

# 2022 - 2023 ANNUAL REPORT -127 Europe

HI7europe.org

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## HL7 Europe

Health Level Seven<sup>®</sup> (HL7<sup>®</sup>) 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)

The HL7 Europe Foundation is a not-for-profit, regional European office of Health Level Seven<sup>®</sup> (HL7<sup>®</sup>) International established in Brussels, Belgium, in 2010 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 22 European Affiliates, HL7 Europe supports the creation of health information technology standards that are widely used enabling interoperability in healthcare to encourage use of HL7 standards in European health systems and provide education services, promote tools and facilitate testing and certification. HL7 Clinical Document Architecture (CDA) is used by myHealth@EU to record patient summaries and ePrescriptions. HL7 is also the home of Fast Healthcare Interoperability Resources (HL7<sup>®</sup> FHIR<sup>®</sup>). HL7 Europe is a member of the eHealth Stakeholder Group. HL7 Europe is also active in the development of EHRxF specifications for the European Health Data Space developing and supporting work with HL7<sup>®</sup> FHIR<sup>®</sup> IGs. (https://fhir.org)

In January 2023, a new HL7 Europe Board of Directors (BoD) was formed to include Anne Moen, PhD., as Chair and 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.

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. 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. These activities and initiatives are made possible through participation in EU funded research programs.

## **General Secretary Summary**

## General Secretary, HL7 Europe

HL7 Europe continued to grow in 2022 and 2023 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.

The Technical Steering Committee (TNT) for Europe continues to oversee and coordinate the development of HL7 standards in Europe. 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.

The **Hospitals on FHIR**<sup>®</sup> (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. At the same time, HL7 Europe collaborates closely with the **HL7**<sup>®</sup> **FHIR**<sup>®</sup>**Accelerator** to connect healthcare data and clinical trial data effectively. HL7 Europe continues to be active in the HL7<sup>®</sup> FHIR<sup>®</sup> Vulcan Accelerator. In collaboration with **HL7**<sup>®</sup> **FHIR**<sup>®</sup>**Accelerator**, we co-organized the EuroVulcan meeting in Paris (March 2023) in alignment with EMA and US FDA a global HL7<sup>®</sup> FHIR<sup>®</sup> IG for ePI was delivered and made freely available. These activities were part of the Gravitate Health project which is funded by the EU IHI program.

In the area of funded projects, we successfully concluded **X-eHealth** in November 2022. The **IDEA4RC** for solid tumor cancers started in September 2022. 2023 marked a significant year for HL7 Europe, with a surge in funded projects. Our first climate-related project, **OneAquaHealth**, linking urban stream health to human well-being started in January 2023. The work on European EHR Exchange format continued with the start of the **XpanDH** project also in January 2023. **Flute** for synthetic data in pancreatic cancer started in May 2023, and **xShare** which aims to deliver the "yellow" button for EHDS/European EHRxF, with HL7 Europe as Technical Director, started in December 2023.

The significant increase in funded projects in 2023 has enabled HL7 Europe to expand its team by six new members, positioning us for substantial future growth. The impact of this funded expansion will accelerate the delivery of fit-for-purpose, HL7 specifications and IGs, making them freely available and empowering European healthcare organizations and patients to exchange health information.

