HL7® International

THE OFFICIAL PUBLICATION
OF HEALTH LEVEL SEVEN® INTERNATIONAL

SUMMER 2023

NEWS

It's here!
FHIR® R5 Published

PLUS:

DaVinci to Update Implementation Guides

Using FHIR to Streamline Value-Based Performance Reporting

ART-DECOR® Release 3

In This Issue

HL7 News

is the official publication of

Health Level Seven International

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Back to LIVE events!

Update from Headquarters

After producing several events virtually, we're thrilled to get our HL7 family back together for in-person FHIR connectathons and working group meetings (WGM).

January Working Group Meeting

The January WGM was held at the Hilton Lake Las Vegas Resort in Henderson, Nevada. The events attracted 327 participants to the FHIR connectathon and a total 503 attendees to the WGM and/or connectathon. A thousand kudos are extended to our work group co-chairs for continuing to manage the HL7 workload with our army of dedicated volunteers. We are also grateful to Redox and AEGIS for their sponsorship of the January WGM.

By Mark McDougall,
HL7 International Executive Director

HIMSS 2023

HL7 has exhibited at the HIMSS convention for more than 30 years. This year's HIMSS convention convened in Chicago the week of April 17th. The HL7 booth featured 28 presentations including several standing-room only panel presentations. Kudos to HL7's Director of Communications, Andrea Ribick, and Pat Guerra, Director of Marketing, for their leadership in planning and producing our HL7 booth at HIMSS again. We would also like to thank the volunteers who helped staff our booth to field questions from the HIMSS attendees.

Continued from page 2

May Working Group Meeting Plus

The May WGM+ was produced at the Hilton New Orleans Riverside Hotel. The events attracted 347 participants to the FHIR connectathon and 621 attendees to the WGM and/or connectathon. WGMs typically have over 30 work groups convening meetings to refine the HL7 specifications and tracks on tutorials.

As part of the rollout of HL7's Implementation Division, the organization offered Plus content, which was comprised of over 40 sessions targeted to standards implementers, on policy, workforce development, implementation guides, open-source tools, reference implementations, accelerator updates, demo sessions, hot topics in the FHIR community, and many more. For example, some of the WGM+ sessions included keynote presentations from:

- **Micky Tripathi**, PhD, MPP, ONC National Coordinator for Health Information Technology
- **Michelle Schreiber**, MD, Deputy Director of Center for Clinical Standards & Quality
- **Steven Posnack**, Deputy National Coordinator for Health Information Technology, ONC
- **Teresa Zayas Caban**, PhD, Assistant Director for Policy Development, National Library of Medicine
- **Jennifer Layden**, MD, PhD, Acting Director for the Office of Public Health Data, Surveillance and Technology, CDC
- **Ken Gersing**, MD, Director of Informatics, National Institutes of Health
- **Jose Galvez**, MD, Deputy Director Office of Strategic Programs, FDA
- **Scott Gordon**, PhD, Senior Health Informatics Officer, Food and Drug Administration
- **Garrett Mehl**, PhD, Head, Digital Health Technology Unit, Department of Digital Health and Innovations, WHO
- **Carl Leitner**, PhD, Technical Officer, Digital Health & Innovation, WHO
- **Marcelo D'Agostino**, Unit Chief, Information Systems and Digital Health, PAHO
- **Ernesto Lembcke**, Advisor, Global Health on Data and Digital Health, GIZ
- **Phillipe Veltsos**, Digital Health Technical Director, PATH
- **Jose Costa Teixeira**, Global Standards and Interoperability Expert, FHIR Lead, Digital Square

We are happy to report that we received very positive feedback on the new WGM+ content from our meeting attendees. We are also grateful to FEvIR Platform Computable Publishing and Point-of-Care Partners for their sponsorship of the May WGM+.

Mark Your Calendars

We hope to see you at our upcoming events that are listed below:

- 37th Annual Plenary, Working Group Meeting and FHIR Connectathon will convene at the Sheraton Phoenix Downtown Hotel
- FHIR Connectathon will occur September 9-10, 2023
- Plenary & WGM will convene September 11-15, 2023
- January 2024 events will be produced virtually:
  - FHIR connectathon will occur virtually January 27-28, 2024
  - January 2024 WGM will convene virtually January 29-February 2, 2024
- May 2024 events will occur at the Renaissance Dallas Hotel in Dallas, Texas:
- FHIR connectathon will occur May 18-19, 2024
- May 2024 WGM will occur May 20-24, 2024

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 2023 benefactors and gold members who are listed on page 25. 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 27-29, 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.

HL7 data standards and guides will be integrated with AMA CPT codes and descriptors

New Collaboration Opens CPT Content for Developers

Under a new collaboration between Health Level Seven® International (HL7®) and the American Medical Association (AMA), technology developers using HL7 data interoperability standards and guides will have increased accessibility to AMA-published medical codes and descriptors. The collaboration will work to fully integrate HL7 Fast Healthcare Interoperability Resources (FHIR®) with the AMA's Current Procedure Terminology (CPT®) code set to advance the organizations' mutual goal of promoting the efficient exchange of interoperable health information.

"Collaboration with the AMA will provide invaluable opportunities for the communities of developers to seamlessly incorporate this critical terminology within the HL7 development and implementation processes," said HL7 CEO Charles Jaffe, M.D., Ph.D.

"As the health system's foundational terminology for coding and describing medical services, CPT is the uniform code set trusted to efficiently exchange data that identifies specific treatments and procedures provided to patients," said AMA CEO James Madara, M.D. "By working toward greater CPT accessibility for developers, the collaboration between AMA and HL7 allows the use of CPT in the development and testing of FHIR-based technology to further advance the next generation of health information solutions. We also look forward to working more closely with HL7 on educational opportunities and collaborating on industry conferences and events."

