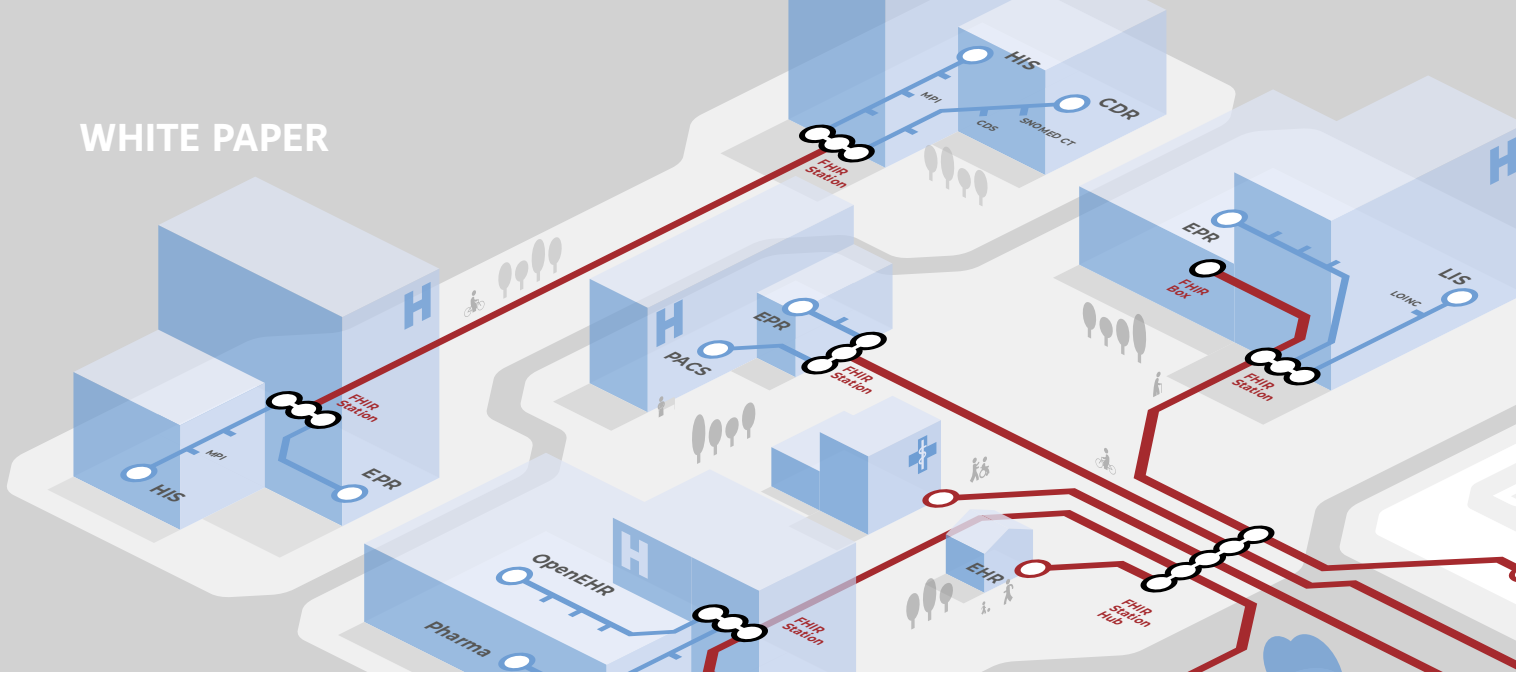




Getting started with FHIR: why and how to approach it?



Healthcare organisations generate vast amounts of data every day, and the need to make use of this data is rapidly growing. Whether for patient care, improving efficiency, informing policy decisions, or conducting research, the demand is growing exponentially. New laws and regulations are further driving this trend. As a result, healthcare organisations are increasingly required to share data with external parties and systems.

It goes without saying that this is a complex challenge. Working with patient data, which is inherently sensitive, means you must adhere to strict privacy regulations. Additionally, the various types of data involved each require a different approach and must be exchanged in a standardised manner. Moreover, efforts to make this data accessible will continue to intensify in the coming years, while resources will remain limited. All this means an ad hoc approach is unsustainable in the long term.

It is therefore crucial for healthcare organisations to thoroughly prepare and develop a thoughtful, structured and forward-looking data sharing strategy.

