

THE ROAD TO **SEMANTIC INTEROPERABILITY**

C-CDA to and from HL7 FHIR

PLUS:

HL7 FHIR in Europe

New CDex Implementation Guide

Da Vinci Takes on
Value-Based Care

CodeX Expands

INSIDE: HL7 MEMBERS
RECOGNIZED FOR DIGITAL
HEALTHCARE EXCELLENCE



THUN



JAFFE

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We Miss Our HL7 Family and Look Forward to Seeing You Soon

Update from Headquarters

The global pandemic has required everyone to change how they do things. For HL7, we have produced our working group meetings (WGM) virtually. Based upon the feedback from our attendees, we are pleased to hear that our approach to producing virtual events has provided an experience that is still productive and rewarding.

For example, our January WGM attracted 485 attendees and 596 participated in the January FHIR connectathon. HL7 has continued conducting business as usual and has advanced the development



Wayne Kubick



John Cleese

of our FHIR standard. We are grateful to Computable Publishing for their Gold Sponsorship of the January WGM. At the January WGM we also said farewell to Wayne Kubick following six years as serving as HL7's Chief Technology Officer, where we shared a short video thanking Wayne for his leadership and guidance that included toasts from several individuals including his favorite comedian, John Cleese. Watch the video recording here:

<https://www.youtube.com/watch?v=s88rJ9Yf3qA>



The World's Largest FHIR Event
<https://www.devdays.com>

First Hybrid FHIR DevDays a Success!

The first hybrid FHIR DevDays was a success with over 600 attendees. FHIR DevDays is where the FHIR community thrives and where you can learn all about FHIR and refine your FHIR expertise. HL7 FHIR DevDays is the largest FHIR event in the world! Whether in-person, virtual or a combination of both formats, the event delivered strong educational content including keynotes and tutorials, plus specialty tracks including patient innovation, startup and community. This year's FHIR DevDays event was a hybrid version that occurred June 6-9, in collaboration with our partners at Firely.

Mark Your Calendars

We were thrilled to realize that our HL7 WGMs and FHIR connectathons are productive, meaningful and successful in person or virtually. However, we are excited see our HL7 family again when we restart our in-person events in September. In fact, please be sure to add to your calendar the dates and locations of our upcoming in-person HL7 events:

September 2022 meetings in Baltimore, Maryland:

- FHIR connectathon in Baltimore will occur September 17-18
- 36th Annual Plenary and Working Group Meeting will convene September 19-23

January 2023 events near Las Vegas at the Hilton Lake Las Vegas Resort in Henderson, Nevada:

- FHIR connectathon will occur January 14-15, 2023
- January 2023 WGM will convene January 16-20, 2023

May 2023 events in New Orleans, Louisiana:

- FHIR connectathon will occur May 6-7, 2023
- May 2023 WGM will occur May 8-12, 2023

We look forward to seeing many of you at these HL7 events. For more details on these events, please visit www.HL7.org/events

Benefactors and Supporters

We are pleased to recognize HL7's 2022 Benefactors and Gold Members who are listed on page 38. Their support of HL7 is very much needed and sincerely appreciated. We are pleased to recognize our benefactors in all of our HL7 newsletters, on the HL7 website, in all of our HL7 press releases, and at all of our HL7 Working Group Meetings.

Organizational Member Firms

As listed on pages 38-41, HL7 is very proud to recognize the organizations who are HL7 organizational member companies. We sincerely appreciate their ongoing support of HL7 via their organizational membership dues.

Best wishes to you and your loved ones for staying healthy and finding time to enjoy plenty of hugs and laughter.




By Mark McDougall, HL7
International Executive Director



HL7 FHIR Fundamentals Course

**Next edition begins
July 14, 2022!**

July 14-August 11, 2022

- An introductory online course on HL7 FHIR - no experience necessary!
- Four week course includes new module each week
- Guided real-world exercises with instructor assistance and feedback
- Interactive online community with students and instructors

<http://HL7.me/FHIRfun>

**MARK YOUR
CALENDARS NOW**

HL7 FHIR Fundamentals

will also be offered in the Fall:

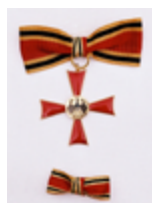
**October 27-
November 24, 2022**

HL7 Germany Vice-Chair Recognized for Health IT Contributions

Sylvia Thun Receives German Cross of Merit



Sylvia Thun



FURTHER INFORMATION

Press release:

“Sylvia Thun is setting standards for medical data”

<https://www.bihealth.org/en/notices/sylvia-thun-is-setting-standards-for-medical-data>

Core Facility Digital Medicine and Interoperability at the BIH

<https://www.bihealth.org/en/research/scientific-infrastructure/core-facilities/interoperability/home>

German President Frank-Walter Steinmeier has awarded Professor Sylvia Thun the Cross of Merit on Ribbon of the Order of Merit of the Federal Republic of Germany in recognition of her services in the field of healthcare digitalization. Both a physician and engineer by training, Thun is the Director of the Core Facility Digital Medicine and Interoperability at the Berlin Institute of Health at Charité (BIH). She has made special contributions to medical data standardization, with the aim of pulling together health data from different sources in order to facilitate better diagnostic and therapeutic decisions.

The healthcare sector generates countless data every day—information about diagnoses, treatments and disease progression as well as information about molecular details and metabolic processes. “We have a vast treasure trove of data,” Professor Sylvia Thun says. “It would be unethical not to use these data.” Yet data from research and healthcare are recorded differently in every laboratory and every hospital—they are formulated differently, formatted differently and stored in different software systems, if not on paper. That makes the data difficult to use. Interoperability, the ability to exchange and share data from a variety of sources, is now being addressed by a new expert panel.

Communication Standards in Healthcare

“We need communication standards in the healthcare system,” says Thun, a physician and medical IT specialist. “So we have made it our mission to process data from medical care, from molecular biological findings, from tissue and blood examinations, and from pathology reports in a structured way.” After heading the national standards developing organizations IHE and HL7 Germany for many years, Thun currently chairs the German umbrella organization for IT standards in healthcare (SITiG) and serves as an expert to the international standards bodies DIN, CEN and ISO. She has

recently become head of the Interop Council for Digital Health in Germany, which was set up by the Federal Ministry of Health.

All standards organizations are globally connected, because health and disease do not stop at borders. The HL7 international community has stressed in an open letter about the conflict in Eastern Europe that its “mission is one of peace, care, mutual understanding and non-violent resolution of all conflicts.” It said that its thoughts and goodwill are “with our fellow community members in the region as they endure these events.”

Professor Christopher Baum, Chair of the BIH Board of Directors and Chief Translational Research Officer of Charité, congratulates Sylvia Thun for receiving this prestigious award: “We are pleased to see the German President honor Sylvia Thun with this outstanding recognition. Professor Thun’s work is of immense importance to the BIH’s goal of advancing healthcare digitalization for the benefit of patients and science. We are therefore delighted to have her in our ranks.”

Professor Sylvia Thun is excited to receive this award and honor from the German President: “This award is in recognition of our network’s activities around the world. I see myself as representing all the things we have achieved technologically in the last 20–30 years through working together, mostly in our spare time. I am thrilled to receive this award because it shows the importance that the German government gives to this issue. And I warmly thank them for that.”

But her real goal is to improve the care patients receive. “There are excellent projects that have shown how well things can be done when everybody works together. Many projects have clearly demonstrated that digitalization and interoperability can make healthcare better. And that’s what drives me: a desire to make healthcare better.” ■

DirectTrust™ Initiative Recognizes Organizations, Teams, and Individuals That Make Significant Contributions Advance Interoperability in Health Care

HL7 International CEO Dr. Charles Jaffe Named an Interoperability Hero



Charles Jaffe, M.D., Ph.D.

DirectTrust named HL7 International Chief Executive Officer Charles Jaffe, M.D., Ph.D. an Interoperability Hero for the organization's Q4 2021 awards. DirectTrust is a non-profit healthcare industry alliance created to support secure, identity-verified electronic exchanges of protected health information. The organization's Interoperability Hero Initiative was established in 2021 to recognize organizations', teams' and individuals' commitment to advancing interoperability across the health care continuum. Today's announcement recognized Dr. Jaffe's work as a tireless champion of both interoperability and the communities that rely upon them to improve health care. It also highlights how his "engagement with academic, industry and professional organizations has led to the growth and adoption of interoperability standards, fostering innovation in patient care, reducing clinician burden and advancing population health."

Throughout his tenure at HL7, Dr. Jaffe has advocated for the development, adoption, and implementation of HL7 FHIR on a global scale and has led the formation of the HL7 FHIR Accelerator Program. "So much of the credit for the progress toward true interoperability rests with the passionate efforts of the entire HL7 community as well as the organizations with which we collaborate," comments Dr. Jaffe. "The vision of HL7 will foster better care for our patients worldwide and for the legions of health care providers and researchers that rely upon information when and where its needed."

"HL7 International is enormously proud of the history of leadership provided by Dr. Jaffe," said HL7 Board Chair Andy

Truscott. "His vision for standards-based interoperability as the fuel for optimizing and improving patient outcomes has driven the global health IT ecosystem for over a decade. A consummate medical professional, Dr. Jaffe's compassion for patients is matched by his sincerity in improving the care experience for all healthcare professionals."

HL7 Chief Standards Implementation Officer, Viet Nguyen, M.D., noted that Dr. Jaffe's efforts have brought together diverse stakeholder communities to form HL7 FHIR Accelerators and advance interoperability. "I am honored to serve with him in modernizing health IT, expanding HL7's reach to the implementer community and improving health care for all," he said. HL7 Chief Standards Development Officer Daniel Vreeman, DPT, shares his colleagues' praise for Dr. Jaffe, stating, "His sustained and enduring contributions have radically advanced health data interoperability around the world through his leadership of HL7 International and in partnership with countless other organizations. His efforts are constantly improving the capabilities of patients, care teams, and researchers to improve health."

About the Interoperability Hero Award

Each quarter, DirectTrust selects nominees to be an Interoperability Hero for their significant contributions to advancing interoperability and for making significant contributions in areas such as collaboration, patient engagement, use of trust framework and utilizing Direct with other standards/works, such as Query and HL7 Fast Health Interoperability Resources (FHIR®). ■



FURTHER INFORMATION

DirectTrust's Interoperability Hero initiative

<https://directtrust.org/interop-hero>

InteropHeros for Q4 of 2021

<https://directtrust.org/blog/interop-heroes-q4-2021/%E2%80%8B>

HL7 Internal Projects and ONC Grant-Funded Projects

HL7 Policy Update

HL7 would like to congratulate the new Chair of its Policy Advisory Committee (PAC), Alexandra (Alix) Goss. Alix serves as Vice President and Senior Consultant at Imprado Consulting, a division of DynaVet Solutions.

For 30 years, Alix has held leadership roles in developing national healthcare standards, implementing and complying with federal regulations, and aligning business strategies, systems integration and operations management in both private and public sectors of healthcare. She will lead the PAC in this dynamic era where increasingly pro-active, integrated and strategic HL7 policy feedback is required at both the national and global level. We are attuning and expanding our U.S. and international HL7 outreach plans and efforts in response to this environment.

Policy and regulatory action with which the HL7 Policy Advisory Committee deals has started off briskly in 2022. The 117th Congress is considering sixty pieces of legislation in global health alone and federal proposed rules and Requests for Information continue to be issued at a rapid pace.

Key 2022 HL7 Policy Responses: Current

Two notable responses HL7 has filed recently include the:

1. White House Office of Science and Technology Policy (OSTP) Connected Health RFI
<https://www.federalregister.gov/documents/2022/01/05/2021-28193/request-for-information-rfi-on-strengthening-community-health-through-technology>
2. ONC Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria (RIN 0955-AA04)
<https://www.federalregister.gov/public-inspection/2022-01309/request-for-information-electronic-prior-authorization-standards-implementation-specifications-and>

Regarding White House Office of Science and Technology Policy (OSTP) Connected Health RFI, HL7's letter offers perspectives in the RFI areas of: barriers, trends from the pandemic, health equity and international models. Our key recommendations and observations are that:

- HL7 supports additional federal incentives for provision and use of discrete patient-centric health data, including patient generated data
- HL7 recommends a continued, sustained and well-funded focus on electronic public health tools and related infrastructure to ensure citizen health in the COVID-19 pandemic and beyond
- HL7 suggests that HHS provide guidance to state governments so requirements for public health data exchange are not passed without first determining if the applicable PHA and electronic exchange standards can support the proposed state requirements
- HL7 recommends that adequate funding which supports the appropriate work of all stakeholders in public health reporting be ensured
- Technical public health reporting changes should support and promote data being reported from the "source of truth" where the data originates

HL7 also highlights and endorses the Gravity Project's four key Connected Health RFI recommendations, which are to:

- Explicitly incorporate Gravity's standards across federal regulations, federal programs, contracts, grants, cooperative agreements, and pilots to enable nationwide interoperability and use of SDOH data—as federal agencies are already beginning to do
- Contribute funding and training to help the community- and social-service organizations on the ground, which never had a Medicare or Medicaid health IT incentive program, build out capacity, workflows and use cases
- Bridge digital divides that continue to be barriers for underserved communities

- Integrate bi-directional exchange and “write” API access in HHS payment rules and certification requirements, so patients, family caregivers, and community organizations can contribute SDOH data, and providers, public health agencies, health plans, etc., have access to these critical missing data

Regarding the ONC Electronic Prior Authorization RFI, the HL7 letter includes perspectives from our leadership, Policy Advisory Committee and two HL7 FHIR Accelerators, the HL7 Da Vinci Project and the HL7 CodeX (Common Oncology Data Elements Extensions) Accelerator.

