Reverse Healthcare Supply Chains for Circular Economy (REHEAL)

Open Market Consultation (OMC) Document

Version 1.3

Updated 22 April 2026

Project Name	REHEAL (Reverse Healthcare Supply Chains for Circular Economy)
Grant Agreement Number	101226919
Duration	48 months (September 2025 – August 2029)
Funding Programme	Horizon Europe
Call	HORIZON-HLTH-2024-CARE-14-01
Type of Action	HORIZON-PCP (Pre-commercial Procurement)

Funded by the European Union

This project has received funding from the Horizon Europe Framework programme (HORIZON) under Grant Agreement No. 101226919

Version History

Version	Date	Author(s)	Issued to	Change description
V0.1	12.01.2026	A Pavlickova		First draft for review
V1.0	12.02.2026	D Henderson	REHEAL website	V1.0 made available for OMC
V1.1	14.04.2026	R Apostol	REHEAL partners	Challenge Definition was updated and issued for feedback
V1.2	20.04.2026	D Henderson	R Apostol	Amendments before reissue
V1.3	22.04.2026	D Henderson	REHEAL website	For final OMC supplier feedback

Disclaimer

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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This document may be updated, amended, or withdrawn at any time.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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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
PPE	Personal Protection Equipment
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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Glossary of Terms

In preparing this glossary, the following references have been used:
Categorisation System for the Circular Economy, European Commission (2020)
ISO 59004:2024: Circular economy — Vocabulary, principles and guidance for implementation. Edition 1. 2024

Term	Proposed REHEAL definition
Re-use	Using a product or component again for its intended purpose without significant processing
Re-processing	Applying a process to a product to prepare or enable it for re-use, this may include (but is not limited to): sorting, cleaning and decontamination to an approved and verified standard *e.g. Sterile services processing of surgical instruments*.
Remanufacture	Restoring or rebuilding a used product or component to meet required specification, allowing the product to be placed back on the market.
Recovery – materials	Deconstruction of product and/or component to enable recovery of materials.
Recovery – energy	Deconstruction of product and/or component to enable recovery of energy via incineration or composting

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Table of Contents

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1. Objective of Document

The purpose of this document is to present the common Challenge that will form the basis of the subsequent Pre-Commercial Procurement (PCP) procedure. Specifically, this document:

- Describes the background and strategic context that underpins the REHEAL Challenge;
- Defines the consolidated REHEAL Challenge as a single shared procurement need;
- Defines the functional and performance requirements of the desired solution
- Defines the evaluation criteria that will be used to select the PCP offers during the PCP.

The Buyers in the REHEAL consortium recognise that the PCP alone will not be sufficient to achieve the transition towards circular healthcare supply chains. That is why they applied a structured co-design process to ensure that the Challenge reflects real operational, regulatory and organisational constraints. This included analysing existing procurement practices, mapping data and infrastructure gaps, and testing the Challenge in concrete use cases through workshops and Living Labs. As a result, the Challenge is grounded in how hospitals actually operate, and key issues such as regulatory compliance, data interoperability and workflow impact have been explicitly taken into account from the start.

In addition, the Buyers will actively support implementation readiness during and after the PCP. This includes involving end-users in the development and testing of solutions, using the PCP phases to learn what works in practice, and facilitating exchange between participating healthcare systems. From the later stages of the project onwards, targeted capacity-building activities will be deployed, such as training, guidance materials and dissemination of results to a wider group of hospitals. By combining research and development (R&D) with practical testing, stakeholder involvement and concrete preparation for adoption, the Buyers aim to ensure that the solutions developed are not only innovative, but also usable and scalable in real healthcare settings.

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2. Background and Context

REHEAL (Reverse Healthcare Supply Chains for Circular Economy) is a cross-border Horizon Europe funded project designed to accelerate the transition of healthcare supply chains from predominantly linear, single-use models to more circular, climate-neutral and digitally traceable systems, with a focus on improving system resilience and increasing the life-cycle of products and materials.

Across Europe, healthcare systems are facing increasing environmental, economic and regulatory pressures. Linear supply chains, largely based on single-use medical products, contribute significantly to waste generation, resource depletion and greenhouse gas emissions. At the same time, healthcare organisations must maintain high standards of patient safety, regulatory compliance and operational efficiency.

Despite growing strategic commitment to circular economy principles, large-scale adoption remains limited. This is due to a set of systemic barriers, including fragmented lifecycle data, limited interoperability between systems, regulatory complexity, commercial uncertainty, and misalignment between procurement models and circular business approaches.

The REHEAL Buyers' Group encompasses healthcare systems in Denmark, Greece, Poland, Spain and the United Kingdom. They represent 261 hospitals and healthcare facilities, employing over 160,000 health professionals and serving 15–17 million citizens across Europe:

Buyers' Group Organisation in REHEAL	Type of procurer	Country / Region	Notes / unique competences
Public Services Delivery Scotland (PSD Scotland)	Public procurer (Lead Procurer)	**United Kingdom (Scotland)**	Leads PCP procurement; strong experience with circular economy innovation and the CivTech model.
Servicio Galego de Saúde (Galician Health Service) (SERGAS)	Public procurer	**Spain (Galicia)**	Experienced in innovative public procurement; supported by ACIS (Axencia de Coñecemento en Saúde).
Region Hovedstaden (Capital Region of Denmark) (REGIONH)	Public procurer	**Denmark**	Known for advanced green healthcare policies and digital integration.

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Klaster LifeScience Krakow (KLSK)	Public health cluster	**Poland**	Represents a large regional innovation ecosystem, supporting life science SMEs and health system collaboration.
Diagnostic & Therapeutic Centre of Athens Hygeia (HYGEIA)	Private procurer	**Greece**	Largest private hospital in Greece; provides insight into private sector challenges and circularity implementation.

The Buyers have undertaken a structured co-design process to analyse local barriers and define a shared Challenge. While national contexts differ, the process confirmed that the underlying structural issues are common across participating systems. The Buyers' Group therefore confirms that this constitutes a **single shared procurement need**, to be addressed through a joint cross-border Pre-Commercial Procurement (PCP) procedure.

The Challenge is intentionally framed as a **problem-based, performance-oriented definition**, rather than a technical specification, in order to stimulate innovation and enable competitive, phased R&D in line with Horizon Europe PCP principles.

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3. Strategic Drivers for Transition

3.1. Environmental and Climate imperatives

Healthcare value chains are estimated to account for approximately 4–5% of global greenhouse gas emissions, with a significant share arising from the production, transport and disposal of medical products and devices.

At EU level, climate neutrality targets under the European Climate Law, together with the European Green Deal, Circular Economy Action Plan and Circular Economy Act[1], create increasing expectations for healthcare systems to reduce waste, material consumption and lifecycle emissions.

Evidence indicates that transitioning from single-use to reusable or remanufactured products, where clinically appropriate, can significantly reduce environmental impacts, particularly in terms of carbon emissions and material extraction. However, achieving these benefits requires robust, comparable and decision-ready lifecycle data, which is currently fragmented or unavailable at system level.

3.2. Supply Chain Resilience

Healthcare supply chains are highly globalised and optimised for low upfront purchase costs, but they often fail to account for total lifecycle costs. While this has supported innovation and affordability, it has also created structural vulnerabilities.
One key issue is resilience. Many medical products depend on scarce raw materials, including so-called critical raw materials (as defined by the European Commission Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs). These materials are becoming harder to access due to depletion of non-renewable resources and geopolitical restrictions, leading to price volatility, sudden price increases, and unreliable supply.

At the same time, global supply chains are vulnerable to disruptions in logistics. Geopolitical tensions and climate change—especially extreme weather—can delay transport and reduce reliability. Together with the concentration of production in a limited number of regions (including for advanced semiconductors), this shows how fragile current linear, just-in-time supply models are.

