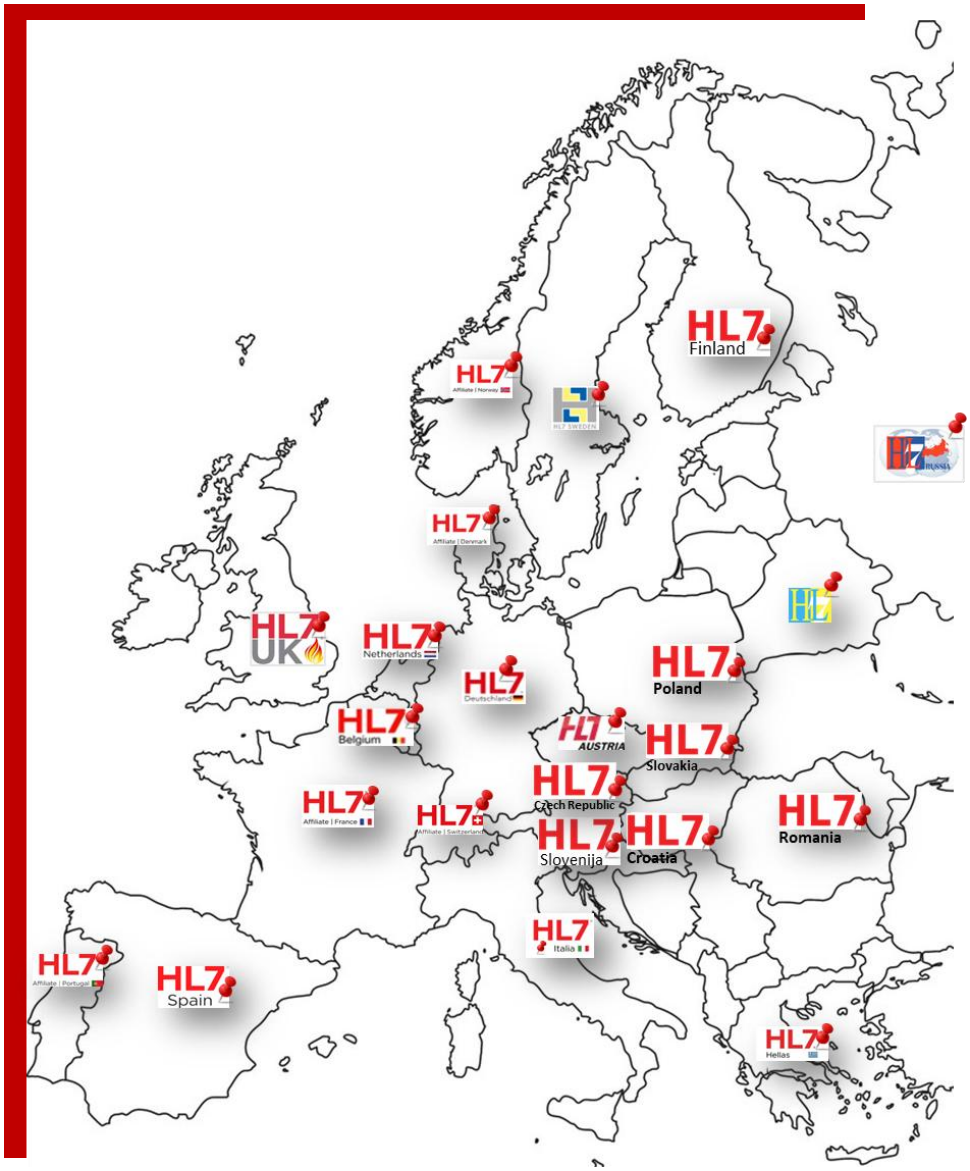
Annual Report 2021



HL7® Europe

Table of Contents

HL7 Europe Profile 4

Introduction: HL7 Europe on FHIR 5

European Union Funded Projects 6

UNICOM: Up-scaling the global univocal identification of medicines 7

Gatekeeper: Smart Living Homes – Whole Interventions Demonstrator for People at Health and Social Risks 8