## **BoD Chair Summary**

#### Chair, Board of Directors, HL7 Europe

It has been a true honor to serve as Board Chair of the HL7 Board of Directors the last year. Reflecting on the activities in 2023-2024 it is nice to see how HL7 Europe grew and matured with the extensive interest in the development and use of HL7<sup>®</sup> FHIR<sup>®</sup> interoperability resources. As I step down, I look forward to continued engagement with HL7 Europe in projects and interest areas. Allow me to mention Gravitate-Health (<u>www.gravitatehealth.eu</u>), a project I coordinate and HL7 Europe is a key partner. I look forward to continued effort to ensure there are relevant interoperability resources and HL7<sup>®</sup> FHIR<sup>®</sup> Implementation Guides (IGs), to liberate personal health data, and the use of such personal 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 towards reliable exchange data and the evolving European Health Data Space (EHDS) that ensures diversity, equity and inclusion, where advanced interoperability standards are part of solutions in a future and 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 development of the European EHR Exchange Format spearheaded by the health 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. Current HoF Co-Chairs are Maria Bastos Salazar (CIO, ULSS Antonio Porto, Portugal) and Stefano Dalmiani (CIO, FMTH, Italy). The Terms of Reference were recently updated to provide guidance for members of HoF. (https://www.hospitalsonfhir.eu)



**HL7® FHIR®Accelerator Vulcan**: the accelerator for connecting clinical research to health care. Under the umbrella of the EU Gravitate-Health project and in close collaboration with regulatory agencies European Medicines Agency, and regulatory agencies outside Europe including US FDA and the Japanese PMDA.

Key initiatives include 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 and other stakeholders. (<u>http://www.hl7.org/vulcan/</u>)

During 2022- 2023 several HL7<sup>®</sup> FHIR<sup>®</sup> specification and Implementation Guides were developed by HL7 Europe within the European Union funded projects. Notable among these are the HL7<sup>®</sup> FHIR<sup>®</sup> ePI IG and the Gatekeeper HL7 FHIR IG. Additionally, the "<u>EFMI FAIR – FAIR data in Health</u> <u>Research Performing Organizations (HRPOs)</u>" working group was established to further maintain the HL7 FAIRness for HL7<sup>®</sup> FHIR<sup>®</sup> IG, that was developed in the project FAIR4HEALTH.

## **EU Funded Projects Pipeline**

## Introduction

HL7 Europe has a proven track record of securing grant funding from prestigious sources like the EU Horizon, IMI, and IHI. This success is attributed to our strong network of connections and collaborations. By aligning grant-funded projects with our strategic goals, we ensure that our work contributes to the advancement of healthcare IT and interoperability. The following section provides an overview of current funded and unfunded projects.



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.

**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>, co-lead Vulcan ePI project, ePI creator, server and <u>viewe</u>r dedicated to the Gravitate-Health ePI services.

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

**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: €729 428,75

**HL7 Europe Team**: Joao Almeida, Giorgio Cangioli, Catherine Chronaki and Henrique Martins **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<sup>®</sup> FHIR<sup>®</sup> 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 and Catherine Chronaki
- Project Website: <u>https://www.pancaresurpass.eu/</u>
- For more information: https://cordis.europa.eu/project/id/899999



## X-eHealth: X-echanging electronic Health Records in a Common Framework

Towards a common European health data structure. 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.

**Role for HL7 Europe:** Serve as Specifications co-leader (WP6) and Case-study and innovation co-lead.

**Funded under**: H2020-EU.3.1. Health, demographic change and well-being H2020-EU.3.1.5.1. - Improving health information and better use of health data. Topic: SC1-HCC-07-2020 - Support for European eHealth Interoperability roadmap for deployment

Duration: 1 September 2020 to 31 November 2022

Overall budget: € 2 999 980

EU contribution: € 2 999 980

Coordinated by: SPMS - SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE SPMS -

SERVICOS PARTILHADOS DO MINISTERIO DA SAUDE EPE, Portugal

Funding for HL7 Europe: € 225 875

**HL7 Europe team:** Robert Hausam, Roberta Gazzarata, Giorgio Cangioli and Catherine Chronaki **Project Website:** https://www.spms.min-saude.pt/x-ehealth/

For more information: https://cordis.europa.eu/project/id/951938/reporting



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

The 2019 Commission recommendation on the European Electronic Health Record Exchange Format 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 <u>XpanDH project</u> 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.

