GET REHDY

European Health Data Space — Kick-Off Meeting Report

30 March 2026 | COOCK Programme

Partners: VITO · UHasselt · KU Leuven CiTiP · imec-SMIT · i~HD

Executive Summary

The GET REHDY kick-off meeting brought together project partners and an Advisory Committee of 30+ stakeholders from across the Belgian health data ecosystem — covering hospitals, pharma, health tech, primary care, intermediaries, and academia. The session introduced the project structure, the three technical Work Packages, and opened a first structured dialogue with the Advisory Committee through an interactive workshop focused on the main work packages.

Three overarching themes emerged from the full day:

- There is significant uncertainty and a clear knowledge gap across stakeholder groups regarding what the EHDS means in practice for their specific role.
- Legal and technical frameworks are evolving rapidly, demanding an agile and modular project approach.
- Stakeholder trust, transparency, and tailored communication are prerequisites for meaningful participation.

Project Context & Background

Project leads & project introduction (Elfi, Erik, Charlotte – VITO and Jens, Dipak and Sonia - i~HD)

Why EHDS Matters

The European Health Data Space (EHDS) represents the EU's flagship initiative to enable the reuse of health data — both for direct patient care (primary use) and for research, policy, and innovation (secondary use). Get Rehdy focuses primarily on secondary use readiness, supporting Belgian stakeholders to navigate the legal, technical, and skills challenges ahead.

Project Structure: Three Core Work Packages

Work Package	Focus Area	Key Deliverables
WP1 – Technical	Data platforms & interoperability	Blueprint, modular demonstrator, quality frameworks, toolkit

WP2 – Legal	Compliance & governance tooling	Legal mapping, PETs overview, legal-tech translation, consolidation toolkit
WP3 – Skills & Awareness	Stakeholder readiness & literacy	Stakeholder mapping, fact sheets, self-assessment toolkit, co-creation sessions

COOCK Programme Introduction (VLAIO Cluster-Coock+ programme, supported by BioVia)

- Programme structure: Part A (research & development) and Part B (valorisation & dissemination).
- KPI overview presented; all partners aligned on reporting requirements.
- Advisory Committee formally introduced as a key governance and knowledge-sharing body.

Advisory Committee — Set-Up & Governance

Composition

The Advisory Committee brings together a broad cross-section of the Belgian health data ecosystem, including:

- Hospital networks and care organisations
- Pharma and RWE specialists
- Health tech start-ups and intermediaries
- Data managers, analysts, and IT providers
- Research & academic institutions
- Policy and coordination bodies

Operational Agreements

- President & Secretary: Elfi confirmed as President & VITO taking up Secretary role as well.
- Meeting frequency: 2 formal meetings per year.
- Agenda focus: project progress, planning, and emerging sector priorities.
- Formal agreement to join (Reglement van Orde) to be circulated and signed.

Key Expectation from the Advisory Committee
→ Act as champions: spread knowledge of EHDS and Get Rehdy within your own networks.
→ Provide early-stage input on demonstrators, use cases, and validation priorities.
→ Serve as a feedback loop on the relevance and quality of project deliverables.
→ Today's session: getting acquainted and identifying collaboration opportunities.

Work Package 1 — Technical Solutions

Lead: UHasselt (Ilse, Liesbet, Joeri)

WP1 develops the technical infrastructure and frameworks enabling EHDS-compliant health data reuse. The approach is grounded in a 'data as a product' philosophy: data must be valuable, usable, FAIR (Findable, Accessible, Interoperable, Reusable), and trustworthy.

Core Pillars

- Data Quality — linked to the Quantum Label quality assurance framework.
- Interoperability & Portability — enabling cross-platform and cross-border data flows.
- Governance, Privacy & Security — tightly integrated with WP2 legal frameworks.
- Re-usable, modular, open-source building blocks — UHasselt platform and the University MS Centre (UMSC) as reference use case; OMOP as the Common Data Model (CDM).

Workshop Findings (WP1 Stakeholder Session)

The WP1 working session with the different stakeholder organisations generated concrete requirements across all four tasks:

Priority 1: Blueprint - Key Gaps Identified
→ The distinction between primary and secondary data use remains unclear for many stakeholders; the blueprint must define and delineate both explicitly.
→ FHIR and OMOP: need for more clarification/education on when and how to use. A clear position on standards is required.
→ Absence of a reusable data dictionary was flagged as a concrete gap; the blueprint must specify how data definitions are standardised and shared.

Priority 2: Modular Demonstrator - Requirements
→ Stakeholders want process data and the patient journey captured, not only outcomes.
→ The ROI of data sharing is questioned. The demonstrator is an opportunity to make the value proposition tangible and increase participation willingness.

Priority 3: Quality & Metadata Frameworks - Priorities
→ Metadata was the most discussed topic: minimum fields, patient counts, completeness metrics, last update, update frequency, and accessibility are all considered essential.
→ A 'marketplace-style' metadata catalogue was viewed as highly attractive. This is strongly aligned with the data product approach. Inspiration can be taken from EHDEN and EMA
→ Unstructured data is a priority concern: the framework must explicitly address how unstructured sources are handled.

