Reverse Healthcare Supply Chains for Circular Economy (REHEAL)

Open Market Consultation (OMC) Document

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This Open Market Consultation (OMC) Document (including any annexes) has been prepared by the REHEAL Buyers Group in the context of the REHEAL project, funded by the European Union under the Horizon Europe Framework Programme (Grant Agreement No. 101226919).

The purpose of this document is to inform and consult the market in preparation for a potential future Pre-Commercial Procurement (PCP). This document does not constitute:

- a call for competition
- a call for tender
- a commitment to launch a procurement procedure, or
- an offer to enter into any contractual agreement.

Participation in this OMC is voluntary and will not be remunerated. Participation or non-participation in the OMC will not confer any advantage or disadvantage in any future procurement procedure. No pre-qualification or preferential treatment will result from participation.

The OMC will be conducted in accordance with Article 40 of Directive 2014/24/EU and relevant national transposition legislation. Appropriate measures will be taken to ensure that participation in the OMC does not result in any distortion of competition in any subsequent procurement procedure.

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The Buyers Group reserves the right to use information provided during the OMC solely for the purpose of refining the potential procurement strategy and documentation.

This document may be updated, amended, or withdrawn at any time. Any updates will be made available through the REHEAL project website and/or relevant publication portals.

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The Challenge Statement contained in this document (Annex 1) represents the current articulation of the REHEAL Challenge (V0.4) and forms the basis for the Open Market Consultation. It may be refined following analysis of feedback received through the OMC, prior to finalisation of the PCP Call for Tenders.

This document reflects the views of the REHEAL project partners only. The European Commission is not responsible for any use that may be made of the information contained herein and is not participating as a contracting authority in any future procurement.

EC Disclaimer

Acronyms

Acronym	Open-form
BG	Buyers Group
CDE	Communication, Dissemination and Exploitation
DDI	Data-Driven Innovation Programme (University of Edinburgh)
EC	European Commission
ERP	Enterprise Resource Planning
EU	European Union
GA	Grant Agreement
GDPR	General Data Protection Regulation
HaDEA	European Health and Digital Executive Agency
HEU	Horizon Europe Programme
ICT	Information and Communication Technology |
KER	Key Exploitable Results
KPI	Key Performance Indicator
OMC	Open Market Consultation
PCP	Pre-Commercial Procurement
PIN	Prior Information Notice
PPI	Public Procurement of Innovation
REHEAL	Reverse Healthcare Supply Chains for Circular Economy
TED	Tenders Electronic Daily
TRL	Technology Readiness Level

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1. Introduction

REHEAL is a Horizon Europe funded project focused on supporting the transition of healthcare supply chains from predominantly linear, single-use models to more circular, climate-neutral and digitally traceable systems.

Healthcare systems across Europe face increasing regulatory, environmental, operational and economic pressures to reduce waste, improve resource efficiency, and support safe reuse, remanufacturing and recovery of medical products. However, the implementation of circular models in healthcare is constrained by fragmented data systems, regulatory variability, limited interoperability, commercially sensitive supply chains, and uncertainty regarding operational and economic viability.

REHEAL aims to address these challenges through the development of innovative, system-level solutions capable of supporting evidence-based decision-making across the full lifecycle of medical products.

As part of this process, REHEAL is launching an Open Market Consultation (OMC) to engage with the market prior to a potential Pre-Commercial Procurement (PCP) where the project will challenge the market to develop innovative solutions that enable reverse logistics, material recovery, digital product passports and federated data models aligned with emerging EU regulatory frameworks.

REHEAL is aligned with the objectives of the European Green Deal, the Circular Economy Action Plan, and emerging EU regulatory initiatives including digital product passport frameworks and strengthened sustainability reporting requirements. By focusing on data-driven, interoperable and regulatory-compliant lifecycle management, REHEAL aims to contribute to the development of an EU-wide market for circular healthcare innovation.

The REHEAL Buyers Group comprises of five healthcare organisations: NHS National Services Scotland (United Kingdom); Servizo Galego de Saúde (Spain); Region Hovedstaden (Denmark); Fundacja Klaster LifeScience Krakow (Poland); and MITERA (Greece) acting collaboratively under a cross-border Pre-Commercial Procurement framework.

Together, these organisations represent 261 hospitals and approximately 300,000 healthcare professionals, providing diverse operational, regulatory and infrastructure environments for testing system-level circular healthcare solutions. NHS National Services Scotland (NSS) acts as Lead Procurer on behalf of the Buyers Group.

In addition to stimulating market innovation, REHEAL seeks to reduce structural uncertainty in circular healthcare adoption, enabling evidence-based decision-making that balances regulatory compliance, patient safety, operational feasibility, and economic viability.

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2. Purpose of the Open Market Consultation

The purpose of this OMC is to:

- Inform the market about the REHEAL Challenge;
- Assess the state-of-the-art and current market capabilities;
- Test technical, regulatory and commercial feasibility;
- Inform the potential structure, scope and budget of a PCP;
- Ensure transparency and equal treatment prior to any procurement procedure.

This OMC does not constitute a call for competition.

Participation is voluntary and non-binding. Participation does not confer any advantage or disadvantage in any future procurement procedure.

The contracting authorities are not bound to proceed with a procurement as a result of this consultation.

This document should be read together with the annexes, which form an integral part of the Open Market Consultation documentation.

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3. The REHEAL Challenge (Draft – subject to OMC refinement)

3.1. Introduction

This section provides a summary overview of the REHEAL Challenge for consultation purposes. The full Challenge Definition (Draft V0.4) is provided in Annex 1 and should be read in conjunction with this summary.

3.2. Strategic Context

Historically, healthcare systems relied heavily on reusable medical products. Over time, due to advances in plastics manufacturing, infection control concerns, regulatory developments and operational efficiencies, supply chains became dominated by single-use disposable products.

While this model simplified workflows and reduced perceived infection risks, it has resulted in high levels of material consumption and waste generation, alongside growing environmental impact.

Circularity in healthcare refers to designing and managing medical product supply chains so that materials and products remain in use for as long as possible, rather than following a linear “take–make–use–dispose” model.

