HL7 Standards Support COVID-19 Fight

NIST HL7 V2 Testing Tool

ONC Adds 2 COVID-related Grant Projects

Da Vinci Project: Newest Effort Targets Risk Adjustment Issues

Six Champions Who Highlight HL7 FHIR’s Potential

Plus: Updates from CodeX, Gravity and much more!
The COVID-19 pandemic has certainly taken a devastating toll on families and economies around the world. As of May 17, globally there were over 164 million confirmed cases of COVID-19 and more than 3,400,783 deaths. While the USA has about 4% of the world’s population, with more than 600,000 deaths, the USA currently accounts for over 17% of coronavirus related deaths.

We have witnessed a dark chapter that we are all anxious to move beyond and get to the other side.

One can hope that the pandemic experience will lead us to become more engaged in public health practices and also more appreciative to healthcare workers, teachers and all essential workers.

January FHIR Connectathon and Working Group Meeting

We are pleased to report that our virtual events have continued to provide an effective forum for our HL7 community to collaborate in a seamless manner.

The January WGM attracted 496 participants while 798 participated in the FHIR connectathon. Our January WGM also featured several surprise guest speakers that were fun and well-received, including:

- Comedian Cedric the Entertainer
- Meditation guru Deepak Chopra
- Sports reporter Erin Andrews
- Improvisational comedian Colin Mochrie from Whose Line Is It Anyway
- Carol Baskin from Big Cat Rescue, who became infamous via the Tiger King television series
- Actor Sean Astin who starred in The Lord of the Rings, Rudy and The Goonies

We were thrilled to realize that our HL7 WGMs and FHIR connectathons are productive, meaningful and successful whether they are conducted in person or virtually. We anticipate continuing to produce successful WGMs and FHIR connectathons in May and September of this year.

We look forward to seeing our HL7 family again when we resume our in-person events. Our current plans are to begin with our January 2022 WGM on January 15-21, 2022 near Las Vegas at the Hilton Lake Las Vegas Resort in Henderson, Nevada.
Virtual HL7 FHIR Connectathon

Our next FHIR connectathon will occur May 17-19, where we will once again feature hands-on FHIR development and testing. This is a chance to get your hands dirty and learn by helping evolve the FHIR specification (lectures and presentations are not included). Implementers and developers can gain experience developing FHIR-based solutions and exchange data with other FHIR interfaces. Participants select one of several tracks based on level of readiness and area of interest, and can engage in hands-on, heads down development and testing. There is an opportunity to work directly with other FHIR developers and senior members of the FHIR standards development team, and participants are expected to write some software intended to demonstrate FHIR connectivity.

Virtual May Working Group Meeting

The upcoming WGM will occur May 24-28 in a virtual format. As was the case for our January WGM, we have transformed our WGMs to move seamlessly within the Whova and Zoom platforms for a productive collaborating experience.

A very important change for the virtual May 2021 WGM is that it will be held in Coordinated Universal Time (UTC), which is most convenient for those in the Central Europe time zone. For example, the first quarter will start at 9:00 am UTC, which is at 5:00 am Eastern Time zone in the US. Also, the general sessions will occur at 1:30-2:00 pm UTC, which is 9:30-10:00 am ET zone in the US. Please visit the HL7 website for more details on the timing of the May WGM schedule.

Virtual HL7 FHIR DevDays in June

FHIR DevDays is where the FHIR community thrives and where you can learn all about FHIR and refine your FHIR expertise. The event appeals to developers, non-coders, FHIR experts as well as those who are new to FHIR. We look forward to producing our second virtual version of FHIR DevDays on June 7-10, in collaboration with our partners at Firely. Last year’s virtual FHIR DevDays attracted 680 attendees and is expected to attract even more this year.

For more details, please visit [www.devdays.com/june-2021/](http://www.devdays.com/june-2021/)

Benefactors and Supporters

We are pleased to recognize HL7’s 2021 benefactors and gold members who are listed on page 30. Their support of HL7 is very much needed and sincerely appreciated. We are happy to recognize our benefactors in all of our HL7 newsletters, on the HL7 website and at all of our HL7 working group meetings.

Organizational Member Firms

As listed on pages 30-33, HL7 is 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, giving thanks to all essential workers, and also finding time for enjoying plenty of hugs and laughter!

Mark A. Messing
The HL7 Job Board

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!

**HL7.org/jobs**

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 waving all fees to post open positions.

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**HL7 FHIR Fundamentals Course**

**Next edition begins July 15, 2021!**

**HL7 FHIR Fundamentals**

[http://HL7.me/FHIRfun](http://HL7.me/FHIRfun)

**July 15–August 12, 2021**

- 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

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**HL7 International**

**EDUCATION ON DEMAND**

Find the training you need, straight from the source! HL7 Education on Demand is your online source for HL7-related professional development and certification resources

- HL7’s Fast Healthcare Interoperability Resources (FHIR®) standard
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- Health IT policy issues

➤ **Check it out online at** [bit.ly/HL7EdOnDemand](http://bit.ly/HL7EdOnDemand) ➤
## HL7 Standards Published Since January 2021

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## Benefactors

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Member Spotlight on John J. Garguilo

Professional Background

**John Garguilo** is a supervisory computer scientist at the National Institute of Standards and Technology (NIST), a non-regulatory bureau within the United States Department of Commerce.

John is the group leader of the Systems Interoperability Group (SIG) within the Information Technology Laboratory (ITL) with a mission of advancing rigorous test methods. He focuses on developing conformance test tooling in support of standardization to better achieve interoperability of information. John’s team works and collaborates with standards development organizations (e.g., HL7 and ISO/IEEE), prominent healthcare domain working groups (e.g., Integrating the Healthcare Enterprise), and supports and provides measurement science and test method expertise to national efforts and Federal and State Agencies (e.g., ONC, HHS, and CDC) – primarily within the healthcare arena. The ITL/SIG has developed an end-to-end test framework and seeks to advance and expand software tools to enable Industry interoperability. Such tools are often adopted by major national conformity assessment and certification efforts.

