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OCTOBER 2020

HL7® International

THE OFFICIAL PUBLICATION
OF HEALTH LEVEL SEVEN® INTERNATIONAL

NEWS

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Personal Health Train, FAIR and FHIR

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Plus: ONC Grant Update, Member Spotlight and much more!

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is the official publication of

Health Level Seven International

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Update from Headquarters

COVID-19 Takes a Heavy Toll

By Mark McDougall, HL7 Executive Director

The devastating toll that COVID-19 has had on families and economies around the world has been unprecedented in my lifetime. As of late September, there were over 33 million confirmed cases of COVID-19 and more than one million deaths. According to the World Bank's 238-page *Global Economic Prospects* June 2020 report, the pandemic is expected to plunge many countries into the deepest recession since the second world war and have a lasting impact on our economies for many years. The global recession is forecasted to last longer if countries fail to bring the pandemic under control. Unfortunately, with over 7.3 million cases and more than 209,000 deaths the USA is leading the way on what NOT to do. While the USA has about 4% of the world's population, the USA has accounted for 21% of coronavirus related deaths.

Given the real-world situation we are all facing, I view this article highlighting recent HL7 activities as small potatoes. However, let's pray and hope that "this too shall pass". In fact, let's also hope that HL7 may contribute to helping clinicians, care providers, and vendors improve the healthcare that is being provided to those in need.

Since COVID-19 continues to spread causing so many deaths, and without a reliable vaccine yet available, HL7 Board of Directors also made the decision to cancel for our working group meetings and HL7 FHIR DevDays through 2021. Instead, these events will be produced virtually.

Virtual FHIR Connectathon in May

I am pleased to report that the three-day event was a smashing success. The 667 participants were provided hands-on experience developing FHIR-based solutions and testing the exchange of data with one another. Kudos to Grahame Grieve, David Hay, Sandy Vance and our HL7 staff for producing the virtual event with general session presentations along with 35 tracks. We were thrilled to confirm that our HL7 FHIR connectathons are meaningful and successful in person or virtually.

Virtual FHIR DevDays in June

Producing a first ever virtual version of FHIR DevDays required our team to take a new approach and adapt the plans we had already made for a face-to-face format. This pivot required research of new platforms and execution of the best approach to deliver content and an experience that was as valuable as an in-person meeting and maintained the DevDays vibe.

Congratulations to our HL7 team for rising to the challenge and producing a well-received and successful event for 679 participants. Special thanks to Mary Ann Boyle for managing the HL7

staff on the aspects of the event planning and coordination of speakers from around the world. Since many components of the meeting production approach were first-time uses, we were thrilled that the event went smoothly and was well-received.

We would also like to thank our CTO Wayne Kubick as well as the Firely team, particularly Rien Wertheim and Marita Mantle-Kloosterboer, for their partnership in producing another successful event.

Virtual HL7 FHIR Connectathon and 34th Annual Plenary and Working Group Meeting

Highlights from our virtual events in September include:

- HL7 FHIR connectathon on Wednesday-Friday, September 9-11 attracted over 600 attendees
- Plenary program featured timely presentations from around the world, including:
  - Bernardo Mariano, WHO Chief Information Officer and Director of Digital Health and Innovation
  - Renato Sabbatini, PhD, FIAHSI, CEO, Edumed Institute, Co-Chair Education, HL7 Brazil, Sao Paulo, Brazil
  - Amy Abernathy, MD, PhD, Principal Deputy Commissioner and Acting CIO, US Food & Drug Administration (FDA)
  - Ken Goodman, PhD, Director, Institute for Bioethics and Health Policy, University of Miami
  - Chesley Richards, MD, Deputy Director for Public Health Science and Surveillance, Centers for Disease Control & Prevention (CDC)
  - Atul Butte, MD, PhD, Priscilla Chan and Mark Zuckerberg Distinguished Professor and Institute Director, University of California, San Francisco
  - Jennifer Khoe, MD, General Surgeon, Southern California Permanente Medical Group – Kaiser Permanente
- Over 25 work group convened productive meetings Monday-Friday, September 21-25

Despite the new challenges of producing a WGM virtually, we are pleased that the Plenary meeting, HL7 Work Groups and FHIR connectathon were all productive and successful. A sincere thank you to our work group co-chairs for their role in facilitating the virtual meetings

Benefactors and Supporters

We are pleased to recognize HL7's 2020 benefactors and gold members who are listed on page 21. Their support of HL7 is very much needed and sincerely appreciated. HL7 recognize sour 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 26-29, 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, counting our blessings and also finding time for enjoying plenty of hugs and laughter!

Member Spotlight on Stuart Myerburg

Professional Background

Stuart received a BA in history and psychology from Emory University in 1991 and a JD from Emory University School of Law in 1994. He began his career working as a law librarian for internet services at his alma matter where he maintained and develop the School of Law's first websites, which was one of the earliest academic web presences at Emory. While there, he also developed the Federal Courts Project, which provided web access to court opinions for seven federal circuit court of appeals. This marked the first time these opinions were made available to the public on the Internet, increasing traffic to the School's web site and dramatically boosting its visibility within the legal community.

Public Health

In 1997, Stuart became involved in public health when he began working at the Rollins School of Public Health of Emory University as the associate director for project management. While there, he supervised the web and application development team and developed the school's first web-based distance learning application, which allowed the school to move from a graduate certificate program to a full Master of Public Health (MPH) degree online. While there, he also collaborated with researchers and developed data collection applications and data warehouses for studies on topics such as influenza, pesticide exposure in individual's diets, the effects of Vitamin D and calcium on colorectal cancer, nutrition and physical activity, perimenopausal women and migraines, and cancer registries.

CDC

In 2010, Stuart moved to the Centers for Disease Control and Prevention (CDC) as a health scientist to continue his career in public health sector. Since that time, he was worked at the National Center for Immunization and Respiratory Disease (NCIRD)/ Immunization Services Division (ISD)/Immunization Information Systems Support Branch (IISSB). Stuart leads several projects, including:

- Project Lead for the Clinical Decision Support for Immunization (CDSi) Project – CDSi is the first implementation-neutral expression of the ACIP recommendations, increasing the accuracy and consistency of immunization evaluation and forecasting services and improving the ease of developing and maintaining immunization CDS products in the IIS, EHR, and HIE communities.
- Project Lead for a collaboration with the National Institute of Standards and Technology (NIST) – Support an interagency effort to create testing tools for data exchange protocols, conformance, and functional standards. This effort provides flexible tools for the immunization community to easily test their conformance to national standards, thereby improving interoperability and data quality.
- Project Lead for the Vaccine Code Set Management Service (VCSMS) Center – An initiative to provide targeted immunization community users and EHRs with comprehensive and consolidated mapping and translation services for vaccine and vaccine-related codes. The codes represent components of vaccine ordering, inventory management, barcodes, and the documentation of vaccines administered to patients and are managed by diverse governmental and non-governmental agencies such as CDC, the Food and Drug Administration (FDA), the American Medical Association (AMA), and GS1.

In addition, Stuart is now the team lead for the Informatics Team, which is responsible for the following areas:

- Immunization Data exchange and vocabulary standards, including the HL7 Implementation Guide for Immunization Messaging
- Clinical Decision Support for Immunizations (CDSi)
- 2D bar codes and related standards for vaccine products
- Vaccine ordering and inventory through the Vaccine Tracking System (VTrckS)
- Best practices guidance
- Business rules maintenance

- Collaborations with national and international standards and policy organizations, such as the Department of Health and Human Services' Office of the Chief Technology Office (CTO), the Centers for Medicare and Medicaid Services (CMS), the Office of the National Coordinator for Health Information Technology (ONC), Integrating the Healthcare Enterprise (IHE), and Healthcare Information and Management Systems (HIMSS)
- COVID-19 pandemic response activities to prepare for distribution, administration, and electronic data exchange of vaccine information in response to the pandemic

HL7 Activities

Stuart became a member of HL7 in 2010 and is actively involved in the Public Health Work Group. He manages a team that provides technical support for HL7 messaging and vocabulary standards, develops and maintains the HL7 Implementation Guide (IG) for Immunization Messaging, and ensures that information and code sets that support the needs of the HL7 standard are maintained, updated, and align with industry standards.

Personal Life

Stuart grew up in Cape Coral, Florida but moved to Atlanta, Georgia for college and has lived there since 1987. His roommates include two cats, Farley and Montgomery. A third cat who he likes to call Nandor lives outside and has decided it's his home, too. 12

Stuart enjoys art, film and live music and will travel for any and all of them, especially for a concert of music festival. He especially loves international travel. He originally planned to visit art exhibits in London and the Primavera Music Festival this year but has shifted them to 2021 due to the COVID pandemic. In addition, Stuart has had a side gig as a DJ ins the early 2000s. He has a regular gig on Friday nights, which has become a virtual event during COVID times. He grateful that today's technology allows for him to continue his pursuits.

