HL7 30 YEARS OF STANDARDS DEVELOPMENT

Update from Headquarters

By Mark McDougall,
HL7 Executive Director

**Pat's Coronation and Gearing up for
HL7's 30th Annual Plenary Meeting**

Survey says....

During the week of our recent Montreal Working Group Meeting (WGM), HL7's online "member pulse" question asked members to identify their favorite member benefit among six options. I was not surprised to learn that the number one favorite benefit was *participating in a community of like-minded individuals*. In fact, members ranked this higher than all of the other benefits combined. As many of you have heard me say from the podium, HL7's community of brilliant, hardworking and dedicated volunteers is HL7's most valuable asset. It is heartwarming to learn that you, the members of our community, also value those that you collaborate with throughout the meetings, the years and decades. On behalf of the HL7 staff and those who served on the HL7 Board over the last 30 years, we extend sincere thanks for your role in our HL7 family.

30th Annual Plenary Meeting in Baltimore

We are looking forward to producing weeklong activities that will be informative, productive, educational and fun. The meeting will run September 17-23, 2016 and will be held at the Hyatt Regency Inner Harbor in Baltimore, Maryland. The FHIR connectathon and TSC meetings begin on Saturday, September 17th.

The theme for the 30th Plenary meeting is *securely accessing and using the right health data when and where it is needed*. If this theme looks familiar, it may be because it comes from HL7's vision statement. Keynote presentations will be given by industry leaders such as Mark McClellan, MD, PhD, from Duke University and former Administrator at CMS; Betsy Humphreys, Deputy Director at the National Library of Medicine; Robert Califf, MD, Commissioner at the US Food and Drug Association; Jonathan Perlin, MD, PhD, President, Clinical Services and Chief Medical Officer at Hospital Corporation of America. The plenary will also include an HL7 blast from the past panel that promises to be entertaining.

Montreal WGM

We were pleased that 428 attendees participated in our May WGM held in Montreal, Quebec, Canada from May 8-13, 2016. Fifty HL7 work groups convened meetings in Montreal and 17 conducted co-chair elections. Attendees also took advantage of a FHIR connectathon and 30 tutorials during that week.

HL7® FHIR®

Coronation of "Princess" Pat

During our networking reception in Montreal, we had fun with our Board Chair, Pat Van Dyke, who is a registered nurse and works in an emergency room. Pat recently told me that some of her coworkers gave her a hard time when she would occasionally take a short four hour shift, known as "princess shifts". I saw an opportunity that I could not pass up and bought a tiara. I was not sure how or when I would present the tiara to Pat, until Philip Scott suggested that we do so during the networking reception. Philip also suggested that we ask Ken McCaslin to serve as HL7's Archbishop of Canterbury and perform the coronation. On my way to the stage, I saw a red trench coat on an attendee's arm which I quickly borrowed and placed on Pat's shoulder just as Ken finished his eloquent comments and crowned Pat HL7's Princess. On cue, a chorus of *God Save the Queen* filled the ballroom.

A special thank you to Pat for being such a good sport, and for the invaluable roles played by Philip, Ken and the person who lent me her red trench coat that served well as Pat's coronation robe. As you see in the photo above, Pat was a wonderful sport about this and laughed as hard as the 400 witnesses. This moment illustrates the fun side of our HL7 family.

Meeting Sponsors

I am pleased to recognize the following organizations that once again sponsored key components of our May Working Group Meeting in Montreal. The additional sponsorship support provided by the organizations listed below contributed significantly to HL7's meeting budget and is much appreciated.

- AEGIS
- GEVITY
- Hi3
- Intelligent Medical Objects (IMO)
- iNTERFACEWARE
- PenRad Applicadia
- QVERA Interface Engine

HL7 Chair Pat Van Dyke with May Working Group Meeting sponsors

Benefactors and Gold Members

We are pleased to recognize HL7's 2016 benefactors and gold members who are listed on page 39. Their support of HL7 is very much needed and sincerely appreciated. We are pleased to recognize our benefactors in all of our HL7 newsletters, on the HL7 website, in all of our HL7 press releases, and at all of our HL7 working group meetings. We also look forward to presenting plaques of appreciation to them during our upcoming 30th Plenary Meeting week.

Organizational Member Firms

As listed on pages 40-43, HL7 is proud to recognize the organizations who are HL7 organizational member companies. We sincerely appreciate their ongoing support of HL7 via their organizational membership dues.

In Closing

As I write this column we are approaching the longest day of the year (June Solstice) in the northern hemisphere. So, the rest of the days this year will become shorter (less sunlight) with each day. To some, the image of the days getting shorter may also represent life, as many of us may be in the second half of our lives. Fortunately, I am reminded that while my days are becoming shorter, I am blessed with many friends in the southern hemisphere (e.g., Marivan, Diego, Fercam, Patricia, Vince and David to name a few), whose days will now become longer and will enjoy more sunshine each day. I choose to remind myself that my glass is half full (not half empty), and that longer days may be available by simply booking a flight.

Best wishes to you and your loved ones for good health and plenty of sunshine.

News from the HL7 Project Management Office

HL7 Making Progress on ONC Grant Projects

The Office of the National Coordinator for Health IT (ONC) has awarded Health Level Seven International two grant funded cooperative agreement projects: Enhancing Consolidated CDA® Implementation and Standards Development Organization Collaboration to Enhance Standards Alignment, Testing, and Measurement.

By Dave Hamill,
Director, HL7 Project
Management Office

ONC Grant Project: Enhancing C-CDA Implementation

Last year, The Office of the National Coordinator for Health IT (ONC) awarded HL7 a grant to enhance and improve Consolidated Clinical Document Architecture (C-CDA) implementation.

