MAY 2019

International

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OF HEALTH LEVEL SEVEN® INTERNATIONAL

NEWS

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Healthcare Information Management on HL7 FHIR

Blazing a Path for Digital Clinical Research Using HL7 FHIR®

HL7® Launches FHIR® Accelerator Program

Point-of-Care Enabled Precision Medicine Service with GACS

HL7°FHIR°

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3300 Washtenaw Avenue, Suite 227 Ann Arbor, MI 48104-4261 USA Phone: +1 (734) 677-777 Fax: +1 (734) 6777-6622 www.HL7.org

Mark McDougall, *Publisher*Andrea Ribick, *Managing Editor*Karen Van Hentenryck, *Technical Editor*Kai Heitmann, *Photographer*

Update from Headquarters

HIMSS19 Became Known as "HIMSS on FHIR"

HL7 has exhibited each year at the annual conference of the Healthcare Information and Management Systems

Society (HIMSS) for 30 years. This year's HIMSS conference convened in Orlando, Florida during the week of February 11.

The opening keynote presentation at the HIMSS conference took place on Tuesday, February 12 and featured a panel of industry leaders who quickly articulated their support of HL7 Fast Healthcare Interoperability Resources (FHIR®).

Seema Verma, Administrator of the Centers for Medicare & Medicaid Services, highlighted the proposed rules that were released one day earlier on February 11, 2019. HL7 and its standards—such as FHIR—are central to

these proposed rules. For example, HL7 FHIR would be required as the standard for supporting all APIs under the ONC's proposal.

"The embrace of (HL7) FHIR APIs means that we're not going to have a Betamax-VHS fight in healthcare," said Aneesh Chopra, President of CareJourney and the first CTO of the United States.

Comments like these quickly led to the convention becoming known as "HIMSS on FHIR."



HL7 Executive Director

The HIMSS Opening Kenote Panel

Dedicated Volunteers

For decades HL7 has been blessed with incredibly dedicated volunteers and their support for the HL7 booth at HIMSS is no exception. I wish to express our appreciation and sincere thanks to the dozens of individuals who volunteered to staff our booth and/or make presentations in our HL7 booth at the HIMSS convention as listed below. This year's MVP award goes to Mary Kay McDaniel who provided the most hours of booth duty.

James Agnew
Calvin Beebe
Paula Braun
Mark Braunstein, MD
Michael Brody, DPM
Hans Buitendijk
Janet Campbell
Chris Carr
Patrick Combes
Durwin Day
Dave deBronkart
Gay Dolin
Richard Esmond
Howard Follis, MD
Dan Gottlieb

Michael Gould Grahame Grieve Michael Hansen, PhD Eric Heflin Chuck Jaffe, MD PhD Roman Jahnke Robert Jenders, MD Jocelyn Keegan Wayne Kubick Russ Leftwich, MD Carol Macumber Josh Mandel, MD Susan Matney, PhD David McCallie, MD Mary Kay McDaniel Patrick Murta
Lisa Nelson
Craig Newman
Viet Nguyen, MD
Philip Parker
Julie Rockey
Nikolai Ryzhikov
Kanwarpreet Sethi
Mark Schrimshire
Howard Strasberg, MD
Micky Tripathi
Isaac Vetter
Grant Wood
Pele Yu

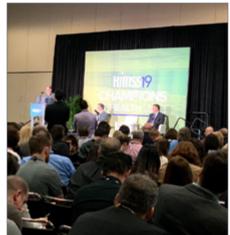
HL7 Exhibit at HIMSS

HL7's Director of Communications, Andrea Ribick, once again was exceptional at developing an attractive and functional booth for HL7 and producing 27 presentations **Andrea Ribick** on HL7 standards and relevant topics. Most of the presentations attracted crowds that filled the theater area and were standing room only. Presentations that attracted the most attendees were on:

- FHIR presentations (7)
- Da Vinci Project
- Argonaut Project
- CDS Hooks







In addition to presentations in the HL7 Exhibit, HL7 was also well represented at other HIMSS Sessions.



Above: Josh Mandel, MD, discusses CDS Hooks and HL7 FHIR to a standing-room only crowd at HIMSS19.

Second HL7 FHIR DevDays Event in the US will be on the Microsoft Campus

We are pleased to announce that our next HL7 FHIR DevDays event will occur June 10-12, 2019 at the Microsoft Conference Center in Redmond, Washington. Given the tremendous interest in HL7 FHIR during the HIMSS conference, along with the ONC's proposed rules requiring it as the standard for supporting all APIs, we anticipate that the June DevDays will once again sell out.

HL7 FHIR DevDays offers focused hackathons, 102 tutorials, six keynotes and plenty of networking opportunities. Experts from around the world will instruct, guide and discuss further improvement of the HL7 FHIR standard. Another valuable component of the DevDays event is that we provide a work room with over 30 tables organized by topic and supported by subject matter experts.

This event offers health IT professionals the chance to learn about FHIR in a collaborative environment. The DevDays pillars are education, sharing of ideas and networking, which create a unique opportunity to work with the specification surrounded by others doing the same thing, along with experts to answer any questions.



DevDays attendees will also enjoy an incredible outing to the Museum of Pop Culture (MoPop) in Seattle that features dozens of one of a kind exhibits that will certainly be a night to remember.

As a reminder, our June 2018 FHIR DevDays event in Boston sold out and over 100 were placed on a waiting list that were not able to attend. This year's meeting space is certainly larger, but we encourage you to register early to ensure you will be able to join the largest FHIR event in the US. For general information on the program and to register, please visit: http://www.hl7.org/events/fhir/devdays/2019/

For program content details, please visit: https://www.devdays.com/us/

Board Changes

As previously announced, we are pleased to welcome three new directors of the HL7 Board of Directors each serving two-year terms: Kensaku Kawamoto, MD; Janet Marchibroda; and Diego Kaminker. Melva Peters has also started a two-year term as the Secretary of the Board, and Walter Suarez, MD, started a four-year term that includes Chair-elect (or Vice Chair) for 2019, Board Chair for 2020-21, and Past Chair (or Vice Chair) for 2022.

During the January WGM, Board Chair, Calvin Beebe, welcomed the new members of the Board of Directors and also recognized the exceptional contributions over many years from these outgoing Board members whose terms concluded December 31, 2018:



Pat Van Dyke



Hans Buitendijk



Frank Oemig, PhD

We look forward to working with the new Board members along with the entire 2019 HL7 Board of Directors that are listed on page 42. On behalf of the entire HL7 organization, I thank each member of the HL7 Board for their ongoing leadership, contributions and dedication to HL7.



2019 HL7 International Board of Directors

January WGM and Payer Summit

We are pleased to report that 600 attendees participated in our January Working Group Meeting activities held in San Antonio, Texas January 12-18, 2019, at the Hyatt Regency San Antonio Riverwalk Hotel. Over 50 HL7 work groups met in San Antonio, of which 18 conducted co-chair elections. Attendees also took advantage of 26 tutorials that week, as well as the FHIR Connectathon and our annual Payer Summit—both of which were very well attended.

Benefactors and Gold Members

We are very thankful for the organizations for their ongoing support of HL7 through their membership at the HL7 benefactors and gold member levels, who are listed on page 30. Their support of HL7 is very much needed and sincerely appreciated. We are pleased to recognize our benefactors in all of our HL7 newsletters, on the HL7 website and at all of our HL7 working group meetings. A special thank you is extended to the list of firms that represent our 2019 HL7 benefactors and gold members.

Organizational Member Firms

HL7 is proud of the impressive list of HL7 organizational member companies listed on pages 30-32. We appreciate their ongoing support of HL7 via their organizational membership dues.

In Closing from the Home Front

While our oldest son is a mechanical engineer working at Bell Helicopter, our youngest will soon graduate from college and start working for a software vendor. Of course, we are very proud of both sons. However, I also have mixed feelings about officially becoming "empty nesters." The last 25 years have truly flown by so quickly. May you and your loved ones be blessed with the invaluable skill and discipline to smell the roses and enjoy each and every day.

Meeting Sponsors

I am also pleased to recognize the following organizations that sponsored key components of our January 2019 Working Group Meeting in San Antonio:

WGM Sponsors

- AEGIS
- Corepoint Health
- iNTERFACEWARE

Payer Summit Sponsors

- HULFT
- Virence
- Edifecs
- HealthLX
- Juxly
- · Lexigram

The sponsorship support provided by these organizations is much appreciated.



Process Points by PIC

Getting the Most from the 80-20 Rule

One of the core tenets underpinning the HL7 Fast Healthcare Interoperability Resources (FHIR®) specification and the culture of our FHIR community is the so-called "80-20 Rule." However, it isn't a rule at all, but rather a guideline (and not even part of the formal documentation). How that guideline is applied in practice has significant implications to the standard and the community. Let's take a few moments to explore this in a bit more detail, both to understand the context and how to best use this tool.

Part of the power in the HL7 FHIR standard draws upon long experiences from HL7 Version 3 (V3) work, which attempted to fully specify every nuance within the health domain. What we collectively learned was that such approaches were impractical and unsustainable, as there were countless exceptions to be managed and complexities to be addressed.

From this experience, when FHIR was conceived, the intention was established early to very deliberately address the core need, and leave disagreements, as well as nuanced and organizationally or geopolitically-specific requirements outside of the core specification. In addition, new and advanced use cases that do not yet have community endorsement can be trialed before coming forward for wider endorsement.

To complement the 80% "coverage" within the core specification, we defined an inherent extension mechanism to allow for requirements beyond those catered to by the standard to be specified and formalized. In this way, HL7 FHIR was "more implementable" and developer-friendly than V3 had been, yet still allowed for those exceptions and organizational or regional considerations to be addressed without violating the standard.

The result has been broad support and marketplace adoption.

So, what then is the problem?

Problems with the 80-20 Rule

There are varying interpretations about how the 80-20 rule is intended to be applied, which can result in disenfranchisement of HL7 stakeholders and lessened utility of the standard. Let's dispel some misconceptions.

The "80-20" Rule is not a rule; it is a guideline.
The intention of the guideline is to home in on

areas of broad agreement and support, and to include those within the core standard. In so doing, some deliberate decisions are made about content that varies among implementations. What implementations have implemented is an important input into this process since it measures what is real; however, it is not the only input.

The "80-20" Rule is about requirements, not clinical cases. The guideline says that we look for requirements "where 80% of implementations support a requirement or approach." This is inherently qualitative as it is not assessed scientifically, but it does convey an important intent. It does not mean that 80% of attendees vote for a proposal. Further, it does not mean that 80% of organizations will agree to a proposal nor that 80% of data instances will meet this requirement.

Our work group isn't sure whether a requirement falls within the 80% or not. What should we do?

Start by looking at other existing specifications. Finding elements that are common across other specifications is a good indicator of common use, making the candidate a more likely part of the 80%. It is also beneficial to consult the implementer community, both through work group meetings and through http://chat.fhir.org.

If there's continued uncertainty, the community best-practice is to define a standard extension and monitor HL7 FHIR Connectathons as well as early implementations for adoption patterns that would indicate promotion of the extension into the core specification.

I have a critical requirement; therefore, it should be part of the 80%. HL7 FHIR seeks to strike a balance between addressing the needs of systems implementers and pragmatic interoperability concerns while meeting health and healthcare business functional needs. There will be some critical requirements that will fall outside of the 80%, thus affirming the need for extensions. If a critical requirement is not widely implemented, it should be subject to considerable review as to the circumstance (e.g., newly documented safety concerns/recommendations, for instance). Critical requirements that are broadly accepted and recognized should be addressed in the core standard.

A decision has been made about something being excluded from the core specification. How do we revisit that? We need to strike a balance between moving work forward (not constantly revisiting decisions already made) and being judicious and thoughtful about our work and continuous improvement. While immediately revisiting a decision is probably not appropriate, a periodic check-in on older decisions may be warranted, as market situations change, and needs evolve. For example, something that was a fringe use case a year ago may evolve into a mainstream need. When revisiting decisions, committees need to follow procedures for re-opening issues, as documented in their decision-making practices (DMPs).

Consideration should also be made as to the potential/likely impact on implementers, and whether such changes would be substantive. For instance, if the community has already standardized the use of an extension, they may prefer to retain that implementation mechanism rather than shift to a core element even if adoption patterns would justify the change. Implementer sentiment will be determined following the usual process for substantive change for any artifacts that have a maturity level of four or higher.

Note: Maintaining and curating a backlog of issues will allow for better identification and management of these needs as well as serve as indicators for when to revisit historical decisions. Work groups that feel that more implementation experience or time to measure adoption patterns is necessary before re-evaluating a decision can mark an issue as deferred. Such

items will automatically come up for review each time there's a new release of the specification.