News from the HL7 Project Management Office

ONC Grant Funded Project Update

By Dave Hamill,
Director, HL7 Project
Management Office

Confluence/Jira and the Project Scope Statement (PSS)

The PMO and TSC members have teamed up to assist HL7's Application Manager, Josh Procious, in creating the PSS template in Jira. Ultimately, this will be the foundation of a new project database and will replace Project Insight and the associated "HL7 Searchable Project Database".

As part of the work, the team is reviewing every field on the PSS to determine whether it should remain on the new template or can be removed. Expect to see a more streamlined, shorter PSS template in the future.

The goal is to pilot the Jira PSS in Q4 2020. Until then, PSS's should still be created within Confluence and can be viewed at https://confluence.hl7.org/display/PSS/Project+Scope+Statement.

Zoom Migration/Rollout

In January, HL7 began its interest in providing work groups a replacement for FreeConferenceCall.com for their conference call/screen sharing needs. In February, we settled on Zoom; in March, the rest of the world did too!

COVID-19 certainly has presented a unique turn for our planned migration to Zoom, but nonetheless, we are persevering and working our way through the obstacles. However, we've been able to provide dedicated Zoom accounts to 16 work groups that are 'heavy users' (those that have many conference calls per week).

After successfully piloting three shared Zoom accounts for work groups that meet once per week or less, we rolled out the pilot to the rest of the work groups. Now any work group can utilize Zoom for their calls if they choose to do so.

ONC Grant Funded Project Update

Work continued on projects funded by the Office of the National Coordinator for Health IT's (ONC) 2020 $1,360,000 grant for Maturing C-CDA and FHIR standards. As of Q3, 2020, efforts underway included the following:

1. Implement the Unified Terminology Governance (UTG) process and tooling
2. Complete improvements to the FHIR Jira ballot process
3. Continued support for FHIR IG publishing and balloting processes
4. Continue to provide administration for the FHIR Connectathons
5. Continue work on Bulk Data Access and Push
6. Produce additional HHS/ONC FHIR fact sheets and other educational material
7. Publish errata to the US Core Implementation Guide
8. Continued support for the FHIR Terminology Server
9. Support for the HL7 FHIR build and implementation guide publishing tasks
10. Conduct a survey to inform the ONC about the current and envisioned uses of the HL7 FHIR standard
11. Perform enhancements to the FHIR Registry
12. Conduct additional C-CDA Implementation-A-Thons
13. C-CDA R2.1 Value Set Updates
14. C-CDA Web Publishing Tool - Phase 2

HL7 appreciates ONC's continued support of C-CDA and FHIR for 2020 and beyond. ■

For more information:

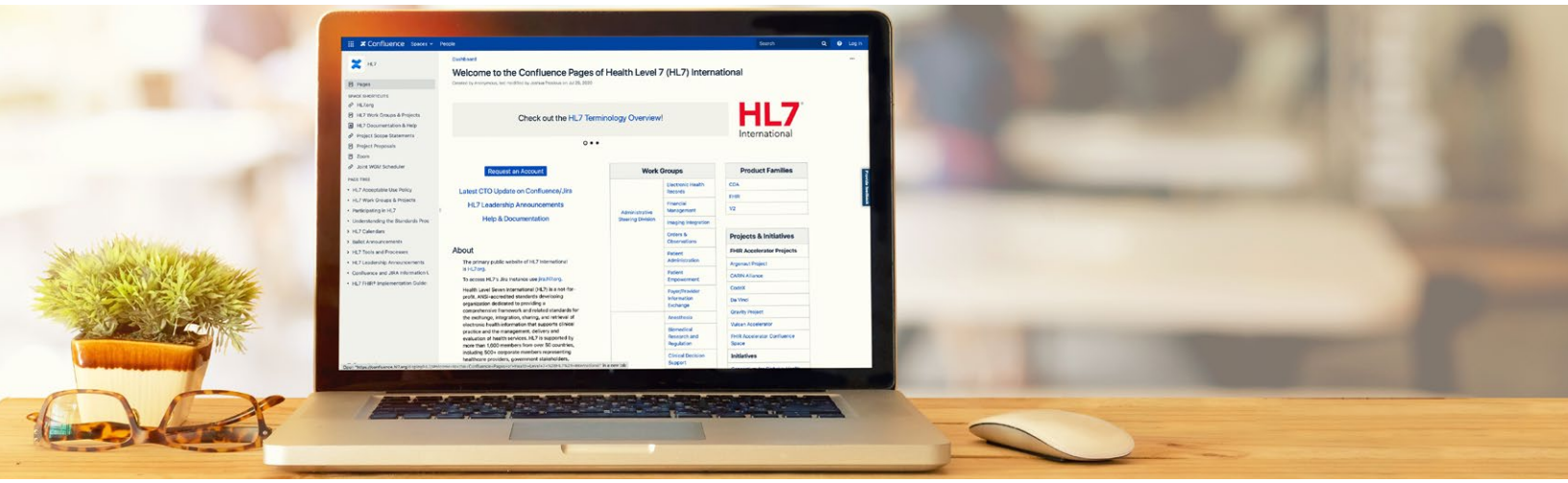
Details and deliverables for the above ONC funded projects can be found on HL7's Confluence space at:

who.int/nmh/publications/be-healthy-be-mobile/en

HL7 Standards Approved by ANSI Since April 2020

Name	Designation	Date
HL7 Version 3 Standard: Shared Messages, Release 3	ANSI/ HL7 V3 COMT, R3-2010 (R202	4/27/2020
HL7 Version 3 Standard: Patient Administration; Person Registry, Release 1	ANSI/HL7 V3 PAPRSNREG, R1-2015 (R2020)	4/27/2020
HL7 Version 3 Standard: Implantable Device Cardiac - Follow-up Device Summary, Release 2	ANSI/ HL7 V3 IDC, R2-2013 (R2020)	4/27/2020
HL7 Cross Paradigm Implementation Guide: UDI Pattern, Release 2	ANSI/HL7 IG UDI, R2-2020	6/24/2020
HL7 Electronic Health Record System Functional Model, Release 2.1	ANSI/HL7 EHR, R2.1-2020	6/30/2020
HL7 Version 3 Standard: Regulated Product Submission, Release 2	ANSI/ HL7 V3 RPS, R2-2015 (R2020)	7/27/2020
HL7 Version 3 Standard: Privacy and Security Architecture Framework, Release 1	ANSI/HL7 V3 PSAF, R1-2020	7/28/2020
HL7 Version 2.6 Implementation Guide: Newborn Screening for Critical Congenital Heart Defects (CCHD), Release 1	ANSI/HL7 V26 IG CCHD, R1-2020	8/3/2020

Benefactors



Tooling Update

Doing Less, But Better

By Wayne Kubick,
CTO
HL7 International

For many of us, this desperate pandemic year has led to plenty of introspection. This has also been true for the HL7 Board, which has been contemplating the future of the HL7 organization after emerging from the current crisis.

Among a set of core principles adopted by the Board are agility and focus. To be agile, we need to simplify and refine the organization and core processes, as well as provide support with continued improvements to our tooling.

This also requires getting our global community to better understand and use the processes more consistently and effectively, so we can better focus on our core work of developing and implementing interoperability standards. Which is a perfect segue back toward my long-held core belief in essentialism.

Back to Basics

I first espoused the concept of essentialism to an enthusiastic Board and Technical Steering Committee back in 2016. While we've only made small incremental progress in the four years since, it has been guiding our process improvement and tooling initiatives.

Essentialism was a driving force behind our adoption of Confluence and JIRA as well as efforts to simplify our product portfolio. Of course, we operate in a complex field, and there were many confounding forces acting at the same time. The HL7 community is more adept at introducing new processes, tools and content than at retiring or eliminating the old stuff. Thus, our commitment to essentialism faded over time, tempered by inertia and continuing demands, not the least of which has been the black swans of 2020.

Perhaps it's time to once again review the key elements of essentialism and discuss how it fits with our ongoing tooling strategy and plans.