The ONC grant to enhance and improve C-CDA implementation covered seven components:	
1	Discovery of C-CDA content inconsistencies via surveys and in-person Implementation-a-thons
2	Extension and/or modification of template samples to address inconsistencies identified by item 1 above
3	Creation of an updated C-CDA Release 2.1 (R2) Companion Guide informed by items 1 and 2 above
4	Updates to the HL7 Help Desk section specific to C-CDA to address items 1-3 above
5	A C-CDA rendering prize challenge
6	A C-CDA scoring methodology
7	Enhance/Upgrade the platform where C-CDA sample templates reside
8	National Institute for Health and Welfare

The First RFPs

The first Request for Proposal (RFP) for discovery of C-CDA content inconsistencies via surveys and in-person Implementation-a-thons (IAT) has been completed. Duteau Design issued two surveys and conducted two IATs (Orlando and Chicago); analyzed and documented the results of each; produced a final report that prioritized and recommended the necessary resources to implement consistent C-CDA results; and reviewed that report with the Structured Documents Work Group. The IATs were so well received that the ONC and HL7 agreed to utilize some of the grant funds to have Duteau Design conduct a third IAT in Washington, DC, just prior to HL7's 30th Annual HL7 Plenary and Working Group Meeting in Baltimore, Maryland.

The next RFP, awarded to Duteau Design and Life Over Time Solutions, was for the creation of an updated C-CDA Companion Guide. This project's goal is to produce a new C-CDA Companion Guide to support C-CDA R2.1. The purpose of the new Companion Guide is to:

- Supplement the C-CDA R2.1 Implementation Guide to provide additional context to assist implementers and connect them to tools and resources
- Map the common clinical data set (CCDS) to the appropriate C-CDA locations
- Provide technical guidance for representing the 2015 Ed. CEHRT data requirements using the C-CDA Implementation Guide
- Include clinically-valid examples of C-CDA components necessary to meet 2015 Ed. CEHRT requirements
- Recommend an approach to implementations using the C-CDA Implementation Guide to meet the needs of clinicians and achieve ONC Certification

The following deliverables have been completed:

- Created a Common Clinical Data Set (CCDS) requirements mapping spreadsheet from the 2015 certification rule to the appropriate C-CDA location

- Created a Meaningful Use (MU) mapping for additional data specified for: CCD, Discharge Summary, Referral Note, and Care Plan

- Created a draft version of the C-CDA R2.1 Companion Guide which is currently available to the public through the HL7 Wiki. A webinar was conducted to advise the industry of its availability and review its content

- The C-CDA R2.1 Companion Guide was balloted in the September 2016 ballot cycle; reconciliation will occur for the coming weeks and then it will be published

HL7 Wiki pages have been created to store documents and deliverables for the above components of the grant project. The pages are accessible a couple of ways — via the Structured Documents Work Group wiki page or under the projects listed on the HL7 Wiki main page. The URL is:

http://wiki.hl7.org/index.php?title=C-CDA:_Enhancing_Implementation_(ONC_Grant_Project)
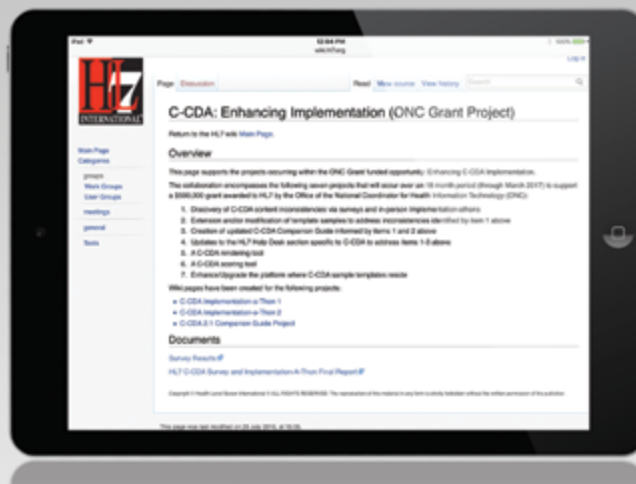
The C-CDA Rendering Tool Challenge

The next component of the grant supported a challenge to improve C-CDA rendering tools. The objective of the tool is to reduce frustration by clinicians with the usability of C-CDA documents, make it easier to find relevant clinical information, and decrease the overabundance of rendered data sent to providers. The challenge to participants was to develop a viewer that enables clinicians to efficiently review clinically relevant patient data from C-CDA documents by:

- Presenting requested data quickly and clearly

- Providing section based view preferences

- Providing filter and sorting functions

- Being easy to use

Evaluating and judging was conducted in June and July. The first prize winner, Bryn Lewis, PhD, is featured in an article on page 21. The winners will be recognized at HL7's 30th Annual Plenary & Working Group Meeting in Baltimore, Maryland. The ONC allocated $20,000 of the grant funds to the winning entries and the entries will be made freely available on the HL7 website for use.

The C-CDA Scoring Methodology

The focus of the C-CDA scoring methodology component is to create a methodology, approach and requirements with the ultimate goal of creating a tool to score C-CDAs that have been created or received.

Thanks to Calvin Beebe who extracted the rubrics that were used to create the SMART C-CDA Scorecard tool. The Structured Documents Work Group reviewed the data and it was ultimately provided to the ONC for the development of their tool.

Upcoming Project Elements

The final components of the cooperative projects are still in their infancy. Work on extending/modifying C-CDA template samples to address inconsistencies identified by the surveys and implementation-A-Thons will ramp up soon. Additionally, funds have been allocated to enhance or upgrade the platform where these sample templates reside. Currently, they are located on the HL7 Wiki at: http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force.

The last element of the grant project is to update the C-CDA FAQs and articles on the HL7 Help Desk. Work on this can begin as the other components draw to a close.

HL7 Making Progress on ONC Grant Projects

ONC Grant Project: Standards Development Organization Collaboration to Enhance Standards Alignment, Testing, and Measurement

ONC also awarded HL7 with a modest grant to develop a plan to ensure that conformance testing is available across its portfolio of implementation guides. Note that the grant deliverable is a plan and does not include implementation of the plan.

While the grant is modest, if implemented, it has the potential to drastically improve and make implementation easier as conformance tooling could be developed concurrently with our standards.

The project was scoped to include only those implementation guides (IG) that were developed for the US and/or Universal realms, which resulted in a catalogue of 55 IGs. While the project specifically does not address implementation guides developed for non-US or non-Universal realms, the assumption is that the recommended approach can be extended to include those implementation guides as a later time.

HL7 contracted with Gevity Consulting to identify the conformance tooling currently available for each IG in the catalog, prioritize the need for tooling, and provide a means of rating the available tools. Gevity's research determined that for the 55 IGs, 24 conformance tools exist but 19 IGs lack any associated conformance tools. Gevity's report provided an assessment of the need to develop tooling for those 19 IGs and the estimated effort required for development.

