"ONLY ONCE" BEST PRACTICE USE CASE: BELGIUM

XShare WP4

Principal editor: Sasha Milbeck– SCIENSANO

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Abstract

Belgium's federated health system presents both challenges and opportunities for digital transformation and standardization. The Health Data for Data Providers (HD4DP) application is an ambitious effort to harmonise data flows from clinical care to secondary use. Successful during the COVID-19 pandemic, HD4DP enabled standardised and timely data transmission for surveillance and early response. Yet, in the years following the pandemic, when applied for less "urgent" and "incentivized" health manners, its enforcement faced backlash and revealed structural tensions between fragmented electronic health record (EHR) systems, and expectations of data for clinical versus research and policymaking purposes.

This report aims to outline Belgium's health data standardisation journey. Interviews with clinicians, researchers, and technical experts shed light on issues such as reliance on free-text documentation, limited vendor interoperability, and lack of end-user incentives hindering adoption of standardization techniques. The example of the HD4DP application serve as a lens to examine broader governance, semantic alignment, and European Health Data Space (EHDS) preparedness in Belgium.

Introduction

Background on xShare Project

This report forms part of a deliverable for Work Package 4 (WP4) of the European xShare Project. xShare is a 3-year Horizon Europe Project (2023-2026) supporting the design of the European Electronic Health Record Exchange Format (EEHRxF) and the xShare "Yellow Button."

The xShare yellow button will allow patients to share their health data with care providers on health portals and patient apps, and exercise their data portability rights under the GDPR. The data shared is anticipated to be harmonised, structured, and coded in the EEHRxF. The EEHRxF, introduced by the European Commission in 2019, is a set of technical requirements and specifications to ensure secure, interoperable, cross-border exchange of electronic health record (EHR) data across the EU. The format currently focuses on six priority categories of personal electronic health data for primary use as defined in the European Health Data Space (EHDS) regulation approved on April 24, 2024:

1. Patient summaries
2. Electronic prescriptions
3. Electronic dispensations
4. Medical imaging studies / related imaging reports
5. Medical test results, including laboratory and diagnostic results and related reports
6. Discharge reports

Within xShare, WP4 aims to identify best practices across EU member states in already promoting health data reuse through methods similar to the foreseen EEHRxF and following the "only once" principle. The philosophy of "only once" is to ensure that data collected is good-quality and can be reused for numerous purposes, thus reducing administrative and financial burden of data collection. An example of this exists in Belgium and is the focus of the following report. The Health Data for Data Providers (HD4DP) application is a system developed by Sciensano and RISIV/INAMI to improve

standardisation, reduce administrative burden, and align health data reporting with both national and European objectives.

Background on Belgian eHealth Strategy

Belgium's public health data domain, particularly around interoperability in health records and laboratory data, reflects a fragmented but ambitious history shaped by regional and national policies, as well as European initiatives. Due to the country's distinct regional federated structure, hospitals and laboratories in different regions in Belgium (Flanders, Wallonia, and Brussels) developed their own systems and standards without standardised national data formats or protocols. The lack of interoperability between regional systems made it challenging to create cohesive national standards and efficient systems to collect data that can be processed and reused more than once.

A better alignment between primary and secondary use of data has been discussed quite early in the Belgian Digital Health journey. In 2012, the first Digital Health roadmap was created through a co-creation process inclusive of all stakeholders of the value chain. This process led to the description of 20 SMART actions. Action 18 was dedicated to the inventory and consolidation of all datasets in the context of secondary use. Multiple new data collection initiatives had been launched, often without coordination between them, and as consequence, resulted in a new burden for the healthcare organisations and professionals. Hence, the very rationale of this action point was to rely as much as possible on an "only once" strategy where data for secondary use would be captured as much as possible from existing EHRs. The action point mentioned the following priorities:

- The creation of a detailed inventory of all existing registers and databases by Sciensano. This inventory had to provide a precise description of the data fields collected, their status (optional or not), their format, the codifications (proprietary or not) used, the type of user and institutions concerned as well as any other essential contextual information.
- The establishment of governance rules for the creation of any new register which would require the consideration of data available in EHR systems as apriority.
- The systematic adoption of standardised system-to-system communication protocols and the gradual phasing out of dedicated data collection platforms tied to specific datasets in the mid-term