The COVID-19 pandemic further exposed the vulnerability of healthcare systems to disruption in global manufacturing and logistics. Reuse, remanufacture, and localised recovery models offer potential resilience benefits by reducing dependency on virgin material extraction and long-distance supply chains. Circular models may also mitigate exposure to

[1] The Circular Economy Act is due to be released by the EU in 2026: Circular Economy - Environment - European Commission

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single points of failure within upstream manufacturing networks.

However, resilience benefits can only be realised where reliable system-level visibility of materials, flows, capacity, and compliance exists.

3.3. Economic and Financial Pressures

Healthcare expenditure continues to rise due to demographic ageing, increasing clinical complexity, and technological advancement. At the same time, public finances across Europe are under pressure, and healthcare systems face structural constraints on budget growth.

Linear supply chains, dominated by high-volume single-use products, are optimised for short-term unit cost rather than whole-life value optimisation. Circular models offer potential material cost savings, improved asset utilisation, and new service-based business models. While requiring upfront investment, changing to circular models is likely to generate longer-term economic benefits for Member States. Such models can strengthen resilience and reduce supply fragility, insulating healthcare systems from price volatility. In addition, increased reprocessing and remanufacturing of medical devices to existing high standards can create skilled jobs and boost economic output, contributing to greater overall healthcare investment within the EU. Preprocessing and remanufacturing also create opportunities for both inward and outward investment for EU companies.

However, the evidence base remains incomplete, and uncertainty regarding operational cost implications, infrastructure investment requirements, and regulatory constraints limits adoption.

As a result, healthcare procurers often lack the information required to make long-term, system-level investment decisions regarding circular alternatives.

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4. Structural Barriers to Circular Transition

The common barriers to the transition to circular medical products across the five Buyers Groups in the REHEAL consortium are outlined below, despite some differences in the operational contexts.

4.1. Fragmentation and Misaligned Incentives

Healthcare supply chains are competitive, and procurement processes are often fragmented across multiple institutions and regions.

Large healthcare systems may contract with tens of thousands of suppliers, often under multiple separate agreements. This fragmentation weakens purchasing leverage, complicates data aggregation, and limits the ability to implement harmonised lifecycle assessment or traceability models.

Circular transition requires collaboration and access to relevant data, respecting both patient and commercial confidentiality, across traditionally siloed actors — including manufacturers, healthcare providers, remanufacturers, regulators, and waste operators — whose incentives are not currently aligned.

4.2. Limited Availability and Interoperability of Lifecycle Data

Current procurement models rely heavily on supplier-provided data, which may not be standardised, comparable, or sufficiently granular to support whole-life-cycle costing or environmental modelling.

Commercial confidentiality, intellectual property protection, patient data protection obligations, and technical interoperability limitations restrict the flow of information across lifecycle stages. Even where standards exist — such as GS1 identifiers, Unique Device Identification (UDI) under the EU Medical Device Regulation, or emerging Digital Product Passport (DPP) frameworks — they are not yet integrated into a coherent, decision-supporting system.

As a result, decision-makers lack:

- Comparable lifecycle cost data;
- Reliable material composition and recovery information;
- Cross-border visibility of regulatory and certification status;
- Infrastructure capacity data for reuse, sterilisation, or remanufacturing;
- Chain-of-custody traceability across multiple product life cycles.

This information gap constitutes a core market failure limiting circular adoption.

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4.3. Risk Aversion and Regulatory Complexity

Healthcare systems operate within a strongly risk-averse culture towards change. The EU Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR) impose stringent conformity assessment and traceability requirements. Article 17 of the MDR provides for reprocessing of single-use devices only under specific conditions and subject to national variation.

In addition, GDPR, emerging European Health Data Space (EHDS) provisions, the EU AI Act, Ecodesign for Sustainable Products Regulation (ESPR), Digital Product Passports (DPPs), Extended Producer Responsibility (EPR) schemes, and national legislation create a complex and evolving regulatory landscape.

Regulation can act both as a barrier and as an enabler. However, uncertainty regarding liability, certification pathways for remanufactured products, cross-border recognition of standards, and data governance obligations contributes to hesitancy in adopting circular models.

To accelerate the transition to circular models, a joined-up approach is required that supports compliance requirements and alignment with practical operational needs.

4.4. Market and Commercial Uncertainty

There is limited availability of integrated, scalable circular solutions, and uncertainty regarding supplier readiness in Europe, business models and long-term cost implications. This reduces investment confidence on both demand and supply sides.

The solution envisaged by REHEAL PCP aims to address this by developing and validating integrated, data-driven solutions that combine lifecycle traceability, operational management, and business case decision support, thereby reducing uncertainty, improving transparency, enabling both buyers and suppliers to make better-informed decisions.

4.5. Conclusion

The analysis demonstrates that the transition to circular healthcare supply chains is not solely a technological challenge. It is a system-level transformation requiring:

- Increased availability and interoperability of lifecycle data (including data on location of manufacturer, relevant geographical location of product, etc);
- Integration of regulatory-compliant traceability mechanisms;
- Robust evidence to support risk-based decision-making;
- Data to support regional and national compliance and allow the movement of product between EU countries, ensuring high levels of safety as well as supporting EU-wide resilience.

Incremental improvements to existing isolated systems are unlikely to overcome the

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structural information barriers and interdependencies identified. Instead, a coordinated innovation approach is required to develop interoperable, regulatory-aligned, and operationally viable system architectures capable of supporting evidence-based decisions across design, procurement, operational use, and recovery stages. This will reduce uncertainty and create the conditions for circular adoption within diverse European healthcare systems.

The consolidated findings presented in **Section 4** demonstrate that the REHEAL Challenge cannot be addressed through the purchase of existing, market-ready solutions. While isolated digital tools, lifecycle assessment systems, reverse logistics services and sustainability reporting platforms exist, no integrated, interoperable and regulatory-aligned system currently provides:

- Cross-lifecycle decision support spanning design, procurement, operational use and recovery stages;
- Harmonised, comparable lifecycle data suitable for evidence-based procurement decisions;
- Interoperability across diverse healthcare IT environments and supplier systems;
- Validated approaches to integrating circular economy principles within regulatory-constrained medical device contexts;
- Scalable architectures adaptable to differing national regulatory and operational settings.

The identified barriers are structural and systemic in nature. They require the development, prototyping and validation of new solution architectures rather than incremental enhancement of existing commercial products.

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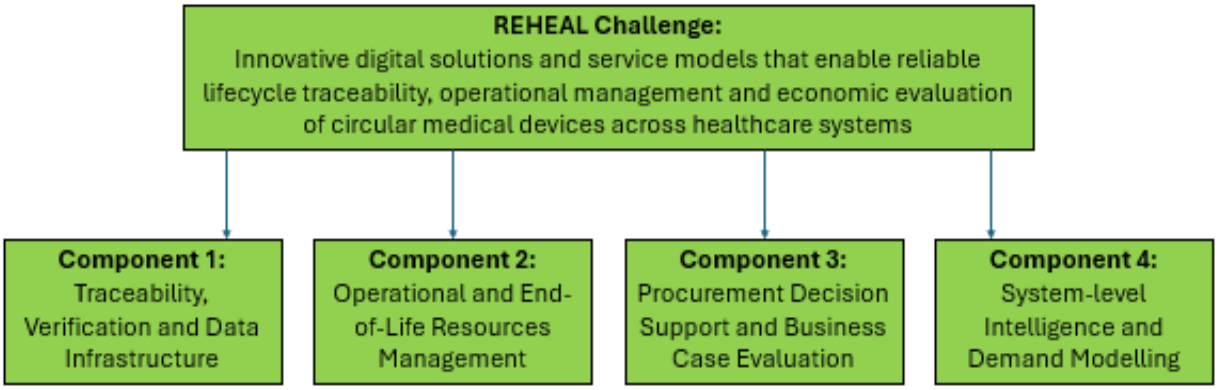
5. The REHEAL Challenge

5.1. Challenge scope

The REHEAL project aims to enable healthcare systems to transition from single-use medical devices to economically viable, circular supply and management systems that reduce waste and resource use, while ensuring regulatory compliance, patient safety and cost efficiency.