The agreement builds on more than a decade of cooperation between AMA and HL7 in support of standardization that drives health data interoperability and opens new opportunities for developers and promotes innovation in FHIR-based technology that use CPT for measurement, analysis, and benchmarking of medical services. ■

HL7 Benefactor Members

HL7 Standards Published Since January 2023

STU Publication of NHSN Healthcare Associated Infection (HAI) Reports Long Term Care Facilities (HAI-LTCF-FHIR), Release 1 – US Realm
STU Update Publication of HL7 FHIR® Implementation Guide: Subscription R5 Backport, Release 1, STU 1.1
STU Update Publication of Minimal Common Oncology Data Elements (mCODE) Implementation Guide 2.1.0 – STU 2.1
STU Publication of HL7 FHIR® Implementation Guide: Clinical Data Exchange (CDex), Release 1 STU 2 – US Realm
STU Publication of HL7 FHIR® R4 Implementation Guide: At-Home In-Vitro Test Report, Release 1 – US Realm
STU Update Publication of HL7 FHIR® Implementation Guide: Vital Records Death Reporting (VRDR), Release 1 STU2.1 – US Realm
STU Publication of HL7 FHIR® Implementation Guide: Longitudinal Maternal & Infant Health Information for Research, Release 1 – US Realm
STU Publication of HL7 FHIR® Implementation Guide: International Patient Access (IPA), Release 1
STU Publication of HL7 FHIR® Implementation Guide: Patient Cost Transparency, Release 1 – US Realm
Normative Publication of HL7 CDA® R2 Implementation Guide: Emergency Medical Services; Patient Care Report Release 3 – US Realm
STU Publication of HL7 Consumer Mobile Health Application Functional Framework (cMHAFF), Release 1
STU Publication of HL7 FHIR® Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1
STU Publication of HL7 FHIR® IG: SMART Application Launch Framework, Release 2.1
STU Publication of HL7 Version 2 Implementation Guide: Diagnostic Audiology Reporting, Release 1- US Realm
STU Publication of HL7 FHIR® R4 Implementation Guide: Clinical Study Schedule of Activities, Edition 1
STU Update Publication of HL7 FHIR® Implementation Guide: NHSN Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (HAI-LTCF-FHIR), Release 1 STU 1.1 – US Realm
STU Publication of HL7 CDA® R2 Implementation Guide: Personal Advance Care Plan (PACP) Document, Edition 1, STU3 – US Realm
STU Publication of HL7 CDA® R2 Implementation Guide: Pharmacy Templates, Edition 1 STU Release 2
STU Publication of HL7 FHIR® R4 Implementation Guide: Single Institutional Review Board Project (sIRB), Edition 1- US Realm
STU Publication of HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes STU Companion Guide Release 4 – US Realm Standard for Trial Use May 2023
STU Publication of HL7 FHIR® US Core Implementation Guide STU6 Release 6.0.0
STU Publication of HL7/NCPDP FHIR® Implementation Guide: Specialty Medication Enrollment, Release 1 STU 2 – US Realm

HL7 International

Newly Certified HL7 Specialists

Congratulations to the following people who recently passed an HL7 Certification Exam!

HL7 FHIR R4 Proficient Certified

FEBRUARY 2023

Naveen Jakkamputi
Iker López Rodríguez
Thomas Kakanowski
Mohamed Saadawy Abdelwahab Mohamed
Ruben Larenas
Frederic Laurent
Michael Campbell
Elijah Nicholas Bagos

MARCH 2023

Radhika Verma
Verónica Cascante
Himabindu Kondoju
Sheljina Ibrahim Kutty
Alan Vitale

APRIL 2023

Juan Pedro Díaz García
Udyam Parulekar
Ghislain Bellemare
Ramsey Bitar
John Williams
Dhairya Kothari
Vishnu Vardhan Reddy Cirra
Robert Brown
Michaela Ziegler
Oliver Ulrich Egger
Glen Vasa
Joseph Lyle

MAY 2023

Roger Moulton
Omar Guendouz
Seuad Kassa
Oswaldo Crespo Perez
Christopher Pound
Andrew Morican
Larry Bearking

Certified HL7 Version 2.x Chapter 2 Control Specialist

FEBRUARY 2023

Jose Fernando Luengo
Natalia García Marey
Verónica González Iglesias
Subhash Shahu
Sharmeenbanu Shaikh

MARCH 2023

Abhishek Dey
Evgeny Landau
Josh Bagley
Juan Carlos De Diego Lominchar
Philip Slover
Beatriz Llaneza Rodriguez
David Valles
Jayashree V

APRIL 2023

Jennifer Starling
Carmen Cachón Vigil
Gregory Watkins
Nerea Echevarria
Eider Arbilla
Enric Rodríguez Galán
Alfonso Conde Osete
Mandar Wairkar
Apurva Jain

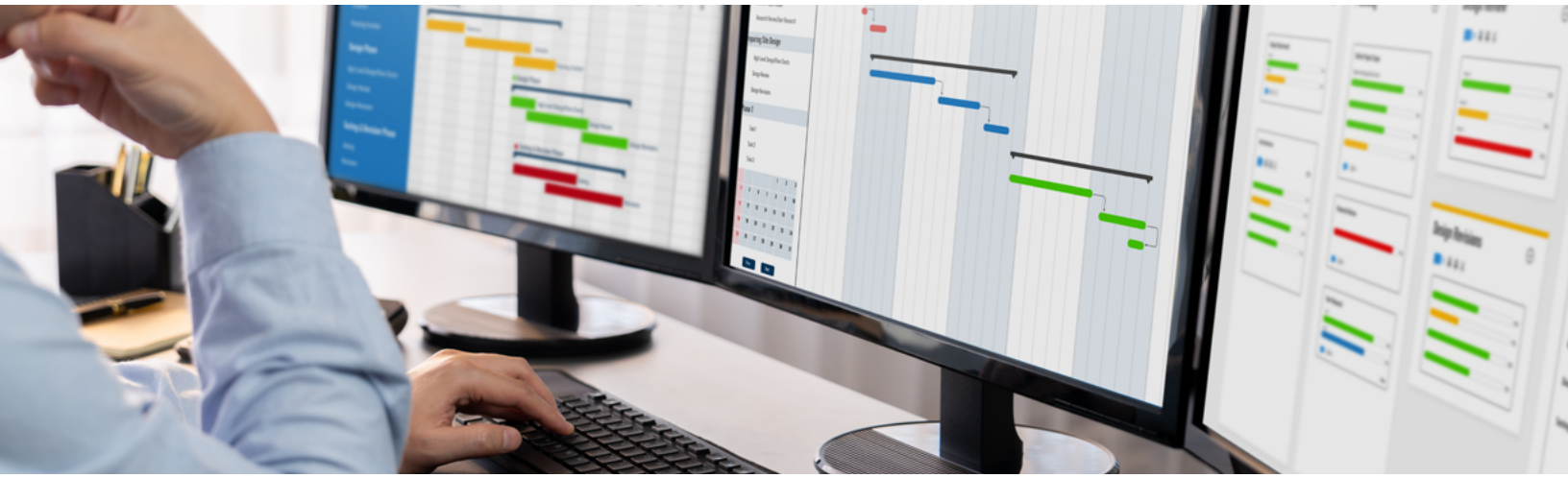
MAY 2023

Yan Meng
Jose Francisco Masero Guzmán
Lucia Mendez
Mohammed Tariq Qureshi
Devashri Mankar

Certified HL7 CDA R2.0 Specialist

APRIL 2023

Jennifer Starling



HL7 Internal Projects and ONC Grant-Funded Projects

News from the HL7 Project Management Office

Fonteva: The New Meetings and Membership Software System

We thank everyone for their patience as staff and users learned to navigate the new association management and membership system implemented last November. Staff meets regularly to review report issues, bugs and establish continuous improvement.