During the first revision of the action plan in 2015, it was specified that the datasets in question are not limited to those managed by Sciensano but should also encompass datasets created to support epidemiology, vigilance and quality of care. The revised plan also provides significantly more details on the 13 sub-actions required to achieve its goals. The Healthdata.be platform is mentioned for the first time, with the HD4DP connector identified as a key channel for implementing the "only once" strategy. Additionally, new types of data, such as Next Generation Sequencing (NGS), are considered. Among other initiatives, the extended use of a Belgian adaptation of the Dutch Clinical Building Blocks, referred to as Care Sets, was planned, along with the adoption of SNOMED CT concepts for all values supported by these building blocks. However, these efforts have not yet resulted in practical implementation, though the rollout of Care Sets is expected to occur soon. Very significant progress has however been achieved to create a structured and governed connection between primary and secondary use.

Today, Belgium has placed a strong focus on improving coordination and interoperability across its regional healthcare systems and supporting centralised and standardised data registries and warehouses. A central component of this effort is healthdata.be, a collaborative initiative between Sciensano and the National Institute for Health and Disability Insurance. To support these goals, healthdata.be developed the Health Data for Data Providers (HD4DP) application. This report

examines how hospitals and laboratories are interacting with this application, shedding light on the challenges they face and the successes they have achieved.

Methodology

This report forms part of a deliverable for Work Package 4 of the European xShare Project, which seeks to document best practices across EU member states in implementing the "only once" principle and explore how the European Electronic Exchange Format (EEHRxF) can support data reuse, standardisation, and interoperability. This report focuses on one specific application used for data collection and standardisation in the Belgian health data landscape: the Health Data for Data Providers (HD4DP) application developed by Sciensano and RISIV/INAMI. The goal is to understand the purpose, technical infrastructure, and user's feedback of the application, to better understand the Belgian health data ecosystem and data producers' and users' opinions on data standardization to support primary and secondary use of health data.

For the report, a qualitative multi-stakeholder methodology was implemented. In-depth semi-structured interviews were conducted with key stakeholders including:

- Researchers using HD4DP for data collection in laboratory and hospital settings
- Technical experts from healthdata.be involved in the deployment, maintenance, and support of the HD4DP platform
- Chief Medical Offers (CMIOs) and clinicians at Belgian hospitals and clinics
- ICT experts and national representatives from standards organisations responsible for health data governance and semantic interoperability

Interview questions were tailored for specific stakeholders but broadly focused on system integration, data quality, administrative burden, standardisation efforts, and the perceived value of the HD4DP application in clinical, laboratory, and research contexts. The qualitative data were analysed to extract common themes, technical challenges, and insights related to the implementation of HD4DP and its alignment with Belgian eHealth priorities.

The findings discussed in this report reflect these stakeholders' perspectives and aim to provide an outline of Belgium's current efforts to standardise health data, while identifying how the EEHRxF and European Health Data Space (EHDS) could streamline improvements in data sharing and governance.

National Roadmap

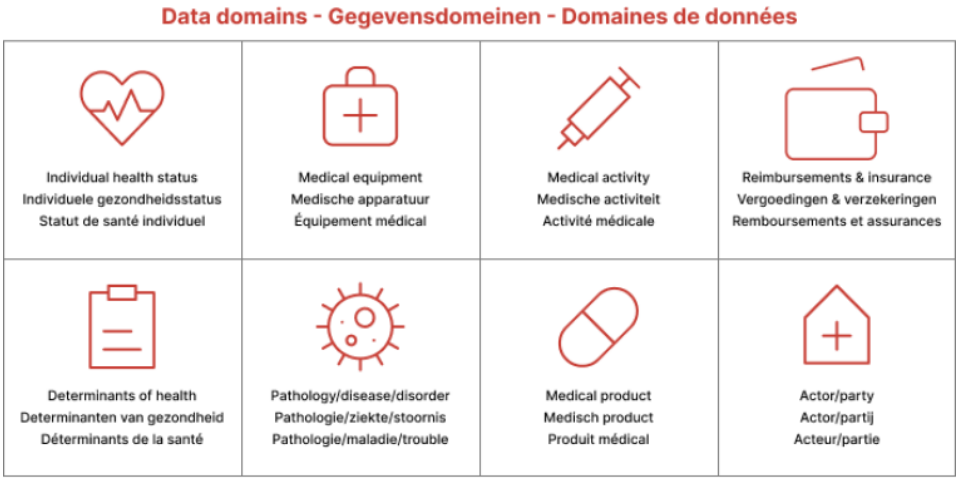
The lack of national standardisation became a key policy issue in the early 2000s, resulting in the Belgian government establishing the eHealth platform in 2008, with the goal of improving coordination and interoperability across the country's regional healthcare systems. To this day, the platform provides a central organisation to coordinate digital health initiatives and secure data exchange across Belgian health systems, and in line with European frameworks.