Suppliers will be invited to **develop innovative digital solutions and service models** that enable **reliable lifecycle traceability, operational management, and evaluation of medical devices** consistent with the objectives of the circular economy, across healthcare systems. The solutions support the **management of medical devices throughout their lifecycle**, including **design, procurement, operational use, remanufacturing, and end-of-life recovery**.

The Challenge encompasses 4 components. The requirements per components will be detailed in the following paragraph 5.2.



The four REHEAL components are designed as complementary building blocks of a coherent, system-level solution that enables the transition towards circular healthcare supply chains. Each component addresses a distinct layer of the problem, while relying on and reinforcing the others, creating an integrated architecture that spans from data generation to strategic decision-making.

Component 1: Lifecycle Traceability, Verification and Data Infrastructure provides the foundational layer by ensuring reliable, interoperable and compliant lifecycle data. It establishes trust in the data through unique identification, traceability, chain-of-custody and process verification. Without this trusted data backbone, higher-level functionalities such as optimisation and decision-making would lack credibility and regulatory robustness. In

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essence, Component 1 answers the question: **"**Can we trust and verify what happened to the device throughout its lifecycle?"

Component 2: Operational Management and End-of-Life/Recovery translates lifecycle data into actionable operational insights. It enables healthcare providers to manage devices efficiently across their lifecycle, including inventory, status tracking, lifecycle monitoring and recovery processes. While Component 1 focuses on trust and verification, Component 2 addresses: "How should we manage and optimise the device in practice?"

Component 3: Procurement Decision Support and Business Case Evaluation further elevates the use of data by enabling evidence-based decision-making. It integrates lifecycle, operational and cost data to support comparisons between single-use, reusable and remanufactured devices, allowing healthcare organisations to assess economic, environmental and regulatory trade-offs. This Component answers the question: "What is the best option to procure and invest in, based on total value and impact?"

Component 4: System-Level Intelligence and Demand Modelling extends the perspective beyond individual organisations to the system level. It aggregates data and insights to model demand, assess infrastructure capacity and evaluate the scalability of circular solutions across regions and countries. This component addresses: "How can circular solutions be scaled and optimised across the wider healthcare system?"

Together, the components form a logical progression: from **data (Component 1) to operations (Component 2), to decisions (Component 3), to system-level intelligence (Component 4)**. Their complementarity ensures that the REHEAL Challenge addresses not only technological gaps, but also organisational, economic and systemic barriers, enabling a holistic and scalable transition to circular healthcare systems.

Categories of medical products

In order to achieve a high impact on material preservation while ensuring feasibility, the Challenge focuses on categories of medical devices that are used in high volumes in healthcare settings and for which reuse and/or remanufacturing pathways are already established or can be realistically developed within the regulatory framework.

The suppliers are requested to develop the required solution around these medical devices at a minimum.

The scope therefore covers medical devices designed for **multiple use (reusable devices)** as well as devices and components that can be **remanufactured to restore their original performance and safety**, in accordance with applicable regulatory requirements. Through this approach, the REHEAL PCP aims to stimulate the procurement and broader uptake of

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reusable and remanufacturable medical devices, thereby supporting their increased availability and integration into healthcare systems.

Indicative device categories to be addressed by the solutions include:

1. **Reusable and remanufacturable instruments (Class Ir)**, such as forceps, scissors, clamps and reusable laparoscopic instruments
2. **Complex reusable devices (Class IIa)**, such as bronchoscopes and gastrointestinal endoscopes
3. **Medical textiles suitable for reuse and remanufacturing**, such as surgical gowns, drapes and hospital linen
4. **Reusable and remanufacturable device systems (Class IIa / IIb)**, such as infusion pumps, monitoring equipment, surgical towers, Catheter, Optic Fiber, Guide Wire
5. **Device systems combining reusable, remanufacturable and single-use components**, such as surgical kits, endoscopy accessories and robotic surgery tools

In addition, the Challenge includes **single-use medical devices and components**, with the objective of enabling **high-value material recovery and remanufacturing pathways**, thereby extending product lifecycles and reducing dependency on virgin materials.

The categories listed above are indicative and reflect groupings based on **similar operational use and circular lifecycle management logic**. Suppliers are encouraged to propose solutions that may extend to comparable device categories, provided they demonstrate relevance in terms of reuse, remanufacturing potential and system-level impact.

5.2. Solution requirements

Solutions developed under this PCP shall address the following functional components. Requirements are expressed in functional- and performance-oriented terms to ensure flexibility and innovation.

For clarity of interpretation:

- **"MUST"** denotes a mandatory baseline requirement.
- **"SHOULD"** denotes a strongly encouraged requirement that will inform qualitative and/or quantitative evaluation scoring.

5.2.1. Component 1 – Lifecycle Traceability, Verification and Data Infrastructure

"Can we trust and verify what happened to the device?"

This component therefore focuses on end-to-end lifecycle traceability and verification of medical devices, supported by a robust and interoperable data infrastructure. The objective

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is to create a foundation for sharing and analysing lifecycle information across stakeholders, while ensuring compliance with regulatory, security and data protection requirements.

By enabling accurate tracking, process verification and data integration, this component aims to reduce uncertainty and strengthen accountability as part of the transition to safe, efficient and scalable circular healthcare systems.

Device Identification
C1.1 – Unique device identification
• **Type:** Functional
• **Priority:** MUST The solution shall enable unique identification of medical devices and their components across their lifecycle.
C1.2 – Advanced identification technologies
• **Type:** Functional
• **Priority:** SHOULD The solution should support integration with identification and tracking technologies (e.g. barcode, RFID or equivalent), where relevant to the operational context.
Lifecycle Event Recording
C1.3 – Lifecycle event capture
• **Type:** Functional
• **Priority:** MUST The solution shall record lifecycle events and processes that a device undergoes, including manufacturing, distribution, clinical use, reprocessing, remanufacturing and end-of-life handling.
C1.4 – Lifecycle history reconstruction
• **Type:** Performance
• **Priority:** MUST The solution shall enable reconstruction of a complete and reliable lifecycle history of each device to support decision-making and compliance verification.
Chain-of-Custody Traceability
C1.5 – Custody tracking
• **Type:** Functional
• **Priority:** MUST The solution shall record chain-of-custody information, identifying the actor responsible for a device at each point in time across its lifecycle.
C1.6 – Accountability and auditability
• **Type:** Performance

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• **Priority:** MUST The solution shall ensure that chain-of-custody records are sufficiently complete and reliable to support audits, investigations and regulatory compliance.
Process Verification (e.g. sterilisation, remanufacturing)
C1.7 – Process recording
• **Type:** Functional
• **Priority:** MUST The solution shall record the processes performed on devices (e.g. cleaning, sterilisation, remanufacturing), including the standards according to which this was performed.
C1.8 – Data linkage
• **Type:** Functional
• **Priority:** MUST The solution shall link process data to device identity, date/time and responsible actor.
C1.9 – Alerting mechanism
• **Type:** Functional
• **Priority:** MUST The solution shall generate alerts where process requirements are not met or deviations occur.
C1.10 – Process compliance reliability
• **Type:** Performance
• **Priority:** MUST The solution shall ensure that process verification outputs are reliable and suitable for regulatory compliance, audits and inspections.
Data Exchange and Interoperability
C1.11 – Cross-system data exchange
• **Type:** Functional
• **Priority:** SHOULD The solution shall enable secure and interoperable data exchange between different stakeholders and systems.
C1.12 – Automated and timely data exchange
• **Type:** Performance
• **Priority:** MUST The solution shall enable automated data exchange, with real-time or near real-time capability where relevant.
C1.13 – Data security and privacy
• **Type:** Performance

