. However, determining which elements to include and how to measure progress remains a challenge, requiring a balanced approach between feasibility and compliance.
- **Engage regulatory experts early in the process.** Involving regulatory experts from the beginning can help suppliers and procurers navigate compliance requirements and avoid missteps.
- **Harmonise PCP evaluation criteria with MDR expectations, if feasible.** Aligning PCP testing, performance metrics, and documentation with MDR requirements—where possible—can help suppliers generate data that supports their eventual certification efforts at a later stage. This alignment may reduce the effort required for formal regulatory submissions later.
- **Consider involving specialized regulatory consultants well-versed in MDR and ethics committee processes.** Their expertise can guide the project through complex regulatory landscapes and speed up the approval process.
- **Begin discussions with ethics committees, regulatory bodies, and national**

authorities early in the process. Clarifying requirements and expectations early can help streamline the approval process and reduce delays.

- **Leverage the European Union pre-assessment or accelerated approval pathways for innovative solutions.** There are provisions for early dialogue with Notified Bodies and regulatory agencies through mechanisms such as Pre-Assessment or scientific advice. The European Medicines Agency (EMA) also provides scientific advice for certain digital health products. Leverage these models to gain early feedback or conditional approvals that can facilitate smoother ethics committee reviews.



Cross-cutting lessons

Commitment and team composition

- **Ensure commitment and a well-structured Buyers Group team.** Procurers must demonstrate a genuine interest in the solution. The proposed challenge should be aligned with the organisation's objectives from the outset. A successful Buyers Group requires a multidisciplinary team, including decision-makers from each organisation, managers and technical experts who can actively contribute to the pilot design and implementation.
- **Integrating legal expertise in the coordination team is crucial:** Given the complexity of the PCP process, the coordination team should include legal experts to ensure compliance and mitigate risks. Their expertise is essential for drafting and publishing the call for tender documents, drafting contracts with suppliers, managing intellectual property rights, and ensuring data protection compliance.

Effective communication

- **Ensure clear and agile communication with suppliers:** Clear and transparent communication with the suppliers is critical across all phases of the PCP to ensure that suppliers understand expectations- both before the call for tender and throughout implementation. In phase III, where site-specific arrangements

for piloting must be made, maintaining coordinated, continuous, and direct communication is essential. This requires strong internal coordination within the project consortium and dedicated project staff to support interaction and exchange, uphold equal treatment of all suppliers, and clearly communicate the pilot objectives.

- **Acknowledge and manage high demands on partners.** PCPs require substantial effort and **long-term commitment** from all partners, especially the buyers' group and the knowledge partners involved in monitoring the suppliers. The complexity and duration of these projects often exceed initial resource expectations, requiring sustained dedication that may go beyond the budget allocated by the European Commission. Continuous resource planning, monitoring and efficient workload distribution are essential to ensure the successful execution of PCPs despite these challenges.

Strategic planning and adaptability

- **Start pilot design, protocol preparation and KPI alignment early:** Pilot design and protocol work should begin as early as possible—ideally from the start of the project—to ensure readiness by phase 3. However, the outcomes from phases 1 and 2 may lead to necessary adjustments to the initial plan. Additionally, all pilot design and protocol preparations must be aligned with the Key Performance Indicators (KPIs) defined for the PCP project. Since data collected through these phases will serve as the basis to assess performance against these KPIs, ensuring early KPI alignment will facilitate smoother data integration, enhance reporting efficiency, and facilitate a more structured evaluation process.
- **Plan enough time to develop the research protocol and get the ethical committee approval.** One of the bottlenecks in PCP implementation is the ethical committee clearance, which often requires more time and effort than anticipated. Those involved in the protocol design and preparation must have adequate time to thoroughly understand the solutions, structure the research protocol effectively, and prepare high-quality documentation for submission. Proper planning ensures a smoother approval process and prevents disruptions in project timelines.

Time and resource management

- **Mitigate the impact of institutional and political changes.** Due to the long duration of PCP projects, internal changes within participating organisations—including political changes affecting decision-makers—can disrupt continuity and engagement. Maintaining consistent communication with key stakeholders and implementing knowledge transfer mechanisms (such as documentation repositories and structured handovers) can help sustain project momentum. Additionally, team changes at all levels require time for new members to understand the project and sometimes build new relationships and trust. The provision of concise project overviews, key milestones, and tailored briefings to accelerate their understanding and integration is recommendable as part of a structured project onboarding process.



Conclusions and Recommendations for the European Commission

Conclusions and Recommendations for the European Commission

Successful implementation of PCP projects requires a robust framework that addresses the immediate challenges faced by procurers and suppliers and ensures long-term sustainability and impact. This section provides key recommendations aimed at strengthening the PCP ecosystem, fostering innovation, and enabling the adoption of market-ready solutions.

By refining regulatory processes, enhancing financial and technical support, and fostering multi-stakeholder collaboration, the European Commission can play a pivotal role in shaping the future of PCPs. The following recommendations are structured to improve policy and procurement strategies, increase the market viability of developed solutions, and create a more supportive environment for digital health innovation within the EU.

Policy and process improvements

- **Establish a dedicated regulatory helpdesk to support PCP implementation.** A centralised helpdesk could guide procurers and suppliers on legal, compliance, and procurement-related challenges, ensuring smoother PCP execution and reducing administrative burden.
- **Encourage more flexible procurement models** that allow for iterative development, phased funding mechanisms, and adaptability to emerging technologies while maintaining compliance with EU procurement rules.
- **Simplify ethical and regulatory approvals:** Streamlining ethical clearance and MDR compliance processes would prevent lengthy delays that currently hinder PCP implementation. Coordinating with national regulatory bodies to align approval processes would enhance efficiency.

Strategic vision for the future of PCPs

- **Enhance monitoring and impact assessment of PCP-funded solutions.** Implement systematic tracking of PCP-funded innovations to assess their long-term adoption, scalability, and economic impact. This would provide valuable data such as adoption rates and/or cost savings to improve future PCP funding and policy decisions.
- **Align PCPs with broader EU Health and Data Strategies.** Ensuring PCPs align with initiatives like the European Health Data Space (EHDS), AI Act, and Digital Health Strategy will improve integration and adoption.

Enhancing PCP impact

- **Ensure timely allocation of funding for sustainability actions beyond project timelines.** Many PCP innovations fail to transition to full-scale adoption due to a lack of financial support after project completion. Dedicated funding mechanisms should be available at the right time to bridge this gap, ensuring that promising solutions receive the necessary resources for commercialisation, deployment, and long-term impact.
- **Expand support for clinical trials, MDR certification, and early-stage pilot design.** Many PCP solutions face barriers in obtaining market approval, particularly in regulated sectors like healthcare. Additional funding and advisory support for clinical trials, CE/MDR certification, and regulatory navigation would improve the market readiness of innovative solutions.
- **Encourage public-private partnerships (PPPs) for co-financing PCP innovations.** Establish incentives and funding schemes to attract private-sector investment in PCP-developed solutions.
- **Reduce the administrative burden on PCP participants.** PCPs' administrative complexity can deter participation from small companies and startups. Streamlining application processes and compliance requirements would improve inclusivity and participation rates. Besides, more agile and flexible mechanisms may be better adapted to healthcare organizations' innovation needs and challenges.



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