BETTER CONNECTING PRIMARY AND SECONDARY USE OF DATA FOR ADDITIONAL SOCIETAL VALUE

Report based on 26 June 2025 Imagining 2029 webinar organised by EHTEL together with the xShare project

TABLE OF CONTENTS

Overview

This webinar was hosted in the context of the **xShare project** and the EHTEL "Imagining 2029" work programme. It gathered together leading experts to explore how to better connect the primary use of health data (for patient care) with the secondary use of the data (for purposes of public health, research, and policy). The event had **three aims**: to address the persistent fragmentation in Europe's health data ecosystem, offer insights from pioneering countries, and discuss concrete use cases and tools (such as the International Patient Summary + Research (IPS+R)), with the overarching goal of **maximising societal value** from health data.

Introduction

Luc Nicolas, representing EHTEL, set the scene by introducing the **xShare project**[1] and by introducing **the need to bridge divides between types of health data**.

xShare bridges innovation and implementation. It is closely tied to the preparation of the **European Health Data Space (EHDS)**. It examines how the European Electronic Health Record Exchange Format (EHRxF or EEHRxF) can support continuity of care, public health, and clinical research. The project explores placing patients at the centre through a "yellow button"[2], which will enable individuals to share their quality-assured data for multiple purposes. Luc emphasised that, since 2000, primary and secondary uses of data have evolved largely in isolated ecosystems, which has led to duplication, inefficiencies, and missed opportunities. The webinar's purpose was therefore **how to better bridge these divides** and **better connect primary and secondary uses** of health data.

The Case for Bridging Primary and Secondary Uses of Data

Fidelia Cascini, a leading public health professor and author of a book on secondary use of health data, provided **foundational insights** on the case for bridging different types of health data. She outlined three essential messages:

- **Multiple data families exist**: Electronic health records (EHRs) are only one among many types of electronic health data. **Other examples** include registries, patient-generated data (e.g., apps and wearables), surveys,

[1] https://xshare-project.eu Accessed 14 July 2025.
[2] https://xshare-project.eu/the-xShare-button/ Accessed 14 July 2025.

laboratory systems, and administrative datasets. Each example has unique characteristics.

- **Real-world data (RWD) has a role**: Collected routinely in uncontrolled environments, RWD can complement randomised controlled trials (RCTs). For example, RWD reveal **actual adherence patterns** to e.g., pharmaceuticals or recommended behaviours or **post-market outcomes** that RCTs cannot capture.
- **Emerging applications strengthen evidence**: These new applications include **training/testing artificial intelligence (AI) in healthcare**, where combining RCT data with RWD can strengthen evidence.

Fidelia also described the **benefits and limitations** of RWD and contrasted them. On the one hand, RWD can enable disease discovery, the monitoring of outcomes, and inform innovation. On the other hand, however, the data are often unstructured, incomplete, and observational, which leads to variability, bias, and analytical complexities. RWD complements rigorous RCT data, but does not replace it.

Fidelia emphasised that four minimum conditions for **effective secondary use of data** need to be ensured. They are:

1. **Robust data models** to reduce errors, biases, and inconsistencies.
2. **Data quality frameworks**, including possible EU-wide "labels" for data quality and utility (citing Article 78 of the EHDS Regulation[3]).
3. **Semantic interoperability**, implying shared meanings for data elements across sources.
4. **Mapping tools** that allow aligning disparate data models.

Fidelia concluded by inviting attendees to access her open-access book[4], which provides a synthesis of international best practices for secondary use.

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L_202500327 Accessed 14 July 2025.
[4] https://link.springer.com/book/10.1007/978-3-031-88497-9 Accessed 14 July 2025.

Learning from the first "only once" public implementations

In his presentation, **Luc Nicolas** compared lessons learned from Denmark, Belgium, and Finland, which have each taken distinctive routes towards **"only once" (once-only) data strategies**.

The once-only approach was originally based on a principle set out by the European Union at the end of the first decade of the 21st century, which aims to ensure that citizens, institutions, and companies have to **provide only once certain standard information to the authorities and administrations**. In the healthcare domain, the principle could be translated into "*collect once, use many*" times – when data produced in a clinical setting is reused for other purposes with either minimal or no effort.