Essentialism at HL7

To paraphrase author Greg McKeon, Essentialism can be summed up as the disciplined pursuit of less by learning to discern what really matters most and eliminating everything else. Among its principles are:

- A commitment to simplicity and clarity in thought and actions
- Prioritization and choice: If it isn't a clear "hell, yes!" – then it must be a clear "no" – there is no in-between. We must recognize that we can do anything but not everything, so we must be ready to aggressively purge whatever impedes the path forward
- Replacing habitual but faulty assumptions with three core truths: 'I choose to', 'Only a few things really matter', and 'I can do anything but not everything'

All of these require a major change in our thinking and our cultural attitudes. In the words of James Clear, "Progress requires unlearning." In order to move ahead more dramatically, HL7 needs to leave behind much of our past, even when we have invested so much sweat equity in that past. All of us must develop the courage to, as Stephen King once said, "Kill your darlings." Once we have accomplished that, we can focus on the essential few, instead of struggling to hack our way through the many trivial items that distract even the most wizened of HL7 veterans—while perplexing and frustrating many others who we'd like to get more engaged in our community.

HL7 Tooling Update

Now that we've reviewed the basics of essentialism, we can return to the core topic of HL7 tooling. While we have continued advancing multiple tooling initiatives since my last tooling update (http://blog.hl7.org/hyl7_tooling_update_spring_2020), 2020 has been largely dedicated to completing the transition to major programs like Unified Terminology Governance (UTG) rather than introducing many additional new initiatives. In addition, we have transitioned to Zoom as our primary web meeting environment, completed migrating content to Confluence, and introduced incremental improvements like a new document storage system integrated with Confluence. We have also made significant improvements to the FHIR IG publisher, expanding its scope as our backbone publishing tool to support UTG and the Consolidated Clinical Document Architecture (C-CDA). Furthermore, we're on the verge of releasing a new FHIR Registry update that will greatly increase our ability to search and reuse implementation guides, resources, profiles and extensions. Since new features and capabilities are being rolled out almost every month, it's much more practical to rely on the regular tooling and process updates posted at the CTO Tooling Update page in Confluence.

As I indicated in my last update, 2020 is our time for JIRA. Our timing has slipped a bit, but we're now close to completing the transition to JIRA for tracking and to replace the old STU Comment website page. Our plans to use JIRA as the standard platform for recording and resolving ballot comments and liberating us from the tyranny of spreadsheets has also slipped and is now scheduled for piloting in the January cycle. Nevertheless, we're determined to roll out the new JIRA-based workflow this summer, followed by workflow-enabling the other forms that drive our standards processes.

Moving Together as One

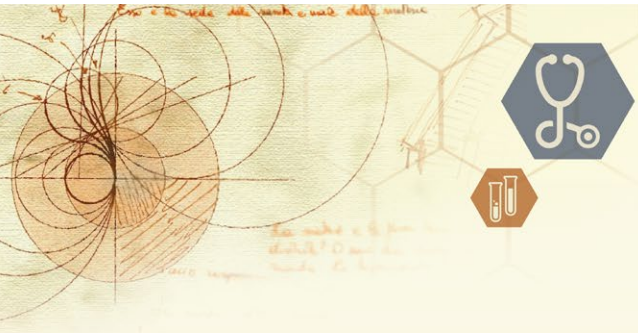
Another James Clear precept is "Living with a bias toward action," which we will continue to acknowledge by moving ahead, recognizing we'll have some indigestion along the way before fully emerging as a healthier, more focused and agile HL7.

And a commitment to essentialism, to eliminating the trivial many in search of the vital few, is not a concession to indolence, but a conscious recognition that we can only do the right things correctly by focusing on the vital few, and aggressively eliminating the rest. Adding new tooling won't make a difference unless we can focus on doing the right things with agility. For the HL7 community, this includes:

- Continuing to refine Confluence as the single, essential source of truth and learning and not just using it as a storage closet
- Aggressively retiring or archiving outdated, conflicting, or distracting information on our website and wikis that confounds understanding of essential processes with clutter
- Incorporating visuals to emphasize the most essential key points, along with hyperlinked drill downs to the details
- Introducing new, quick, training capabilities to help membership understand those essentials, based on short summaries, tip sheets and five-minute webinars
- Asking the community – and especially those in leadership positions – to take a bit of time to review those essentials, commit to them, attest to having read them, and trying to forget much of the rest

For HL7 International to adapt to a brave new future, a commitment to essentialism will be fundamental to the success of our retooling and processing programs – and toward achieving our critically important vision of "A world in which everyone can securely access and use the right health data when and where they need it."

In a troubling uncertain world that needs HL7 more than ever, now is the time for us to take these steps forward together.



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hl7.me/davincinews

Implementation Guides Progress

Community Roundtables Advance the Use of FHIR

By Fred Bazzoli,
Communications Co-Lead,
HL7 Da Vinci Project

The HL7 Da Vinci Project continues to make strides this year to find ways to use the HL7® Fast Healthcare Interoperability Resources (FHIR®) to use the standard to enable data exchange that will support the shift to value-based care.

The multi-stakeholder initiative—one of the HL7 FHIR accelerator programs intended to improve the uptake of FHIR in the healthcare industry—has identified particular use cases for the standard, and several of its members have been working hard to implement code to solve vexing information exchange problems.

The Da Vinci Project's work has accelerated as it seeks to develop implementation guides for the use of FHIR to meet information exchange requirements included in recent final regulations released by the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health IT (ONC).

The project has hosted a series of community roundtables this year with the intent of illustrating members' progress in implementing use cases to solve business problems.

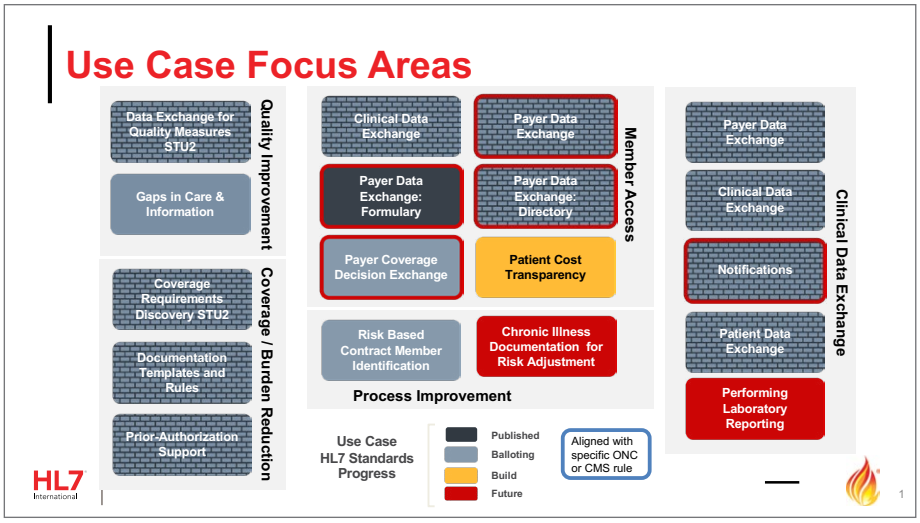
One of the roundtables described the efforts to improve data exchange on quality measures in a collaboration between Cigna, healthcare technology vendor InterSystems and Rush

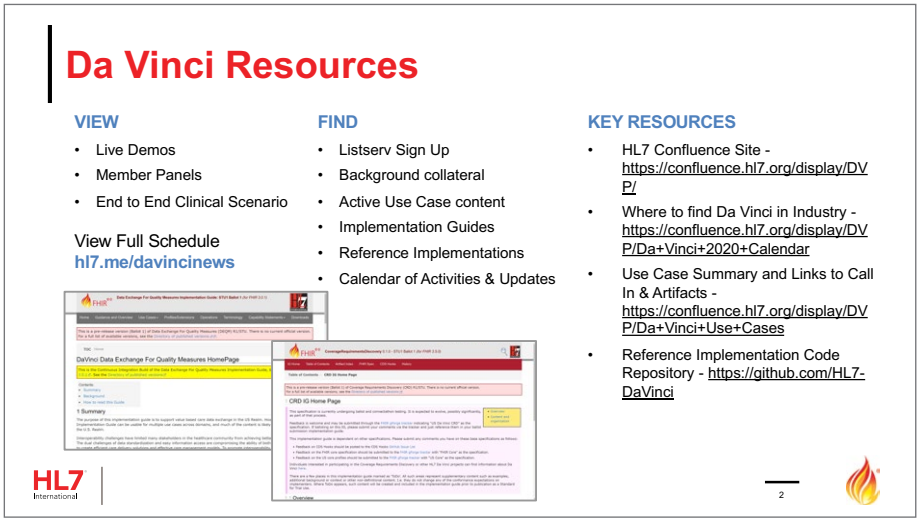
Health, a clinically integrated network of healthcare providers and hospitals in the Chicago area. While FHIR connectivity had not been implemented in live production systems as of that date, the organizations had tested functionality in a non-production environment and continue to work, committing to regular meetings and consistent communication on the project until the scheduled go-live.

