

2024

# ANNUAL REPORT



HI7europe.org

**December 9, 2025** 

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## **HL7** Europe

Health Level Seven® (HL7®) International, a not-for-profit, ANSI-accredited, Standards Development Organization (SDO), dedicated to developing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information. Our standards support the efficient management, delivery, exchange and evaluation of healthcare data and services. (https://www.hl7.org)

HL7 Europe Foundation is a not-for-profit private foundation, established in 2010 by HL7® International, as regional European office of Health Level Seven® (HL7®) International in Brussels, Belgium, to address European standardization requirements in digital health. The mission of HL7 is to provide standards that empower global health data interoperability to realize the vision of a world in which everyone can securely access and use the right health data when and where they need it. Working in close cooperation with 23 HL7® Affiliates in the European region, HL7 Europe is responsible for the EU Realm and supports the creation of health information technology standards that are widely used enabling interoperability in healthcare. HL7® Europe also encourages the consistent adoption of HL7® standards in European health systems and provides education services, promotes tools and facilitates testing and certification. HL7 Clinical Document Architecture (CDA) is used by myHealth@EU to record patient summaries and ePrescriptions and slowly we witness the uptake of HL7 Fast Healthcare Interoperability Resources (HL7® FHIR®), in specifications for laboratory results, hospital discharge reports and imaging reports. HL7 Europe is a member of the eHealth Stakeholder Group of the European Commission. HL7 Europe is also active in the development of EEHRxF specifications for the European Health Data Space developing and supporting work with HL7® FHIR® IGs. (https://fhir.org)

The incumbent HL7 Europe Board of Directors (BoD), took office in 2023 for two years, and was formed to include Anne Moen, RN, PhD, FACMI, FIASHI, HonEFMI as Board Chair, Robert Stegwee, PhD., as treasurer and Henrique Martins, MD, PhD., as Secretary. The BoD includes a total of thirteen Directors, of which five members are from HL7 International Board (US) and eight are Europeans. This ensures that the BoD has a strong European perspective, limits control of HL7 International and ensures that HL7 Europe is solely responsible for the HL7 EU Realm and contributes to the development of global, connected digital health standards. The list of BoD members is on page 21 along with the Directors to take office on January 1, 2025.

HL7 Europe is committed to advancing interoperability in healthcare by creating and fostering the adoption of widely used health IT standards. Through the dedication of our community, volunteers, and associates, we strive to achieve our mission of advancing towards a world where individuals can securely access and utilize their health data at any time and in any place.

### What we do

HL7 Europe is responsible for the HL7 EU Realm and participates in European and Global collaborations that drive widespread use of HL7 frameworks, protocols, standards and specifications within and across healthcare organizations to enable data sharing and interoperability with special focus on the European Union and the European region by WHO. HL7 Europe is an active participant in European Union funded Research and Technological Innovation projects, including the Horizon Program, and has been coordinator or 4 projects (Trillium Bridge, Trillium II, eStandards and xShare) all of which highlight cooperation among standards organizations across Europe and globally. The currently active xShare (2023-2026) aims to empower individuals to share their health data at the click of a button in the EHDS using the EEHRxF that is based on HL7® FHIR®. HL7 Europe also delivers educational resources supporting the development of essential tools and facilitating the rigorous testing and certification of information systems to optimize healthcare delivery and reduce costs. HL7 These activities and initiatives are made possible through participation in EU funded research programs.

## Secretary General, Highlights 2024



HL7 Europe continued to grow in 2024 under the strong leadership of the HL7 Europe Board of Directors. Key areas of focus include actively monitoring developments in the European digital health landscape and ensuring that the focus areas and activities of HL7 Europe align with cross-European digital health initiatives and activities to promote interoperability and the advancement of digital health in Europe for citizens. HL7 Europe has been active in EHDS with XpanDH and as

technical leader of the xShare project that presented innovative uses of the xShare "yellow" button in the 2<sup>nd</sup> EEEHRxF summit in Brussels, this December. HL7 Europe is also active in Cancer related projects i.e. Flute, PCSP, and IDEA4RC contributing into a logical model for Cancer in Europe. There are also projects related to federated learning and Genomics, beyond cancer, i.e. NextGen and Protect-Child. Meanwhile we continue to work with Vulcan Accelerator electronic Product Information (ePI) program under the Gravitate-Health IMI project, where HL7 Europe are the interoperability lead and program owner. Finally, we contribute to the green deal and climate action with our participation in the OneAquaHealth project, a project that looks to connect the health of the environment, animals and plants to the health of people in a OneHealth context.

The Technical Steering Committee (TNT) for Europe, chaired by Giorgio Cangioli, the Technical Lead of HL7 Europe continues to oversee and coordinate the development of HL7 standards in Europe. More than a hundred people follow the conference calls of HL7 Europe Standardization projects. HL7 Europe continues to advance and promote the following key programs and initiatives. The European Strategic Advisory Board, comprising affiliates in European region, continues to advise HL7 on matters of their jurisdiction and collaborates

on requirements for HL7 standards. In January 2024, we had the first HL7 Europe WGM and FHIR Marathon, where the HL7 Europe Board of directors convened with the European Strategic Advisory Board represented by 20 HL7 Affiliate Chairs in Europe or their representatives. The decision was made and immediately adopted, henceforth to rename it to European Affiliate Council

The **Hospitals on FHIR®** (HoF) initiative, started in 2023, continues to grow and will play a crucial role in shaping the future of healthcare in Europe. Over the last two years we have seen a significant increase in interest in HoF User Days and webinars where the primary focus is on sharing implementation experiences and networking to generate implementation solutions. In the area of funded projects, the surge in funded projects won in 2023 continues to support the organization and the increase in team members to position HL7 Europe for future growth. The impact of this funded expansion will accelerate the delivery of fit-for-purpose, HL7 specifications and HL7 FHIR IGs, making them freely available and empowering European healthcare organizations and patients to exchange health information. The HL7 Europe team has grown quite significantly with now more than 20 people working in various exciting projects. Already planning of the 2<sup>nd</sup> HL7 Europe WGM is planned for Lisbon 10-14 of February 20025, under the leadership Kai Heitmann, CEO of HL7 Germany, and HL7 Europe community events manager.

Current ongoing projects include the **IDEA4RC** project focused on solid tumor cancers started in September 2022, **OneAquaHealth**, linking urban stream health to human wellbeing. The **Flute** project for synthetic data in pancreatic cancer is ongoing and progress on the European EHR Exchange format continues with the **XpanDH** project, and in **xShare**, which aims to deliver the "yellow" button for, with HL7 Europe as Technical Director, are among the most high-profile projects. At the same time, HL7 Europe collaborates closely with the **HL7® FHIR® Vulcan Accelerator** to connect healthcare data and clinical trial data effectively, co-leading the ePI track as part of the Gravitate Health project which is funded by the EU IHI program. We look forward to the start of **READi** project which seeks to address diversity in Clinical Trials and connects with the HL7 FHIR Vulcan Accelerator Utilizing the Digital Protocol (UDP) project in the definition of protocol inclusion/exclusion criteria.

Catherine Chronaki Secretary General, HL7 Europe

## **HL7 Europe BoD Chair, Opening Remarks**



It has been a true honor to serve as Board Chair of the HL7 Board of Directors. Reflecting on the activities during my tenure (2023-2024) it is nice to see how HL7 Europe grew in terms of participation in important EU projects, and that the organisation grew and matured following the extensive interest in development and use of HL7® FHIR® interoperability resources. As I step down, I look forward to continued engagement with HL7 Europe in projects and interest areas. Allow me to mention that Gravitate-Health (www.gravitatehealth.eu), a project I coordinate and HL7 Europe is a key partner, illustrates what can be achieved to progress interoperability resources necessary to progress our project goals. I

look forward to continued effort to ensure there are relevant interoperability resources and HL7° FHIR° Implementation Guides (IGs), to liberate personal health data, and the use of such personal health data in combination with relevant evidence-based and trusted health information resources for patients and their support networks. Other areas I will closely follow include the progress on the EEHRxF enabling reliable exchange data under the European Health Data Space (EHDS). Acknowledging the diversity across Europe, the responsibility to understand regional and local contexts are important for equitable and inclusive services. Advanced interoperability standards are indeed part of solutions in a future where health data follow the patient and is available, accessible and understandable at the point of need.

Anne Moen, RN, PhD, FACMI, FIAHSI, Honorary Fellow EFMI. Professor, Faculty of Medicine, University of Oslo

## **Key Achievements**

Outreach and Collaboration



Hospitals on FHIR® (HoF): This community of practice is vital to the adoption of the European EHR Exchange Format and the engagement of European Healthcare Facilities with the EHDS, aims to promote the adoption of HL7® FHIR® within the European healthcare landscape, focusing on hospitals, and the IT companies supporting them. HL7® FHIR® designed to be flexible and adaptable, making it easier to share data between different systems and organizations to help improve interoperability, healthcare and to drive innovation. Current HoF Co-Chairs are Maria Bastos Salazar (CIO, ULSS Antonio Porto, Portugal) and Stefano Dalmiani (CIO, Monasterio, Italy). The Terms of Reference were provide members recently updated to guidance for of HoF. (https://www.hospitalsonfhir.eu).