If you encounter any issues or have questions, feel free to email *HelpDesk@HL7.org*.

ONC Grant Funded Projects

The ONC extended the current cooperative agreement for continued maturation of the Consolidated Clinical Document Architecture (C-CDA) and Fast Healthcare Interoperability Resources (FHIR®) standards, and with that, awarded HL7 an additional $1.36 million for fiscal year 2024. Specific projects funded under the extension had not been identified at the time of writing this article.

The fiscal year 2023 cooperative agreement provided HL7 $1.36M to work on the following projects, many of which are still underway:

- Continued support for the Gender Harmony project
- Reconcile and publish the At-Home Test Result Report FHIR Implementation Guide
- Continued work on the HL7 FHIR Build and Implementation Guide Publishing tasks
- Additional C-CDA Implementation-A-Thons
- Continued support for International Patient Summary
- Provide specific enhancements to Trifolia on FHIR to support FHIR IG Publisher C-CDA Web Publications tooling
- Continued support of the FHIR Registry
- Continued support of Unified Terminology Governance (UTG)
- Updating the C-CDA Value Sets for 2023

In addition to the above, work progressed on two additional COVID related ONC grant-funded opportunities for HL7:

A 4-year $2M (FY2021-2024) cooperative agreement titled “HL7 Public Health Standards and Solutions for Future Pandemics”. Projects under this endeavor include the following:

- 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
- Update, ballot and publish the PDMP HL7 FHIR Implementation Guide
- Update, Ballot and Publish the eLTSS Implementation Guide

- Plan, prepare, facilitate and provide a 2-day virtual FHIR Security Event
- Provide HL7 FHIR Technical support to the Helios FHIR Accelerator
- Testing of the Gravity SDOH Clinical Care GHIR Implementation Guide (Complete)
- Gravity SDOH Clinical Care FHIR Implementation Guide Standard for Trial Use 2 Publication (Complete)
- Gravity Pilots Affinity Group Support (Complete)
- Analyze and document which HL7 v2 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 (Complete)
- Support development, advancement, and harmonization of Social Determinants of Health (SDOH) standards by analyzing the current state and emerging activities of SDOH related data (Complete)
- Expanding the clinical domains supported by HL7 standards by balloting the COVID-19 FHIR Profile Library implementation guide (Complete)
- Improve the privacy and security of health information by examining the current landscape of relevant security, privacy, and public health standards (Complete)
- Advance HL7 Public Health Standards by developing and publishing a Physician Orders for Life-Sustaining Treatment (POLST) CDA implementation guide (Complete)

The 5-year (FY 2021-2025) $3.5M contract "COVID-19 support for Accelerating Standards Development for the US Realm"; projects under this effort include the following:

- Ballot, reconcile and publish updates to HL7's US Core Implementation Guide
- Financial support for the US Realm Steering Committee (USRSC) Project Manager, Senior Advisor, Content Administrator and Dashboard Developer
- Fund Helios, the HL7 FHIR Accelerator for Public Health
- Update, re-ballot and publish C-CDA, including the C-CDA Companion Guide Guidance and templates using structure Definition tooling and publishing

The objectives of this federal contract are:

- Assist the ONC in gathering, organizing, monitoring, and managing work products associated with HL7 standards development and implementation activities for the US Realm
- Assist the ONC in developing, maintaining, and enforcing governance of US Realm standards and implementation specifications
- Assist the ONC in engaging the US standards development community to increase awareness of US Realm guidelines and identify strategic priorities for US Realm standards development and implementation activities
- Lead the development of new versions of the US Core Implementation Guide and C-CDA standard (including the C-CDA Companion Guide)
- Implement relevant aspects of the governance plan and strategic roadmap to manage and oversee standards development and implementation activities in the US Realm

Progress for all 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 since 2016. ■

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.

Project Use Case Goal Implements Standards So That We're All Speaking the Same Language

An Update on Using FHIR to Streamline Value-Based Performance Reporting

Applying HL7's Fast Healthcare Interoperability Resources (FHIR®) standard to value-based performance reporting (VBPR) cumbersome reporting process that's essential to successfully implementing quality and risk contracts.

HL7's effort to develop a FHIR implementation guide for VBPR is progressing, with a goal of balloting a standard for trial use, or STU, by fall.

Standardizing how data is exchanged, as well as how data elements are defined, would improve efficiency in two ways, says Semira Singh, Director of Informatics, Population Health, at the Providence health system, which is involved in the VBPR use case project.

In addition to eliminating many of the time-consuming, manual tasks now involved in exchanging and normalizing data, which could lower costs, a standardized approach would enable healthcare providers to make better—and timelier—decisions about treatment of populations because data could be more easily monitored over the course of a contract, Singh explains.

"Data normalization to come up with data elements that are meaningful to us now is very challenging," she points out. For example, Providence, which has more than 150 value-based contracts, employs analysts that perform additional calculations on data from payers "to make data usable on our end. If we don't do that, we can't ingest it" because each payer uses different data definitions, Singh says.

If an organization frequently received standard data from payers that did not require normalization, it could, for example, analyze in April how it's performing on quality indicators under an annual contract, Singh says. "Then you'd have nine months to address the issues. If you don't have that data, then you're kind of in the dark."

The Da Vinci Project's Value-based Performance Reporting Use Case conducted preliminary tests at the HL7 Connectathon, May 6-7 in New Orleans. Balloting on specifications, a critical review step toward publishing the STU, will begin in September, says Teresa Younkin, Project Co-Lead and Senior Consultant at Point-of-Care Partners.