The organizations are implementing the Da Vinci Project's Data Exchange for Quality Measures (DEQM) use case with the goal of using it to initially share information on three quality measures – medication reconciliation, high blood pressure control and colorectal screening.

Another recent community roundtable showcased work that is continuing on applications that can seamlessly deliver healthcare data to consumers using application programming interfaces (APIs) to pull data from payers' information systems. CMS will require payers to make claims payment data and other patient or member clinical information available to consumers with no obstacles, ideally through simple apps that query for, gather and organize the data in meaningful ways that create value for the user.

The CMS implementation resources for the pending rules mentions several implementation guides developed by the Da Vinci Project to meet the regulations: Payer Data Exchange: Provider Directory (Plan-Net) to share details on available providers and pharmacies for a particular plan design, Payer Data Exchange for payers to share clinical data, and access to clear formulary information to support patient choice capabilities regarding prescription drugs and potential purchasing alternatives through Payer Data Exchange: Formulary. The use of FHIR can help standardize approaches for achieving the requirements, noted John Kelly, principal business advisor at Edifecs, a technology vendor working on developing and testing the implementation guides that detail how to use the standardized FHIR standards.





Watch Recordings of the Da Vinci Project Community Roundtables Today!

Recordings of these and other Da Vinci Project community roundtable events can be found on the project's confluence page, by going to: https://confluence.hl7.org/display/DVP/Da+Vinci+Video+Presentations.

Likewise, information on the Da Vinci Project and work on developing use cases and supporting implementation guides are on its main Confluence page, https://confluence.hl7.org/display/DVP/Da+Vinci

Smarter Data on FHIR for Improved Cancer Care and Research

CodeX Community Stress-Tests the Value of a Common Language for Cancer Data

By Steve Bratt, Leader, CodeX FHIR Accelerator; Leader, Health Standards and Interoperability Group, MITRE

CodeX (Common Oncology Data Elements eXtensions) is an HL7 FHIR Accelerator, launched in late 2019, that is building a community to enable interoperable cancer data modeling and applications. The ultimate goal is to leverage standardized "smarter data" to enable step-change improvements in cancer patient care and research, as well as reduce burden and cost.

The *lingua franca* of the CodeX community is mCODE (minimal Common Oncology Data Elements), a FHIR implementation guide (IG) that became an HL7 Standard for Trial Use (STU) in March. The STU 1 status signals to vendors and other implementers that mCODE is stable and ready for testing. In fact, we are already seeing vendors implementing this version of mCODE.

Like other accelerators, CodeX's work progresses within projects based on specific use cases and workflows. We aim to have short development phases (3-6 months) with increasingly ambitious workflows and deliverables. Deliverables include FHIR IGs based around mCODE, reference implementations to show people how to use the IGs, pilots that validate the concepts and work, and adoption in commercial and open source products. To be successful, we ensured that all roles needed to execute a workflow are represented as participants in the CodeX projects.

Four use case projects are in the execution phase. A common theme throughout CodeX is to enable health systems to collect cancer patient data once in the EHR [NOTE: See slide for possible graphic], and then leverage these mCODE-based data elements to feed a variety of use cases using FHIR.

Let's take a deeper dive into two projects:

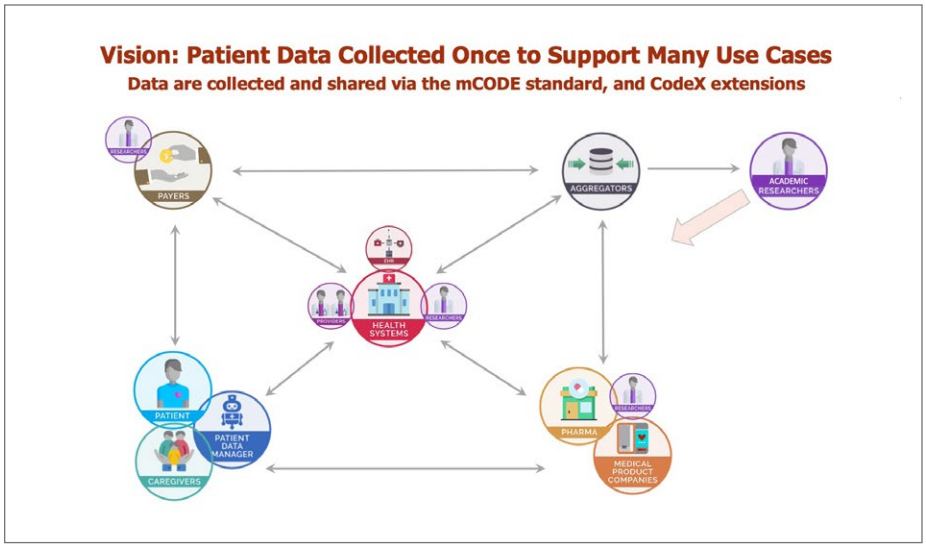
The most mature project is "Integrated Trial Matching for

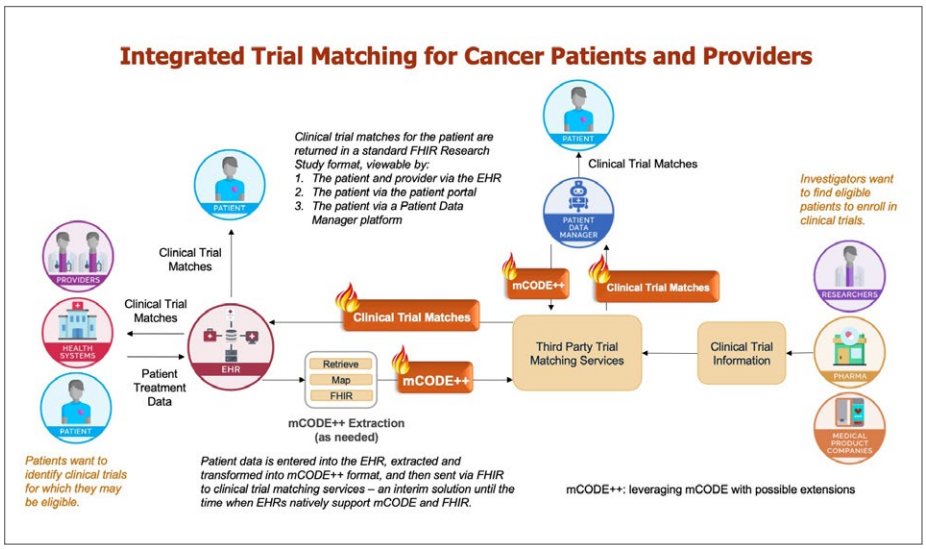
Cancer Patients and Providers." The American Cancer Society's Cancer Action Network, Cancer Insights, TrialScope, BreastCancerTrials.org, and health systems are collaborating to develop and pilot open data standards and APIs to access trial matching services, via a patient's EHR data, for possible matches.

The aim is to speed the process and provide a more equitable and comprehensive list of the best options for trials for review by patients and their oncologists. The first phase which includes a Proof of Concept using only mCODE data elements is nearly complete. The next public meeting and demonstration will take place on September 16, 2020.

Initial collaborators in the Cancer Registry Reporting project include the Centers for Disease Control and Prevention (CDC) and the Center for International Blood and Marrow Transplant Research. Health systems are being engaged now. Today, a cancer patient's data is reported to different registries for different purposes using different standards and channels (e.g., spreadsheets, forms, faxes, specialized messages). The vision is to replace this with a more efficient approach, using standardized, FHIR-based sharing of mCODE data and additions that carry patient data directly from EHRs to state cancer registries, research registries and other aggregators. The group aims to collaborate with other initiatives with similar aims.