Something's been included in the core specification, but I don't think it meets the 80% 'rule'. Can that be changed? Just as it's possible to move elements previously designated as extensions into the core specification, it's also possible to move elements out. Concerns about the inclusion of an element should be based on a belief about the lack of industry consensus and adoption rather than the behavior of any specific system or environment. Also, once a resource has gone normative, elements won't be removed from core.

I am not sure my work group chair is fairly applying the 80-20 rule. What should I do? There are several potential courses of action open to you. We recommend discussing the matter with the presiding chair, or other work group co-chairs. You may approach the FHIR Management Group or any of its members to request an independent assessment or raise the matter to the Process Improvement Committee to advocate on your behalf. Work groups need to strive for transparency and consistency around these rules, and any review will consider what process was engaged in when deciding not to include something in the core specification. Change proposals should specifically document pertinent facts considered when making the decision.

Note: This process point has been brought to you courtesy of the HL7 Process Improvement Committee. Our role is to help keep HL7 working smoothly, or to advocate on behalf of the membership to help address issues and concerns that are raised. We are available at working group meetings, or at pic@lists.hl7.org.

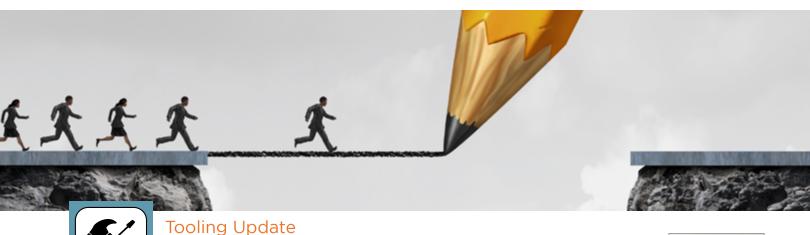
Special thanks to Grahame Grieve for his assistance and contribution to this article.

* * * * *

We encourage questions and comments:

By email to: pic@lists.hl7.org

or by post to our Confluence site: https://confluence.hl7.org/display/ PIC/WorkGroup+Home



Our ongoing tooling journey at HL7 continues, neither as a sprint nor a marathon. For us, it's really more like an odyssey—an ongoing journey where there is always something more to be done, another path to explore, and a final destination (retirement, for example) seems far out of reach. In the case of HL7 tooling, a fair number of tooling retirements are well overdue.

Neither a Sprint nor a Marathon



By Wayne Kubick, CTO, HL7 International

Despite the wait, it's gratifying to see when tangible progress is actually achieved. On the Confluence front, we're in the home stretch of phase 1 of the rollout, though there's a whole new course to pursue just around the bend. We now have all work groups on Confluence (!) and have also migrated many more projects, committees and collaborations. New functions and help features in Confluence (including a major facelift for confluence.hl7.org) are being added regularly, and you can keep up with these by checking the CTO Tooling Update page. This enabling platform is already unleashing many new opportunities within the HL7 community. Our next target is to work toward optimizing our processes with online forms and workflow. The online project scope statement (PSS) pilot is now underway and will give us an opportunity to speed up reviews

and approvals as well as make new projects more visible to the community in the hope we can avoid last minute catchups.

Having 1-click access to forms will help enormously, but we also need to broaden our thinking. For example, we want all project leads to recognize that it's important to declare the intention to begin a new project at the earliest stages rather than just before ballot. We need to see a more streamlined process to announce a new project at the earliest stage in order to allow those who want or need to participate to have the opportunity to jump in as well as to identify potential problems or risks before too much time is sunk navigating blind alleys. Because the Notification of Intent to Ballot (NIB) deadline is always too late. Early transparency leveraging the wisdom of crowds is critical to the operation of a healthy HL7 community.

This brings our focus on another critical destination in our journey-making each of these new collaboration tools excel as a single source of truth. For Confluence, this will encompass not just meeting agendas and minutes, but also provide quick and easy access to all the information the committee needs to sail through the HL7 processes, including a new online handbook, precepts, TSC guidance, forms and FAQs all one click away. Like the rest of our move, it means a search and destroy operation to remove all redundant, obsolete or inaccurate versions that can generate so much confusion and frustration. We want a simpler, leaner, more shipshape organization carrying us on this journey.

For JIRA, we're beginning to implement solutions based on JIRA workflow, with Unified Terminology Governance process (UTG) entering a pilot stage with a goal to replace harmonization within a year, and for online forms like the PSS. The Fast Healthcare **Interoperability Resources** (FHIR®) community is already migrating issue tracking to the more robust JIRA environment, recognizing that building comfort and familiarity with JIRA is a useful prerequisite to making the transition to JIRA balloting. We still expect to begin balloting in JIRA later this year once we complete our system testing. Also, as mentioned previously, we'll be using JIRA and Confluence to replace many other feedback, FAQ and support systems.

Another priority of the tooling roadmap is web publishing on microsites, which will become increasingly common in the future for other standards in addition to FHIR and Clinical Quality Language (CQL). Current efforts are under way to publish CDS-Hooks, Clinical Document

Architecture (CDA®), Consolidated CDA (C-CDA), UTG terminologies and even Version 2 as web pages, among many others.

A less visible but critically important effort has been led by our Webmaster, David Johnson, on moving HL7 systems to the Cloud. This effort has been made possible through the support of Amazon Web Services. This increases reliability, scalability and performance for the basic activities of HL7, just as the support we've gotten from Google Cloud has achieved similar benefits in hosting FHIR servers. These advances, like so many, are made possible due to the generous support of HL7 members.

Making the Switch

Some have asked about whether we plan to sunset GForge and MediaWiki. Recognizing how difficult it is to migrate decades of content, we don't have plans to sunset either of these tools in 2019.

However, moving forward, we would prefer all new committee content to be created on Confluence instead of MediaWiki. Once the dust settles in moving from Tracker to JIRA later this year, we'll be encouraging all work groups to forbear from creating new content in GForge.

Upcoming Destinations

Meanwhile, we're continuing to move along a new series of projects to improve our tooling for standards development, with the help of ongoing funding support from the US Office of the National Coordinator for Health IT (ONC). Projects to re-engineer FHIR publishing and replace the ballot systems are already underway. We will continue to issue new requests for proposals (RFPs) for assistance from the community through the contractwork@lists.hl7.org listserv. The journey continues, and glad to have you all along on the ride.

Upcoming International Events

May 26-29, 2019	www.e-healthconference.com	
e-Health Canada 2019	Toronto, Canada	
June 10-12, 2019 HL7 FHIR DevDays	www.fhirdevdays.com/	
	Redmond, Washington	
July 16-17, 2019 Australia eHealth Summit	www.himssasiapac.org/events/ australia-ehealth-summit	
	Sydney, Australia	
August 12-14, 2019 HIC 2019	www.hisa.org.au/hic/	
	Melbourne, Australia	
August 26-30, 2019 MedInfo 2019	www.medinfo-lyon.org/en	
	Lyon, France	

September 12, 2019	www.ehealthsummit.ch	
Swiss eHealth Summit 2019	Bern, Switzerland	
October 7-10, 2019 HIMSS AsisaPac19	www.himssasiapacconference.org	
	Bangkok, Thailand	
October 23-24, 2019 IHIC 2019	www.ihic.info/	
	Warsaw, Poland	
February 1-7, 2020	www.HL7.org	
HL7 February International Conference & Working Group Meeting	Sydney, Australia	

News from the HL7 Project Management Office

ONC Grant Funded Project Updates

Confluence/Jira and the Project Scope Statement (PSS)

Continuous improvement is happening for the Project Scope Statement within Confluence. The initial PSS template has been replaced by a Confluence 'form'. This replaces the existing template made from tables with a form containing dropdowns and checkboxes (both of which are dynamic) meaning, based on the information entered, the form will add or remove areas of the PSS. Logic has also been added to ensure required fields/information are provided when necessary.

The PSS review/approval workflow has been piloting since March. A centralized overview for each PSS is available in Confluence and includes the progress of approval, involved work groups, and links to the applicable Jira workflow. It can be viewed at https://confluence.hl7.org/display/PSS/Project+Scope+Statement.

The Jira workflow systematically alerts necessary groups that a project has been submitted to them for review. The group can approve, reject or request additional information from the project facilitator. Additionally, the workflow alerts the PMO of any stagnant review requests thus insuring a PSS proceeds smoothly and quickly through all the required approvals.

ONC Grant Project Updates

Work continued on projects funded by the ONC's \$1,360,000 extension of the grant for Maturing C-CDA and FHIR Standards. As of Q1, 2019, efforts underway included the following:

- Piloting the Unified
 Terminology Governance
 (UTG) process and tooling
- 2. Flat FHIR (Bulk Data & Push)
- Migrating FHIR issue/ project tracking and ballot reconciliation to Jira
- 4. Provide a coordinator to support FHIR implementation guide (IG) publication
- 5. Support FHIR Connectathons by providing an administrator
- 6. HL7 FHIR Product Director support
- Compare IPS & Argonaut US Core Implementation Guides
- 8. US Core Ballot Reconciliation Support
- 9. Create additional FHIR education
- 10. Continuing C-CDA
 Implementation-A-Thons
 (IAT) as tracks within
 FHIR Connectathons
- 11. Conduct a virtual FHIR
 Connectathon focusing on
 the Health Care Directory

Details regarding each project are as follows:

Unified Terminology Governance

The Unified HL7 Terminology Governance (UTG) Pilot project will develop a working demonstration pilot for UTG-based terminology maintenance system. It will also conduct beta testing and prepare for production in 2019, where UTG will replace Harmonization.



By Dave Hamill, Director, HL7 Project Management Office

Flat FHIR

Flat FHIR (Bulk Data & Push) will ballot the FHIR Bulk Data Implementation Guide (IG) in HL7's 2019 May ballot cycle. It will also develop a test suite and utility to verify vendor compliance with the bulk data spec Flat FHIR format, design a Bulk Data import approach, and maintain reference implementation by adding performance monitoring and user/traffic management.

FHIR Jira Ballot Process & Tooling Project

Work continued on the Improving the FHIR JIRA Ballot Process & Tooling project, including establishing how best to get information to participants without overwhelming them. It also included creating dashboards that allow users to quickly see relevant information, documenting the JIRA ballot process and completing and testing the MIF conversion process.

FHIR IG Publication Coordinator

The FHIR Implementation Guide (IG) Publication Coordinator role was created. Responsibilities will include monitoring the FHIR IG publishing and balloting processes, facilitating review/approval of the IGs that will be published in a given ballot cycle, and providing educational materials on processes related to the publication and balloting of IGs.

FHIR Connectathon Administrator

Funding for a FHIR Connectathon Administrator continued. This position was created to support the growing needs of HL7's FHIR Connectathons. The primary objective of the administrator is to maximize the participant's experiences and outcomes at the FHIR Connectathon, Responsibilities of the FHIR Connectathon Administrator include preparing a FHIR Connectathon communication plan, a pre-connectathon and post-connectathon survey; an orientation package for all track leads and an event report.

HL7 FHIR Product Director Support

Support for the HL7 FHIR Product Director continued in order to provide increased administrative support for standards development, publication and maintenance to facilitate the release of each new version of the FHIR core specification work as well as with other key FHIR subject matter experts to implement specific improvements for long-term, sustainable FHIR processes and tools.

Compare IPS & Argonaut US Core Implementation Guides

The Compare IPS & Argonaut US Core Implementation Guides project performed a comparison between the International Patient Summary and the Argonaut / US Core Implementation Guides. The primary deliverables were an HL7 white paper, ready for publication, containing a narrative description of the similarities and main differences of the two guides along with a detailed list of the differences in terms of FHIR resources used, required elements, vocabularies, constrains and REST interactions and operations.

US Core Ballot Reconciliation Support

The US Core Ballot Reconciliation Support project provided support for reconciliation and publication of the US Core Implementation Guide, based on FHIR Release 4 (R4), which was balloted in the January 2019 ballot cycle. That ballot added support for clinical notes, fixed errata logged since publication of release 3, and upgraded all the resources to support the FHIR R4 release.

Additional FHIR Education

Creating additional FHIR education will result in webinars and other learning material targeted for federal government project/program managers leading HL7 related projects. The deliverables will provide guidance on selection of FHIR releases, implementation guides and profiles to be used within projects.

C-CDA Impmentation-A-Thons

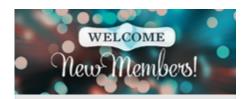
January's C-CDA Implementation-A-Thon was held as a track within the FHIR Connectathon. Discussion topics and notes from the IAT can be found at: https://confluence.hl?.org/display/ IAT/C-CDA+Implementation-A-Thon+Track+Agenda.

Virtual FHIR Connectathons

A Virtual FHIR Connectathon
- Health Care Directory
was held in December.
Documented discussions,
findings and conclusions
reached from each topic within
the event can be found at:

http://wiki.hl7.org/index.php?title=201901_vhdir.

As a final note, HL7 appreciates ONC's continued support of C-CDA and FHIR for 2019 and beyond.