FAIR4Health: Improving Health Research in EU through FAIR Data 9

Gravitate-Health: Empowering and Equipping Europeans with health information for Active Personal Health Management Adherence to Treatment 10

x-eHealth: eXchanging electronic Health Records in a commom framework 11

WHO - ITU mHealth Hub in EU 12

New Initiatives: Hospitals on FHIR 14

Liaison with European Organizations 15

CEN/CENELEC Technical Committee 251 15

European Federation for Medical Informatics (EFMI) 15

eHealth Stakeholders Group (eHSG) 15

Advisors to EU funded Projects 15

Pharmaledger 15

InteropEHRate Interoperable EHRs at user edge 16

Governance 17

Board of Directors 2020-2022 17

European Strategic Advisory Board 18

Milestone decisions and results 18

The HL7 Europe Team ..... **Error! Bookmark not defined.**

HL7 Europe Technical Coordination Committee 19

The HL7 Europe Day to Day Management and 20

HL7 Europe Newsletter #10 21

Outlook 2022 and beyond 22
VAT Exception received in 2021 23
Financial Figures 2021 in perspective 24
Balance Sheet & Income Statement 2021 25
Statement of certified accountant 28

HL7 Europe Profile

HL7 International is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery, and evaluation of health services.

"HL7 Vision: A world in which everyone can securely access and use the right health data when and where they need it."

HL7 Europe Foundation was established in Brussels in 2010 to serve the HL7 mission and address European needs in digital health standards. Working with European HL7 Affiliates, contributes health information technology standards that are widely and easily used to advance interoperability in healthcare toward the HL7 vision of a world in which everyone can securely access and use the right health data when and where they need it.

"HL7 Mission: To provide standards that empower global health data interoperability"

HL7 Europe aims are to serve the HL7 mission by:

- promote and encourage use of HL7 frameworks, protocols, and specifications that serve the needs of the European community by health systems and service providers
- provide education services, promote tools and facilitate testing and certification
- high quality, cost-effective use of information systems in health and health care.

Introduction: HL7 Europe on FHIR

HL7 Europe continued to grow in 2021 and under the leadership of the new HL7 Europe board of directors, engaged in developing a workplan and new initiatives. Following closely developments in the European scene and in particular cross-European digital health initiatives, steps towards organizing the European Realm were taken. The first step was formation of the Technical Coordination Team (TNT). The TNT was formed to play the role of the HL7 International Technical Steering Committee for the European Realm. The TNT, established in March 2021, started its work with listening sessions, which indicated the need for coordination in the development of HL7 standards in Europe. Another important event that started in 2021, was the hospitals on FHIR initiative outlined in a seminal article by Henrique Martins and Giorgio Cangioli. The initiative, aims to put hospitals on the map and allow them to communicate their move towards adopting FHIR. Giorgio Cangioli developed a maturity scale and Hospitals on FHIR started to build a community of practice vital to the development of the European EHR Exchange Format spearheaded by the xeHEatlh project. At the same time, HL7 Europe engage more actively with global HL7 FHIR accelerators and Vulcan, the accelerator for connecting clinical research to health care. Under the umbrella of the Gravitate-Health project and in close collaboration with regulatory agencies and the European Medicines Agency, the ePI/eLabeling Vulcan project was formed contributing to a global implementation guide of electronic product information. Global alignment was achieved through engagement in HL7 International FHIR Connecthathons.

This year, 2021 initiated initiatives that will no doubt have great impact moving forward.

European Union Funded Projects

- UNICOM
- GATEKEEPER
- FAIR4Health
- Gravitate-Health
- x-eHealth
- mHealth Hub
- WHO - ITU mHealth Hub in EU
- PanCareSurPass (New!)

UNICOM: Up-scaling 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 will centre 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-Dec-2019 to 30-Nov-2023

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: € 322 500

HL7 Europe team:

- Giorgio Cangioli
- Catherine Chronaki

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

For more information: https://cordis.europa.eu/project/id/875299

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 FHIR, development of Gatekeeper HL7 FHIR Implementation guide

Funded under: H2020-EU.3.1.SOCIETAL CHALLENGES Health, demographic change and well-being, 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:

- Giorgio Cangioli
- Catherine Chronaki

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

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

FAIR4Health: Improving Health Research in EU through FAIR Data

Applying the FAIR principles in health research. The EU-funded FAIR4Health project aims to facilitate and encourage the European Union health research community to apply the FAIR principles (to make research data Findable, Accessible, Interoperable and Reusable), and share and reuse their datasets derived from publicly funded research initiatives. The project includes the delivery of an effective outreach strategy at the EU level, a set of guidelines to set the foundations for a FAIR data certification roadmap, an intuitive user centred FAIR4Health platform, as well as demonstrations of the potential impact that the implementation of a FAIR data strategy will have on health outcomes and health and social care research.