Using the above information as well as input from the TSC, HL7 submitted an initial report to the ONC in April. HL7's proposed approach is to require that its implementation guides provide relevant conformance statements that are machine computable and robust enough to enable conformance tooling vendors to develop conformance tooling concurrent with the development of the implementation guide. HL7 feels very strongly that it should not develop conformance testing tools internally but should provide robust conformance statements that allow tooling experts to do so.

To achieve the desired future state, HL7 will need to accomplish the following:

- Develop a policy that requires conformance statements in all implementation guides
- Develop a guidance document that defines how to develop robust conformance statements
- Train work groups to develop the conformance statements
- Recruit conformance facilitators
- Develop a plan for creating conformance statements for all or some subset of extant implementation guides for which there is not conformance tooling
- Develop a certification program to certify conformance tools and/or tooling vendors
- Develop and maintain a tooling catalog
- Continue efforts to create examples (CDA) and models (CIMI) for representing data
- Identify method to collect and report implementation/usage metrics annually

In the months following the initial report, we reached out to various groups including the TSC, Architectural Review Board, Conformance and Guidance for Implementation/Testing, Infrastructure and Messaging, Modeling and Methodology Structured Documents, as well as AEGIS and NIST. The focus was to determine how HL7 can achieve the above goals as well as estimate the time and resources associated with the work. This information will be included in the final report to the ONC, due at the end of September. ◼

Member Spotlight on Julia Skapik, MD, MPH

Julia (R) with her sisters, (Jackie (L) and Allie (Center), on the top of the Glacier Les Diablerets in the Swiss Alps, where they rode the world's highest roller coaster after the HL7 May 2016 WGM in Paris.

Julia Skapik, MD, MPH has been a member of HL7 through the Office of the National Coordinator for Health Information Technology (ONC) since 2014. She is a board-certified Internist and Medical Officer at the ONC, where she has stewarded governance, standards, and terminology for electronic clinical quality measures (eCQMs) in the EHR Incentive Program since 2012. Julia led ONC's role in the creation of the Value Set Authority Center at the National Library of Medicine, including content harmonization, governance, and quality assurance processes. She currently acts as the ONC lead, working with CMS, on the Clinical Quality Framework to harmonize data elements, models and expression language standards across clinical decision support and eCQMs. She also looks forward to ongoing opportunities with health IT stakeholders working toward common data elements; modularization of eCQM specifications and certification; a national testbed for health IT data; LEAN for federal business processes; as well as to improvements in federal health IT regulations that enable innovation and usability in the private sphere.

Julia joined the ONC after an AAAS Science & Technology Policy Fellowship at the National Science Foundation. She was introduced to health IT policy during a Mirzayan Policy Fellowship at the Institute of Medicine in 2007. She completed her MD and MPH in Epidemiology and Biostatistics at the Johns Hopkins University. During her time in school, she heavily engaged in health policy as a national medical student leader in the American Medical Student Society (the subversive counterpart to the AMA Student Society). Despite a strong interest in health policy, health IT and systems administration, Julia completed her internal medicine residency at the University of Pittsburgh. She then quickly returned to policy in health IT innovation and research at the National Science Foundation, to which she accredits her disruptive innovation mindset in health IT. She currently moonlights at Inova Mount Vernon Hospital in Virginia as a hospitalist.

Julia grew up in Licking County, Ohio, about an hour east of Columbus. However, her family is from Pittsburgh and she is an avid fan of the Steelers, Penguins (Stanley Cup winners 2016!) and Pirates. Her love of sushi and spas was cultivated during a three month student exchange to Japan as a senior in high school. She is a lifelong soccer player and the proud owner of a karaoke listserv in Washington, DC (as well as an HL7 karaoke instigator!). Julia has also completed two century (100 mile) bicycle rides in the past year and plans to do more (she invites anyone who wants to go for a ride at HL7 to reach out to her). Julia is the oldest of three girls. She recently got engaged to her long time nurse informaticist boyfriend, Jeff, who regularly complains to her about the onerous nature of HHS regulations. Finally, be aware that Julia is in the running for "HL7's Most Gregarious Fed," so feel free to go up to her and strike up a conversation any time! ◼

Calling all Patients and Caregivers!

There's a New Birds of a Feather (BoF) at HL7!

By Lisa Nelson, HL7 Member and Founder of the Janie Appleseed Network

A new birds of a feather (BoF) session flew onto the scene at the May 2016 HL7 Working Group Meeting in Montreal. The group is seeking HL7 members interested in adding the voice of patients and caregivers to the flock of stakeholders developing standards to improve information interoperability in healthcare.

> **Birds of a Feather sessions (or BoFs) are informal gatherings of like-minded individuals who wish to discuss a certain topic without a pre-planned agenda.**

The group was convened by Lisa Nelson, an active participant in Structured Documents, Patient Care, Templates, and other HL7 work groups. Lisa co-authored the Patient Generated Document Header template that is now part of the HL7 Consolidated CDA® (C-CDA) standard. She also authored the recently released CDA standard for trial use (STU) for Personal Advance Care Plan Documents.

Nelson is the founder of a non-profit organization called the Janie Appleseed Network (www.JanieAppleseed.net). The mission of the Janie Appleseed Network is to cultivate the adoption of consumer-controlled electronic personal health records through a wide range of activities including participation in standards development. She hopes this new HL7 BoF will attract other HL7 members passionate about adding the voice of patients and caregivers within the HL7 organization.

Nelson believes it is the right time to start a group like this at HL7. The recent vision expressed in the *Connecting Health and Care for the Nation* report clearly spells it out, explained Nelson at the BoF session. "This report is our shared nationwide interoperability roadmap for the path forward," she said. "It tells us to 'embrace the value of the individual inside and outside the health care system for improving both health and care', and it paints a picture of 'individuals becoming effective managers of their health and wellness where they live, work and play, using information and technology'," she quoted directly from the report.

At the BoF, the flock discussed a version of the IHI Triple Aim graphic that Nelson modified to show patient-centered care at the center of the targeted goals for health IT (HIT) adoption. Changing the paradigm to a person-centered ecosystem is vital to improving health, given that an individual's actions greatly impact health outcomes, Nelson argued.