We offer observations and recommendations on the themes of:

- Leveraging the HL7 FHIR Da Vinci Burden Reduction Implementation Guides
- Incremental ePA approaches (including testing and piloting)
- Workable requirements
- Improved workflow solutions
- NCPDP-FHIR standards alignment
- Other issues

We also emphasize that, “HL7 and its Da Vinci Project are committed to incrementally advancing these Electronic Prior Authorization Standards in an effort to benefit all patients, providers, payers and vendors. It is an important aspect of our on-going work with ONC and other federal agencies.

Regarding this point, we also want to acknowledge the recommendations of the ePA Task Force recently presented to the Health Information Technology Advisory Committee (HITAC). Particularly important is Recommendation 8, that ONC should develop and fund a proving ground to support maturation of IGs supporting ePA.

HL7 supports this recommendation and can support such work with its HL7 Standards Development Division, focusing on the development and maintenance of HL7 specifications and the HL7 Standards Implementation Division concentrating on helping communities discover, access and understand the specifications as well as test their implementations.”

Key 2022 HL7 Policy Responses: Upcoming

The PAC also recently finalized two more HL7 policy responses. First, are recommendations on ONC’s Draft United States Core Data for Interoperability (USCDI) v3 including:

- New data classes and elements added
- Improvements and changes to existing data elements
- Feedback requests for specific data elements

More information on ONC’s Draft United States Core Data for Interoperability (USCDI) v3 can be found at:

<https://www.healthit.gov/isa/sites/isa/files/2022-01/Draft-USCDI-Version-3-January-2022-Final.pdf>

https://www.healthit.gov/sites/default/files/page/2022-01/Standards_Bulletin_2022-1.pdf

The PAC also submitted an HL7 response in April on the Notice and Request for Information (RFI), “Evaluating and Improving National Institute of Standards and Technology (NIST) Cybersecurity Resources: The Cybersecurity Framework and Cybersecurity Supply Chain Risk Management.”

As background and as stated in the RFI, “NIST is seeking information to assist in evaluating and improving its cybersecurity resources, including the Framework for Improving Critical Infrastructure Cybersecurity and a variety of existing and potential standards, guidelines, and other information.”

NIST is considering updating the NIST Cybersecurity Framework to account for the changing landscape of cybersecurity risks, technologies, and resources. In addition, NIST recently announced it would launch the National Initiative for Improving Cybersecurity in Supply Chains (NIICS). Responses to this RFI will inform a possible revision of the Cybersecurity Framework as well as the NIICS initiative.

The NIST Cybersecurity RFI and additional information can be found at:

<https://www.govinfo.gov/content/pkg/FR-2022-02-22/pdf/2022-03642.pdf>

<https://csrc.nist.gov/News/2022/rfi-evaluating-and-improving-nist-cyber-resources> ■

*HL7 Internal Projects and ONC Grant-Funded Projects***News from the HL7 Project Management Office****Jira and the Project Scope Statement (PSS)**

Work continues to add the ability for the Jira PSS to accommodate reaffirmation and specification withdrawals. For the time being, those actions will continue to use the PSS form in Confluence.

Other efforts by the project team includes migrating all active non-Jira PSSs to Jira as well as planning to sunset Project Insight.

Fonteva: The New Meetings and Membership Software System

As everyone knows by now, HL7 is replacing their 10+ year old meetings and membership software with Fonteva, a leading association management and membership software solution powered by Salesforce.

This project has run into a few bumps and we are pushing back the time frame. Please change this to: [1:06 PM] Andrea Ribick

We expect to migrate everyone's account and membership information to the new platform sometime in Q4 of this year.

Users of HL7's website will continue to notice the improved user experience as they navigate through their account and membership and register for events, education and training.

ONC Grant-Funded Project Update

The five-year renewal grant for maturation of the C-CDA and FHIR standards will come to an end on September 18, 2022. Projects that were funded during its final year include:

- Unified Terminology Governance (UTG) maintenance and enhancements
- Continued improvements to the FHIR Jira Ballot process
- Continued administration of the FHIR Connectathons
- Continued work on Bulk Data Access and Push
- Continued support for the FHIR Terminology Server
- Continued work on the HL7 FHIR Build and Implementation Guide Publishing tasks

- Support of the FHIR Registry
- Additional C-CDA Implementation-A-Thons
- Continued support for International Patient Summary
- Support for Gender Harmony
- Updating the C-CDA Value Sets
- Develop / deploy key infrastructure for the FHIR-OMOP community (Observational Medical Outcomes Partnership)
- Complete the QA review of the StructureDefinition web publication of the 215 C-CDA R2.1 Templates
- Prepared and balloted the At-Home Test Result Report FHIR Implementation Guide

At the time of writing this article, the ONC had not approved any additional grant funds to continue the above effort.

Work has also progressed on two additional COVID related ONC grant-funded opportunities for HL7.

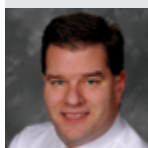
The four-year \$2M cooperative agreement titled "HL7 Public Health Standards and Solutions for Future Pandemics," which includes the following projects:

- Expanding the clinical domains supported by HL7 standards by balloting the COVID-19 FHIR Profile Library implementation guide
- Improve the privacy and security of health information by examining the current landscape of relevant security, privacy, and public health standards
- Advance the use of HL7 Bulk Data Access API and other relevant standards-based API technologies to improve surveillance capacity for future pandemics and other public health emergencies by assessing available open-source natural language processing (NLP) tools which unlock high-value information contained in the text of clinical notes
- Support development, advancement, and harmonization of Social Determinants of Health (SDOH) standards by analyzing the current state and emerging activities of SDOH related data

- Advance HL7 Public Health Standards by publishing a Physician Orders for Life-Sustaining Treatment (POLST) CDA implementation guide
- Analyze and document which HL7 Version 2 messaging standards or FHIR IGs, resources and profiles can be used to support submission of test results from at-home COVID testing applications to state and federal government agencies

The five-year \$3.5M contract “COVID-19 support for Accelerating Standards Development for the US Realm” which include the following projects:

- Ballot, reconcile and publish updates to HL7’s US Core Implementation Guide
- Financial support for the US Realm Steering Committee (USRSC) Project Manager and US Realm Senior Advisor, US Realm Content Administrator and US Realm Dashboard Developer
- Creation of HELIOS, the FHIR Accelerator for Public Health ■



By Dave Hamill, Director, HL7 Project Management Office

Progress for all of the above ONC work can be found on HL7’s Confluence page at:

<https://confluence.hl7.org/display/PMO/ONC+Grant+Project+Page>

HL7 appreciates ONC’s continued support of C-CDA and FHIR for 2022 and beyond.

HL7 Welcomes New Members

Benefactor

AmeriHealth Caritas

CVS Health

MAK-SYSTEM
GROUP Limited

Gold

ACS Solutions

Optimoz

Seoul Medical Informatics
Intelligence Lab Inc.

Amazon Web Services, Inc.

OtisHealth

Thenoz Médica S.A. de C.V.

Cohere Health

P.G.M.D. Sontuling S.r.l.

Zocdoc, Inc.

Datavant

PROMTIME

Flexpa

Reliv

Henry M. Jackson Foundation

Security Identification Systems
Corporation

Johnson & Johnson

Organizational

3 Net Wise, Inc.

Georgia Department of Public
Health

QS Systems

almerys

Guidewell

SavantSolutions4HIT, LLC

Caristix

JBH Solutions

Smart Reporting GmbH

Conéctate Soluciones y

LexisNexis Risk Solutions

SynergyReactor LLC

Aplicaciones SL

Stedi

Consento

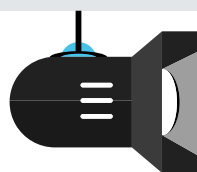
MayJuun

Vitamin Software Inc.

Curai Health

PA Health and Human Services
Delivery Center

Zane Networks LLC



Member Spotlight on Joanie Harper



Career, Education, HL7

Joanie began her IT career doing Y2K conversions on the AS400 platform followed by a stint in financial services. In 2002, she found herself in Bermuda working as a computer programmer in the insurance industry for eight and a half years. Upon leaving Bermuda in 2010, Joanie was able to fulfill her dream of going to university. She initially planned for a degree in computer science but after taking a course about the history of disease, she switched her major and graduated from the University of Toronto in 2013 with a Bachelor of Science in Health Studies. She kept computer science as a minor. She followed that with a Master's in Health Informatics from the University of Waterloo, which she received in 2017.

While completing her bachelor's degree, Joanie began working at the Rouge Valley Health System in Toronto, Canada, where Joanie was initially tasked with building an e-learning management system for the hospital and progressed to working on various other systems. In 2016, she became an interface analyst for the hospital, which introduced her to HL7. In preparation for her new role, she completed the HL7 Fundamentals course offered by HL7 and immediately began putting that knowledge to work.

In 2020, Joanie joined Canada Health Infoway, an independent, not-for-profit organization funded by the Canadian federal government that works with provincial and jurisdictional governments, healthcare organizations, clinicians, and patients to make healthcare in Canada more digital. She is now an active participant in HL7, attending regular meetings and working group meetings for Vocabulary, the Terminology Services Management Group, HL7 Terminology Authority, the UTG Project, and various policy and subcommittee meetings. Joanie is also a member of the HL7 Canada Council, which represents the HL7 Canada Affiliate. As such, she is a liaison between the HL7 Canada community and HL7 International and does her best to represent Canadian interests to HL7 International and keep the HL7 Canada community aware of the goings on at HL7 International. In 2021, Joanie received her FHIR R4 Proficiency Certification.

Joanie has a vision of a world where patients can access their healthcare information as easily as they can access their banking information. Interoperability, using HL7 standards, is one of the keys elements of that vision.

Personal

Joanie is a native of Toronto, Canada though she considers Bermuda to be a second home given her time spent living there. Near the beginning of the pandemic, Joanie and her partner, Alan, ditched their condos and bought a townhouse together in the eastern end of Toronto. The two spare bedrooms were converted to offices and a room in the basement was converted into a gym. Joanie has had a lifelong love of sport and while living in Bermuda, she participated in many sports including representing Bermuda in both volleyball and softball. She also played squash, soccer, field hockey, golf, and did scuba diving, running, biking, and triathlons. Joanie goes to her gym regularly and plays squash. She is currently training for a triathlon in June and for some obstacle course

aces in September and October. She is also looking forward to the day when the Toronto Blue Jays win their third World Series.

Before finding computers, Joanie had some interesting jobs: retail sales, the military, receptionist, secretary, air traffic control trainee, courier. She had her first paper route at age seven.

Joanie loves to travel. One year for her vacation, she worked on an archaeological dig on Easter Island for a few weeks. Another year she did a 10-day Baltic cruise that visited seven countries, followed by 10 days of taking the train around Switzerland. The highlight in Switzerland was paragliding in the Swiss Alps. While representing Bermuda, she traveled to Atlanta to play in the US Open, Guernsey in the UK, the Island of Rhodes in Greece to play in the Small Island Games, and to the Bahamas. ■

***Are you looking for health IT experts with HL7 and FHIR experience?
Or are you looking for the next step in your career?***



Be sure to check out the HL7 Job Board! It's a great resource to address the growing demand for specialized IT skills, as well as the increasing adoption of HL7 FHIR and the ONC/CMS rule!

The Job Board provides a central location for the HL7 community to learn about openings aligned with their skills and for employers to gain visibility with implementers that have HL7 experience. During the pandemic we are waiving all fees to post positions.





HL7 FHIR in Europe

Recap of the Hospitals on FHIR Launch Event

On March 31, HL7 Europe hosted a virtual “Hospitals on FHIR” launch event. Hospitals on FHIR builds upon the vision of Professor Henrique Martins, HL7 Europe board member and Giorgio Cangioli, the Technical leader of HL7 Europe, envisioning all European hospitals part of the European Health Data Space.

Approximately a year ago, they co-authored two articles in the HL7 Europe News (page 9) and in HealthcareManagement.org. The Technical Coordination Team of HL7 Europe (TNT for short) that Giorgio Cangioli leads was enthusiastic and worked on a FHIR maturity scale for hospitals.