The three examples presented illustrated **three different approaches** to implementing this data strategy. Luc drew a set of conclusions at the end of his presentation.

In **Denmark**, **implementation started practically**, with diabetes benchmarking, before expanding to other specialties and quality registers. The initiative was accepted well as it built on an **incremental consensus with clinicians**, which created "buy-in" by showing direct clinical benefits. The use **of Extract, Transform, Load (ETL) processes**[5] embedded in EHRs minimises additional burdens, and the Return on Investment (ROI) – from using it – was clear: clinicians gained tools with which they could benchmark and improve care. There are, however, limitations to the strategy: local standards dominated, which limited international interoperability. This situation has **made the EHDS into a timely opportunity** for upgrading the approach.

In **Belgium**, the original push for once-only came from healthcare professionals themselves, who were frustrated by repeated data requests. Hence, since 2013, Belgium has decided that **system-to-system communication** should be the road to follow while inventorising registries and aligning them with a national metadata catalogue. A **public application** has been developed called HD4DP (Healthdata for data providers)[6], which has been installed in all Belgian hospitals and which extracts

[5] https://risingwave.com/blog/a-complete-guide-to-etl-pipeline-for-beginners/ Accessed 14 July 2025.
[6] https://healthdata.sciensano.be/en/node/18 Accessed 14 July 2025.

data for over 40 registries directly from EHRs. It thus supports public health, research, and data quality. A second component has been developed to enable data quality controllers to interact with data providers. Although Belgium invested in a national SNOMED CT subset and has referred to LOINC codification[7], semantic interoperability remains a hurdle. Belgium showed that having generic "data warehouses" is not enough; **aligning real registries** matters. Multiple data collection systems still exist and they continue to provoke frustrations on the part of data providers who do not yet see a proper ROI for themselves. The implementation of a single system for secondary use will prevent duplication and user frustration.

Finland is known for its strong **infrastructure** and **legislative integration**, which makes primary use data available by default for secondary use. Finland is thus in a truly unique position to **make the best of available RWD** and use it for secondary use. Yet **challenges remain**. Clinicians struggle to use structured data consistently (which affects downstream quality); researchers cite, as problems, a lack of data granularity and validation as well as achieving slow, costly permissions.

In online discussions during the webinar, attendees also discussed some important **issues related to data quality and its implementation** which they believe are not yet covered by the content of the EHDS Regulation.

In conclusion, the following first overall cross-country lessons identified highlight a number of potential **steps to implementation**:

- Start with **practical use cases** since, even in the absence of clinical RoI – if implementation leads to administrative simplification and a "time win" for the clinicians – buy-in can already have been achieved.
- **Invest in usability, automation, and tools** to make structured data effortless.
- **Align standards with international models** to avoid legacy pitfalls.
- **Provide tangible returns** to data providers to maintain engagement.

[7] https://www.health.belgium.be/nl/gezondheid/organisatie-van-de-gezondheidszorg/delen-van-gezondheidsgegevens/terminologiecentrum Accessed 14 July 2025.

Having looked at how important it is to build bridges between the primary and secondary uses of health data (and what tips for implementation emerge), the webinar looked at one specific enabler — the **international patient summary** — which has been somewhat adapted to support both clinical research and public health.

The International Patient Summary (IPS+R) as a key enabler

Rebecca Kush and **Rebecca Baker** from CDISC, the reference standard organisation for clinical research[8], explained how **leveraging international standards** can enable efficient reuse of data.

First, Rebecca Kush provided an **historical perspective**. Since the 2010s, projects have tried to integrate EHR data with clinical research, e.g. HL7 Clinical Document Architecture (CDA) + CDISC studies[9]. Early pilots demonstrated that adverse event form completion could be reduced from 34 minutes to under one minute. Uptake was, however, limited due to fragmented terminologies, a lack of regulatory push, and delayed global alignment.