- 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: <u>https://xpandh-project.iscte-iul.pt</u>
- 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 and Catherine Chronaki.
- Project Website: <u>https://xshare-project.eu</u>
- For more information: <u>https://cordis.europa.eu/project/id/101136734/de</u>



GATEKEEPER Smart Living Homes – Whole Interventions Demonstrator for People at Health and Social Risks Digital applications for elders independent living.

The rising population of elderly in the EU member states is

giving rise to new challenges in relation to independent living. The EU-funded GATEKEEPER project aims to ensure healthier independent lives for the ageing populations. It will connect healthcare providers, businesses, entrepreneurs, elderly citizens and the communities they live in. The goal is to create an open, trust-based arena for matching ideas, technologies, user needs and processes. The project will also incorporate data protection while underpinning value creation using advanced marketing patterns. The solutions deployed will involve 40 000 elderly citizens, as well as authorities, institutions, companies, associations and academics, and 8 regional communities from 7 EU member states.

**Role for HL7 Europe:** Support the implementation of HL7<sup>®</sup> FHIR<sup>®</sup> development of Gatekeeper HL7<sup>®</sup> FHIR<sup>®</sup> IG

**Funded under**: H2020-EU.3.1. SOCIETAL CHALLENGES Health, demographic change and wellbeing, H2020-EU.3.1.4.1. Active ageing, independent and assisted living, H2020-EU.2.1.1.3.Future Internet: Software, hardware, Infrastructures, technologies and services

Duration: 1 October 2019 to 31 March 2023

**Overall budget**: € 20 730 965,50

**EU contribution**: € 19 598 327,19

**Coordinated by:** Medtronic Iberia, ES

Funding for HL7 Europe: € 311 250

HL7 Europe team: Roberta Gazzarata, Giorgio Cangioli and Catherine Chronaki.

Project Website: https://www.gatekeeper-project.eu/

For more information: https://cordis.europa.eu/project/id/857223



## 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<sup>®</sup> FHIR<sup>®</sup>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 and Catherine Chronaki.
- Project Website: <u>https://www.idea4rc.eu</u>
- For more information: https://cordis.europa.eu/project/id/101057048/reporting



## FLUTE: Pioneering secure healthcare AI 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<sup>®</sup> FHIR<sup>®</sup> IG</u> and works on HL7<sup>®</sup> FHIR<sup>®</sup> 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 and Giorgio Cangioli
- Project Website: <u>https://www.fluteproject.eu</u>
- For more information: <a href="https://cordis.europa.eu/project/id/101095382">https://cordis.europa.eu/project/id/101095382</a>

## OneAquaHealth 鎀

## 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<sup>®</sup> FHIR<sup>®</sup> (Fast Healthcare Interoperability Resources). The use of FHIR<sup>®</sup> 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, Catherine Chronaki and Giorgio Cangioli.
- Project Website: <u>https://www.oneaquahealth.eu</u>
- For more information: https://cordis.europa.eu/project/id/101086521



#### UNICOM: Upscaling the Global Univocal

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)

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 Kommunicakations and technologie forschung MBH, Germany

Funding for HL7 Europe: € 337 753,73

HL7 Team: Joao Almeida, Giorgio Cangioli and Catherine Chronaki

For more information: https://unicom-project.eu

## Key Initiatives

## Hospitals on FHIR®



Hospitals on FHIR<sup>®</sup> (HoF): 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<sup>®</sup> FHIR<sup>®</sup> within the European healthcare landscape, focusing on hospitals. HL7<sup>®</sup> FHIR<sup>®</sup> 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

Since its launch in March 2022, European Hospitals on FHIR has organized several highly successful events:

- November 2022: Joint xEHEALTH HoF meeting
- January 2023: HL7<sup>®</sup> FHIR<sup>®</sup> for Data Protection Officers webinar
- April 2023: CDA to HL7<sup>®</sup> FHIR<sup>®</sup> HL7 Europe Workshop
- September 2023: Inaugural Hospitals on FHIR® User Days in Rennes, France

For a map of Hospitals on FHIR<sup>®</sup> members visit: <u>https://www.hospitalsonfhir.eu/map</u>

## Hospitals on FHIR® Maturity Model

The Hospitals on FHIR<sup>®</sup> maturity model is a framework to determine the status of a hospital's HL7<sup>®</sup> FHIR<sup>®</sup> 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<sup>®</sup> Maturity Model, hospitals can effectively navigate the complexities of HL7<sup>®</sup> FHIR<sup>®</sup> implementation and realize its full potential to improve patient care, enhance interoperability, and drive innovation in healthcare.