John leads the NIST Semantic Interoperability of Medical Devices (SIMD) project focused on medical device communication research and testing aimed at enabling the adoption of medical device communication standards by acute, point-of-care, and personal health medical device manufacturers.

In addition to his role at NIST, John continues to serve, and has so for nearly a decade, as a co-chair for the HL7 Device Work Group (recently renamed from “Healthcare Devices”). He is also the secretary for the ISO/IEEE Medical Device Communication (11073) Point of Care Devices Working Group and previously served as the Integrating the Healthcare Enterprise - Patient Care Device (IHE-PCD) Technical Committee co-chair. John has enjoyed the knowledge sharing, learning, advancements, and many wonderful HL7 worldwide friendships formed by being an active member for nearly 15 years. This includes what now has become a traditional Wednesday Q3 back massage he gives to HL7 staff members Mary Ann Boyle and Dave Hamill for all the terrific, tireless work they do over each of the working group weeks. 😊

John holds a master’s degree from the Johns Hopkins University and an undergraduate degree from the State University of New York, Potsdam, both in computer science. John has extensive experience over the past 35 years working on and managing software systems and information technology to support research, testing, automating workflow applications, data communications, and electronic commerce.

John received an offer from NIST while a college senior way back in 1985 – packed up his belongings – and headed 400 miles south to Maryland from his humble upstate NY beginnings in a small leather producing blue collar town of Gloversville (yes, named after the one-time world leader in producing leather gloves/products).
Personal Life

John still feels blessed for the wonderful lifelong friends, opportunities, and good fortune that acceptance led to over the past 35+ years – including the many talented, committed and hardworking friends from HL7. While at NIST, he met his “Angel” Ramona (who also works at NIST on Mutual Recognition Agreements as part of the Standards Coordination Office) and is the very proud “Daddio” and “PaPa” of his two talented and beautiful children, Emily (25) and Dominic (23). Emily is nearing the end of her second year of a three-year Doctor of Physical Therapy program at the University of Maryland – Baltimore (after achieving an undergrad in Kinesiology from “Terpville” – the University of Maryland, Fear the Turtle!). Dominic graduated from Towson University (also in Maryland) with a degree in Computer Science in May 2020, and recently started a terrific computer programming job. John will, of course, convince Em and Dom to also one day become HL7 members to further learn, grow, share and advance themselves – in addition to the wonderful networking HL7 affords.

John has had a lifelong passion for playing, coaching and (as he gets older) watching a variety of sports. Over the years he has run four marathons and numerous other distance events, participated in, and won championships in the NIST softball, golf, and basketball leagues. John claims his mother “weaned him on blue milk” and thus he’s an avid fan of the New York Giants. He believes in serving others and (during non-COVID times) helps provide communion to elderly folks in a local Frederick Maryland nursing home as an aspect of his church activities.

For the most part, John tries to not take himself or things too seriously and to always live by the mantra his beautiful partner Ramona has taught him, “Can’t go back, can only move forward” and whenever possible to “live, love, laugh and be happy”.

Jira and the Project Scope Statement (PSS)
The PMO, HL7 staff and Jira PSS project team members thank all those that participated in the pilot. The seven projects submitted provided ample opportunities to modify the workflow to ensure a smooth launch. HL7 plans to roll out the Jira PSS form to everyone in Q2 of 2021, after which the project team will focus on sunsetting Project Insight. Additionally, the PMO and TSC have been working together to utilize Jira for the reaffirmation and withdrawal processes. Doing so will provide systematic notifications to work groups and co-chairs of expiring artifacts and decisions/actions needed.

ONC Grant Funded Project Update
Work continued under the ONC’s $1.36 million grant to mature the Consolidated Clinical Document Architecture (C-CDA) and Fast Health Interoperability Resources (FHIR®) standards. Projects under this endeavor include the following:

- Rollout and support of the Unified Terminology Governance (UTG) process and tooling
- Complete improvements to the FHIR Jira ballot process
- Continue to provide administration for the FHIR Connectathons
- Continue work on Bulk Data Access and Push
- Continued support for the FHIR Terminology Server
- Continue work on the HL7 FHIR build and implementation guide (IG) publishing tasks
- Provide support to the FHIR Registry
- Conduct additional C-CDA Implementation-A-Thons
- Continue work on the C-CDA Web Publishing Tool
- Annual updates to C-CDA R2.1 value set
- Analysis of transferring C-CDA value sets from NLM VSAC to terminology.hl7.org
In addition to the existing ONC grant project, work progressed on two additional COVID-related ONC grant-funded opportunities for HL7:

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

- 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 developing 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 5-year $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 and US Realm Senior Advisor

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

HL7 appreciates ONC’s continued support of C-CDA and FHIR for 2021 and beyond.

For more information:
Progress for all of the above ONC work can be found on HL7’s Confluence page at:
who.int/nmh/publications/be-healthy-be-mobile/en
My last tooling update was titled Focus on Finishing. Thus, in homage to the inimitable Yogi Berra, it would be hypocrisy to change focus now. Focus on finishing is still the principal theme for the year, building on essentialism, my other guiding light, as expressed in the axiom “Do less, better.”

Toward that end, we continue to move ahead with our transition to our core collaboration tool stack and processes based on workflow-driven online forms. As of this writing, we’re completing final improvements to make the online PSS available to all later this spring. We’ll be working to finish automating most other key form-driven processes after that.

In addition, we hope to finish our transition to a new JIRA-based balloting system, which is also being piloted as of this writing. This, together with the recent transition from GForge Tracker and the STU Feedback web page to JIRA, puts all of our specification feedback in one repository moving forward.