In healthcare, circularity must not compromise patient safety or regulatory compliance. Instead, it requires safe, regulated and operationally viable approaches to reuse, reprocessing, remanufacturing, repair and material recovery.

However, there is currently no system-level understanding that enables healthcare systems and suppliers to make regulatory-compliant, operationally viable and economically robust decisions regarding circular medical products.

3.3. Challenge Development Process

The REHEAL Challenge has been developed through structured co-design activities including Local Buyers Group workshops, Whole Buyers Group sessions, and Living Lab engagements across partner regions. This process has identified shared systemic barriers while recognising national regulatory and operational variation.

The Challenge Definition describes specific barriers:

- Lack of European product group classification
- Regulatory variability
- Commercial sensitivity

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- Fragmented lifecycle data

Key structural barriers include:

- Absence of harmonised product group classifications at EU level;
- Variability in national and regional regulatory systems for medical device registration and certification;
- Limited interoperability between lifecycle data systems;
- Commercial sensitivity restricting data sharing across supply chain actors;
- Insufficient visibility of materials and recovery routes.

The Challenge Statement and associated system-level components described in this document are presented for consultation purposes. They may be refined, clarified or adjusted following analysis of OMC feedback in order to ensure alignment with market capability, technical feasibility, and regulatory considerations. Any such refinements will be transparently documented in the OMC Evaluation Report and reflected in the subsequent Call for Tenders.

3.4. Overarching Challenge Statement

REHEAL partners have identified a shared overarching Challenge:

"How can innovation support a system-level, evidence-based understanding that enables healthcare systems and suppliers to make regulatory-compliant, operationally viable, and economically robust decisions on the adoption, management, reuse, and recovery of medical products across their full lifecycle - in contexts where such decisions are currently constrained by fragmented data, limited interoperability, and high uncertainty?"

This Challenge is intentionally broad and is likely to be refined following the OMC.

3.5. System-level Components

Through workshops, REHEAL partners identified four interdependent components of the healthcare product lifecycle:

- Design, Development and Manufacture
- Procurement
- Operational Use and Inventory Management
- Management of Waste and Recovery Streams

A defining characteristic of the Challenge is the interdependency between lifecycle components. Decisions in design and manufacture depend on demand and infrastructure

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data from healthcare providers. Procurement decisions depend on regulatory and operational data from other lifecycle stages. Yet these data flows are currently siloed and non-interoperable, creating systemic decision uncertainty.

A central feature of the Challenge is the lack of integrated data flows across these components, particularly in relation to regulatory and standards-related data. Decision-making in one component is frequently dependent on data generated in another.

Proposed solutions should, therefore:

- consider cross-lifecycle interoperability and regulatory-compliant traceability.
- demonstrate how data generated in one lifecycle component can meaningfully inform decision-making in another, reducing uncertainty across design, procurement, operational management, and recovery stages.
- pay particular attention to regulatory data interoperability, traceability across multiple product life cycles, and integration with existing healthcare information systems.
- account for variability across product types, regulatory environments, infrastructure capacity and healthcare system maturity.

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4. Potential Procurement Approach – Fast-track PCP

The complexity of the REHEAL Challenge — in particular the need to address regulatory variability, fragmented lifecycle data, limited interoperability, commercially sensitive information flows, and cross-component system interdependencies — means that existing off-the-shelf or incremental integration solutions are unlikely to provide a sufficient system-level response. The Challenge therefore requires structured research and development activities under a Pre-Commercial Procurement (PCP) framework prior to any potential commercial deployment.

Addressing this Challenge requires coordinated research and development activities that:

- Integrate data across multiple lifecycle stages;
- Develop regulatory-compliant traceability and decision-support mechanisms;
- Enable interoperable system architectures capable of operating across national and organisational boundaries;
- Support validation in real healthcare environments.

REHEAL intends to implement a fast-track Pre-Commercial Procurement (PCP) in line with the approach described in the Grant Agreement (GA No. 101226919), combining elements traditionally associated with sequential PCP phases (solution design, prototyping and validation) into an accelerated competitive R&D framework.

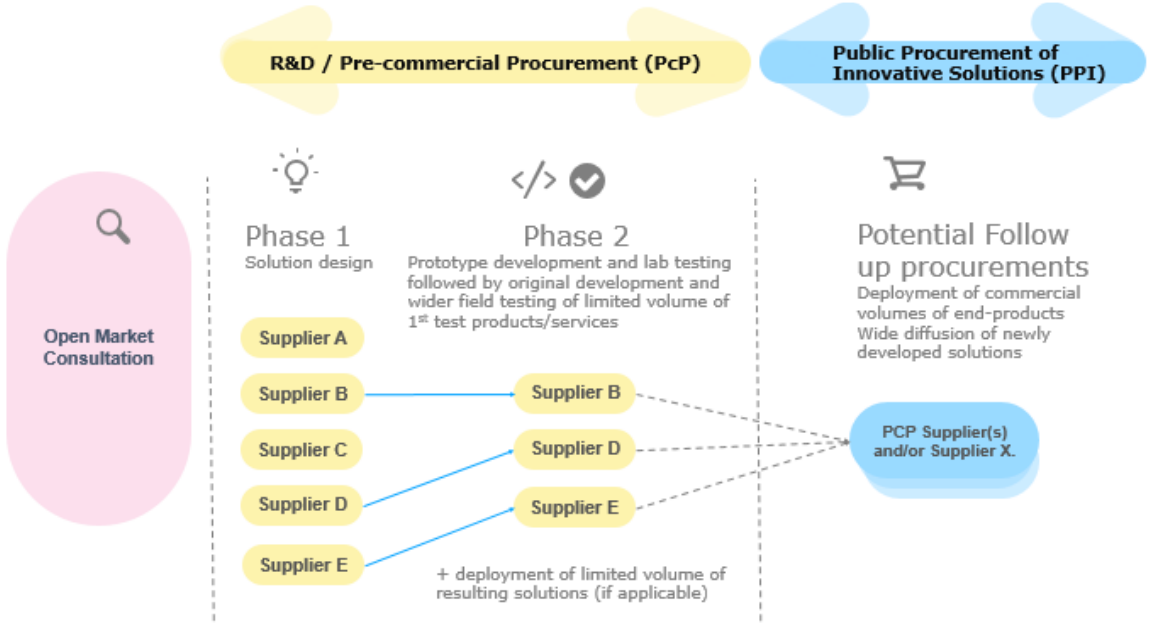

Figure 1. Fast-Track PCP structure (indicative)[1]

[1] Source: European Commission, "Horizon Europe: How to set up and manage HE PCP and PPI grants", October 2023

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For the purposes of REHEAL, "fast-track PCP" refers to an accelerated competitive R&D procedure combining structured solution design, prototyping and validation within a streamlined timeframe.