Nelson also shared a compelling call to action for HIT standards and application development based on vision set forth in the roadmap. She stated the need for systems that make it possible for the power of each individual to be developed and unleashed so they can become active in managing their health and partnering in their healthcare, enabled by information and technology.

The problem, Nelson said, is that people are center-stage in the model of care we are aiming to create, but currently they have no seat at the table—no voice in how systems are created and what systems are required to do. This is what Nelson hopes the new HL7 BoF will change.

"It is essential that we add people to the flock of HIT stakeholders," advocated Nelson. "The challenge is to find a feasible way to do that. There is no organization or collective that's raising money to send individual patients and caregivers to HL7, HIMSS, and IHE to represent their requirements for health information technology. Most people don't speak the language of standards development. They don't have the knowledge to really understand what's being discussed, and they may not even find it interesting. But, these are the subject matter experts we need to engage. People are intimately aware of the details of what health and wellness really mean in life. They know what they need and what they want in terms of the type of care and support that would help them. They know what information they want to share and access to help them get well, stay healthy, and live better lives."

Nelson presented an idea. She suggested the group could bring the voice of patients and caregivers into HL7 by documenting a collection of patient stories based on real life experiences with health and care. The stories would be real, but techniques like those used when writing a Harvard Business Review Case would be employed to anonymize the story without eliminating essential information. The stories would be highly accurate and rich with personal, clinical, and financial information. They could be used to create use cases that add patient and caregiver perspectives when standards are being developed. They also could be used to create synthetic data that could be used to support trial implementations and testing of standards.

Nelson showed examples of these type of patient stories generated through the Janie Appleseed Network (www.janieappleseed.net/value-stories.html). She also reported that the HIMSS Health Story Project (HSP) had developed a patient story of this type and created a synthetic Continuity of Care Document (CCD®) Document to encode the details of the story. The HSP story was used in an experiment at the 2016 IHE North America Connectathon with a new type of story-based testing
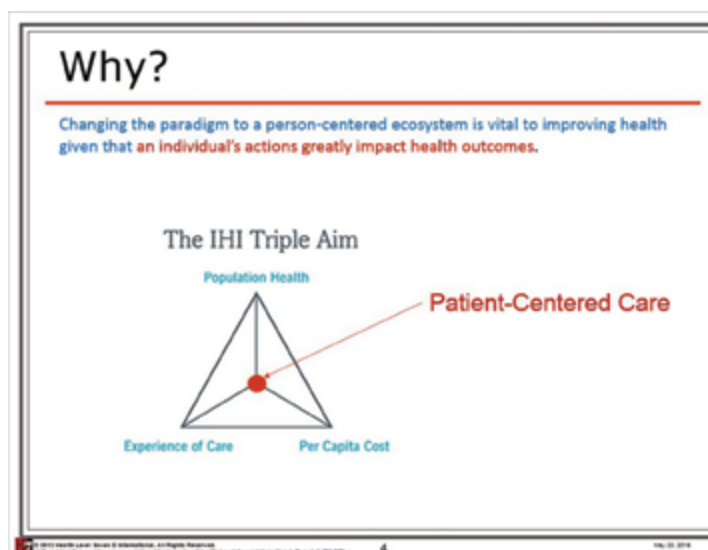
At the BoF, the flock discussed a version of the IHI Triple Aim graphic that Nelson modified to show patient-centered care at the center of the targeted goals for health IT (HIT) adoption.

that focused on the degree to which a CCD was able to capture all the details of the patient's story.

A similarly detail-rich patient story was developed about a man managing multiple chronic conditions. This became a user story in the recently published Care Plan Domain Analysis Model. A segment of that story also was used to guide a proof of concept project to explore the electronic exchange of care plan information using the C-CDA Care Plan Document standard.

The new BoF session was a great success. Twelve people met, shared personal stories, and exchanged ideas about how to grow a flock of HL7 members interested in bringing the voice of patients and caregivers into the HL7 working group. Participants expressed interest in creating patient stories and committed to developing some examples before the September meeting. "This session gave me goose bumps," said Virginia Lorenzi, a strong supporter who offered many exciting ideas to expand the impact of this initiative at the September Plenary. "The energy in the room was amazing," said John Ritter, an active member of the Electronic Health Records Work Group and co-author of the Personal Health Record Functional Model. "May the wind be at our backs as we work together to move this idea forward," he closed.

If you missed participating in the first BoF meeting, it's not too late to get involved. If you have interest and want to help add the patients and caregivers to the flock of stakeholders represented in HL7, send an e-mail to Lisa@JanieAppleseed.net, and join us! ■

Making the Most of WGM Opportunities

HL7 Working Group Meeting: A First-Time Attendee's Perspective

By Tim Hricik,
Consulting
Analyst,
Accenture

My name is Tim Hricik and I am a consultant with Accenture. I have been with the firm since late 2011 and have been a member of the HL7 community since 2013.

In May, I had the opportunity to attend my first HL7 working group meeting (WGM) in Montreal. As I attempted to navigate the WGM, I was introduced to a fellow Accenture colleague and longtime HL7 leader, Ken McCaslin. Ken is the head of HL7's Technical Steering Committee and kindly helped shepherd me through the agenda and activities of the WGM. He provided introductions, shared his past experiences, and gave general words of wisdom to help me get the most out of my own experience.

Subsequently, Ken asked if I would write an article that might serve as a guide for future first-time attendees. Wishing that I had had a little more information about the WGM before my first visit, I jumped at the opportunity to share my observations with others. So, for all those attending a WGM for the first time in the near future, here is a little bit about my experience and what you might expect.

What did I anticipate for the working group meeting?

I really had no idea what to expect for my first visit to an HL7 WGM, but I knew that this would likely be different from other types of conferences I had previously attended. My initial intention was to simply attend the Fast Healthcare Interoperability Resources (FHIR®) sessions and connectathon in hopes of learning as much as I could about the emerging standard. I knew the HL7 organization was actually more than just one standard, but

I will admit I let myself get a bit pessimistic about what I would encounter. Is this going to be the usual bunch of tech people laboring and debating over dry discussions of standards? Am I going to be stuck attending lengthy, drawn out lectures, struggling to maintain interest and attention? Will it be relevant to my interest areas and career development? I am pleased to report that with the guidance of Ken and many of the new contacts I made, my apprehension quickly dissipated and allowed me to have a productive and, more importantly, enjoyable time.