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• **Priority:** MUST The solution shall ensure data security, integrity and compliance with applicable regulations (e.g. GDPR).
C1.14 – Interoperability across contexts
• **Type:** Performance
• **Priority:** SHOULD The solution should support interoperability across different national, organisational and technical environments.
System Integration
C1.15 – Integration with existing systems
• **Type:** Functional
• **Priority:** MUST The solution shall be capable of integrating with existing IT systems used by Buyers (e.g. procurement, logistics, traceability or sterilisation systems).
C1.16 – Configurability and adaptability
• **Type:** Functional
• **Priority:** SHOULD The solution should allow configuration to different organisational workflows, device categories and regulatory contexts.
Data Aggregation and System-Level Insight
C1.17 – Data aggregation across stakeholders
• **Type:** Functional
• **Priority:** MUST The solution shall aggregate data from multiple stakeholders to create a coherent lifecycle record for each device.
C1.18 – System-level lifecycle visibility
• **Type:** Performance
• **Priority:** MUST The solution shall enable a system-level view of device lifecycles, supporting decision-making across organisations.
C1.19 – Advanced analytics and insights
• **Type:** Performance
• **Priority:** SHOULD The solution should enable generation of insights such as use cycles, remanufacturing rates, inefficiencies and waste reduction potential.

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5.2.2. Component 2: Operational and End-of-Life Recovery Management

"How should we manage and optimise the device in practice?"

Component 2 focuses on enabling the effective operational management of reusable and remanufacturable medical devices, as well as supporting informed end-of-life and recovery decisions. It aims to provide healthcare organisations with real-time visibility of device inventory, status, location and lifecycle usage, while also offering insight into infrastructure capacity and potential operational bottlenecks.

In addition, the component supports safe and efficient recovery processes by making relevant information available on material composition, contamination status and regulatory constraints, and by enabling decision-making on appropriate pathways such as reuse, remanufacturing, recycling or disposal.

Inventory Management and Stock Visibility
C2.1 – Inventory visibility
• **Type:** Functional
• **Priority:** MUST The solution shall provide visibility of reusable and remanufacturable medical devices, including information on availability, quantity and location across departments. Solutions must integrate with existing inventory and stock management solutions, if already in place.
C2.2 – Stock level monitoring
• **Type:** Functional
• **Priority:** MUST The solution shall track stock levels per department or organisational unit and enable monitoring of device availability. Solutions must integrate with existing inventory and stock management solutions, if already in place.
C2.3 – Alerts for stock imbalances
• **Type:** Functional
• **Priority:** MUST The solution shall generate alerts in cases of shortages, overstock or critical inventory thresholds. Solutions must integrate with existing inventory and stock management solutions, if already in place.
C2.4 – Real-time inventory overview
• **Type:** Performance
• **Priority:** SHOULD The solution should provide real-time or near real-time overview of inventory status where relevant to operational workflows. Solutions must integrate with existing inventory and stock management solutions, if already in place.

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Device Status and Location Tracking
C2.5 – Device status tracking
• **Type:** Functional
• **Priority:** MUST The solution shall track and display the operational status of devices throughout their lifecycle (e.g. in use, awaiting sterilisation, sterilised and ready, under maintenance, end-of-life).
C2.6 – Device location tracking
• **Type:** Functional
• **Priority:** MUST The solution shall be capable of tracking of device location across departments and processes. Where available, it should integrated with existing systems.
C2.7 – Timely status updates
• **Type:** Performance
• **Priority:** MUST The solution shall ensure that device status and location information is updated with sufficient timeliness to support operational decision-making.
Lifecycle Monitoring for Operational Use and Safety
C2.8 – Monitoring of lifecycle events
• **Type:** Functional
• **Priority:** MUST The solution shall monitor lifecycle events relevant to operational use and safety, including use cycles, sterilisation cycles, inspections and maintenance activities.
C2.9 – Usage history tracking
• **Type:** Functional
• **Priority:** MUST The solution shall record and provide access to device usage history, including frequency of use and reprocessing.
C2.10 – Compliance with usage limits
• **Type:** Functional
• **Priority:** MUST The solution shall support verification of compliance with predefined limits for safe use (e.g. maximum number of use cycles or reprocessing cycles).
C2.11 – Decision-support for safe use
• **Type:** Performance
• **Priority:** SHOULD The solution should support decision-making regarding continued use, maintenance or withdrawal of devices based on lifecycle data.

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Infrastructure Capacity Visibility
C2.12 – Capacity monitoring
• **Type:** Functional
• **Priority:** SHOULD The solution shall provide visibility of infrastructure capacity relevant to circular device management, including sterilisation (e.g. CSSD), storage and logistics capacity.
C2.13 – Bottleneck identification
• **Type:** Performance
• **Priority:** SHOULD The solution shall enable identification of capacity constraints and bottlenecks that may impact operational efficiency.
C2.14 – Capacity optimisation insights
• **Type:** Performance
• **Priority:** SHOULD The solution should provide insights to support optimisation of infrastructure utilisation.
End-of-Life and Recovery Management
- Material Composition and Safety Information
C2.15 – Material composition visibility
• **Type:** Functional
• **Priority:** MUST The solution shall provide access to information on material composition of devices, where available, to support recycling and recovery decisions.
C2.16 – Contamination status identification
• **Type:** Functional
• **Priority:** MUST The solution shall indicate the contamination status of devices (e.g. clean, contaminated, hazardous) to ensure safe handling and appropriate processing.
C2.17 – Safety and handling compliance
• **Type:** Performance
• **Priority:** MUST The solution shall ensure that information provided supports safe handling and compliance with relevant safety and regulatory requirements.
- Decision Support for Recovery Pathways
C2.18 – Recovery decision support
• **Type:** Functional

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• **Priority:** MUST The solution shall support decision-making on appropriate recovery pathways, including reuse, remanufacturing, recycling or disposal.
C2.19 – Criteria-based recommendations
• **Type:** Functional
• **Priority:** SHOULD The solution should provide recommendations based on relevant criteria such as device condition, lifecycle history, material composition and regulatory constraints.
- Waste Segregation and Recovery Optimisation
C2.20 – Waste segregation support
• **Type:** Functional
• **Priority:** MUST The solution shall support correct segregation of devices and materials to enable appropriate recovery or disposal.
C2.21 – Optimisation of recovery processes
• **Type:** Performance
• **Priority:** SHOULD The solution should provide guidance or insights to improve material separation, reduce contamination of recyclable streams and enhance recovery rates.
- Remanufacturing Pathway Identification
C2.22 – Identification of remanufacturing eligibility
• **Type:** Functional
• **Priority:** MUST The solution shall enable identification of devices or components that are eligible for remanufacturing.
C2.23 – Link to remanufacturing ecosystem
• **Type:** Functional
• **Priority:** SHOULD The solution should support linkage to relevant actors (e.g. certified remanufacturers) and associated processes.
C2.24 – Optimisation of remanufacturing flows
• **Type:** Performance
• **Priority:** SHOULD The solution should support optimisation of logistics and operational pathways for remanufacturing.

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5.2.3. Component 3: Procurement Decision Support and Business Case Evaluation

"What is the best option to procure and invest in, based on total value and impact?"
Component 3 enables evidence-based procurement and investment decisions by providing robust tools for business case evaluation of circular medical device solutions. It focuses on the calculation of whole-life-cycle costs, incorporating both conventional and circular cost components.

The components enables comparison between single-use, reusable and remanufactured devices across key dimensions such as cost, operational complexity, environmental impact and regulatory compliance. It also allows users to model scenarios based on hospital-specific conditions.