Most recently, Belgium has committed to digitalising health spaces, in alignment with the European Commission's 2019-2024 political priority 'A Europe for the Digital Age' and the creation of the European Health Data Space (EHDS) that serves as a secure, interoperable, and privacy-respecting digital health landscape. The creation of the Belgian Health Data Agency (HDA) in 2023 strives to facilitate the use of health data for secondary use, and prepare Belgium for interoperability and compliance with the EHDS and European legal requirements. The HDA and EHDS alike facilitate

reliable, standardised, and secure data usage and exchange, and support innovation in the European digital health landscape.

Central inventory of registries and metadata used to categorise them

The Health Data Agency (HDA) has introduced a comprehensive data catalogue that aims to make data findable, accessible, interoperable, and reusable (FAIR) for secondary use. The HDA catalogue is a centralised repository that stores metadata about Belgian health data sets. The catalogue currently holds around 250 datasets provided by the Federal Agency for Medicine and Health Products (FAMHP), Federal Public Services for Health, Food Chain Safety, and Environment (FPS Health), Flemish Authorities, the National Institute for Health and Disability Insurance (NIHDI), and Sciensano. The metadata provided is then organised into 8 domains:



Another Belgian initiative that is meant to centralise and standardise data registries is Healthdata.be, a dual platform between the NIHDI and Sciensano. The objective of the platform is to provide users a secure and efficient data warehouse that prioritises single collection of multifunctional data that can be used to increase population health knowledge and improve healthcare management in Belgium. In accordance with Belgian's e-Health action plan of 2013-2018, the project created an inventory of registers in 2014 and since then more than 160 databases have been registered. The registers collect information gathered from Belgian hospitals, laboratories, physicians, and patients, and aim to provide health professionals and researchers an up-to-date insight on diseases and health care in Belgium. The data can be accessed via web with search function healthstat.be.

Belgium also offers more specific registers such as the Belgian Cancer Registry (BCR), which is a national, population-based registry that has been collecting data on cancer incidence since 2004. Hospitals with oncological care programs and offering basic cancer care, along with pathological anatomy/clinical biology/haematology laboratories are legally required to cooperate in cancer registration and register all test results corresponding to a cancer diagnosis according to specifically established standards and guidelines. These data are transferred and collected by BCR in the form of structured datasets. Additionally, the BCR maintains a central cyto-histopathologic register, for which it receives certain test results from Belgian laboratories to assist in the early detection of breast, colorectal, and cervical cancer. The BCR has the legal duty to collect, validate, make accessible, and protect cancer data in Belgium. The registry offers frequent information sessions for healthcare providers to ensure compliance and proper handling of the data.

Strategy established to map semantic resources and avoid unnecessary misalignment

Belgian Care sets

The Belgian e-health action plan has identified "multidisciplinary electronic exchanges" as a top priority, and several initiatives have since began developing and implementing solutions via structured, standardised, and codified "care sets." Care sets are Belgium-specific information packages structured for data exchange between healthcare providers. Each care set consists of a logical functional model tailored to healthcare needs, Hl7 FHIR profiles for technical interoperability, predefined value sets coded with SNOMED CT and LOINC, and business rules for data use based on real-world cases.

Care sets support the "only once" strategy that emphasises minimising data redundancy and avoiding misalignment. Care sets advance this principle by structuring data into reusable modular blocks that can be configured for multiple use cases, storing structured data in secure vaults and focusing on centralisation, and supporting interoperability by facilitating seamless data sharing between hospitals, general practitioners, and patients.

The care sets are organised as part of the Be-Safe Share Project (Belgian Coordination Authority for Secure, Standardised, Multidisciplinary Health Data Exchange) which aims to structure and standardise primary care information, and promote data reuse. Data are exchanged within country via Belgian regional vaults (Vitalink for Flanders, Brussels Health Network for Brussels, Réseau Santé Wallon (RSW) for Wallonia). The project is led by INAMI-RIZIV in coordination with the e-Health team and the Belgian Terminology Center.