While finishing our transition for balloting is critically important, we also have to update and replace some peripheral systems supporting the balloting process for members, as well as our core business systems for managing membership, events and operations. While we don’t expect to complete this transition to a new Association Management System before the end of 2021, we’ll be focused on finishing this as rapidly as possible since it’s an essential foundation to further systems improvements for the HL7 organization.

2020 saw the production release of the new terminology.hl7.org web page and the Unified Terminology Governance (UTG) system to manage its content. Getting this out was a major milestone, yet we recognize that there’s more to be done to make the tooling easier to use and improve the quality and completeness of the content. In this sense, finishing is not really bringing closure to a long-running project; rather, it’s more like...
passing through a doorway from one place to another through a process of staged improvements. This analogy is also a good way to look at the incredible progress that’s been made with the FHIR IG Publisher tooling environment. Over the past two years, IG Pub has been significantly improved and expanded. In 2021, we hope to finish a long-term effort to operationalize the tool, so it doesn’t require as much human intervention (mostly, alas, by our venerable FHIR Product Director).

Twists and Turns

In all these cases, we can only finish what we know. As HL7 re-envisions itself for a rapidly changing world, we can expect a steady stream of what Donald Rumsfeld so memorably characterized as “known unknowns” and “unknown unknowns.” We can stabilize tools like IG Pub for a while, but as we expand it to support publishing other standards like Clinical Document Architecture (CDA®), Consolidated CDA (C-CDA) and other HL7 terminologies, we introduce or uncover other issues that affect what may have been stable before - a constant circle. As HL7 Fast Healthcare Interoperability Resources (FHIR®) expands to address new communities and use cases, we recognize that IG Pub and other tools will need to evolve to support new initiatives by a much larger community. Any evolutionary change has the potential to have unexpected effects.

Thus, when I speak of finishing, I’m generally thinking about the visible horizon. Once you get there, you will likely see additional twists and turns you need to navigate to reach the ultimate desired destination. There’s a difference between making something newly available and making it a value-adding core part of the way we work. Finishing one stage generally involves beginning another, and we have many more journeys ahead.

Meanwhile, no matter how many times I repeat “focus on finishing” and “do less, better,” the incoming tide never quite abates, so we need to balance the need to meet critical new challenges while finishing the older ones. Therefore, it bears repeating that we’re still struggling against a catastrophic pandemic, and no matter how firm our plans, we need to be ready to do what we must even if it strays from the intended plan.

This brings up a new target focus area: improving the way we look at work in progress, so the community has more visibility and insight into what’s coming. The Standups page helped with this for published specifications. However, it’s also often necessary for implementers to know whether there are items in the pipeline that may affect their internal projects so they can plan accordingly. Under our new ONC-funded US Realm contract, we’ll be working to deliver new systems and tools to help the broader community of HL7 members, stakeholders and beneficiaries gain more visibility into our ongoing work and upcoming publications.

Give Us a Break

After more than a year of social distancing in place, with an endless stream of meetings and incoming to-dos, we can often find ourselves overwhelmed as we lurch from meeting to meeting. I’ve proposed adopting the 55-minute meeting at HL7. Like most humans, I need to deal with stuff in between abutting Zoom calls, and just like it’s important to incorporate intermittent rest into your workouts, it’s healthy and productive to plan for a break in between back-to-back meetings. Realistically, we start most meetings several minutes late waiting to achieve quorum anyway. Additionally, most of us would welcome a few moments to take a deep breath, switch gears and redirect our attention spans to the next meeting after leaving the prior one. The 55-minute meeting is simply acknowledging an intent to allow each other to take five minutes in between to reset. You can still join early to chat with your colleagues – but let’s drop the gavel to formally commence at three minutes after and finish up 55 minutes later. Maybe that will allow attendees time to overcome the occasional Zoom hiccups, misplaced notes or simply pour that extra cup of coffee. A slightly delayed start will also help us start strong and focus on an on-time finish, which should bring another five-minute break before we start all over again.

I believe the 55-minute meeting will improve our health, satisfaction and our meeting effectiveness, so we can do more better, in less time. Like muscle memory, it will get better with repetition, making participating at HL7 just a bit easier on us all. Which should be something we can all appreciate.
The Da Vinci Project is beginning work on another use case to solve a problem that is administratively burdensome for many organizations in healthcare that are looking to improve efficiency in managing risk-based contracts.

The newest effort focuses on risk adjustment, which involves providers, payers and other organizations. These entities utilize risk adjustment to facilitate communication and clearly define patients’ conditions and severity levels, while also ensuring that risk-adjusted premium calculations are correct and accurately reflect the levels of care that patients require.

The initial meeting to organize work on the new use case occurred in late March, and the effort will involve using the HL7 Fast Healthcare Interoperability Resources (FHIR®) standard to create a framework for a solution. The workgroup has set a target of having a standard ready for the first ballot in January 2022.

Risk adjustment is a compensation methodology that funds managed care insurers, often through government plans such as Medicare, ACA or Medicaid, based on the health acuity of patients for whom they are responsible. Documentation of all risk-adjusted conditions must occur at least annually, at a minimum.

As it now stands, making risk adjustments requires a lot of administrative interaction, and the manual processes and requests for information can be frustrating for both providers and payers. These types of contracts are becoming more common as government managed care plans require annual reviews of documentation on patients for whom payers are responsible.

Furthermore, as such contracts are more widely adopted for treating other patient populations, the complexity of risk adjustment, and the burden of meeting various contractual requirements, is expected to grow. Thus, facilitating data sharing through a standardized data flow is important because multiple stakeholders are involved that need to effectively collaborate.

Development of the new use case will better inform clinicians of opportunities to address patients’ risk-adjusted conditions, and,
conversely, it will better enable payers to communicate risk-adjusted information to providers. Finally, standardizing how information is communicated will eventually enhance a sponsors’ ability to allocate funding accurately.