A FHIR implementation guide for VBPR will enable providers and payers to use a uniform reporting

By Howard Anderson, HL7 Da Vinci Project Writer

process, easing the exchange of information and standardizing data definitions used to monitor population-based performance, Younkin explains.

"Value-based care is increasingly becoming the way we pay for healthcare across the industry," she says. "So having standardization of the elements that are used to pull together a report means that at least you know when you get a measurement from one payer, it will have the same meaning as for other payers."

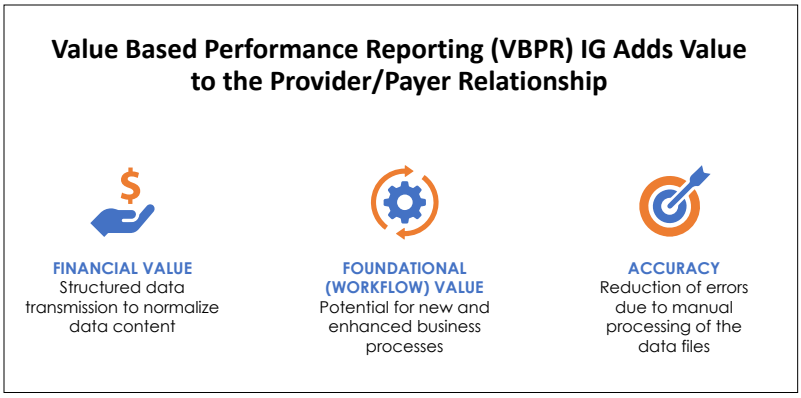
Value-Based Contracts

Unlike fee-for-service medicine, a value-based contract ties payment for healthcare goods and services to predetermined terms that are based on clinical circumstances, patient outcomes, financial benchmarks and other specified measures of the appropriateness and effectiveness of the services rendered. Payers can use value-based contracts to better align their contracting structures with broader changes in the healthcare system.

"Standardization of payer/provider performance reporting for quality and risk contracts is crucial for health systems and other provider organizations to receive timely interim reports to track and manage their performance on value-based contracts during the term," according to the VBPR project.

"Payer-generated value-based performance reports are crucial because payers are generally in the best position to be the arbiters in determining financial performance on risk contracts with health systems. Unfortunately, there is a lack of standardizations for reporting format, the process is usually resource intensive, not very scalable and data reconciliation process is complex."

That's why Da Vinci's VBPR project is so important, Younkin says. "We are trying to standardize any value-based performance reports so that, for example, providers can check in to see how they are doing against their contracts on both financial and quality measures."



Testing in May

At the Connectathon in May, Younkin says, "we tested profiles to make sure we are able to exchange them. We're in the process of creating a sample report and defining the profiles and resources that would be needed to create the report."

The team working on the VBPR use case meets every Monday from 2 to 3 p.m. ET. In addition to Providence, initial implementers include Humana, Edifecs, Novillus and Optum/United Healthcare.

Other organizations are welcome to join the development effort, which kicked off last October, Younkin stresses. For more information, visit the project's Confluence page: https://confluence.hl7.org/pages/viewpage.action?pageId=94643888

The VBPR team isn't starting from scratch on the standardization effort; it's leveraging other use cases already developed by the Da Vinci Project. Among those are Data Exchange for Quality Measures (DEQM), Risk Adjustment, Member Attribution (ATR), Clinical Data Exchange (CDex), Payer Data Exchange (PDex) and Health Record Exchange (HRex). "We can reuse profiles that have already been developed," Younkin says.

The goal of the VBPR project, Singh says, is to implement standards "so that we're all speaking the same language." Otherwise, she says, it will prove difficult for value-based contracts to achieve their number one goal: improving the health of patient populations while controlling costs. ■

New Federal Rules Spur Update

Da Vinci to Update Implementation Guides

The wait is over for the proposed rules that will greatly impact how HL7 Fast Healthcare Interoperability Resources (FHIR®) is advanced and the Da Vinci Project's part in it. Momentum within the Project has shifted from one of waiting and commenting, to preparing to help the regulation move forward.

Last December, the Centers for Medicaid & Medicare Services (CMS) issued two notices of proposed rule-making (NPRM), both of which Da Vinci commented on. Da Vinci *officially commented*[1] March 13 on one the rules, the *Advancing Interoperability and Improving Prior Authorization Processes, or "Interop 3."*[2] The group submitted comments March 20 on the other rule, the *Attachments NPRM*[3], a set of HIPAA attachment standards and related definitions for electronic exchange of clinical administrative data to support both prior authorizations and claims adjudication.

Da Vinci plans to update its implementation guides to provide the tools needed to meet the functional requirements as they are finalized in rulemaking.

Da Vinci is no longer simply advocating for an idea or concept—progress is taking hold, says Kirk Anderson, Chair of the HL7 Da Vinci Project Steering Committee and Vice President and Chief Technology Officer at Cambia Health Solutions. Da Vinci has been "leaning into the vision of healthcare interoperability," but with the release of these two NPRMs, is now "truly moving into the full on implementation phase."

"We've been in limbo, waiting for this rule to drop," says Jocelyn Keegan, Program Manager for Da Vinci, and payer practice lead at POCP. "And everyone's been getting their ducks in a row. But now that it's dropped, I think that there's a palpable change."

In terms of trends, Keegan noted, "We are seeing a pattern across ONC and CMS that continues to move us towards FHIR. And we see momentum with go-lives and success stories coming out of the Da Vinci community—of people that are successfully implementing these APIs and removing burden for both the provider and the payer side of the equation."

"If you're not doing this work, you're putting yourself at a competitive disadvantage," Keegan says. "The people that figure out how to lean in and leverage this focus on standards are going to be positioned to be ahead of their competition because they're going to have the flexibility that's needed for whatever's coming next," she says. ■

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1 https://confluence.hl7.org/display/DVP/Da+Vinci?preview=/21857465/161057239/Da%20Vinci_CMS-0057-P%20Response_Final_Proof_CLEAN.docx

2 https://www.federalregister.gov/documents/2022/12/13/2022-26479/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability

3 https://www.federalregister.gov/documents/2022/12/21/2022-27437/administrative-simplification-adoption-of-standards-for-health-care-attachments-transactions-and

By Diana Manos, Writer, HL7 Da Vinci Project

Vulcan FHIR® Accelerator Connects CDISC, HL7, and ICH M11 in Project

Digitizing Exchange of Clinical Research Protocols

HL7 Vulcan and CDISC are announcing a project that will deliver an electronic exchange standard for the ICH M11 Clinical electronic Structured Harmonised Protocol (CeSHarP)

A structured, harmonized, digitized protocol accessible to the biopharmaceutical industry and to researchers in the care setting will enable transformations to improve clinical research. The project announced by HL7 Vulcan and CDISC will build on work products of ICH M11 to accelerate this vison.