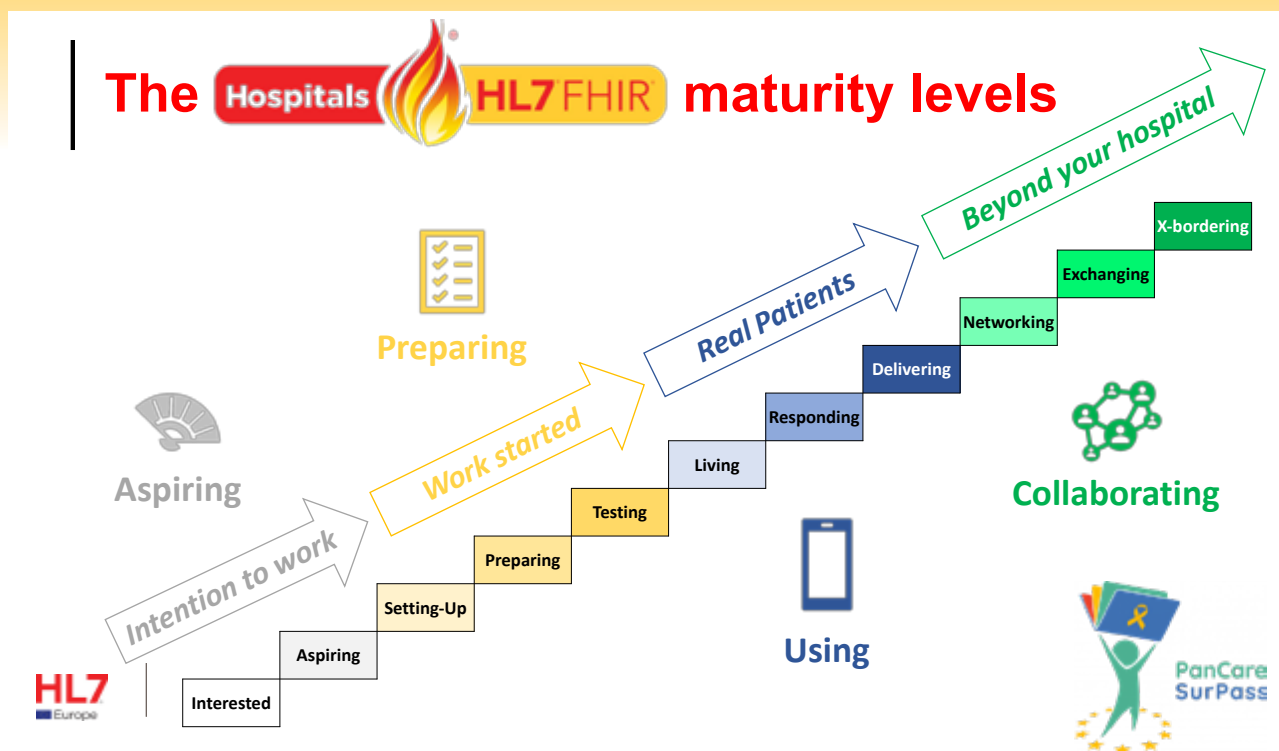
As a result, the www.hospitalsonFHIR.eu website was created, and we were all ready to go. More than 140 people joined the event, which was initially planned as a small meeting of like-minded individuals. The positive energy in the meeting created a halo effect that lasted days.

The meeting was opened by Kyriacos HATZARAS, Program Officer—EU Policies, at the unit of eHealth, Well-Being and Ageing, DG Connect, European Commission. He spoke about the interoperability initiatives of the European Commission. He was followed by Diego Kaminker, Deputy Standards Chief Implementation Officer at HL7 International,

who discussed the new HL7 Implementation Division. Next, Professor Henrique Martins explained “Why Hospitals on FHIR is urgent and timely,” and Giorgio Cangioli presented the Hospitals on FHIR maturity model.

Open discussion occurred in two panels. The first panel focused on shaping expectations for national initiatives and was moderated by Giorgio Cangioli. The panelists represented affiliates (Jose Teixeira, HL7 Belgium), national initiatives (Prof. Pierluigi Plebani, HealthBigData), EHR vendors (Pier Alberto Gibellini, Dedalus SpA), and hospitals engaging in research activities such as rare disease networks (Maurizio Scarpa, MetabERN).

The second panel tackled the topic of expanding and scaling up at both the European and global levels and was moderated by Dr. Martins. Among the panelists were Pascal Garel (CEO HOPE - European Public Hospitals Federation) and John Rayner (Digital Health Strategist, EMEA, HIMSS). Pascal noted the importance of such events for European public hospitals that have to address market fragmentation as they struggle with the digital health transformation. Rayner covered the connection to the EMRAM and other maturity models developed by HIMSS.



Next Steps

We are currently looking to connect the dots with strategic European

Commission support actions. This includes x-eHealth, which addresses the European EHR exchange format (EHRxF) and PanCareSurPass, which studies the barriers, enablers, and costs of adopting the Survivorship Passport, a version of the International Patient Summary for Childhood Cancer Survivors in Europe.

In the x-eHealth project we are already working on the specification for the European EHRxF, based on the recommendation of the European Commission. It is our aspiration to create and widely use interoperability specifications for labs, images and discharge reports based on HL7 standards and IHE profiles. Preliminary versions are already available in Art Decor. We have also developed a training plan to build capacity among developers of health solutions.

In the PanCareSurPass project, we look forward

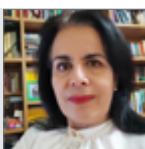


to validating implementations of the Survivorship Passport for childhood cancer survivors, a kind of an extended patient summary, through an HL7 FHIR infrastructure. Hospitals in the survivorship network which are also connected to regional or national infrastructures, could serve as a layer in the Hospitals On FHIR Map.

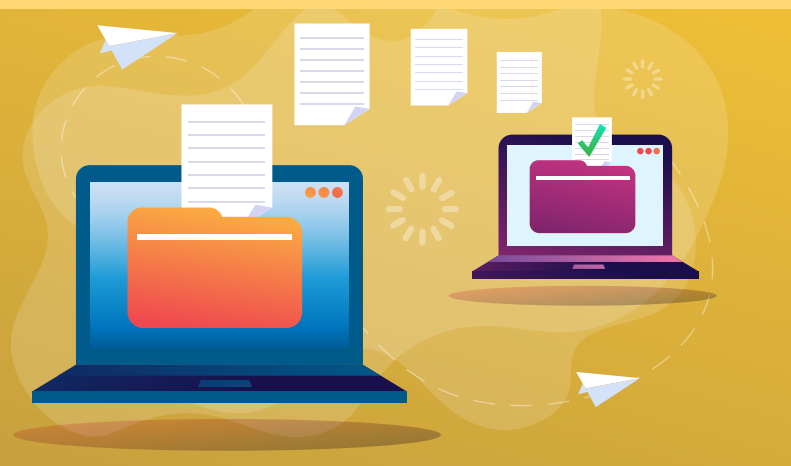
In addition, we are reaching out the European Reference Networks (ERNs) to investigate if similar layers may be created to help

citizens and health professionals around Europe connect to the European Health Data Space. HL7 FHIR is well positioned to simplify processes and make ERNs a reality. There are many more opportunities we are exploring, and we hope that HospitalsOnFHIR will not only accelerate the adoption of FHIR in Europe, sustaining the investments in myHealth@EU and modernizing the European Health data systems.

For more information: www.hospitalsonfhir.eu ■



By Giorgio Cangili, Board Member and Technical Leader, HL7 Europe; Henrique Martins, MD, PhD, Board Member, HL7 Europe and Associate Professor, Health Management and Leadership, FCS-UBI, ISCTE-IUL; and Catherine Chronaki, Secretary General, HL7 Europe and President, European Federation for Medical Informatics



Moving Past Screenshots and Faxes to Transfer Data

CDex Eases Burden of Data Exchange Between Providers and Payers



The HL7 Da Vinci Project's recent publication of the *Clinical Data Exchange (CDex) Implementation Guide (IG)* makes data exchange between payers and providers better.

Considered by Da Vinci to be the "Swiss Army Knife" of IGs, CDex identifies, documents and constrains specific patterns of exchange. CDex also aids in other workflows, like risk adjustment and quality reporting for sharing specific clinical data. Da Vinci began work on CDex in 2019, and the IG has evolved and improved to what is now version 1.0, published March 28, to be used with HL7's Fast Healthcare Interoperability Resources (FHIR®) version 4.0.



Jocelyn Keegan, Da Vinci program manager, and senior health information technology consultant with Point-of-Care Partners, says prior to CDex, the lack of a good utility for this kind of exchange is what has kept payers and providers stuck using faxes and big PDFs to exchange information. "The majority of times when it comes to data exchange between a provider and a payer today, it's just easier to use a fax," she says.

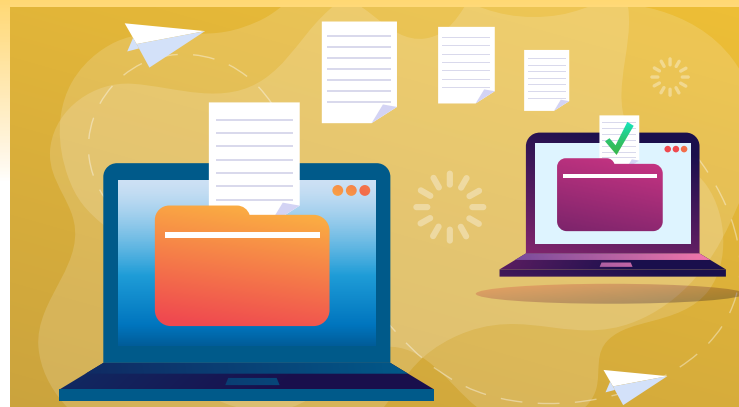
"Today providers screenshot lab results because that's the easiest thing to do to get the data out of an EHR," Keegan says. "And so, [with CDex] we want to be able to get the data flowing, but have it flowing from where it's at rest, in a standardized way so that we can move to the promise of full automation."

According to Viet Nguyen, MD, technical director for the Da Vinci Project, chief standards implementation officer at HL7, and clinical informaticist at Stratametrics, LLC, healthcare clinical data is shared at high volumes today, and the process is burdensome to payers and providers. "It's not very timely, and it's not very structured." That's where FHIR plays a significant role, he says. "FHIR, as a technology, is perfectly situated to address that, and especially because it's 10 years old, it's in wide adoption by EHRs."

"The part where DaVinci has come in, and what we do, is to develop implementation guides that are, for lack of better terms, standard operating procedures that allow the stakeholders to utilize FHIR in not only the elements, just like the ingredients in a recipe, but in a clear order," Nguyen says. "So that the exchange from either party is clear, the expectations are clear at both a workflow and a technical aspect." ■



By Diana Manos, Writer, HL7 Da Vinci Project



Improving Data Exchange Between Payers and Providers

Da Vinci Takes on Value-based Care Performance Metrics in its Newest Implementation Guide

HL7's Da Vinci Project is working on a new focus area for implementation guides (IGs)—a set of standards to help payers and providers exchange data electronically to manage and monitor their value-based care contracts.

Da Vinci already has put out two prior IGs, one on risk adjustment and one on quality measures, and is now setting out to address what its members have identified as missing in standards-based data exchange in value-based care (VBC).

The Da Vinci Operating Committee reports that four out of five Da Vinci member organizations say a standards framework is needed “to realize the value of value-based care relationships.”

The VBC IG, now in its beginning stages of development, will aim to help payers and providers that are working together in risk-based payment models to exchange data in the most streamlined way possible, says informaticist Teresa Younkin, senior consultant at Point-of-Care Partners, and lead on the project.

“Right now, there is this disjointed and manual way of data exchange between payers and providers in value-based care contracts,” Younkin says. It requires faxing, emailing, the use of PDFs and printing—and then putting all that data together. “We’re trying to get everything standardized, so that providers can have more information at the point of care,” she says. The whole point of this new IG is to try and get payers and providers “to meet in the middle.”

According to Younkin, the fledgling VBC IG group is starting the process by looking to see what aspects of the other use cases they could possibly lean on. It doesn’t make any sense for this group to recreate the wheel. But even with that preliminary help from other use cases, the process will take time. “There are so many touch points and data points and workflows to work through,” she says.

Jocelyn Keegan, program manager for Da Vinci and senior consultant for Point-of-Care Partners, says this is a work in progress to identify other missing workflows. The group handling the mapping began work in January and also has had some informal conversations around the value-based care journey. “That work is actually coming along—I don’t want to say to completion—but to sort of the first round of findings coming back to the larger group,” Keegan says.

There is a big gap in understanding for payers and providers on what’s happening at the population level because of how the data flows on a weekly or monthly basis, Keegan says. “It isn’t very actionable on either side.” The goal is to achieve standards-based real-time or near real-time data-sharing, and that’s where the VBC IG will come in.

To learn more about this use case, please join our listserv at hl7.me/davincinews/ ■



Initial Crosswalk Activity Focuses on Prior Authorization Support FHIR Implementation Guide

Announcing X12 and HL7 Da Vinci Crosswalk Project



X12 and the HL7 Da Vinci Project are working to improve health information data exchange by collaborating to ensure the health care industry has definitive crosswalks connecting the data in HL7 Fast Healthcare Interoperability Resources (FHIR®) transactions and the data in the associated EDI Standard transactions. Both American National Standards Institute (ANSI)-accredited standards development organizations, which convene industry to develop data exchange standards and specifications, are pleased to announce the availability of the first interoperability crosswalks.

A crosswalk is a document mapping the relationships between different data sets that enable reliable translation across standards.

This initial crosswalk activity focuses on the Da Vinci Project's Prior Authorization Support Implementation Guide (PAS). PAS provides a format for creating FHIR-based messages that, among other things, contain the data necessary in X12's transactions, and the crosswalks contain the specific instructions necessary for implementers to have a common, semantic mapping between the two standards transactions on a data field by data field basis.