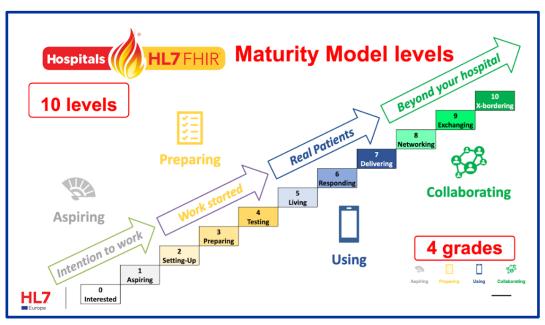


Figure 1: Hospitals on FHIR® Maturity Model

## Hospitals on FHIR<sup>®</sup> Events 2022 - 2023

2022

- European Hospitals on FHIR<sup>®</sup> Launch Event, March 31, 2022
- European Hospitals on FHIR<sup>®</sup> at MIE 2022 Nice, France, May 2, 2022
- European Hospitals on FHIR<sup>®</sup> at HIMMS Helsinki, Finland, May 16, 2022
- X-EHEALTH (Partnership with HOF) November 24, 2022

#### 2023

- HL7<sup>®</sup> FHIR<sup>®</sup> For Data Protection Officers Webinar. January 30, 2023
- Experiences on FHIR Adoption #2, Webinar, April 5, 2023
- CDA to HL7 FHIR<sup>®</sup> HL7 Europe Workshop Webinar, April 28, 2023
- L'Eclozr in Rennes, September 25th, 2023
- Hospitals on FHIR<sup>®</sup>: Experiences on FHIR Adoption #1, Webinar, November 30, 2023

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

#### Governance

In 2023, Marias Bastos Salazar (CIO, UHPorto, PT) and Stefano Damiani, (CIO, FMTH, IT) assumed the role of co-chairs for the initiative.

Terms of Reference were recently updated to provide guidance for members and potential members of Hospitals on FHIR<sup>®</sup>.

HL7 Europe extends its gratitude to the HoF Steering Committee for their invaluable support and engagement in the success of the Hospitals on FHIR<sup>®</sup> User Days.

#### Participation in HL7®FHIR®Accelerator

HL7<sup>®</sup>FHIR<sup>®</sup>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. (<u>http://www.hl7.org/vulcan/</u>)

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

## **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.

## 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 represent HL7 Europe in the eHSG.

## Advisors to European Union Funded Projects

Pharmaledger



A digital boost for the healthcare industry. The internet and other digital advances are playing an increasingly bigger role in daily life by enabling industries to innovate, thus delivering improved services to both consumers and providers. Unfortunately, the healthcare industry hasn't caught up as fast. The EU-funded PharmaLedger project will create and introduce a

blockchain-based framework that will efficiently digitalise the healthcare industry and empower patients. It plans to do this by bringing together 29 partners including 10 EU member states, several large pharmaceutical companies and many other specialists in blockchain development, security, privacy and business intelligence. The goal of the project is to provide a widely trusted platform that will support the design and adoption of blockchain-enabled healthcare solutions while accelerating delivery of innovation that will benefit the entire ecosystem, from manufacturers to patients.