Vulcan is an HL7® FHIR Accelerator dedicated to connecting clinical and translational research to clinical care through Fast Healthcare Interoperability Resources (FHIR®).

CDISC is a non-profit standards development organization that develops standards that support acquisition, exchange, submission, and archive of biopharmaceutical data. CDISC is also a member of Vulcan. ICH M11 is the topic of the International Council for Harmonization to create a Clinical electronic Structured Harmonised Protocol (CeSHarP).

"The project marks an important milestone in the long journey towards a digital protocol" said Vulcan Co-Chair, Amy Cramer. "Over the years, various organizations have contributed key building blocks. Vulcan is pleased to serve as a convener where contributors across the global research community can collaborate towards this shared and important goal."

"We are looking forward to partnering with ICH M11 and HL7 on this important project that aims to enable the digital transformation of protocols in support of automation," said David Evans, President and CEO, CDISC. "This project represents another step in CDISC's strategic evolution to embrace governance of clinical research information standards, not just clinical data standards."

FHIR-based exchange standard for ICH's Clinical electronic Structured Harmonised Protocol (CeSHarP), aligned to CDISC standards, will enable value across the clinical trials ecosystem. ICH M11 is developing a clinical protocol template, guideline, and technical specification, which will serve as the project's foundation.

CDISC's Unified Study Definition Model (USDM), co-developed with TransCelerate BioPharma, will be leveraged to accelerate development of the content model in addition to other inputs such as CDISC Controlled Terminology and Vulcan FHIR® Implementation Guides,

The project will be executed within the HL7 Vulcan Project Framework and supplemented by a Joint Leadership Forum to foster alignment among CDISC, ICH M11, and HL7 Vulcan. It is now in the discovery and scoping phase with full kick off anticipated this summer. ■

Current focus on three priority areas, focusing on core principles: desirability, feasibility and compatibility

Helios FHIR Accelerator Update

The Helios FHIR Accelerator™ for Public Health is a multi-sector alliance working together to tackle long-standing challenges and explore new opportunities to enhance public health data sharing.

The accelerator aims to align with the widespread standardization and transformation that is happening around digital health data today to promote more flexible and effective data exchange with healthcare, the public and other sectors beyond public health.

Helios continues to explore three priority areas, focusing on our core principles of desirability, feasibility, and compatibility. With a solid foundation of existing HL7 Fast Healthcare Interoperability Resources (FHIR®) specifications and community input, we are now in the testing and piloting phase in several of our priority areas.

Making Data in Public Health Systems Accessible in Bulk

Led by John Stamm (Epic), Leslie Lenert (Medical University of South Carolina) and Mary Beth Kurilo (American Immunization Registry Association), this priority area is exploring ways to enable authorized users of Immunization Information Systems (IIS) data to access complete, accurate, and timely immunization history information on their patient and member populations in bulk.

The January 2023 HL7 FHIR Connectathon featured a track focused on the use of the Bulk Data Access FHIR Implementation Guide (*https://hl7.org/fhir/uv/bulkdata/index.html*) defined Group Level Export operation to access immunization history data held by IIS. We had great participation from eight different organizations, and we met our goal of being able to exchange Patient and Immunization data on up to 100,000 test patients. Everyone walked away feeling positive about the real-world feasibility of applying the bulk data method to public health immunization data. But of course, a lot remains to be done, and one of our next steps will be to gather feedback from partners to define a viable product that will appeal to implementers and pilot sites.

By the Helios Program Management Team

Deliver Aggregate Information to Public Health

Spearheaded by Hans Buitendijk (Oracle Cerner) and Ravi Kafle (Washington Department of Health), this priority area aims to identify standardized and scalable ways of providing high-quality, timely, and on-demand summary data (e.g., bed count, supply inventory, and other sentinel indicator measures) in ways that lessen the strain on both healthcare and public health.

This priority area was also part of the January 2023 HL7 FHIR Connectathon where another eight organizations came together to successfully test the creation and exchange of MeasureReport FHIR resources for key situational awareness indicators. Future efforts will focus on working with public health agencies at all levels and other partners to define an initial catalog of measures for further testing.

Align and Optimize Public Health Data Sharing

Under the leadership of Michelle Barber (Oregon Health Authority), Steve Hill (Oracle Cerner), Gillian Haney (Council of State and Tribal Epidemiologists) and Ryan Howells (Leavitt Partners), this priority area is working to demonstrate how specific FHIR-based paradigms can help meet high-priority public health needs efficiently and effectively, while also returning valuable and actionable information to care providers.

Working with a wide variety of public health experts, our Align and Optimize team has made great progress in identifying a set of public health uses cases for exploration. We are also working with public health, technical and legal subject matter experts to develop a process to evaluate those use cases to better understanding their current and future data sharing needs and identify FHIR-based approaches for improving data interoperability. We are already seeing clear patterns arise across use cases and are identifying reusable approaches to apply to many different scenarios.

How You Can Get Involved

Across all these areas, we are continuing to integrate and work with other public health interoperability and modernization efforts to ensure that a cohesive approach to implementing FHIR is achieved in the public health space.

Helios is currently recruiting organizations to actively participate in current discussions, future testing events and piloting efforts for 2023. There are ways for everyone to get involved!

If you are with a public health program, tell us which aggregate measures (are important to your jurisdiction. What information do you need from healthcare providers about their system health and availability?

Are you a healthcare provider and another user of immunization data? If so, share your functional requirements for acquiring and using immunization data on your patient populations. What immunization related data do you need on the populations of individuals in your care?

Everyone can participate by:

- Bringing your public health interoperability pain points to our Align and Optimize project team to learn what FHIR can do for you. FHIR offers new possibilities for public health and we can help you understand how to address your current interoperability needs.
- Applying your FHIR tools to public health use cases at the upcoming HL7 FHIR Connectathon and other Helios testing events. We need tool developers playing a wide range of roles in public health data exchange to help evaluate FHIR-based approaches and develop technical solutions.
- Joining the discussion on how to identify rosters of individuals for bulk data sharing and other purposes. Patient identification is a critical aspect of sharing data and we need your input on your needs and capabilities.