This approach is justified because:

- The Challenge has already been developed through structured co-design activities across the REHEAL Partnership;
- Significant preparatory analysis has been undertaken to define system components and interdependencies;
- The objective is to rapidly test and validate system-level prototypes capable of demonstrating regulatory-compliant circular decision-support in real operational contexts.

The PCP will be implemented as a joint cross-border procurement by the REHEAL Buyers Group under a single Lead Procurer structure.

The REHEAL Buyers Group comprises of five healthcare organisations:

- NHS National Services Scotland (United Kingdom),
- Servizo Galego de Saúde (Spain),
- Region Hovedstaden (Denmark),
- Fundacja Klaster LifeScience Krakow (Poland), and
- MITERA (Greece).

NHS National Services Scotland (NSS) acts as Lead Procurer on behalf of the Buyers Group.

The PCP is expected to operate under a competitive parallel development model, whereby multiple suppliers may be contracted during early R&D stages, with objective evaluation and potential down-selection based on predefined award criteria. This structure is intended to stimulate innovation, reduce technological risk, and ensure fair competition. This fast-track PCP model is therefore intended to:

- Reduce procedural fragmentation;
- Accelerate the progression from concept refinement to demonstrator-level validation;
- Maintain competitive development while ensuring efficient use of public funding;
- Deliver solutions reaching advanced Technology Readiness Levels appropriate for validation in operational healthcare environments.

The final configuration of the fast-track PCP — including duration, number of suppliers, validation environments and indicative budget envelope — will be informed by the outcomes of this Open Market Consultation.

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The OMC will in particular test:

- The maturity of current market capabilities;
- The degree of R&D required beyond existing state-of-the-art solutions;
- The realism of accelerated validation timelines;
- The feasibility of system-level integration across the identified lifecycle components.

No final procurement design decisions have been taken at this stage. The results of the OMC and any associated RFI will directly inform the preparation of the PCP tender documentation and will be documented in the OMC Report and subsequent Preparation Phase reporting.

The overall indicative budget envelope for the PCP will be defined in the Call for Tenders and will reflect the need to support credible system-level R&D activities across multiple lifecycle components, while ensuring proportionality and effective use of public funding.

Participation in any future PCP will be open to individual economic operators or consortia of operators. The Buyers Group does not require multi-partner consortia; however, given the system-level nature of the Challenge, collaboration across complementary expertise areas may be beneficial.

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5. OMC Activities and Timeline

This Open Market Consultation follows the publication of a Prior Information Notice (PIN) in Tenders Electronic Daily (TED) on 22 December 2025 (Reference No. 850409-2025). The PIN formally announced the OMC and potential future PCP in accordance with Horizon Europe requirements. The PIN and associated procurement notice provide the formal framework for this consultation.

The OMC formally opened on 11 February 2026. Planned activities include:

- OMC briefing session: 11 February 2026 (link to recording)
- Live OMC events: 16 February – 4 March 2026
- Publication of Request for Information (RFI): 16 February 2026
- Deadline for RFI responses: 23 March 2026
- Final EU webinar to present learning and feedback: 31 March 2026
- Publication of OMC Evaluation Report (summary findings): 30 April 2026

The Open Market Consultation (OMC) is open to all interested organisations globally. Participation in the OMC is not restricted by geographic location.

While certain local OMC events may be delivered in national languages to support local engagement, all core documentation and the Request for Information (RFI) are available in English.

Participants registering for OMC events will also be invited to complete a short Market Positioning Survey (see **Annex 2**) as part of their registration.

The final EU webinar will present preliminary learning from the Open Market Consultation. Full analysis of RFI responses and other inputs will be reflected in the OMC Evaluation Report.

Findings from the Open Market Consultation will be documented in the OMC Evaluation Report, which will summarise aggregated market feedback and explain how insights have informed the refinement of the Challenge Definition and preparation of the PCP tender documentation.

Updates on OMC activities will be published on the REHEAL website - Open Market Consultation | Engage Now: Shape Circular Healthcare — REHEAL

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6. Request for Information (RFI)

As part of this OMC, REHEAL will issue a structured Request for Information (RFI) questionnaire. The full RFI template is provided in **Annex 3**.

The RFI will seek information on:

- Market capability
- Technical maturity (TRL)
- Regulatory feasibility
- Data interoperability approaches
- Indicative development timelines and cost considerations
- Feedback on PCP structure

RFI responses will be analysed in aggregated and anonymised form and summarised in the OMC Evaluation Report. Participation in the RFI is voluntary and non-binding.

The RFI is intended to gather structured market input on the REHEAL Challenge and potential PCP design. It does not replace the OMC clarification mechanism.

Suppliers may submit clarification questions separately via the REHEAL OMC Helpdesk. All relevant clarification responses will be published in anonymised form to ensure transparency and equal treatment.

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7. Transparency and Equal Treatment

This OMC is conducted in accordance with Horizon Europe requirements regarding transparency and equal treatment.

All relevant information will be made publicly available.

Any clarification questions received during the OMC will be published in anonymised form on the REHEAL website to ensure equal access to information.

Information provided during the OMC may be used to refine the Challenge Definition and inform potential procurement documentation. Where information provided during the OMC is used in the preparation of procurement documentation, appropriate safeguards will be applied to ensure equal access to information and to prevent any distortion of competition.