Role for HL7 Europe: Lead development the FAIR Certification roadmap, lead the FAIRforFHIR Implementation Guide project in HL7 International, Liaise with CEN TC/251.

Funded under: H2020-EU.5.e. - Coordinate the accessibility and the use of the results of publicly-funded research; Topic: SwafS-04-2018 - Encouraging the re-use of research data generated by publically funded research projects

Duration: 1 December 2018 to 30 November 2021

Overall budget: € 2 999 053,75

EU contribution: € 2 999 053,75

Coordinated by: Servicio Andaluz de Salud, Spain

Funding for HL7 Europe: € 216 125

HL7 Europe team:

- Giorgio Cangioli
- Catherine Chronaki

Project Website: https://www.fair4health.eu/

For more information: https://cordis.europa.eu/project/id/824666

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 digitisation 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.

Role for HL7 Europe: Serve as interoperabily lead, WP5 lead, and liaise with HL7 WGs, coordinate development of the Gravitate-Health HL7 FHIR Implementation Guide

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:

- Giorgio Cangioli
- Catherine Chronaki

Project Website: https: https://www.gravitate-health.eu

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

x-eHealth: eXchanging 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 halth information and better use of health data. Topic: SC1-HCC-07-2020 - Support for European eHealth Interoperability roadmap for deployment

Duration: 1 November 2020 to 31 October 2025

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:

- Giorgio Cangioli
- Catherine Chronaki

Project Website: https://www.x-ehealth.eu/

For more information: https://cordis-europa-eu.translate.goog/project/id/951938

WHO - ITU mHealth Hub in EU

Creation of the mHealth Hub aspires to support: (1) The development of national mHealth interventions in selected EU member states to champion the uptake of mHealth and (2) The foundation and maintenance of a centralised 'Knowledge and Innovations Hub for mHealth' to monitor and enable mHealth adoption and innovation. In future, the mHealth Hub will serve as a standalone resource for EU member states to support them in deploying and regulating mHealth in their national health services. The Hub will work as a unifying convening platform for existing national country programs on mHealth. It will bring together researchers, projects, knowledge and lessons learnt from individual mHealth projects and clinical trials. From these it will create a "big picture" which will both allow the identification of best practices and standardized guidelines, and also enable researchers to identify gaps in current research which can then help shape new studies. The support requested from the EC in the following proposal will help the initiative and WHO to assist countries to fulfil their commitment of achieving Universal Health Coverage, avoiding vertical intervention models and moving towards integrated health care systems. This will be critical in the coming years for the reduction of national health expenditures without a loss in quality or quantity of national health services.

Role for HL7 Europe: The role of HL7 Europe in the project, as subcontractor to SAS, is to provide support in the formation of the hub, related to standards and interoperability.

Funded under: H2020-EU.3.1.5.-Methods and data. Topic:SC1-HCO-09-2016-EU mHealth hub including evidence for integration of mHealth in the healthcare systems

Duration: 1 March 2017 to 28 February 2022

Overall budget: € 3 000 000

EU contribution: € 3 000 000,00

Coordinated by: International Telecommunications Union, Switzerland

Funding for HL7 Europe: € 31800

HL7 Europe team:

- Catherine Chronaki
- Gora Datta
- Frank Ploeg

Project Website: https://mhealth-hub.org/

For more information: https://cordis.europa.eu/project/id/737427

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, taking into account various scenarios and issues. Work will result in a prediction model that will ease successful SurPass implementation across Europe.