Whole-Life-Cycle Costing (WLCC)
C3.1 – Lifecycle cost calculation models
• **Type:** Functional
• **Priority:** MUST The solution shall provide models to calculate whole-life-cycle costs of medical devices, including acquisition costs, operational costs, labour costs, maintenance and reprocessing costs, and end-of-life or waste management costs.
C3.2 – Inclusion of circular cost components
• **Type:** Functional
• **Priority:** MUST The solution shall account for cost components specific to circular models, including reuse, remanufacturing, reverse logistics and recovery processes.
C3.3 – Hospital-specific input parameters
• **Type:** Functional
• **Priority:** MUST The solution shall allow users to input context-specific data (e.g. usage volumes, labour costs, infrastructure capacity, procurement conditions) to ensure relevance to local operational settings.
C3.4 – Flexibility and configurability of cost models
• **Type:** Functional
• **Priority:** SHOULD The solution should allow configuration of cost parameters and assumptions to reflect different organisational contexts and procurement strategies.
Scenario Analysis and Forecasting
C3.5 – Scenario modelling capability
• **Type:** Functional

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• **Priority:** MUST The solution shall enable scenario analysis, allowing users to assess the impact of different assumptions (e.g. usage volumes, reuse rates, cost structures, infrastructure constraints).
C3.6 – Comparative scenario evaluation
• **Type:** Functional
• **Priority:** MUST The solution shall enable comparison of multiple scenarios to support decision-making under uncertainty.
C3.7 – Decision-support relevance of scenarios
• **Type:** Performance
• **Priority:** MUST The solution shall ensure that scenario outputs are sufficiently robust and transparent to support procurement and investment decisions.
C3.8 – Advanced forecasting capabilities
• **Type:** Performance
• **Priority:** SHOULD The solution should support forecasting of long-term impacts, including cost evolution, demand patterns and infrastructure needs.
Comparative Assessment of Device Options
C3.9 – Comparison of device types
• **Type:** Functional
• **Priority:** MUST The solution shall enable comparison between different device options, including single-use, reusable and remanufactured devices.
C3.10 – Multi-criteria comparison framework
• **Type:** Functional
• **Priority:** MUST The solution shall support comparison across multiple dimensions, including: • total lifecycle cost; • operational complexity; • environmental impact; • regulatory and compliance requirements.
C3.11 – Transparent comparison methodology
• **Type:** Performance
• **Priority:** MUST The solution shall ensure transparency in the assumptions, data sources and methodologies used for comparisons.
C3.12 – Customisable weighting of criteria
• **Type:** Functional

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• **Priority:** SHOULD The solution should allow users to adjust the relative importance of comparison criteria according to organisational priorities.
Environmental and Impact Assessment
C3.13 – Environmental impact calculation
• **Type:** Functional
• **Priority:** MUST The solution shall support estimation of environmental impacts associated with different device options, including resource use, emissions and waste generation.
C3.14 – Integration with lifecycle data
• **Type:** Functional
• **Priority:** MUST The solution shall use lifecycle data (where available) to improve accuracy of environmental assessments.
C3.15 – Decision-ready impact indicators
• **Type:** Performance
• **Priority:** MUST The solution shall present environmental information in a format suitable for decision-making and comparison.
C3.16 – Advanced impact modelling
• **Type:** Performance
• **Priority:** SHOULD The solution should support more advanced environmental modelling, where data availability allows.
Decision Support for Procurement
C3.17 – Integrated decision-support outputs
• **Type:** Functional
• **Priority:** MUST The solution shall provide integrated outputs that combine cost, operational, environmental and compliance information to support procurement decisions.
C3.18 – User-oriented decision interfaces
• **Type:** Functional
• **Priority:** SHOULD The solution should provide user-friendly dashboards or visualisations tailored to procurement and management stakeholders.
C3.19 – Support for evidence-based procurement processes
• **Type:** Performance
• **Priority:** MUST The solution shall support evidence-based decision-making aligned with public

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procurement requirements, including transparency, traceability and auditability of decisions.
C3.20 – Integration with procurement workflows
• **Type:** Functional
• **Priority:** SHOULD The solution should support integration with existing procurement systems and processes.

5.2.4. Components 4: System-Level Intelligence and Demand Modelling

"How can circular solutions be scaled and optimised across the wider healthcare system?"

Component 4 focuses on enabling system-level intelligence to support the large-scale adoption of circular medical devices across healthcare systems. It targets capabilities to estimate demand for reusable and remanufactured devices, assess the capacity of supporting infrastructure such as sterilisation, logistics and remanufacturing, and model device flows across lifecycle stages to identify inefficiencies and optimisation opportunities.

By generating strategic insights—such as priority device categories, infrastructure investment needs, and expected system-wide impacts—the components aims to inform long-term planning, policy development and coordinated scaling of circular solutions across regions and countries.

Demand Estimation for Circular Devices
C4.1 – Demand estimation capability
• **Type:** Functional
• **Priority:** MUST The solution shall estimate demand for reusable and remanufactured medical devices across one or multiple healthcare organisations, regions or countries.
C4.2 – Data-driven demand modelling
• **Type:** Functional
• **Priority:** MUST The solution shall base demand estimations on relevant data inputs, including but not limited to number of procedures, current device usage volumes, reuse rates and device lifespan (e.g. number of use cycles).
C4.3 – Estimation of substitution potential
• **Type:** Functional
• **Priority:** MUST The solution shall estimate the potential reduction in single-use devices resulting from the adoption of reusable or remanufactured alternatives.
C4.4 – Scenario-based demand forecasting

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• **Type:** Functional
• **Priority:** MUST The solution shall support modelling of future demand scenarios under different assumptions (e.g. adoption rates, policy changes, infrastructure development).
C4.5 – Strategic relevance of demand outputs
• **Type:** Performance
• **Priority:** MUST The solution shall ensure that demand estimations are sufficiently robust and transparent to support strategic planning and investment decisions.
Infrastructure Capacity Analysis
C4.6 – Capacity assessment of key infrastructure
• **Type:** Functional
• **Priority:** MUST The solution shall assess the capacity of infrastructure relevant to circular device management, including sterilisation (e.g. CSSD), storage, logistics and remanufacturing facilities.
C4.7 – Alignment between demand and capacity
• **Type:** Functional
• **Priority:** MUST The solution shall enable analysis of whether existing infrastructure can support projected circular device demand.
C4.8 – Identification of capacity gaps
• **Type:** Performance
• **Priority:** MUST The solution shall identify capacity constraints and gaps that may limit implementation of circular solutions.
C4.9 – Infrastructure optimisation insights
• **Type:** Performance
• **Priority:** SHOULD The solution should provide insights to support optimisation of infrastructure utilisation and planning of future investments.
Modelling of Device Flows Across Lifecycle Stages
C4.10 – Lifecycle flow modelling
• **Type:** Functional
• **Priority:** MUST The solution shall model the flow of devices across multiple lifecycle stages, including use, reprocessing, remanufacturing, storage and transport.
C4.11 – Circulation and utilisation tracking
• **Type:** Functional