In this white paper, you will learn:

- The current challenges in data sharing
- How the FHIR standard can facilitate smooth and structured data sharing
- Why it is essential to start exploring the potential of FHIR now
- Amaron's vision for transmural data sharing
- Practical examples of how this can be done

Challenges in transmural data disclosure

The healthcare sector strives to fully harness the potential of the vast amounts of data available, not just for patient care but across a range of other applications.

In this context, we can differentiate between primary and secondary uses of data:

- **Primary use:** This involves the generation and utilisation of data within hospitals and medical facilities to meet the direct care needs of individual patients.
- **Secondary use:** This refers to the use of clinical data for purposes beyond individual care, such as the operational management of healthcare facilities, support for government policies, clinical research and more.

The demand for sharing information with external parties is rapidly increasing for both primary and secondary data use. As a healthcare organisation, you are expected to share data with:

- Other healthcare organisations
- Healthcare professionals in the field
- Patients
- The government
- Other stakeholders such as pharmaceutical companies or providers of AI applications and health apps

This data exchange presents several complexities, including:

- The **diversity of data types** stored across **numerous sources**, ranging from structured to unstructured data (such as free text). Even when information is structured, it is often not coded or standardised, which is essential for clear and consistent interpretation.
- Handling **sensitive patient data** requires ensuring that only the necessary information is shared and that it does not fall into the wrong hands.
- There are necessary precautions to take regarding **patient privacy and data security**, and the processes established for these purposes must be monitored and documented.
- Laws and regulations aimed at closing loopholes are becoming increasingly stringent and are subject to change. As a healthcare organisation, you need to be **able to adapt to these changes** smoothly.

FHIR: part of the solution

HL7® FHIR® (Fast Healthcare Interoperability Resources) is the latest HL7 standard, and is increasingly being used to exchange health data in a consistent and structured manner.

Sometimes called 'the new HL7 v2', FHIR is a comprehensive and straightforward standard for data exchange. Modular and flexible, it is differentiated from its predecessors by its use of modern web technology.

The FHIR data model is customisable, giving developers a range of implementation options. However, this flexibility means that both robust governance and clear agreements within healthcare institutions are essential, especially if FHIR is to be deployed on a larger geographical or national scale. In terms of flexibility, FHIR differs from OMOP and openEHR, which focus more on the data model and less on the exchange standard.

FHIR is suited to all forms of data communication in healthcare. Its easy-to-use, web-based technology presents significant opportunities for mobile apps and other internet applications for patients and healthcare providers, whether in hospitals, at home, or in the field. Governments in an increasing number of countries are also recognising the benefits of FHIR and are advocating for its use in health information exchange¹.

Modern web technology

FHIR's strength lies in its flexibility and simplicity. Unlike HL7v2, FHIR employs modern web standards such as RESTful APIs (Application Programming Interfaces), JSON (JavaScript Object Notation), and XML (eXtensible Markup Language), enabling data to be shared openly and in a user-friendly way.

While FHIR does not build on HL7v2 technologically, it does incorporate the functionality and healthcare content of the earlier standards.

Resources and attributes

FHIR organises various aspects of health information using standardised building blocks called 'resources'. These can pertain to doctors, patients, admissions, medications, diagnoses, laboratory results, appointments, treatments and more.