Use cases in the planning phase include Radiation Therapy Treatment Data and Oncology Clinical Pathways as well as Prior Authorization Support,

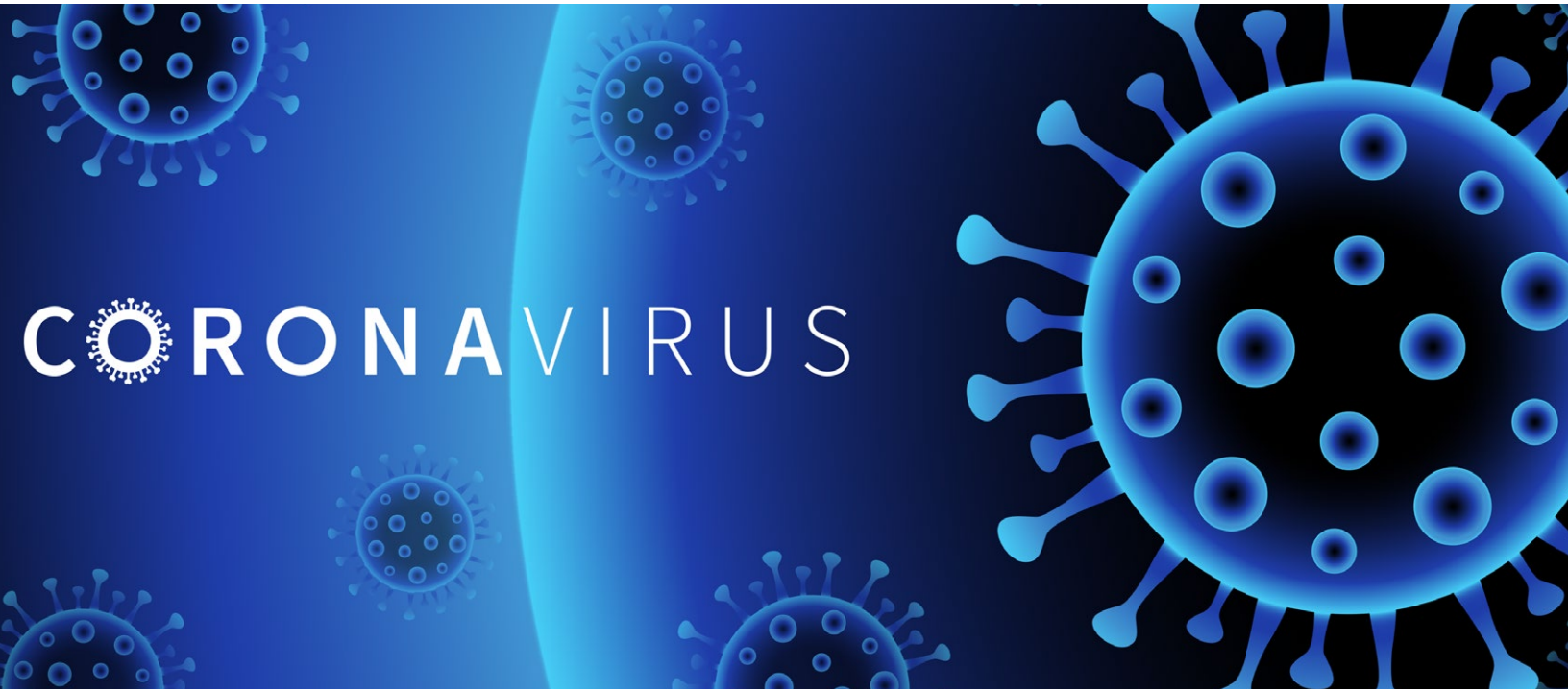




where we plan to work with the HL7 Da Vinci Project. Visit the CodeX Confluence page for launch announcements in the coming months, and to keep updated on all projects.

The CodeX/mCODE Community of Practice (CoP) has been an amazing forum. The CoP is open to the public as a place for sharing updates on CodeX use case projects as well as sharing independent initiatives that organizations are conducting with mCODE as their lingua franca. To receive notices about future CoP calls, go to the CodeX homepage, click on "Join a CodeX Listserv" (upper right side of homepage), and add your name and organization to the CoP and other email lists.

Many thanks to our Founding CodeX members! There are also a number of other organizations in the process of joining. Our first member meeting/call is being planned this fall. Please email me, Steve Bratt (sbratt@mitre.org), if you'd to like to become a CodeX member. Should you do so, you'll help drive the future of smarter data for the fight against cancer, as well as be part of a growing network of passionate and talented people driving the future of FHIR.



Multiple Stakeholders Join Forces

Germany-wide Standards for Coronavirus Data

Scientists across Germany are studying the novel coronavirus, SARS-CoV-2 and the disease it causes, COVID-19. To streamline research about the novel coronavirus, it is important to bring together findings and facilitate collaborative data use.

By Professor Dr. Sylvia Thun, Director of the Core Unit "eHealth & Interoperability," Berlin Institute of Health (BIH) and Chair, HL7 Germany;

Julian Sass, Master's student at the Core Unit "eHealth & Interoperability," Berlin Institute of Health (BIH)

Stakeholders from the German healthcare system have therefore joined forces under the Corona Component Standards (cocos) Initiative. The aim of the initiative is to establish common data formats and standards for data related to COVID-19 and SARS-CoV-2. University hospitals have agreed on a German Corona Consensus (GECCO) Dataset for use in a national research network against COVID-19.

Scientists throughout Germany are currently researching the novel coronavirus SARS-CoV-2. They want to find out how to keep the infection rate low; why some people get severely ill while others have only mild symptoms; how the virus affects the bodies of those who recover; and of course, what is the most promising route for treatment. A large number of organizations – institutes, universities, startup companies and government agencies – are gathering data, results and information, which are most valuable when shared. The Corona Component Standards (cocos) Initiative (http://www.cocos.team) seeks to ensure that the different approaches come together and thus become more effective.

"In order to reap the greatest possible benefit from the myriad data, it is necessary that they are

collected and stored in common formats and standards," explains professor Sylvia Thun, head of the Core Unit eHealth and Interoperability at the Berlin Institute of Health (BIH) and chair of HL7 Germany. "By using standardized languages like SNOMED and LOINC, the data cannot only be clearly interpreted, but also pooled Europewide, across national borders and used for research purposes."

The first task was to define what data should be collected and in what format. The team led by Professor Thun created a "consensus dataset" of COVID-19 patients for a national research network of university medicine to study COVID-19 funded by the German Federal Ministry of Education and Research (BMBF). The dataset contains all relevant information, starting with personal data like age, gender, height and weight, followed by lab results such as blood pressure readings or cholesterol levels, risk factors, medication use, as well as symptoms and therapeutic procedures performed. Julian Sass, a master's student working with Professor Thun at the BIH, reports that the team made fast progress: "Although we had to reach an agreement with more than 30 university hospitals on more than 80 core data elements, we needed just under three weeks to complete the data set."

Scientists throughout Germany…want to find out how to keep the infection rate low; why some people get severely ill while others have only mild symptoms; how the virus affects the bodies of those who recover; and of course, what is the most promising route for treatment.

The data elements were annotated with international terminologies (SNOMED CT, LOINC, UCUM, ICD-10-GM and ATC) using the ART-DECOR tool (the dataset can be accessed at https://art-decor.org/art-decor/decor-datasets--covid19f-). Subsequently, the HL7 standard Fast Healthcare Interoperability Resources (FHIR®) was used to define profiles for interoperable data exchange. When defining the FHIR profiles, care was taken to build on previous work where possible, especially the FHIR profiles of the Medical Informatics Initiative, a project aiming to improve data use and exchange across German university hospitals, and the basic FHIR profiles of HL7 Germany. The FHIR profiles of the GECCO dataset are published on the Simplifier platform at: https://simplifier.net/ForschungsnetzCovid-19.

The cocos Initiative was launched by the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KBV), the health innovation hub (hih), the Federal Ministry of Health (BMG) and Health Level Seven (HL7) Germany. Additional institutions and organizations in the health sector have since joined the initiative, including the Robert Koch Institute (RKI), the Federal Institute for Drugs and Medical Devices (BfArM), the German Institute for Medical Documentation and Information (DIMDI), the Medical Informatics Initiative (MII), the Network of University Hospitals, and the German Association of Health IT Vendors (bvitg). The number of organizations supporting the initiative continues to grow. ■

Version 2.5 Indispensable in Netherlands COVID-19 Fight

HL7 Supports Large-scale COVID-19 Testing in the Netherlands

By Robert Stegwee, PhD, Board Member, HL7 Netherlands; Independent Consultant in Health IT

As of June 1, all people in the Netherlands with mild symptoms of COVID-19 can get tested. On June 30, the national association of regional health centers announced that 250,000 tests had been administered. For a population of a mere 17 million, that is quite impressive. How did we achieve testing at this unprecedented scale? HL7 plays an essential role.

Testing for infectious diseases in the Netherlands is the responsibility of regional centers for public health (GGDs). Across the country we have 25 such organizations, jointly represented by their national association, GGD GHOR Nederland. Under normal circumstances, testing for infectious diseases is not such a big deal. The Centers for Sexual Health, part of the GGDs, reports 150,000 visits annually. The number of active cases of tuberculosis has not risen above 1,000 for the last couple of years.

Suddenly the GGDs were told to prepare for 30,000 tests per day, with a possible increase to 70,000 per day in the fall. This meant opening over 60 drive-thru testing locations, educating personnel on how to properly conduct the test, and opening a call-center to schedule appointments. The national number was called over 300,000 times on the first day alone.