“Collaboration is now where we start, not where we end, as noted by our crosswalks with X12 to meet industry needs for prior authorization automation. HL7 and X12 members are advancing interoperability and leaning into the intersection of clinical and administrative data with modern technology. By providing complementary standards to existing X12 standards, the HL7 Da Vinci Project's FHIR-based Prior Authorization Support

Implementation Guide offers additional options to create efficiencies and reduce abrasion for providers, payers and their partners,” said HL7 CEO Charles Jaffe, MD, PhD.

X12's Executive Director, Cathy Sheppard, agreed: “Pairing emerging and proven technologies in new ways presents opportunities for entities to better leverage their technology investments while meeting the needs of healthcare consumers. These crosswalks illustrate the importance of standardizing the connections between complementary standards and X12's mandated standards and will enable increased automation of existing prior authorization standards by empowering implementers to pull critical clinical information needed for prior authorization determinations in provider's primary workflows.”

X12 implementation guides with crosswalking information are available in Glass, X12's online viewer.

- 005010X215 The Health Care Services Review Inquiry and Response Implementation Guide (278)
- 005010X217 The Health Care Services Review Request and Response Implementation Guide (278)
- 006020X316 Additional Information to Support a Health Care Services Review (275)

X12 and the HL7 communities will continue to collaborate on activities that support the health care industry's use of these complementary syntaxes. Stakeholders interested in getting involved in active work currently underway can visit: [Da Vinci Reference to External Standards and Terminologies](#). ■



By the Da Vinci Project Communications Team

FAST to focus on scalability approaches for implementers to leverage across use cases

HL7® Launches FAST FHIR® Accelerator to Jumpstart FHIR-Based Interoperability Solutions

HL7 recently announced that the Office of the National Coordinator for Health Information Technology's (ONC's) FHIR at Scale Taskforce (FAST) will transition into an HL7 FHIR Accelerator.

The FAST project was originally founded to identify Fast Healthcare Interoperability Resources (FHIR) scalability barriers and define a common set of infrastructure standards for scalable FHIR solutions. As an Accelerator, FAST will continue its work under the purview of HL7® with a broad range of stakeholders informing and participating in the initiative.

“As a widely adopted standard supported by many of the most notable stakeholders in the health IT community, FHIR is making rapid, real-world progress toward addressing the biggest challenges of health data interoperability,” said HL7 International Chief Executive Officer Charles Jaffe, M.D., Ph.D. “The FAST Accelerator will bring us closer to defining a consistent and scalable approach to deploying FHIR across high-value use cases and disseminating these best practices to the industry.”

FAST will complement and support the work of HL7's other accelerators. While groups such as Vulcan, the Da Vinci Project, and CodeX develop standards to support specific functional use cases, FAST focuses on scalability approaches that implementers can leverage across use cases to simplify deployment and use of FHIR in disparate environments.

In early 2022, FAST formed a cross-stakeholder team to begin the transition from an ONC-convened initiative to an HL7® FHIR Accelerator. The team has been working to develop a framework for the accelerator's scope of work, governance principles, and operating and funding models.

“HL7 International has been an exceptional partner and its standards are a key part of what drives interoperability in the U.S. healthcare system.



HL7's FHIR standard is stimulating innovation and quickly transforming how data is exchanged between providers, payers, and patients,” said Micky Tripathi, Ph.D., national coordinator for health information technology. “Along with the Sequoia Project, we recently published a FHIR Roadmap as part of the implementation of the Trusted Exchange Framework and Common Agreement (TEFCA). FHIR Accelerators like FAST are poised to play a key role in advancing technical specifications that can be implemented at scale within TEFCA and we look forward to what's to come.”

HL7 is currently seeking organizations interested in becoming members of the FAST Accelerator. Members will take a leadership role in the interoperability ecosystem by helping to prioritize projects and use cases and drive standard development and implementation. Participants will be able to shape and guide industry-wide efforts to eliminate implementation barriers and support real-time, secure data exchange between stakeholders implementing FHIR APIs.

“The FAST Accelerator is an exciting opportunity for technology solution companies, providers, payers, and government entities to innovate around data exchange and find common approaches to implementation problems that we all face,” said Deepak Sadagopan, Senior Vice President Value Based Care & Population Health Informatics with Providence. “When everyone sits at the same table, we can make meaningful progress on the lingering barriers that prevent us from maximizing the value of true interoperability. This is the place where we can have those necessary conversations about scaling FHIR in a way that works for everybody.”

The FAST Accelerator is currently accepting applications for membership. To learn more about the program and how to participate, please contact fast@hl7.org or visit the HL7 FAST webpage at <http://www.hl7.org/fast/>.



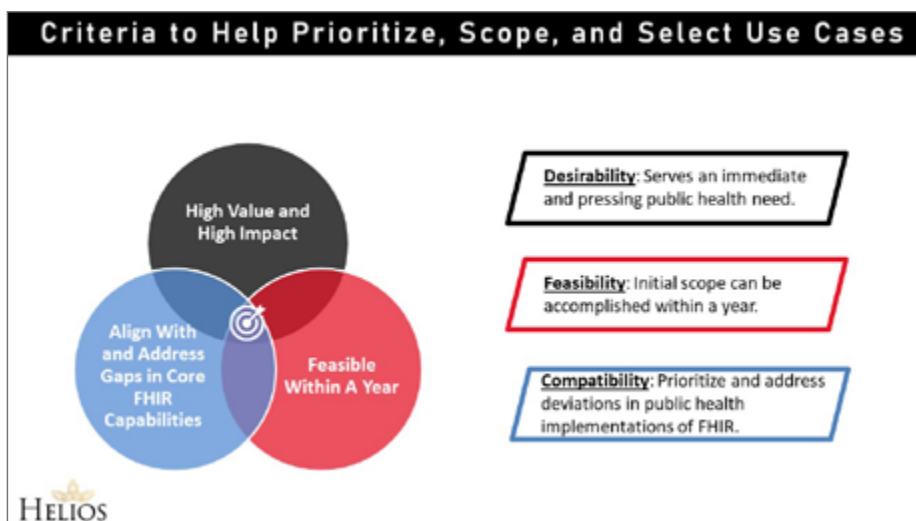


Helios Tackles Three Priority Use Cases in 2022

Join Helios—The FHIR Accelerator for Public Health

Public health is complex. It operates at all levels of government and with many partners across the healthcare sector and beyond, which creates challenges in coordinating efforts around data. Members of Helios—the FHIR® Accelerator for Public Health—commit to tackle these challenges head on in ways that deliver the greatest net benefit overall.

Each year, the Helios Accelerator will select strategic priority areas to focus on. Each priority area will be scoped to allow significant progress within a year and to address a significant public health need. Priority areas will also align with activity in healthcare and the private sector to make it easier for public health to adapt to changes in policy, technology, and the marketplace.



During 2022, Helios will focus on three priority areas:

Make Data in Public Health Information Systems Accessible in Bulk (Starting with Immunization Information Systems)

Ensure authorized users of immunization information systems can access vaccination data in bulk.

This will help health providers and payers to proactively support their patient populations by addressing gaps in care and preventing redundancies while lowering burden on state public health agencies and on data requestors. Helios members will help create a uniform process for querying immunization data in IIS, leveraging BulkFHIR. Helios members will also assist in developing implementation guidance and open-source code samples, conducting pilots and participating in Connectathons.

Align and Optimize Public Health Data Sharing

Identify commonalities and optimal ways for public health to access data in EHRs that would not be easily available under existing data channels.

This will demonstrate ways in which FHIR can help support public health action and improve the quality and consistency of public health data shared nationwide while saving time, money, and effort. Helios members will identify common requirements and assess various FHIR-based paradigms for accessing and exchanging patient-level data in EHRs. Helios members will also identify opportunities for collaboration and accelerated development with industry and will pilot a subset of the approaches identified. The assessment and pilots will inform a strategic roadmap to help align and advance public health adoption of FHIR moving forward.

Deliver Aggregate Information to Public Health

Provide public health critical data needed on healthcare resource capacity during emergencies and other events of public health importance.

This will help address a wide range of public health preparedness and data aggregation needs while lessening the strain on healthcare and public health during times when both systems are most taxed. Helios members will focus on one or two measures (e.g., bed count, supply inventory) and demonstrate ways FHIR can help deliver mission-critical capacity information to public health partners on the front lines both during emergencies and routine operations.

These priority areas were selected by an interim steering committee that consisted of representatives from public health, healthcare, and health IT implementers. Helios members will consider and build on current work in these priority areas to identify synergies and opportunities for acceleration. ■

To Join and For More Information

Helios is actively recruiting pilot partners and members. Interested parties are encouraged to email helios@hl7.org.

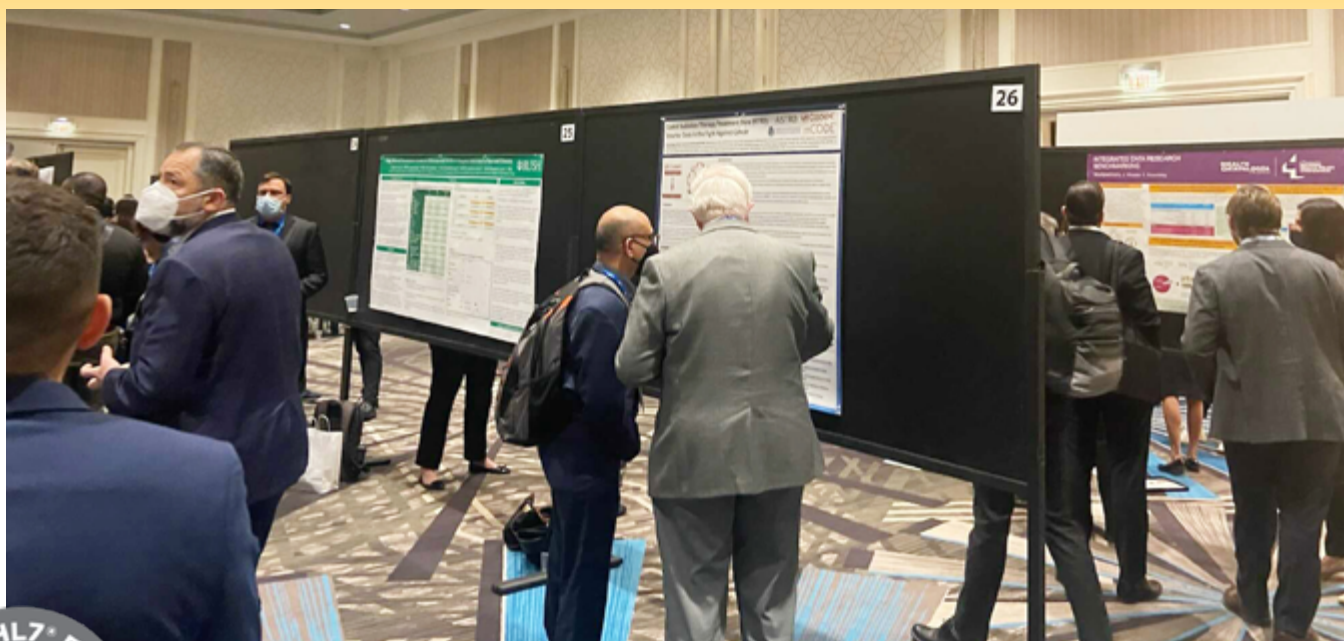
To learn more about Helios, please visit:

- Helios HL7 Homepage: <https://www.hl7.org/helios/>
- Helios Zulip Chat: <https://chat.fhir.org/#narrow/stream/307807-Helios-Accelerator>
- Helios Confluence Page: <https://confluence.hl7.org/display/PH/Helios+FHIR+Accelerator+for+Public+Health+Home>
- Join Helios ListServ: <http://www.hl7.org/myhl7/managelistservs.cfm>

Organizers of Helios are encouraging other entities to participate in the effort.

More information about Helios and the project's goals can be found on HL7's website, www.hl7.org/helios/





Attracting New Funding and Exploring New Clinical Domains

CodeX Expands Membership & Oncology Use Cases

CodeX members continue to improve system-to-system communication by integrating and testing the minimal Common Oncology Data Elements (mCODE) FHIR Implementation Guide—an open standard language for cancer data—within use cases that enhance new workflows supporting better cancer care and research. Use case teams reached milestones in integrating oncology trial matching, developing and automating the exchange of radiation therapy end of treatment summaries, and growing the collection of real-world clinical trial data in workflow at the point of care.

The member-driven HL7 FHIR Accelerator now has its sights set on hosting a growing community that works together to enable broader FHIR-based

interoperability to solve even more important challenges and opportunities in patient health. In late 2021, CodeX began exploring how to leverage the CodeX/mCODE experience within two potential new domains: cardiovascular and genomics. As CodeX explores these new areas, we'd like to invite others to join the conversation on how we can work together on building interoperability solutions in other clinical specialty realms.