HL7 Welcomes New Members

Benefactor

- CRISP
- Guidewell
- NewWave

Gold

- AbleTo, Inc.
- Audacious Inquiry
- Chorus Software Solutions
- Community Care HIE
- Community Care Network of Virginia, Inc.
- d-wise
- immutaMED, LLC
- Inovalon Inc.
- IRIS Health Solutions, LLC
- Prime Healthcare Management, Inc.
- Prime Therapeutics LLC
- State of New Hampshire

Organizational

- Adeptia Inc.
- Conéctate Soluciones y Aplicaciones SL
- Exscribe, Inc.
- Fleet Health
- Gillette Children's Specialty Healthcare
- MedEvolve, Inc.
- Mettle Solutions LLC
- Montefiore Medical Center
- MYHEALTH ACCESS NETWORK, INC.
- MyHealthcare Online Inc.
- · Secure Health Chain

Scenarios for Potential Election Issues and Their Solutions

Troubleshooting Co-Chair Election Problems

Over a year ago, we replaced our manual, paper ballot system for electing co-chairs at the working group meetings (WGMs) with Election Runner, an electronic polling/election tool. Overwhelmingly, the response to Election Runner has been positive, with most individuals reporting that the new process is both easier and faster.



By Karen Van Hentenryck, Associate Executive Director, HL7 International

- At the January 2019 Working Group Meeting, some individuals reported that they did not receive the invitation to vote in a co-chair election for which they felt they were eligible. Most of the reported problems were due to one of the easilycorrected issues outlined below:
- A member is subscribed to the work group listserv using a different email than the one attached to his/her member record.
 - One of the first criteria for determining who is eligible for a work group's co-chair election is whether any of the emails in our membership database match those on the work group listserv. If there is a match and the member was subscribed by the appropriate date, the email is added to the list of eligible voters. In about 98% of the cases where a problem is reported, this is the culprit. The only way to correct this problem permanently is to ensure that you are subscribed to all listservs using the same email address that is attached to your member record.
- 2. A non-voting member employed by an organization member is subscribed to the work group listserv using an email address whose domain differs from that of the organizational member. Let's say you are employed by Epic but subscribed to the listserv using a gmail account. This is essentially the same problem noted above. Since we are using email addresses to verify eligibility, you aren't going to be on the list of eligible voters because we can't verify that you are employed by Epic unless you use an email with the same domain.
- 3. You are a non-voting member of an HL7 organizational member and are subscribed to the work group listsery but register onsite.
 - Since one of the criteria for non-voting members to vote is attendance at the working group meeting you won't automatically be an eligible voter as we determine this prior to the start of the WGMs using our registration list. To correct this problem, come see me at the meeting or send me an email. Once I verify that you are eligible and have registered, I will add you to the list of eligible voters.

Your server rejects/won't accept the Election Runner invite. This happens infrequently, but it does happen. Election Runner sends me a note whenever one of the intended recipient's servers rejects the message. If possible, check with your IT staff in advance of the meeting to ensure that your server will accept emails from Election Runner. If I can verify your eligibility and you have a secondary (usually personal) email address, I can usually add you to the list of eligible voters and allow you to vote.

Election Runner is flexible, so

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Bringing Life-Saving Therapies to Market More Quickly

Blazing a Path for Digital Clinical Research Using HL7 FHIR®

Why Digitize Clinical Research?

Female cardiac symptoms differ from those of men. This is well known and published now, but a decade ago, knowledge of this was not as prevalent. That was when my mother had a myocardial infarction (MI). She arrived at the emergency department (ED) with signs that presented more like the flu than an MI, had no electrocardiograph (EKG) changes, and her troponins were within normal limits. Her cardiologist conducted an exploratory catherization which discovered major coronary artery disease. After angioplasty and a stent, she was released from the hospital.

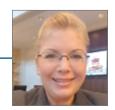
Disaster adverted, or so we thought. Within the week, my mother returned to the ED with more extreme symptoms. Again, the cardiologist conducted a catherization and discovered that despite the appropriate anti-coagulant/anti-platelet therapies, the stent had occluded. He saved her life

that day. However, no at-market medications existed to prevent the stent from re-occluding. Thankfully, there was a clinical trial for a new therapeutic that my mother could join, which she did. That was over a decade ago. That drug is now on the market, and my mother has not suffered another episode since. My mother was lucky; every mother should be this lucky. The reality that it takes between 12 and 15 years to bring a breakthrough therapy to market limits everyone's opportunity to be treated with the clinically appropriate medication. Clinical research needs to be streamlined so that lifesaving therapies

Background of Clinical Research Interoperability

are available to patients faster.

For the last sixty years, the cost and time of clinical trials has increased^{1,2}; however, these problems persist despite effort to reduce them. Improvement in data collection is an area ripe for impactful advancement. Since



By Amy Nordo, MCCi, RN, CPHQ

2007, with the Starbrite study³, the industry has searched for a better way to exchange data for clinical research. While there have been small steps made in various settings since then, a full-scale production use of interoperability to collect clinical care data for clinical care is needed.

The current "swivel chair"⁴ data collection process requires that the clinical research coordinator not only document the necessary data within the electronic health record (EHR), but then also manually search for that necessary data within the EHR and retype it into the electronic data capture system (EDC). In the current state, clinical research is reusing clinical data in a manual, duplicative data entry that is error prone, time consuming, and raises patient

¹ Eisenstein, E.L., et al., Reducing the costs of phase III cardiovascular clinical trials. Am Heart J, 2005. 149(3): p. 482-8.

Eisenstein, E.L., et al., Sensible approaches for reducing clinical trial costs. Clin Trials, 2008. 5(1): p. 75-84.

³ Kush, R., et al., Implementing Single Source: the STARBRITE proof-of-concept study. J Am Med Inform Assoc, 2007. 14(5): p. 662-73

[[]Cited: February 2016], Bain, Landen

safety risks⁵. Multiple studies have been conducted globally to address the electronic exchange of clinical data for clinical research6 and many have found improved evaluative outcomes. Still, these improved evaluative outcomes have not been sufficient for the clinical research community to adopt interoperability. Why? One of the main reported barriers by industry stakeholders is the low amount of data available for exchange and the difficulty in producing a scalable, reproducible process.7 The joke that "if you have seen one continuity of care document (CCD), you've seen one CCD," is an unfortunate reality in this use case. Semantic and structural interoperability standards have existed for years but not in a way that has driven adoption.

Solution

To overcome this barrier, a new standard that the clinical research community could align with was needed in order to drive interoperable exchange of clinical care data for clinical research. HL7 Fast Healthcare Interoperability Resources (FHIR®) is a standard that will positively disrupt the way clinical trials are conducted. Clinical care's disruption by FHIR has gained the attention of the clinical research community. Stakeholders from clinical research are actively engaged with HL7 investigating the use of FHIR for research for the last several years. One example

of this involvement in HL7 is a project scope statement (PSS) for an implementation guide on FHIR to Structural Data Tabulation Model (SDTM), a Clinical Data Interchange Standards Consortium (CDISC) standard, is currently under way in the Biomedical Research and Regulatory (BR&R) Work Group. This is representative of just some of the work on FHIR for research both completed and in progress in BR&R.

Clinical research needs to be streamlined so that lifesaving therapies are available to patients faster.

It's time to put the good work from BR&R into action. Data availability when reusing clinical care data for clinical research is reported to range between 45-70% without the use of the HL7 FHIR standard. Industry experts hypothesize that the clinical research data that is available with the use of the existing FHIR resources (for domains such as demography, labs, vitals signs...) ranges between 60-90%. Reuse of the current FHIR domains for clinical research is a scalable, reproducible process that is technologically feasible.

Lessons Learned

Some of the previous barriers are removed with the use of HL7 FHIR for research, but key opportunities remain:

- 1. Matching the patient medical record number (MRN) to patient subject ID, ensuring the patient's status on a study and even what study the patient is currently enrolled in, needs a more scalable solution. While there are many flavors of solutions, FHIR research resources hold the most promise.
- 2. Representational data quality mismatch is not exclusive to clinical research, but is an area that provides opportunity for improvement. The Common Clinical Registry Framework (CCRF) project in the Clinical Interoperability Council (CIC) is actively addressing representational data quality issues.
- 3. The cultural divide separating the current process and the future digital clinical trials must be bridged. Clinical research is a risk adverse, conservative industry.

Conclusion

Research data collection utilizing HL7 FHIR, although nascent in its maturity, is the path forward in digitizing clinical trials. There is work to be done, but as a community, HL7 can deliver the necessary solutions to make digitized clinical trials a production capable, scalable, reproducible process. Healthcare technology is a rapidly expanding environment and the opportunities for clinical research are just beginning to be discovered.

⁵ Nordo, A., eta al., Evaluative Outcomes in Direct Extraction and Use of EHR Data in Clinical Trials. International conference addressing Information Technology and Communications in Health (ITCH): February 14-17, 2019, Victoria, BC, Canada.

⁶ Garza, M., et al., eSource for Standardized Health Information Exchange in Clinical Research: A Systematic Review. International conference addressing Information Technology and Communications in Health (ITCH): February 14-17, 2019, Victoria, BC, Canada.

⁷ Nordo, A., et al., Use of EHRs Data for Clinical Research: Historical Progress and Current Applications. Learning Health Systems, 2018.







Fast Track Development and Adoption of FHIR Standard

HL7® Launches FHIR® Accelerator Program





By Andrea Ribick, Director of Communications

HL7 recently announced the launch of the HL7 FHIR®

Accelerator Program. The program is based on an innovative model piloted by the HL7

Argonaut Project and, more recently, the HL7 Da Vinci Project. The goal is to strengthen the FHIR (Fast Healthcare Interoperability Resources) standard and enhance market adoption through a programmatic approach available to myriad stakeholders.

"HL7 FHIR has achieved remarkable adoption on a global scale," said Dr. Charles Jaffe, CEO of HL7. "An ever-growing community of implementers has emerged across a broad spectrum of health care, eager to participate in an agile onramp for FHIR adoption and implementation. The HL7 FHIR Accelerator Program provides the framework for that community to leverage the technical capability, management expertise and experience gained during the creation and growth of the Argonaut and Da Vinci Projects."

Building on the success of current projects—Argonaut (provider-provider and provider-patient) and Da Vinci (payer-provider)—The CARIN Alliance has recently been approved as an HL7 FHIR Accelerator project (payer-patient). The three projects are complementary initiatives.

"On behalf of the CARIN Alliance. its board and membership, we are grateful for the opportunity to work more closely with HL7 as part of the FHIR Accelerator Program as we work to develop additional FHIR implementation guides so consumers can get access to more of their health information," stated Ryan Howells, CARIN Alliance Project Manager and Principal at Leavitt Partners. "Consumers and their authorized caregivers are requesting more access to health care data with less friction to empower them to become more informed, shared decisionmakers in the care they receive."

The original concept behind accelerating HL7 FHIR began approximately four years ago with the advent of the Argonaut Project.

"In 2015, HL7 and the Argonaut Project successfully established a new model for engaging implementers to accelerate FHIR maturity and adoption to support emerging market needs for provider-provider and providerpatient clinical information exchange," said Micky Tripathi, Project Manager of the Argonaut Project. "We are excited to see the HL7 FHIR Accelerator Program institution-alizing this model to support other FHIR adoption initiatives working on complementary use cases."

The Da Vinci Project began September 2018 to accelerate the standards required to advance value-based care through the use of HL7 FHIR.

"Through Da Vinci, we have worked with HL7, CMS and other stakeholders from the private sector to bring together the best and brightest minds in the FHIR community to create an 'industry first' environment that not only values innovation but drives forward-thinking momentum to promote standards," said Jocelyn Keegan, Da Vinci Program Manager. "It's this collaborative environment that has made it possible for Da Vinci to accelerate the development

of multiple balloted standards in just one year. We look forward to collaborating on best practices, tools, and lessons learned with other organizations so we can work to fuel interoperability." Additional impetus for the introduction of the HL7 FHIR® Accelerator Program initiative comes in the form of shared priorities with

The Centers for Medicare & Medicaid Services (CMS).

Seema Verma, Administrator of CMS within the Department of Health and Human Services outlined the Centers' priorities for the upcoming year in a letter she sent to HL7 on February 7, 2019.

"It's more apparent than ever that HL7 will play a critical role

Continued on page 18

The Argonaut Project

- 1. R4 update: Add Encounter resource and clinical notes. Update existing resources to R4. Develop 'write' capabilities for selected resources
- FHIR Clinical Data Subscriptions: Develop FHIR Subscriptions resource to push updates of
 medical record information to authorized recipients. Eliminates need to continuously poll FHIR
 servers for updates. Supports 'push' use cases such event notifications.
- 3. **Provenance:** Define expectations on what provenance information is retained when information is imported into a FHIR server. Test round trip write, update, retrieve
- 4. Web Messaging and CDS Hooks for Radiology Ordering: Create CDS Hooks profile to support radiology ordering (to support Protecting Access to Medicare Act requirements), add web messaging channel to allow apps to functionally communicate with EHR sessions.