What did I learn as first timer?

I learned so much at the WGM that it's hard to narrow down specific points, but with a bit of

time for reflection, there are three distinct aspects that have stuck with me: the actual "work" entailed by a working group meeting, the wonderful members of the HL7 community, and all the fun that can be had while actually "working"! For a long time I held an overly simplistic and superficial view that WGMs simply existed to produce standards. Yes, these meetings indeed focus on the HL7 mission of developing standards and enabling their adoption, but I learned that work groups do significant work toward managing the overall direction of HL7, sponsor innovative projects, and serve as stewards for the associated standards. This impressive scope of work could not be done if not for the outstanding contributions of the people in the HL7 community. They come from a variety of interesting backgrounds and all have a common passion to grow and enhance HL7's mission of global health data interoperability. Finally, I learned that, yes, while there is important work that needs to be done, the people of HL7

make sure to laugh and enjoy the fellowship with one another.

What helped?

There are a few things that will help you navigate the WGM, most of which can be found if you attend the first-time attendees' presentation. This presentation provided a warm welcome to the conference. Here I received all the tangible materials needed to navigate the venue and learned how the sessions, blocks, and breaks work. More importantly, I got to meet all kinds of friendly faces who were well-versed in the operations of HL7 and the WGMs. The presenters shared their first WGM experiences and gave us the inside scoop on how to make the most of the conference. An important artifact to take away from this presentation was the "First-Time Attendee" ribbon. Having this ribbon is a great ice-breaker for getting to know fellow newbies and experienced members alike. I recommend not being shy and joining in, as participation is encouraged and you will always be

made to feel welcome. Everyone in the WGM was a first-time attendee at one point and fellow members go out of their way to make you feel part of the group. If you have questions about lost session tickets or are wondering what those ribbons on some people's name tags mean, don't be afraid to approach a member with a red "STAFF" ribbon. In addition to these social aspects, the breadth of educational sessions that are offered assure you will find several that either introduce you to interesting new topics or enhance your current understanding of others. Don't be afraid to attend a session even if you know nothing of the topic. You may be pleasantly surprised.

If you are considering attending an HL7 WGM for the first time, I highly recommend doing so and hope that reading about my experiences will help you get the most out of your time. I look forward to meeting you at future WGMs! ◼

HL7 Welcomes New Staff Member

David Johnson comes to HL7 with over 20 years in the information technology field. He has a history of developing solutions in the automotive, healthcare, and print marketing industries. His most recent position of Lead Technical Consultant allowed for growth in software delivery methodologies while managing a team of international developers.

Early in his career, David led a group responsible for integrating dictation and transcription systems in hospitals around the United States. This was his first experience working with HL7 standards. He went on to deliver business-to-business supply management solutions for a leading distributor of wholesale medical supplies.

David, his wife, and three children moved to Ann Arbor, Michigan, in 2012. He has a deep love of music and plays guitar, drums and piano. He is a volunteer with the University of Michigan campus radio station. David also enjoys attending various user group meetings and staying active in technical communities.

Please join us in welcoming David to our staff! ◼

**David Johnson
Director of Technical
Services**

pHealth 2016 Sponsored by HL7 International and HL7 Hellas

Impacting Personal Health with Wearables/Implantables

By Dr Alexander Berler, HL7 Hellas Chair

pHealth2016, the 13th International Conference on Wearable, Micro & Nano Technologies for Personalized Health, was held in Crete, Greece on May 29-31, 2016.

This was the second time that Greece hosted pHealth, as pHealth2007 was held in Porto Carras in Chalkidiki. Professor Nikos Maglaveras chaired both events. The conference was organized by the Institute of Molecular Biology and Biotechnology (IMBB) of the Foundation for Research and Technology – Hellas (FORTH) in collaboration with the Lab of Computing & Medical Informatics of the Aristotle University of Thessaloniki (AUTH) and the Institute of Applied Biosciences of the Centre for Research and Technology – Hellas (CERTH) in Thessaloniki, Greece.

pHealth 2016 opened a new chapter in the success story of the series of international conferences on wearable or implantable micro, nano and biotechnologies for personalized health which began in 2003 with personal

FORTH, Heraklion, Crete, Greece
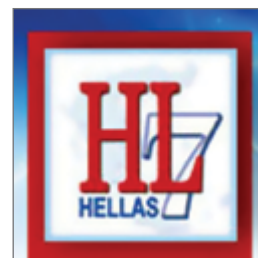
health management systems. Since then, pHealth has increasingly combined medical devices and eHealth based services with public health, prevention, social and elderly care as well as wellness and personal fitness to establish participatory, predictive, personalized, preventive and effective care settings.

Smart mobile systems, eHealth and telemedicine have become important enablers for ubiquitous pervasive health as the next generation health services. Social media and gamification has added even further knowledge to pHealth, both as a business domain and as a community safety-net.

Overall, there were 35 presentations, including 23 oral and 12 posters. All poster presentations included a ten minute slot for a short presentation. An award for the student with the best poster was presented at the event. EU funded projects in the areas of Micro-Bio-Nano systems and the ICT for Health, Active and Healthy Aging and DG RTD-HEALTH presented their innovative solutions.

pHealth2016 was sponsored by the European Commission, the European Federation of Medical Informatics (EFMI), FORTH, the COST-ENJECT action, and HL7 Hellas. The conference proceedings were published by IOS Press the series of 'Studies in Health Technology and Informatics', vol. 224, which was made possible with the sponsorship of the HL7 International Council.

The conference was attended by approximately 100 delegates from academia, industry and graduate/postgraduate students from more than 15 countries worldwide.

The topics presented at the conference covered two main areas. The first area covered integrated biosensors, including implants for biomolecular and genetics oriented point of care diagnostics; wearables related to multi-parametric biosignal monitoring systems; and machine learning and multiparametric analytics at implantable, phenotypic and behavioral/ambient levels. Professor Niilo Saranummi, founding chair of HL7 Finland, presented a keynote on the adoption space for knowledge transfer with concerns to medical devices and eHealth related with clinical and translational practice.