There are obvious benefits for providers in using standards to facilitate information exchange around risk adjustment. Those providing care need to be aware of all of a patient’s chronic conditions to address them at least annually. Payers also would benefit from a technology-enabled system, because a better flow of information from providers will result in them receiving more accurate risk-based payments from the government. To achieve this, payers are dependent on providers submitting complete and accurate diagnosis and treatment information.

The initial work in this use case will center around developing a standard methodology or format for payers to communicate risk-based coding gaps to providers. The initiative also aims to give payers the ability to communicate risk-based coding gaps either for individuals or groups of patients. Further work in an eventual second phase of the initiative is expected to enable facilitated communication among other parties involved in risk adjustment.

All players in the industry will see benefits from developing this standard. Payers will see less need to chase down patient records and will experience workflow improvements. Providers are likely to field fewer requests for medical records from payers and are more likely to get correct payments reflecting the care that higher-risk patients need. Providers will also benefit from receiving a standardized communication from all payers, rather than having to interpret multiple reports or formats from each one and having to interpret the information. And patients will see more informed decision making by providers and thus are likely to be more satisfied with their care.

The new Da Vinci workgroup will assess if other FHIR use cases can be adopted or modified as part of a solution. An intermediate goal is to have potential test scripts in place for testing in the September Connectathon before balloting as a standard for trial use (STU) early next year.

For more information on this emerging use case, please contact either Phung Matthews, project manager, at phung.matthews@pocp.com or Viet Nguyen, MD, technical director for the Da Vinci Project, at vietnguyen@stratametrics.com.
Initiatives such as the Da Vinci Project make strides toward interoperability as organizations adopt the vision and push it forward to reality.

To achieve the progress the HL7 Da Vinci Project has made to date, it relies on the extraordinary efforts of individuals who consistently work to advance the organization’s goals. This might entail stepping forward to lead a work group of peers, spending extra hours editing and reviewing work in progress workflows, recruiting business partners to test early versions as early adopters, or scouring their organization to find the right subject matter expert for a particular business challenge or question, all to ensure that early HL7 Fast Healthcare Interoperability Resources (FHIR®) implementation guides work.

These team members exemplify the spirit and intent of our collaborative industry-first Da Vinci efforts, said Jocelyn Keegan, program manager for the Da Vinci Project. “The work of Da Vinci is, at its core, a human powered effort,” she noted.

“It is imperative that we publicly acknowledge the contributions of the smart, dedicated thought leaders who are redefining how (FHIR use cases)...improve efforts to coordinate records on medication reconciliation, improving care records for patients and automating the process so as to not require extra staff time or workflow changes.

payers and providers collaborate.”

To recognize individuals who are taking a lead role in working to make the outputs of Da Vinci real, the project has named six leaders as the initial class of the Da Vinci Community Champion program for their contributions in 2020.

With the ascent of value-based care, interoperability is expected to evolve at an even faster pace to meet the business demands that new reimbursement incentives are producing.

“The people involved with the Da Vinci project play a pivotal, enabling role in advancing the data exchange infrastructure that is essential to making the healthcare system work better for all constituents,” said Sagran Moodley, chair of the project’s steering committee and Senior Vice President of Clinical Data Services & Technology for UnitedHealthcare’s Clinical Services organization. “This passion comes from a community that is anchored to a common vision to share best practices and innovate and in an ‘industry-first’ manner.

“To transform healthcare delivery, we need to foster new, and attract diverse talent that can bring fresh, disruptive perspectives to take on a bold but essential interoperability agenda,” Moodley added. “This initial class of the Da Vinci Community Champions embodies this culture of paying forward with unique traits – industry above self, a passion for making the healthcare system work better, growing others, and promoting change.”

The 2020 class of Da Vinci Champions have taken lead roles in implementing pilot projects using implementation guides.
innovators are beginning to use FHIR in production, solving real-life challenges facing healthcare organizations dealing with new business pressures arising from value-based care arrangements between providers and payers.

For example, Anna Taylor and David DeGandi’s efforts helped MultiCare Connected Care and Regence BlueShield implement FHIR use cases for Data Exchange for Quality Measures (DEQM): Medication and Reconciliation Post-Discharge (MRP) to improve efforts to coordinate records on medication reconciliation, improving care records for patients and automating the process so as to not require extra staff time or workflow changes.

Pioneering efforts from these champions are helping the Da Vinci Project accelerate the use of FHIR in support of value-based care to reach its goals of improving the healthcare delivery model, supporting efforts to meet regulatory mandates and better managing healthcare spending while improving healthcare outcomes.
CodeX has seven active use cases: mCODE++ Extraction; EHR Endpoints for Cancer Clinical Trials (ICAREdata); Integrated Trial Matching for Cancer Patients and Providers; Cancer Registry Reporting; Radiation Therapy Treatment Data for Cancer; Oncology Clinical Pathways; and Prior Authorization in Oncology, and Genomics Data Sharing.

Project updates for two of the use cases in current Execution Stage – EHR Endpoints for Cancer Clinical Trials (ICAREdata) and Integrated Trial Matching for Cancer Patients and Providers are provided:

**EHR Endpoints for Cancer Clinical Trials (ICAREdata)**

The ICAREdata (Integrating Clinical Trials And Real-World Endpoints) project is the trailblazing pilot of the CodeX EHR Endpoints for Cancer Clinical Trials use case. This work aims to expand the capabilities of cancer clinical research by introducing computable data standards (mCODE) and effective data collection methods into the electronic health record (EHR) of clinical care sites activating participating clinical trials. The ICAREdata project is a collaboration between the Alliance for Clinical Trials in Oncology and The MITRE Corporation, in partnership with clinical trial study teams, National Clinical Trials Network (NCTN) institutions, and EHR vendors.