The DaVinci Project

- 1. Data Exchange for Quality Measures In HL7 ballot reconciliation as draft standard
- 2. Coverage Requirements Discovery In HL7 ballot reconciliation as draft standard
- 3. Documentation Templates and Coverage Rules Under Active Development
- 4. Health Record Exchange: Clinical Data Exchange Under Active Development
- 5. Health Record Exchange: Payer Data Exchange Under Active Development
- 6. Prior Authorization Support Under Active Development
- 7. Gaps in Care and Information 2019 Use Case
- 8. Risk Based Contract Member Identification 2019 Use Case
- 9. Alerts: Notification (ADT), Transitions in Care, ER Admit/Discharge 2019 Use Case
- 10. Performing Laboratory Reporting Use Case Awaiting Resourcing
- 11. Chronic Illness Documentation for Risk Adjustment Use Case Awaiting Resourcing
- 12. Patient Cost Transparency Use Case Awaiting Resourcing

HL7® Launches FHIR® Accelerator Program

The CARIN Alliance

- 1. Blue Button 2.0 for Commercial health plans Under Active Development Focus: Develop a common consumer payer data set (similar to Blue Button 2.0) and corresponding implementation guide for the set of resources that payers can display to consumers via a FHIR API
- Real-time Pharmacy Benefit Check Under Active Development Focus: Develop a consumerfacing API version of real-time pharmacy benefit check to enable consumers to access their drug formulary and benefit information, financial responsibility, therapeutic alternatives, and cash price in accordance with the 'Patient Right to Know Drug Prices Act' (Gag Clause legislation; 10/10/2018).
- 3. Post-Acute Care / Data Element Library Under Active Development Focus: Develop a consumer-facing API related to the post-acute care assessment information that is found in the CMS data element library.
- 4. Consumer ID and Authentication Under Active Development Focus: Develop a set of best practices and a framework for implementing the NIST Identity Assurance Level 2 (IAL2) and Authenticator Assurance Level 2 (AAL2) guidelines in health care
- 5. Application Endorsement Framework using Open APIs Under Consideration Focus: Using UDAP and POET, develop a portable, digital certification and endorsement framework to send verified attributes about a client application to an OAuth server.

in furthering CMS's objectives this year and well into the future," said Jaffe. "We're delighted that CMS has clearly acknowledged HL7's contribution and integral role in creating a more interoperable health system that supports patients, providers, payers and many others.

"Through collaboration with many other contributors, HL7 will promote the acceleration and implementation of the FHIR platform with the new HL7 FHIR® Accelerator Program initiative," Jaffe added.

Implementation communities will be able to select a range of solutions based on their own needs and resources, ranging from

self-service templates and tools, to contracted project management, SME and infrastructure services.

Certain minimum program requirements for implementation communities seeking to become HL7 FHIR Accelerator Projects include the following:

- Maintaining HL7 brand and trust in the community
- Covering the cost of HL7
 activities and not imposing
 additional work on volunteers
 and working groups

Applicants must also demonstrate clear goals, governance, commitment to creating balloted artifacts, access to adequate resources, and HL7 member representation.

A baseline project package is available for an initial setup fee and annual fees thereafter. Additional fees vary depending on services selected beyond the base package.

For more information about the HL7° FHIR° Accelerator Program, see:

www.hl7.org/about/fhiraccelerator





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Implementation Use Case for Health IT Standards in Poland

Małopolska Medical Information System

Małopolska, also known as "Lesser Poland", is one of the sixteen regions forming the highest level of Polish administrative subdivision units.



The region is located in the southern part of the country. Its population exceeds 3.4 million citizens. The capital city, Krakow, is visited by 13 million tourists annually. **Małopolska Medical Information System** is a health

information exchange project run by the Marshal's Office, which is a regional public administration office, in cooperation with 38 public hospitals operating in the region.

The project receives 85% (41 million Euro) of its funding from the European Regional Development Fund (Project no. RPMP.02.01.05-12-0228/18). The region is active in the proliferation of interoperability standards and profiles in Poland and became an organizational member of HL7 Poland last year.

The main goals of the project include the delivery of IT infrastructure for electronic clinical document sharing between healthcare provider organizations, as well as providing patients with access to their documents and to the regional e-scheduling service. The overall architecture of clinical document exchange will be based on the



By Michael Rigby, PhD, Visiting Professor, Imperial College London

IHE Cross-Enterprise Document Sharing (XDS.b) integration profile accompanied by the PIX, PDQ, ATNA and CT profiles.

All documents to be shared must conform to the regional specification derived from the Polish National Implementation of the HL7 Clinical Document Architecture (CDA®) standard, which is a legally binding standard for the entire country. Certain classes of documents are intended to be stored and shared through the regional documents' repository. These are comprised of discharge summaries, admission refusal documents, information for GPs from specialized care units and radiological examination results. However, any type of an HL7 CDA document may be shared using local repositories belonging to the participating hospitals as long as these documents conform to the regional documents' specification. Laboratory test results are the first type of documents to be shared this way.

Medical image sharing will also be supported by implementing the IHE Cross-Enterprise Document Sharing for Imaging (XDS-I.b) integration profile. The images will remain stored in the local picture archiving and communications system (PACS) instances of the participating hospitals, while DICOM manifest and key objects selection will be registered and stored regionally to facilitate the data retrieval from local PACS servers.

Documents delivered to the regional repository for sharing will also become the source of data for future secondary use of data. Certain data will be

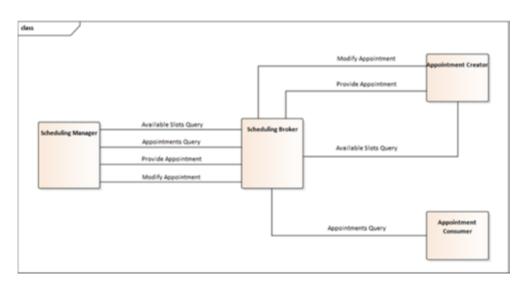


Fig. 1. Regional e-scheduling architecture

extracted from those documents and stored in conformance to the openEHR standard. These data may then become subject to querying with the Archetype Querying Language (AQL). There are two special data sets already planned for initial extraction. One is an emergency data set which will be based on deliverables of HL7 International Patient Summary (IPS) project. The set will contain patients' demographic data, diagnoses, performed medical procedures, medication lists, allergies, vaccinations and implants. The second set will gather data intended for the 'medical event', that will be required to be reported to the Polish national e-Health platform. In case of the above two special sets, the data are made available by dedicated HL7 Fast Healthcare Interoperability Resources (FHIR®) interfaces and the appropriate structure definitions and operations are specified. Clinical documents exchange

Clinical documents exchange with other medical data sharing communities, including national, regional and corporate platforms, will be based on the IHE Cross-Community Access (XCA) profile and gateways.

The regional e-scheduling service for patients will be implemented almost exclusively in HL7 FHIR standard. A number of new profiles are defined along with dedicated FHIR operations that allow the ability to query, create, manage and modify appointments. The solution is based on the concept of a regional scheduling broker that processes transactions between the respective actors, i.e. units in participating hospitals, patient portal and medical practitioner portal, with the hospitals retaining a high degree of independence in the management of their local schedules.

Substantial financial support is provided to the participating hospitals so that they are able to achieve a high efficiency in creating electronic clinical documents and effectively utilize the regional services delivered by the project. Thus, the hospital systems will be well integrated

Continued on page 22

Continued from page 21

Małopolska Medical Information System

with the regional HIE using interoperability standards and profiles. However, to assist medical practitioners when they need access to medical data while outside of a hospital environment, the project will also deliver a dedicated medical practitioner portal. The portal will enable its users to locate and display clinical documents, including HL7 CDA documents and DICOM objects, using a web browser. A medical practitioner will also be able to schedule an appointment for a patient in any of the medical facilities taking part in the regional project.

The patient portal will provide web access to the services for the patients themselves, their legal representatives, their parents (if juvenile) or any other individuals authorized by a patient. The main functionalities of the portal are access to clinical documents and ability to schedule appointments. The latter requires the possibility to search for or browse regional facilities and medical services provided. Users will also be able to create and manage consents regarding sharing and accessing their clinical documents. A consent may refer to a single document or a set of them and pertain to a single medical provider or an organization. Both opt-in and opt-out policies will be implemented. National law enumerates cases where access to a document may be permitted to a medical practitioner irrespective of the patient consent, which includes care continuity and emergency cases. However, all cases involving access to the documents will be logged and

presented to the portal users. The IHE Advanced Patient Privacy Consent (APPC) profile will be implemented and consent documents in XACML format will be stored in the regional repository. Both portals will be constructed according to the responsive web design approach to make them available on mobile devices. To further support mobile solutions, the system will conform

to the IHE Mobile Access to

Health Documents (MHD)

profile that is based on HL7

FHIR Terminology Services.

FHIR and will make use of HL7

The public tender for the regional part of the system is expected to be announced in the middle of 2019, while the whole platform should be operational in the beginning of 2021.

HL7 Standards Approved by ANSI Since November 2018

Name	Designation	Date
HL7 Version 3 Standard: Core Principles and Properties of Version 3 Models, Release 2	ANSI/HL7 V3 CPPV3MODELS, R2-2018	11/1/18
HL7 CDA® R2 Implementation Guide: Trauma Registry Data Submission, Release 2 - US Realm	ANSI/HL7 CDAR2 IG TRAUMAREG, R2-2019	1/17/19
ANSI/HL7 Implementation Guide: UDI Pattern, Release 1	HL7 IG UDI, RI	2/21/2019
Characteristics of a Value Set Definition, Release 1	ANSI/HL7 VSD, R1-2019	3/1/2019

October 23 - 24, 2019 / Warsaw, Poland

Invitation to Warsaw for IHIC 2019



by Roman Radomski, Chair, HL7 Poland

HL7 Poland cordially invites you to the International HL7 Interoperability Conference.

The International HL7 **Interoperability Conference** (IHIC) has been held for 18 years as a healthcare interoperability scientific conference that provides a review of standards implementation projects around the world. IHIC 2019 will be held on October 23-24 at the Polin Conference Center in Warsaw, Poland. IHIC 2019 will be co-located with Integraton 2019, the second edition of the interoperability testing event that was successfully led by HL7 Poland as a domestic conference in 2018.

Conference Format and Program

The IHIC format will remain similar to what we have seen in the previous years but will include some modifications. Tutorials and seminars, led by top international experts, will take place on the first day of the event, along with a demonstration of interoperability testing tools. IHIC participants and Integration testing team members are invited to take part in all tutorials and seminars without any extra fee. A key difference this year is that the main conference on the second day will not focus on scientific papers, but rather on presentations about practical implementation of interoperability standards.

European, national, regional and local projects will be presented by invited speakers to share experiences, best practices, project deliverables and specifications and tools that might be useful for other implementers. The main goal is to attract representatives of planned or running projects in healthcare interoperability from all over the world and to fulfill their needs and expectations.

Interoperability Testing Event

Integration 2019 will be a satellite event of IHIC and will begin on October 22. It will cover testing of conformance to HL7 standards and IHE integration profiles. Several derived specifications, including the Polish national HL7 CDA implementation guide, HL7 FHIR profiles and operations for scheduling and regional IHE XDS.b metadata and transactions specifications as well as other IHE integration profiles will serve as a basis for content validation and peer-to-peer integration tests. Due to the fact that this year Integration is organized in conjunction with IHIC 2019, the international track for interoperability testing will also take place. All tests are to be performed on the Tukan platform, the national testing tool delivered and maintained by HL7 Poland.

City of Warsaw

Warsaw, the capital and largest city in Poland, lies halfway



between the Baltic Sea and the Carpathian Mountains, in the heart of Europe. It has several hundred years of rich history and is a major international tourist destination as well as a significant cultural, political and economic hub. Almost completely destroyed during World War II, the city has been reconstructed, including historic Old Town, which is now designated a UNESCO World Heritage Site. Undoubtedly, the most beautiful part of the city is the Royal Route, running from the Royal Castle to the south through the heart of Warsaw, passing Łazienki Park with the Palace on the Water, and ending at another royal residence, the Wilanów Palace. The city straddles the Vistula, the longest river in Poland, which flows through many other Polish cities like Cracow in the south and Gdańsk in the north.



Open-Source Modules Key to Software Implementation

Success with Telemedicine for Pregnant Women with Complicated Pregnancies





A recently completed project in Denmark within telemedicine has shown that remote monitoring of pregnant women with complicated pregnancies makes a big difference. The number of hospital admissions is reduced, women feel more secure, and often they do not have to attend follow-up appointments at the hospital.