All of these are major achievements in their own right. But where do you find the labs that can actually carry out the analysis at this scale? The required tests are PCR tests, which require rather advanced equipment. During the early stages of the pandemic, some 60 labs were accredited for SARS-CoV-2 virus detection, using the PCR test. In order to fill the projected numbers, all these labs were needed to pitch in.

So how do you process that many tests on a daily basis? GGD GHOR Nederland has chosen to develop one national solution for COVID-19 diagnostics, called CoronIT. The rationale behind this decision is that the available testing capacity needs to be allocated to the places where it is most needed. That won't work when you have to connect the existing 25 regional solutions with 60 different labs across the country. Even with one national solution, connecting 60 different labs is already quite challenging. Fortunately, we have HL7 well established in our labs in the Netherlands.

A dedicated first group of "pandemic labs" (normally working in other fields, such as veterinary labs or cervical cancer screening) had already established connections to the national CoronIT system using a highly simplified version of HL7 Version 2.5 messaging. Being pandemic labs, they were only commissioned to run the PCR analysis, and hence did not receive any patient information.

In times of crisis regular labs also assist the regional GGD in epidemiological analysis, so they go well beyond the technical analysis of the swab. They need fully functional clinical information exchange based on the full scope of HL7 Version 2.5 lab ordering and results reporting.

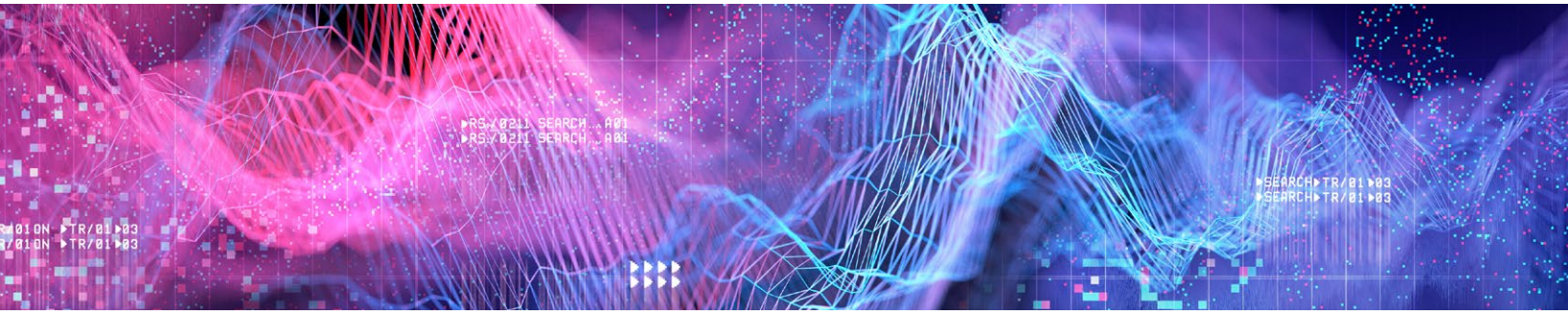
In the middle of April, a pilot implementation was launched to connect a COVID-19 lab to the national CoronIT solution. People at the lab, their laboratory information management system (LMIS) vendor and the team behind CoronIT worked closely together to make this happen. Luckily, they could build upon all the work on lab information exchange that had been done in the past by LIMS vendors, professional lab associations, HL7 Netherlands, IHE Netherlands and Nictiz (the national competence center for electronic exchange of health and care data).

Combined with recent experiences on routine reporting of antibiotics resistance data to the national Center for Infectious Disease Control and Lab2lab communications for national genetic typing of resistant bacteria, a solid community of expertise and trust could be engaged. The common understanding was, "We can do this!"

Before the pilot was actually in operation, other labs began to join the effort. The pilot was operational in early May and, by the end of the month, the first phase of 20 labs was connected to the national CoronIT system and ready for the June 1 launch.

Together with the dedicated group of pandemic labs, the testing capacity was sufficient to serve the needs of the population. Luckily, the numbers didn't rise to the predicted 30,000 tests per day, but instead have stabilized around 10,000 per day. However, as the country lifted more of the lock-down measures, preparations for an increase of up to the predicted 70,000 tests per day in the fall is ongoing. The next phase consists of another 20 labs that worked hard to get their connection up and running in July. In all, we will have connected 50 of the 60 accredited labs, including the pandemic labs, within the course of four months.

It is still a lot of hard work on all levels, from firewalls and character sets, using OML, ORU, OBR and OBX, by coding LOINC and SNOMED CT, all the way to contracts between regional GGDs and labs and the national funding of COVID-19 diagnostics. Without the dedicated community of expertise around IHE/HL7 lab information exchange in the Netherlands, we would never have been able to pull this off. The tried and true Version 2.5 has proven to be indispensable in the fight against COVID-19 in the Netherlands, because it has united people around a common purpose. In times of crisis, these people will roll up their sleeves and get the job done. ■



COVID-19 Generates Big Data Worldwide

Personal Health Train, FAIR and FHIR

Digitalization in the healthcare sector has resulted in an explosion of data—known as big data. Recently with the COVID-19 pandemic, nearly 12 million people have been found positive, of which more than 500,000 died.[1]

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Big Data and AI in Healthcare

These figures are massive, but what is even more enormous is the amount of data these 12 million patients have created. This is big data and most of the answers that scientist across the globe are looking for are actually hidden in the data itself.

Another example of big data can be seen with cancer. An estimated 18 million new cases and 9.6 million deaths were recorded worldwide in 2018 alone.[2] Considering each patient generates about 1-10 gigabytes of data, the total amount of data generated is about 200 petabytes!

In the last 20 years, electronics and computing devices have decreased in size but have significantly increased in processing power. One of the major benefits of this advancement has come in the form of artificial intelligence (AI) and machine learning technologies.

The healthcare industry is adopting and benefiting from these technologies. From surgery assisting robots, improved and accurate diagnosis in cancer, to personalized treatments and developing new medicines, AI and machine learning is causing a paradigm shift in modern healthcare. With machines that can predict, diagnose, comprehend and learn healthcare sector is empowered like never before.[3]

Data Exchange, Interoperability and Data Protection Laws

Big data and AI are the driving force in modern day healthcare innovation. However, the healthcare sector is far from harnessing the true power of AI. This is because big data is contained in silos that are:

- Located within hospital boundaries and not accessible for research – data exchange and
- Unstructured or poorly structured making them unusable outside the source organization – data interoperability

Lastly, even if we can exchange the data, we may not be allowed to due to data protection laws.

Historically, sharing and exchanging patient data has been guided by the institute which generated the data. In the modern digitalization era, individuals are increasingly becoming aware of the consequences of uncontrolled data sharing. This poses a threat to individual's privacy and confidentiality.

Governments are fast adopting policies and formulating laws that regulate the collection, use and sharing of personal data. Data protection laws in the United States, GDPR in Europe, PIPEDA in Canada, Data Protection Act (DPA) in the UK, China Data Protection Regulation (CDPR) in China, and the IT act in India all reflect the increasing global awareness regarding the importance of preserving data privacy and confidentiality.[4,5,6,7]

In popular discussion, this is often regarded as the *Health Data GoldiLocks Dilemma*—whether to share data or to protect privacy? Or do both? Sharing too little data will prevent care providers from quality clinical decision making. Next generation AI technologies will be starved and promises like personalized medicine will be repressed. Sharing too much data could lead to a possible violation of personal privacy and confidentiality. Trust in healthcare providers would be eroded and value created by healthcare data could be captured by third parties e.g., large technology companies.[8]

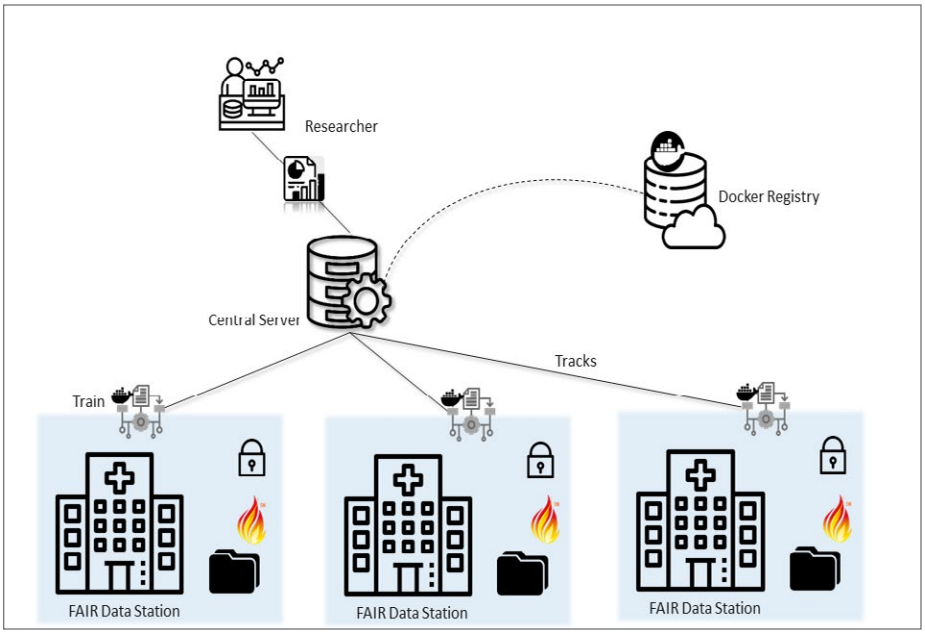

Figure 1: Personal Health Train architecture

Personal Health Train, FAIR and HL7 FHIR

In a world where we are restricted to collect and share data outside the source organization, we can share the analytics to the data. Current healthcare data sharing platforms are focused on performing queries on remote data sources and obtaining the results of these data queries.