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• **Priority:** MUST The solution shall enable analysis of how often devices circulate and how long they remain in each lifecycle stage.
C4.12 – Identification of inefficiencies
• **Type:** Performance
• **Priority:** MUST The solution shall identify inefficiencies in device flows, including delays, bottlenecks, losses or underutilisation.
C4.13 – Flow optimisation capabilities
• **Type:** Performance
• **Priority:** SHOULD The solution should provide insights or recommendations to optimise flows and reduce inefficiencies.
Recovery Pathway Feasibility Assessment
C4.14 – Assessment of operational feasibility
• **Type:** Functional
• **Priority:** MUST The solution shall assess whether recovery pathways (e.g. reuse, remanufacturing, recycling) are operationally feasible within healthcare settings, considering workflow constraints.
C4.15 – Assessment of logistics constraints
• **Type:** Functional
• **Priority:** MUST The solution shall evaluate logistics-related factors, including transport distances, collection systems and timing constraints.
C4.16 – Assessment of economic feasibility
• **Type:** Functional
• **Priority:** MUST The solution shall support evaluation of economic viability of recovery pathways, considering costs and potential value of recovered materials or components.
C4.17 – Integrated feasibility analysis
• **Type:** Performance
• **Priority:** SHOULD The solution should integrate operational, logistical and economic dimensions into a coherent feasibility assessment.
Generation of System-Level Insights
C4.18 – Strategic insight generation
• **Type:** Functional

• **Priority:** MUST The solution shall generate system-level insights to support strategic planning and policy-making across healthcare systems.
C4.19 – Identification of priority areas
• **Type:** Functional
• **Priority:** MUST The solution shall identify where circular solutions are likely to have the highest impact (e.g. specific device categories, regions or use cases).
C4.20 – Estimation of system-wide impacts
• **Type:** Functional
• **Priority:** MUST The solution shall estimate system-level impacts, including waste reduction, cost implications and resource efficiency gains.
C4.21 – Long-term planning support
• **Type:** Performance
• **Priority:** MUST The solution shall provide outputs suitable for long-term strategic planning, including infrastructure investment needs and scaling pathways.
C4.22 – Advanced analytics and policy support
• **Type:** Performance
• **Priority:** SHOULD The solution should support advanced analytics to inform policy development and cross-border coordination.

5.3. Pre-commercial Procurement (PCP) and award criteria

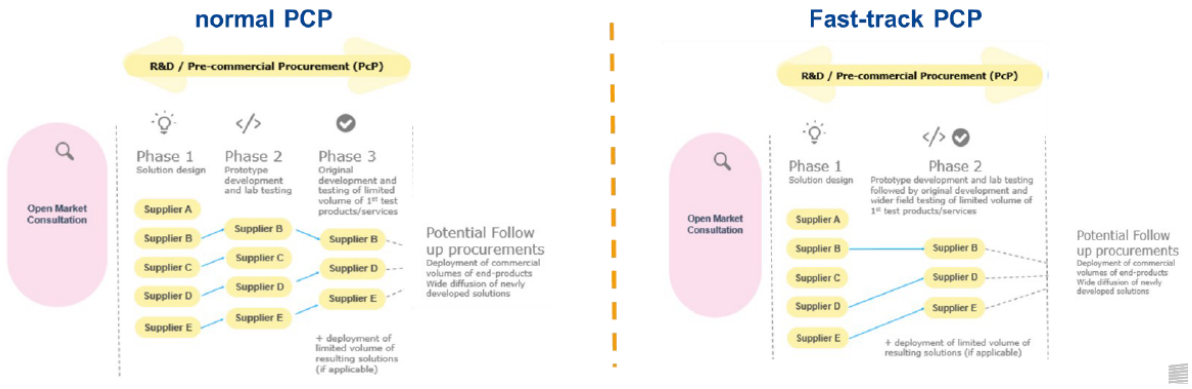
The Challenge will be addressed through a Fast-Track PCP, in accordance with the Horizon Europe Work Programme General Annex H and the PCP Model Grant Agreement. PCP is the procurement of research and development (R&D) services involving risk-benefit sharing under market conditions and competitive development in phases, with a clear separation between the procurement of R&D services and any potential future deployment of commercial volumes of end-products.

The REHEAL Challenge aligns with these principles in the following ways:

- **R&D Necessity:** The absence of integrated system-level solutions confirms that research, prototyping and validation activities are required.
- **Risk-Benefit Sharing:** The PCP structure will enable participating procurers to share development risks with suppliers under market conditions, while allowing suppliers to retain intellectual property rights in line with Horizon Europe rules.

- **Competitive Phased Development:** Multiple suppliers will be selected to develop competing solution approaches through phased R&D, with evaluation and potential down-selection at the end of each phase.
- **Separation from Commercial Deployment:** The PCP will focus exclusively on R&D services. Any potential future deployment of commercial solutions would be subject to separate procurement procedures in compliance with applicable public procurement rules.

Under the fast-track approach, the PCP combines structured preparation, competitive research and development (R&D), validation and follow-up procurement preparation within an accelerated and integrated timeline, as reflected in the REHEAL Grant Agreement work plan.



Detailed performance indicators, measurable evaluation criteria, scoring methodology and stage-gate assessment metrics will be developed during the preparation of the PCP Call for Tenders (CfT), informed by OMC feedback and further technical refinement.

The CfT will specify:

- the formal award criteria and their weighting;
- measurable Key Performance Indicators (KPIs);
- minimum thresholds for progression and continuation;
- evidence requirements for demonstrating compliance and performance;
- contractual and risk-benefit sharing arrangements consistent with Horizon Europe PCP rules.

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The award criteria, on the basis of which the submitted proposals will be evaluated, may include:

1. Innovation, Relevance and Technical Quality

- Level of innovation (beyond state of the art)
- Relevance to the challenge and use cases
- Technical quality and feasibility
- Compliance (legal, regulatory, ethical)

2. Economic Feasibility and Value

- Economic viability of the solution
- Cost-effectiveness and value for procurers
- Feasibility of adoption in real healthcare settings
- Scalability and market potential

3. Quality of the Implementation Plan

- Work plan across PCP phases
- Project and risk management
- User involvement / user-centred design
- Feasibility to deliver within timeline and budget

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6. Request for Information Survey

As part of the OMC, REHEAL has issued an updated Request for Information (RFI) survey which can be found on the REHEAL website OMC page – https://www.rehealhorizon.eu/open-market-consultation.

The RFI seeks supplier's feedback on the REHEAL Challenge and its requirements in order to refine it in preparation for the upcoming PCP Call for Tender which is due to be launched in July 2026.

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 (accessed via the REHEAL website OMC page). All relevant clarification responses will be published in anonymised form to ensure transparency and equal treatment.

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Annex 1 – REHEAL Use Case Stories (Examples)

Component 1 Use Case:
Circular Use of a Reprocessable Guidewire

Context

In a large European hospital, guidewires are extensively used in interventional procedures (cardiology, radiology, urology) to guide catheters and devices. Traditionally, many of these devices are treated as single-use, contributing to significant medical waste and reliance on virgin materials. This use case explores a safe, traceable, and scalable system for reprocessing selected guidewires categories, aligned with circular healthcare principles.

Actors

- Healthcare professionals (nurse/physician)
- Sterilisation unit (CSSD)
- Hospital procurement & logistics
- Reprocessing service provider (internal or external)
- Patient
- Digital tracking system

Scenario

1. Preparation and Use

A reprocessable-certified guidewire (or approved for reprocessing) is selected.

Before use, **Mark (ICU nurse)** scans the guidewire using the digital tracking system.
The system confirms:

- Reprocessing eligibility
- Number of previous uses
- Sterilisation status
- Compliance with safety thresholds

The guidewire is safely inserted and used during the patient's treatment by **Elena (ICU physician)**.

2. Post-Use Collection

After removal, instead of disposal, the catheter is placed in a designated protected, kink-free sealed container for reprocessing.

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The device is scanned again by **Mark (ICU nurse)**, registering:

- End of use cycle
- Patient unlinking (ensuring GDPR compliance)
- Transport to sterilisation

3. Transport and Reprocessing

The catheter is transported to the Central Sterile Services Department (CSSD) or an accredited external reprocessor.