By Jacob Andersen, PhD, Senior Software/ ICT Engineer, Alexandra Institute; Member, HL7 Denmark

In 2010, Skejby Hospital in Central Denmark Region wanted to analyze if they could do something for pregnant women who were predisposed to e.g. premature rupture of membranes or pregnancy toxaemia. This category of pregnant women often goes for checks and is admitted to the hospital at a much greater extent than other pregnant women. Because of this, Skejby Hospital wanted to investigate whether it was possible to make the process easier for the pregnant women and perhaps reduce the number of admissions.

The Central Denmark Region launched a regional pilot project that included home monitoring for

the pregnant patients, where the women were equipped with a tablet, a sphygmomanometer and equipment for measuring contractions and fetal heart beats. The results of the measurements were subsequently sent to relevant staff at Aarhus University Hospital, the new name for Skejby Hospital after it merged with Aarhus Hospital in 2011.

Due to the resources and finances of the pilot project, there was a need for the basic software to be simple, flexible, adjustable and possible to subsequently roll out on a larger scale. Such software did not exist, and they therefore decided to develop new software.

Telemedicine Based on Open-Source Modules

Together with the Alexandra
Institute, which helps to develop
the software, the Central Denmark
Region decided (as part of the
research in telemedicine) to explore
the possibility of building the IT
system of modules, each module
being easily replaceable and
transferable to other applications.
The idea was to also develop the
system via open source, thereby
enabling several parties, including
other municipalities, to help
develop and finance the software.

The fundamental concept of a "module" in this architecture is a unit of software which has a single, isolated purpose, also known as a "single responsibility". This approach offers a fine-grained reuse of modules, which can be compared to building creations out of LEGOs. On a concrete system running on a server, each module will be a microservice - a small service executing in an independent Docker container and communicating with other modules on an asynchronous bus. For apps on the users' own devices, such as smartphones and tablets, we have developed a similar run-time environment that will accept and orchestrate an assembly of independent modules - much like a light version of a micro-services architecture for tablets and smartphones.

Standardization as Quality Assurance of Open-Source Software

When software is developed in many places, control and quality assurance present special challenges. Therefore, it is necessary that the responsibility for ensuring uniform interpretation, correct data exchange, and integration of software should lie with one company only.

Today, the Alexandra Institute has governance and responsibility for quality assurance and process documentation. However. data interchange between the systems (personal health device, smartphone, server etc.) was already settled in 2013 when Danish regions and municipalities agreed on the national "Reference Architecture for Collecting Health Data from Citizens", which refers to the Continua Design Guidelines published by the Personal Connected Health Alliance (PCHA). Following this decision, national profiles were developed for the three central HL7 Clinical Document Architecture (CDA®) document types: Personal Healthcare Monitoring Reports (PHMR) for measurements, Questionnaire Form Definition Document (QFDD)/Structured Form Definition Document (SFDD) for questionnaires, and Ouestionnaire Response Documents (QRD) for questionnaire responses. Furthermore, a national XDS-based infrastructure was established to collect, store, and exchange these CDA documents.

Data interchange between individual modules on the same system requires the same level of attention. Because of this, HL7 Fast Healthcare Interoperability Resources (FHIR®) was chosen as the appropriate foundation. Currently, a profile of all the main resources needed for this application is in place and is based on HL7 FHIR Release 4 (R4).

Observations and devices are modelled according to the recently developed implementation guide for HL7 FHIR R4 based communication of Personal Health Device [PHD] observations, which was on the Jan 2019 HL7 ballot.

Generic Modules of Great Value to the Business Model

The open-source business model is not very well defined; therefore, one of the objectives has been to find a feasible business model. An outline of the model is now in place. The business case of offering telemedicine treatment to pregnant women has proven successful and is generating fantastic results. The Central Denmark Region is now putting the system into operation, and it will be offered to the entire country in the coming years.

The thesis is that more regions will use this IT system, also for other telemedicine solutions, because of its flexibility and facility to design the modules as needed.

The modules will be applied in many ways. Many of the components are generic and can also be used in other countries, such as Australia or China. Although the modules were developed for this project, the components can be used for other projects as well. Some of the modules manage questionnaires or gather measurements from smart home monitoring systems, which can be used in other systems, such as those for COPD patients. Other modules could show data on the indoor climate. The modules should be viewed as building blocks to be selected and combined depending on what you would like to build.



Clinical Genomics Track Tests Pharmacogenomics Project

Point-of-Care Enabled Precision Medicine Service with GACS

After several months of preparation, a collaboration during the Clinical Genomics track has created and tested the first point-of-care enabled FHIR application with a Genomics Archiving and Communication System (GACS) service.

Members from Elimu Informatics, Intermountain Healthcare, Cerner Corporation and Harvard Medical School/Boston Children's Hospital worked to integrate these pieces into a production EHR system using CDS Hooks and the FHIR Genomics components in the emerging HL7 FHIR data standard. The test took place during the 20th HL7 FHIR connectation on January 12, 2019.

The pharmacogenomics service is designed to function inside clinicians' existing workflows, so providers don't need to consider genomics details until they are determined to be both applicable and actionable for the current patient.

The Clinical Genomics track, led by Dr. Gil Alterovitz, filled three tables of participants and brought together organizations from around the world. The pharmacogenomics project team included Elimu's product team, Bret Heale, James Jones, Kevin Power and Gil Alterovitz, with remote participation from Grant Wood.

By Gil Alterovitz, PhD, Assistant Professor, Harvard/MIT Division of Health Sciences and Technology, Boston Children's Hospital



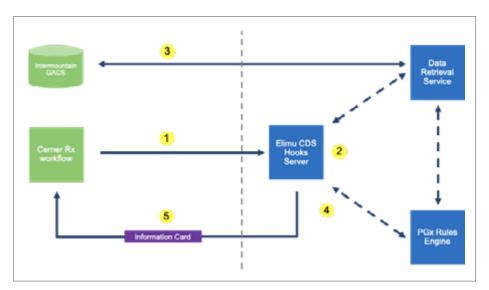
Aziz Boxwala, MD, PhD, President, Elimu Informatics



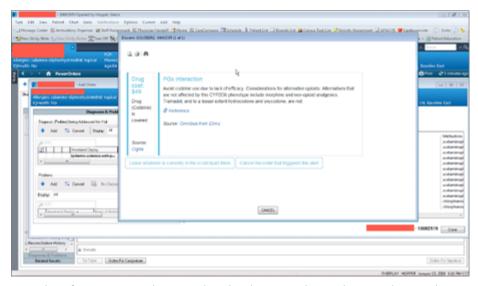
Bret Heale, PhD, Solutions Architect, Intermountain Healthcare

First, a test cloud-server hosted by a representative from Intermountain was populated with example FHIR genomic data translated directly from public VCF files from the 1000 Genomes Project. A sample EHR patient was linked with a de-identified individual in the 1000 Genomes Project data, and CDS Hooks were implemented between the Cerner EHR and Elimu's Omnibus CDS platform. New pharmacogenomic CDS rules were written for this scenario, designed so that when a medication with a known druggene interaction was prescribed in the EHR's prescription workflow, the Intermountain GACS would be queried for any FHIR observations containing information of that gene for the selected patient. The rules evaluated the bundle of FHIR resources that the GACS system retrieved, and determined whether there was data corresponding to a genetic variant that may impact the drug's efficacy. If a match was found, a CDS information card was provided directly to the EHR suggesting an alternative dose or drug. This test run was calibrated

for querying observations of the CYP2D6 gene for its ability to convert the common drug codeine into its active metabolite, morphine. The system provided actionable feedback and reasoning based on the expected phenotype from the information in the server. Future work is planned to extend the capabilities of this system to cover the Clinical Pharmacogenetics Implementation Consortium (CPIC) top 60 druggene interactions. Where sufficient data about the interacting gene regions is unavailable,



Workflow of the platform triggered by the EHR



Sample Information Card returned to the clinician when ordering a drug with evidence of pharmacogenomic implications

the CDS platform may suggest ordering a genetic test prior to prescription if it is warranted. This remarkable integration tes

This remarkable integration test shows just one use case that is greatly benefited by using HL7 FHIR to communicate genomics data. The components used in the FHIR interface between Elimu's CDS platform and Intermountain's GACS were seen to be fast, scalable and easily interpreted both by developer and machine. The success highlights

that HL7 FHIR and its genomics capabilities are ready for further testing in production-ready environments across the globe. Organizations everywhere are welcome to join in the emerging integration efforts through future HL7 FHIR Connectathon events. Those looking to take FHIR Genomics to the next level in terms of implementations can also join the HL7 FHIR Foundation and explore initiatives like the Consortium for Agile Genomics.



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2019 TECHNICAL STEERING COMMITTEE MEMBERS

CHAIR

Austin Kreisler, FHL7

Leidos, Inc.

Phone: +1 706-525-1181

Email: austin.j.kresler@leidos.com

CHIEF TECHNOLOGY OFFICER

Wavne Kubick

Health Level Seven International

Phone: +1 847-842-1846 Email: wkubick@HL7.org

ARB CHAIR

Anthony Julian, FHL7

Mayo Clinic

Phone: +1 507-266-0958 Email: ajulian@mayo.edu

ARB VICE CHAIR

Lorraine Constable

HL7 Canada

Phone: +1 780-951-4853 Email: lorraine@constable.ca

INTERNATIONAL **REPRESENTATIVES**

Giorgio Cangioli

HL7 Italy

Email: giorgio.cangioli@gmail.com

Jean Duteau

Duteau Design Inc. Phone: +1 780-328-6395

Email: jean@duteaudesign.com

ADMINISTRATIVE CO-CHAIRS

Mary Kay McDaniel

Cognosante, LLC

Email: marykay.mcdaniel@cognosante.com

Ulrike Merrick

Vernetzt, LLC

Phone: +1 415-634-4131

Email: rikimerrick@gmail.com

CLINICAL CO-CHAIRS Floyd Eisenberg, MD

iParsimony LLC

Phone: +1 202-643-6350

Email: feisenberg@iparsimony.com

Melva Peters

Jenaker Consulting Phone: +1 604-512-5124

Email: melva@jenakerconsulting.com

INFRASTRUCTURE CO-CHAIRS

Russell Hamm

Intelligent Medical Objects (IMO)

Phone: +1 847-613-6645

Email: russellhamm@gmail.com

Paul Knapp

Knapp Consulting Inc. Phone: +1 604-987-3313 Email: pknapp@pknapp.com

ORGANIZATIONAL SUPPORT CO-CHAIRS

Virginia Lorenzi, FHL7

New York-Presbyterian Hospital Email: vlorenzi@nyp.org

Sandra Stuart

Kaiser Permanente Phone: +1 925-519-5735 Email: sandra.stuart@kp.org

AD-HOC MEMBERS

Ken McCaslin MAR, FHL7

Accenture

Phone: +1 267-216-1428

Email: H.Kenneth.McCaslin@accenture.com

John Roberts

Tennessee Department of Health

Phone: +1 615-741-3702 Email: john.a.roberts@tn.gov

Steering Divisions

ADMINISTRATIVE

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Publishing

HL7 Work Group Co-Chairs

ANESTHESIA

Martin Hurrell, PhD

Phone: +44 7711-669-522 *Email:* martinhurrell@outlook.com

Ellen Torres

Email: etworks@outlook.com

John Walsh, MD

Partners HealthCare System, Inc. *Phone:* +1 857-282-3953 *Email:* jwalsh@partners.org

ARCHITECTURAL REVIEW BOARD

Lorraine Constable

HL7 Canada

Phone: +1 780-951-4853 *Email:* lorraine@constable.ca

Anthony Julian, FHL7

Mayo Clinic

Phone: +1 507-293-8384 Email: ajulian@mayo.edu

ARDEN SYNTAX

Peter Haug, MD

Intermountain Healthcare *Phone:* +1 801-507-9253 *Email:* peter.haug@imail.org

Robert Jenders, MD, MS

Charles Drew University/UCLA Phone: +1 323-249-5734 Email: jenders@ucla.edu

ATTACHMENTS

Durwin Day

Health Care Service Corporation *Phone*: +1 312-653-5948 *Email*: dayd@bcbsil.com

Christol Green

Anthem, Inc.