No individual response will be attributed to a specific organisation in published outputs.

Participation or non-participation in the OMC, including submission of RFI responses, will not influence eligibility, evaluation, or selection in any future procurement procedure.

The REHEAL consortium reserves the right to modify this document during the OMC period. Any updates will be published openly.

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8. Data Protection (GDPR)

Personal data collected in the context of the OMC will be processed solely for the purposes of conducting the consultation and preparing potential procurement documentation, in accordance with Regulation (EU) 2016/679 (GDPR).

Responses will be analysed and reported in anonymised and aggregated form.

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Annex 1 – REHEAL Challenge Definition (Full Version)

(DRAFT 0.4 – subject to refinement following OMC)

Status of this Document

This Challenge Definition is issued as part of the REHEAL Open Market Consultation. It represents the current articulation of the Buyers Group's needs and system-level Challenge. It is not a final technical specification and may be refined following OMC feedback prior to publication of the Call for Tenders.

REHEAL Challenge Definition (Draft V0.4 – 12.02.26)

1. Background

1.1. Challenge Development Process

The Challenge Statement below has been collaboratively developed across the REHEAL Partnership with engagement from a wider range of stakeholders. Activities to develop the Challenge Statement include: REHEAL Local Buyers Groups workshops; Whole Buyers Group Workshops; and local REHEAL Living Labs sessions.

In addition to the overarching REHEAL Challenge Statement, it is anticipated that Local Buyer Group-specific annexes will be developed for inclusion in the Call for Tender documentation. These annexes will describe national or regional variations within the Challenge themes and outline relevant regulatory contexts, including medical device registration and certification systems.

The whole approach is based not on setting specifications but describing a problem statement that suppliers are invited to respond to. This approach is intended to foster innovative solutions.

The Challenge Statement in this document represents the current articulation of the REHEAL Challenge as of 12 February 2026 and forms the basis for the Open Market Consultation (OMC). It is provided for consultation purposes and may be refined following analysis of feedback received through the OMC, prior to finalisation of the PCP Call for Tenders.

1.2. The Shift to Dominance of Single Use Items in Medical Supply Chains

For much of the 20th century, healthcare relied primarily on reusable medical products. Instruments and consumables were typically made of metal, glass, or rubber and were cleaned and sterilized between uses in hospital central sterile departments. This model assumed that effective sterilization could reliably manage infection risk and was supported by durable product design and established in-house reprocessing infrastructure.

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From the 1960s–1980s, this system began to change. Advances in plastic manufacturing made it possible to mass-produce medical products that were lightweight, inexpensive, and pre-sterilized. At the same time, growing awareness of healthcare-associated infections, coupled with high-profile infectious disease crises (notably HIV/AIDS), reshaped clinical and regulatory thinking. Using a product once and discarding it came to be seen as the safest option.

Operational factors accelerated this shift. Single-use products reduced dependence on labour-intensive sterilisation processes, eliminated turnaround delays, and simplified hospital workflows. As medical devices became more technically complex, concerns grew that some reusable items could not be reliably cleaned, further strengthening the case for disposables.

Manufacturers and regulators reinforced the trend. Device labelling, procurement standards, and marketing increasingly favoured single-use products, creating a self-reinforcing supply chain built around predictable, high-volume consumption. By the late 20th century, many everyday medical items that had been reusable had become single-use.

Together, these forces transformed medical supply chains from systems centred on reuse and reprocessing to ones dominated by procurement of disposable products

1.2.1. What do we mean by circularity?

In the context of sustainability, circularity refers to designing and managing medical product and device supply chains so that materials or products are kept in use for as long as possible, rather than following a linear “take–make–use–dispose” model.

Traditionally, many medical supply chains are linear: raw materials are extracted, products are manufactured, used once (or for a limited time), and then discarded as waste. Circularity challenges this model by asking how products and materials can circulate back into the system safely, repeatedly, and with minimal environmental impact.

In healthcare, circularity does not mean compromising patient safety. Instead, it focuses on safe, regulated ways to reduce resource use, waste, and emissions while maintaining clinical performance and infection control. **Circularity can include** the following elements:

Design for longevity and recovery

Products are designed from the outset to be durable, repairable, reusable, or recyclable. This may include modular device design, fewer mixed materials, and clearer material labelling to support recovery at end of life.

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Reuse and reprocessing

Where clinically appropriate, products are reused through validated cleaning, sterilization, and reprocessing systems (e.g., reusable surgical instruments, gowns, sharps containers, or reprocessed single-use devices under regulatory oversight).

Maintenance and repair

Medical devices are maintained, refurbished, or repaired to extend their functional life rather than being replaced prematurely.

Recycling and material recovery

When products cannot be reused or can no longer be used, their materials (such as plastics or metals) are recovered and recycled into new products, reducing reliance on virgin raw materials.

Waste prevention and reduction

Circularity prioritises preventing waste altogether — for example, by reducing unnecessary packaging, standardizing components, or eliminating low-value disposables.
Crucially optimal circularity will be different for different types of products and while classifications are emerging for certain product categories, there are currently no harmonised European standards or operational classifications covering different groups of medical products. This lack of product group classification and associated operational standards, forms part of the challenges of increasing circularity.

For the purposes of this Challenge, the term ‘medical products’ refers to medical devices as defined under applicable regulatory frameworks, as well as other healthcare products and materials used in clinical care and associated supply chains.

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2. REHEAL Challenge Statement

2.1. Overarching Challenge Statement

At a strategic level, REHEAL aims to transform healthcare supply chains from largely linear, single-use models to more circular systems. However, multiple complex and interdependent barriers currently limit the implementation of circular systems.

In particular, the Challenge recognises that decisions regarding circular adoption are often constrained not only by cost and regulatory factors, but by operational feasibility at system level — including infrastructure capacity, workforce implications, logistics, and change management across diverse healthcare settings.

The Challenge recognises that circular approaches will not be uniform across all product categories; solutions must allow for differentiation, granularity, and flexibility according to product type, risk classification, and operational context.