#### **InteropEHRate**



Electronic health records made easy for patients to manage. The electronic health record (EHR) collects, Interopehrate systematises and stores patient data in a digital format to

EHR in people's hands across Europe improve healthcare systems. However, there is a low level of systems interoperability in Europe since data are collected in different silos and managed under converging security and safety conditions. This creates legal hurdles in the availability of data. The EU-funded InteropEHRate project will reverse trends by ensuring that health data are available when and where needed. It will provide patients with full control in usage and routes of their medical information through device-to-device and peer-to-peer protocol standards. It will also outline a set of new protocols for secure and cross-border exchange of medical evidence.

#### NFDI4Health: National Research Data Infrastructure for Personal Health Data



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 principles<sup>1</sup>) 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

### HL7 Europe Board of Directors 2022 – 2023:

- Anne Moen, PhD., Chair, Norway
- Robert Stegwee, PhD., Treasurer, Netherlands
- Henrique Martins, MD, PhD., Secretary, Portugal
- Catherine Chronaki, Secretary General, Admin Delegate, Greece\*
- Giorgio Cangioli, PhD., Technical Lead, Italy (EC)\*
- Roeland Luykx, Dr. sc. nat. EAC, Switzerland
- Jens Christian Villadsen, EAC, Denmark
- Line Saele, EAC, Norway
- Julia Skapik, MD, MPH, USA, HL7 International
- W. Edward Hammond, PhD, FHL7, USA, HL7 International
- Andrew Truscott, FHL7, HL7 International, UK
- Charles Jaffe, MD, PhD, FHL7, CEO, HL7 International, USA (EC)\*
- Karen Van Hentenryck, Ex Admin Director, HL7 International, USA (EC)\*
- \* Board members who also serve on the HL7 Europe Executive Committee.

## 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	Francois Maçary	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
Alexander Mense HL7 Austria	Hynek Kružík HL7 Czech Republic	Rik Smithies HL7 United Kingdom	Leonardo Alcaro HL7 Italy
Jose Costa-Teixeira HL7 Belgium	Sebastian Bojanowski HL7 Poland	Øyvind Aassve HL7 Norway	João Almeida HL7 Portugal

Oliver Egger	Alexander Henket	Daniel Karlsson	Mikael Rinnetmäki
HL7 Switzerland	HL7 Nederland	HL7 Sweden	HL7 Finland
Rutt Lindström		1	
HL7 Estonia ( <i>observer</i> )			

Table 1: European Technical Coordination Team
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## European Strategic Advisory Board

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

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 Moldoveanu	
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 Strategic Advisory Board

#### Affiliate Map



Figure 2: Affiliate Map

## 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<sup>®</sup> FHIR<sup>®</sup> 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<sup>®</sup> FHIR<sup>®</sup> 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 inaugural Hospitals on FHIR<sup>®</sup> User Days, held in Rennes, France in 2023, was a resounding success. The event was well-attended, with strong industry support, and received overwhelmingly positive feedback. Moving into 2024, HL7 Europe will continue to support FHIR adoption in European healthcare, focusing on hospitals and will continue to grow the Hospitals on FHIR<sup>®</sup> initiative, attracting more membership and activating national and regional chapters.

HL7 Europe will also continue to focus on close collaboration with HL7<sup>®</sup> FHIR<sup>®</sup> Accelerator <u>Vulcan</u> 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 are committed to 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, we will actively participate in eHealth Stakeholder Group of the European Commission engaging with umbrella organizations in digital health to advance interoperability