The current Phase 2 of the ICAREdata project focuses on validating the ability to prospectively collect research-quality data in the EHR, based on a subset of mCODE. These data will be compared to those obtained through traditional clinical trial data capture methods. The primary goal is to confirm that ICAREdata EHR-based study data are equivalent in accuracy to those achieved via the traditional clinical trial pathway. ICAREdata Phase 2 also establishes an infrastructure with participating clinical care sites that supports mCODE-enabled data collection, extraction and sharing.

To date, eight clinical site partners have begun to implement the ICAREdata collection and extraction tools. Data collection is underway at three clinical sites. Clinical trial partnerships are also growing with the introduction of a companion study protocol enabling collaboration with ongoing trials. Five clinical trials have ICAREdata language embedded in their protocols. These trials are activated and open for participant enrollment; participants on these trials will support the collection of ICAREdata EHR-based study data.

ICAREdata Phase 2 also lays the groundwork for expanded exploration of the use of EHR data for clinical research. Alliance has received several grants, including from FDA and NCI, to pursue this broader investigation in areas such as adverse event reporting. Planning for further ICAREdata projects is underway.
Integrated Trial Matching for Cancer Patients and Providers

While there are many barriers deterring patient participation in cancer clinical trials, a foundational requirement is identifying trials whose eligibility criteria match the patient’s clinical history. At most institutions, matching patients with trials requires a challenging amount of manual effort that occurs outside of clinical workflows. Even at research institutions, only around 1 in 4 patients will have an onsite clinical trial option. For the remaining patients, or those seen at non-research institutions, patients interested in trials are typically on their own and must use third-party matching services to find offsite trials. This reduces enrollment numbers, prevents diverse patient representation, generates additional costs, and hinders greater knowledge generation that can lead to better outcomes.

The MITRE Corporation and the American Cancer Society Cancer Action Network (ACS CAN) are championing a use case on Integrated Trial Matching for Cancer Patients and Providers under CodeX. This use case aims to make clinical trial participation equitable and easy for all patients and providers. The approach is to develop mCODE-based open data standards and open APIs that enable interoperable, scalable, and accessible clinical trial matching services that are integrated into existing clinical workflows. Due to the complexity of clinical trial eligibility criteria, the project team is focusing on a subset of data elements. These elements, called the “optimized patient data elements” (OPDE), are thought to be the most important data elements in clinical trial matching. Although a full, complete match will not be possible when using only the OPDE, the number of potential trials a patient may match to will be filtered to a manageable amount for a patient/provider to then manually review. This integration creates opportunities for patients to consider clinical trial participation regardless of where they are initially treated.

A proof-of-concept for this capability has been developed, which demonstrates the ability of a clinical trial matching service to receive an mCODE record, analyze the record to make matches, and then present the matches back to the patient or provider. Synthetic patient data was used and the matching service TrialScope was “mCODE-enabled”. Please visit the Phase 0 page on Confluence to view a demonstration and documentation of the results.

The team is now completing a retrospective study (Phase 1) to evaluate if the list of optimized patient data elements is enough to filter potential clinical trial matches. The team will send real patient records to multiple mCODE-enabled trial matching services and view the results when only the OPDE is analyzed and when the full patient record is analyzed. By comparing the results from the two searches, the team will understand how many true matches, false positives, and false negatives are found when using the OPDE. This will enable the team to finalize a list of OPDE that are most important in clinical trial matching.

After the retrospective pilot is complete, a prospective pilot (Phase 2) will be conducted, focusing on the integration of this capability into existing health systems and EHRs to show the value of this service. This use case will drive awareness and commitment to use these standards in the industry and improve clinical trial matching for patients and their care teams. Clinical trial participation will be more equitable, and we will all benefit from the creation of smarter data for the fight against cancer. To join this project team and participate on these work group meetings, please contact Caroline Potteiger (cpotteiger@mitre.org).

The FHIR Implementation Guide development fueling this use case is sponsored by the HL7 Biomedical Research and Regulation (BR&R) Working Group. The Project Scope Statement can be found here.

Stay in Touch!

To stay up to date, go to our CodeX Confluence home page, click “Join a CodeX Listserv” or contact Steve Bratt sbratt@mitre.org, Kim Ball kimball@pocp.com or Anthony DiDonato adidonato@mitre.org with questions!
The Gravity Project convenes multi-stakeholder groups from across the health and human services sectors through an open and transparent collaborative process where they develop and test consensus-based standards to facilitate social determinants of health (SDOH) data capture, exchange, and use across a variety of systems and settings of care and social services.

**Project Accomplishments**

Since May 2019, over 1,900 stakeholders across the healthcare, health IT, community-based, federal and state agency, payer, academic, and consumer advocacy sectors have signed up as members of the Gravity Project. Here are five key project accomplishments and target milestones from the past quarter.

**ONC USCDI SDOH Data Class Submission.** In October 2020, the Gravity Project made a formal submission of a new SDOH data class to the United States Core for Data Interoperability (USCDI). The data class was categorized as level 2 and remains in consideration for upcoming publications of USCDI.

**Multi-domain SDOH ICD-10 CM Code Submission.** In December 2020, the Gravity Project submitted its multi-domain ICD-10 CM submission representing a year and a half of collective labor. The submission was presented to the ICD-10 CM Coordination and Maintenance Committee on March 10, 2021. The submission was accepted for the October 2022 publication date. The Gravity Project is currently seeking support for an earlier October 2021 publication date.

**HL7 SDOH Clinical Care FHIR Implementation Guide.** The Gravity Project submitted its first FHIR IG for ballot as part of the HL7 January 2021 ballot cycle. The ballot received the required passing votes and is on target for publication as a Standard for Trial Use (STU) in June 2021.

**Multi-domain SDOH Data Set Development.** In January 2021, the Gravity Project completed the development of data sets for the SDOH domains of: inadequate housing, transportation, demographic status (veterans, employment, education) and financial insecurity. These data sets represent SDOH concepts collected across the activities of: screening, diagnosis, goals setting, and interventions. These data sets are available for download via the Gravity Terminology Dashboard.