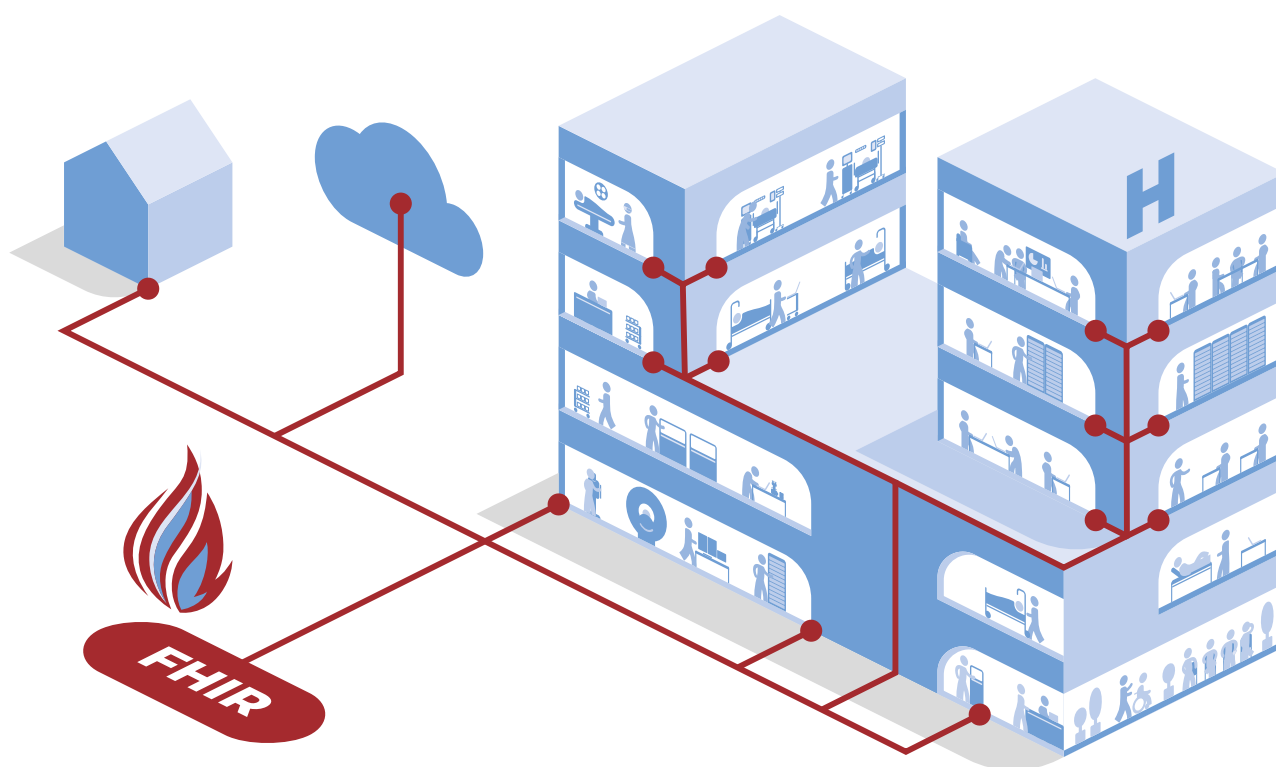
Each resource has a unique identifier and is structured according to a common set of data elements or 'attributes'. Resources may also have relationships with each other. For instance, a 'Condition' resource might refer to a specific patient and indicate their medical condition. Such references help connect related data, creating a more comprehensive picture of a patient's health.

¹ https://health.ec.europa.eu/document/download/8d34b6f6-a7e0-462a-9fc0-4812f3c1175c_en?filename=ehealth_20230330_sr_en.pdf&prefLang=hr

Why FHIR?

- FHIR is a modern standard that enables health information to be exchanged in a consistent and structured way between healthcare providers across various settings (e.g., hospitals, rehabilitation centres, home care) and with external parties such as the government and software vendors.
- FHIR ensures interoperability. Terminologies such as LOINC, SNOMED CT and ICD, which provide a 'unity of language', are closely linked to FHIR, ensuring semantic consistency.
- Data exchange via FHIR supports common data models, such as storing data in OMOP format or in data lakes such as Azure.
- FHIR is ideal for mobile technology and integrating different applications and devices.
- Developers can easily learn the technology, even with limited experience in healthcare or integrations. They can work with a RESTful web service more quickly than with FTP or TCP/IP socket (MLLP)-based communication of a text file with an unreadable structure. Moreover, extensive documentation is available through a large international community.
- Despite its relative simplicity, the FHIR standard is comprehensive enough to allow for a customised approach.
- FHIR reduces the complexity and costs traditionally associated with developing and managing health information exchange applications.

Read more about FHIR:
<https://www.hl7.org/fhir>



Why start with FHIR now?

In 2019, the **United States** issued the **Information Blocking Rule** to promote innovation in healthcare. Part of the 21st Century Cures Act, it requires healthcare organisations to exchange data amongst themselves, while electronic health records (EHRs) must facilitate this exchange. This has significantly boosted the adoption of the FHIR standard.

In **Europe**, the **European Health Data Space (EHDS)** was adopted in early 2024. The aim of EHDS is to optimise the use of available health data for both patient care (primary data use) and research (secondary data use). FHIR will play a key role in achieving this.

However, several European countries did not wait for EHDS to launch various FHIR initiatives:

- The Belgian government has embraced FHIR, e.g. for unlocking laboratory results and referral prescriptions.
- In the Netherlands, FHIR is used by MedMij for data exchange between healthcare providers and patients. Additionally, FHIR is employed for birth care (BabyConnect) and eOverdracht². The IZA implementation agreement for national data sharing and reuse has also been ratified. The exchange of a defined set of core data (mandatory from 2025 for healthcare providers and suppliers) will also take place via the FHIR standard.