There is also significant variation across the REHEAL Buyers Group, with representation from 5 different countries, in how these barriers influence decisions regarding the adoption and use of circular products.

Despite these variations, partners identified a shared overarching **Challenge Statement**:

"How can innovation support a system-level, evidence-based understanding that enables healthcare systems and suppliers to make regulatory-compliant, operationally viable, and economically robust decisions on the adoption, management, reuse, and recovery of medical products across their full lifecycle - in contexts where such decisions are currently constrained by fragmented data, limited interoperability, and high uncertainty?"

Addressing this Challenge requires new approaches that go beyond the integration of existing systems, due to the need to manage regulatory variability, commercially sensitive data, and complex interdependencies across lifecycle stages — making it well suited to a Pre-Commercial Procurement approach.

This Challenge therefore seeks solution(s) that can enable progress towards **a system-level understanding** of circularity, supporting better-informed decisions across the system. A particular focus is placed on how data from different stages of the product lifecycle can be gathered and integrated to provide the evidence required to support decision-making across the healthcare ecosystem. This includes enabling the generation of credible, comparable evidence that can support regulatory authorities, policymakers, and procurement bodies in assessing the safety, performance, and system-level impacts of circular models.

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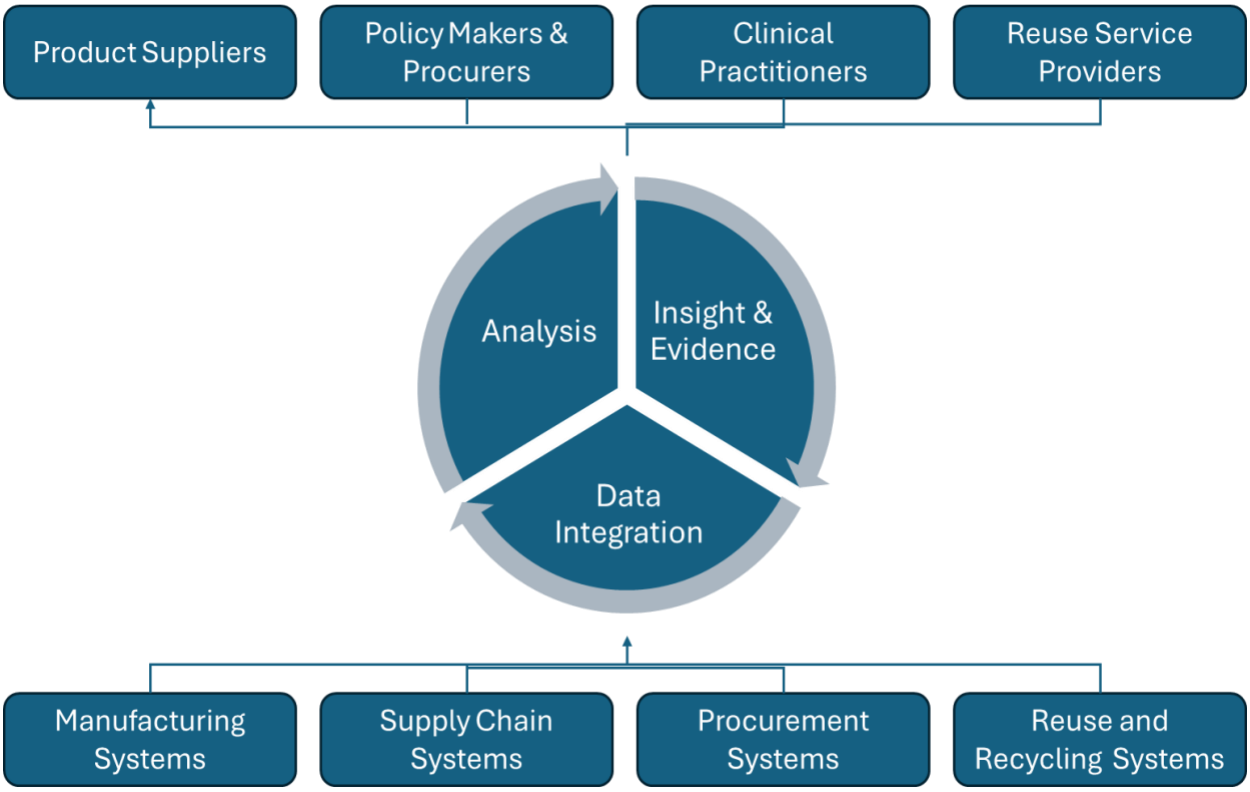
2.2. What Is Meant by "System-Level" Understanding?

Through a series of workshop REHEAL Partners identified broad "components" of the system through which medical products are developed, procured, used, and ultimately disposed of, remanufactured, or recycled were identified. These are outlined below.

A central feature of this Challenge is the **interdependency between these components**, combined with a lack of integrated data flows both within and across them. This lack of integration is particularly acute in relation to regulatory, certification, and standards-related data, where requirements differ across countries and regions, and where limited interoperability makes it difficult to establish consistent assurance of compliance for circular or remanufactured products.

Limited interoperability between data systems restricts access by healthcare providers and procurement professionals to reliable information demonstrating that products—whether virgin or remanufactured—meet required certification and regulatory standards.

Decision-making within one component is often dependent on data generated in another. For example, the feasibility of developing new circular products is frequently dependent on data relating to demand, usage patterns, and operational constraints within health systems.



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Any proposed solution must therefore explicitly consider the relationships between these components and how data can be connected across the system.

2.3. System Components

Component 1: Design, Development and Manufacture

Medical product and device design, development and manufacture processes are commercially sensitive, complex, and highly regulated. These regulations include differing national and regional systems for medical device registration and certification, which directly affect the feasibility, development timelines, investment risk, and costs associated with developing both new and circular medical products. These regulatory requirements apply equally to single-use and circular products. Products already in use will have demonstrated safety and regulatory compliance.

Given the dominance of single-use, non-circular products in the market, there is a clear need for the development of more circular alternatives. However, the costs of developing new products are high, and reusable or circular products often require new business models, which may include services such as remanufacturing, decontamination or recovery rather than simple product sales.