**CMS State Health Official Letter Integration.** On January 7, 2021, the Centers for Medicare and Medicaid Services (CMS) released guidance for States on opportunities under Medicaid and the Children’s Health Insurance Program (CHIP) to address SDOH. The guidance encourages states to review and participate in the Gravity Project as they work towards designing and implementing interoperable data integration and data sharing systems.

**Upcoming Activities**

Gravity terminology and technical standards will be tested through real-world pilots in 2021. We anticipate pilots will advance the maturity of the SDOH Clinical Care FHIR IG and validate coded SDOH data elements. To learn more about the pilots, please email: gravityproject@emiadvisors.net

For more information on the multi-SDOH domain ICD-10 CM submission, please visit: https://confluence.hl7.org/display/GRAV/ICD-10+Coding+Submissions

To view the latest consensus voted master datasets by SDOH domain, please visit: https://confluence.hl7.org/display/GRAV/Terminology+Workstream+Dashboard
HL7 Welcomes New Members

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On January 18, 2021, we celebrated HL7 Europe’s 10-year anniversary with a webinar reflecting on the past and thinking about the future.

Roel Barelds (HL7 Netherlands), Christof Gessner (HL7 Germany, HL7 Europe board member) and Catherine Chronaki served as the organizing committee. Opening the program, Catherine looked back on the achievements of the last decade, including participation in more than 15 European Commission funded projects; three in leadership roles (i.e. Trillium Bridge, Trillium II, and eStandards); collaboration with more than 250 organizations throughout Europe; an impactful presence in the European interoperability space; publishing nine HL7 in Europe newsletters; and cooperation across standards development organizations (SDOs) bringing forward the International Patient Summary.

Line Saele, chair of HL7 Norway and HL7 Europe board member, moderated the panel “HL7 Europe—What’s Next?” with the following distinguished panelist: Jasper van Lieshout, enterprise architect, Ministry of Health, Welfare and Sport, The Netherlands; Miroslav Koncar, chair of HL7 Croatia; and Kai Heitmann, MD, director interoperability, Health Innovation Hub, Germany. In her introduction, Line recognized HL7 as a catalyst for health information technology standards starting with HL7 Version 2 (V2) and continuing with HL7 Clinical Document Architecture (CDA®) and HL7 Fast Healthcare Interoperability Resources (FHIR®). Today, large scale digital health projects across Europe such as myHealth@EU and eHDSI, are based on HL7 standards. Line asked the panelists to share their expectations from HL7 Europe in the next decade, commending on the role of national HL7 affiliates and HL7 communities, while also highlighting actions necessary to support diverse stakeholders of health services.

Perspective from the Dutch Ministry of Health and Sports

Jasper offered insight from the Dutch Ministry of Health and Sports, department of information policy, and his involvement in the standardization policy. He also discussed the development of a new law on health data exchange so that the right information is available at the right place, at the right time. Achieving this objective would require establishing an information network that is both patient- and professional-centered,
where data and processes are digital first, and special attention is paid on outcomes.

Jasper expressed his hope that there will be more cooperation among SDOs serving as platforms to one another, for the benefit of simpler implementation and greater interoperability.

Working with standards, while maintaining relentless focus on implementation, the ministry works with several umbrella organizations in the Netherlands. Most notable among them are NEN, NICTIZ, the HC Information Council for all stakeholders, the SDO-NL platform for standards bodies, RSO regional organizations implementing digital health, and the OIZ platform for manufacturers and vendors.

In parallel to working across standards bodies in the Netherlands, the Ministry is committed to international collaborations with the aim of sharing information and knowledge with other countries through the Global Digital Health Partnerships (GDHP) spanning 30 health authorities across the globe, the Global Interoperability Consortium of HIMSS, IHE, HL7, and the Joint Initiative Council for Global Health Informatics Standardization.

The View from a National HL7 Affiliate, HL7 Croatia

The second panelist was Miroslav Koncar, who is currently serving his third tenure as the chair of HL7 Croatia. He shared the experience gained from his involvement in implementing eHealth programs as part of the industry, but also as an associate professor teaching interoperability and standards.

HL7 Croatia was established after the HL7 Roadshow stopped in Dubrovnic in 2001. It is a small affiliate with approximately 20-30 members. HL7 standards are well adopted in Croatia where the National eHealth Backbone is based on HL7 Version 3, delivering ePrescriptions for more than eight years. HL7 V2 is also well established in hospitals and labs.

In addition, Croatia has been active in cross-border services and programs. As a result, Croatia is sixth in Europe’s digitization index.

Miroslav stressed that “Collaboration and knowledge sharing are key.” He went on to note that “In most countries, there is a gap between how we expect to use HL7 and the actual implementation, where interoperability is frequently lacking. Affiliates, and more so, HL7 Europe, are platforms for information sharing.”

Volunteers run localization efforts, projects carry localization on their own, and implementation guides end up project-based. “Thus, for the
Celebrating 10 Years of HL7 Europe

HL7 community of implementers, collaboration is key, and if I could ask for three things, those would be: capacity building, capacity building, capacity building.”

He went on to say that he would advise HL7 Europe to apply for EU funding, such as social funds to set curriculum programs for CxOs. He also advised teaching public servants how to deal with HL7 and offered some hard questions to ask the implementers.

As Seen by a Long-Time Member

Kai Heitmann, MD, shared his HL7 story with the audience, which began in 1994 when he joined HL7 Germany and continued with his term as international affiliate director on the board of HL7 International for five years (2004-2008).

Following his tenure as a professor of medical informatics at the University of Cologne, and consulting work, he joined the Health Innovation Hub of the Federal Ministry of Health as director of interoperability in 2017. For Kai, the European values of focus, freedom, welfare, and mutual support closely align with the values of HL7. Kai stressed that “Interoperability is a social thing... we need to strengthen the HL7 community, start early and spread knowledge.” Quoting himself from 1997, he said, “Not only do the right thing, talk about that too.”