Care sets are the precedent for corresponding Belgian HL7 FHIR profiles, which is the multidisciplinary data exchange standard adopted by the Belgian eHealth plan as of 2019. Care sets also use the national value sets of SNOMED CT (and LOINC for laboratories), the international healthcare terminologies chosen by the Belgian eHealth plan since 2013. Due to official Belgian translations of SNOMED-CT through the value sets, providers and patients are able to receive automatic translations of health information exchanged across Belgium in their language of choice. Care sets aim to reduce misunderstanding, promote semantic interoperability, and support single encoding of data. The only two care sets that are ready for publication at the moment are for vaccinations and allergies, but more care sets are being developed and are anticipated to be made available in the upcoming year.

Future Strategy and Goals

Belgium aims to continue to align their health data and support greater standardisation within the country. Specifically, the creation of a Belgian Integrated Health Record (BIHR) has been identified as a top priority for 2025-2027. Rather than creating a new electronic patient record (EPR) for patients, the BIHR aims to provide a cohesive, interdisciplinary IT framework that connects a patient's different health and social data. The BIHR aims to integrate patient data into a personalised dashboard that brings together all of their health data, allowing the patient to better understand their health status and make informed decisions about their care. The dashboard will be secure, standardised, and safely store health data that patients and their relevant healthcare providers can access.

Initiatives launched to avoid duplication of data and collect data from primary systems

Health Data for Data Providers (HD4DP)

Health Data for Data Providers (HD4DP (currently version 2.0)) is a data collection application used by healthcare providers in hospitals and laboratories for the recording of health and healthcare data. Installed locally at hospital sites and laboratories, it enables the secure and standardised submission of medical data. The software is maintained by the healthdata.be platform within Sciensano.

Technical Architecture and Installation of HD4DP

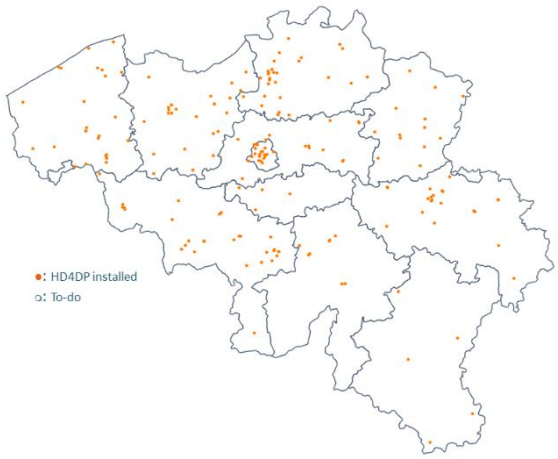
The HD4DP 2.0 Local is an electronic data capture (EDC) system: a computerised system designed for the collection of clinical data in electronic format for use in research supporting human public health policy. The application is meant to replace traditional paper-based data collection methodology and streamline data collection, analysis and reporting.

HD4DP 2.0 local application contains the following components: NextGen Connect, Form.io, HD Connect (LOCAL Proxy), and Local data warehouse. All components work together to translate standards, support more efficient API development, store data securely in localised data warehouses, and ensure that data is in the correct formats for reporting and extraction. Additional technical details of the HD4DP application can be found here.

The software is provided without cost and installed remotely on the infrastructure of the healthcare organization by healthdata.be. Healthcare organisations are provided the system requirements for installation of HD4DP 2.0. The application is then maintained without cost remotely on the infrastructure of the healthcare organization by healthdata.be. The infrastructure on which the application HD4DP v2 Local is installed, should be maintained by the healthcare organisation.
The technical components that must be present at the data provider to participate in the data collections of the healthdata.be platform are:

- primary operational systems of the data provider (e.g. electronic medical record, laboratory information management system,...)
- HD4DP software of the healthdata.be platform
- an encryption module
- sending client for the eHealthbox,
- eHealthbox

Except for the HD4DP software and the encryption module, the other components are mostly already present in hospitals and laboratories. HD4DP software is usually installed by the healthdata.be team in hospitals and labs.