Suppliers currently have a limited understanding of:

- The level of demand for circular products within healthcare systems.
- The operational and service requirements associated with circular business models.

In addition, opportunities for structured collaboration between suppliers and key operational stakeholders — including clinicians, procurement professionals, infection prevention specialists, and waste management services — are often limited at the design stage. This constrains the ability to ensure that new circular products are not only technically compliant, but operationally viable across diverse healthcare settings.

Enabling earlier and more informed design-stage engagement may therefore be critical to reducing commercial uncertainty and ensuring that circular solutions are safe, effective, scalable, and aligned with real-world system requirements.

This lack of shared understanding makes it difficult for suppliers to make informed commercial investment decisions and contributes to an overall absence of a shared vision between healthcare systems and potential suppliers.

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To address this component of the Challenge, suppliers should demonstrate how their approach enables:

a) Traceability and the ability to ensure and verify remanufacture standards and decontamination have taken place.

b) Providing insight and evidence drawing on system-level data from across healthcare systems and suppliers on demand for circular products and devices.

c) Improved understanding by suppliers of healthcare system requirements for services that support circular products and devices.

d) Mechanisms that improve structured collaboration between suppliers and relevant healthcare stakeholders during the design and development phase of circular products and associated service models.

Component 2: Procurement

Current procurement processes within healthcare systems are largely designed around linear, single-use products and devices. The information required to support purchasing decisions for single-use products is comparatively simple. Such products can typically be:

- Purchased with clear cost and quality comparisons based on supplier-provided data (e.g. materials, CO_2e impact).
- Distributed based on consumption volume.
- Disposed of using standardised waste management processes, with limited need to understand more than waste volume.

By contrast, procurement of circular products requires more complex and integrated data, including:

- Information on both the product and the management processes required to support reuse or recovery.
- Understanding of infrastructure capacity for reuse, reprocessing, or materials recovery, including sterilisation and decontamination capacity and associated operational constraints.
- Consideration of operational implications and change management associated with reuse or recovery.
- Confidence that products, whether virgin or remanufactured, meet applicable registration, certification, and standards requirements, supported by accessible and interoperable data systems.
- Whole-life-cycle costing that includes operational costs and end-of-life disposal or recovery.

This includes the need for transparent and, where possible, harmonised calculation methodologies for life-cycle assessment, costing, and environmental impact metrics (including CO_2e), to ensure comparability of circular models across products, suppliers, and healthcare systems.

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This component of the Challenge is highly dependent on data from other system components.

To address this component, suppliers should demonstrate how their approach enables:
a) Systems that support robust business cases and evaluation of reusable products, incorporating true whole-life-cycle costing, including operational and waste management costs, and providing clear, accessible evidence of regulatory and standards compliance.

Component 3: Operational Use of Circular Products / Devices

Specific challenges related to the operational use and management of circular products that limit system-level understanding include:

- Limited methods to quantify non-financial (operational) costs associated with circular products.
- Increased requirements for active inventory management, coupled with a lack of chain-of-custody data and traceability data across multiple product life cycles (including remanufacturing).
- Limited or poorly understood health system infrastructure capacity (e.g. decontamination), which can constrain adoption.
- Variation in infrastructure capability and maturity across healthcare systems and countries, creating uncertainty regarding scalability and transferability of circular models.

To address this component of the Challenge, suppliers should demonstrate approaches that enable:
a) new methods for inventory management and product tracking to support regulatory-compliant chain-of-custody.
b) Improved understanding and sharing of data on healthcare system infrastructure capacity relevant to circular products and traceability across single and multiple product life cycles.
c) Mechanisms that support transparent verification of remanufacture processes and decontamination efficacy in line with applicable national and international standards, appropriate to product type and risk classification.
d) Approaches to quantifying healthcare system human resource costs associated with managing circular products.

Component 4: Management of Waste and Recovery Streams

The management of waste and recovery streams for circular products is complex and currently constrained by several factors, including:

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- Limited visibility of materials contained within products, often due to commercial sensitivity.
- Lack of clarity regarding viable remanufacturing routes.
- Uncertainty around regulatory requirements for recovery and remanufacturing.
- Variable availability and clarity of standards for remanufactured medical devices across countries or regions.

In addition to these structural constraints, healthcare waste streams are subject to strict infection prevention and control requirements, including segregation rules for clinical, hazardous, and non-hazardous waste. These requirements can limit opportunities for material recovery where contamination risk cannot be clearly mitigated or verified.

There is also significant variation across regions in the availability of certified remanufacturing facilities, materials recovery infrastructure, and specialised logistics services. This variation creates uncertainty regarding the scalability and cross-border transferability of circular recovery models within the REHEAL Buyers Group.

Furthermore, limited end-of-life traceability data and insufficient visibility of product composition restrict the ability of healthcare systems and recovery operators to determine whether products can safely and economically enter remanufacturing or recycling pathways.

Improved integration of waste management and recovery data into procurement and design decision-making processes is essential to close the information loop across the product lifecycle.

Even where technically feasible, recovery routes must also demonstrate economic viability, including viable secondary markets for recovered materials and clarity on regulatory status following remanufacture.

Many of the constraints within waste and recovery streams are intrinsically linked to earlier lifecycle stages — particularly design decisions (Component 1), procurement models (Component 2), and operational traceability systems (Component 3). As such, improving outcomes in this component requires consideration of how design specifications, procurement criteria, and data interoperability influence downstream recovery and remanufacturing viability.

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To address this component of the Challenge, suppliers should demonstrate approaches that enable:

a) Improved visibility of product material composition and contamination status to enable safe segregation and optimisation of recycling and materials recovery processes.

b) Data infrastructure and traceability mechanisms that support the identification, verification, and development of remanufacturing routes, aligned with applicable standards and regulatory requirements for remanufactured medical devices.

c) Approaches that enable assessment of the operational and economic feasibility of recovery pathways, including infrastructure capacity, logistics implications, and market viability of recovered materials.