Role for HL7 Europe: In PanCareSurPass HL7 Europe's main role as WP3 leader is the creation of an HL7 FHIR Implementation Guide 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 28 February 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:

- Catherine Chronaki
- Giorgio Cangioli
- Iliana Charalambous

Project Website: https://www.pancaresurpass.eu/
For more information: https://cordis.europa.eu/project/id/899999

New Initiatives: Hospitals on FHIR

In 2021, HL7 Europe started work on the Hospitals on FHIR initiative a community that would allow hospital leadership to cooperate on the implementation of HL7 FHIR.

The Hospitals on FHIR Initiative was proposed by Prof. Henrique Martins and co-led with Giorgio Cangioli. The intend has been transition to Hospital leadership.

The website of the the initiative is www.hospitalsonFHIR.eu.

HealthManagement.org
Promoting Management and Leadership

Communities | I-I-I Series | Events | Journals | Point-of-View

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Digital Healthcare Focus: European Hospitals on Fire (FHIR) EMH-onFHIR

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In this space I will explore monthly topics, from concepts to technologies, related to the necessary steps to build Digital Healthcare Systems. For this month, I have invited Mr Giorgio Cangioli to co-author a brief article on Fast Healthcare Interoperability Resources (FHIR), as hospitals and their interconnections are a critical asset and next step for European health data interoperability.

As patients and citizens move, health data needs to move with them. While primary care is fundamental and other community based social and healthcare solutions are increasingly important in the provision of healthcare and prevention, hospital remain, and are likely to remain, the largest health data holders. Their interconnectedness is key to the European Health Data Space. Not only for networks of care for people with rare conditions to support inter-hospital communication and ad-hoc research collaboration, but also as organised systematic networks – the prime example of which being the European Reference Networks.

Hospital management and healthcare personnel are concerned with internal interoperability within the hospital network. Hospitals may serve as the fine capillarity network of intra and inter regional and national health data exchange. In the EU, this complements efforts to create the European Health Data Space, the regulation of which is currently under discussion. This creates a new or another way to think about the role of hospitals and large healthcare organisations in fostering cross-border exchange and interoperability standards.

Hospitals, and indeed large healthcare organisations in Europe have two fundamental responsibilities regarding the health data they collect and manage:

1. To share it amongst health institutions, including cross-border, to provide responsible, safe, and easy patient care.
2. To make health data available for regional national and European secondary use, within safe and regulated means, fostering research, public policy and public health, adhering to the FAIR (Findable Accessible Interoperable Reusable) principles.

Liaison with European Organizations

CEN/CENELEC Technical Committee 251

HL7 Europe continues to collaborate with CEN/CENELEC and CEN TC251 committee in particular. 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 with support from HL7 international is participating close in the European Federation for medical informatics (www.efmi.org). Through this relationship, Catherine Chronaki, Secretary General at the HL7 foundation has been member of the Executive Board since 2016 and was elected as president of EFMI for 2020-2022 in April 2020. She assumed office in November 2020.

eHealth Stakeholders Group (eHSG)

HL7 Europe is part of the eHealth Stakeholders Group of the European Commission for 2020-2023. Catherine Chronaki, Secreatry of the Board and Christof Gessner, Member of the Board, and chair of the European Strategic Advisory Board represent HL7 Europe in the eHSG.

Advisors to EU funded Projects

Pharmaledger.

PharmaLedger
BLOCKCHAIN ENABLED HEALTHCARE

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.

Catherine Chronaki serves on the advisory board of the Pharmaledger IMI2 Project

InteropEHRate Interoperable EHRs at user edge

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

Giorgio Cangioli and Christof Gessner serve on the advisory board of InteropEHRate.

For more information: https://cordis.europa.eu/project/id/826106

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 FAIR principles, 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 nfdi4health.

Governance

Board of Directors 2020-2022

The board of Directors of HL7 Europe took office in August 2020. The members are:

Giorgio CANGIOLI, PhD, Italy

Giorgio is the CTO of HL7 Italy and the technical lead of HL7 Europe

Mark McDOUGALL, USA

Mark is the executive Director of HL7 International

Catherine CHRONAKI, Greece

Catherine is Secretary General of HL7 Europe and president of EFMI (2021-2022).