Phone: +1 303-435-6195

Email: christol.green@anthem.com

Russell Ott

Deloitte Consulting LLP *Email:* rott@deloitte. com

BIOMEDICAL RESEARCH AND REGULATION

Boris Brodsky

Food and Drug Administration *Phone*: +1 301-796-5179 *Email*: boris.brodsky@fda.hhs.gov

Myron Finseth, BS, MSc

Medtronic

Phone: +1 763-526-3071

Email: myron.finseth@medtronic.com

Hugh Glover, FHL7

Blue Wave Informatics Email: hugh_glover@ bluewaveinformatics.co.uk

CLINICAL DECISION SUPPORT

Guilherme Del Fiol, MD, PhD

University of Utah Health Care

Phone: +1 801-213-4129

Email: guilherme.delfiol@utah.edu

Robert Jenders, MD, MS

Charles Drew University/UCLA *Phone:* +1 323-249-5734 *Email:* jenders@ucla.edu

Kensaku Kawamoto, MD, PhD

University of Utah Health Care

Phone: +1 801-587-8076

Email: kensaku.kawamoto@utah.edu

Bryn Rhodes

Database Consulting Group *Phone:* +1 801-210-0324 *Email:* bryn@

databaseconsultinggroup.com

Howard Strasberg, MD, MS

Wolters Kluwer Health *Phone:* +1 858-481-4249

Email: howard.strasberg@wolterskluwer.com

CLINICAL GENOMICS

Gil Alterovitz, PhD

SMART Health IT *Email:* gil@chip.org

Robert Freimuth, PhD

Mayo Clinic

Phone: +1 507-266-4078

Email: freimuth.robert@mayo.edu

Bob Milius, PhD

National Marrow Donor Program *Phone:* +1 612-627-5844

Email: bmilius@nmdp.org

Kevin Power

Cerner Corporation

Phone: +1 816-201-3026

Email: kpower@cerner.com

Patrick Werner

HL7 Germany

Phone: +49 15150602008 Email: pa.f.werner@gmail.com

CLINICAL INFORMATION MODELING INITIATIVE

Richard Esmond

PenRad

Phone: +1 763-475-3388

Email: richard.esmond@gmail.com

Stanley Huff, MD, FHL7

Intermountain Healthcare *Phone:* +1 801-507-9111 *Email:* stan.huff@imail.org

Galen Mulrooney, MBA

U.S. Department of Veterans Affairs

Phone: +1 703-815-0900

Email: galen.mulrooney@jpsys.com

Claude Nanjo

University of Utah Health Care *Phone*: +1 810-587-6092 *Email*: cnanjo@gmail.com

CLINICAL INTEROPERABILITY COUNCIL

Laura Heermann Langford RN, PhD

Intermountain Healthcare *Phone:* +1 801-507-9254

Email: laura.heermann@imail.org

Lindsey Hoggle

IRIS Health Solutions, LLC

Email: lhoggle@irishealthsolutions.com

Russell Leftwich, MD

InterSystems

Phone: +1 617-551-2111

Email: russell.leftwich@intersystems.com

Amy Nordo, MMCi, RN

Pfizer

Email: amy.nordo@pfizer.com

CLINICAL QUALITY INFORMATION

Patricia Craig, MS, MIS

The Joint Commission

Phone: +1 630-792-5546

Email: pcraig@jointcommission.org

Floyd Eisenberg, MD

iParsimony LLC

Phone: +1 202-643-6350

Email: feisenberg@iparsimony.com

Yan Heras

Optimum eHealth *Phone:* +1 949-566-3361

Email: yanheras@gmail.com

Juliet Rubini, MS, MSIS

Mathematica Policy Research *Phone:* +1 609-750-3181

Email: julietkrubini@gmail.com

Kanwarpreet Sethi

Lantana Consulting Group *Phone:* 802-785-2623

Email: kp.sethi@lantanagroup.com

COMMUNITY-BASED CARE AND PRIVACY

Johnathan Coleman

Security Risk Solutions, Inc. (SRS)

Phone: +1 843-442-9104 Email: jc@securityrs.com

Suzanne Gonzales-Webb

Department of Veteran Affairs

Phone: +1 727-605-5081

Email: suzanne.webb@bookzurman.com

James Kretz

SAMHSA

Phone: +1 240-276-1755

Email: jim.kretz@samhsa.hhs.gov

David Pyke

Ready Computing Inc. *Phone:* +1 212-877-3307 x101

Email: david.pyke@readycomputing.com

HL7 Work Group Co-Chairs (continued)

CONFORMANCE

Nathan Bunker

American Immunization Registry Association *Phone*: +1 435-635-1532

Email: nbunker@immregistries.org

Frank Oemig, PhD, FHL7

HL7 Germany *Phone:* +49 208-781194 *Email:* hl7@oemig.de

Ioana Singureanu, MSCs, FHL7

U.S. Department of Veterans Affairs

Phone: +1 603-548-5640

Email: ioana.singureanu@bookzurman.com

Robert Snelick

National Institute of Standards & Technology

Phone: +1 301-975-5924 Email: robert.snelick@nist.gov

ELECTRONIC HEALTH RECORDS

Michael Brody, DPM

Email: mbrody@cmeonline.com

Gary Dickinson, FHL7

CentriHealth

Phone: +1 951-536-7010

Email: gary.dickinson@ehr-standards.com

Stephen Hufnagel, PhD

Apprio, Inc.

Phone: +1 703-575-7912

Email: shufnagel@apprioinc.com

Mark Janczewski, MD, MPH

Medical Networks, LLC

Email: mark.janczewski@gmail.com

John Ritter, FHL7

Phone: +1 412-372-5783

Email: johnritter1@verizon.net

Feliciano Yu, MD, MS

University of Arkansas Medical Sciences Email: pele.yu@archildrens.org

ELECTRONIC SERVICES AND TOOLS

David Burgess

Laboratory Corporation of America

Phone: +1 615-221-1901 Email: burgesd@labcorp.com

Elizabeth Newton

Kaiser Permanente *Phone*: 925-997-8150

Email: elizabeth.h.newton@kp.org

Brian Pech, MD, MBA

Kaiser Permanente Phone: +1 678-245-1762 Email: brian.pech@kp.org

Andrew Statler

Cerner Corporation *Phone:* +1 816-201-3336

Email: andrew.statler@cerner.com

Michael Van der Zel, BSc

HL7 Netherlands *Phone:* +31 503619876

Email: m.van.der.zel@umcg.nl

EMERGENCY CARE

Dominik Brammen

HL7 Germany

Phone: +49 700-7777-6767

Email: dominik.brammen@aktin.org

Laura Heermann Langford, RN, PhD

Intermountain Healthcare *Phone:* +1 801-507-9254

Email: laura.heermann@imail.org

James McClay, MD

University of Nebraska Medical Center

Phone: +1 402-559-3587
Email: jmcclay@unmc.edu

FHIR INFRASTRUCTURE

Rick Geimer

Lantana Consulting Group *Phone:* +1 650-209-4839

Email: rick.geimer@lantanagroup.com

Ewout Kramer

HL7 Netherlands / Firely

Phone: +31 3467171 Email: ewout@fire.ly

Joshua Mandel, MD

SMART Health IT

Phone: +1 617-500-3253 Email: jmandel@gmail.com

Lloyd McKenzie, FHL7

HL7 Canada / Gevity

Email: lloyd@lmckenzie.com

FINANCIAL MANAGEMENT

Kathleen Connor, FHL7

U.S. Department of Veterans Affairs

Phone: +1 727-519-4607

Email: kathleen_connor@comcast.net

Paul Knapp

Knapp Consulting

Phone: +1 604-987-3313

Email: pknapp@pknapp.com

Mary Kay McDaniel

Cognosante, LLC

Email: marykay.mcdaniel@

cognosante.com

Benoit Schoeffler

Almerys

Phone: +33 473982044

Email: benoit.schoeffler@almerys.com

HEALTH CARE DEVICES

Todd Cooper

Intermountain Healthcare

Phone: +1 801-290-6887

Email: toddcooperafc@gmail.org

Chris Courville

Epic

Phone: +1 608-271-9000 Email: ccourvil@epic.com

John Garguilo

National Institute of Standards *Email:* john.garguilo@nist.gov

John Rhoads, PhD

Philips Healthcare

Phone: +1 978-659-3024

Email: john.rhoads@philips.com

IMAGING INTEGRATION

Jonathan Whitby

Vital (Canon)

Phone: +1 678-245-1762

Email: jwhitby@vitalimages.com

IMPLEMENTABLE TECHNOLOGY SPECIFICATIONS

Paul Knapp

Knapp Consulting Inc.

Phone: +1 604-987-3313

Email: pknapp@pknapp.com

Brian Pech. MD. MBA

Kaiser Permanente

Phone: +1 678-245-1762

Email: brian.pech@kp.org

Andy Stechishin

HL7 Canada

Phone: +1 780-903-0885

Email: andy.stechishin@gmail.com

INFRASTRUCTURE & MESSAGING

Anthony Julian, FHL7

Mayo Clinic

Phone: +1 507-293-8384 *Email:* ajulian@mayo.edu

Nick Radov

UnitedHealthcare *Phone:* +1 800-328-5979 *Email:* nradov@uhc.com

Sandra Stuart, FHL7

Kaiser Permanente Phone: +1 925-519-5735 Email: sandra.stuart@kp.org

HL7 Work Group Co-Chairs (continued)

INTERNATIONAL COUNCIL

Peter Jordan, MSc LLB

HL7 New Zealand *Phone*: +64 21-758834 *Email*: pkjordan@xtra.co.nz

Melva Peters

Jenaker Consulting *Phone:* +1 604-512-5124

Email: melva@jenakerconsulting.com

Line Saele

HL7 Norway

Phone: +47 9592-5357

Email: line.sele@nasjonalikt.no

LEARNING HEALTH SYSTEMS

Russell Leftwich, MD

InterSystems

Phone: +1 617-551-2111

Email: russell.leftwich@intersystems.com

John Roberts

Tennessee Department of Health *Phone*: +1 615-741-3570 *Email*: john.a.roberts@tn.gov

MOBILE HEALTH

Nathan Botts, PhD, MSIS

Westat

Phone: +1 760-845-8356 *Email:* nathanbotts@westat.com

Gora Datta

CAL2CAL Corporation *Phone:* +1 949-955-3443 *Email:* gora@cal2cal.com

Matthew Graham

Mayo Clinic

Phone: +1 507-284-3028 Email: mgraham@mayo.edu

Frank Ploeg

HL7 Netherlands *Email:* r.f.ploeg@umcg.nl

MODELING AND METHODOLOGY

Jean Duteau

Duteau Design Inc. *Phone:* +1 780-328-6395 *Email:* jean@duteaudesign.com

Grahame Grieve, FHL7

HL7 International; Health Intersections Pty Ltd Phone: +61 3-98445796

Email: grahame@hl7.org; grahame@healthintersections.com.au

AbdulMalik Shakir, FHL7

Hi3 Solutions

Phone: +1 626-644-4491 Email: abdulmalik.shakir@ hi3solutions.com

Ron Shapiro

Qvera

Phone: +1 801-335-51-1 x7011 *Email:* ron@qvera.com

ORDERS/OBSERVATIONS

Hans Buitendijk, MSc, FHL7

Cerner Corporation *Phone:* +1 610-219-2087

Email: hans.buitendijk@cerner.com

David Burgess

Laboratory Corporation of America *Phone:* +1 615-221-1901 *Email:* burgesd@lapcorp.com

Lorraine Constable

HL7 Canada

Phone: +1 780-951-4853
Email: lorraine@constable.ca

Robert Hausam, MD, FHL7

Hausam Consulting, LLC *Phone:* +1 801-949-1556

Email: rob@hausamconsulting.com

Patrick Loyd, FHL7

Email: patrick.e.loyd@gmail.com

Ken McCaslin, MAR, FHL7

Accenture

Phone: +1 267-216-1428

Email: h.kenneth.mccaslin@accenture.com

Ulrike Merrick

Vernetzt, LLC *Phone:* +1 415-634-4131

Email: rikimerrick@gmail.com

John David Nolen, MD, PhD

Children's Mercy Hospitals and Clinics

Phone: +1 816-701-4882 Email: jdlnolen@gmail.com

PATIENT ADMINSTRATION

Alexander de Leon

Kaiser Permanente *Phone:* +1 626-381-4141

Email: alexander.j.deleon@kp.org

Irma Jongeneel-de Haas, FHL7

HL7 Netherlands

Phone: +31 681153857

Email: jongeneel@vzvz.nl

Brian Postlethwaite, BaSc

HL7 Australia

Phone +61 420-306-556 *Email:* brian_pos@hotmail.com

Line Saele

HL7 Norway

Phone: +47 9592-5357

Email: line.sele@nasjonalikt.no

PATIENT CARE

Stephen Chu, MD

HL7 Australia

Phone: +61 416960333

Email: chuscmi88@gmail.com

Laura Heermann Langford, RN, PhD

Intermountain Healthcare *Phone:* +1 801-507-9254

Email: laura.heermann@imail.org

Emma Jones

Allscripts

Phone: +1 919-859-8441

Email: emma.jones@allscripts.com

Jay Lyle

U.S. Department of Veterans Affairs

Email: joseph.lyle@va.gov

Michelle Miller

Cerner Corporation *Phone:* +1 816-201-2010

Email: mmoseman@cerner.com

Michael Padula, MD, MBI

The Children's Hospital of Philadelphia

Phone: +1 215-590-1653

Email: padula@email.chop.edu

Michael Tan

NICTIZ

Phone: +31 7031-73450 *Email:* tan@nictiz.nl

PHARMACY

Jean Duteau

Duteau Design Inc Phone: +1 780-328-6395 Email: jean@duteaudesign.com

John Hatem, FHL7

Email: jnhatem@hotmail.com

Melva Peters

Jenaker Consulting *Phone:* +1 604-512-5124

Email: melva@jenakerconsulting.com

Scott Robertson, PharmD, FHL7

Kaiser Permanente *Phone:* +1 310-200-0231

Email: scott.m.robertson@kp.org

PROCESS IMPROVEMENT COMMITTEE

Ken Rubin

U. S. Department of Veterans Affairs

Phone: +1 301-613-3104 Email: ken.rubin@utah.edu

Sandra Stuart, FHL7

Kaiser Permanente *Phone*: +1 925-519-5735 *Email*: sandra.stuart@kp.org

HL7 Work Group Co-Chairs (continued)