If you are ready, willing, and able to help drive forward public health interoperability in these areas, please reach out to us at helios@hl7.org to become part of our team! ■

CodeX *Quality Measures for Cancer* Project

New Effort Aims to Streamline the Gathering, Executing, and Sharing of Quality Measures for Cancer Care with 11 Addressing Needs in Oncology, Cardiovascular Health and Genomics

One of the newest CodeX HL7 FHIR Accelerator projects aims to use health data standards to help eliminate the tedious manual processes associated with gathering, executing, and sharing data for measuring the quality of cancer care. Ultimately, this could help researchers improve cancer care, patient outcomes, and quality data reporting to support value-based care programs.

The **Quality Measures for Cancer** project, one of 10 projects in CodeX, seeks to leverage minimal Common Oncology Data Elements (mCODE), a data standard for cancer care that was built using HL7's Fast Healthcare Interoperability Resources (FHIR®) standard.

"Our long-term goal is to have an ecosystem of healthcare organizations exchanging data via FHIR that can be consolidated into a framework for oncology quality measures to gather the data, process it, execute the measurement statistics and visualize results, for actionable data that can be used for improved care," explains Gail Winters, integrations architect at Telligen. "mCODE assists with the development of detailed oncology measures for disease assessment, treatment and outcomes. With the mCODE IG, there is potential to support more detailed oncology measures across Medical Oncology, Surgical, Radiotherapy and Genomics domains that would not otherwise be feasible," adds Winters.

The Quality Measures for Cancer use case will build on other CodeX efforts, including the Radiation Therapy Treatment Data project which has provided a significant expansion to FHIR standards for radiation oncology. "This project illustrates the broader CodeX goal of collecting data once and using it for multiple purposes," notes Randi Kudner, Assistant Director of Quality Improvement at the American Society for Radiation Oncology.

The project expects to create a technical framework for gathering and sharing data for oncology quality measures. This may not necessarily require the creation of a new FHIR Implementation Guide (IG), given the existing quality measures standards work that is already available in FHIR, explains Anthony DiDonato, Senior Healthcare Analyst at The MITRE Corporation. He serves as CodeX's associate director of operations and the use case lead for quality measures. "Instead, researchers may be able to provide a roadmap for leveraging other quality-focused FHIR IGs to support the authoring and execution of oncology quality measures," he explains.

Streamlining the Process

Right now, gathering necessary data needed to measure the quality of cancer care is a time-consuming, manual process. For example, if a particular measure has five clinical components, researchers have to pull these components manually from electronic patient records—and other health information sources—and then import this information into a measurement tool, says Stephanie Jones, Director, Performance Measurement at the American Society of Clinical Oncology.

Even identifying all the appropriate patients in a given population is a significant challenge without the use of standards and automation, with the risk of not having data representative of the entire population, Jones says.

By Howard Anderson, HL7 Da Vinci Project Writer

CodeX™
Common Oncology Data Elements eXtensions

Project Status

The first step for the Quality Measures for Cancer project is to test the feasibility of using FHIR and a supplemental technical architecture to author and execute oncology quality measures. The project initially focused on two medical oncology measures and is now moving into modeling a pair of radiation-focused measures. Later, those involved in the project will work with health systems, software vendors, registries, payers, additional accreditation associations, and other key players in the quality space, to launch further tests.

"There is significant value in demonstrating that quality measure authoring will be easier and more feasible using a FHIR and mCODE-based solution," the use case team notes in a description of the project. The goal is to "provide a path to data collection with reduced burden."

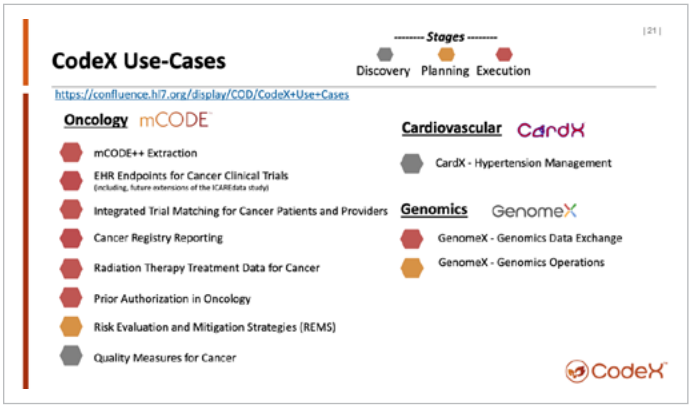
The Quality Measures for Cancer project is led by the American Society for Radiation Oncology (ASTRO), Cigna/Evernorth, MITRE, the American Society of Clinical Oncology (ASCO), and Telligen.

The preliminary Discovery stage of the Quality Measures project is expected to end in May 2023. The project team is beginning to connect with additional organizations who may be interested in collaborating and expanding the footprint of the team's recent successes.

Those who want to get involved in the Quality Measures for Cancer project team should contact Anthony DiDonato (*adidonato@mitre.org*) and Doug Williams (*doug@centannipark.com*), co-coordinators for the project. For more information on the project, visit:

https://confluence.hl7.org/display/COD/Quality+Measures+for+Cancer

Other CodeX Projects



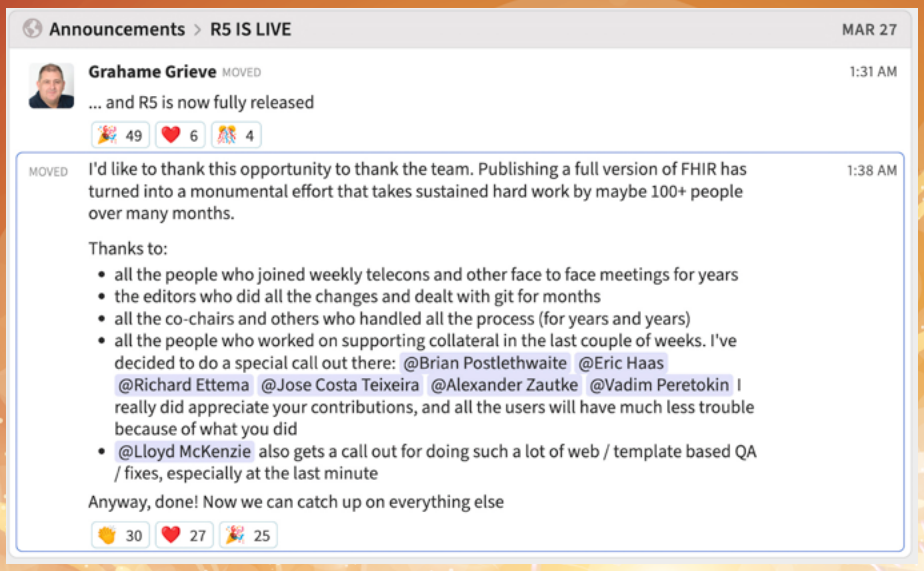
Here's a wrap-up of the status of other CodeX projects:

In Discovery stage:
Risk Evaluation and Mitigation Strategies

In Planning stage:
CardX Hypertension Management and Genomic Operations

In Execution stage:
EHR Endpoints for Cancer Clinical Trials (ICAREdata)
Integrated Trial Matching for Cancer Patients and Providers
Cancer Registry Reporting
Radiation Treatment Therapy Data for Cancer
Prior Authorization in Oncology; and Genomics Data Exchange

To learn more about CodeX use cases, send a message to CodeX*@hl7.org*.



Further Streamlining Data Exchange and Transforming Patient Care

HL7® Announces FHIR® R5 Standard

Latest release supports the development of innovative healthcare applications, improves interoperability, enhances data management, streamlines workflow

This spring, HL7 announced the publication of HL7 Fast Healthcare Interoperability Resources Release 5 (HL7 FHIR® R5), the latest version of its healthcare data exchange standard. Building on feedback from the global healthcare community's implementation experience since Release 4 was published in December 2018, FHIR R5 is a 'trial use' standard that retains prior mature, normative content while incorporating enhancements that are ready for implementation and feedback.

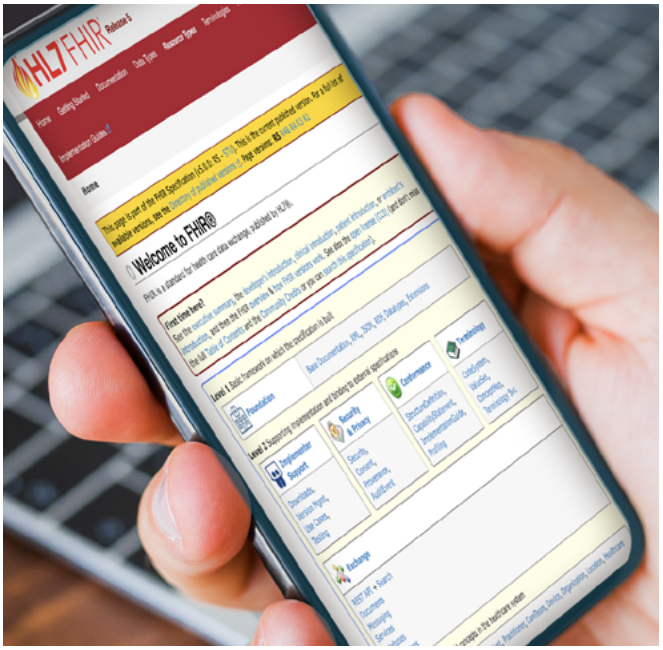
"We are grateful for the incredible contributions and dedication from the global healthcare community in developing FHIR R5," said Grahame Grieve, HL7 FHIR Product Director. "The feedback and collaboration have been invaluable in shaping this latest version of the standard, which will further advance healthcare interoperability and improve healthcare outcomes."

Benefits for Clinicians and Patients

"FHIR R5 provides significant end-user benefits to the clinical community and ultimately to the patients for whom they care," explained HL7 Chief Executive Officer Charles Jaffe, M.D., Ph.D.

These benefits include the following:

- **Improved interoperability:** HL7 FHIR R5 provides a robust and standardized framework for exchanging healthcare information between different systems and applications, making it easier for clinicians to access the patient data they need to make informed decisions.
- **Enhanced data management:** With FHIR R5, clinicians can manage and access patient data more efficiently, reducing errors and improving the quality of care.
- **Streamlined workflow:** FHIR R5 enables faster and more efficient information exchange, allowing clinicians to spend less time on administrative tasks and more time focused on patient care.
- **Support for innovative applications:** FHIR R5 provides a flexible and extensible data model, enabling the development of innovative healthcare applications that can improve patient care and outcomes.



Technical Standards Benefits

"Release 5 represents the collective progress and implementation experience of the FHIR community," said Daniel Vreeman, DPT, HL7 Chief Standards Development Officer. "With its many incremental updates, this release enables growing capabilities for interoperability in clinical care, public health, and research."

FHIR R5 contains thousands of incremental updates, corrections, and enhancements that improve the overall quality and capability of the standard. It includes several notable enhancements, such as the following:

- Capabilities for topic-based subscriptions are now part of the core specification, enabling proactive event notifications based on data changes in the source system.
- Significant revisions to the Medication Definition resources to better support the needs of manufacturers and regulators and use in drug catalogs and pharmacopoeias.
- More than a dozen new resources defining structures for different types of health-related information. FHIR now defines 157 different resource types.
- New operations are defined for efficiently managing large resources such as Groups and Lists
- Several changes to the specification's infrastructure further enable management of coded terminologies as well as extensions to be managed more appropriately alongside the core FHIR specification.

We plan to publish the next milestone release of FHIR as a normative standard, based on the implementer experience and feedback on R5. With FHIR R5, HL7 continues to support the development of innovative healthcare applications that can improve patient care and outcomes.

For more information on HL7 FHIR R5, and to download the standard, please visit: *HL7.org/fhir* ■

New Release Updates Open-Source Tools Suite

ART-DECOR® Release 3 – Next Generation Tooling

The ART-DECOR® Open-Source Tools Suite was established in 2009 as Release 1, and in 2018 with Release 2. Since then, ART-DECOR® Open Tools has hosted hundreds of standardization projects across Europe with thousands of artefacts like templates and value sets, including large scale national infrastructure programs such as Nictiz (Netherlands), eHealth Suisse (Switzerland), ELGA (Austria) as well as various projects hosted by IHE Europe, in France and the European Commission. The tool is designed for experts from medical, terminological, and technical domains with the aim of creation and maintenance of collaborative interoperability specifications.