He emphasized that we need European governance around standards and training since we can’t regulate something that we can’t understand. “Talk legibly, simply to policy makers about the benefit and relevance of HL7 standards,” he continued.

Kai highlighted the importance of meetings like the International HL7 Interoperability Conference and the newsletters like the Dutch, the German, and HL7 Europe’s sharing news with a light spirit.

Panel Discussion

In the discussion that followed, when asked about the role of affiliates, Jasper stated that we need more integrated standards to make implementation simpler. Cooperation and sharing of information among affiliates would
help to achieve smoother transition to HL7 FHIR.

When asked about the role of HL7 Croatia and HL7 Europe, Miroslav said that both organizations are connectors, helping local stakeholders get the latest input about standards and develop the strong momentum needed to drive implementation.

Emergence of HL7 FHIR proved that communication and peer-to-peer exchange are key. “HL7 Europe is in position to make sharing of information more coherent and structured,” said Miroslav.

When asked about the family of HL7 and the inability to meet and connect in person, Kai said that we should continue collaboration, strengthening the feeling of family, with conference calls and speaking on the phone. In closing, Kai stated he is confident that we return to normality soon, and that the upside amidst this challenge is that many countries were able to enhance their degree of digitization.

Making It Happen—Reviewing the Details

Giorgio Cangioli, technical lead for HL7 Europe, then shared the plans for coordinated information sharing among HL7 affiliates in Europe through the recently established TNT workgroup under HL7 Europe. The TNT workgroup aims to support the realization of the core five principles of the Re-envisioning HL7 initiative, while at the same time strengthening the HL7 community in Europe.

Re-envisioning HL7

Walter Suarez, MD, PhD, the chairman of the Board of HL7 International, expanded on the five principles of re-envisioning HL7, namely: focus, global relevance, sustainability, agility, and community. He then recognized the efforts of W. Ed Hammond, PhD, as chairman of HL7 in making HL7 Europe a reality. Upon receiving the award, Ed reflected on the early days of HL7 Europe.

Watch the recording:

For more information, you can access the full recording here:

https://register.gotowebinar.com/register/8766406620520498189
NIST HL7 V2 Testing Tool

Collection of Patient Vaccination Information

Agency’s HL7 V2 Immunization Test Suite is facilitating the submission of accurate patient vaccination information to immunization registries nationwide. NIST and immunization domain experts at the CDC are developing an HL7 V2 Test Plan for COVID-19 immunization information messages.

The Immunization Test Suite, a software tool created by NIST, is helping ensure that the healthcare information technologies (HIT) being used by clinicians can communicate with the Immunization Information Systems (IIS) that are collecting patient vaccination information.

“Valid computerized vaccination information must be submitted to immunization registries, that is, Immunization Information Systems, maintained at public health jurisdictions across the U.S.,” explained NIST computer scientist Rob Snelick. “And healthcare information technologies, such as electronic medical records, are used to transmit that information, to query the registry, and then to display to the clinician the patient-specific immunization forecast information the registry sends back in response to that query.” Within the box on page 23 is a real-world example of this process:

The NIST Immunization Test Suite, created with the assistance of the Centers for Disease Control and Prevention (CDC) and the American Immunization Registries Association (AIRA), is used for testing whether a clinician’s EMR system, for example, is prepared to be “interoperable” with (i.e., able to exchange data meaningfully with) an IIS for collecting patient vaccination information via HL7 Version 2 (HL7 V2) messaging.

Interoperability Between the HIT and IIS is Key

When sending and receiving systems do not use the same data exchange standards for electronic transmission of data, the patient data that are exchanged may be incomplete, inaccurate, invalid or untimely. If any of these faults occur, then the patient’s immunization record may be erroneous, the legitimacy of
A parent brings their infant to a pediatrician’s office for their first well-baby checkup two days after birth. Based on the ACIP scheduling recommendations for children and adolescents published by the CDC, the Hepatitis B vaccine had been given to the baby before they were discharged from the hospital where they were born. The hospital clinician used the electronic health record system (EHR-S) to document the administration of it and to electronically submit the patient’s immunization information to the jurisdictional IIS.

During this first well-baby visit, the pediatrician uses their office electronic medical record (EMR) system to query the jurisdictional IIS for the infant’s immunization history and forecast (NIST December 2020 article about the Forecasting for Immunization Test Suite (FITS) is viewable at: https://www.nist.gov/news-events/news/2020/12/nist-software-tool-improves-your-doctors-vaccination-advice) and sees when first Hepatitis B vaccination was given. Per the forecast, the pediatrician also sees that the next dose of that vaccine is due when the patient is 1-2 months old and asks the office nurse to schedule the next routine visit for when the baby is one month old.

When the infant is brought back to the pediatrician for the scheduled visit a month later, the doctor uses the office EMR system to query the IIS. The IIS responds by sending patient-specific information, including the prior administration of the first dose of the Hepatitis B vaccine and the recommendation to administer the second dose of that vaccine now. In addition, the forecast shows that the first doses of the Rotavirus, DTaP, Hib, PCV, and IPV vaccines are due when the baby is two months old. The second dose of the Hepatitis B vaccine is given to the infant, and the clinician uses the office EMR system to document the administration and to submit the immunization information to the IIS. An appointment is made for the parent to bring the baby in for another routine visit in one month.

At this point, the information about both Hepatitis B vaccinations given to this infant is stored in the jurisdictional IIS and is available to all authorized clinicians who access that IIS to use it for immunization forecasting. Currently, in accordance with the decentralized approach to public health in the U.S., no national-level IIS exists.
Continued from page 26

NIST HL7 V2 Testing Tool

<table>
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<th>Patient Identifier</th>
<th>Patient Name</th>
<th>Tied Subsection</th>
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<th>Gender</th>
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<td>03/14/2009</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

When displayed in the DRF, the Dengue Immunization History and Immunization Forecast, these patient demographics data may be derived from within the received immunization message or the DRF patient record. When displaying demographics from the patient record, the DRF must be able to demonstrate a linkage between the demographics in the message (primarily the patient ID in F4-0.1) and the patient record used for display to ensure that the message was associated with the appropriate patient.