**Key achievements**: The Hospitals of FHIR initiative closed in 100 members and 7 ambassadors. HL7 Europe partnered with Agoria for Hospitals on FHIR in Belgium. For more details see the dedicated HL7 Europe Facility

In 2024, the HL7 Europe Board of Directors approved the creation of the HL7 Europe facility and appointed Joao Almedia as responsible.

The HL7 Europe Facility provides a comprehensive suite of tools and services to assist both current and potential users in understanding, testing, validating, and implementing HL7 EU standards and EU project specifications.

The facility includes a set of sandboxes equipped with HL7 FHIR APIs, which enable users to experiment with storing, searching, and retrieving HL7 FHIR examples, as well as validating them. A collection of reference examples is also provided to help users get started. These sandboxes are often enhanced with dedicated plugins for displaying stored examples and managing associated questionnaires.

In future, the sandboxes will be further supported by an HL7 FHIR Terminology Server, which will manage the terminology resources relevant to HL7 EU standards and EU project specifications.

Click here to go to the HL7 Europe sandboxes: https://sandbox.hl7europe.eu

Hospitals on FHIR® section.



HL7® FHIR®Accelerator Vulcan: the accelerator for connecting clinical research to health care. Under the umbrella of the IHI Gravitate-Health public-private partnership project and in close collaboration with regulatory agencies European Medicines Agency (EMA), and regulatory agencies outside Europe including the United States Food and Drug Administration (FDA) and the Japanese Pharmaceutical and Devices Agency (PMDA) and the Brazilian Health Regulatory Agency, Agência Nacional de Vigilância Sanitária (ANVISA).

HL7 Europe co-leads the Vulcan electronic Product Information (ePI) / eLabeling project, which was formed to develop a global Implementation Guide (IG) for ePI in collaboration with the EU funded Gravitate-Health Project (<a href="www.gravitatehealth.eu">www.gravitatehealth.eu</a>) and other stakeholders (<a href="http://www.hl7.org/vulcan/">http://www.hl7.org/vulcan/</a>).

**Key achievements:** Development and alignment of HL7® FHIR® ePI IG with the EMA FHIR IG as well as those of member states. Partnership with the GIDWG (<a href="www.gidwg.org">www.gidwg.org</a>) network of regulators to promote IDMP.



Several HL7® FHIR® Implementation Guides were delivered or maintained supported by EU projects: the Gatekeeper HL7 FHIR IG, PCSP HL7® FHIR® IG, IDEA4RC HL7® FHIR®.

Additionally, the "<u>EFMI FAIR – FAIR data in Health Research Performing Organizations</u> (<u>HRPOs</u>)" working group was established to further maintain the HL7 FAIRness for HL7° FHIR° IG, that was developed in the project FAIR4HEALTH.

Key among them was the work on the HL7® FHIR® Laboratory IG, one of the priority data categories in the EHDS. Several well attended webinars supported the launch of the vote, the promotion of adoption and the alignment with EU specifications. HL7 Europe participated in the January, May and October HL7 FHIR Connectathons.

**Key achievements:** HL7® FHIR® IG for Laboratory Reports (EU realm): following ballot reconciliation, the TNT in February 2024 approved the publication of the HL7 FHIR IG STU 1 (EU REALM). There were several attended WGs for EHDS priority data categories. Participation in the GIDWG group for IDMP.

## **EU Funded Projects Update**

#### Introduction

HL7 Europe consistently secures grant funding from public funding sources in the European Union, such as the EU Horizon, IMI, and IHI, a testament to our robust network and collaborative spirit. We strategically align these grant-funded projects with our core objectives, ensuring our efforts directly contribute to the progress of healthcare IT and interoperability. The subsequent section details our current portfolio of both funded and unfunded initiatives.



Figure 1: Funded Projects 2011 - 2024



**Gravitate Health** - Empowering and Equipping Europeans with health information for Active Personal Health Management Adherence to Treatment

Making the most of health information for an optimal patient experience. The digitization of healthcare information has infinite benefits for clinicians, patients and their support network. When it comes to patient engagement, digital information tools can facilitate patients' journey by offering them access to actionable, understandable, relevant, reliable and evidence-based information that meets their specific needs, health context and literacy level. The EU-funded Gravitate-Health project aims to demonstrate how an integrated, digital, user-centric health information solution could enable tangible improvements in the availability and understanding of health information from a set of trusted sources. Moreover, Gravitate-Health will highlight how improved availability and understanding of health information can lead to better adherence to treatment, safer use of medication and improved health outcomes, and overall health-related quality of life. Key activities include a Hackathon in 2024, (January 24) and the HIMSS interoperability showcase. HIMSS Europe June 24.

**HL7 Europe Role:** Interoperability lead, WP5 lead, and liaise with HL7 Working Groups (WGs), coordinate development of the <u>Gravitate-Health HL7® FHIR® Implementation Guide</u> for ePI co-lead Vulcan ePI project, ePI creator, server and <u>viewer</u> dedicated to the Gravitate-Health ePI services.

**Funded under**: Innovative Medicines Initiative 2 (IMI2) with Grant Agreement 945334. H2020-EU.3.1. Health, demographic change and well-being; H2020-EU.3.1.7.

**Topic**: IMI2-2019-18-03 - Improving patient access, understanding and adherence to healthcare information: an integrated digital health information project

Duration: 1 November 2020 to 31 October 2025

Overall budget: € 18 561 750 EU contribution: € 9 280 000

Coordinated by: UNIVERSITETET I OSLO, Norway

Funding for HL7 Europe: €729 428,759

**HL7 Europe Team**: Joao Almeida (Product Owner), Giorgio Cangioli, Catherine Chronaki (interoperability lead) and Henrique Martins (advisor), Rhonda Facile (communities), Kai

Heitmann (Style Sheets, synthetic data)

Project Website: https://www.gravitatehealth.eu

For more information: https://cordis.europa.eu/project/id/945334



**PanCareSurPass:** PanCare studies of the scale-up and implementation of the digital Survivorship Passport to improve people-centred care for childhood cancer survivors

Hundreds of thousands of childhood cancer patients in Europe continue to have unique health issues as they grow. Their long-term follow-up care is critical, due to increased morbidity and mortality. Unfortunately, treating healthcare professionals often lack access to their past medical data.

The Survivorship Passport (SurPass) solution was designed to overcome this knowledge gap. In this context, the EU-funded PanCareSurPass project will scale up the SurPass and evaluate the implementation of a digital Survivor Passport in six European countries, considering various scenarios and issues. Work will result in a prediction model that will ease successful SurPass implementation across Europe.

• **HL7 Europe Role:** WP3 leader is the creation of an <u>HL7® FHIR® Implementation Guide</u> that will allow the semi-automatic creation of the Survivorship passport.

• Funded under: SOCIETAL CHALLENGES - Health, demographic change and well-being

• **Duration:** 1 March 2021 to 31 August 2025

Overall budget: € 4 000 000.00
 EU contribution: € 4 000 000.00
 Coordinated by: UMC-Mainz

• Funding for HL7 Europe: € 346 875.00

• **HL7 Europe Team**: Roberta Gazzarata, Giorgio Cangioli, Michael Strubin, Rhonda Facile, and Catherine Chronaki

• Project Website: <a href="https://www.pancaresurpass.eu/">https://www.pancaresurpass.eu/</a>

For more information: <a href="https://cordis.europa.eu/project/id/899999">https://cordis.europa.eu/project/id/899999</a>



### **XpanDH:** Expanding Digital Health through a pan-European EHRxF-based Ecosystem

The 2019 Commission recommendation on the European Electronic Health Record Exchange Format (EEHRxF) proposed a

process for interoperability specifications; EHDS regulation has given it legislative force. The Commission has been funding research actions to develop and refine the EEHRxF. The XpanDH project supports an expanding ecosystem developing, experimenting and adoption the EEHRxF between 2023 and 2024.

The EU envisages the creation of the European eHealth Union for the benefit of citizens and health entities. The EU-funded X-eHealth project will lay the groundwork for a practical, interoperable, secure and cross-border Electronic Health Record exchange format, working towards the improvement of the eHealth sector. With the support of over 40 entities, the project will promote a faster and more sustainable EU digital transformation: consisting of eight work packages, of which four focus exclusively on technical and functional activities, it aims to move towards a uniform interoperable data-sharing format structure. X-eHealth will build on the already existing Patient Summary service and lay the foundations for a common structure for medical imaging, discharge letters, laboratory results and rare diseases.

This project is now concluded. Key achievements include the development of the XpanDH repositories and artefacts includes the following HL7 FHIR IGs: Lab Report IG, Hospital Discharge Report IG, Patient Summary IG, Medicinal Prescription and Dispense (MPD) IG, as well as the development of open-source tooling.