Moreover, numerous European hospitals are running initiatives and projects to explore the possibilities of FHIR. This is beneficial, as it allows them to build in-house knowledge and prepare for new laws and regulations that will mandate the use of the FHIR standard in several domains.

Healthcare organisations that miss this opportunity risk falling into a new point-to-point chaos, with a tangle of integrations between individual systems, reminiscent of what was seen a few decades ago. Such a situation could make it cumbersome to comply with data privacy and security regulations.

Other institutions that have not adequately prepared may be tempted to make hasty purchasing decisions, leading to the acquisition of multiple overlapping solutions or of a disproportionate solution, potentially driving up costs unnecessarily.

By experimenting and gaining experience now, healthcare organisations can make informed decisions and purchase systems tailored to their specific needs.

² eOverdracht (eTransfer) is an information standard for the nursing handover. This includes agreements on what data is relevant for the handover and how it should be registered in the electronic health record.

Amaron's vision for transmural data sharing

Hospitals today often manage data-sharing projects on an ad hoc basis, but this approach is time-consuming and labour-intensive. As more projects arise, the efforts will inevitably expand, while resources remain limited. A broader, forward-looking approach is essential.

Building on our existing solutions for interoperability and process automation, we at Amaron have developed an integrated data access solution. This solution enables healthcare organisations to initiate projects and unlock data from their existing sources (whether FHIR-, XDS-, openEHR- or OMOP-based) quickly and in a controlled manner, using HL7, FHIR or another format.

This modular solution consists of the following components:

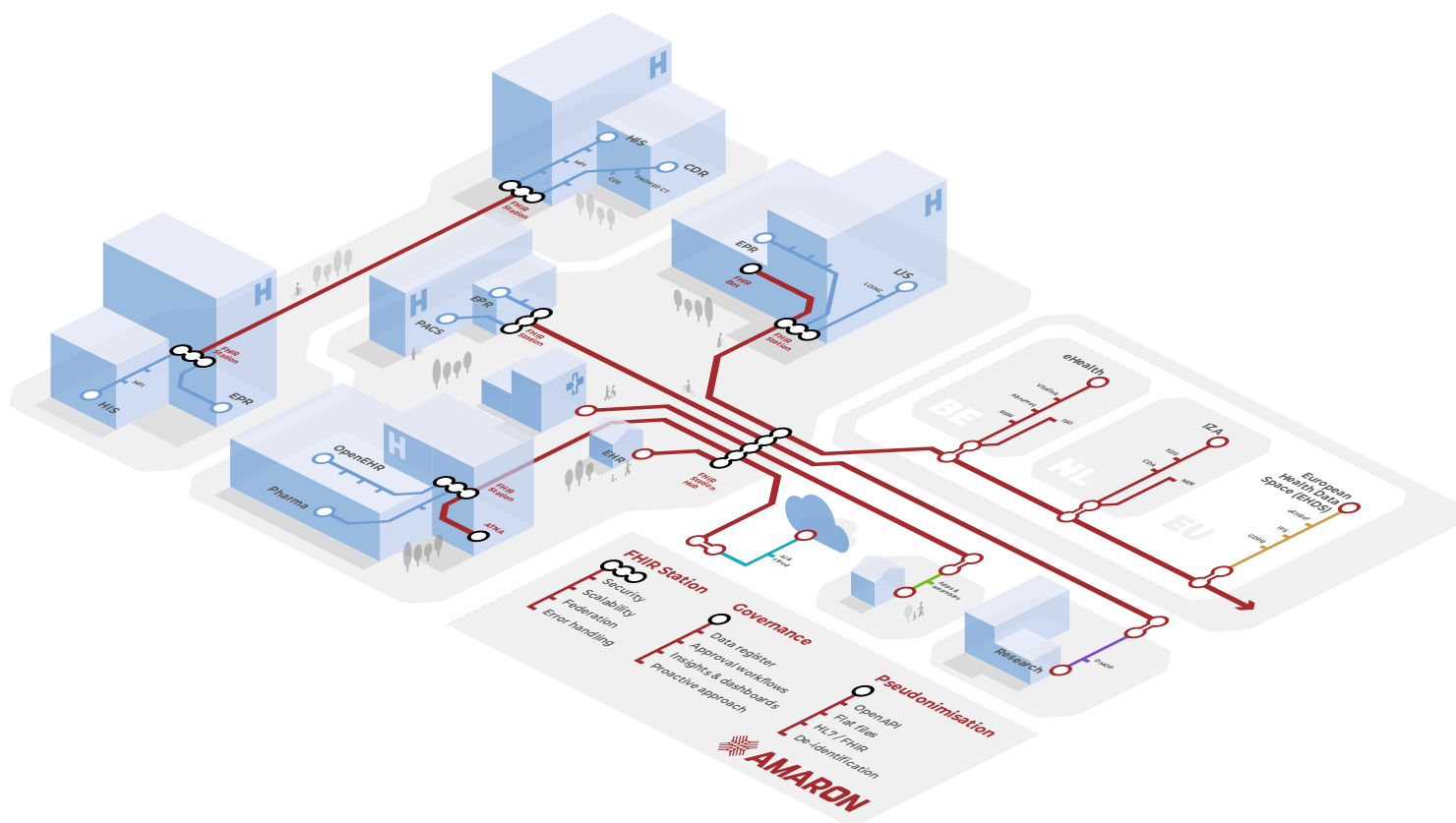
1. FHIR Box

The FHIR Box serves as a **data repository** in which information is stored in FHIR format:



- It allows you to capture data from other information systems in a structured and unambiguous way.
- All processes follow a web-based approach, enabling the stored information to be accessed and exchanged efficiently.

Additionally, our portfolio includes solutions to translate streams of HL7 v2 messages (ORU, ADT and SIU) into FHIR resources, ensuring they are made available in a high-quality manner according to the needs of modern healthcare systems.



2. FHIR Station

FHIR Station acts as a central point of contact for opening up various data sources within your healthcare organisation to applications and services that support FHIR.



- With FHIR Station, you can query existing sources (FHIR Box or others) online, **without duplicating or storing data**.
- You can feed the underlying FHIR Box or other FHIR repository accurately and in a verified manner, ensuring that you are always working with **high-quality data**.
- **You share only the strictly necessary information.** A clear interface allows you to define in detail, for each project, which data you are sharing, from which source, and with whom. For example, you can granularly unlock specific patient data linked to hospital admissions within a specific period. If necessary, you can even **pseudonymise** the data (see point 4).
- All interactions with FHIR Station are carefully recorded in a **central ATNA-based audit component**³.
- This ensures that you can trace all incoming and outgoing data streams, and know exactly who accessed patient-sensitive information, why, and in what manner. If abnormal behaviour is detected, you can intervene immediately if needed.
- The solution offers **rigorous security** in accordance with the OAuth 2.0 industry standard, with attribute-based security that determines whether access to specific information sources can be granted.
- A **powerful support tool** clearly indicates errors or anomalous results. Logs provide insight into which query or connection is failing, along with detailed information to help you resolve the issue.
- FHIR Station is **scalable**: as your projects increase, you can expand the solution step by step. The advanced settings allow you to run **federated queries**, i.e., send out **queries to multiple data sources and receive the results in a consolidated format**.

3. FHIR Station Hub

FHIR Station Hub is an extension of FHIR Station, ideally suited for **regional or national use**. In addition to the functionalities of FHIR Station, FHIR Station Hub offers several additional features:



- It enables the management of data exchange over a **larger geographical area** as well as queries of a wide range of connected FHIR sources in a **controlled** manner.
- It supports the ability to direct queries based on **regional registers**, enabling highly efficient consultation of connected data sources.
- If desired, before sharing any information, it can communicate with external software systems that register **therapeutic relationships and patient consent** for health data sharing.

³ Audit Trail and Node Authentication (ATNA) is an international standard for securing and accounting for communication between healthcare systems by logging key actions and authenticating systems. It includes security measures such as encryption and access controls to protect patient data during transmission and storage. It also complies with international standards for security and data protection in healthcare.

4. Pseudonymisation

Whether you are working with structured datasets or unstructured information, patient privacy must never be compromised. That is why we offer **robust algorithms**

that allow you to efficiently remove patient identifiers from the data you share. If re-identification is necessary, the data can be linked to a unique code (pseudonym) that can only be traced back to the individual by authorised users under strict conditions.



- You can configure the pseudonymisation as required, for both medical and administrative data (HL7, FHIR, DICOM, CSV, etc.).
- Separate keys are applied for each project, ensuring that patients appearing in multiple projects cannot be linked to the same identity.

The pseudonymisation component is part of FHIR Station and FHIR Station Hub, but it is also available as a separate module to pseudonymise data from other sources and in other formats (such as HL7).