Walter SUAREZ, MD, USA

Walter is the Chair of HL7 International (2020-2021) and the Executive Director HIT and Policy at Kaiser Permanente

Christof GESSNER, Germany

Christof is the chair of the European Strategic Advisory Board and past chair of HL7 Germany, a strategic consultant at Gematik the eHealth competence center in Germany

Anne MOEN, RN, PhD, Norway

Anne is a professor at the Institute of Health and Society at the University of Oslo and Director UiO:eColab.

Charles JAFFE, MD, PhD USA

Charles is the CEO of HL7 International.

Jens VILLADSEN, Denmark

Jens is chair of HL7 Denmark, and software pilot for Trifork

Line Andreassen SAELE, Norway

Line is the chair of HL7 Norway and enterprise architect at the Norwegian Institute of Public Health

Julia SKAPIK, MD, USA

Julia is on the HL7 International board, Medical Director at National Association of Community Health Centers (NACHC)

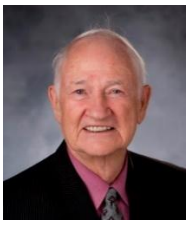
Robert STEGWEE, PhD, The Netherlands

Robert is a member of the board of HL7 Netherlands and the Chair CEN TC251 the technical committee on health informatics

Henrique Manuel GIL MARTINS, MD, PhD, MLaw, FIAHSI, Portugal

Henrique is past chair of the eHealth Network established by the Member States and the European Commission under article 14 of the European Directive on Patients' rights to cross border care, past president at the SPMS the Portuguese eHealth competence center of the Ministry of Health, and associate professor at Health Management and Leadership at FCS-UBI, ISCTE-IUL, ISCSP-U Lisboa.

William HAMMOND, PhD, USA



Ed is chair Emeritus at HL7 International, director of the Duke Center for Health Informatics, Clinical and Translational Science Institute, Director, Applied Informatics Research, Duke Health Technology Solutions, Director, Master of Management in Clinical Informatics (MMCi) Program, School of Medicine, as well as professor in multiple departments at Duke University.

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European Strategic Advisory Board

The European Strategic Advisory Board comprises from the chairs of all HL7 Affiliates (http://www.hl7.org/Special/committees/international/leadership.cfm) in Europe. It elects 3 members of the HL7 Europe Board of directors. These are: Christof Gessner (DE), Line Andreassen (NO), and Jens Kristian Villadsen (DK)

Milestone decisions and results

- Formation of the Technical Coordination Team, led by Giorgio Cangioli.
- Establishment of the Vulcan ePI Project coled by C Chronaki and C Anderson

HL7 Europe Technical Coordination Committee

The Technical Coordination team of HL7 Europe Kicked off meeting in March 2021. A set of Listening Sessions were set up over the year establishing stronger links over the year.

TNT aims to support to HL7 EU goals (technical perspective) It is currently a “self-organized” team TNT activities are not to overlap or conflict with any existing HL7 groups or activities at the affiliate and international levels.

The HL7 Europe Day to Day Management and

The HL7 Europe team comprises from Catherine Chronaki (Greece), secretary general, who si the legal representative, and Giorgio Cangioli (Italy) who is the technical lead. They are supported by volunteers and additional in house consultants that engage in specific European funded projects. Frank Oemig manages the HL7.eu web site on a volunteer basis. Kai Heitmann is the editor of the annual HL7 Europe newsletter.

The team of HL7 Europe engaged in EU project is multidisciplinary and its members in 2021 are from left Catherine Chronaki and Giorgio Cagioli (across projects), Eliana Charalambous (PanCareSurPass, Gravitate-Health), Henrique Martins (Gravitate-Health), Gora Data and Frank Ploeg (mHealth Hub), Marilena Varveraki (Trainee).