- HL7 Europe Role: Leading WP2 and development of the Asset Registry
- Funded under: EU-wide digital health solutions
- **Duration:** 1 January 2023 31 December 2024
- Overall Budget and EU contribution: € 193 176,25
- Coordinator: ASSOCIACAO ISCTE CONHECIMENTO E INOVACAO CENTRO DE VALORIZACAO E TRANSFERENCIA DE TECNOLOGIAS (Portugal)
- Funding for HL7 Europe: € 346 875.00
- **HL7 Team**: Hynek Kruzik, Rutt Lindstrom, Robert Hausam, Jose Teixeira, Luc Chatty, Catherine Chronaki, Giorgio Cangioli.
- Project Website: <a href="https://xpandh-project.iscte-iul.pt">https://xpandh-project.iscte-iul.pt</a>
- For more information: <a href="https://cordis.europa.eu/project/id/101095594">https://cordis.europa.eu/project/id/101095594</a>



**xShare:** Expanding the European EHRxF to share and effectively use health data within the European Health Data Space (EHDS)

Digitalization of the healthcare sector, interoperability remains a persistent challenge. Fragmented systems hinder the seamless exchange of vital health data, impeding patient care and stifling research efforts. As such, GDPR obligations further complicate matters, as individuals struggle to navigate the complex landscape of data sharing consent. This EU-funded xShare project will develop an innovative button for health portals and patient apps that can be used to effortlessly share personal health data in compliance with the GDPR. xShare will establish common specifications and elements, fostering collaboration among stakeholders. From hospital networks in Italy to national portals in Greece and Ireland, xShare promises a future of interconnected healthcare systems.

- **HL7 Europe Role**: Scientific coordinator and responsible for technical specifications.
- Funded under: EU-wide digital health solutions
- **Duration**: 1 December 2023 30 November 2026
- Overall Budget and EU contribution: € 7 803 632,50
- Coordinator: Medcom, DK
- Funding for HL7 Europe: € 346 875.00
- **HL7 Team**: Kai Heitmann, Hynek Kruzic, Giorgio Cangioli, Rutt Lindstrom, Rhonda Facile, Elena Petelos, and Catherine Chronaki.
- Project Website: https://xshare-project.eu
- For more information: <a href="https://cordis.europa.eu/project/id/101136734/de">https://cordis.europa.eu/project/id/101136734/de</a>



## **NextGen**: Personalised Medicine, Prediction, Prevention, Diagnosis, Treatment of Cardiovascular Disease

NextGen, is building novel and synergistic tools to enable portable multimodal, multiomic and clinically oriented research in high-impact areas of cardiovascular medicine. NextGen tools will benefit researchers, innovators and healthcare professionals by identifying and overcoming health data linkage barriers in exemplar use cases which are complex or intractable with existing technology. Consequently, it will benefit patients, providing faster diagnosis, and better treatments (including personal medicine). A comprehensive gap analysis of the existing landscape, factoring in ongoing initiatives will ensure NextGen deliverables are forward-looking and complementary.

- **HL7 Europe Role:** Standards Update, policy, EHDS connection
- Funded under: NextGen project has received funding by the European Union's Horizon Europe, under grant agreement No 101136962; The British associated partners of NextGen were funded by UK Research and Innovation (UKRI) under the UK government's Horizon Europe funding guarantee [grant agreements No 10098097, No 10104323]; The Swiss Federation.
- **Duration**: 1 January 2024 31 December 2027
- Overall Budget and EU contribution: € 7 601 771,25
- Coordinator:UMC Utrecht
- Funding for HL7 Europe: €104.000
- **HL7 Team**: Giorgio Cangioli, Catherine Chronaki and Evangelia Anna Markatou
- Project Website: https://www.nextgentools.eu/personalised-medicine/
- For more information: https://cordis.europa.eu/project/id/101136962



## **Protect-Child**: Data integration for improved outcomes in child transplants

The EU-funded PROTECT-CHILD project aims to improve outcomes for these patients by integrating high-throughput data from various sources. It focuses on developing a secure infrastructure,

harmonising data standards, and assembling large datasets to enhance clinical outcomes. The project brings together a consortium of specialists in technology, data standardisation, clinical expertise, legal experts, patient representatives, and policymakers. It aims to enable the secure and compliant processing, analysis, and sharing of sensitive personal data while preserving privacy and security.

HL7 Europe Role: Development of HL7 FHIR IGs

• Funded under: Health

• **Duration**: 1 June 2024 – 31 December 2028

• Overall Budget and EU contribution: €8091327,50

Coordinator: UNIVERSIDAD POLITECNICA DE MADRID

• **Funding for HL7 Europe**: € 351 875.00

• HL7 Team: Giorgio Cangioli, Catherine Chronaki and Evangelia-Anna Markatou

Project Website: https://protect-child.eu

For more information: https://cordis.europa.eu/project/id/101137423



## **IDEA4RC:** Intelligent Ecosystem to improve the governance, the sharing and the re-use of health Data for Rare Cancers

The EU-funded IDEA4RC project aims to establish an Artificial Intelligence (AI) assisted data ecosystem for Rare Cancers (RC) to enable access and the possibility to re-use existing health-related data

from different sources. These include cancer registry data, electronic health records, electronic health care utilisation database across several European healthcare systems. The creation of the RC data ecosystem will increase understanding of these types of cancers and promote research and improve the quality of care for patients. The project will be executed within the framework of the **European** reference network for rare adult solid cancers (ERN EURACAN).

- **HL7 Europe Role:** creation of an <u>HL7® FHIR®Implementation Guide</u>.
- Funded under: Health
- **Duration:** 1 September 2022 31 August 2026
- Overall Budget and EU contribution: € 8 190 468,13
- Coordinator: FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI (Italy)
- Funding for HL7 Europe: € 346 875.00
- **HL7 Europe team**: Roberta Gazzarata, Luc Chatty, Giorgio Cangioli, Rhonda Facile, and Catherine Chronaki.
- Project Website: <a href="https://www.idea4rc.eu">https://www.idea4rc.eu</a>
- For more information: https://cordis.europa.eu/project/id/101057048/reporting



#### **FLUTE:** Pioneering secure healthcare Al across borders

The FLUTE project will advance and scale up data-driven healthcare by developing novel methods for privacy-preserving cross-border use of data hubs. The focus is on improving predictions of aggressive

prostate cancer through AI support to physician, while minimising unnecessary biopsies. The project will deliver a secure environment for federated healthcare AI solution development, testing and deployment, including the integration of real-world health data from the data hubs and the generation and utilisation of synthetic data. To demonstrate the practical use and impact of the results, the project will integrate the FLUTE platform with health data hubs located in three different countries, use their data to develop a novel federated AI toolset for diagnosis of clinically significant prostate cancer and perform a multi-national clinical validation of its efficacy. Led by INRIA (FR), the project will deliver results by 2026.

- **HL7 Europe Role:** HL7 Europe is responsible for the <u>HL7® FHIR® IG</u> and works on HL7® FHIR® Questionnaires and CQL applications.
- **Funded under**: HORIZON-HLTH-2022-IND-13-02 Scaling up multi-party computation, data anonymisation techniques, and synthetic data generation.
- **Duration:** 1 May 2023 30 April 2026
- Overall Budget and EU contribution: € 6 304 750,00
- Coordinator: INSTITUT NATIONAL DE RECHERCHE EN INFORMATIQUE ET AUTOMATIQUE (France)
- Funding for HL7 Europe: Health
- **HL7 Europe Team**: Evangelia-Anna Markatou, Luc Chatty, Catherine Chronaki, Rhonda Facile, and Giorgio Cangioli
- Project Website: <a href="https://www.fluteproject.eu">https://www.fluteproject.eu</a>
- For more information: <a href="https://cordis.europa.eu/project/id/101095382">https://cordis.europa.eu/project/id/101095382</a>

## **One Aqua Health:** Protecting Urban Aquatic Ecosystems to Promote One Health

OneAquaHealth aims to improve the sustainability and integrity of freshwater ecosystems in urban environments. By investigating the interconnection of ecosystem health and human wellbeing, the project will identify early warning indicators and enhance environmental monitoring with AI-assisted tools. As a result, the project will support decision-makers in finding adequate and timely decisions as well as effective measures to restore aquatic ecosystems health and promote OneHealth. The project is a Research and Innovation Action funded under the Horizon Europe programme, led by the University of Coimbra (PT) from 2023 until 2026.

- **HL7 Europe Role:** To support the use of health data standards with the use of HL7® FHIR® (Fast Healthcare Interoperability Resources). The use of FHIR® enables the rapid transfer of information through the project's various digital health and environmental monitoring tools in real time.
- **Funded under**: HORIZON-CL6-2022-GOVERNANCE-01-09 Environmental observations solutions contributing to meeting "One Health" challenges
- **Duration:** 1 January 2023 31 December 2025
- Overall Budget: € 5 085 113,75
- EU contribution: € 4 939 558,00 EU HORIZON Grant agreement ID: 101086521
- Coordinator: UNIVERSIDADE DE COIMBRA (Portugal)
- Funding for HL7 Europe: € 400,000
- **HL7 Europe Team**: Gora Datta, Eleni Kokkinou, Stratos Kokolakis, Marilena Anastasaki, Catherine Chronaki, and Giorgio Cangioli.
- Project Website: https://www.oneaquahealth.eu
- For more information: https://cordis.europa.eu/project/id/101086521

## UNICOM: Upscaling the Global Univocal Identification of Medicines

The cross-border mobility of European patients and the univocal identification of medicinal projects are directly related. Currently, 22 Member States are part of the eHealth Digital Service Infrastructure and are expected to exchange e-prescriptions and patient summaries by the end of 2021. However, this requires EU-wide adoption of the International Organization for Standardization's (ISO) Identification of Medicinal Products (IDMP) suite of standards. The EU-funded UNICOM project will focus on the conversion of key regulatory and clinical processes to use IDMP. By bringing together all relevant actors, the project will help to address all the associated challenges. Work centered on the implementation of EU and national SPOR (substances, products, organisations, referentials) databases, including establishing an EU Substance Reference System (EU-SRS).