At the facility, **Sophie (CSSD technician)** uses the digital tracking system to register and guide the process:

- The device undergoes validated cleaning, disinfection, and sterilisation
- Integrity checks are performed (e.g., Tip integrity, Coating condition, flexibility, straightness)
- The system logs the reprocessing cycle and updates device status

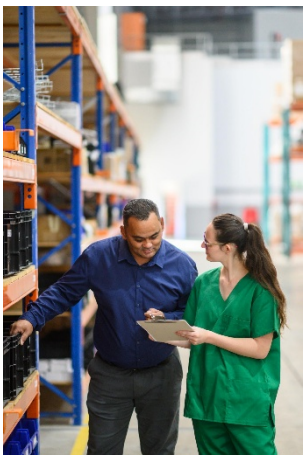
If the catheter meets safety and quality criteria, it is approved for reuse. If not, it is safely discarded and recorded.

4. Redistribution

The reprocessed guidewire is repackaged and returned to hospital inventory.
The digital system updates:

- Remaining lifecycle (e.g., max 10 uses)
- Certification and compliance documentation

Anika (procurement manager) uses this information to ensure that procurement systems prioritise these reusable devices over new ones where available.



5. Monitoring and Optimisation

Hospital management and procurement teams access dashboards showing:

- Reduction in single-use device procurement
- Waste reduction metrics
- Cost savings
- Safety and incident reports

Anika (procurement manager) and logistics staff use these insights to support policy decisions and scaling across departments.

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Component 2 Use Case Story: Operational and End-of-Life Recovery Management

Context

In a large European hospital within the REHEAL Buyers' Group, reusable anaesthetic masks are used in operating theatres for routine procedures. While these devices are designed for multiple uses, the hospital faces challenges in managing them efficiently across their lifecycle. Devices are sometimes misplaced, sterilisation capacity is not always optimally used, and there is limited visibility on how often masks have been reused or when they should be removed from circulation.

In addition, decisions regarding end-of-life handling—such as whether a mask should be remanufactured, recycled or disposed of—are often made without complete information on device condition, material composition or recovery options.

Actors

- **Anna (procurement officer)**
- **Dr. Mark (anaesthesiologist)**
- **Elena (nurse)**
- **Elena (logistics manager)**
- **Sophie (sustainability officer)**
- **Lars (financial controller)**
- Central Sterile Services Department (CSSD) staff
- External remanufacturing and waste management providers

Scenario

1. Preparation and Allocation of Devices

Before a surgical procedure, **Elena (nurse)** retrieves a reusable anaesthetic mask. Using the system, **Elena (nurse)** checks:

- current status (e.g. sterilised and ready for use);
- number of previous use cycles;
- last sterilisation date.

The system confirms that the mask is compliant and ready for safe use.

2. Tracking of Use and Status

After the procedure, **Elena (nurse)** updates the system to indicate that the mask has been used. The device status automatically changes to "awaiting sterilisation."

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The system records:

- the use event;
- the responsible department;
- time and location of use.

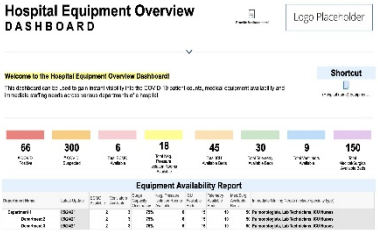
This ensures full visibility of the device's lifecycle at operational level.

3. Reprocessing and Capacity Management

The used mask is transported to the sterilisation unit. CSSD staff scan the device and initiate the reprocessing cycle.

The system:

- tracks the sterilisation process;
- updates the device status to "in sterilisation";
- monitors sterilisation capacity and workload.



Elena (logistics manager) uses the system dashboard to monitor bottlenecks in the sterilisation unit and adjust logistics flows if needed.

4. Inventory and Location Management

Once sterilised, the mask is returned to storage. The system updates its status to "ready for use" and records its location.

Elena (logistics manager) and **Anna (procurement officer)** can view:

- real-time inventory levels per department;
- location of masks across the hospital;
- alerts for shortages or overstock situations.

This reduces loss, unnecessary purchases and delays in care delivery.

5. Monitoring of Lifecycle and Usage Limits

The system continuously tracks the number of use cycles and sterilisation events per mask. When a predefined threshold is reached, the system flags the device for inspection or removal.

Dr. Mark (anaesthesiologist) is notified if a mask is no longer suitable for clinical use, ensuring patient safety is maintained.

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6. End-of-Life Identification and Classification

When a mask reaches the end of its usable life, the system provides information on:

- material composition;
- contamination status;
- regulatory constraints.

Sophie (sustainability officer) reviews this information to determine the most appropriate recovery pathway.

7. Decision Support for Recovery Pathway

The system suggests possible options:

- remanufacturing (if eligible);
- recycling (based on material composition);
- disposal (if no other option is feasible).

Anna (procurement officer) and **Lars (financial controller)** assess the economic implications, while **Sophie (sustainability officer)** considers environmental impact.

8. Execution of Recovery Process

The selected pathway is executed:

- the mask is sent to a certified remanufacturer or recycling facility;
- logistics are coordinated through the system;
- the device lifecycle is closed with full traceability.

The system records the final outcome for reporting and analysis.

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Component 3 Use Case Story: – Procurement Decision-Making and Business Case Evaluation

Context

In a large European hospital within the REHEAL Buyers' Group, procurement teams are under pressure to reduce costs, meet sustainability targets and comply with regulatory requirements. The hospital is considering replacing a high-volume single-use medical device (e.g. laparoscopic instruments or surgical gowns) with reusable or remanufactured alternatives.

However, procurement decisions are currently based mainly on unit price and supplier information. The hospital lacks reliable, comparable data on lifecycle costs, environmental impact and operational implications of different options. This makes it difficult to justify investments in circular solutions.

Actors

- **Procurement officer**
- **Surgeon**
- **Nurse**
- **Sustainability officer**
- **Financial controller**
- Suppliers of single-use and reusable/remanufactured devices
- Digital decision-support system (Module 3 solution)

Scenario

1. Identification of Procurement Need

Anna (procurement officer) identifies that a contract for single-use surgical devices is due for renewal. At the same time, **Sophie (sustainability officer)** highlights the potential to reduce waste and emissions by switching to reusable or remanufactured alternatives.

Together with **Dr. Mark (surgeon)** and **Elena (nurse)**, **Anna (procurement officer)** agrees to assess different options using the digital decision-support system.

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2. Input of Hospital-Specific Data

Anna (procurement officer) inputs relevant data into the system, including:

- annual procedure volumes;
- current device usage and costs;
- labour costs for handling and reprocessing;
- available infrastructure (e.g. sterilisation capacity);
- waste management costs.

Lars (financial controller) validates the financial assumptions, while the system retrieves additional lifecycle and operational data.

3. Lifecycle Cost Calculation

The system calculates the **whole-life-cycle costs** for each option:

- single-use devices;
- reusable devices;
- remanufactured devices.

Costs include acquisition, operational handling, reprocessing, logistics and end-of-life management. **Anna (procurement officer)** and **Lars (financial controller)** review the results, which are presented in a transparent and comparable format.

4. Scenario Analysis

Anna (procurement officer) explores different scenarios in the system, such as:

- increased procedure volumes;
- higher reuse rates;
- changes in labour or energy costs;
- investment in additional sterilisation capacity.

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The system shows how these variables affect total costs and operational feasibility.

5. Decision Support Output

The system generates a **decision-support summary**, highlighting:

- the most cost-effective option over the lifecycle;
- expected environmental benefits;
- operational implications and risks;
- key assumptions and uncertainties.

Anna (procurement officer) uses this output to prepare a business case, supported by **Lars (financial controller)** for financial validation and **Sophie (sustainability officer)** for sustainability justification.

6. Procurement Decision

Based on the analysis, **Anna (procurement officer)** presents the findings to the internal decision board. With input from **Dr. Mark (surgeon)**, **Elena (nurse)**, **Sophie (sustainability officer)** and **Lars (financial controller)**, the hospital decides to proceed with a reusable or remanufactured solution.