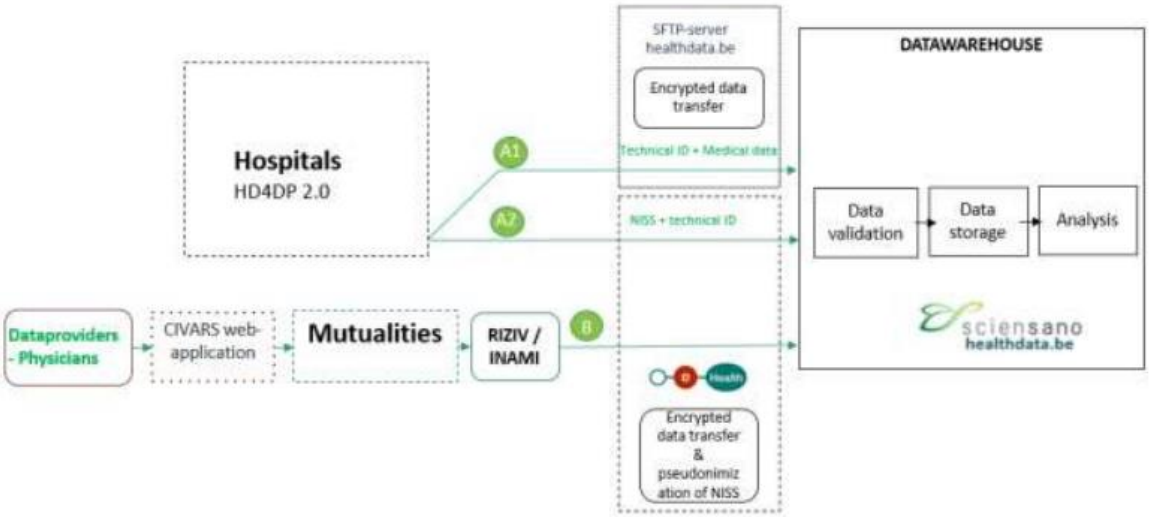


Data Extraction Using HD4DP

Data can be submitted to the application via: Manual entry, CSV upload, or through an API integration. Then once data is in the HD4DP 2.0 application, data is split into two streams:

1. Patient Data: Transmitted through eHealth, where the patient's ID is pseudonymised. Healthdata.be only receives a technical identifier to ensure patient anonymity.

2. Medical Data: Sent via SFTP and tagged with the technical identifier. This allows the pseudonymised patient ID and medical data to be later combined for research purposes.



Once data is uploaded – typically via CSV files exported from EHRs or web service integrations – it enters a validation phase. This automated validation checks mandatory fields and overall data quality. If issues arise, researchers sent a validation request with comments, which hospitals must address before the dataset is accepted. Hospitals contribute metadata about their datasets, including institutional identifiers and pseudonymized patient IDs, supporting quality control and traceability.

After proper collection, the data is stored in the healthdata.be data warehouse and made available for research purposes to approved clients such as Sciensano researchers, scientific organisations, pharmaceutical companies, and universities. Clients seeking access to healthdata.be data must submit a formal request form and undergo an internal assessment to ensure the project aligns with healthdata.be's scope and procedures. This structured process ensures transparency, compliance, and alignment with institutional priorities.

HD4DP Under EHDS

It is expected that HD4DP will be phased out as Belgium aligns its infrastructure with the European Health Data Space (EHDS). Technical architects are currently developing the successor platform, which will integrate international standards such as HL7 FHIR and SNOMED CT. Until then, HD4DP versions 1 and 2 remain in production, with version 2 offering superior speed and architectural capabilities.

Laboratory use of HD4DP application in the context of the Epilabo Project

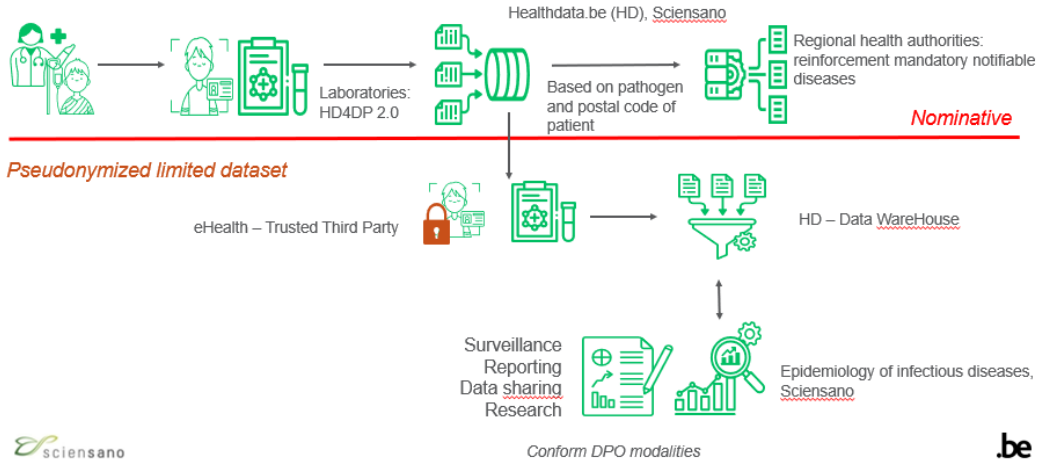
Epilabo is a project aiming at collecting laboratory test results from a network of sentinel microbiology laboratories in order to monitor the epidemiology of various infectious diseases in