Key Achievements: The UNICOM partners have opened and developed a conversation between key stakeholders on medicinal product identification. They have worked to break down silos between the actors in the medicinal product value chain to build a strong consensus on medicinal product data interoperability and governance as a shared responsibility. The UNICOM project scaled up IDMP implementation, developed a sandbox, educational resources and implementation guides, enhancing cross-border healthcare services, together with the European medicines regulatory network (EMRN), a new tool for creating ISO IDMP compliant application forms was developed. (Source: https://unicomproject.eu/wp-content/uploads/2024/04/UNICOM-WHITE-PAPER.pdf)

**Role for HL7 Europe:** Support the creation of robust HL7 standards and implementation guides. Liaise with HL7 standardization WGs and other standards bodies on ISO/IDMP

**Funded under**: H2020-EU.3.1.5.2. - Improving scientific tools and methods to support policy making and regulatory needs; H2020-EU.3.1. - SOCIETAL CHALLENGES - Health, demographic change and well-being.

Topic: SC1-DTH-09-2019 - Scaling up the univocal Identification of Medicinal Products

**Duration:** 1-December 2019 - 31 May 2024

**Overall budget**: € 20 730 965,50 **EU contribution**: € 18 994 883,50

Coordinated by: Empirica Gessellschaft fur Kommunications and technologie forschung

MBH, Germany

Funding for HL7 Europe: € 337 753,73

**HL7 Team:** Joao Almeida, Giorgio Cangioli and Catherine Chronaki

Project Website: https://unicom-project.eu

## **Key Initiatives**



#### **HL7 Europe Cancer Initiative**

Cancer has a significant impact in Europe and globally, in terms of diagnosis and death numbers and economic costs. Updated strategies in cancer prevention, treatment, and care are needed. The European Union has responded to these needs with the "Europe's Beating Cancer Plan" aimed to address cancer comprehensively through prevention, early detection, treatment, and improving

patients' and survivors' quality of life. A Common (European) cancer data model, agnostic to the type of cancer, usable across different use cases was needed to support data sharing and assure sustainability.

In response, in 2014 the Phoenix HL7 Europe Cancer Initiative (following the principles for an HL7 FHIR Accelerator) was started comprising representatives from multiple projects and organizations collaborating in a neutral space with clear governance goals.

The Phoenix HL7 Europe Cancer Initiative is a multifaceted effort to improve the exchange and use of cancer-related data across Europe, aiming to enhance research, treatment, and ultimately, patient outcomes. It recognizes the critical need for interoperability in oncology data, bringing together various stakeholders like laboratories, clinicians, researchers, and registries to facilitate a learning health system. The vision is to move towards a future where seamless data interoperability transforms cancer care and research, enabling breakthroughs that improve patient outcomes and empower collaborative innovation across Europe

The Phoenix HL7 Europe Cancer Initiative will play a leading role in the development and adoption of European digital health standards for cancer to support cancer research and care delivery through interoperable data standards, by promoting a unified approach that enhances patient treatment, accelerates research, and closes the loop between care provisioning and research insights, aligning with and contributing to the European Health Data Space (EHDS) initiatives and to foster a unified ecosystem where healthcare providers, researchers, and policymakers collaborate to enhance patient outcomes and accelerate innovation.

To achieve this vision, the primary goals are to Drive Consistency: ensure that healthcare data is consistently structured and interoperable across different systems and settings. Speed Up Implementation: accelerate the development of HL7 standards, particularly HL7 FHIR (Fast Healthcare Interoperability Resources), by focusing on specific clinical or administrative use cases. Foster Collaboration: bring together industry stakeholders to codevelop solutions that meet real-world needs and regulatory requirements. Ensure Relevance: tailor standards to address pressing needs in specialized areas, such as oncology, public health, or social determinants of health.

The core team, which is an open group, currently includes representatives from Institut Paoli Calmettes (FR), Institut National du Cancer (FR), Berlin Institute of Health @ Charité (DE),

Paris Saclay Cancer Cluster (FR) and Netherlands Comprehensive Cancer Organisation (IKNL) (NL).



#### Phoenix HL7 Europe FHIR Accelerator Project Phases

The Phoenix project phases in include Inception, Formation, Operational and Growth. The inception phase included validate that the proposed Accelerator project and the evaluation of long-term viability, establishment of core founding member support (figure above) and confirmation of broad industry value. The Formation phase included SOU development and founding members have agreed and committed to funding and/or in-kind support. A Steering Committee is established to authorize spending and a PMO contract process was completed, and the on-boarding of members was commenced. The operational phase included the formation of a use case team to develop and deliver standards artifacts while engagement with HL7 work groups and community started to anchor the project across these teams and encourage participation. Outreach to broader a community to educate and promote the accelerator was also begun. We are now in the growth phase where operational activities are ongoing, these include identification and engagement with additional members, securing funding for new use case activities, maturation processes achieved for standards artifacts (IGs) and initiation of pilot projects, strengthen ties with the implementer community and management of growth and maturation processes.

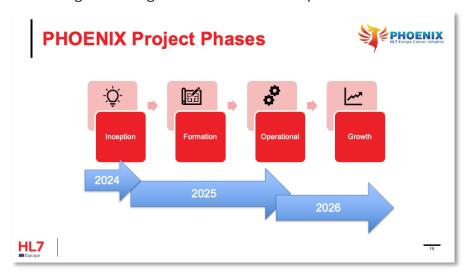


Figure 2: Phoenix European Initiative Phases

#### The Phoenix 3 Year Plan – Major Objectives

#### 2025

- The PHOENIX kick off (Feb (25)
- 1st version of Common Cancer Data Model / HL7 FHIR IG Balloted and Published (STU) (Fall '25)
- New members engaged (> 5 by the end of the year)
- Join the HL7 FHIR Accelerator Program



#### 2026

- Consolidated educational and dissemination activities
- At least one -a-thon event organized
- At least one proposal for funded projects submitted
- Pilot adoption of the HL7
   FHIR IG for care
   provisioning and research in
   at least two countries.
- Membership growth (> 5 by the end of the year)

#### 2027

- New standardization project started
- Revenue from events and funded projects
- Common Cancer Data Model used in operation
- At least two -a-thon event organized
- Membership growth (> 10 by the end of the year)

Figure 3: Phoenix 3-year Plan

#### Common Cancer Data Model Project

The goal of the HL7 Common Cancer Data Model Project is to define a minimal, extensible, non-exhaustive European cancer data model that is agnostic to the type of cancer; usable across different use cases; leverages on the experiences of the European projects working with primary and secondary usage, considers the availability and usability of reliable data in the EHR systems and its HL7 FHIR representation in the form of a HL7 FHIR Implementation Guide. Design principles include inclusive and cross-cutting and applicable to cancer domains and purposes of use, considers the needs of different communities. To accomplish this an incremental approach has been adopted to focus on a minimal core set that can be extended or enhanced iteratively and purpose designed to facilitate representation in the HL7 FHIR exchange standard. Key benefits include an implementation independent data model (the cancer data set) accompanied by an HL7 FHIR Implementation Guide that includes HL7 FHIR logical models of the cancer model and HL7 FHIR profiles for ready implement of this core data set.

#### Collaboration and Cross Project Synergy

HL7 Europe has a strong track record of collaborating with various EU-funded projects and national initiatives in cancer research and data sharing. This extensive experience, including work with projects like IDEA4RC, OSIRIS, PanCareSurPass, FLUTE, INCISIVE, and the MEDOC dataset, helps us foster synergies and prevent fragmented efforts. Moving forward, HL7 Europe will partner with these groups and stakeholders and work towards aligning deliverables and ensuring that the emerging European Common Cancer Model and HL7 FHIR standards are usable across all relevant projects.

#### **HL7** Europe Facility

In 2024, the HL7 Europe Board of Directors approved the creation of the HL7 Europe facility and appointed Joao Almedia as responsible.

The HL7 Europe Facility provides a comprehensive suite of tools and services to assist both current and potential users in understanding, testing, validating, and implementing HL7 EU standards and EU project specifications.

The facility includes a set of sandboxes equipped with HL7 FHIR APIs, which enable users to experiment with storing, searching, and retrieving HL7 FHIR examples, as well as validating them. A collection of reference examples is also provided to help users get started. These sandboxes are often enhanced with dedicated plugins for displaying stored examples and managing associated questionnaires.

In future, the sandboxes will be further supported by an HL7 FHIR Terminology Server, which will manage the terminology resources relevant to HL7 EU standards and EU project specifications.