Priority 4: Toolkit & Capacity Building
→ 'What does good onboarding for a data holder look like?' -> This is a direct user requirement for the toolkit.
→ Examples on how medication and allergy data spread across multiple platforms illustrates workflow integration complexity that must be addressed in the mapping.
→ Stakeholders requested clarity on minimum requirements to set up a data catalogue, confirming the need for low-threshold, modular templates.

Suggestion to Advisory Committee

Advisory Committee Request — WP1
→ Provide early input on demonstrator build, validation approaches, and use cases.
→ Act as champions: promote awareness of the technical building blocks in your organisation.
→ Feedback requested on re-usability: ensure tools fit on the We Are framework and Belgian DS primary use infrastructure.

Work Package 2 — Legal Solutions

Lead: KU Leuven CiTiP (Jan, Daniela, Natalie)

WP2 treats legal compliance not as a constraint but as an integrated, enabling component of the project. Given the rapid pace of EU regulatory change, the approach is deliberately agile and iterative.

Scope & Approach

- Monitor and consolidate the legal and ethical frameworks applicable to EHDS.
- Support the definition of synthetic datasets and privacy-enhancing technologies (PETs).
- Sector-specific deployment guidance, drawing on EU pilot debriefs.
- Actionable technical specifications: technical tagging, data governance layers.
- Toolkit approach: role-specific and stakeholder-tailored legal guidance.
- Main message: the regulatory landscape is moving fast — continuous monitoring and iteration are essential.

Key Legal Research Questions (from Advisory Discussion)

The Advisory Committee session surfaced several priority legal questions shaping WP2's research agenda:

Priority 1: Definition of 'scientific research' under EHDS
→ Where does the boundary lie between public-interest research and commercially driven research for data access purposes?
→ How will this be assessed by the HDABs, and how to ensure fair access (e.g. different interpretations of this by different HDABs)?

Priority 2: Intellectual property and value of data
→ How is IP protected under EHDS?
→ How can new IP be set up if everyone has equal access to all data?
→ What are viable business models?

Priority 3: Procedural clarity
→ Data processing agreements, the role of the IVC, DPO responsibilities versus ethical committees and AI agents, how different legislations interact & how this needs to be taken up from a compliance viewpoint.
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Priority 4: Indivudual rights and privacy
→ Overarching need: legal certainty that balances enabling innovation with protecting individual rights and privacy.
→ What are the assurances on e.g. the opt-out mechanism in EHDS and how does this work in practice?

Advisory Committee Request — WP2
→ Provide early feedback on legal priorities most relevant to your sector.
→ Share information needs from your organisation to help shape the toolkit content.
→ Engage in the interactive feedback loops planned throughout the project.
→ Key open question: how can the latest legal news be shared rapidly with the full ecosystem?

Work Package 3 — Knowledge, Skills & Literacy

Lead: imec-SMIT (Anouk, An, Melissa, Christel)

WP3 builds EHDS readiness through stakeholder-specific knowledge development, accessible communication, and co-creation. The central principle: meaningful literacy interventions must be deeply tailored to the role, context, and existing knowledge level of each stakeholder group.

Scope & Approach

- Stakeholder identification and EHDS readiness benchmarking.
- Co-creation and participation models as the design methodology.
- Accessible communication development across stakeholder segments.
- Main message: access to the right stakeholders is a prerequisite for success — the Advisory Committee plays a critical role here.

Findings from the Kick-off Plenary

The kick-off session revealed five priority needs that directly shape WP3's work program:

Priority 1: Foundational Knowledge

→ Many stakeholders lack a basic understanding of what EHDS means for their organisation.

→ Strong demand for 'EHDS for dummies' materials, short explainer videos, micro-courses, and decision trees.

→ Stakeholder-specific guides (per role: data holder, data user, care organisation, intermediary, HDA).

Priority 2: Role Clarity & Expectations

→ Stakeholders want to know exactly what is expected of each actor type.

→ Specific questions: compliance timelines, monitoring mechanisms, possible sanctions.

→ Distinction between primary and secondary data users must be made concrete.

Priority 3: Trust & Transparency

→ Concerns about commercialisation of health data, control mechanisms, and administrative burden.

→ Proposed responses: transparent communication, sector testimonials, governance clarity, feedback culture.

→ Transparency about what happens to data and how data sharing decisions are made is essential.

Priority 4: Practical Implementation Support

→ Concrete guidance needed: data catalogues with metadata, historical data depth guidance, data quality support.

→ Interest in learning from other sectors (e.g. financial sector governance models).

→ Coordination among intermediary actors needs improvement to avoid duplication.

Priority 5 — Structured Stakeholder Engagement

→ Engagement must go beyond informing — structural co-creation is expected.

→ Calls for working groups with data holders, shorter feedback loops with clinicians, training for care professionals and students.

→ Important note: communication must complement, not duplicate, existing initiatives like the HDA Academy.

Upcoming Events

- 18 September 2026: first general GET REHDY Symposium