## **Financial Report**

## HL7 Europe Annual Reserves 2011 – 2023

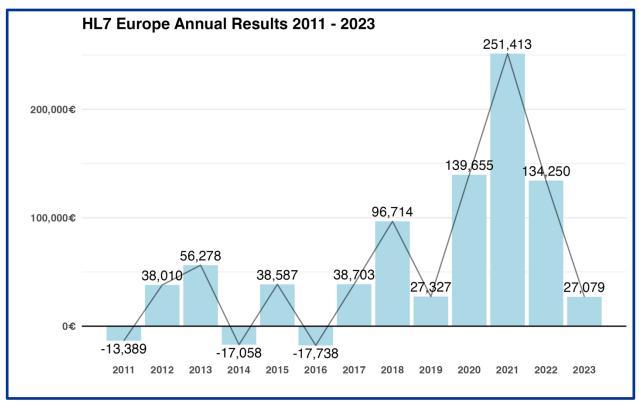


Figure 3: Annual Reserves 2011 – 2023

## Annual Accounts Statement 2023

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	ILS (at the filing	date)					-
NAME: HL7 INTERNA	TIONAL						
Legal form <sup>1</sup> : Private fo							
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Postal code: 1000 Country: Belgium		Town: Brussel 1					
Register of legal persons	s - commercial cou	urt: Brussel, French-s	peaking				
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E-mail address <sup>2</sup> :				Enterpris	e numbe	r 🗌	0826.312.613
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N*. 0826.312.613	MIC-npi 2
LIST OF DIRECTORS AND AUDITORS	
LIST OF DIRECTORS AND AUDITORS	
COMPLETE LIST with sumame, first names, profession, place of residence (address, number, postal code and town) within the association or foundation	and position
Chronaki Catherine Ermi AG Ioanni 30, 71409 Heraklion, Greece	
Mandate: Delegated director, start: 31/07/2020	
Jaffe Charles Jack Forest Way 1619, 92014 Del Mar, United States of America	
Mandate: Director, start: 31/07/2020	
Stegwee Robert Arjen Spoorstraat 31, 7471 BV Goor, Netherlands	
Mandate: Director, start: 31/07/2020	
Hammond William Edward PO Box 3054, 27712 Durham NC, United States of America	
Mandate: Director, start: 31/07/2020	
Gil Martins Henrique Manuel R. Nova 38, 2640-73 Sao Miguel De Alcainca, Portugal	
Mandate: Director, start: 31/07/2020	
Dougali Mark Douglas	
Chesley Armstrong Drive 1333, 48188-1 Cheslea MI, United States of America	
Mandate: Director, start: 31/07/2020, end: 15/01/2024	
Gangioli Giorgio Viale della Cristallina 3, FI50019 Sesto Florentina, Italy	
Mandate: Director, start: 31/07/2020	
Saele Line Andreassen Steinvikkroken 37, 5237 Radal, Norway	
Mandate: Director, start: 31/07/2020	
Moen Anne Gulikrokken 5, 0377 Oslo, Norway	
Mandate: Director, start: 31/07/2020	
	2/9

#### N\*. 0826.312.613

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LIST OF DIRECTORS AND AUDITORS (continued from previous page)

#### Villadsen Jens Kristian Stalhojen 24, 8240 Risskov, Denmark

Mandate: Director, start: 31/07/2020

Skapik Julia Lynn 16th street 7810, 20012 Washington DC, United States of America

Mandate: Director, start: 31/07/2020

LUYKX Roeland Thomas Nicolaas Märzengasse 23, 5430 WETTINGEN, Switzerland

Mandate: Director, start: 02/12/2022

TRUSCOTT Andrew John Barby Lane 1, CV22 QJ Rugby, United Kingdom

Mandate: Director, start: 02/12/2022

N*. 0826.312.613				MIC-npi 3.1
	ANNUAL	ACCOUNTS	5	
BALANCE SHEET AFTER APPROPRIATIO	N			
	Notes	Codes	Period	Preceding period
ASSETS				
FORMATION EXPENSES		20		
FIXED ASSETS		21/28	2.730	2.73
Intangible fixed assets	6.1.1	21		
Tangible fixed assets	6.1.2	22/27		
Land and buildings		22		
Plant, machinery and equipment		23		
Furniture and vehicles		24		
Leasing and other similar rights		25		
Other tangible fixed assets		26		
Assets under construction and advance payments		27		
Financial fixed assets	6.1.3	28	2.730	2.73
CURRENT ASSETS		29/58	1.249.149	918.62
Amounts receivable after more than one year		29		
Trade debtors		290		
Other amounts receivable		291		
Stocks and contracts in progress		3		
Stocks		30/36		
Contracts in progress		37		
Amounts receivable within one year		40/41		
Trade debtors		40		
Other amounts receivable		41		
Current investments		50/53		
Cash at bank and in hand		54/58	1.245.623	915.32
Accruals and deferred income		490/1	3.526	3.30