Click here to go to the HL7 Europe sandboxes: https://sandbox.hl7europe.eu

#### Hospitals on FHIR®



This community of practice is vital to the development of the European EHR Exchange Format spearheaded by the X-heath project and aims to promote the adoption of HL7® FHIR® within the European healthcare landscape, focusing on hospitals. HL7® FHIR® designed to be flexible and adaptable, making it easier to share data between different systems and organizations to help improve interoperability, healthcare and to drive innovation. https://www.hospitalsonfhir.eu/home

#### Membership and Country Ambassadors

At the close of 2024, our community consisted of 91 active members, our community continues to grow, with membership efforts ongoing in 2025.

#### **HoF Ambassadors**

HL7 Europe extends its sincere gratitude to our **14** dedicated Hospitals on FHIR Ambassadors, representing **8** countries: Luc Chatty and Frederik Laurent (France), Marie-Alexandra Lambot and Karlien Erauw (Belgium), Stefano Dalmiano and Ricardo Haupt (Italy), Maria Manuel Salazar and Victor Costa (Portugal), Giueppe Fico (Spain), Eugenia Rinaldi and Sylvia Thun (Germany), Anne Moen (Norway), and Justas Trinkunas and Paulius Ragauskas (Lithuania). Thank you for your invaluable contributions!

#### HoF Events 2024

In 2024, HoF organized four impact events: in-person sessions in Athens, Greece (January 16), Experiences on FHIR Adoption (April 5), the second annual HoF Users Days in Brussels, Belgium (November 25-26), which included both in-person and remote options, and the FHIR Camp in Cascais, Portugal (November 27-29).

The second "Hospitals on FHIR® User Day" in Brussels, Belgium, represented significant growth, with 41 in-person and remote attendees from over 10 Eurozone countries engaging in 14 sessions featuring 45 presentations and round tables led by 42 in-person and 3 remote speakers. The event focused on a wide array of crucial topics in the healthcare and health data interoperability landscape including presentations on the European Health Data Space (EHDS), the HL7 Europe Cancer imitative, the Digital First Transition for Medical Product Information in Hospitals, Artificial Intelligence (AI), AI Act application, Cancer care and FHIR, The xShare Yellow Button, FHIR for Rare Diseases, FHIR & Federated Research, Cybersecurity, Information Assurance and Business, Telemonitoring, and numerous presentation on the state of HL7 FHIR implementation by national affiliates and representative.

This record-breaking Hospitals on FHIR event highlights the growing importance and adoption of FHIR as a key standard for achieving interoperability and advancing digital transformation in healthcare. The diverse range of topics covered underscores the multifaceted role FHIR plays in addressing current and future challenges in the healthcare ecosystem. We extend our sincere gratitude to our Platinum Sponsor, Intersystems, and our Silver Sponsors, Amaron, OVHcloud, and Lifeline, and finally, our Bronze Sponsor, the Vidal Group, for their generous support of the event.



"2024 demonstrated sustained growth and interest in Hospitals on FHIR events and membership. Looking ahead, our focus remains on maintaining this momentum through our ongoing membership campaign and by delivering a strong program of User Days and workshops in 2025. These efforts are crucial in supporting the development of the European EHR Exchange Format and fostering the broader

adoption of HL7° FHIR° within the European healthcare landscape, with a particular emphasis on hospitals" Stefano Dalmiani, Co-Chair, Hospitals on FHIR, HL7 Europe, Board of Directors

#### Hospitals on FHIR European Network



Figure 4: Hospital on FHIR Network map

### Hospitals on FHIR® Maturity Model

The Hospitals on FHIR® maturity model is a framework to determine the status of a hospital's HL7® FHIR® implementation status. It assigns a maturity levels to ranging from 0 (intention to work) to 10 (cross border data exchange). Benefits of Using the Model include:

- **Self-Assessment**: Hospitals can assess their current FHIR maturity level to identify strengths and weaknesses.
- **Goal Setting:** The model provides a clear roadmap for progressing towards higher maturity levels.

- **Benchmarking:** Hospitals can compare their progress to industry peers and best practices.
- **Education and Training:** Tailored educational resources can be developed based on the specific needs of hospitals at different maturity levels.
- **Community Building:** The model fosters collaboration and knowledge sharing among hospitals and other healthcare organizations.

By utilizing the Hospitals on FHIR® Maturity Model, hospitals can effectively navigate the complexities of HL7® FHIR® implementation and realize its full potential to improve patient care, enhance interoperability, and drive innovation in healthcare.

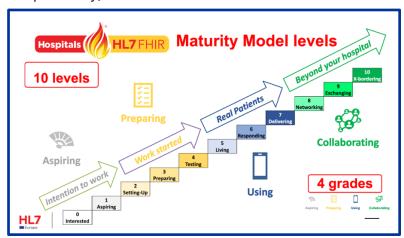


Figure 5: Hospitals on FHIR® Maturity Model

For more information on HoF events, recorded webinars and presentations visit: <a href="https://www.hospitalsonfhir.eu/events">https://www.hospitalsonfhir.eu/events</a>

#### HoF Governance

Current HoF Co-Chairs are Maria Bastos Salazar (CIO, ULSS Antonio Porto, Portugal) and Stefano Dalmiani (CDO, Monasterio, Italy). The Terms of Reference were updated to provide guidance for members of HoF. (https://www.hospitalsonfhir.eu).

HL7 Europe expresses sincere appreciation to the HoF Steering Committee for their vital support and active engagement, which were instrumental in the success of the Hospitals on FHIR® User days.



## **HL7 Europe Working Group Meeting and FHIR Marathon**

The marathon (from Greek Μαραθώνιος) is a long-distance 42.195 km foot race – usually run as a road race, but the distance can be covered on "trail" routes. For the first HL7 Europe Working Group Meeting (WGM) mid-January 2024 in Athens, the agenda was planned, including a room full of hackers connecting with each other, learning together and from each other with benefits for specifications and projects.



The "trails" were of course FHIR "tracks", a typical topic-oriented grouping of the activities. The FHIR Marathon in Athens was conducted from Tuesday to Thursday that week and highlighted the HL7 FHIR for Labs implementation Guide (European Realm), the Vulcan ePI/GH track focusing on ePI/eLabeling with Global IDMP WG, the International Patient Summary (IPS) and alignments of European HL7 FHIR Implementation Guides, the International Patient Access (IPA) and a special broader activity addressing FHIR achievements in European Cancer Mission Projects. Even for the sleepless hackers we offered the opportunity to join the HL7 International FHIR Connectathon online that took place later in the evening due to the time zone shift. Looking back at the busy week in Greece, we must admit that we were a bit overwhelmed by number of participants of the



FHIR Marathon but improvising made it even more an unforgettable community event.

It's no secret that there were ideas around since a longer time to have an HL7 **Europe** Working Group meeting and to bring the regional community closer together. Such an event would allow a better focus on EU activities, projects, and the people! While this was a slumbering thought for moments, recent activities on the European level like the progress made on the European e-Health Record Exchange Format,

achievements in actual projects or the European Health Data Space made it obvious: let's do it! HL7 Europe's Secretary General Catherine Chronaki started early announcing that event, planning started in fall 2023 (short for such a first event), and with the collective efforts of an Organizing Committee and the help of the team that supported the Athens Digital Health Week (ADHW) that took place at the same time and location in Athens, a colourful program was created.

We as the organizers were pleased with the attendance (more than 120 participants) and outcome. Next to working sessions also a few strategical meetings happened, such as the HL7 Europe Board meeting, preceded by the European Strategic Advisory Board (ESAB) that

now is called European Advisory Council to better reflect their role. Also, the Technical Coordination Team TNT had separate meetings, but many other parts of the week were filled with technical activities anyway, along with project meetings. Worth to mention at least the kick-off of the X-Share project, a three-year Horizon Europe project envisioning everyone sharing their health data in European e-Health Record Exchange Format EEHRxF with a click-of-a-button, embracing the findings and specifications of several other recent and current EU projects.

Interoperability is a social thing in the first row, that was another well-received aspect. No wonder that the idea persisted to continue this kind of events. Quickly possible next locations were identified and once a year was seen as a good starting frequency. I personally suggest having the next HL7 Europe Working Group Meeting again next year, maybe that time in March.

I am confident that this HL7 Europe Working Group Meeting and HL7 FHIR Marathon was not a "nine-day wonder" but has the potential to strengthen our community during and between this kind of events. We have the people, the enthusiasm, knowledge, and a lot of opportunities in Europe to add the "interoperability bits" to the future of health for our citizens. Let's do it.

Dr. Kai U. Heitmann CEO, HL7 Germany Community Events Manager, HL7 Europe

#### Participation in HL7®FHIR®Accelerators

#### HL7®FHIR®Accelerator Vulcan: Connecting Clinical Research to Health Care



Under the umbrella of the EU Gravitate-Health project and in close collaboration with regulatory agencies including the European Medicines Agency, US FDA and the Japan PMDA. Key initiatives include the Vulcan electronic Product

Information (ePI) eLabeling project which was formed to develop a global IG for ePI in collaboration with the EU funded Gravitate-Health Project and other stakeholders. (http://www.hl7.org/vulcan/)

HL7 Europe co- organized the first Eurovulcan meeting in March 2023 in Paris, France. This meeting was well attended by industry, academia and regulators.