HL7 Europe Newsletter #10

The 10th newsletter of HL7 Europe included many articles reflecting on the progress of digital health in Europe and the impact of HL7 standards. Some articles included are:

- EMH-on-FHIR: European Hospitals on FHIR, *H. Martins, G. Cangioli, HL7 Europe*
- European Health Data Space: Need for large data volume standards and its piloting, *H Martins, HL7 Portugal*
- HL7 Europe Technical CoordiNation Team, *G Cangioli, HL7 Europe, O Egger, HL7 Switzerland, R Smithies, HL7 United Kingdom, J Costa-Teixeira, HL7 Belgium, R Radomski, HL7 Poland, J Villadsen, HL7 Denmark, Chr Gessner, HL7 Germany, F Macary, HL7 France, A Henket, HL7 NL*
- Towards a mHealth Policy Framework, *S Jacinto, V Mendes, Shared Services of the Ministry of Health in Portugal*
- cMHAFF and CEN / ISO, *F Ploeg, HL7 NL*
- A Consumer Mobile Health Application Functional Framework & CEN / ISO 82304-2 Quality and Reliability Criteria for Health and Wellness Apps, *F Ploeg, HL7 NL*
- Supplementary or subsequent? Clinical Document Architecture (CDA) compared with Fast Healthcare Interoperability Resources (FHIR), *R Mulders, HL7 NL*
- Approach to and Status on FHIR Profiling in Norway, *Øy Aassve, HL7 Norway*
- HL7 FHIR for the German Medical Informatics Initiative, *S Thun, HL7 Germany*
- National Terminology Server goes Dutch: a further step to interoperability,
- eHealth Interoperability in Europe – 10 years of productive European projects, *K Bourquard, IHE Europe*
- Obituary for Libor Seidl, *B Blobel, HL7 Germany*
- Remembering Nicole Denjoy, Secretary General of COCIR, *C Chronaki, HL7 Europe*

Outlook 2022 and beyond

In the years to come, we expect that HL7 Europe will grow further, with a strong core team to support engagement with the HL7 Community in Europe, developing HL7 FHIR Implementation Guides for the European Realm under the guidance of the Technical Coordination Team led by Giorgio Cangioli.

HL7 Europe will also invest further in Hospitals on FHIR and if resources allow also to startups and SMEs in an effort to support HL7 FHIR implementation in Europe connected to European wide initiatives like myHealth@EU.

We also hope for closer collaboration with European Federation for Medical Informatics (EFMI) to further engage in the education of young professionals and develop productive synergies with CEN TC/251 and other Standards Organizations in Europe. In the European standards policy team, HL7 Europe will continue to engage with eHDSI and the eHealth Stakeholders Group aim to play a strong role in EHDS, through TEDHAS.

VAT Exception received in 2021

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22/04/2021	HL7 International	E.T. 56000/CQ/17	

Page 1/1

Bruxelles, le 20 décembre 2021.

Taxe sur la valeur ajoutée

Contrat n° 899999 – Projet « PanCareSurPass » conclu le 21 janvier 2021 entre la Commission européenne (C.E.) et entre autres, le HL7 INTERNATIONAL FONDATION.

Monsieur,

Nous avons l'honneur de répondre à votre lettre susmentionnée, relative au contrat sous rubrique.

Les dépenses relatives à l'exécution de ce contrat de recherche à réaliser en 48 mois à partir du 1er mars 2021 sont évaluées à 346.875,00- EUR en ce qui concerne HL7. La C.E. participe à concurrence de 100 %.

La présente dépêche autorise l'application de l'exemption de la T.V.A. pour les dépenses susmentionnées effectuées par votre établissement, selon les règles définies dans le document n° E.U. 423 dont un exemplaire vous est transmis en date du 21 mai 2013.

Veuillez agréer, Monsieur, l'assurance de notre considération distinguée.

Pour le Ministre,
Pour l'Administrateur général de la Fiscalité,

Alain Van Delsen (Signature)
Digitaal ondertekend door Alain Van Delsen (Signature)
Datum: 2021.12.17 15:47:01 +01'00'