The second topic area included smart personal health systems, deep learning approaches, connected health and behavioral informatics, interoperability issues related to mHealth applications, and big biodata management and analytics platforms leading to an ecosystem enabling precision medicine.

HL7 had a strong presence during the conference and its standards were referenced in many presentations. HL7 Hellas Chair Dr. Alexander Berler gave a short welcome address to the attendees where he stressed that interoperability and standardization are key infrastructure elements for the success of personalized health and the integration of medical devices in the daily health practice.

The conference proceedings were published by IOS Press the series of 'Studies in Health Technology and Informatics', vol. 224, which was made possible with the sponsorship of the HL7 International Council.

He noted that HL7 Fast Healthcare Interoperability Resources (FHIR®) has revolutionized the way healthcare information is managed by the patients, the healthcare providers, the payers and the policy enforcers. Professor Mantas, Chair of the Greek Biomedical and Health Informatics Association Chapter of EFMI, highlighted the role of education in biomedical research.

In his keynote speech, Alexander Berler described the need for interoperability architecture based on the reuse of standards such as HL7's Clinical Document Architecture (CDA®).

The keynote presentation featured a case study called the Greek Patient Summary service design reported in the eStandards project to demonstrate the consistent and scalable use of standards (http://www.estandards-project.eu/).

Marita Perälä-Heape, Director at Centre for Health and Technology, University of Oulu, Oulu, Finland, gave an outstanding presentation on shared developments in the "Digital Health Revolution" research program. This program studies the transformation toward "My Data" based health and wellness solutions to support individual's capability and involvement in health promotion and disease management.
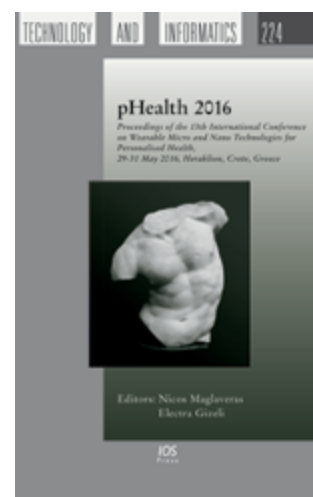
Impacting Personal Health with Wearables/Implantables

Professor Vince Emery from the University of Surrey delivered an inspiring talk titled *Going Viral: The Digital Future of Global Health*, where he asked the question: How we can pick up infections at the onset of symptoms and provide a global early warning system?

Catherine Chronaki spoke about the European Commission initiative concerning the development of mHealth assessment guidelines for interoperability and highlighted the power and potential of HL7's FHIR. She also described the vision of HL7 FHIR, current developments, and the ongoing standardization project in the HL7 Mobile Health Work Group.

The Google iGlass presentation by Fredrich Ehler covered the outcomes of the relevant experiments in conducted by Professor Christian Lovis' lab at the University Hospital of Geneva.

The pHealth2016 conference was a success both in terms of scientific quality, brainstorming, exploring future technologies and health applications, as well as connecting scientists from all pertinent areas in the wider ICT for health, medical devices and industry. The explosion in scale of medical devices and wearables availability, data monitoring, deep learning and advanced biodata analytics, smart medical decision support systems, interoperability challenges, public health and regulatory challenges and barriers, user empowerment and the connection of pHealth and precision medicine, can be catalyzed through the use of standards.

HL7 International should continue to support such events in the future in order to bring HL7 standards closed to the researcher community and integrate them in the R&D process from day one.

For more information about the pHealth conference please visit the following sites:

Conference site: www.phealth2016.eu

Conference proceedings: http://bit.ly/29THVPg ◼

Despite being less than a decade old, the field of cancer genomics is making significant progress towards early detection of cancer and targeted treatment plans for patients.

Join HL7 at this unique two-day event to learn how the cross-section of genomics, interoperability and cancer detection/care are pioneering new pathways in the field.

HL7 INTERNATIONAL

GENOMICS CONFERENCE

Washington, DC
October 26-27, 2016

http://www.HL7.org/events/policyconference201610/

Collaborating for improved interoperability

By Jane Millar, Head of
Collaboration, IHTSDO

IHTSDO and HL7 International Working Together

In August 2014, IHTSDO and HL7 International signed a new collaboration agreement with a focus on key joint work areas to be undertaken over a two year period. Since that time, we have made progress in several areas in the steps to ensure that our standards can work together in health information systems.

This progress includes the following:

- We have worked together to ensure that HL7 International developers and implementers throughout the world are aware of the licensing requirements for SNOMED CT by including licensing statements in products and providing FAQs on the topic.

- To facilitate the use of SNOMED CT in HL7 International products, developers anywhere in the world who are contributing are able to access the latest version of SNOMED CT International through a portal set up by HL7 International.

- We are in the process of finalizing a SNOMED CT Development Licence which will allow HL7 affiliate countries to undertake their own development work using SNOMED CT, regardless of whether they are an IHTSDO member country or not.

- HL7 and IHTSDO have worked together on the content in the latest version of TermInfo, currently a Standard for Trial Use (STU), related to SNOMED CT to ensure the guidance is up-to-date and accurate.

- IHTSDO has started work with the Fast Healthcare Interoperability Resources (FHIR®) leadership on defining best practice for binding SNOMED CT in FHIR profiles. This work is ongoing and we expect it to be a key component of the updated work plan currently being refined. This approach is also being applied to CIMI which is now a work group in HL7, thus maintaining consistency.

- HL7 has established the HL7 Terminology Authority which, as a single point of contact, is responsible for dealing with any requests to IHTSDO for changes and additions to SNOMED CT as required for HL7 products. This will reinforce that there is an efficient and effective process for ensuring HL7 value sets have relevant and up-to-date SNOMED CT content.

- HL7 is undertaking a review of its value sets and IHTSDO is happy to review any SNOMED CT requirements that arise from this to ensure a smooth and timely update to value sets.