#### EuroVulcan Athens, Greece Conference

Building on the success of the first EuroVulcan Conference & Connectathon held in Paris, France (March 15-16, 2023), this event was strategically timed to coincide with the inaugural HL7 Europe Working Group meeting. Hosted by HL7 Hellas as part of Athens Digital Health Week, this meeting took place from January 15 to 19, 2024.

EuroVulcan 2 was a full-day event centered on "Regulatory Policy Development and Agile HL7 FHIR Implementation in Europe and Worldwide." This invitation-only gathering showcased prominent speakers from leading clinical and translational research organizations across Europe and beyond. Presentations highlighted key initiatives such as the Vulcan ePI/eLabeling Project and EMA/SPOR, alongside updates on the Utilizing the Digital Protocol / UDP Project (formerly ICH M11), with a focus on its mission, plans, key challenges, European involvement, and the transition of regulators to FHIR with support from the Vulcan Accelerator.

## **Advising, Collaboration, and Liaison Activities**

#### Liaison CEN/CENELEC Technical Committee 251



HL7 Europe continues to collaborate with CEN/CENELEC and CEN TC251 committee. In the context of this collaboration, it has established a liaison relationship and participates in the biannual meetings of the organization.

### European Federation for Medical Informatics (EFMI)



**HL7 Europe and EFMI Collaboration:** HL7 Europe works closely with EFMI, the European Federation for Medical Informatics. (www.efmi.org). Catherine Chronaki, Secretary General, HL7 Europe has been member of the Executive Board since 2016 and served as

president of EFMI 2020-2022, and past-president 2022 - 2024

#### eHealth Stakeholders Group (eHSG)



HL7 Europe was part of the European Commission eHealth Stakeholders Group 2020-2026. Catherine Chronaki, Secretary and chair of the European Strategic Advisory Board represents HL7 Europe in the eHSG.

#### Advisor to NFDI4Health



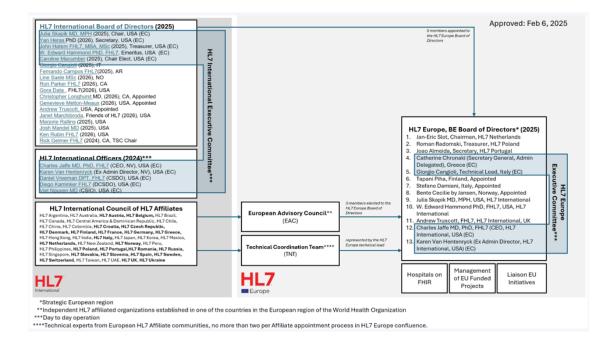
The mission of NFDI4Health is to provide new opportunities for the scientific use of personal health data while respecting privacy requirements. Based on the Findable, Assessable, Interoperable, Reusable (FAIR principles¹) services are provided to researchers

to permanently store, semantically enrich and share data in interoperable form and to merge data from different sources. Catherine Chronaki is in the advisory group of ndi4health.

## **HL7 Europe Governance**

#### Organizational Structure

The following figure shows the current organizational chart of HL7 Europe, showing the connections between the HL7 International Board of Directors, the HL7 Europe Board of Directors, the Technical Coordination Team, and the European Advisory Council. It also lists the members of the HL7 International Board of Directors and the members of the Board of HL7 Europe.



#### HL7 Europe Board of Directors 2023 - 2024:

- 1. Anne Moen, EN, PhD., FACMI, FIASHI, honEFMI, Board Chair, Norway\*\*
- Robert Stegwee, PhD., Treasurer, Netherlands\*\*
- 3. Henrique Martins, MD, PhD., Secretary, Portugal
- 4. Catherine Chronaki, Secretary General, Admin Delegate, Greece\*
- 5. Giorgio Cangioli, PhD., Technical Lead, Italy (EC)\*
- 6. Roeland Luykx, Dr. sc. nat. EAC, Switzerland\*
- 7. Jens Christian Villadsen, EAC, Denmark
- 8. Line Saele, EAC, Norway\*
- 9. Julia Skapik, MD, MPH, USA, HL7 International
- 10. W. Edward Hammond, PhD, FHL7, USA, HL7 International
- 11. Andrew Truscott, FHL7, HL7 International, UK
- 12. Charles Jaffe, MD, PhD, FHL7, CEO, HL7 International, USA (EC)\*
- 13. Karen Van Hentenryck, Ex Admin Director, HL7 International, USA (EC)\*

- \* Board members who also serve on the **HL7 Europe Executive Committee**.
- \*\*Outgoing board members

#### Incoming HL7 Europe Board of Directors 2025 - 2026

- 1. Jan-Eric Slot CIP, MD, MBA, MSc, HL7 Netherlands
- 2. Joao Almieda, PhD, HL7 Portugal
- 3. Roman Radomski, MD, MDA, HL7 Portugal
- 4. Catherine Chronaki, Secretary General, Admin Delegate, Greece\*
- 5. Giorgio Cangioli, PhD., Technical Lead, Italy (EC)\*
- 6. Bente Cecile By Jansen, Cand. Pharm, Norway
- 7. Tapani Piha, MD (FI)
- 8. Stefano Dalmiani (IT)
- 9. Julia Skapik, MD, MPH, USA, HL7 International
- 10. W. Edward Hammond, PhD, FHL7, USA, HL7 International
- 11. Andrew Truscott, FHL7, HL7 International, UK
- 12. Charles Jaffe, MD, PhD, FHL7, CEO, HL7 International, USA (EC)\*
- 13. Karen Van Hentenryck, Ex Admin Director, HL7 International, USA (EC)\*

#### Acknowledgement of Outgoing BoD Members

HL7 Europe deeply appreciates the dedicated service of our outgoing board members. Your unwavering advocacy and active engagement have been instrumental in the success of our organization. Thank you for your invaluable contributions!



Figure 6: Acknowledgement and Award to past members of the HL7 Europe Board

#### **European Technical Coordination Team**

Technical CoordiNation Team (TNT) supports the HL7 Europe goals by facilitating the technical collaboration among affiliates and experts, promoting capacity building and developing European standards, IGs, educational materials and other documents to support the HL7 Europe mission and goals.

Giorgio Cangioli	Jens Villadsen	Yohan Poiron	Nicolas Riss
HL7 Europe	HL7 Denmark	HL7 France	HL7 France
Christof Gessner	Kai Heitmann	Gabriel Kleinoscheg	Alexander Berler
HL7 Germany	HL7 Germany	HL7 Austria	HL7 Greece
Painbard Egalkrout	Hynek Kružík	Rik Smithies	Leonardo Alcaro
Reinhard Egelkrout HL7 Austria	HL7 Czech Republic	HL7 United Kingdom	HL7 Italy
Jose Costa-Teixeira	Roman Radomski	Øyvind Aassve	João Almeida
HL7 Belgium	HL7 Poland	HL7 Norway	HL7 Portugal
Oliver Egger	Alexander Henket	Daniel Karlsson	Mikael Rinnetmäki
HL7 Switzerland	HL7 Nederland	HL7 Sweden	HL7 Finland
Rutt Lindström HL7 Estonia (observer)	Nikos Kyriakoulakos HL7 Greece	Michaela Ziegler Hl7 Switzerland	

Table 1: European Technical Coordination Team

#### European Standardization Projects under the EU Realm

In 2024, TNT approved the start of the following standardization projects:

- Base and Core Profiles
- Medication Prescription and Dispense, Edition 1
- European Patient Summary, Edition 1
- Hospital Discharge Report, Edition 1

Preliminary activities started on exploring an Cancer Common Model Project, as part of the 1<sup>st</sup> HL7 Europe WGM in Athens, in January 2024.

Following ballot reconciliation, the TNT in February 2024 approved the publication of the HL7 FHIR Laboratory Report IG STU 1, for the EU Realm.

### **European Advisory Council**

The Chairs of the European Affiliate Members of HL7 International, or their designated representatives, comprise the European Advisory Council

HL7 Affiliate Member	Chair	HL7 Affiliate Member	Chair
HL7 Austria	Stefan Sabutsch	HL7 Poland	Roman Radomski
HL7 Belgium	José Costa Teixeira	HL7 Portugal	João Almeida
HL7 Croatia	Miroslav Koncar	HL7 Romania	† Florica Moldaveanu
			Andrei Vasilateanu
HL7 Czech Republic	Karel Zvara	HL7 Russia	Sergey Shvyrev
HL7 Denmark	Thea Mentz Soerensen	HL7 Slovakia	Eva Sabajova
HL7 Finland	Jari Porrasmaa	HL7 Slovenia	Brane Leskosek
HL7 France	Nicolas Riss	HL7 Spain	Francisco Perez
HL7 Germany	Silvia Thun	HL7 Sweden	Bjorn-Erik Erlandsson
HL7 Greece	Panagiotis Bamidis	HL7 Switzerland	Roeland Luykx
HL7 Italy	Stefano Lotti	HL7 UK	Ben McAlister
HL7 Netherlands	Jan-Eric Slot	HL7 Ukraine	Leonid Stoyanov
HL7 Norway	Line Saele		

Table 2: European Advisory Council (2024)

#### In Memoriam

#### Prof. Dr.-Ing. Florica Moldoveanu (1949 – †2024)



Prof. Dr.-Ing. Florica Moldoveanu was a pioneering figure in the field of medical informatics and a driving force behind the development of HL7 standards in Romania. She served as co-founder and chair of HL7 Romania from its inception in 2006 until her passing in 2024.