How to Engage in New CodeX Domains

- Laboratories, clinicians, researchers, and others interested in driving a high level of interoperability in genomic data and exploring ways to improve patient outcomes, please reach out to Mallory Carellas (mcarellas@mitre.org)
- Patients, clinicians, registries, payers, regulators, researchers, information systems, and others who are interested in developing and harmonizing an open-source standard and common language for cardiovascular concepts should contact Kim Ball (kim.ball@pocp.com)

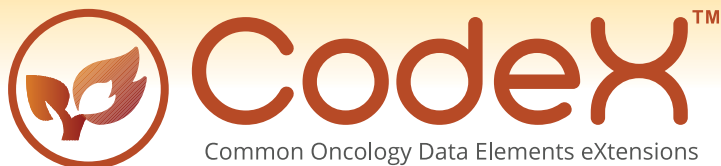
FOR MORE INFORMATION

Goals and objectives of the Genomics domain

<https://confluence.hl7.org/display/COD/Genomics>

Goals and objectives of the Cardiovascular domain

<https://confluence.hl7.org/display/COD/Cardiovascular>



CodeX Radiation Therapy Treatment Data (RTTD): Smarter Data in the Fight Against Cancer



Chuck Mayo, PhD, University of Michigan/AAPM, Randi Kudner, MFA, ASTRO, Mary Feng, MD, University of California San Francisco/ASTRO, James Hayman, MD, University of Michigan/ASTRO, Rishabh Kapoor, PhD, Virginia Commonwealth University/AAPM, Anthony DiDonato, MS, MITRE, Michelle Caserio, MS, MITRE, Sharon Sebastian, RN-BC, MS, MITRE, Saul Kravitz, PhD, MITRE, Su Chen, MD, MITRE, Steve Bratt, PhD, MITRE, John Kildea, PhD, McGill University, Martin von Siebenthal, PhD, Varian, John Christodoulos, MD, University of Pennsylvania/Elekta



BACKGROUND

- **mCODE** (minimal Common Oncology Data Elements) is a publicly released, HL7 FHIR data standard, comprised of data elements centered around oncology. mCODE – as a health data standard – leverages these elements to achieve interoperable exchange of cancer patient data.
- **CodeX** is a member-driven HL7 FHIR Accelerator, building a community to accelerate interoperable data modeling and applications leading to step-change improvements in patient care and research.
- **RTTD** is a CodeX use case that is drawing on the community of healthcare and radiation oncology organizations to develop an implementation guide (IG) that defines radiation therapy elements for exchanging radiation treatment summary data to support care coordination and data reuse.
- **OORO** (Operational Ontology for Radiation Oncology) is a publicly released standardized ontology developed by professional societies (**AAPM** – American Association of Physicists in Medicine, **ASTRO** – American Society for Radiation Oncology) organizing major concepts used in clinical practice to support practice quality measures and research improving care for patients with cancer.

PROBLEM

Radiation therapy (RT) treatment details – critical for care coordination – are typically only available in specialized radiation oncology information systems (ROIS) and not readily available in electronic health records (EHR). Outside ROIS, radiation treatment details are commonly recorded as free text notes that are manually entered to create radiation therapy treatment summary documents.

This results in high clinician burden, transcription errors, and highlights a lack of standardization in recording, generating, and sharing a patient's radiation therapy treatment summary report. Additionally, providers are unable to leverage the data to meet reporting requirements or support comparative effectiveness research.

GOAL

Drawing on the work of professional societies (ASTRO, AAPM) in standards development, the RTTD use case will use mCODE and additional radiotherapy FHIR profiles as a core foundation for this project's structured data exchange model to:

- Develop, test and deploy open data standards and open application programming interfaces (API) that enable interoperable, multi-purpose exchange of radiation treatment summary data for care coordination and data reuse.
- Enable ROIS to generate and share a patient's RT treatment summary information, both at the end-of-treatment and during treatment (as an in-progress summary) across health systems and providers.
- Make RT treatment information readily available and display the information in a meaningful way to enable providers to make informed, impactful decisions that will improve patient safety and quality of care.

APPROACH

Phase	Milestone	Timeline
Phase 0	Expand the radiation therapy concepts in mCODE in preparation for mCODE Standard for Trial Use (STU) 2	Complete March '21
Phase 1	Radiation oncology system generates an end of treatment summary that can be retrieved by another information system	Complete December '21
Phase 2	Radiation oncology system generates a radiation therapy in-progress treatment summary that can be retrieved by another information system or health system	On Track May '22
Phase 3	Radiation oncology system generates treatment summaries that are retrieved by a health system and displayed within the EHR interface	On Track Fall '22

RTTD PILOT

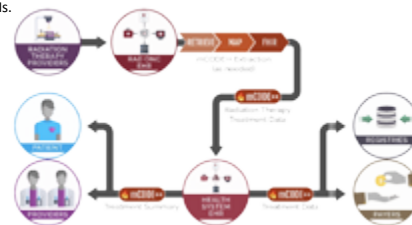
The RTTD use case is executing an incremental, multi-phase pilot to test mCODE, the radiation therapy concepts and the IHE-RQ Exchange of Radiotherapy Summaries (XRTS) profile.

Pilot Objectives:

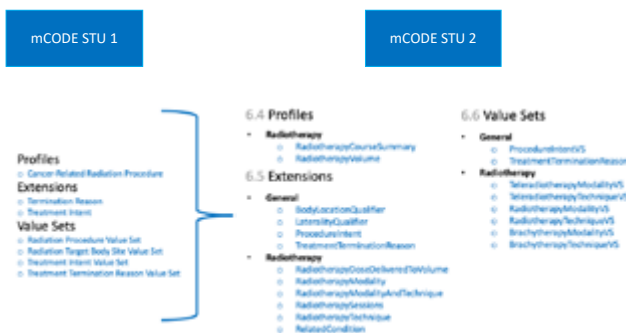
- Demonstrate interoperability between ROIS and another vendor system to exchange RT treatment summaries.
- Evaluate the completeness of mCODE and RTTD radiotherapy FHIR profiles to share the appropriate level of RT information – initially for end of treatment summary reports and then for in-progress summary reports.
- Identify gaps in the data model and APIs.

Pilot Value to Participating Health Sites:

- Catalyze health IT system adoption of cutting-edge standards development.
- Provide feedback on the current RTTD radiation oncology standards and how they can be efficiently leveraged within health IT systems.
- Train health IT system technical implementation teams and interested clinicians on the standards language.
- Generate qualitative feedback.



OORO → RADIATION THERAPY CONCEPTS



COLLABORATORS

American Society for Radiation Oncology (**ASTRO**),
American Association of Physicians in Medicine
(**AAPM**), Canadian Organization of Medical Physicists
(**COMP**), Society for Imaging Informatics in Medicine
(**SIIM**), MITRE, Varian, Wemedeo, University of
Michigan, Virginia Commonwealth University, Veterans
Health Administration, McGill University, University of
Pennsylvania, University of California San Francisco,
RaySearch, Elekta, Epic, Integrating the Healthcare
Enterprise-Radiation Oncology (**IHE-RO**)

REFERENCES

- mCODE STU 2 IG: <https://build.fhir.org/ig/HL7/fhir-mCODE-ig/>
- RTT2 IG: <https://build.fhir.org/ig/HL7/codex-radiation-therapy/>
- Fast Healthcare Interoperability Resources (FHIR): <http://hl7.org/fhir/>
- American Association of Physicians in Medicine: <https://fw3.aapm.org/>
- American Society for Radiation Oncology: <https://www.astro.org/>

Continued from page 22

CodeX Expands Membership & Oncology Use Cases

Project Accomplishments

With eight active use cases, CodeX covers extensive ground crosscutting several facets of oncology care. These use cases range from standardized data extraction tools to provider and patient-centric trial matching optimization to the automation of cancer registry reporting and prior authorization in oncology. A few recent highlights follow.

Risk Evaluation and Mitigation Strategies

CodeX launched the Risk Evaluation and Mitigation Strategies (REMS) use case—the first new use case since the accelerator’s inception in 2019. REMS is a drug safety program that the FDA (Food and Drug Administration) can require for certain medications with potential for serious adverse side effects to help ensure the benefits of the medication outweigh its risks. These drugs would not otherwise be available because of safety issues. Although few drugs require REMS, the required actions vary with each drug or drug class (e.g., opioid) and introduce workflow burden and ultimately may cause delays in therapy for patients, treatment abandonment, limited access to REMS drugs, time taken away from patient care, overwhelmed stakeholders, and sub-optimal care for patients.

Spearheaded by the FDA, the REMS team is hosting monthly public calls to explore how FHIR

standards can be leveraged in the development of an open-source, interoperable REMS solution aimed to reduce burden and address stakeholder needs. The team is looking to add more voices to develop a real-world REMS solution for oncology and beyond.

Integrated Trial Matching for Cancer Patients and Providers

The Integrated Trial Matching for Cancer Patients and Providers (TM) use case is planning to launch a phase two pilot to test sending current patient records to multiple mCODE-enabled trial matching services and to measure the ease of finding clinical trials for patients when a matching service is mCODE enabled. In collaboration with use case champion American Cancer Society Cancer Action Network, the use case team secured nearly \$1 million in support from Amgen for this pilot to expand cancer clinical trial enrollment through improved technology and patient support.

The TM use case team also convened an advisory committee representing patients, clinicians, manufacturers, and researchers in April. The diverse group will provide feedback and suggestions on the pilot protocol and overall design, especially regarding the patient experience.

FOR MORE INFORMATION

REMS use cases, view a prototype that demonstrates the REMS process from the prescriber’s point of view and the public call schedule
<https://confluence.hl7.org/display/COD/Risk+Evaluation+and+Mitigation+Strategies+%28REMS%29+Integration>

TO JOIN THE USE CASE

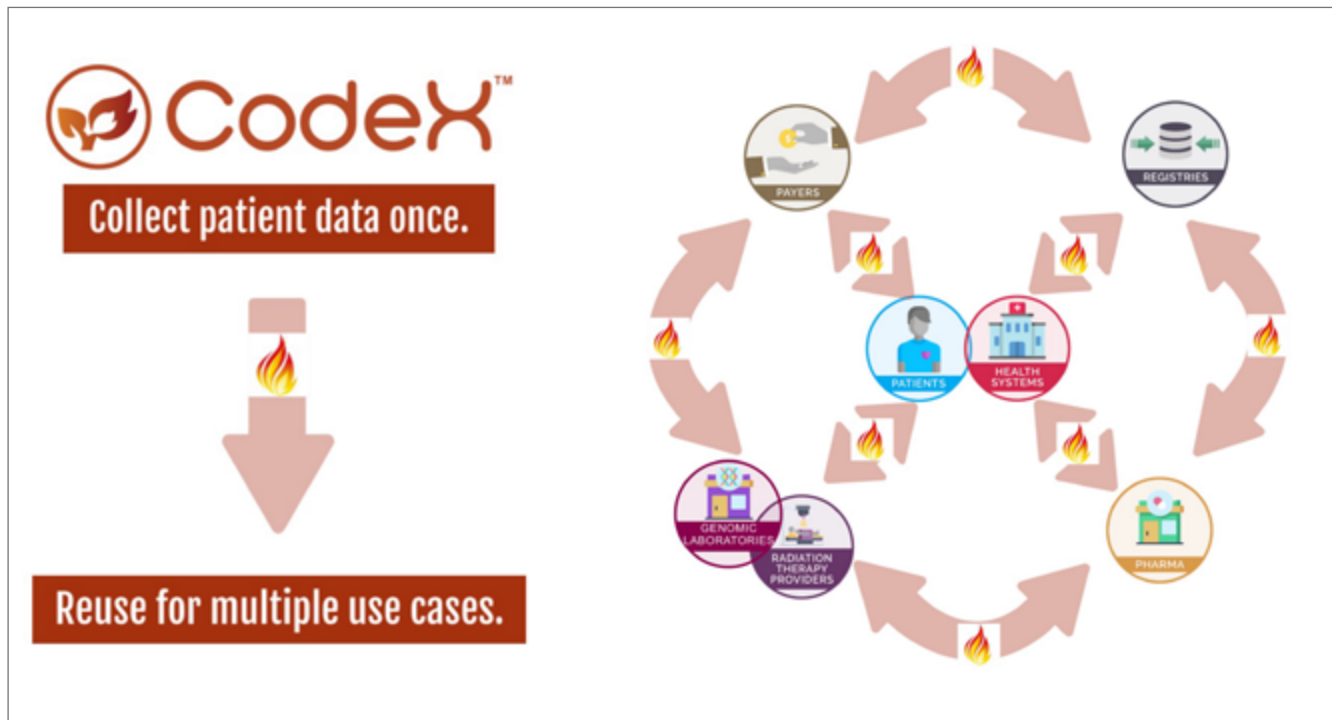
Contact Kelee Petzelt
kelee.petzelt@pocp.com

FOR MORE INFORMATION

Trial matching use case work and the organizations involved
<https://confluence.hl7.org/display/COD/Integrated+Trial+Matching+for+Cancer+Patients+and+Providers>
Amgen funding
<https://www.fightcancer.org/releases/acs-can-provided-nearly-1-million-support-amgen-expand-cancer-clinical-trial-enrollment>

TO JOIN THE USE CASE

Contact Caroline Potteiger
cpotteiger@mitre.org



Radiation Therapy Treatment Data

Members of the Radiation Therapy Treatment Data (RTTD) for Cancer team recently tested and validated its radiation therapy end-of-treatment summary as part of the IHE-RO XRTS Workshop. The RTTD FHIR Implementation Guide (IG) also leverages the XRTS technical specification. Use case leadership presented a poster session titled “Data to Improve Health and Well-Being” at AcademyHealth’s Health Datapalooza (HDP) in April.