The data used for immunization forecasting is at risk, and a vaccination may be omitted or given at the wrong time. The NIST Immunization Test Suite is used to determine if HIT applications are capable of supporting the data exchange standards.

The American Recovery and Reinvestment Act of 2009 (ARRA), including the Health Information Technology for Economic and Clinical Health Act (HITECH), allocated over $25 billion for HIT investments and incentive payments. The incentive payments were allotted to hospitals and “eligible professionals” (e.g., office-based MDs) to help off-set the cost of adopting, that is, installing and using, HIT.

Part of the HITECH Act funding was used to set up and run HIT certification testing relative to data exchange standards that are legally specified by a division of the HHS. Some of the named standards were authored by HL7 work groups.

The NIST Information Technology Laboratory (ITL) has been supporting standards development and testing in the public health domain for over a decade, including: helping with development of HL7 V2 domain-specific implementation guides; helping improve writing of the basic requirements; and development of conformance testing tools for the CDC programs and HIT certification programs.

“Over the course of testing through the HIT certification programs, hundreds of HIT applications have been certified for conformance to public health messaging criteria using NIST tools such as the Immunization Test Suite,” said Snelick. “As ‘ONC Certified HIT Modules,’ these applications have successfully demonstrated the capability to generate HL7 V2 messages for transmission, and to process HL7 V2 acknowledgement and response messages received.”

AIRA and IIS Use of the NIST HL7 V2 Immunization Testing Tool

AIRA recommends that IIS use the NIST Immunization Test Suite to test their capabilities when they are developing and improving their utilization of the HL7 V2 data exchange standards. AIRA conducts assessments of how well the IIS are in alignment with the immunization community’s accepted standards and recommendations.

As part of the AIRA IIS Measurement and Improvement Initiative, the results of the assessments are published on a quarterly basis. For Q4 2020, the Submission and Acknowledgment Assessment Aggregate Report 2020 and the Query and Response Assessment Aggregate Report 2020 were published. The assessment results reported show definite improvement in the ability of IIS to communicate with HIT such as EMR systems.
COVID-19 Vaccinations and Use of the NIST HL7 V2 Immunization Testing Tool

NIST currently is in the process of working with immunization domain experts at the CDC in development of test cases related to COVID-19 vaccination messages. The intent is that these test cases will be used for measuring the ability of HIT to generate HL7 V2 patient immunization information messages for COVID-19 vaccine administration. This context-based (or scenario) type of testing will also provide clinicians and clinical informaticists several examples of valid computerized vaccination information messages specific to situations related to administration of the new COVID-19 vaccines – including documentation of first and second doses of the vaccines as well as a patient’s refusal of the vaccination.

The dataflow of patient immunization information for COVID-19 vaccinations is still being finalized by the CDC. Here is an example of the vaccination process that might occur with COVID-19 vaccines:

A patient comes to their primary care physician’s office to receive a COVID-19 vaccination. The physician uses their EMR system to query the IIS for immunization forecasting information to determine what dose of which vaccine is due to be given to this patient.

The IIS responds by sending patient-specific information, including that the first dose of the Pfizer COVID-19 vaccine was given 21 days ago at a mass vaccination site and that the patient is due to receive the second dose of that vaccine. This second Pfizer vaccine dose is given to the patient. The clinician documents the administration in the EMR system and electronically submits the immunization information to the IIS.

Now the information about both Pfizer COVID-19 vaccinations given to this patient is stored in the jurisdictional IIS and is available to all authorized clinicians who access that IIS to use it for immunization forecasting. Ultimately, the CDC and AIRA anticipate that IIS may collect the patient COVID-19 immunization information via electronic messages transmitted from HIT applications (including EMR systems and Vaccine Administration Management Systems (VAMS)) used in doctor’s offices, hospitals, pharmacies, urgent care centers, ambulatory clinics, COVID-19 mass vaccination sites, and emergency departments. With this information, clinicians would be able to use their HIT to forecast accurately what doses of which COVID-19 vaccines need to be given to their patients.
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<td><a href="mailto:markmcd@HL7.org">markmcd@HL7.org</a></td>
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### NON-VOTING MEMBERS

<table>
<thead>
<tr>
<th>Wayne Kubick</th>
<th>Mark McDougall</th>
</tr>
</thead>
<tbody>
<tr>
<td>HL7 CTO</td>
<td>HL7 Executive Director</td>
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<td>+1 847-842-4846</td>
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<tr>
<td><a href="mailto:wkubick@HL7.org">wkubick@HL7.org</a></td>
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Get Your Training Straight from the Source!

<table>
<thead>
<tr>
<th>Course</th>
<th>Format</th>
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<tbody>
<tr>
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<td>5/27/21</td>
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<tr>
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<td>7/15/21</td>
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Schedule subject to change
2021 Virtual Meetings

HL7 FHIR Connectathon – Virtual
May 17 – 19, 2021

May Working Group Meeting – Virtual
May 24 – 28, 2021

HL7 FHIR DevDays – Virtual Edition
June 7 – 10, 2021

HL7 FHIR Connectathon – Virtual
September 13 – 15, 2021

35th Annual Plenary & Working Group Meeting – Virtual
September 20 – 24, 2021

2022 Meetings

January 15 - 21, 2022
January 2022 Working Group Meeting
Henderson, Nevada

June 6 - 9, 2022
HL7 FHIR DevDays 2022
Cleveland, Ohio

September 17 - 23, 2022
36th Annual Plenary & Working Group Meeting
Baltimore, Maryland