5. Governance module

This module allows you to **define, automate, enforce** and **document** the entire governance process for each project:



- How does the approval process work? Who is involved (DPO, legal department, ethics committee, etc.)? Which tasks are assigned to which roles?
- Which specific data will you share, and with whom?
- What security measures will be applied when data is disclosed?
- How will you manage changes over the course of the project?
- How will you check the quality of the transmitted data?
- How will you document and demonstrate all of this? (Which is also a requirement under the European privacy act (GDPR).)

Use cases

Primary use of data example:

Regional unlocking of allergies and patient-related problems within the CoZo/SHIFT project

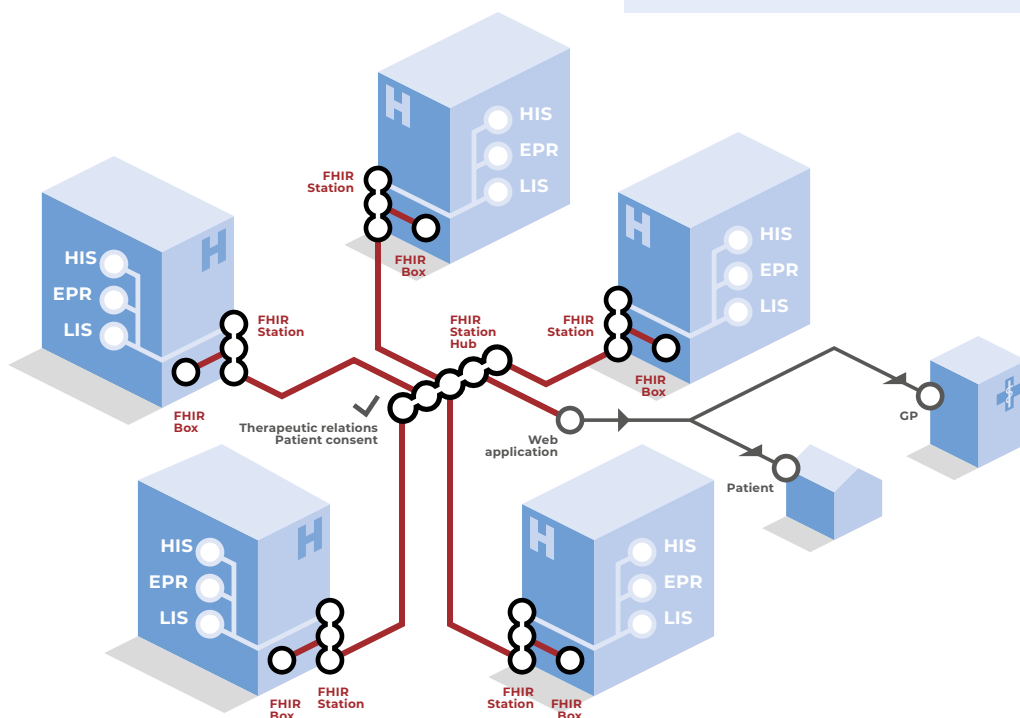
Over time, the goal is for Belgian hospitals to make the data from 'care set profiles' (such as problems, diagnoses, etc.) available from their electronic health records (EHRs) in a structured manner. The FHIR standard plays a key role in this process.

At Ghent University Hospital (UZ Gent), the SHIFT pilot project was launched with this objective in mind. SHIFT, which stands for Structured Healthcare InFormation Transmural, aims to develop a robust solution that enables healthcare organisations to make data on allergies and patient-related problems available across institutions via the existing Collaborative Care Platform (CoZo)⁴. For instance, if a patient is admitted to a Belgian hospital, healthcare providers will be able to check directly via CoZo whether the patient has had an allergic reaction to certain drugs in the past.

CoZo will retrieve data through FHIR queries from the five hospitals participating in the SHIFT project. Amaron will install a FHIR Station Hub at CoZo. Participating local hospitals that are not yet equipped to exchange data via FHIR can choose to install a FHIR Box or another FHIR repository, with or without a FHIR Station.

SHIFT is one of the 'data capability' projects funded by the Belgian government to facilitate the reuse of health data beyond hospital walls.

- **Who:** CoZo, together with 5 participating hospitals (using 4 different EHRs)
- **What:** FHIR communication of allergies and patient-related problems
- **Goal:** To make this data available across institutions for patient care (primary use of data)
- **How:** Translate data from the EHRs into FHIR profiles; make them available in a FHIR repository and retrievable via the CoZo-infrastructure



⁴ In Belgium, patients and healthcare providers can view relevant results registered in any Belgian hospital through a network of hubs, with CoZo being one of the largest players.