Both HL7 and IHTSDO have been able to explore approaches to collaboration, management of licensing and how to deal with terminology. This knowledge can be applied to other collaborations. This also feeds in to the work of the Joint Initiative Council. At this time we are exploring the next phase of joint work which will include the use of SNOMED CT in FHIR, potential opportunities for collaboration with education as well as other guidance about our standards working together. ■

Success with ART-DECOR in British Columbia

By Patrick E. Loyd, Co-Chair, HL7 Orders & Observations Work Group and Lorraine Constable, Co-Chair, HL7 Orders & Observations Work Group, Vice Chair Architecture Board, and Chair Standards Governance Board, with coordination from the BC Team

The Doctors of British Columbia, in conjunction with the BC Health Information Standards Standing Committee, recently embarked on a pilot project to research current repository tooling to manage HL7 Clinical Document Architecture (CDA®) artifacts, including both the base standard artifacts as well as the pan-Canadian and BC-specific resources.

This pilot occurred from January 2016 through March 2016. The project was staffed by HL7 experts to maximize learning and testing while minimizing schedule, cost, effort, and risk.

Following a review of available tooling, the ART-DECOR tool (Advanced Requirements and Tooling, Data Elements, Codes, OIDs and Rules) was chosen for a pilot project. This tooling was developed by a team of open source developers to capture and manage CDA templates and other artifacts (e.g. terminology).

The pilot utilized the ART-DECOR tool to input the British Columbia Header constraints, a CDA

with unstructured body document, and level 3 templates that were adapted for BC from the IHE XD-LAB profile for testing.

The local BC planning and technical team included Carol Rimmer, Cindie Robertson, Shamil Nizamov, Jeremy Chapman and Dennis Cabel. The project was facilitated through expert resources consisting of Lorraine Constable, Patrick E. Loyd, and Dr. Kai Heitmann. Dr. Heitmann was one of the primary architects of the ART-DECOR tool set and was retained to ensure efficiency for testing and issue resolution.

Dr. Kai Heitmann

The project began with discussions about the optimal environment setup, security configuration, and other startup items. After initial configuration, the team began entering templates, terminology, OIDS, and other CDA resources to assess the viability of the tool.

The ART-DECOR tool includes functionality for template development and management as well as terminology and governance activities. ART-DECOR implements the HL7 methodology and CDA best practices to guide creation of artifacts conformant to the CDA schema as well as compliant to the HL7 CDA standard.

The testing primarily included using the basic functions to build out the existing constraints and other artifacts from the existing *BC eHR CDA Implementation Guide*. Partial vocabulary information was also loaded for utilization by the templates and testing of the terminology features.

Building Block Repositories

As testing was conducted, one function stood out as a key architecture of the tool—namely the building block repositories (BBRs).

BBRs are a shared resource utilized by each project which includes development of new templates or modification of existing templates or other resources. Profiles contain the artifacts and resources specific to that project's scope. Those shared resources can afterwards be used by downstream projects during the creation or modification of templates to ensure they are conformant. The base CDA standard itself is included in a BBR so conformance rules and

templates are properly derived. The strength of the BBRs is that they encapsulate prior project templates and rules within a governance domain for reuse.

During the project, there were a few initial issues with using the tooling. They have been either resolved or documented and escalated to BC healthcare management. All basic functionality was tested for usage first at the most basic functional level, and then subsequently increasingly complex input was tested.

Conclusions and Recommendations

The conclusions and recommendations were reported in detail. In short, the following high-level observations were made:

- The tool is stable and ready for input. An upgrade to performance has been installed, lowering screen refresh timing issues
- The tool includes all mandatory functionality needed for a repository
- The tool met all BC criteria for use as a provincial repository including the ability for business analysts to interact directly with the tool
- The tool can be implemented as a locally hosted solution
- The team recommended to BC Health that the tool meets the functional requirements for use

The project team has gone forward with building out the environments and configuration necessary to use the ART-DECOR tool to implement current CDA templates and other artifacts as a provincial resource.

Hosting the repository is one of the primary issues still to be determined. By the end of the build out project, there will still be functions which have not been exercised fully—namely the requirements lifecycle and template lifecycle features—so further work on the governance functions of the tool will be an ongoing effort by the internal teams.

The BC Health Information Standards Working Group is making plans for rollout of the CDA Provincial Repository and Resources by the end of this year (2016).
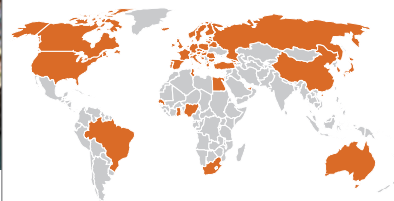
Any questions on the BC ART-DECOR project or CDA standards can be directed to HLTH.CISSupport@gov.bc.ca. ■

eHealth week
8 – 10 JUNE 2016
BEURS VAN BERLAGE
AMSTERDAM

eHEALTH WEEK 2016 BY THE NUMBERS

2,230 attendees total
539 ministerial delegates
54 exhibitors
130+ speakers
from **55** countries
from **6** continents

HL7 Activities at Europe's Premier Event: eHealth Week

Report from the eHealth Week 2016

eHealth Week 2016, the premier European event in eHealth, was held June 6-8 in Amsterdam. Organized by the Dutch Presidency of European Union (EU), it attracted more than two thousand policy makers, healthcare providers, patients, researchers and industry from across Europe and beyond.

By Catherine Chronaki, Secretary General, HL7 Foundation

The event had three pillars: *Empowering People, Social Innovation & Transition, Trust & Standards.* Its focus was the transformative power of eHealth on people.

In the opening session, the EU commissioner for Health, Vytenis Andriukaitis, highlighted the demographic aging and chronic disease challenges that put increasing pressure on the European healthcare systems. He called for innovative solutions, sending a message to the entire eHealth Community:

"It is now time to make a move from developing and testing to actual implementation of eHealth solutions."

FHIR Exhibition

HL7 had a strong presence at eHealth Week. The HL7 Fast Healthcare Interoperability Resources (FHIR®) booth was one of the most visited areas of the exhibition hall. The Dutch personal health record program is very much grounded on FHIR and is raising strong interest in the FHIR developer days planned for November 16-18, 2016.

Director of the Office of Standards and Technology at the ONC and HL7 Member Steve Posnack visits the HL7 FHIR exhibition at eHealth Week.

## Toward a Digital Health Compass: My Data, my Decision, our ePower

Following the successful "Interoperability in Action: Information + Integration = Innovation" session in the eHealth Week 2015 organized by the Latvian EU presidency in Riga, HL7 joined forces with the European Federation of Medical Informatics (EFMI) and HIMSS Europe again.