PROJECT SERVICES

Rick Haddorff

Mayo Clinic

Email: haddorff.richard@mayo.edu

Freida Hall, FHL7

Quest Diagnostics, Inc. *Phone:* +1 610-650-6794

Email: freida.x.hall@questdiagnostics.com

PUBLIC HEALTH AND EMERGENCY RESPONSE

Erin Holt, MPH

Tennessee Department of Health *Phone:* +1 615-741-3570

Email: erin.holt@tn.gov

Joginder Madra

Madra Consulting Inc. *Phone:* +1 780-717-4295

Email: hl7@madraconsulting.com

Craig Newman

Altarum

Phone: +1 608-345-3606

Email: craig.newman@altarum.org

Laura Rappleye

Altarum

Email: laura.rappleye@altarum.org

Danny Wise

Allscripts

Phone: +1 919-239-7401

Email: danny.wise@allscripts.com

PUBLISHING COMMITTEE

James Agnew

University Health Network *Email:* james.agnew@uhn.ca

Brian Pech, MD, MBA

Kaiser Permanente *Phone:* +1 678-245-1762 *Email:* brian.pech@kp.org

SECURITY

Kathleen Connor, FHL7

U.S. Department of Veterans Affairs

Phone: +1 727-519-4607

Email: kathleen_connor@comcast.net

Alexander Mense

HL7 Austria

Phone: +43 01-1-333-40-77-232 *Email*: alexander.mense@hl7.at

John Moehrke

By Light Professional IT Services LLC

Phone: +1 703-224-1000

Email: john.moehrke@bylight.com

Chris Shawn

U.S. Department of Veterans Affairs *Phone*: +1 518-681-1858 *Email*: christopher.shawn2@va.gov

Patricia Williams, PhD, MSc

HL7 Australia

Phone: +61 420-306-556

Email: patricia.williams@flinders.edu.au

SERVICES ORIENTED

ARCHITECTURE

Jerry Goodnough

Cognitive Medical Systems

Phone: +1 541-338-4911

Email: ferret@stormwoods.com

Stefano Lotti

HL7 Italy

Phone: +39 06-42160685 *Email:* slotti@invitalia.it

Vince McCauley, MBBS, PhD

Telstra Health (Australia) *Phone:* +61 298186493

Email: vincem@bigpond.com.au

Diana Proud-Madruga

U.S. Department of Veterans Affairs

Phone: +1 619-467-5568

Email: diana.proud-madruga@va.gov

STANDARDS GOVERNANCE BOARD

Lorraine Constable

HL7 Canada

Phone: +1 780-951-4853 *Email:* lorraine@constable.ca

Paul Knapp

Knapp Consulting Inc.

Phone: +1 604-987-3313

Email: pknapp@pknapp.com

STRUCTURED DOCUMENTS

Calvin Beebe, FHL7

Mayo Clinic

Email: cbeebe@mayo.edu

Gay Dolin, MSN RN

Intelligent Medical Objects (IMO)

Phone: +1 847-613-6645

Email: gdolin@imo-online.com

Benjamin Flessner

Redox

Email: benjamin@redoxengine.com

Austin Kreisler, FHL7

Leidos, Inc.

Phone: +1 706-525-1181

Email: austin.j.kreisler@leidos.com

Sean McIlvenna

Lantana Consulting Group *Phone:* +1 802-785-2623

Email: sean.mcilvenna@lantanagroup.com

Andrew Statler

Cerner Corporation *Phone:* +1 816-201-3336

Email: andrew.statler@cerner.com

TEMPLATES

Kai Heitmann, MD, FHL7

HL7 Germany

Phone: +49 172-2660814 *Email:* hl7@kheitmann.de

Mark Shafarman, FHL7

Shafarman Consulting *Phone:* +1 510-593-3483

Email: mark.shafarman@earthlink.net

VOCABULARY

Reuben Daniels

HL7 Australia

Phone: +61 408749769 Email: reuben@saludax.com

Heather Grain

eHealth Education

Phone: +61 3-956-99443
Email: heather@lginformatics.com

Russell Hamm

Intelligent Medical Objects (IMO)

Phone: +1 847-613-6645

Email: russellhamm@gmail.com

Robert Hausam, MD, FHL7

Hausam Consulting, LLC

Phone: +1 801-949-1556

Email: rob@hausamconsulting.com

William Ted Klein, FHL7

Klein Consulting Informatics LLC

Phone: +1 307-883-9739 Email: kci@tklein.com

Caroline Macumber

Apelon, Inc.

Phone: +1 203-431-2530

Email: cmacumber@apelon.com

Robert McClure, MD, FHL7

MD Partners, Inc.

Phone: +1 303-926-6771

Email: mcclure@mdpartners.com

HL7 Work Group Facilitators

BIOMEDICAL RESEARCH AND REGULATION

D. Mead Walker, FHL7

Modeling and Methodology Mead Walker Consulting Phone: +1 610-518-6259 Email: dmead@comcast.net

Myron Finseth, BS, MSc

Publishing Medtronic

Phone: +1 763-526-3071

Email: myron.finseth@medtronic.com

Julie James

Vocabulary
Blue Wave Informatics
Email: julie_james@
bluewaveinformatics.co.uk

CLINICAL DECISION SUPPORT

Craig Parker, MD, MS, FHL7

Modeling and Methodology; Publishing Email: craigparkermd@gmail.com

Robert McClure, MD, FHL7

Vocabulary MD Partners, Inc. Phone: +1 303-926-6771 Email: mcclure@mdpartners.com

CLINICAL GENOMICS

Amnon Shabo, PhD, FHL7

Modeling and Methodology Philips Healthcare Email: amnon.shvo@gmail.com

Grant Wood

Publishing Intermountain Healthcare Phone: +1 801-408-8153 Email: grant.wood@imail.org

Joel Schneider

Vocabulary National Marrow Donor Program Phone: +1 763-406-8207 Email: jschneid@nmdp.org

CLINICAL INFORMATION MODELING INITIATIVE

Susan Matney, PhD, RN

Vocabulary
Intermountain Healthcare
Email: susan.matney@imail.org

CLINICAL INTEROPERABILITY COUNCIL

AbdulMalik Shakir, FHL7

Modeling and Methodology Hi3 Solutions Phone: +1 626-644-4491 Email: abdulmalik.shakir@ hi3solutions.com

Amy Nordo, MMCi, RN

Publishing Pfizer

Email: amy.nordo@pfizer.com

Sarah Ryan

Vocabulary Email: ryansarahal@earthlink.net

COMMUNITY-BASED CARE AND PRIVACY

Ioana Singureanu, MSCs, FHL7

Modeling and Methodology; Publishing U.S. Department of Veterans Affairs Phone: +1 603-548-5640 Email: ioana.singureanu@ bookzurman.com

Kathleen Connor, FHL7

Vocabulary
U.S. Department of Veterans Affairs
Phone: +1 727-519-4607
Email: kathleen_connor@comcast.net

EDUCATION ADVISORY COUNCIL

Heather Grain

Vocabulary eHealth Education Phone: +61 3-956-99443 Email: heather@lginformatics.com

ELECTRONIC HEALTH RECORDS

Corey Spears

Modeling and Methodology Infor Phone: +1 917-426-7397 Email: corey.spears@infor.com

John Ritter, FHL7

Publishing

Phone: +1 412-372-5783 Email: johnritter1@verizon.net

EMERGENCY CARE

Kevin Coonan, MD

Modeling and Methodology Email: kevin.coonan@gmail.com

FINANCIAL MANAGEMENT

Kathleen Connor, FHL7

Modeling and Methodology; Vocabulary U.S. Department of Veterans Affairs Phone: +1 727-519-4607 Email: kathleen_connor@comcast.net

Beat Heggli, FHL7

Modeling and Methodology; Publishing HL7 Switzerland Phone: +41 44-297-5737 Email: beat.heggli@netcetera.com

Mary Kay McDaniel

Publishing; Vocabulary Cognosante, LLC Email: marykay.mcdaniel@ cognosante.com



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http://www.hl7.org/training/calendar.cfm

HL7 Work Group Facilitators

HEALTH CARE DEVICES

Ioana Singureanu, MSCs, FHL7

Modeling and Methodology U.S. Department of Veterans Affairs

Phone: +1 603-548-5640

Email: Ioana.singureau@bookzurman.com

Todd Cooper

Vocabulary Intermountain Healthcare Phone: +1 801-290-6887

Email: toddcooperafc@gmail.com

Christof Gessner

Vocabulary HL7 Germany

Phone: +49 172-3994033

Email: christof.gessner@gematik.de

IMAGING INTEGRATION

Elliot Silver, MSc

Vocabulary

Change Healthcare

Phone: +1 604-279-5422 x2686

Email: elliot.silver@changehealthcare.com

INFRASTRUCTURE AND MESSAGING

Grahame Grieve, FHL7

Modeling and Methodology
Health Intersections Pty Ltd./
Health Level Seven International

Phone: +61 3-98445796

Email: grahame@healthintersections. com.au / grahame@HL7.org

Anthony Julian, FHL7

Publishing Mayo Clinic

Phone: +1 507-293-8384 Email: ajulian@mayo.edu

Sandra Stuart, FHL7

Vocabulary Kaiser Permanente

Phone: +1 925-519-5735 Email: sandra.stuart@kp.org

MODELING AND METHODOLOGY

AbdulMalik Shakir, FHL7

Modeling and Methodology

Hi3 Solutions

Phone: +1 626-644-4491 Email: abdulmalik.shakir@

hi3solutions.com

William Ted Klein, FHL7

Vocabulary

Klein Consulting Informatics LLC Phone: +1 307-883-9739

Email: kci@tklein.com

ORDERS AND OBSERVATIONS

Patrick Loyd, FHL7

Modeling and Methodology Email: patrick.e.loyd@gmail.com

Lorraine Constable

Publishing HL7 Canada

Phone: +1 780-951-4853

Email: lorraine@constable.ca

Robert Hausam, MD, FHL7

Vocabulary

Hausam Consulting LLC Phone: +1 801-949-1556

Email: rob@hausamconsulting.com

PATIENT ADMINISTRATION

Alexander Henket

Modeling and Methodology; Publishing NICTIZ Nat.ICT.Inst.Healthc.Netherlands

Phone: +31 7031-73450 Email: henket@nictiz.nl

Wendy Huang

Vocabulary

Email: wendyyjhuang@gmail.com

PATIENT CARE

Jean Duteau

Modeling and Methodology Duteau Design Inc. Phone: +1780-328-6395 Email: jean@duteaudesign.com

Susan Matney, PhD, RN

Vocabulary

Intermountain Healthcare Email: susan.matney@imail.org

PHARMACY

Jean Duteau

Modeling and Methodology Duteau Design Inc. Phone: +1 780-328-6395 Email: jean@duteaudesign.com

Scott Robertson, PharmD, FHL7

Publishing

Kaiser Permanente Phone: +1 310-200-0231 Email: scott.m.robertson@kp.org

Julie James

Vocabulary
Blue Wave Informatics
Email: julie_james@
bluewaveinformatics.co.uk

PUBLIC HEALTH

Joginder Madra

Modeling and Methodology Madra Consulting Inc. Phone: +1 780-717-4295 Email: hl7@madraconsulting.com

Jean Duteau

Publishing
Duteau Design Inc.
Phone: +1 780-328-6395
Email: jean@duteaudesign.com

Susan Barber

Vocabulary

Email: subarber3@gmail.com

Sunanda McGarvey, BS

Vocabulary

Northrop Grumman Technology Services

Phone: +1 404-679-9384

Email: sunanda.mcgarvey@ngc.com

SECURITY

Mike Davis

Publishing

U.S. Department of Veterans Affairs

Phone: +1 760-632-0294 Email: mike.davis@va.gov

Kathleen Connor, FHL7

Vocabulary

U.S. Department of Veterans Affairs

Phone: +1 727-519-4607

Email: kathleen_connor@comcast.net

SERVICES ORIENTED ARCHITECTURE

Diana Proud-Madruga

Vocabulary

U.S. Department of Veterans Affairs

Phone: +1 619-467-5568

Email: diana.proud-madruga@va.gov

STRUCTURED DOCUMENTS

Austin Kreisler, FHL7

Modeling and Methodology Leidos, Inc.