Belgium. The project has been operating since 1983 through Sciensano and relies on the voluntary participation of laboratories across Belgium in weekly submitting diagnostic data for 40 + pathogens. Epilabo aims to improve public health through monitoring epidemiological trends and detecting potential outbreaks, assessing the impact of prevention programs, predicting the potential spread of infectious diseases, and reporting data to international health authorities. Epilabo is a part of the European project EU interoperability with HERA's IT platform (EU-HIP) that develops new IT systems as well as strengthens and enhances existing national IT systems for improving health threat assessment in European countries.

COVID-19 as an enabler for the Epilabo project

During the pandemic, laboratories transmitted daily nominative COVID-19 data to healthdata.be, where the data was standardised and forwarded to regional health authorities, enabling them to trace positive cases back to individual patients. The data was then also pseudonymised and made accessible in the healthdata.be data warehouse and within Sciensano's Epidemiology and Infectious Diseases service. This facilitated the secondary use of the data for research, reporting, and surveillance purposes.

The enhanced data collection process implemented during the pandemic was supported by a technical application developed by healthdata.be called Health Data for Data Providers (HD4DP 2.0). This application enables System-to-System (S2S) transfer of JSON files via an API, ensuring real-time, standardised data exchange that can be efficiently distributed to relevant stakeholders. The application uses the Belgian Preparedness Architecture for Infectious Diseases (be.Prepared), which is designed in response to the need for one central data retrieval for exchanging personal data concerning public health.



Currently, Epilabo has only used this application in the scope of the COVID-19 pandemic, but is gradually hoping to use it in the future for other pathogens in the scope of initiative Epilabo 2.

Epilabo 2: Improving data collection and standardisation

The goal of Epilabo 2 is to build on experience obtained during the COVID-19 pandemic for a sustainable Epilabo data collection. The project aims to:

- implement a system where data is extracted weekly from laboratory systems and sent to healthdata.be
- ensure a consistent weekly update in healthdata.be's data warehouse
- standardise laboratory data, and encourage laboratories to adopt LOINC codes

- facilitate the mapping of data to international SNOMED codes, enhancing interoperability and usability for research and analysis
- collaborate with Belgian authorities on initiatives that incentivise the use of LOINC and HL7 FHIR standards to improve interoperability across healthcare systems.

Further Integration with Healthdata.be and HD4DP

HD4DP 2.0 has yet to be fully implemented for Epilabo. During the COVID-19 pandemic, laboratories were mandated to use the infrastructure and were financially incentivised through payments tied to the number of tests reported. However, in the current context, the rollout for Epilabo requires laboratories to adapt their systems to extract data in the appropriate format and integrate with HD4DP 2.0. This process is both time-intensive and lacks the financial incentives that facilitated rapid adoption during the pandemic. However, pilot projects with two experienced laboratories will commence in January 2025 to test the feasibility of using HD4DP for Epilabo. These pilots will provide valuable insights into the practical challenges and time requirements for full implementation.

Clinician Feedback on the HD4DP Application

Interviews were conducted with clinicians and medical information officers at Belgian hospitals. All were asked to share their experience using the HD4DP application and offer insight on suggestions for improved interoperability between data for primary use (treatment of patients) and secondary use (research, surveillance, and policymaking for Belgian authorities).

Overall, despite increasing use of EHRs, clinicians often rely on free-text documentation, which remains preferred for capturing complex medical narratives. However, this practice limits data reuse due to lack of structure and terminological consistency. Many clinicians lack sufficient training or awareness regarding data exchange standards and formats (like SNOMED CT), and the implications of the EHDS, which contributes to inconsistent data capture. Without clear benefits in their daily practice, clinicians remain hesitant to shift to structured documentation.

