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
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 artificulated 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.”

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.
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 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.
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.
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.

**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.
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](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.
Tooling Update

Neither a Sprint nor a Marathon

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.

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

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<td><a href="http://www.himssasiapac.org/events/australia-ehealth-summit">www.himssasiapac.org/events/australia-ehealth-summit</a></td>
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<td>September 12, 2019 Swiss eHealth Summit 2019</td>
<td><a href="http://www.ehealthsummit.ch">www.ehealthsummit.ch</a></td>
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<td>October 7-10, 2019 HIMSS AsisaPac19</td>
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<tr>
<td>February 1-7, 2020 HL7 February International Conference &amp; Working Group Meeting</td>
<td><a href="http://www.HL7.org">www.HL7.org</a></td>
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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:

1. Piloting the Unified Terminology Governance (UTG) process and tooling
2. Flat FHIR (Bulk Data & Push)
3. 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
7. 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.

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 Implementation-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.hl7.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.
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.

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 easily-corrected issues outlined below:

1. **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 listserv 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.

4. **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 regardless of which of the above issues is preventing you from receiving the email inviting you to vote, we can usually identify a solution to get you onto the list of eligible voters without a lot of fuss. In conclusion, prior to an upcoming WGM, I encourage you to check your listserv subscriptions and subscribe using the email connected with your membership ship record, if possible. This will eliminate most of the problems. Feel free to contact me should you have questions or concerns about our use of Election Runner for co-chair elections.
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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 which discovered major coronary artery disease. After angioplasty and a stent, she was released from the hospital. 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 are available to patients faster.

Background of Clinical Research Interoperability

For the last sixty years, the cost and time of clinical trials has increased\(^1\); however, these problems persist despite effort to reduce them. Improvement in data collection is an area ripe for impactful advancement. Since 2007, with the Starbrite study\(^3\), 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

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4. [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.
HL7 FHIR® Launches FHIR® Accelerator Program

The CARIN Alliance joins HL7 Argonaut and Da Vinci Projects to accelerate FHIR

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 decision-makers 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 provider-patient 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...
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
HL7 Board Elections are open July 1 - July 30

Don’t forget to vote!
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
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 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 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.

Fig. 1. Regional e-scheduling architecture

Continued on page 22
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 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 and will make use of HL7 FHIR Terminology Services.

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.

Małopolska Medical Information System

HL7 Standards Approved by ANSI Since November 2018

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Invitation to Warsaw for IHIC 2019

October 23 – 24, 2019 / Warsaw, 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 Integraton 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

Integraton 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 Integraton 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 Lazienki 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.

For the most up-to-date information about IHIC, visit http://ihic.info and follow #ihic2019
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.

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 LEGO.

On a concrete system running on a server, each module will be a micro-service – 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 Questionnaire 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.
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 connectathon 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.
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 drug-gene 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 drug-gene interactions. Where sufficient data about the interacting gene regions is unavailable, the CDS platform may suggest ordering a genetic test prior to prescription if it is warranted.

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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- CENS
- Center for Medical Interoperability
- Centers for Medicare & Medicaid Services
- Centre for Development of Advanced Computing
- College of American Pathologists
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<td>New York State Department of Health</td>
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<td>Object Management Group (OMG)</td>
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<td>Pharmaceuticals &amp; Medical Devices Agency</td>
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<td>Social Security Administration</td>
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<td>The Joint Commission</td>
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<td>The Sequoia Project</td>
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<td>UC Davis School of Medicine</td>
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<td>United Network for Organ Sharing</td>
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<td>United Physicians</td>
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Financial Management
Imaging Integration
Orders & Observations
Patient Administration

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Biomedical Research & Regulation
Clinical Decision Support
Clinical Genomics
Clinical Interoperability Council
Clinical Quality Information
Community-Based Care and Privacy
Emergency Care
Health Care Devices
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FHIR Infrastructure
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HL7 FHIR Dev Days
Microsoft Conference Center
Redmond, Washington

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

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

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

September 18-25, 2020
Working Group Meeting
Baltimore Renaissance Harborplace
Baltimore, Maryland