2.4. Scope of the Challenge

The remit of this Challenge is intentionally broad. Suppliers may choose to address one or more components of the Challenge, provided that their approach demonstrably contributes to system-level decision-making across multiple lifecycle stages.

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Annex 2 – Initial OMC Survey (Market Positioning Survey)

This short survey is being completed by all registrants of the REHEAL OMC events, as part of the registration process, using an online form. The OMC events started on 11 February 2026 and will conclude on 31 March 2026.

First Name
Last Name
Role
Email

I will participate in the event

- Live
- online

Organisation

Country of Organisation

In which geographic contexts does your organisation operate?

- Regional
- National
- EU
- Global

Type of Organisation (select one)

- Startup
- Scale-up
- SME
- Large company
- Research organisation / university
- Healthcare provider
- Public authority
- Non-profit / third-sector organisation
- Individual / independent expert
- Other (please specify)

What is your organisation's core area of expertise?
(Tick all that apply)

- Healthcare service delivery and operations
- Healthcare supply chain management

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- Logistics and reverse logistics
- Manufacturing and industrial supply chains
- Digital platforms and ICT systems
- Data, analytics, and artificial intelligence
- Sustainability and circular economy
- Public sector systems and governance
- Research and academic expertise
- Other (please specify)

How close is your organisation's main market to healthcare today?

- Healthcare is our core market
- Healthcare is one of several markets we work in
- We primarily work outside healthcare but see strong transfer potential
- We do not currently work in healthcare

How familiar is your organisation with operating in regulated healthcare environments?

- No prior experience
- Limited experience
- Some experience
- Extensive experience

Which best describes the maturity of the solutions your organisation works on?
(Select one)

- Early research / concept stage
- Proof of concept
- Prototype development
- Pilot or early deployment
- Commercially available solutions
- Mixed / depends on project
- Not applicable

Experience with innovation procurement or PCP-type projects

- No prior experience
- Some experience
- Significant experience
- Currently participating in PCP or similar initiatives

What type of support is most important for your organisation when engaging in innovation procurement?
(Select up to three)

- Access to real-world test environments
- Clear technical and functional requirements

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- Engagement with end users
- Adequate funding levels
- Flexible timelines
- Clear IP and exploitation rules
- Administrative simplicity
- Other (please specify)

In your opinion, which drivers are most likely to accelerate adoption of circular approaches in healthcare?
(Tick up to three)

- Cost savings
- Regulatory requirements
- Sustainability targets
- Data availability and transparency
- Technological maturity
- Leadership and organisational culture
- Patient and staff acceptance

Describe how your solution fits within the overall REHEAL mission (if applicable)

What are you hoping to get from this session?

Is there anything else you believe the REHEAL project team should consider at this early stage?

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Annex 3 – Request for Information (RFI)

Submission Instructions

- Responses must be submitted using the online survey by **23 March 2026**.
- Submissions should be done via the online form that is available on the REHEAL website - Open Market Consultation | Engage Now: Shape Circular Healthcare — REHEAL.

The survey template is included below for reference prior to completing it online.

Introduction

The REHEAL project invites interested organisations to respond to this Request for Information (RFI), issued as part of the REHEAL Open Market Consultation (OMC) in preparation for a potential Pre-Commercial Procurement (PCP).

The purpose of this RFI is to better understand the current state of the art, identify innovation gaps, assess market readiness and R&D needs, and refine the potential scope of the REHEAL PCP.

Responses may relate to an existing solution, prototype, capability, or proposed R&D approach.

Before completing this RFI, respondents are strongly encouraged to review the **REHEAL Challenge Statement (Annex 1 of the OMC Document)** to ensure alignment with the system-level objectives and lifecycle components described therein.

Important:

- This RFI is not a call for tenders and is non-binding.
- It does not constitute pre-qualification.
- Responses will not be evaluated or scored.
- Participation is voluntary and not required for any future PCP.
- Non-participation will not disadvantage any future bidder.

Information may be analysed and summarised in anonymised and aggregated form to inform potential future procurement design.

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SECTION 1 – Organisation Profile

1. Organisation Name

2. Country of Establishment

3. Organisation Type *(select one)*

- SME
- Large Enterprise
- Research Organisation
- Healthcare Provider
- Public Authority
- Other (please specify)

4. Website

5. Contact Person Name

6. Contact Email

SECTION 2 – Relevance to REHEAL Challenge

The REHEAL Challenge focuses on enabling system-level, evidence-based decision-making across the lifecycle of medical products and devices. This section explores how your solution, proposed approach or relevant capability may contribute to the REHEAL system-level Challenge. If you do not yet have a defined solution concept, please respond based on your organisation's current expertise or exploratory direction.

2.1 Lifecycle Component Coverage

Which REHEAL Challenge component(s) does your existing, proposed solution or relevant capability address? Please refer to the REHEAL Challenge Definition in the OMC Document for descriptions of components. *(Select all that apply)*

- Design, Development and Manufacture
- Procurement
- Operational Use of Circular Products / Devices
- Waste Management and Recovery Streams
- Cross-cutting (data integration across multiple lifecycle components)

2.2 Primary Focus Area

Which component best represents your primary focus? (Select one)

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- Design, Development & Manufacture
- Procurement
- Operational Use of Circular Products / Devices
- Waste Management and Recovery Streams
- Cross-cutting (data integration across multiple lifecycle components)

2.3 Description of Approach

Briefly describe your solution, proposed approach, or relevant capability and how it contributes to system-level, evidence-based decision-making across the lifecycle of medical products. (max 500 words)

SECTION 3 – Stage of Development

This section seeks to understand the technical maturity of your solution / proposed approach and the development effort required under a potential PCP. If you do not yet have a defined solution concept, please respond based on your current capability or exploratory approach.