The key reasons for this are as follows:

Data entry into the HD4DP application takes more time.
Clinicians feel that filling out the application diverts time from patient care, and they are burdened by mandatory compliance without adequate tools for implementation. Hospitals prioritise care production over administrative tasks such as filling out the application. This can create a conflicting paradigm for clinicians who are required to fill out HD4DP to avoid payment delays but also are constrained by hospital mandates and the need for quick production of care. Only recently has the responsibility of data input and coding for registers become a requirement for clinicians rather than designated data providers at hospitals. Thus, there is a natural resistance to change and a need to reorganise responsibilities between the different actors of hospital information systems to ensure that neither quality of care or quality of data are jeopardized.

Clinicians argue that inefficiency arises from re-encoding data that has already been documented elsewhere, and the application requires submission of data that clinicians do not routinely collect for primary use and treatment of their patients.
In many hospitals, other parallel data collection systems are still in place and some registers have not yet been integrated within the HD4DP application. Additionally, some registers ask for data not commonly collected by EHRs, which makes it difficult for data providers to successfully fill in the register. Given this, in order for hospitals and clinicians to maximise the use of the HD4DP application,

it is vital for data producers to align data models and terminologies, and have specific guidelines on what information is needed and how to properly encode it.

Improper integration between HD4DP and electronic health record (EHR) systems forces manual data re-entry for clinicians.
Clinicians argue for better integration of EHR systems in the HD4DP application, and a streamlined process to extract and transfer data between systems using different terminologies. A key area of concern was that misalignment of data models, terminology standards, and exchange formats between clinicians' databases, EHR software, and HD4DP leads to lack of interoperability and harmonisation of data. Unfortunately, many EHR vendors resist aligning with international standards like SNOMED CT or HL7 FHIR, limiting interoperability and data reuse. Some even monetize data exchange, charging hospitals per data element. Without binding regulations, vendors deprioritize integration, creating silos and redundant work for clinicians. This undermines the goals of initiatives like HD4DP and the EHDS and highlights the need for certified, standards-compliant systems.

Guidance for Improvement

While at its core, HD4DP is meant to facilitate the only once strategy and bridge the gap between primary and secondary use of data, some improvements are needed to support clinicians and data providers.

Single input, multiple output
Clinicians emphasise the importance of a unified data entry system that supports both primary and secondary data use cases. This can be facilitated by greater adoption of international standards. Many hospitals are already using SNOMED CT, LOINC, ICD-10 and OMOP CDM terminology standards, and HL7 FHIR for data exchange. Universal adoption and push for international standards can support interoperability and ease data production for care providers.

Clear guidelines and support
Greater collaboration between care providers, EHR developers, and federal authorities can streamline data collection and support both primary and secondary use cases. Initiatives such as the Belgian Terminology Center and the Community Support for Clinical terminologies (CSCT) aim to support healthcare professionals in standardisation and understanding the benefits of using international terminology such as SNOMED CT.

Key messages regarding HD4DP and data standardization for primary and secondary use

HD4DP exemplifies Belgium's effort to standardise and streamline the process of acquiring data from EHRs through a unified application. However, clinician feedback highlights the urgent need for greater harmonisation across systems. The fragmentation within the Belgian healthcare system could be mitigated by adopting international standards and data exchange formats, such as those proposed by the EEHRxF. With the support of Belgian authorities, and the current evidence of hospitals pushing for the use of international standards such as SNOMED CT and OMOP CDM, Belgium stands to significantly benefit from the implementation of the EEHRxF. Changes are essential to ensure that data collection systems are interoperable, prioritise patient care, and alleviate the burden on data providers.

Conclusion

To ensure lasting change, Belgium must address the knowledge and skills gap among clinicians and technical experts, incentivize structured documentation, and enforce vendor accountability for interoperability. A unified governance strategy with shared standards, medical education reform, and visible return on investment for clinicians are essential for realising the “only once’ principle in practice.

Belgium’s progress towards standardising health data systems offers both challenges and achievements. The country continues to address fragmentation by implementing national platforms and aligning with international terminology standards and data exchange formats. Efforts to centralise data collection systems, ensure semantic interoperability, and minimise data redundancy are key to improving data quality and usability.

The HD4DP application can be presented as an example of Belgium’s dedication to bridging the gap between primary and secondary use. However, based on the feedback from hospitals and laboratories working with the application, it is evident that greater priority needs to be placed on using international standards and simplifying data entry for users.