Phone: +1 706-525-1181

Email: austin.j.kreisler@leidos.com

Sheila Abner, PhD

Vocabulary

Centers for Disease Control and Prevention/CDC Phone: +1 470-344-2864

Email: sha8@cdc.gov

TEMPLATES

Douglas Baird

Publishing

Boston Scientific Corporation Phone: +1 651-582-3241

Email: douglas.baird@guidant.com

Mark Shafarman, FHL7

Vocabulary

Shafarman Consulting Phone: +1 510-593-3483

Email: mark.shafarman@earthlink.net

VOCABULARY

William Ted Klein, FHL7

Vocabulary

Klein Consulting Informatics LLC

Phone: +1 307-883-9739 Email: kci@tklein.com

20, 022'20 0:04.94.

HL7 ARGENTINA

Fernando Campos, FHL7

Phone: +54 11-4781-2898 Email: fernando.campos@ hospitalitaliano.org.ar

HL7 AUSTRALIA

Jason Steen

Phone: +61 488881882 *Email:* chair@HL7.org.au

HL7 AUSTRIA

Stefan Sabutsch

Phone: +43 664-3132505 Email: stefan.sabutsch@hl7.at

HL7 BOSNIA & HERZEGOVINA

Samir Dedovic

Phone: +387 0-33-721-911 Email: samir.dedovic@medit.ba

HL7 BRAZIL

Marivan Abrahao, MD

Phone: +55 11-5573-9580 Email: marivan@mac.com

HL7 CANADA

Ron Parker

Phone: +1 416-595-3448 *Email:* ron@parkerdhc.com

HL7 CHINA

Professor Baoluo Li

Phone: +86 010-65815977 Email: liblpumch@qq.com

HL7 CROATIA

Miroslav Koncar

Phone: +385 99-321-2253 *Email:* chair@HL7.hr

HL7 CZECH REPUBLIC

Libor Seidl

Phone: +420 605740492 *Email:* seidl@HL7cr.eu

HL7 DENMARK

Sofia Stokholm

Phone: +45 39966222 *Email:* svs@ds.dk

HL7 FINLAND

Juha Mykkanen, PhD

Phone: +358 29-524-8038 *Email:* juha.mykkanen@thl.fi

HL7 FRANCE

Francois Macary

Phone: +33 786-160-591 *Email:* francois.macary@phast.fr

HL7 GERMANY

Christof Gessner

Phone: +49 172-3994033 *Email:* christof.gessner@gematik.de

HL7 GREECE

Alexander Berler

Phone: +30 2111001691 Email: a.berler@gnomon.com.gr

HL7 HONG KONG

Chun-Por Wong

Phone: +852 3488-3762 *Email:* chair@HL7.org.hk

HL7 INDIA

Naresh Yallapragada BDS, MSc

Email: chairman@HL7india.org

HL7 ITALY

Giorgio Cangioli

Phone: +39 06-42160685
Email: giorgio.cangioli@gmail.com

HL7 JAPAN

Michio Kimura, MD, PhD

Phone: +81 53-435-2770

Email: kimura@mi.hama-med.ac.jp

HL7 KOREA

Byoung-Kee Yi, PhD

Phone: +82 234101944

Email: byoungkeeyi@gmail.com

HL7 NETHERLANDS

Rob Mulders

Phone: +31 30-689-2730 Email: r.mulders@furore.com

HL7 NEW ZEALAND

Peter Jordan, MSc, LLB

Phone: +64 21-758834 Email: pkjordan@xtra.co.nz

HL7 NORWAY

Line Saele

Phone: +47 9592-5357

Email: line.sele@nasjonalikt.no

HL7 PAKISTAN

Kahlid Latif

Email: khalid.latif@Hl7.org.pk

HL7 POLAND

Roman Radomski, MD, MBA

Phone: +48 605-404-363 Email: radomski@iehr.eu

HL7 PORTUGAL

Paulo Alves

Email: paulo.alves@proside.pt

HL7 ROMANIA

Florica Moldoveanu

Phone: +40 21-4115781

Email: florica.moldoveanu@cs.pub.ro

HL7 RUSSIA

Sergey Shvyrev, MD, PhD

Phone: +7 495-434-55-82

Email: sergey.shvyrev@gmail.com

HL7 SAUDI ARABIA

Wael Al Dahhasi

Phone: +966 11-2021555 *Email*: HL7@cchi.gov.sa

HL7 SINGAPORE

Adam Chee

Email: HL7@binaryhealthcare.com

HL7 SPAIN

Francisco Perez

Phone: +34 637208657

Email: fperezfernan@gmail.com

HL7 SWEDEN

Mikael Wintell

Phone: +46 736-254831

Email: mikael.wintell@vgregion.se

HL7 SWITZERLAND

Roeland Luykx, PhD

Phone: +41 71-279-11-89

Email: roeland.luykx@arpage.ch

HL7 TAIWAN

Yu-Ting Yeh

Phone: +886 2-2552-6990 Email: yuting@tmu.edu.tw

HL7 UAE

Mohamed AlRedha, MD

Phone: +971 50-883-9916 *Email:* maalredha@dha.gov.ae

HL7 UK

Dunmail Hodkinson

Phone: +44 8700-112-866 Email: chair@HL7.org.uk

HL7 UKRAINE

Leonid Stovanov

Phone: +380 443336829 *Email:* leo@hl7.org.ua

Chief Executive Officer



Charles Jaffe, MD PhD +1 858-720-8200 cjaffe@HL7.org

Director of Education



Sadhana Alangar, PhD +1 734-677-7777 x116 sadhana@HL7.org

Director, Project Management Office



Dave Hamill +1 734-677-7777 x142 dhamill@HL7.org

Accounting Manager



Renee Previch +1 734-677-7777 x106 renee@HL7.org

Chief Technology Officer



Wayne Kubick +1 847-842-1846 wkubick@HL7.org

Director of Meetings



Mary Ann Boyle +1 734-677-7777 x141 maryann@HL7.org

Director of Membership and Administrative Services



Linda Jenkins +1 734-677-7777 x170 linda@HL7.org

Applications Manager



Joshua Procious +1 734-677-777 x107 joshua@HL7.org

Executive Director



Mark McDougall +1 734-677-7777 x103 markmcd@HL7.org

FHIR Product Director



Grahame Grieve +1 734-677-7777 grahame@HL7.org

Director of Technical Services & Webmaster



David Johnson +1 734-677-7777 x125 davidj@HL7.org

Director of Communications



Andrea Ribick +1 734-677-7777 x165 andrea@HL7.org

ector Associate Executive Director



Karen Van Hentenryck +1 734-677-7777 x104 karenvan@HL7.org

Director of Marketing



Patricia Guerra +1-773-516-0943 patricia@HL7.org

Web Developer



Director of Technical

Publications

Lynn Laakso, MPA +1 906-361-5966 lynn@HL7.org

Education Marketing Manager



Melinda Stewart +1 734-677-7777 x101 melinda@HL7.org



Laura Mitter +1 740-963-9839 laura@HL7.org

HL7 Project Manager



Anne Wizauer +1 734-677-7777 x112 anne@HL7.org

2019 HL7 Board of Directors

BOARD CHAIR

CHAIR-ELECT

BOARD SECRETARY

BOARD TREASURER

CHAIR EMERITUS



Calvin Beebe, FHL7 Mayo Clinic cbeebe@mayo.edu



Walter Suarez, MD, MPH Kaiser Permanente +1 301-801-3207 walter.g.suarez@kp.org



Melva Peters Jenaker Consulting +1 604-512-5124 melva@jenakerconsulting.com



Russell Leftwich, MD InterSystems +1 617-551-2111 russell.leftwich@intersystems.



W. Edward Hammond, PhD, FHL7 Duke Clinical & Translational Science Institute +1 919-668-2408 william.hammond@duke.edu

AFFILIATE DIRECTORS

APPOINTED DIRECTORS



Dave Shaver, FHL7 Corepoint Health +1 214-618-7000 dave.shaver@corepointhealth. com



Mary Ann Slack Food and Drug Administration +1 301-796-0603 maryann.slack@fda.hhs.gov



Andrew Truscott
Accenture
+1 713-855-8402
andrew.j.truscott@accenture.com



Diego Kaminker HL7 Argentina +54 11-4781-2898 diego.kaminker@kern-it.com.ar

DIRECTORS-AT-LARGE



Line Saele HL7 Norway +47 9592-5357 line.sele@nasjonalikt.no

TSC CHAIR



Austin Kreisler, FHL7 Leidos, Inc. +1 706-525-1181 austin.j.kreisler@leidos.com



Jennifer Covich Bordenick eHealth Initiative +1 202-624-3270 jennifer.covich@ehidc.org



Kensaku Kawamoto, MD, PhD University of Utah Health Care +1 801-587-8076 kensaku.kawamoto@utah.edu



Janet Marchibroda Bipartisan Policy Center +1 202-379-1634 jmarchibroda@ bipartisanpolicy.org



Nancy Orvis, MHA U.S. Department of Defense, Military Health System +1703-681-6350 nancy.j.orvis.civ@mail.mil

NON-VOTING MEMBERS





Charles Jaffe, MD, PhD HL7 CEO +1 858-720-8200 cjaffe@HL7.org



Wayne Kubick HL7 CTO +1 847-842-1846 wkubick@HL7.org



Mark McDougall HL7 Executive Director +1 734-677-7777 x103 markmcd@HL7.org



Newly Certified HL7 Specialists

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

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DECEMBER 2018

Ramakanth Poralla Roopasree C S Sai Venkat Sarang Tade Shivali BR

Anurag Dongre Binaya Kumar Patel

Joy Merson Pavitra B I Rajratna Mihir

Sachin Kumar Suman

Mandara K R

Sushmitha Jayaraman

Frank Parth

Abdul Kalam Azad Abhishek Kumar Singh

Abhishek Pradhan

Akanksha Priya Aravind Raghunath

Ashish Shroff Bipin Singh Chetan Palavalli

Divya Rajput

Eunice Esther Lovel M

Faraasha K. A

Mohammed Khalid Nehan

Murari Kiran Kumar

Padmashree K V

Prashanth Prakasha Pratyush Kumar Singh

Satinder Singh Butter

Chetana G

Atul Shah

Sana Moin

Iván Florencio Sosa Ménde

Namrata Anand Anubhay Seth

ZhaoHui Liu

Michael Lipton

JANUARY 2019

Avinash Kumar Singh Pegeen Ladeau Odysseas Batsios

Vivek S

Mason Dansie Ana Belen Jaime Disha Verma Kavvashree H R

Manish Kumar

Mohammed Sajid Mustfa

Namita Anand

Navaneetha Krishnan P

Neeraj Bora

Praveen Kumar Sekaran

Puneet Valad

Ranu Goyal

Sonu Kumar

Yogesh Shukla

Gaurav Singh

Anarghya V Kini

FEBRUARY 2019

Ruchir Bhardwaj Miguel Bras

Daniel Martinez Rodriguez

MARCH 2019

Marcos Suñen Asim Ahmed

Certified HL7 CDA 2.0 Specialist

DECEMBER 2018

Jose Antonio Pardos Mateo Jesús Roman Ledesma Clara Cirac Nerin Jesus Campos Alvarez Luis López Alonso Francisco Mansilla de Sebastian Wojciech Parchanski Manan Kansara

JANUARY 2019

Eduardo Muntané Molina Mathias Ghys

FEBRUARY 2019

James Blue

HL7 FHIR STU Proficient Certified

DECEMBER 2018

Rakesh Waghulde Daniel Nebot Alece Studtmann Nilesh Sawal Rohan Chavan abhijeet badale Neha Kadmane Alka Jain Rashmi Nair Ravindra Kulkarni Shailesh Nair Mallika Padte Aarti Naik Phong Nguyen
Nisarg Khandekar
Sharad Sinha
Vicky Nathani
sameer singh
Sunny Goyal
Ramandeep Dhanoa
Mukul Matkar
Rajat Sharma



JANUARY 2019

Sushant Komawar Sumankumar Kareti Srinivas Velamuri Hemant Garg Divya Ahuja

FEBRUARY 2019

Vivek Chaudhari Shital Surve

MARCH 2019

Rajesh Saini



Upcoming HL7 Meetings



June 10-12, 2019 HL7 FHIR Dev Days Microsoft Conference Center

Redmond, Washington



February 1-7, 2020 International Conference & Working Group Meeting To be announced

Sydney, Australia



September 18-25, 2020 Working Group Meeting

Baltimore Renaissance Harborplace

Baltimore, Maryland



September 14-20, 2019 33rd Annual Plenary & Working Group Meeting Atlanta Marriott Marquis

Atlanta, GA



May 16-22, 2020 Working Group Meeting Hyatt Regency San Antonio on The Riverwalk

San Antonio, TX