3.1 Current Technology Readiness Level (TRL) *(select one)*

- Concept not yet defined / exploratory capability only
- TRL 1–2 – Concept stage
- TRL 3 – Proof of concept
- TRL 4 – Laboratory validation
- TRL 5 – Validation in relevant environment
- TRL 6 – Prototype demonstrated in relevant environment
- TRL 7 – System prototype demonstrated in operational environment
- TRL 8 – System complete, integrated and validated in operational environment (pre-commercial stage)
- TRL 9 – Commercially deployed system

3.2 Anticipated TRL of proposed R&D development at completion of a PCP

Please note: PCP is expected to support R&D up to prototype validation and testing stages, rather than full commercial deployment. *(select one)*

- Not applicable – no defined R&D concept at this stage
- TRL 1–2 – Concept stage
- TRL 3 – Proof of concept
- TRL 4 – Laboratory validation
- TRL 5 – Validation in relevant environment
- TRL 6 – Prototype demonstrated in relevant environment
- TRL 7 – System prototype demonstrated in operational environment

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- TRL 8 – System complete, integrated and validated in operational environment (pre-commercial stage)

3.3 Additional R&D Required

Based on your current solution, proposed approach or relevant capability, what additional research and development activities would be required to meet the REHEAL Challenge and reach demonstrator stage? *(Max 300 words)*

3.4 Estimated Time to Demonstrator

From a PCP contract start date, how long would it take to reach a demonstrator validated in a real healthcare operational setting? *(select one)*

- Not applicable – no defined R&D concept at this stage
- Less than 12 months
- 12–18 months
- 18–24 months
- 24–36 months
- More than 36 months

SECTION 4 – Data, Interoperability & Regulatory Considerations

A core element of the REHEAL Challenge concerns fragmented lifecycle data, interoperability barriers, and regulatory variability. This section therefore seeks to understand the data requirements, interoperability constraints and regulatory considerations relevant to your solution, proposed approach or relevant capability.

4.1 Types of Data Required

Which types of data would your solution, proposed approach or relevant capability require? *(select all that apply)*

- Usage / demand data
- Inventory data
- Material composition data
- Regulatory / certification data
- Traceability / chain-of-custody data
- Waste / recovery data
- Infrastructure capacity data
- Other (please specify)

4.2 Data Governance Constraints

Are there any data governance constraints that may affect implementation? *(select all that apply)*

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- GDPR considerations
- Cross-border data sharing restrictions
- Commercial confidentiality constraints
- Data ownership / controllership issues
- No major constraints identified
- Not yet known
- Other (please specify)

4.3 Interoperability Readiness *(select one)*

- Already integrates with hospital ERP/inventory systems
- API-based integration possible
- Requires custom integration
- Standalone solution
- Not applicable

4.4 Interoperability Barriers

What interoperability barriers currently exist (technical, semantic, standards-related, organisational)? *(Max 300 words)*

4.5 Regulatory Readiness of Your Solution, Proposed Approach or Relevant Capability

Based on your current solution, proposed approach or relevant capability, how would you describe the clarity of the applicable regulatory pathway? *(select one)*

- Regulatory pathway is clear and largely established
- Regulatory pathway is identifiable but requires further clarification
- Significant regulatory development or guidance would be required
- Regulatory pathway is currently uncertain or unclear
- Not applicable

4.6 Regulatory Uncertainties

Where do regulatory uncertainties constrain development or adoption? *(Max 300 words)*

SECTION 5 – Operational & Infrastructure Implications

This section explores the operational, workforce and infrastructure implications of adopting your solution or proposed approach in real healthcare settings.

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5.1 Operational Impact Level

Adoption of your solution or proposed approach would require: *(select one)*

- Not applicable – no defined solution or deployment model at this stage
- Minimal operational change
- Moderate process changes
- Significant workflow redesign
- Major infrastructure transformation

5.2 Infrastructure Dependencies

Does your solution or proposed approach depend on specific infrastructure? *(select all that apply)*

- Not applicable – no defined solution or deployment model at this stage
- Sterilisation capacity
- Reverse logistics systems
- Recycling facilities
- Digital tracking infrastructure
- Remanufacturing facilities
- Other (please specify)

5.3 Operational & Infrastructure Considerations

Please describe key operational or infrastructure considerations. *(Max 300 words)*

■ SECTION 6 – Commercial & Market Considerations

This section aims to understand the market maturity and commercial context relevant to the REHEAL Challenge, including how your solution, proposed approach or potential contribution may be positioned within that context.

6.1 Market Maturity of Solutions

Based on your knowledge of the market, how mature are solutions addressing this type of system-level circular healthcare challenge? *(select one)*

- No solutions currently available
- Prototypes or early-stage solutions only
- Commercial solutions exist but are not widely deployed
- Mature solutions widely deployed across multiple healthcare settings
- Don't know

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6.2 Business Model

Which business model best describes how your solution, proposed approach, or anticipated offering would be delivered? *(select all that apply)*

- Not applicable, no defined offering at this stage
- Product sale model
- Service-based model
- Product-as-a-service
- Remanufacturing service
- Data platform subscription
- Hybrid model
- Other (please specify)

6.3 Commercial Barriers or Uncertainties

What commercial or cross-system factors may limit scalability of your solution, proposed approach or potential contribution across different healthcare systems? *(Max 300 words)*

SECTION 7 – Contribution to System-Level Decision Making *(Max 500 words)*

REHEAL seeks to enable system-level understanding across multiple lifecycle stages.
Please explain how your solution, proposed approach or relevant capability contributes to:

- Evidence-based decision-making
- Whole-life-cycle costing
- Regulatory-compliant traceability
- Cross-component data integration

SECTION 8 – Risks, Barriers & Enablers *(max 500 words)*

This section invites your perspective on systemic barriers and enablers affecting circular healthcare innovation.

- What are the main barriers to circular adoption in healthcare?
- What policy, regulatory, or technical enablers would accelerate innovation relevant to the REHEAL Challenge?

SECTION 9 – Engagement & Future Participation *(tick all that apply)*

This final section allows you to indicate your potential interest in future REHEAL activities.

- We would be interested in participating in a future PCP
- We would be interested in matchmaking opportunities
- We would like to be informed of future REHEAL developments via the REHEAL Newsletter
- We would like to be invited to join the REHEAL Followers Community

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