Secondary use of data example:

Central availability of birth care and HOST data across the E17 network

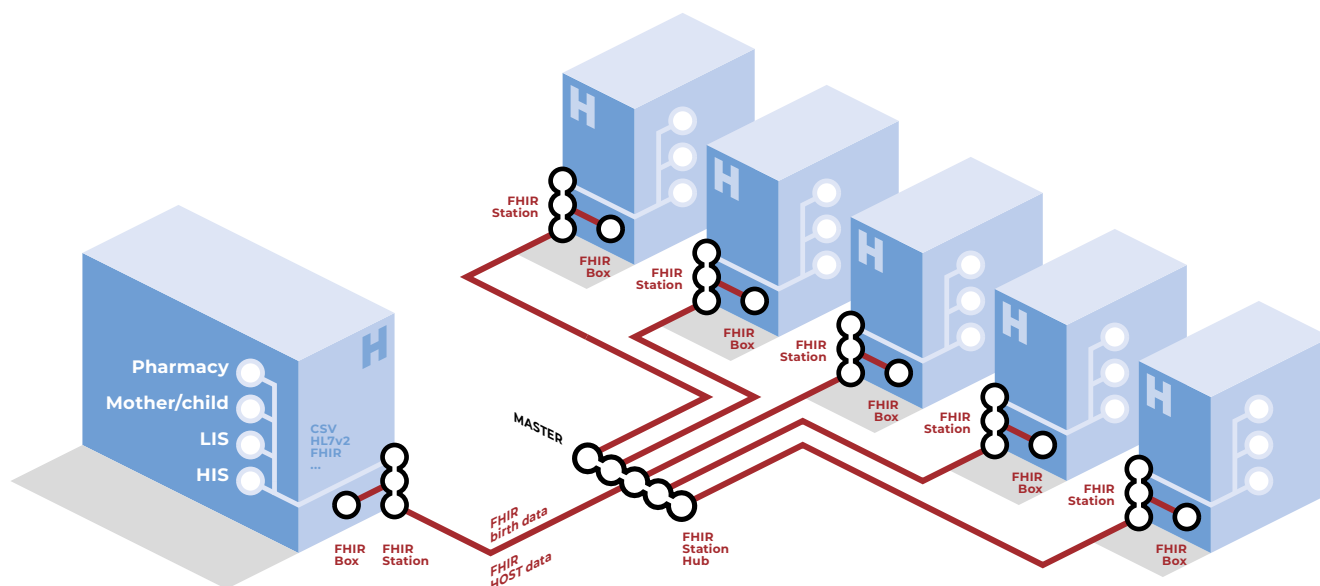
A 'data capability' project has been also initiated within the Belgian E17 network. Its aim is to retrieve birth care data via FHIR from the seven E17 hospitals, pseudonymise this data, and then make it centrally available for statistical purposes and clinical benchmarking (i.e., secondary or operational use of data). For example, the hospital network can quickly map how many caesarean sections or inductions have been performed at each hospital or across the entire network.

A similar approach is applied to HOST (Hospital Outbreak Support Teams) data. Based on the data collected, the E17

hospitals gain insights into prevailing infections (such as influenza) and track the evolution of infection pressure over time.

For this project, we installed a central FHIR Station. Hospitals that are not yet equipped to exchange data via FHIR can choose to install a FHIR Box and/or FHIR Station if they wish.