The rationale of Personal Health Train (PHT) is that instead of requesting and receiving data, we are interested in asking a specific question and receiving a corresponding answer.[9]

PHT infrastructure is designed to deliver questions and algorithms which can be executed at the data source institutes. The entire execution is fully controlled by the data source institutes which means that interpretation and processing will happen at the data source institute as well, rather than at the receiving side. Hence, we are sharing only the necessary information about a patient instead of asking for data.

The metaphor train in PHT refers to the packaged algorithms and analysis script that are sent to the remote data source. Stations contain the FAIR (Findable, Accessible, Interoperable and Reusable) data and also provide a computation environment for executing the algorithms.

Finally, tracks are the communication channels and mechanism by which the researcher (who initiates the analysis and is looking for answers), the central messaging server and the data stations talk to each other. Figure 1 depicts a schematic diagram of the PHT with three FAIR data stations.

Although such an infrastructure would work in an ideal world scenario where there is semantic interoperability, we have to cater to a realistic situation. Hence, such an infrastructure where data stays at the source needs proper definitions of where we can find data (Findable), how we can access this data (Accessible), how we can

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Personal Health Train, FAIR and FHIR

interpret (Interoperable) the data available, and how we can (Re) use the data. This means that this infrastructure heavily relies on the FAIR principles.[10]

HL7 Fast Healthcare Interoperability Resources (HL7 FHIR®) as a clinical interoperability standard also establishes a strong relationship and identification with the FAIR data principles. The "I" (interoperability) in FAIR is the core concept in FHIR. FHIR provides a well-defined structure in the form of resources, profiles and extensions, which are the building blocks for ensuring syntactic interoperability.

FHIR also supports all major medical coding terminology standards (e.g., SNOMED CT, ICD, LOINC). Adopting coding terminology in describing health records is a key step in achieving semantic interoperability.

In addition, FHIR is built on top of a rich information model and is supported by rich metadata descriptions in the resources. Furthermore, with the FHIR API, it is possible to find and query patient data from remote servers.

Finally, it has been experimentally shown that PHT and FHIR can go hand-in-hand in achieving privacy preserving federated data analyis in healthcare. As a proof of concept, we designed a patient cohort counter to calculate the number of matching patients from two public FHIR repositories and calculated basic summanry statistics like mean age, mean BMI, standard deviation, age, and BMI relationship in patients diagnosed with both hypertension and diabetes.[11, 12, 13]

The entire process is executed without patient data leaving the source and is completely data agnostic. PHT relies on the metadata information and is independent of the actual data standard. This makes the PHT a generic infrastructure, independent of the (medical) specialty or research domain.

These proof of concept studies show a promising future where large scale clinical data from hospitals can be utilized and machine learning models can be trained for diagnostic as well as predictive analytics. PHT and FAIR data principles using HL7 FHIR as an interoperability solution has the potential to bring ground breaking research in healthcare.

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HL7 International

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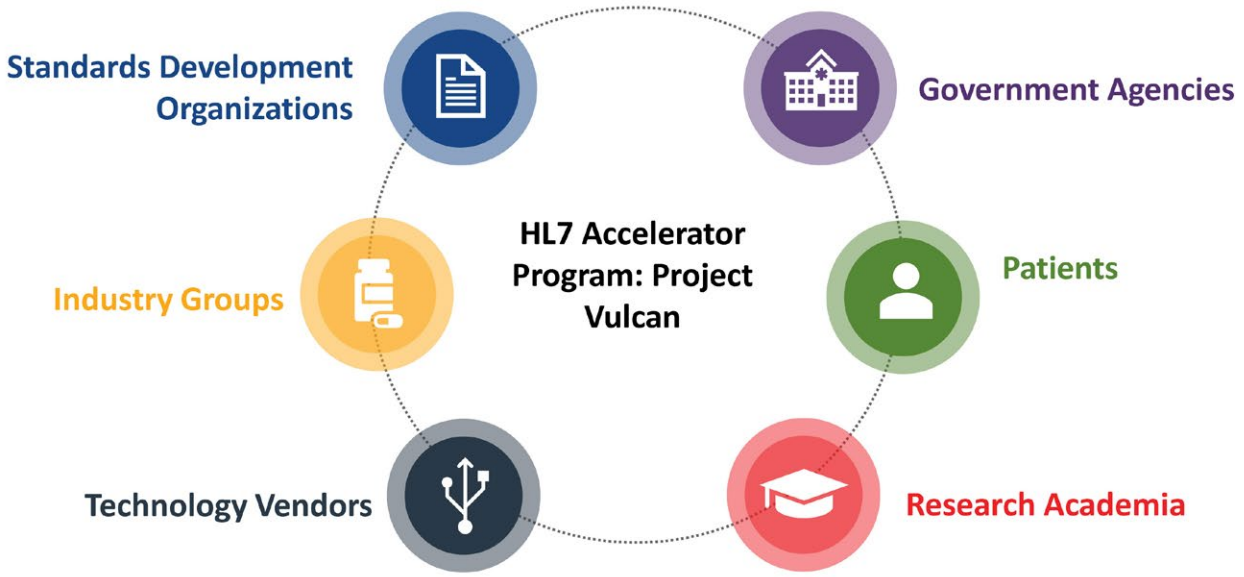
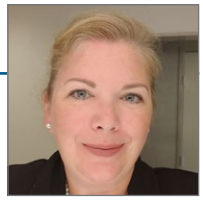
Vulcan HL7 FHIR: Who Are We?

Members of the Clinical and Translational Clinical Research Communities



Multi-Stakeholder Initiative Aims to Streamline Translational and Clinical Research

HL7 Launches Project Vulcan FHIR Accelerator Program



HL7 recently announced the launch of its newest FHIR Accelerator, Project Vulcan. HL7 seeks to use its widely recognized data exchange standards to help healthcare researchers more effectively acquire, exchange and use data in translational and clinical research.

By Amy (Nordo) Cramer, MMCi, RN, CPHQ, Co-Chair, Vulcan Steering Committee; Global Product Development Strategic Partnerships, Pfizer

The effort, called Vulcan, intends to use a model for collaboration among diverse stakeholders in the translational and clinical research community to define a common set of standards that can be implemented internationally, built on current agreements to use the HL7 Fast Healthcare Interoperability (FHIR®) standard to facilitate data exchange.

"Improving data sharing can bring significant benefits to medical research, which is often a time-intensive and costly process that unnecessarily delays progress in discovering treatments for medical conditions because researchers are unable to share critical information," said HL7 International CEO Charles Jaffe, M.D., Ph.D. "Project Vulcan aims to develop common solutions to help partners overcome these challenges."

The initiative is the latest that will use HL7's FHIR Accelerator Program, which seeks to strengthen the FHIR standard and enhance market adoption through a programmatic approach that diverse stakeholders can use. The Accelerator Program aims to motivate and support market collaborations, seeking to speed the availability of FHIR to tackle important interoperability needs. Project Vulcan represents an ambitious new use of the FHIR Accelerator Program, pulling together a diverse multi-stakeholder group that includes government and regulatory agencies, standards development organizations, academic sites, technology vendors and patients.

With the advent of FHIR there is a clear path to utilize FHIR and other existing standards to execute the interoperable exchange of data for clinical research.

"Using FHIR to assist translational and clinical research is a natural extension for the standard," said Rob Goodwin, co-chair of Vulcan and Vice President of Pfizer's Global Product Development Operations Center of Excellence.