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	Notes	Codes	Period	Preceding period
EQUITY AND LIABILITIES				
EQUITY		10/15	619.927	592.848
Association or foundation funds		10	813	813
Revaluation surpluses		12		
Allocated funds and other reserves		13		
Result brought forward	(+)/(-)	14	619.114	592.035
Capital subsidies		15		
PROVISIONS AND DEFERRED TAXES		16		
		160/5		
Provisions for liabilities and charges		160/5		
Pensions and similar obligations		160		
Taxes				
Major repairs and maintenance		162		
Environmental obligations		163		
Other liabilities and charges		164/5		
Provisions for subsidies and legacies to reimburse and gifts with a recovery right		167		
Deferred taxes		168		
AMOUNTS PAYABLE		17/49	631.952	328.505
Amounts payable after more than one year		17		
Financial debts		170/4		
Credit institutions, leasing and other similar obligations		172/3		
Other loans		174/0		
Trade debts		175		
Advance payments on contracts in progress		176		
Other amounts payable		178/9		
Amounts payable within one year		42/48	631.952	328.505
Current portion of amounts payable after more than one year falling due within one year		42		
Financial debts		43		
Credit institutions		430/8		
Other loans		439		
Trade debts		44	611.010	317.544
Suppliers		440/4	611.010	317.544
Bills of exchange payable		441		
Advance payments on contracts in progress		46		
Taxes, remuneration and social security		45		
Taxes Remuneration and social security		450/3		
Remuneration and social security Other amounts payable		454/9 48	20.942	10.961
			20.842	10.501
Accruals and deferred income		492/3		
TOTAL LIABILITIES		10/49	1.251.879	921.353

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PROFIT AND LOSS ACCOUNT				
	Notes	Codes	Period	Preceding period
Operating income and operating charges				
Gross margin	(+)/(-)	9900	41.020	127.778
Of which: non-recurring operating income		76A		
Tumover <sup>6</sup>		70	841.273	295.173
Membership fees, gifts, legacies and subsidies 6		73		
Goods for resale, raw materials, consumables, services and other goods 6		60/61	800.253	167.395
Remuneration, social security and pensions Amortisations of and other amounts written down on	(+)/(-)	62		
formation expenses, intangible and tangible fixed assets		630		
Amounts written down on stocks, contracts in progress and trade debtors: additions (write-backs) Provisions for liabilities and charges; appropriations	(+)/(-)	631/4		
(uses and write-backs)	(+)/(-)	635/9		
Other operating charges Operating charges reported as assets under		640/8		
restructuring costs	(-)	649		
Non-recurring operating charges		66A		
Operating profit (loss)	(+)/(-)	9901	41.020	127.778
Financial income		75/76B	1.321	8.813
Recurring financial income		75	1.321	8.813
Non-recurring financial income		768		
Financial charges		65/66B	15.262	2.341
Recurring financial charges		65	15.262	2.341
Non-recurring financial charges		66B		
Profit (Loss) for the period before taxes	(+)/(-)	9903	27.079	134.250
Transfer from deferred taxes		780		
Transfer to deferred taxes		680		
Income taxes on the result	(+)/(-)	67/77		
Profit (Loss) of the period	(+)/(-)	9904	27.079	134.250
Transfer from untaxed reserves		789		
Transfer to untaxed reserves		689		
Profit (Loss) of the period available for appropriation	(+)/(-)	9905	27.079	134.250

<sup>6</sup> Optional mention.