Stay in Touch

CodeX encourages stakeholders across the oncology and broader patient health ecosystem to stay up to date with the latest mCODE and CodeX news and project updates by visiting the CodeX Confluence home page and clicking “Sign up for CodeX Communications.” Reach out to Steve Bratt sbratt@mitre.org, Su Chen suchen@mitre.org or Kim Ball kim.ball@pocp.com with any questions! ■

FOR MORE INFORMATION

RTTD use case and access the draft IG

<https://confluence.hl7.org/display/COD/Radiation+Therapy+Treatment+Data+for+Cancer>

TO JOIN THE USE CASE

Contact Anthony DiDonato

[Anthony DiDonato](mailto:Anthony.DiDonato@pocp.com)

FOR MORE INFORMATION

CodeX public calls and activities

<https://confluence.hl7.org/display/COD/CodeX+Calendar>

Real-world application of mCODE, register for the monthly mCODE Community of Practice call (last Friday of the month, 12-1pm ET)

<https://confluence.hl7.org/display/COD/mCODE+Community+of+Practice>

high-level CodeX Project Plan

<https://confluence.hl7.org/display/COD/CodeX+Program+Plan>

The Gravity Project

Accelerating National SDOH Data Standards

Key project accomplishments and target milestones over the past year are covered below:

Multi-domain SDOH Data Set Development

To date, the Gravity Project completed the development of consensus approved, expert-driven, evidence-based data sets for 14 SDOH domains: food insecurity, housing instability, homelessness, inadequate housing, transportation insecurity, veteran status, less than a high school education, unemployment, financial insecurity, material hardship, psychological stress, social connectedness, elder abuse, and intimate partner violence. Throughout 2022 and 2023, the Gravity Project will work on new domains that align with

Healthy People 2030 objectives and health equity priorities. These include health literacy, under insurance, medical cost burden, neighborhood safety, food access, minority strain, and measures of discrimination and bias.



SDOH Value Sets Published in VSAC

In November 2021, the National Library of Medicine published the first Gravity Project value sets for completed SDOH domains. These are now available for implementation and reference for US quality measure development and US health data policy.

ONC USCDI SDOH Data Class Submission

On July 9, 2021, the Office of the National Coordinator (ONC) officially announced the inclusion of the SDOH data class to the United States Core for Data Interoperability (USCD) V2. This addition provides health IT stakeholders nationwide clear direction toward standardized electronic exchange of SDOH. It also lays the foundation for the provider community to start systemizing the capture and use of this data

in clinical settings and to adopt health IT that supports the activities.

HL7 SDOH Clinical Care FHIR Implementation Guide & Reference Implementation

The Gravity Project submitted its first FHIR IG for ballot as part of the HL7 January 2021 ballot cycle and completed ballot reconciliation and the development of a reference implementation in June 2021. The ballot was published as a HL7 Standard for Trial Use (STU) version 1 in August 2021. An updated version of this IG was balloted in January 2022 and target for publication in June 2022.

FHIR Connectathons

The Gravity Technical team regularly participates in scheduled HL7 FHIR Connectathons. In January 2022, the Gravity Technical team hosted an SDOH FHIR Track and will participate in the July CMS Connectathon.

CMS Proposed Rule

On January 12, 2022, CMS published proposed policy and technical changes for Medicare Advantage in 2023. Proposes MA Special Needs Plans (SNPs) include standardized questions on housing stability, food security, and access to transportation as part of their currently required health risk assessments. CMS intends to align the required standardized questions with the SDOH Assessment data element integrated in USCDI v2.

Upcoming Activities

The Gravity Project will facilitate the testing and validation of the Gravity terminology and technical standards through real-world pilots in 2022. We anticipate pilots will advance the maturity of the SDOH Clinical Care FHIR IG and validate coded SDOH data elements. If you are interested in learning more about the pilots, please email: gravityproject@emiadvisors.net ■



By Evelyn Gallego, Program Manager, Gravity Project

To learn more about the Gravity Project, please visit: <https://thegravityproject.net/>

To learn more about the pilots, please email: gravityproject@emiadvisors.net

HL7 Standards Published Since January 2022



STU Publication of HL7 CDA® R2 Implementation Guide: Public Health Case Report – the Electronic Initial Case Report (eICR) Release 2, STU Release 3.0 – US Realm

STU Publication of HL7 FHIR Implementation Guide: minimal Common Oncology Data Elements (mCODE) Release 1 STU 2 – US Realm

STU Publication of HL7 FHIR® Implementation Guide: Electronic Case Reporting (eCR), Release 2

STU Update Publication of HL7 FHIR® Profile: Quality, Release 1 STU 4.1- US Realm

STU Publication of HL7 FHIR Implementation Guide: Profiles for ICSR Transfusion and Vaccination Adverse Event Detection and Reporting, Release 1 – US Realm

Normative Publication of HL7 FHIR® Implementation Guide: FHIR Shorthand, Release 2

Informative Publication of HL7 CDA® R2 Attachment Implementation Guide: Exchange of C-CDA Based Documents, Release 2 – US Realm

STU Publication of HL7 FHIR® Structured Data Capture (SDC) Implementation Guide, Release 3

Normative Publication of Reaffirmation of HL7 EHR-System Pharmacist/Pharmacy Provider Functional Profile, Release 1 – US Realm

STU Publication of HL7 FHIR® Implementation Guide: Health Record Exchange (HREx) Framework, Release 1- US Realm

STU Publication of HL7 FHIR® Implementation Guide: Clinical Data Exchange (CDex), Release 1- US Realm

STU Errata Publication of HL7 FHIR® Profile: Quality, Release 1 – US Realm STU 4.1.1

STU Update Publication for HL7 FHIR® Implementation Guide: Payer Data Exchange (PDex) Payer Network, Release 1 – US Realm

Informative Publication of HL7 Cross-Paradigm Specification: Clinical Negation Requirements, Release 1

STU Publication of HL7 FHIR® Implementation Guide: Quality Measures, Release 1 STU 3 – US Realm

STU Publication of CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes; Advance Directives Templates, Release 1 STU 2 – US Realm

Informative Publication of HL7 EHRS-FM Release 2.1 – Pediatric Care Health IT Functional Profile Release 1 – US Realm

STU Publication of HL7 FHIR® IG: SMART Web Messaging Implementation Guide, Release 1

STU Publication of HL7 FHIR® Implementation Guide: Clinical Genomics, STU 2

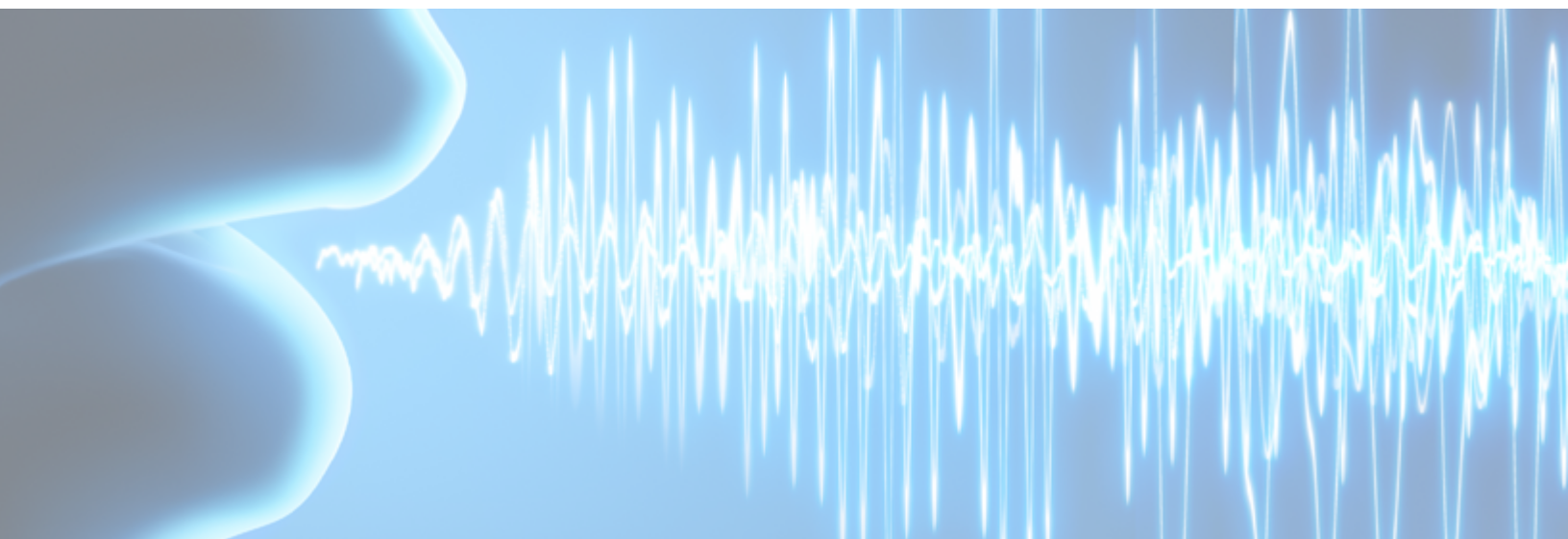
STU Publication of HL7 Domain Analysis Model: Vital Records, Release 5- US Realm

STU Publication of HL7 FHIR® Implementation Guide: Personal Health Device (PHD), Release 1

STU Publication of HL7 CDA® R2 IG: C-CDA Templates for Clinical Notes STU Companion Guide, Release 3 – US Realm

STU Publication of HL7 FHIR® US Core Implementation Guide STU5 Release 5.0.0

STU Update Publication of HL7 CDA® R2 Implementation Guide: National Health Care Surveys (NHCS), Release 1, STU Release 2.1 and STU Release 3.1 – US Realm



Integrating Verbal Production Test Results with HL7 FHIR

Integrating Verbal Production Test Results with HL7 FHIR

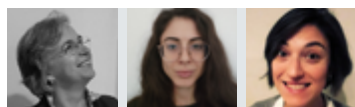
How language disorders are assessed in the clinical setting will be revolutionized in the coming years. The recent advances in Natural Language Processing (NLP) techniques, Voice Analysis (VA), and Automatic Speech Recognition (ASR) software are changing the way we look at language dysfunctions, a common feature in many neurological disorders such as dementia. Language requires the simultaneous activation of multiple cognitive systems, making it a non-invasive, easy-to-collect, rich source of amnesic information. Many language tests and metrics still used today are paper-based, but novel digital mobile-based tools to deliver and analyze speech and language data for clinical and research purposes are now available.

Gatekeeper is a European project (<https://www.gatekeeper-project.eu/>) having as one of its goals to build a trust-based and secure platform to foster large-scale deployment of integrated digital solutions for early detection and intervention in different regions across Europe and worldwide, enabling novel business models.

In the context of this project, the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard has been used to integrate data produced by the SpeakApp application into the Gatekeeper platform. SpeakApp allows the collection of the user's verbal production through a set of standard tests for the purpose of extracting clinically relevant acoustic and semantic features. This is done by processing raw audio and the text content.

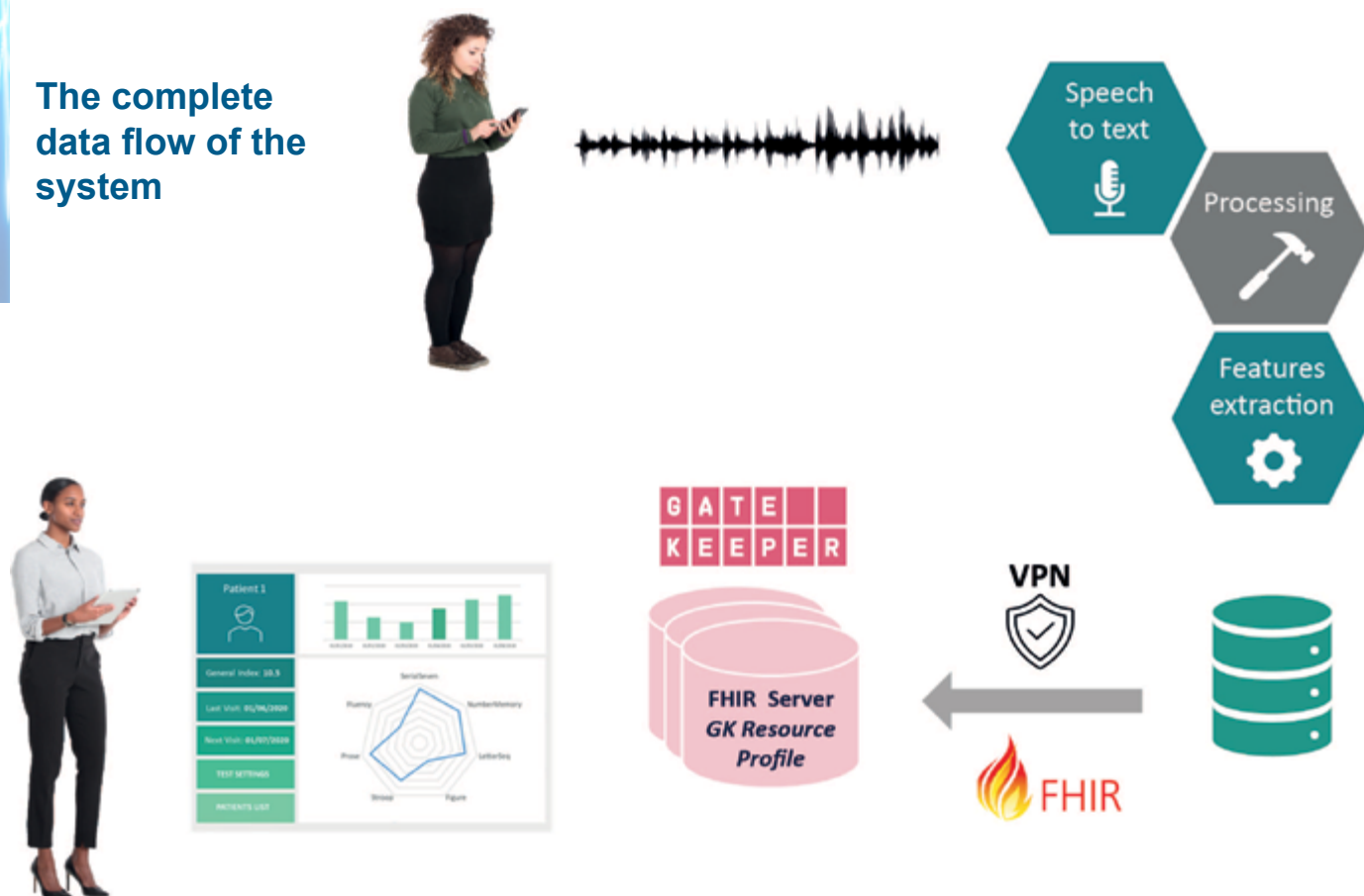
As a first step, a set of FHIR profiles, based on the observation resources, have been specified and published in the on-develop project FHIR IG (<https://build.fhir.org/ig/gatekeeper-project>).