Alain Van Delsen
Conseiller - Directeur

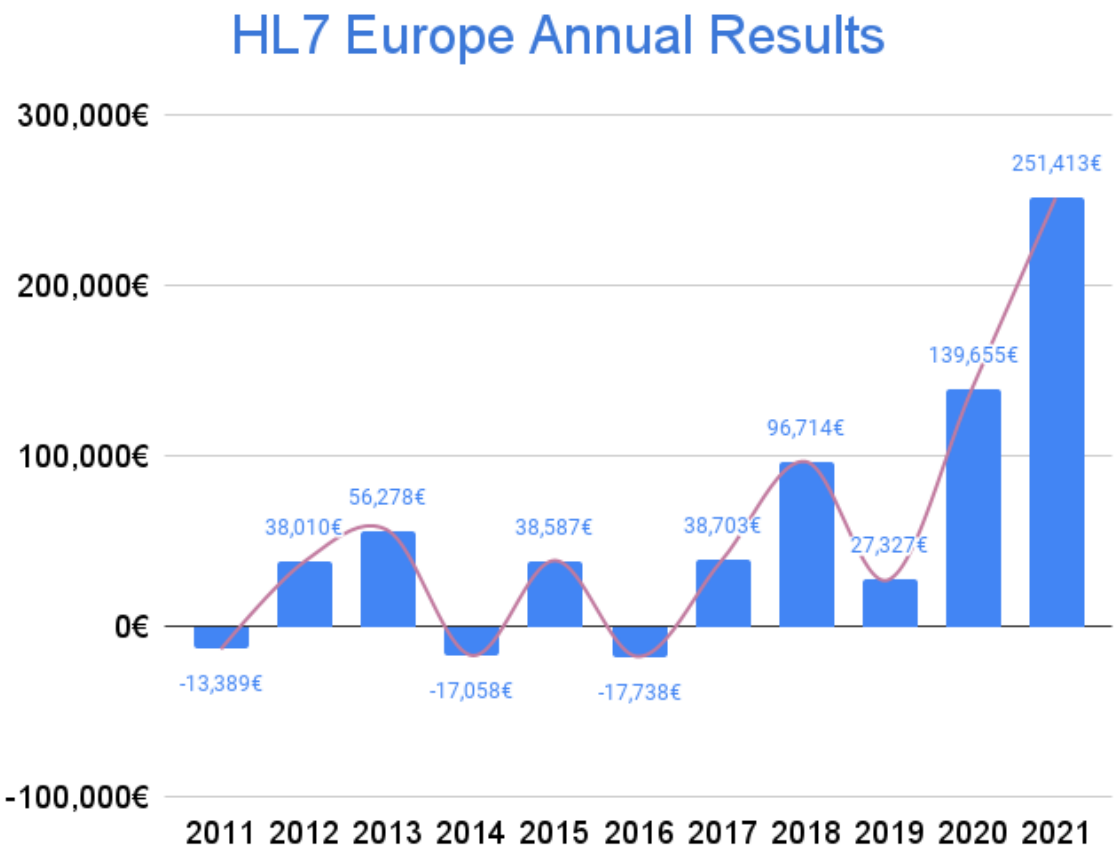
Mme Dominique SPITS
Boulevard du Roi Albert II 33 bte 517 – 1030 Bruxelles
▪Tél. : +32 (0)2 575 37 01
▪E-mail : dominique.spits@minfin.fed.be

Consultez votre dossier en ligne sur
www.myminfin.be

Financial Figures 2021 in perspective

HL7 International provides support to HL7 Europe to the amount of 20000USD annually. The rest of its funding comes from European Union funded competitive projects.

Ove the last 10 years HL7 Europe has strengthened its position in the European Policy arena for digital health standards and interoperability. Although its participation in EU projects has varied through the years, there has been a positive trend.



Balance Sheet & Income Statement 2021

HL7 INTERNATIONAL Fondation Privée
Square de Meeûs 38-40
1000 Bruxelles
N.E. 0826.312.613

BILAN 31/12/2021

A C T I F

ACTIFS IMMOBILISES			0,00
I. Frais de constitution		0,00	
Frais de constitution	2 850,00		
- Amortissement	-2 850,00		
ACTIFS CIRCULANTS			
IX. Valeurs disponibles			884 162,32
ING 363-0741327-93		769 589,53	
ING 363-0741327-93 USD (107.415,15 USD)		114 572,79	
X. Comptes de régularisations			0,00
Charges à reporter		0,00	
Compte d'attente		0,00	
TOTAL DE L' ACTIF			**884 162,32**