People today might, however, be more optimistic about the use of various standards. There are several reasons why there might be increased optimism: the EHDS explicitly commits to EHRxF reuse for secondary purposes; there has been a much stronger collaboration among standards bodies (such as SNOMED International[10], HL7 International[11] (and others), ISO[12], and CDISC); and, furthermore, patients will in the future have tools (i.e., the xShare yellow button[13]) which will enable them to share their own data, thus easing barriers to consent.

What does IPS+R mean concretely

Rebecca Baker, who spoke second, made it clear the IPS+R builds on the HL7 FHIR®[14] International Patient Summary (IPS)[15], by adding minimal extensions for public health and clinical research. The IPS+R identified **100 core data elements** –

[8] https://www.cdisc.org Accessed 14 July 2025.
[9] Among example studies are e.g.: https://www.cdisc.org/news/cdisc-and-hl7-jointly-release-mapping-guide-facilitate-use-electronic-health-record-data Accessed 14 July 2025.
[10] https://www.snomed.org Accessed 14 July 2025.
[11] https://www.hl7.org Accessed 14 July 2025.
[12] https://www.iso.org/home.html Accessed 14 July 2025.
[13] https://xshare-project.eu/the-xShare-button/ Accessed 14 July 2025.
[14] https://www.hl7.org/fhir/ Accessed 14 July 2025.
[15] https://international-patient-summary.net/ Accessed 14 July 2025.

mapped across SNOMED CT, CDISC, and the (USA) National Cancer Institute (NCI) Thesaurus[16] – thus enabling robust semantic linkage. It provides a practical "glide path" so that implementers can start with the existing IPS and extend it to IPS+ for richer use cases. The most prevalent use cases which can benefit from the IPS+R in the context of clinical research have been documented in a working paper which is now available publicly[17].

The two speakers stressed that no new standards are needed – just **harmonisation, alignment, and robust toolkits**.

Public Health Use Cases and Patient-Centric Scenarios

Eugenia Rinaldi from Charité in Berlin, Europe's largest university research and teaching hospital, highlighted how the xShare project team has been linking the six EEHRxF formats to tangible public health priorities. The **use cases** which have been selected by xShare are aligned with both European Union (EU) public health and EHDS priorities. xShare has thus focused so far on e.g., infection surveillance (i.e., European Centre for Disease Control (ECDC) protocols on AMR[18]; intensive care unit (ICU) infections[19]); cancer monitoring (using registries that feed the EU Cancer Information System[20] (ICIS)); long COVID discovery studies; and patient-driven survivorship passports for cancer follow-up. On the one side, using **the EEHRxF as a reference**, the approach followed has been to align the data elements with HL7 FHIR® profiles, semantic codes (e.g., SNOMED CT; LOINC), and ensure cross-disciplinary reuse (One Health[21] for human beings; veterinary laboratories). On the other side, xShare has explored the **new opportunities offered by the yellow button** so that patients can consent to provide their data directly – for example, by volunteering additional health data for long COVID research.

[16] https://evs.nci.nih.gov/evs-download/thesaurus-downloads Accessed 14 July 2025.
[17] https://xshare-project.eu/wp-content/uploads/2025/06/Proposal-for-a-harmonized-core-data-set-across-health-care-population-health-and-clinical-research-working-paper.pdf Accessed 14 July 2025.
[18] https://www.ecdc.europa.eu/en/publications-data/reporting-protocol-antimicrobial-resistance-amr Accessed 14 July 2025.
[19] https://www.ecdc.europa.eu/en/healthcare-associated-infections-acquired-intensive-care-units Accessed 14 July 2025.
[20] https://ecis.jrc.ec.europa.eu Accessed 14 July 2025.
[21] https://www.who.int/health-topics/one-health#tab=tab_1 Accessed 14 July 2025.