"Delivering a new therapy to market now takes 10 to 15 years at an average cost of $2.6 billion," said Goodwin, who's also an ILT member of TransCelerate BioPharma, a non-profit organization that works across the biopharmaceutical research and development community to improve the delivery of new medicines.

"The most powerful way to make research faster and less expensive is to bridge clinical care and clinical research, while keeping patient safety and compliance in mind," said Amy (Nordo) Cramer, Vulcan co-chair and Pfizer Global Product Development Strategic Partnerships. Cramer continued, "Vulcan's contributions in using FHIR to streamline data collection and submission, protocol representation, clinical trial setup and management, and for other data-intensive purposes will be a game changer for clinical research."

Goals for Project Vulcan include:

- Bridge Existing Gaps: Work to close gap between clinical care and clinical research to improve patient lives, decrease costs and improve efficiency.

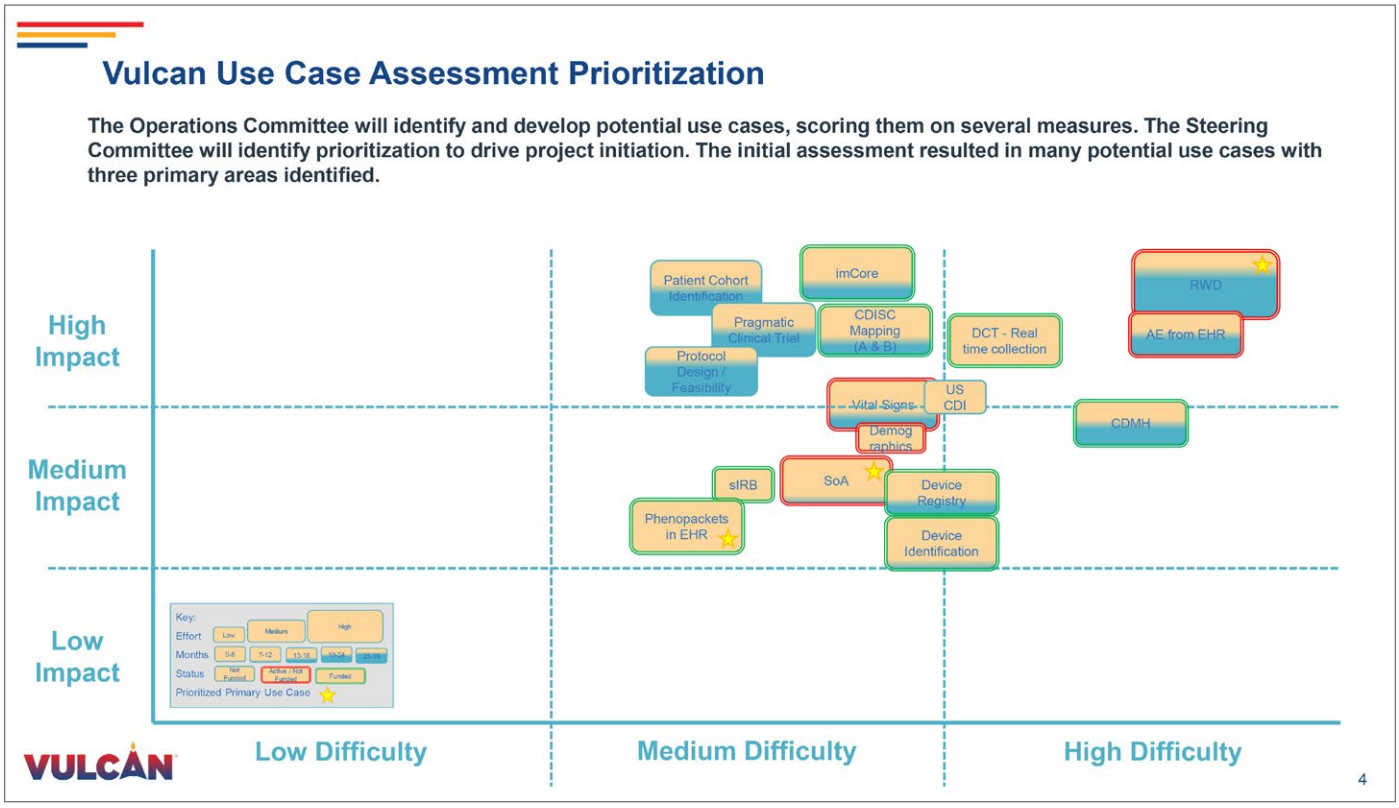
Convening Members of Vulcan

Continued from page 23

HL7 Launches Project Vulcan FHIR Accelerator Program

- Strategically Connect Industry Collaborations: Coordinate strategy between stakeholders and leverage existing work within HL7 and other groups.
- Maximize Collective Resources: leverage shared community and resources to be able to communicate the return on investment and return on value that a unified network could realize to various parties and provide comprehensive recommendations to global regulators.
- Deliver Integrated Tools and Solutions: Develop necessary FHIR Research Resources to maturity. Vulcan will handle identified and prioritized use cases for secondary use of EHR data that meet interested parties needs and goals

Organizers of Vulcan are encouraging other entities to participate in the effort. More information can be found on its website, www.hl7.org/vulcan.



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Vynyl

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Health Intersections Pty Ltd
Healthcare Integrations, LLC
Hi3 Solutions
HLN Consulting, LLC
iNTERFACEWARE, Inc.
IRIS Health Solutions, LLC
J Michael Consulting, LLC
Lantana Consulting Group
M*Modal, Inc.
Mathematica Policy Research
NYSTEC
Point-of-Care Partners
Professional Laboratory Management, Inc.
Ready Computing Inc.
Registry Clearinghouse
Rochester RHIO
Samvit Solutions
Scope Infotech, Inc.
Security Risk Solutions, Inc. (SRS)
Systex, Inc.
Telligen
Vernetzt, LLC
WaveOne Associates Inc.

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Academy of Nutrition & Dietetics
Agence eSante Luxembourg
Alabama Department of Public Health
American Academy of Neurology
American Clinical Laboratory Association
American College of Obstetricians and Gynecologists
American College of Physicians
American Immunization Registry Association (AIRA)
American Medical Association
Arkansas Department of Health
ASIP SANTE
Association of Public Health Laboratories
Australian Digital Health Agency
Baylor College of Medicine
Blue Cross Blue Shield Association
CA Department of Public Health
California Department of Health Care Services
CAQH
CDISC
Center for Medical Interoperability
Centers for Disease Control and Prevention/CDC
Centers for Medicare & Medicaid Services
Centre for Development of Advanced Computing
College of American Pathologists
College of Healthcare Information Mgmt. Executives
Colorado Regional Health Information Organization
CommonWell Health Alliance
Connecticut Department of Public Health
Contra Costa County Health Services
Council of State and Territorial Epidemiologists
Department of State Health Services (Texas)
DGS, Commonwealth of Virginia
DirectTrust
Duke Clinical & Translational Science Institute
eHealth Initiative
European Medicines Agency
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NAACCR
National Association of Dental Plans
National Cancer Institute
National Centre for Healthcare Information Systems
National Council for Prescription Drug Programs
National Institute of Standards and Technology
National Library of Medicine
National Marrow Donor Program
NC Division of Public Health
NCQA
Nebraska Dept of Health and Human Services
Nebraska Health Information Initiative (NeHII)
New York eHealth Collaborative
New York State Office of Mental Health
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NJDOH
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NYS DOH, Office of Quality and Patient Safety
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OCHIN
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Oklahoma State Department of Health
OR.NET
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Oregon Public Health Division
PCPI Foundation
Pharmaceuticals & Medical Devices Agency
Public Health Informatics Institute
RTI International
SLI Compliance

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United Network for Organ Sharing
United Physicians
University of AL at Birmingham
University of Arkansas Medical Sciences
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University of Minnesota
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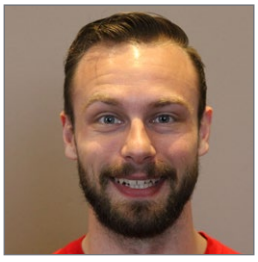

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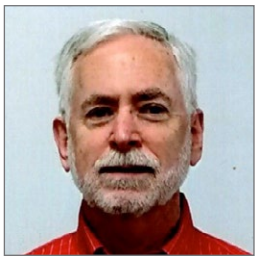

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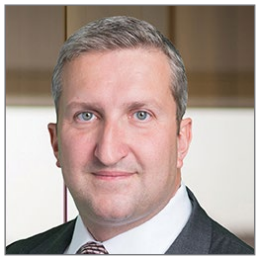

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