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Component 4 Use Case Story: System-Level Intelligence and Demand Modelling

Context

Across the region, healthcare organisations are exploring the transition towards reusable and remanufactured medical devices. While individual hospitals have started assessing circular solutions, there is limited visibility at system level on how demand, infrastructure capacity and device flows interact across regions and countries.

As a result, strategic decisions—such as where to invest in sterilisation capacity, which device categories to prioritise, or how to scale circular solutions—are made with limited evidence. There is a need for a system-level tool that can aggregate data, model demand and provide insights to support coordinated planning across healthcare systems.

Actors

- **Anna (procurement officer)** – hospital level
- **Sophie (sustainability officer)** – hospital level
- **Lars (financial controller)** – hospital level
- **Maria (regional healthcare planner)** – regional authority
- **Johan (national policy advisor)** – national health authority
- **Elena (logistics manager)** – hospital logistics
- Digital system-level intelligence platform (Module 4 solution)

Scenario

1. Identification of Strategic Planning Need

Maria (regional healthcare planner) is tasked with developing a regional strategy to scale circular medical devices across multiple hospitals. At the same time, **Johan (national policy advisor)** is assessing how national policy can support the transition to circular healthcare supply chains.

They recognise that current decisions are based on fragmented data and request support from the system-level intelligence platform.

2. Aggregation of Data Across Healthcare Systems

The system aggregates data from multiple sources, including:

- hospital procurement and usage data (input from **Anna (procurement officer)**);

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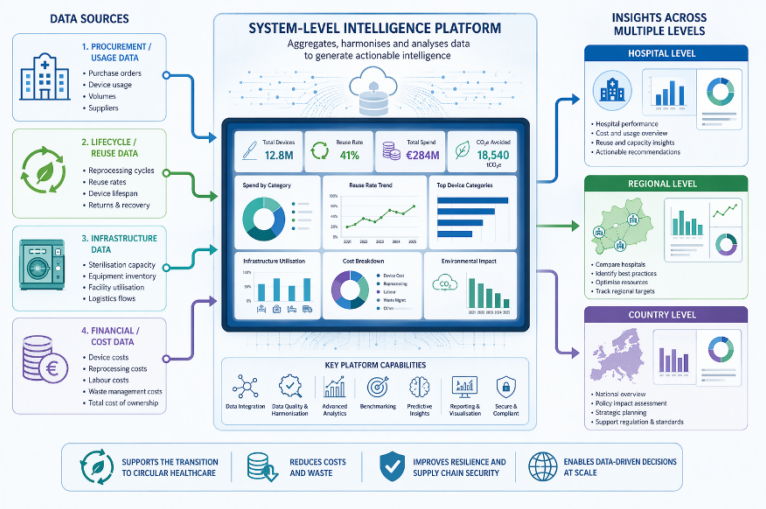
- lifecycle and reuse data from existing systems;
- infrastructure data (e.g. sterilisation capacity, logistics flows) provided by **Elena (logistics manager)**;
- financial and cost data validated by **Lars (financial controller)**.

This creates a consolidated view across hospitals, regions and countries.



3. Demand Estimation for Circular Devices

The system estimates current and future demand for reusable and remanufactured devices based on:

- procedure volumes;
- current use of single-use devices;
- expected reuse rates;
- device lifespan (number of cycles).

Maria (regional healthcare planner) reviews the results, which show the potential reduction in single-use devices and the expected uptake of circular alternatives under different scenarios.

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4. Infrastructure Capacity Analysis

The system analyses whether existing infrastructure can support the projected demand, including:

- sterilisation capacity (CSSD);
- storage and handling capacity;
- internal and external logistics;
- remanufacturing capacity.

Elena (logistics manager) validates the operational assumptions, while **Maria (regional healthcare planner)** identifies capacity gaps and potential bottlenecks.

5. Modelling of Device Flows

The system models how devices move across lifecycle stages, showing:

- how many times devices are reused;
- how long devices remain in each stage (e.g. use, sterilisation, storage);
- where delays, losses or inefficiencies occur.

This allows **Maria (regional healthcare planner)** and **Elena (logistics manager)** to identify opportunities to optimise flows and improve utilisation.

6. Assessment of Recovery Pathways

The system evaluates the feasibility of different recovery pathways (reuse, remanufacturing, recycling), considering:

- operational implications for hospitals (input from **Anna (procurement officer)** and **Elena (logistics manager)**);
- logistics constraints such as transport distances and collection systems;
- economic viability validated by **Lars (financial controller)**.

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This helps determine which pathways are realistic and scalable in practice.

7. Generation of System-Level Insights

The system generates strategic insights, including:

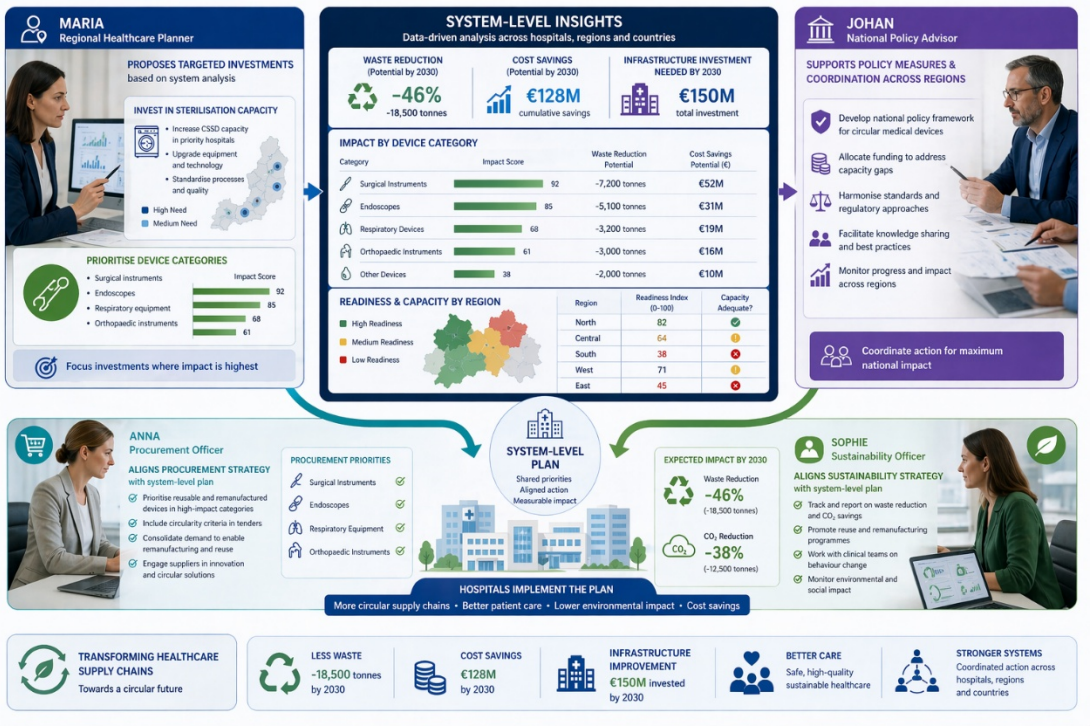
- which device categories offer the highest impact;
- expected waste reduction and cost savings;
- required infrastructure investments;
- regional differences in readiness and capacity.

Johan (national policy advisor) uses these insights to inform national policy and funding priorities, while **Maria (regional healthcare planner)** translates them into a regional implementation roadmap.

8. Strategic Decision-Making

Based on the analysis, **Maria (regional healthcare planner)** proposes targeted investments in sterilisation capacity and prioritisation of specific device categories. **Johan (national policy advisor)** uses the results to support policy measures and coordination across regions.

Hospitals, represented by **Anna (procurement officer)** and **Sophie (sustainability officer)**, align their procurement strategies with the broader system-level plan.



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