A short panel discussion on challenges and outcomes

During the short panel discussion which followed the presentations, feedback was collected from representatives of major public health-related initiatives. They were as follows:

- **Sierk Marbus** (United4Surveillance Joint Action[22]) highlighted that **infectious disease surveillance** is grappling with diverse country systems, making semantic harmonisation essential. He warned, however, that many countries are still far from **patient-driven "yellow button" readiness**.
- **Luis Alves de Sousa** (ECDC) insisted on **anti-microbial resistance (AMR)** as a test case – he commented that if harmonisation can work with AMR data, it can work across all notifiable diseases. He also saw great benefits in deploying cross-border decision support systems.
- **Christos Schizas** (coordinator of ECAN[23]/ECAN+[24] and Xt-EHR[25] Joint Actions) noted how **cancer** initiatives and the implementation guides from Xt-EHR are trying to operationalise EHDS standards by 2027-2030.
- **Beatriz Barros** (TeHDAS2 Joint Action) emphasised the need for **stronger cross-sector dialogue** between primary and secondary use teams. Maturity across Europe is uneven; national investments in semantic services still vary widely; and public investment in standards deployment and alignment is essential.

The webinar discussions enabled identification of a number of important challenges, which may eventually also lead to the formulation of possible **action plans**, at three levels, in order to counterbalance these difficulties.

On the legal and organisational sides: The divergence between General Data Protection Regulation (GDPR)[26] interpretations and national privacy laws impedes data flows. While the EHDS will improve this situation, countries still experience uneven capacities to build EHDS-compatible infrastructures.

---

[22] https://united4surveillance.eu Accessed 14 July 2025.
[23] https://ecanja.eu Accessed 14 July 2025.
[24] https://ehealth.cut.ac.cy/2025/06/10/ecan-plus-ja-launched/ Accessed 14 July 2025.
[25] https://www.xt-ehr.eu Accessed 14 July 2025.
[26] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM%3A310401_2 Accessed 14 July 2025.

On the technical and semantic sides: People are still experiencing persistent semantic heterogeneity – there exist both national codes and international standards. Deployment-related user-friendly tools are still lacking for clinicians to be able to produce structured data effortlessly.

On the change management side: There is a dire need for clear ROI for data providers (such as clinicians and hospitals) to maintain quality data capture. Without multi-purpose drivers (i.e., benchmarking, reimbursement, quality, and research), uptake is slow.

Potential Recommendations and Priorities

As a result of the discussions held in the webinar, a number of **recommendations and priorities** have been developed that are to be discussed further. Here, they have been listed at **three levels** (related to Member States; various European bodies; and projects and/or standards bodies):

For Member States:

- Build **unified metadata inventories** of all official registries to understand needs.
- **Invest in terminology servers and mapping tools** building on international standards. Examples include SNOMED CT, ICD, LOINC, and CDISC.
- **Provide training and user-centred design** to ease structured data capture.

For EU & EHDS bodies:

- **Offer various tools**, such as implementation guides (like IPS+), maintain value sets, and support federated analytics.
- **Ensure investments** that will support both semantic and organisational interoperability. (An example includes an EU terminology server that would be connected with national terminology servers.)
- **Develop governance models** that reinforce patient trust and incentivise data sharing.

For projects & standards bodies:

- **Keep strengthening cross-standard alignment** (such as between FHIR, CDISC, and SNOMED CT).
- **Showcase real-world pilots** – especially pilots that link infection surveillance, cancer monitoring, and long COVID research – to the IPS+R.

Conclusions

In conclusion, the webinar demonstrated vividly both the **complexity and promise** of better connecting primary and secondary uses of health data across Europe. By systematically aligning standards, investing in usability, and building trust frameworks for both patients and clinicians, Europe can unlock vast new **societal value** – which would range from more responsive public health initiatives to accelerated clinical research. The xShare project, along with initiatives like TeHDAS2[27], United4Surveillance[28], and the evolving implementation of the EHDS, **sets the stage** for these ambitions to materialise.

The 26 June 2025 webinar organisers will circulate the **webinar materials** – slides, a recording, the supporting documents, and detailed country reports.

A **follow-up webinar** may be organised before the xShare project ends in November 2026 to assess progress and deepen collaboration.

[27] https://tehdas.eu Accessed 14 July 2025.
[28] https://united4surveillance.eu Accessed 14 July 2025.