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VALUATION RULES	
NA	

### Statement of Certified Accountant 2023





HL7 International, attestation, 3th March 2024

The Beneficiary provided the Auditor all the documentation and accounting information needed by the Auditor to carry out the requested Procedures and evaluate the Findings.

We have received the following data:

- calculation of the total cost for Catherine Chronaki and Goirgio Cangiol
- contracts
- timesheets for the financial years 2019, 2020, 2021, 2022 and 2023
- invoices of the other expensens
- prove of payment of the expenses.

#### Use of this Report

This Report may be used only for the purpose described in the above objective. It was prepared solely for the confidential use of the Beneficiary and the Commission, and only to be submitted to the Commission in connection with the requirements set out in Article 20.4 of the Agreement. The Report may not be used by the Beneficiary or by the Commission for any other purpose, nor may it be distributed to any other parties. The Commission may only disclose the Report to authorised parties, in particular to the European Anti-Fraud Office (OLAF) and the European Court of Auditors.

This Report relates only to the Financial Statement(s) submitted to the Commission by the Beneficiary for the Agreement. Therefore, it does not extend to any other of the Beneficiary's Financial Statement(s).

There was no conflict of interest between the Auditor and the Beneficiar in establishing this Report.

Lier, 3th March 2024



Digitally signed by Guy Franken DN: 01–Guy Franken, 0, 00, errailinguy/franken@nfbedrijfsrevisoren.be, c=LA Date: 2024.03.13 07:27:53 +01100'

Guy Franken Legal Auditor

2

Duwljckstraat 17 -2500 Lier Tel: 03 491 00 59 Fax: 03 491 00 55 BTW: BE 0895.454.411 R.P.R. Mechelen IBR 8 00705

## Acknowledgements

We would like to express our gratitude to our members, volunteers, partners, and staff for their tireless efforts and unwavering commitment. You've been key to our success, and we can't wait to see what we can achieve together in the future.

## Appendices

#### Articles published 2022-2023

Design and Adoption of a FHIR IG to Support a Telemonitoring Environment in Gatekeeper Project R Gazzarata, C Chronaki, F Ricciardi, F Giuliani, P Zampognaro, ... Telehealth Ecosystems in Practice, 106-110

Experience from the Development of HL7<sup>®</sup> FHIR<sup>®</sup> IG for Gatekeeper Project R Gazzarata, C Chronaki, A Gallego, E Gaeta, G Fico, P Zampognaro, ... Healthcare Transformation with Informatics and Artificial Intelligence, 106-109

#### <u>EFMI</u>

C Chronaki, A Benis, J Mantas, P Gallos, J Delgado, CLP Calderón Yearbook of Medical Informatics 31 (01), 369-373

Historical Background of Medical Informatics Development

C Chronaki

Acta Informatica Medica 30 (2), 135

Engage the People: Health Informatics and Personal Health Management

A Moen, A Cramer, C Chronaki

Nursing and Informatics for the 21st Century-Embracing a Digital World, Book ...

EFMI Inside-the Official Newsletter of the European Federation for Medical Informatics-2021-1

I Masie, C Chronaki

Acta Informatica Medica, 137-177

FAIRness for FHIR: towards making health datasets FAIR using HL7<sup>®</sup> FHIR<sup>®</sup> A Martínez-García, G Cangioli, C Chronaki, M Löbe, O Beyan, A Juehne, ... MEDINFO 2021: One World, One Health–Global Partnership for Digital ...

An Agile Approach to Accelerate Development and Adoption of Electronic Product Information Standards C Chronaki, C Anderson, JK Villadsen, P Hurlen, G Cangioli, GM Ferrari, ... Challenges of Trustable AI and Added-Value on Health, 639-643

Factors influencing implementation of the survivorship passport: the IT perspective C Chronaki, E Charalambous, G Cangioli, G Schreier, S van den Oever, ... dHealth 2022, 161-168