She earned her PhD in 1982 and was appointed full professor in 1990 at the Politehnica University of Bucharest, Romania. Between 2007 and 2014, she served as Vice-Dean for MSc and PhD education in the Faculty of Automation and Computers. Over the course of her academic career, she supervised 27 doctoral theses and taught extensively in computer graphics, software engineering, graphical processing systems, volume data visualization, and computer animation.

Prof. Moldoveanu authored over 200 scientific publications, held more than seven patents, and contributed to 26 books or book chapters. She was also a co-author of the ISO/IEEE 11073-20601 standard for personal health device communication.

Under her leadership, HL7 was introduced as the standard for Romania's first national electronic health record (EHR) system, where it was selected as the best among existing international standards. This system remains in use today.

She was instrumental in promoting HL7 knowledge across Romania and Moldova by organizing foundational and advanced HL7 training, including HL7 FHIR courses in collaboration with HL7 International.

Prof. Moldoveanu passed away in November 2024. Her death marked a profound loss to the HL7 and academic community. She will be remembered as a model of professionalism, commitment, and tireless dedication throughout her distinguished career.

# Affiliate Map



Figure 7: Map of HL7 Europe Affiliates

### **Treasurer Report**



The HL7 Europe budget for 2024 consisted mainly of overhead contributions from the projects that HL7 Europe participates in, as well as smaller contributions from HL7 International. The HL7 International Council was kind enough to provide funds to enable the HL7 Affiliate Members across Europe to attend the first HL7 Europe Working Group Meeting (WGM) in Athens. The WGM costs accounted for one of the major costs across the 2024 budget. Financial and auditing expenses are rising, as the requirements from the European

Commission are getting stricter and HL7 Europe wants to make sure the financial statements are a proper reflection of the large amounts of funding that the organisation handles. Even so, the operational costs for the office are less than 40% of the overall budget, allowing room for specific HL7 Europe activities, including the WGM and the Hospitals on FHIR initiative. Also, the redevelopment of the website and extended communications efforts have been funded from the 2024 budget. In all, we had a good year, in which we did not fully meet the budget, meaning that we spent less than projected and agreed upon by the Board. For the future, HL7 Europe will be looking into other means of income, for instance through education and participation in HL7 Europe activities.

Robert Stegwee, Chair CEN TC/251, Treasurer HL7 Europe, 2023-2024

# **Financial Report**

## HL7 Europe Annual Results 2024

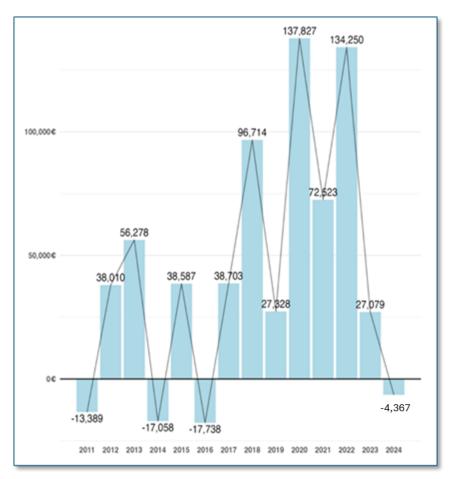


Figure 3: Annual Results 2010-2024

### Annual Accounts Statement 2024



#### **BILAN APRÈS RÉPARTITION**

	Ann.	Codes	Exercice	Exercice précédent
ACTIF				
FRAIS D'ÉTABLISSEMENT		20		
ACTIFS IMMOBILISÉS		21/28	2.730	<u>2.7</u>
Immobilisations incorporelles	6.1.1	21		
Immobilisations corporelles	6.1.2	22/27		
Terrains et constructions		22		
Installations, machines et outillage		23		
Mobilier et matériel roulant		24		
Location-financement et droits similaires		25		
Autres immobilisations corporelles		26		
Immobilisations en cours et acomptes versés		27		
Immobilisations financières	6.1.3	28	2.730	2.7
ACTIFS CIRCULANTS		29/58	1.745.753	<u>1.249.1</u>
Créances à plus d'un an		29		
Créances commerciales		290		
Autres créances		291		
Stocks et commandes en cours d'exécution		3		
Stocks		30/36		
Commandes en cours d'exécution		37		
Créances à un an au plus		40/41	252.168	
Créances commerciales		40	252.168	
Autres créances		41		
Placements de trésorerie		50/53		
Valeurs disponibles		54/58	1.487.905	1.245.6
Comptes de régularisation		490/1	5.680	3.5
TOTAL DE L'ACTIF		20/58	1.748.483	1.251.8



2.730

2.730 1.249.148

1.245.623 3.525 1.251.878

	Ann.	Codes	Exercice	Exercice précédent
PASSIF				
FONDS SOCIAL		10/15	<u>615.559</u>	<u>619.926</u>
Fonds de l'association ou de la fondation		10	813	813
Plus-values de réévaluation		12		
Fonds affectés et autres réserves		13		
Bénéfice (Perte) reporté(e)	(+)/(-)	14	614.746	619.113
Subsides en capital		15		
PROVISIONS ET IMPÔTS DIFFÉRÉS		16		
Provisions pour risques et charges		160/5		
Pensions et obligations similaires		160		
Charges fiscales		161		
Grosses réparations et gros entretien		162		
Obligations environnementales		163		
Autres risques et charges		164/5		
Provisions pour subsides et legs à rembourser et pour dons avec droit de reprise		167		
Impôts différés		168		
DETTES		17/49	<u>1.132.924</u>	<u>631.952</u>
Dettes à plus d'un an		17		
Dettes financières		170/4		
Etablissements de crédit, dettes de location-financement et assimilées		172/3		
Autres emprunts		174/0		
Dettes commerciales		175		

178/9

42/48

42

43

430/8 439

440/4

441

450/3

454/9

492/3

10/49

48

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Acomptes sur commandes

Dettes à plus d'un an échéant dans l'année

Rémunérations et charges sociales

Autres dettes

Dettes à un an au plus

Dettes financières Etablissements de crédit

Autres emprunts

Dettes commerciales Fournisseurs

Effets à payer

Impôts

TOTAL DU PASSIF

Acomptes sur commandes

Dettes fiscales, salariales et sociales

Comptes de régularisation



283.773

274.111

9.662

849.151

1.748.483

274.111

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631.952

611.011

20.941

1.251.878

611.011

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### COMPTE DE RÉSULTATS

		Codes	Exercice	Exercice précédent
Produits et charges d'exploitation				
Marge brute d'exploitation	(+)/(-)	9900	-36.165	41.020
Dont: produits d'exploitation non récurrents		76A		
Chiffre d'affaires		70		
Cotisations, dons, legs et subsides		73		
Approvisionnements, marchandises, services et biens divers		60/61		
Rémunérations, charges sociales et pensions	(+)/(-)	62		
Amortissements et réductions de valeur sur frais d'établissement, sur immobilisations incorporelles et corporelles		630		
Réductions de valeur sur stocks, sur commandes en cours d'exécution et sur créances commerciales: dotations (reprises)	(+)/(-)	631/4		
Provisions pour risques et charges: dotations (utilisations et reprises)	(+)/(-)	635/9		
Autres charges d'exploitation		640/8		
Charges d'exploitation portées à l'actif au titre de frais de restructuration	(-)	649		
Charges d'exploitation non récurrentes		66A		
Bénéfice (Perte) d'exploitation	(+)/(-)	9901	-36.165	41.020
Produits financiers		75/76B	31.798	1.321
Produits financiers récurrents		75	31.798	1.321
Produits financiers non récurrents		76B		
Charges financières		65/66B		15.261
Charges financières récurrentes		65		15.261
Charges financières non récurrentes		66B		
Bénéfice (Perte) de l'exercice avant impôts	(+)/(-)	9903	-4.367	27.080
Prélèvement sur les impôts différés		780		
Transfert aux impôts différés		680		
Impôts sur le résultat	(+)/(-)	67/77		
Bénéfice (Perte) de l'exercice	(+)/(-)	9904	-4.367	27.080
Prélèvement sur les réserves immunisées		789		
Transfert aux réserves immunisées		689		
Bénéfice (Perte) de l'exercice à affecter	(+)/(-)	9905	-4.367	27.080



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#### AFFECTATIONS ET PRÉLÈVEMENTS

Bénéfice (Perte) à affecter
Bénéfice (Perte) de l'exercice à affecter
Bénéfice (Perte) reporté(e) de l'exercice précédent
Prélèvement sur les capitaux propres: fonds, fonds affectés et autres réserves
Affectation aux fonds affectés et autres réserves
Bénéfice (Perte) à reporter

Codes	Exercice	Exercice précédent
9906	614.746	619.113
(9905)	-4.367	27.080
14P	619.113	592.033
791		
691		
(14)	614.746	619.113