By Kai U. Heitmann, MD, Co-Founder and CEO, ART-DECOR Open-Source Tool Suite

Dr. Kai U. Heitmann works in IT and communication standards and interoperability in healthcare. After his time as deputy head of the medical informatics unit at the University of Cologne, Germany, he devoted himself to consulting, development, training, and media-related services for the exchange of information and system integration of application systems in the healthcare sector in several European countries for two decades now. From May 2019 until end of 2021, he worked as Director Interoperability at the health innovation hub advising the Federal Ministry of Health in Germany. He is co-founder and CEO of the ART-DECOR Open-Source Tool Suite.

REQUIREMENTS

Medical domain expertise in a general and broad sense, brought in by patient care givers

PROFILES

Technical expertise for implementable artefacts such as data formats

SCENARIOS

Medical use case expertise for patient care, public health and research processes

IMPLEMENTATION/TESTING

Implementation expertise for building software with benefits to support healthcare providers

TERMINOLOGY

Terminology expertise to allow annotations of real-world terms and concepts with unique codes

PRODUCTION

Use of products based on standard specifications for a maximum of patient safety

Figure 1: Iterative Refinement of Interoperability Specifications

Introduction

As a collaboration platform, ART-DECOR® has four focus feature areas:

1. **Tooling** – a feature ensembles with optimized user experience for creation and maintenance of the supported ART-DECOR artefacts:
   - Datasets and scenarios to capture the medical expert needs
   - Terminologies such as value sets or code systems, and semantic annotations of concepts
   - HL7 templates and profiles to reflect technical representation of the data to be exchanged
   - Implementation guides and other appropriate publication mechanisms

It follows FAIR[1] Guiding Principles for scientific data management and stewardship.

2. **Teamwork** – for comprehensive collaboration among team members within and between governance groups
3. **Sharing** – cloud-based federated Building Block Repositories (BBR) for interoperability specifications to foster re-use for the creation and maintenance of artefacts
4. **Publishing** – adequate publications with separation of concerns and different views for different domain experts

ART-DECOR allows users to iteratively improve recorded data definitions and link together input from various experts with different background knowledge: caregivers, terminologists, modelers, analysts, and interface/communication specialists (see figure 1).

With **architectural changes** and a **new UX and UI** based on modern frameworks, Release 3 comes with a better look and feel, iss more intuitive, offers more functionality. Next to Clinical Document Architecture (CDA®) specifications, the tool can be used to produce many different types of **FHIR artefacts**.

The new Centralized ART-DECOR Terminology Services (CADTS) is optimized for "stable" terminologies such as LOINC, SNOMED-CT, Radlex, ORPHAcode, HPO, HL7, ICD10 etc. It is the basis for the new terminology browser, quick search results across multiple terminologies and rapid creation of value set expansion sets. The extended terminology management now not only includes a **value set management** using the browser and more support for **intentional Value Set** definitions, but also a new **Code System Management** with an editor for code systems as simple lists, hierarchical trees, and networks.

Continued on page 24

1 FAIR Data Principles (Findable, Accessible, Interoperable, and Reusable), see https://www.nature.com/articles/sdata201618

Continued from page 23

ART-DECOR® Release 3 – Next Generation Tooling

Semantic annotations have been possible since the tool was first released. Creating associations between dataset concepts and terminologies, dataset concepts and rules (data formats) and between terminologies and rules have been improved. A new feature includes the area of maintaining **Concept Mappings**, primarily but not exclusively focusing on terminologies (coded Concept maps), again expressible as FHIR concept maps, too.

The extended **Questionnaire Management** acts as a repository and will hold questionnaires and responses with direct questionnaires transform from scenarios, import options, or the creation from scratch. The panel can be used for prototyping, rendering, test responses and publishing. After successful creation and prototyping of questionnaires they can be published as FHIR questionnaires for re-use by external apps and systems.

FHIR® Profiling is new and will soon offer a profiling option using the tool. It works like the well-known CDA Template Editor in ART-DECOR. While this feature will not cover all profiling "edge" cases, we believe that the new profiler will attract many people to master FHIR profiles as well as offer new aspects for education on the art of FHIR profiling.

Additional methods of publications complete the established publication formats HTML, Mediawiki, and PDF with new frameworks such as Confluence and WordPress, already used by customers. A new **Implementation Guide (IG)** Feature is in progress to make creation and publication of CDA- and FHIR- based IGs easier.

Finally, we renewed all our website and documentation, moving away from the classic Mediawiki-based documentation to a true technical documentation tool that allows us to serve our clients with a more consistent and pleasing documentation.

Looking Ahead

Recognizing that ART-DECOR is an integral part of many standard development activities, it acknowledges its large user base using Release 2. Next generation tooling is entered with Release 3, a natural update on all previous features and options to create and maintain interoperability specifications. In addition, new capabilities were added or are in preparation that include management of questionnaires, concept maps, terminologies and FHIR profiles. ■

ART-DECOR® Release 3

Most people from the HL7 community know this tool as a Template and Value Set maintenance and validation tool for CDA. The next generation of the tool—called ART-DECOR Release 3—has been in development since 2020. Meanwhile all functions from Release 2 are available in Release 3, with more performance, more features, exposing a much more intuitive interface to the users. ART-DECOR embraces FHIR artefacts and aims also on more sustainability and re-usability of interoperability specifications.

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Foxit Software Incorporation
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Nava
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NICTIZ
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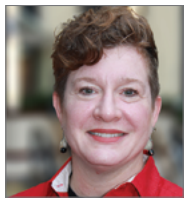

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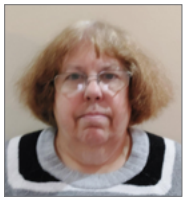

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HL7 International Upcoming HL7 Meetings

September 9 - 15, 2023
37th Annual Plenary, Working Group Meeting and HL7 FHIR Connectathon

Phoenix, Arizona

January 16-18, 2024
HL7 FHIR Connectathon

Virtual Event

Jan 29 - Feb 2, 2024
January Working Group Meeting

Virtual Event

May 18 - May 24, 2024
May 2024 Working Group Meeting and HL7 FHIR Connectathon

Dallas, Texas

March 11 - 15, 2024
HIMSS24 - Booth #3212

Orlando, Florida

August 8 - 9, 2024
HL7 FHIR Security Education Event

Virtual Event

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