This set includes a profile describing the group of measures associated with the verbal tests available in the app. This profile uses four other observation-based profiles, each describing the different measures extracted from the user's verbal production. The observations comprise variables related to the number and type of words, acoustic variables related to the audio, phonation and silence parameters, and Natural Language Processing and semantic features.



By [Maria Bulgheroni](#), MSc Eng, R&D Director, Ab.Acus srl; [Valentina Simonetti](#), MSc Eng, Ab.Acus srl; and [Chiara Barattieri di San Pietro](#), PhD, Ab.Acus srl

The complete data flow of the system



Transaction bundles have been used to send patient verbal test results, via VPN, to the Gatekeeper FHIR server. Data collected are then made available to any authorized users of the Gatekeeper platform for research and clinical use in a secure, standard, and interoperable way.

Integrating novel indexes based on verbal performance with standardized clinical measures will lead to novel insights into mental health conditions and the identification of light and reliable indexes of cognitive functioning. In the long term, identifying a valid marker of treatment efficacy would support clinical research and innovation, facilitating the evaluation of new drug efficacy, the design of targeted approaches and, in the long run, the mental health of the

population served. The defined FHIR observation profile is designed to foster a shared approach in language disorders' technology-based assessment addressing acoustic and semantic features. The compliance of SpeakApp to the HL7-FHIR standard, facilitating integration in commercial EHRs, is expected to speed up the adoption of these novel techniques in clinical practice, assuring by design the conformity to all the mandatory privacy and security regulations while leaving the focus only on the scientific and clinical meaning of the selected variables.

SpeakApp has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement N° 857223. ■



C-CDA to and from HL7 FHIR

The Road to Semantic Interoperability

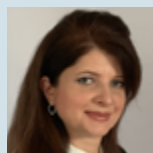
Introduction

Semantic interoperability is a concept that has existed for nearly six decades since computer systems started to exchange data in the “most suitable” format of the time. The current definition of interoperability has evolved and morphed from its earlier concepts of clinical data knowledge, and now includes the ideas of availability, accessibility, ownership, and exchange of information.

The path to attaining semantic interoperability is a difficult endeavor, particularly in the clinical space. Nonetheless, semantic interoperability must be the quest if digital information exchange

is to provide the desired outcomes. In healthcare, where information exchange is expected to produce optimal medical decisions at the point of care, informed patient behavior, better outcomes, and better ways to predict and manage disease progression, semantic interoperability is a must have requirement.

Today, more than ever before, the challenges of semantic interoperability must be addressed for healthcare improvement goals to be met and for the health information technology industry to deliver on the promises made regarding the potential of clinical data.



By Natalee Agassi, MD, PharmD, Cross-Mapping Project: C-CDA to and from US Core Mapping; Clinical Advisor, Cerner

Background

There have been multiple attempts to standardize clinical knowledge expression and to describe patient health artifacts using standardized formats and nomenclature in the US over the course of decades.

More recently, in 2012 as part of the Office of National Coordinator (ONC) for Health Information Technology's 2014 Edition final rule, the HL7 Consolidated Clinical Document Architecture (HL7® C-CDA) was established as a required standard for 2014 Edition EHR Certification Criteria, Meaningful Use Stage 2.

There are several important milestones for interoperability that are worth mentioning:

- The Meaningful Use Stage 1, ONC for Health Information Technology's 2011 Edition with objectives for data capture and sharing has included the National Council for Prescription Drug Programs (NCPDP) SCRIPT for electronic prescribing
- The HL7 Version 2.5.1 Implementation Guide to support bi-directional immunization messaging for electronic data exchange between systems housing healthcare data including population-based repositories, for instance, Immunization Information Systems (IIS) and Electronic Health Record systems (EHRs)
- HL7 Version 2 (V2) included guidance for public health surveillance and reporting of the electronic laboratory data
- The Health Insurance Portability and Accountability Act of 1996 (HIPAA), an electronic version of the Health Care Claim X12 EDI transaction sets, for instance, Eligibility, Coverage or Benefit Inquiry (EDI 270-A1), Eligibility, Coverage or Benefit Information (EDI 271-A1).
- The Consolidated Clinical Document Architecture (HL7® C-CDA) precursor, the HITSP Summary Documents Using HL7 Continuity of Care Document (CCD®) Component used for a consumer's medical status information exchange that includes registration, demographics, insurance information

Nevertheless, HL7 Fast Healthcare Interoperability Resources (FHIR®) is the most recent HL7

standard and defines data elements and application programming interface (API) for exchanging health information on different platforms including web and mobile.¹ HL7 FHIR supports RESTful web services implementation of HL7 with a choice of web technologies including JSON, XML, NDJSON, Turtle, RDF, HTTP, and OAuth. ONC's 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (21st Century Cures Act Final Rule) in June 2020, identified

Patients are leaving trails of medical records in a variety of systems and their data artifacts exponentially are accumulating in different formats due to documentation and reporting requirements.

HL7 FHIR R4 US Core R3.1.1 as a required standard for application programming interfaces (API) certification.

While interoperability has been maturing and evolving in the US and across the globe, electronic health records (EHRs) and healthcare IT (HIT) were transforming from the rigid bookkeeping systems into flexible systems generating patient data artifacts on demand and in several data formats. EHRs also developed infrastructures to support open system capabilities, so that they can receive and consume patient data from external systems. EHRs have integrated the use of data into clinical workflows such as Drug Utilization Review (DUR) checks, reconciliation, merging data for disease tracking, use of data to drive care coordination functionalities, clinical decision support, etc. They are also valuable across a variety of the HITs like population health, research and payers.

One of the facts of modern life in most developed countries is that populations live longer and are more mobile. Patients with complex medical histories in multidisciplinary environments are referred to different specialists, urgent care, and beyond their primary locations. Patients are leaving trails of medical records in a variety of systems and their data artifacts exponentially are accumulating in different formats due to documentation and reporting requirements. For instance, a single discharge document can easily span over 50 pages.

¹ <https://www.healthit.gov/topic/standards-technology/standards/fhir-fact-sheets>

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C-CDA to and from HL7 FHIR

In the non-commercial sector in the US, the Department of Defense (DoD) operates clinics on the military bases, ships, and combat areas around the world and provides care for the active military. In addition, 40% of care is provided in commercial healthcare facilities outside of DoD clinics.

Likewise, the Office of Community Care supports the VA Mission Act that aims to provide better access and greater choice to Veterans in their healthcare at the VA or in the community. The Department of Veteran Affairs provides approximately 35% of Veteran's care for outpatient visits through the community care providers.

Thus, the needs for the C-CDA to FHIR or FHIR to C-CDA documentation exchange is paramount to helping improve interoperability and to provide a more comprehensive medical record for active-duty military and Veterans alike.

As of 2022, there are three major standards used for patient data exchange in the US: HL7 Version 2, HL7 CDA/C-CDA and HL7 FHIR. However, the focus of this paper will be on HL7 CDA/C-CDA and HL7 FHIR documents, and FHIR US Core in particular.

C-CDA

C-CDA enables a document-based communication and has been an export format for Meaningful Use 2 certification for HIT to meet the needs of exchange during transitions of care and referral use cases. It is also used to provide that patient a summary of their encounter

C-CDA documents represent a single moment of time and may include encoded, structured formatted data like medications or problem list entries and unstructured formats for images or pdfs. C-CDA documents do not actively enable workflow but provide information relevant to a workflow.

HL7 FHIR

HL7 FHIR is the most currently developed data exchange format. Its design is supporting workflow management, messages, services, document-based communication, and context-specific queries to foster health care planning and delivery. Many believe that future development and implementations should only be focused on the FHIR-based documents as C-CDA is being gradually replaced by FHIR, particularly to share data sets that need not follow the document paradigm. The Centers for Medicare and Medicaid Services (CMS), in partnership with ONC, has identified HL7 FHIR Release 4.0.1, and HL7 FHIR US Core R3.1.1 in particular, as the foundational standard and implementation guidance to support data access via secure APIs. CMS is adopting the standards for HL7 FHIR-based APIs into their Promoting Interoperability program, referencing use of certified HIT in accordance with ONC's 21st Century Cures Act Final Rule at 45 CFR 170.215 by the end of 2023, which include use of HL7 FHIR US Core to support the API certification criteria.²

The Challenge

The implementation of standards can be challenging. For instance, in 2019 the early version of the "Provenance" in both HL7 FHIR and HL7 CDA C-CDA had been published with the basic components at the entry level, thus resulting in the guidance published in 2020. To reach a more accurate level of data provenance, additions were made to the standards. However, there is not enough clarity about how to resolve the differences within the single format, i.e., between basic and more mature versions of the "Provenance". In the HL7 C-CDA documents generated by EHRs, should the authors more likely be specified in the Problem and Allergy Observations or in the Concern Act, or in both? As of now, these questions remain outstanding. Some EHR systems correlate

² <https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet>



authorship in the Allergy Concern Act and Problem Concern Act, whereas other systems associate the same information in the Allergy Observation and Problem Observation. Mature concepts, such as HL7 C-CDA's Context Conduction with a default value of true are not prescriptive enough. How is Context Conduction used inside of a complex entry that has entry Relationships to nested acts? What is the semantic meaning of the effectiveTime element of the Allergy-Intolerance Observation? Can consensus be achieved on classification of the Condition.category?³ Using HL7 FHIR, for example, some systems have military status as an HL7 FHIR extension to patient and others have it as an observation. Creating a C-CDA is not an easy task as it has dependencies on the sections and entries in the header and it is even harder to create a document from the transform without the composition HL7 FHIR Resource.

The Solution? Can FHIR Alone Resolve Our Interoperability Challenges?

Even though clinical data generated from EHRs is abundantly available in different formats across care settings, not all clinical concepts can be represented in its entirety in HL7 FHIR yet. For instance, 21st Cures Act Final Rule certification and information blocking provisions and the Promoting Interoperability program includes several laboratory requirements. Provenance from the laboratory information systems (LIS) to the first downstream system, typically using HL7 V2 messages, is covered by laboratory accreditation/ Clinical Laboratory Improvement Amendments (CLIA) (i.e., error corrections, amendments) and will need to be represented in the receiving system. To date, there are no LISs with HL7 FHIR support. LIS sends data to the EHR that in turn makes some of the data received through HL7 V2 messages available through HL7 FHIR and HL7 C-CDA.

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C-CDA to and from HL7 FHIR

Why Unlocking C-CDA Is Important

HL7 C-CDA has been a critical mechanism to exchange patient information in a document format across the continuum of care. The significant amount of valuable metadata information locked in HL7 C-CDAs needs to be transformed into the HL7 FHIR format for further consumption. HL7 C-CDA documents are often large and do not present content in a concise, pertinent, and usable form, particularly the Continuity of Care Document (CCD) document type.

1. How will providers review all C-CDA documents to find an immunization administration recorded several years ago or a clinical event?
2. Would it be helpful to know whether a patient under a provider's care has an inactive disease or is in remission from Systemic Lupus Erythematosus (SLE), Acute Lymphoblastic Leukemia (ALL) or Crohn's disease?
3. Prior to determining the next treatment modality, would it be helpful to know whether a patient has the history of recurrent infection disease such as urinary tract infections or otitis media? Additionally, the detailed historical information about frequency, severity, duration, and complications of the infections as well as corresponding antimicrobial treatment can help to demystify the underlining factors of the recurrent infections such as immunodeficiency.
4. When evaluating direct risk of the adverse outcomes for an adult patient with chronic comorbidities, would it be helpful to know whether this patient with a cluster of chronic comorbidities has a history of substance use, or a behavioral condition?
5. How many patients will review all the data in large document sections without becoming overwhelmed?