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#### ANNEXE

#### ETAT DES IMMOBILISATIONS

		Codes	Exercice	Exercice précédent
IMMOBILISATIONS FINANCIÈRES				
Valeur d'acquisition au terme de l'exercice		8395P	XXXXXXXXX	2.730
Mutations de l'exercice				
Acquisitions		8365		
Cessions et retraits		8375		
Transferts d'une rubrique à une autre	(+)/(-)	8385		
Autres mutations	(+)/(-)	8386		
Valeur d'acquisition au terme de l'exercice		8395	2.730	
Plus-values au terme de l'exercice		8455P	XXXXXXXXX	
Mutations de l'exercice				
Actées		8415		
Acquises de tiers		8425		
Annulées		8435		
Transférées d'une rubrique à une autre	(+)/(-)	8445		
Plus-values au terme de l'exercice		8455		
Réductions de valeur au terme de l'exercice		8525P	XXXXXXXXX	
Mutations de l'exercice				
Actées		8475		
Reprises		8485		
Acquises de tiers		8495		
Annulées à la suite de cessions et retraits		8505		
Transférées d'une rubrique à une autre	(+)/(-)	8515		
Réductions de valeur au terme de l'exercice		8525		
Montants non appelés au terme de l'exercice		8555P	XXXXXXXXX	
Mutations de l'exercice	(+)/(-)	8545		
Montants non appelés au terme de l'exercice		8555		
VALEUR COMPTABLE NETTE AU TERME DE L'EXERCICE		(28)	2.730	

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### Statement of Certified Accountant 2024



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#### INDEPENDENT REPORT OF THE AUDITOR REGARDING THE LIMITED REVIEW OF THE ANNUAL ACCOUNTS OF THE YEAR ENDED AS PER DECEMBER 31, 2024 OF HL7 INTERNATIONAL PRIVATE FOUNDATION

We have carried out a limited review on the financial statements of HL7 International Private Foundation ("HL7 International), established at Square de Meeûs 38-40 in 1000 Brussels (company number 0826-312-613), for the period of 1st January 2024 till 31st December 2024, drawn up on the basis of the accounting reference system applicable in Belgium, with a balance sheet total per 31st December 2024 of EUR 1.748.483,50 and whose income statement closes with a loss for the financial year of EUR 4.367,03.

The preparation of the annual accounts is the responsibility of the governing body of HL7 International.

The responsibility includes, among other things: establishing, implementing and maintaining internal control over the preparation and fair representation of the financial statements that are free from material misstatement due to fraud or error, choosing and applying appropriate valuation rules, and making accounting estimates that are reasonable under the circumstances.

Our review is carried out in accordance with the standards of the Royal Institute for Auditors. These professional standards require that our review be organized and conducted in such a way as to obtain reasonable assurance that the financial statements do not contain material misstatements.

In accordance with these standards, we have taken into account the administrative and accounting organization of the association, as well as the procedures of internal control.

The governing body of the foundation has answered our questions for the further clarification or information. On the basis of samples, we examined the justification of the amounts included in the submitted balance sheet and income statement.

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ORB Brussel - BTW: BE045,925,059

During our work, no significant deviations were found in which the operating costs were insufficiently accounted for by supporting documents and where these operating costs were not spent on other than the actual purposes of the foundation.

We have reviewed the valuation rules, the meaningful accounting estimates that the foundation made and the presentation of the balance sheet and income statement. We believe that our work provides a reasonable basis for expressing our opinion.

In conclusion, we declare that based on our limited review of the financial statements as at 31<sup>st</sup> December 2024 of HZ7 International, we are not aware of any material misstatements that would distort the true and fair view of the financial statements prepared by the foundation.

Antwerp, 24st October 2025

Guy Franken

Guy Franken Legal Auditor



### **HL7 Europe's Future Outlook**

HL7 Europe is strategically positioned to strengthen the HL7 EU realm and expand its impact. Our strengthened core team will work closely with the HL7 Community in Europe to develop HL7® FHIR® IGs, specifications and educational material that address and support specific European healthcare requirements and correct implementation, guided by the Technical Coordination Team (TNT) chaired by Giorgio Cangioli, the Technical Lead of HL7 Europe.

HL7 Europe also plans to support healthcare facilities, startups and SMEs, as resources allow, to further accelerate HL7® FHIR® implementation across Europe by supporting with key initiatives within the <u>European Health Data Space</u> (EHDS), most notably the myHealth@EU and HealthData@EU infrastructures. HL7 Europe in collaboration with HL7 Affiliates in Europe commits to support the EHDS with robust HL7 FHIR specifications in the EU realm. In this context the xShare project and our engagement with the xt-EHR and TEDHAS2 joint actions are expected to play a key role. Our support to the community will be demonstrated by investing reserves to develop an environment where interested individuals can work and explore HL7 FHIR IGs and specifications that HL7 Europe has developed in the context of EU funded research projects.

The second Hospitals on FHIR® User Days event in Brussels, Belgium, achieved significant success, drawing a record number of participants both in person and online. That event garnered significant attendance, robust industry backing, and earned overwhelmingly positive feedback regarding its content—especially the clinical implementation use cases—and the networking it facilitated.

In 2024, HL7 Europe continued to support and grow FHIR adoption in European healthcare, focusing on hospitals and will continue to grow the Hospitals on FHIR® initiative, attracting more membership and activating national and regional chapters.

2024 also saw strong continued focus on close collaboration with HL7® FHIR® Accelerator Vulcan and will partner with global SDOs and regulatory authorities to bridge the gap between healthcare and clinical trials. By streamlining data exchange and interoperability between healthcare and clinical trials data, we anticipate significant benefits for EU citizens, including faster drug approvals and swift access to innovative treatments and therapies.

HL7 Europe continues to work towards enhancing the future of digital healthcare and will continue to collaborate with the European Federation for Medical Informatics (EFMI) to shape the education of young professionals, striving to support women in health informatics and advance data and standards literacy.

HL7 Europe will continue its productive synergy with CEN/TC251 and formal participation CEN/CENELEC as liaison member. Additionally, thanks to xShare project, we will continue

to work closely with IHE-Europe, SNOMED, CDISC, and IEEE towards developing the European Standards and Policy Hub. Beyond the EHDS through funded European projects we will explore issues of One Digital Health, Secondary Use of Data focusing on Genomics of Cardiovascular disease, and Cancer data modeling.

At the same time, HL7 Europe actively participate in eHealth Stakeholder Group of the European Commission engaging with umbrella organizations in digital health to advance interoperability

# **Acknowledgements**

We extend our sincere gratitude to our members, volunteers, partners, and staff for their tireless efforts and unwavering commitment. Your contributions have been pivotal to our success, and we eagerly anticipate our future achievements together.

### **Appendix**

### Scientific Articles published in 2024

- An assessment of the European Patient Summary for clinical research: a case study in cardiology by GB Laleci Erturkmen, AA Sinaci, T Namli, MJ Boonstra, K Lekadir, in Frontiers in Medicine 11, 1481551
- Assessment of HL7 FHIR Interoperability Between EHR Systems and the Survivorship Passport v2. 0 Platform to Generate Treatment Summaries for Childhood Cancer Survivors in Six ...by D Saraceno, C Chronaki, G Cangioli, AL Filbert, M Muraca, A Berti, ...Studies in health technology and informatics 316, 1280-1284
- HL7 Fast Healthcare Interoperability Resources (HL7 FHIR) in digital healthcare ecosystems for chronic disease management: Scoping review by R Gazzarata, J Almeida, L Lindsköld, G Cangioli, E Gaeta, G Fico, ... International journal of medical informatics, 105507
- IT-related barriers and facilitators to the implementation of a new European eHealth solution, the digital survivorship passport (SurPass version 2.0): semistructured digital by IAE de Beijer, SR van den Oever, E Charalambous, G Cangioli, in Journal of Medical Internet Research 26, e49910
- Barriers and facilitators to implementation of the interoperable Survivorship Passport (SurPass) v2. 0 in 6 European countries: a PanCareSurPass online survey study by SR van den Oever, IAE de Beijer, LCM Kremer, M Alfes, J Balaguer, by Journal of Cancer Survivorship 18 (3), 928-940
- Scaling up and implementing the digital Survivorship Passport tool in routine clinical care –The European multidisciplinary PanCareSurPass project by AL Filbert, L Kremer, R Ladenstein, C Chronaki, A Degelsegger-Márquez, in European Journal of Cancer 202, 114029
- Monitoring the healthy status of urban streams by S Kokolakis, E Kokinou, C Chronaki in E3S Web of Conferences 585, 09002
- Earth Observation and Geoinformatics to Monitoring the Environmental Status of Urban Streams Inextricably Linked to People's Mental Health by S Kokolakis, E Kokinou, C Chronaki, A Moen, G Datta in Digital Health and Informatics Innovations for Sustainable Health Care
- Childhood Cancer Survivorship Passport Challenges in the European Health Data Space by R Gazzarata, M Strübin, C Chronaki, G Cangioli, D Saraceno, G Schreier, in Digital Health and Informatics Innovations for Sustainable Health Care
- The Role of HL7 FHIR in the European Project GATEKEEPER by R Gazzarata, C Chronaki, A Gallego, E Gaeta, G Fico, P Zampognaro, ... MEDINFO 2023—The Future Is Accessible, 1337-1338