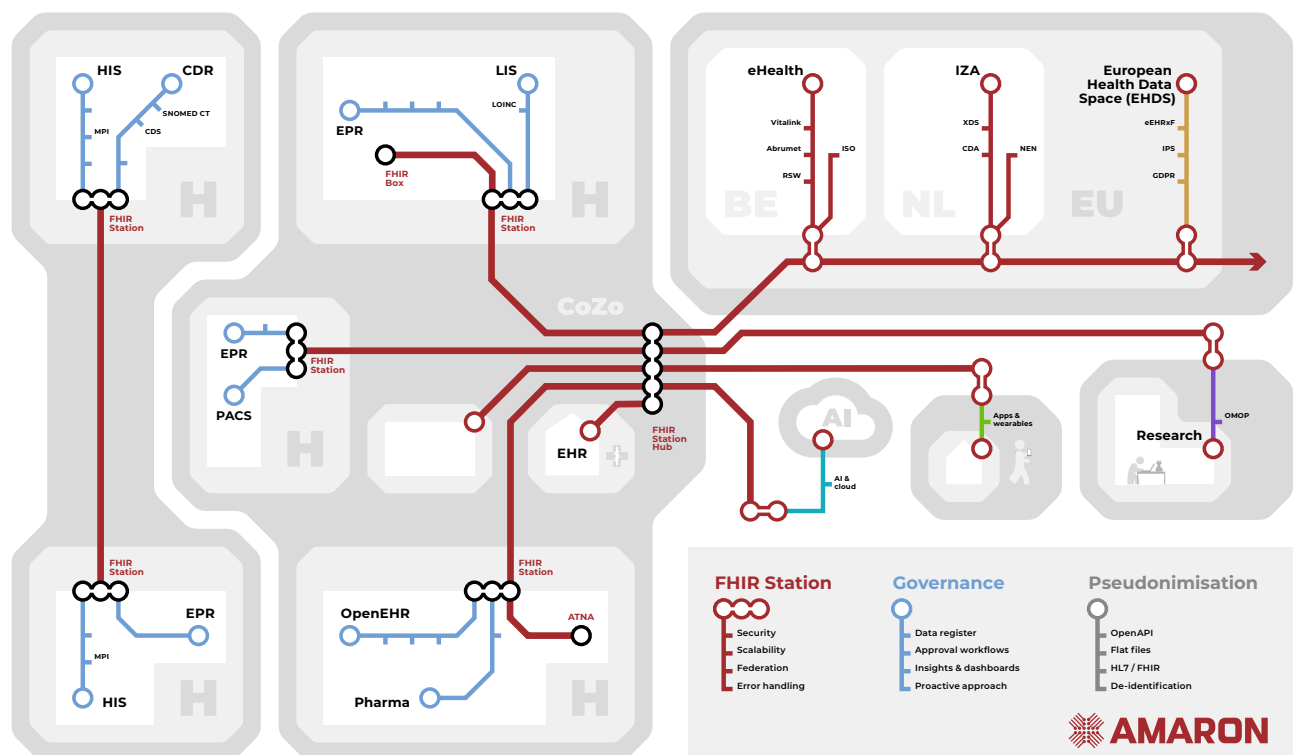
- **Who:** The 7 hospitals of the E17 network (using 3 different EHRs)
- **Aim:** Operational use of data for clinical benchmarking
- **Two projects:** Birth data and Hospital Outbreak Support Teams (HOST)
- **Information exchanged:** ADT, laboratory, medication and birth data



Conclusion

The advance of FHIR as a standard for transmural medical data sharing is unstoppable. FHIR offers numerous advantages – which have not gone unnoticed by public authorities. It is no surprise that more regulations are emerging, requiring healthcare organisations to exchange data using the FHIR standard.

Given the complexity of this matter, it is crucial to start using FHIR now and to develop an appropriate strategy. Interoperability specialists such as Amaron can support you in this process and work with you to develop a secure, future-proof solution that evolves with the needs of your healthcare organisation.



Connect. Collaborate. Care.

Why Amaron?

For the past 15 years, Amaron has been the number one provider of interoperability and process automation solutions in Belgium's healthcare sector. Increasing numbers of healthcare organisations outside of Belgium have also come to rely on Amaron's expertise and innovative solutions.

Amaron's initial specialisation was in HL7 integrations between various hospital information systems. However, as the sector's needs evolved, so did Amaron's offerings, expanding into broader interoperability solutions that enable seamless transmutal data exchange between hospitals, healthcare providers and institutions.

Over the years, we observed that existing information systems left certain gaps unaddressed. To bridge these gaps, we developed Workflower,

a platform that allows healthcare organisations to digitise a wide range of processes. The data generated and collected through Workflower is centralised so it can be readily accessed elsewhere, enabling hospital staff to work more efficiently and easily across domains, disciplines and fragmented IT systems.

The extensive knowledge and expertise we have built up in the healthcare sector provides a solid foundation for our latest portfolio, which focuses on transmutally unlocking data in FHIR and other formats.

Our solutions adhere with the applicable data security and privacy laws and regulations, including GDPR. We are ISO 9001, ISO 27001, and NEN 7510 certified.

**Would you like more information,
a quote or a demonstration?**
Call us on **+32 51 62 73 20**
or email us at **connect@amaron.be**.

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