The Department of Veterans Affairs is interested in all clinical metadata when determining level of coverage, disability rating, benefits, and lifelong healthcare plans they must refer to the documentation. Availability of the full clinical picture reduces delays in care, facilitates decision making, and supports better care for veterans.

This applies to patient access as well, which has also been addressed in particular between the ONC certification rules starting with the 2014 Certification Edition that addressed availability of patient focused view, download, and transmit data using certified EHRs in a timely fashion and CMS' rule CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports in February 2014 that require laboratories to share results directly with patients without clinical review (with exceptions where such sharing can result in patient harm).⁴

C-CDA on FHIR is a Promising Future

C-CDA and FHIR documents frameworks will need to co-exist and may require supporting both complex frameworks for some time. The support of frameworks is expensive, inefficient, and requires overarching collaboration as they have different infrastructures, technologies, and skillsets; however, it is a necessary sacrifice since the transitioning will not happen overnight. It will be very old documents, generated C-CDAs (i.e., discharge summaries referrals) which will continue to be exchanged as they are still part of the record. Therefore, systems should not lose the ability to consume them. Nevertheless, a consuming system requirement is an important consideration for any system that generates data artifacts. On the Clinical Document Architecture (CDA) side, there is a document, an electronic initial case report (eICR) that EHRs are interested to promote to a FHIR-based document format. One of the supporting reasons is related to EHRs that selected the eCR Now FHIR App. This app is an implementation of choice for a public health reporting that can enable EHR companies

⁴ <https://www.govinfo.gov/content/pkg/FR-2014-02-06/pdf/2014-02280.pdf>

that do not have electronic case reporting (eCR) capabilities to support public health reporting for COVID-19. The eCR Now FHIR App uses FHIR-based APIs to retrieve the data necessary for eICR, and then formats collected data into a CDA document. If FHIR document format is considered, the data would be organized data according eICR and kept in the original format. The FHIR document format would reduce the risk of potential data loss and diminish risk of the incorrect transformation.

However, in the United States, the Centers for Disease Control's (CDC's) use of the eICR varies by state. For example, some states can consume Clinical Document Architecture (CDA), and others can consume FHIR. Being able to transform from one format to another will support state-to-state interoperability needs.

The side of the applications where the transformation occurs will need prescriptive guidance for the generation of the specific data formats. For instance, the Data Usability Workgroup for the Sequoia Project believes that guidance is needed for small companies that collect information in FHIR and are exchanging documents with healthcare systems to support patient entered artifacts to be collected via FHIR APIs and be available in C-CDA. Also, an application like Health Exchange requires information to be sent in a C-CDA; therefore, companies with exclusive FHIR data will need a new framework to support this. The same applies to Meaningful Use reporting criteria that expects a percentage of C-CDA documents received as referrals for a measured period.

In addition, there are circumstances where systems could ingest both FHIR and C-CDA but have a strong preference for a FHIR-based data access to support the use of vendor agnostic applications. The use of apps is proliferating as systems are utilizing them rather than leveraging legacy modules to enable and update functionalities. Apps also increase the ability to integrate systems

that were not formerly integrated with typical “medical record” systems. For example, social services systems need to interoperate with healthcare systems for the exchange of social determinants of health data. As healthcare becomes more integrated, the need for interoperability will increase as we move from messages to B2B exchange using writes, pub/sub, queries with or without apps in the middle.

Apps also drive the demand for FHIR APIs. As newer systems integrate with legacy systems that use C-CDA documents as their data exchange method, there is a growing need to support FHIR/C-CDA transformations to ensure care coordination. Moreover, CMS specified that payers maintaining clinical data are required to expose this data through the Patient Access API. Even though the regulation does not specify the C-CDA to FHIR transformation, payers consume data in C-CDAs and to make data available via a Patient Access API, it may require C-CDA to FHIR transformation.⁵

Efforts to Address Today's Semantic Interoperability Gaps

Clinical data generated from EHRs is abundantly available and many companies are attempting to normalize and transform it. However, there is no prescriptive guidance in how data should be transformed consistently, based on standards, remain relevant, clinically meaningful, and to be shared in real time.

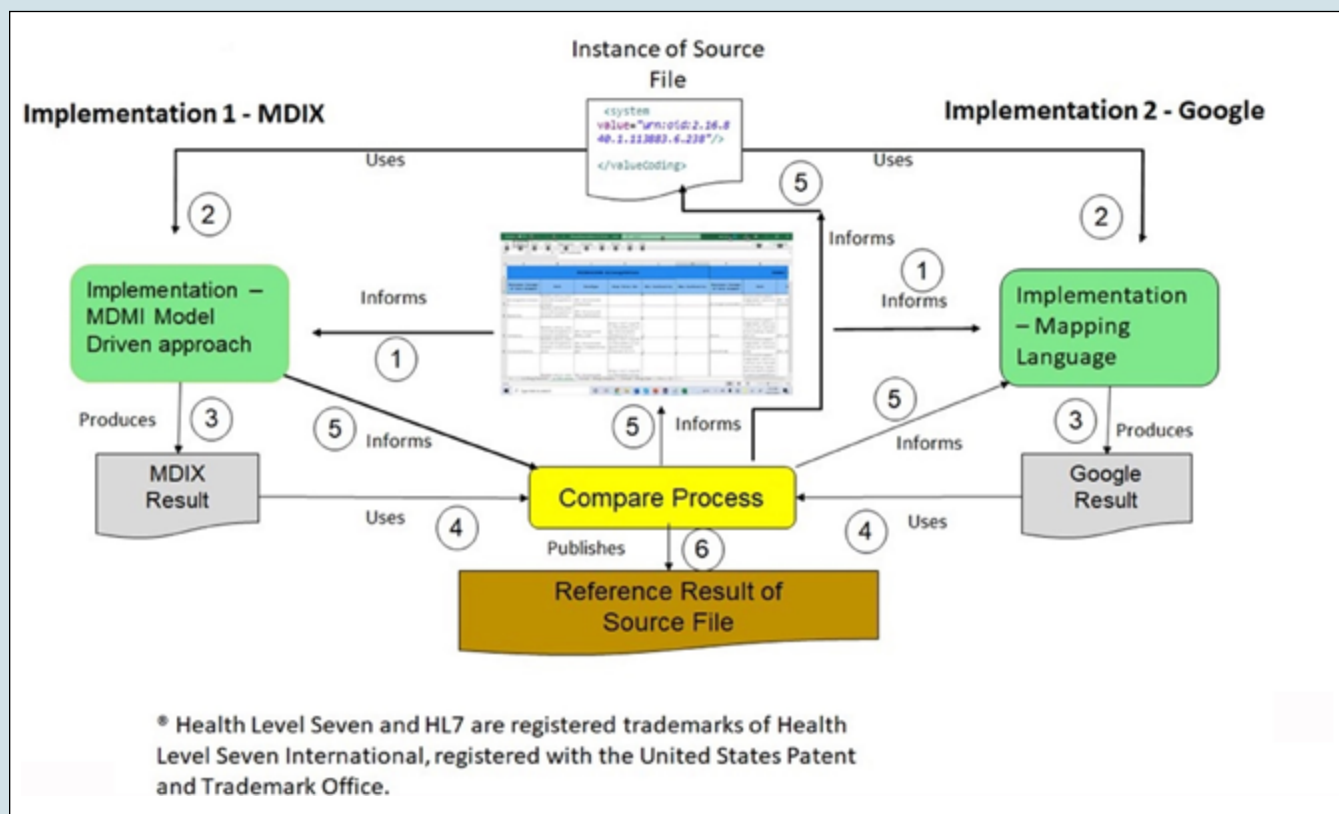
The challenge remains in target system consumption requirements, loss of fidelity, usability, and interpretation of the data. Patient data is fragmented and resides in different formats, so it is important to consistently interpret it. Lack of prescriptive guidance leaves standards open to a wide variability of data interpretation.



5 <https://www.federalregister.gov/documents/2020/05/01/2020-05050/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

Continued from page 34

C-CDA to and from HL7 FHIR



A new attempt is to address interoperability via increasing confidence of the transformed data and unlocking the critical patient data that resides in a variety of clouds and systems. C-CDA to and from FHIR US Core mapping was charted to identify and close structural and vocabulary alignment gaps with the HL7 V2-FHIR R4 mapping approach (and vice versa). It also aims to enable access to cross-paradigm maps consistently from/to HL7 V2, HL7 C-CDA, and HL7 FHIR contexts. In the core C-CDA to and from FHIR US Core, mapping establishes definitive HL7 guidance for C-CDA to FHIR and FHIR to C-CDA mapping. The project scope includes the document types in C-CDA R2.1 and C-CDA Companion Guide R2 referenced or implied in the 2015 Certification Edition Cures Update. This also includes USCDI v1 Clinical Notes data class: CCD, Discharge Summary, Referral Note, Consultation Note, Procedure Note, History & Physical, and Progress Note document

types to enable interoperability, and health information exchange.⁶ The 2015 Certification Edition Cures Update optionally supports certification for the exchange of the C-CDA Care Plan document as a means for supporting care planning and care coordination.

Global health IT leaders Cerner, VA, MaxMD, MDIX, Diameter Health, More Informatics, Allscripts, EMI Advisors, Google along with Sequoia, HL7 Structured Documents and HL7 FHIR leaders are actively engaged and contributing to a variety of efforts such as starting from the map creation and elaboration, capitalizing on existing knowledge, challenging standard guidelines, and reducing ambiguities.

The team has been driven by these questions:

- Can FHIR to C-CDA data be transformed with confidence from one standard to the other?
- What level of confidence has been achieved?
- Should there be a confidence scoring system?

6 <https://confluence.hl7.org/display/CGP/C-CDA+to+and+from+US+Core+Mapping>

Improving data integrity and trust is core to the new methodology, with three components: analysis of structural format and vocabulary, implementation of mapping and transformation, and post implementation review. At onset of the analysis, the domain area, business concepts and definitions are formalized and defined. This step is followed by structural mapping correlations, an explicit set of rules, and documentation of transformation details. For example, to provide guidance on which section and how information from FHIR-based APIs shall be represented consistently in an HL7 C-CDA document, or to establish constraints on the FHIR resources, or other profiles regarding data transformation, ontological mappings, and mismatches in cardinality are required, as well as optionality. The next step is characterized by correlation and evaluation of HL7 C-CDA and HL7 FHIR value set alignment gaps. For example, the clinical concept (i.e., medication) for clinical data exchange from one system to another includes references to standard value sets, such as LOINC, RxNorm, CPT, or SNOMED-CT. This allows the receiving system to map the clinical data concepts to the local representation of that element, which allows the data to be accurately interpreted by the receiving system. Coded data can be incorporated into clinical decision support and automate the reconciliation process workflow. However, all must agree to use the same standard for these resources to fully realize interoperability.

The next step in the analysis is taking inventory of gaps and exposing these gaps to a larger HL7 community for the resolution path and integrating feedback into the guidance. Implementation of mapping and transformation is incorporated into the process used for producing a reference result.

MDIX and Google are consuming structural and value set maps, and then processing samples via transformation engines, resulting in model and formatted output, or just formatted output. The results of the transformation are reviewed by subject matter experts (SMEs) and discussed with implementers. The last step of this process is focused on testing data integrity after transformation, publishing examples, and applying a confidence scoring valuation to measure outcomes.

Conclusion

This effort aims to accelerate the enabling of seamless interoperability and supports better care for every patient. It is an important collaboration that requires major refinements of two standards. We need to get the word out to every organization who is mapping between HL7 C-CDA templates and the HL7 FHIR US Core profiles (or basic HL7 FHIR standard when no US Core profile exists yet), that we are all better off if the industry has one definitive set of mappings if we are to achieve true semantic interoperability. This will enable all organizations to produce the same mapping results. Organizations will do more to advance interoperability by contributing their mapping energy to this collective effort rather than mapping in isolation. Please help get the word out to others that you interact with to spread the word about the effort underway and the opportunity to get engaged in this important interoperability solution. ■

Thank you to all the C-CDA to FHIR and back project members, and in particular, Emma Jones, Catherine Hoang, Lisa Nelson, Ken Lord, John D'Amore, William Ormerod and Hans Buitendijk for contributing to this paper, and Jay Lyle, Sam Pennel, Steve Hill, Marie Swall, Meghan Singleton, Natasha Kreisle, Didi Davis, Gay Dolin, Diego Kaminker for contributing to the mapping transformation content.

Join the Team! Mondays at 10:00-11:00 am ET, every week

Join Zoom Meeting: <https://hl7-org.zoom.us/j/98991373877?pwd=cHZoV2syNkhZaHY0OEsvdTBKUDN1QT09>

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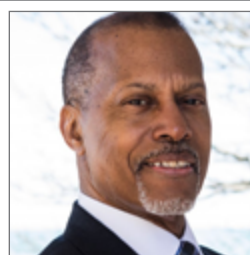
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