Certifié conforme,

P A S S I F

CAPITAUX PROPRES (1.000,00 USD)			812,93
Résultat reporté			855 187,70
Résultat 31-12-2011		-13 388,85	
Résultat 31-12-2012		38 010,41	
Résultat 31-12-2013		56 277,84	
Résultat 31-12-2014		-17 057,86	
Résultat 31-12-2015		38 587,16	
Résultat 31-12-2016		-17 737,87	
Résultat 31-12-2017		38 703,35	
Résultat 31-12-2018		96 714,41	
Résultat 31-12-2019		27 326,71	
Résultat 31-12-2020		356 338,46	
Résultat 31-12-2021		251 413,94	
DETTES			
IX. Dettes à un an au plus			28 161,69
C. Dettes Commerciales		0,00	
Fournisseurs	0,00		
Factures à recevoir	0,00		
Avances founisseurs	0,00		
F. Autres dettes		28 161,69	
HL7 International	28 161,69		
TOTAL DU PASSIF			**884 162,32**

Certifié conforme,

COMPTES DE RESULTATS 31/12/2021

I. Produits d'exploitation				461 548,57
D. Autres produits d'exploitation			461 548,57	
Projekt funding *(wire in - ING)*		441 321,34		
- 20/01/2021 Universiteit I Oslo Ragnskaps	*153 180,09*			
- 16/04/2021 J. Gutenberg Universitat	*167 656,25*			
- 12/10/2021 Medtronic Iberica	*114 125,00*			
- 04/11/2021 Fund. Publica Andaluza	*6 360,00*			
Funding HL7 US		20 227,23		
- 04/04/2021	*3 027,23*			
- 22/10/2021	*17 200,00*			
II. Charges d'exploitation				208 715,96
A. Achats			0,00	
Project funding / awards		0,00		
B. Services et biens divers			208 715,96	
Location immeuble - Multiburo		7 179,48		
Frais de bureau		0,00		
Fournitures informatiques		448,80		
Frais conferences		1 562,21		
Honoraires		179 156,98		
- Giorgio Cangioli	*149 061,66*			
- Giorgio Cangioli (ann. FAR 31-12-2020)	*-50 292,00*			
- Catherine Chronaki	*77 221,82*			
- CEN	*665,50*			
- Eliana Charalambous	*1 500,00*			
- Marianna Papagiannopoulou	*1 000,00*			
- S&V Accountants	*0,00*			
Prestations de services		15 000,00		
Frais de déplacements		1 823,17		
Frais de restaurant		223,90		
Taxis et shuttles		0,00		
Péages - parking - transport		0,00		
Cotisations		591,42		
Imprimés		2 730,00		
Poste		0,00		
Téléphone		0,00		
C. Rémunération et charges sociales			0,00	
D. Amortissements			0,00	
G. Autres charges d'exploitation			0,00	
III. Résultat d'exploitation				252 832,61
IV. Produits financièrs				0,00
Intérêts bancaire			0,00	
Différences de changes pos.			0,00	
V. Charges financières				1 418,67
Intérêts bancaires			0,00	
Différences de change nég.			0,00	
Frais bancaires			1 418,67	
VII. Produits exceptionnels				0,00
VIII. Charges exceptionnelles				0,00
XI. Résultat de l'exercice				251 413,94

Certifié conforme,

Statement of certified accountant

MOORE

I have reviewed the financial statements of HL7 International, Private Foundation, Square de Meeûs 38-40, B-1000 Brussels, NE 0826.312.613, for the period 01/01/2021 – 31/12/2021, drawn up based on the accounting reference system applicable in Belgium, with a balance sheet total per December 31st of € 884 162,32 and whose income statement closes with a surplus for the financial year of € 72 523,16.
The preparation of the annual accounts falls under the responsibility of the Board of Directors of HL7 International.

This responsibility includes, among other things: establishing, implementing and maintaining internal control over the preparation and fair presentation 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.
My review is carried out in accordance with the standards of the Institute for Tax Advisors & Accountants. These professional standards require that my 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, I have taken into account the administrative and accounting organization of the association, as well as the procedures of internal control.

The persons responsible for the foundation have answered my questions for further clarification or information. On the basis of samples, I examined the justification of the amounts included in the submitted balance sheet and income statement.
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.

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

In my opinion, the financial statements closed on 31 December 2021 give a true and fair view of the assets and liabilities, financial condition and results of the foundation.

Declared real and true in Mechelen, on December 5th 2023.

Grete SWINNEN
Certified Accountant