Starting from the premise that "Knowledge is power," the health sector, going digital, is facing its Gutenberg moment as artfully highlighted by Eric Topol, author of the book *The Patient Will See You Now*.

Panelists in the session "In search of a digital health compass" commented on how we can benefit from eHealth investments, when it is our own data that can help us learn and make informed decisions, and it is our ePower as a society to benefit from quality data. Panelists and the audience discussed how citizens look for their own personal digital health compass to be their navigation instrument in increasingly complex health and social systems. Standards developed by HL7, like FHIR, can be catalysts in making that happen (For more information see the digital health compass article on page 24).
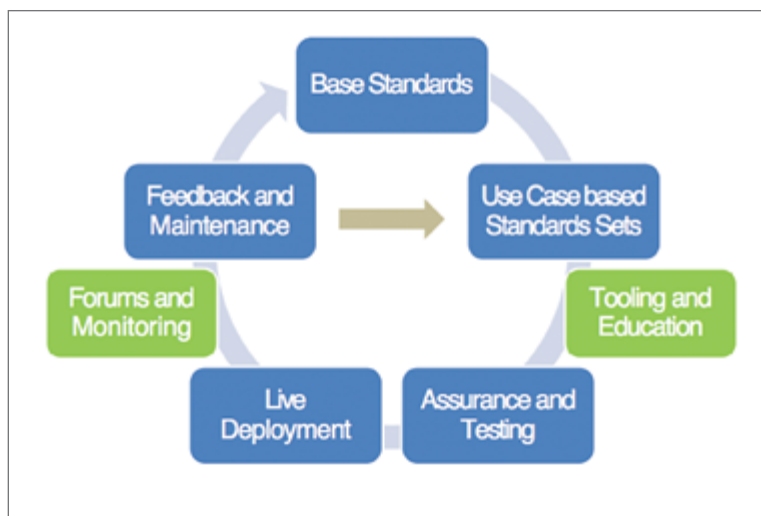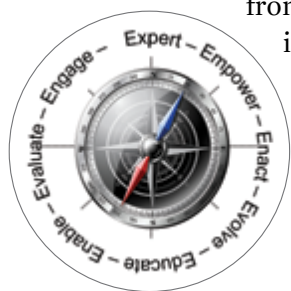
The Standards Lifecycle

EU-US Facilitating Interoperability across the Atlantic

Gerald Cultot and Steve Posnack co-chaired a popular session on the EU-US Memorandum of Understanding on eHealth cooperation. This session covered patient summaries standardization initiatives and the implementation of the ISO IDMP (Identification of Medicinal Products) standard by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). A panel consisting of representatives from industry, drug regulation, and EU member states, discussed the presentations.

Gerald Coultot and Steve Posnack reminded the audience that interoperability challenges in eHealth are the same on both sides of the Atlantic and progress has already been made since 2012 under the EU-US Roadmap in finding common approaches.

Gerald Coultot asked the speakers the following question: "What steps have been taken and what still needs to be done in order to make initiatives like the International Patient Summary (IPS) or a global identification of medicinal products a reality?"

In my talk, I reflected on the Trillium Bridge project, led by the HL7 Foundation with participation of CEN and IHE Europe. Trillium Bridge compared patient summary specifications in Europe and the United States, created a proof-of-concept transformer, and recommended "*To advance an International Patient Summary (IPS) standard and enable people to access and share their health information for emergency or unplanned care anywhere and as needed. At minimum the IPS should include immunizations, allergies, medications, clinical problems, past operations and implants.*" This recommendation was endorsed by all members of the Joint Initiative on SDO Global Health Informatics Standardization (JIC). I then presented the eStandards project which stresses the need of tools that connect across standards organizations and throughout the standards lifecycle from requirements analysis, to testing, implementation, and feedback.

Report from the eHealth Week 2016

Following Trillium Bridge, the JIC started work on the Patient Summary Standards Sets, ISO TC215 began work on bundles for clinical imaging, and HL7 approved the InterPAS project scope statement (currently under revision). In May 2016, the European Commission granted CEN a project to create a European patient summary specification to build on the work of ePSOS and the EU patient summary guideline (currently under revision) in a way that leverages and actively engages in global standardization efforts. The initiative was presented by Stephen Kay, vice-chair of CEN TC251.

It will be quite a challenge to align these and other patient summary initiatives around the world and create a truly international standard that is widely used to reduce the costs of patient summary implementation projects around the world. For once, the HL7 European affiliates have expressed their commitment to a single team to deliver a global standard that can be effectively customized on only for the EU cross-border setting but also for national and regional needs around the world.

Vada Perkins (FDA) and Paolo Alcini (EMA), presented the details of IDMP and the strategy and timeline for implementation in Europe and the audience had the opportunity to participate in the discussion of how developments in the regulatory area can bridge to the health and wellness. ◾

EU-US Facilitating Interoperability Across the Atlantic

For more information and presentations from eHealthweek 2016, see:

http://www.ehealthweek.org/ehome/128630/2016-presentations/

Mark your calendar!

Next year, eHealthweek2017 will be organized by Malta on May 10-12, 2017.

The HL7 C-CDA® — RENDERING TOOL CHALLENGE

Easy-to-use C-CDA Viewer Wins Challenge

Congratulations to the HL7 C-CDA® Rendering Tool Challenge Winner

HL7 congratulates first place winner of the HL7 C-CDA Rendering Tool Challenge, **Bryn Lewis, PhD**, Principal Software Development Consultant at Intelsoft in Melbourne, Australia. The challenge was run jointly by HL7 and the Office of the National Coordinator for Health Information Technology (ONC). The challenge asked participants to develop a viewer that will enable clinicians to more efficiently review the clinically relevant patient data from Consolidated Clinical Document Architecture (C-CDA®).

Intelsoft C-CDA Viewer Tool Description

The Intelsoft C-CDA Viewer is an easy-to-use viewer of complex C-CDA documents, available directly in any web browser. A responsive document layout automatically adjusts to make optimum use of the available screen space. Users can hide, collapse and move any section of a CDA document. Additionally:

- Document sections can be manipulated directly via button clicks, drag and drop or via a document Table of Contents

- All user preferences are saved and automatically applied to subsequent CDA documents opened

- Ability to detect and hide/show duplicates

The result is an intuitive and user-friendly document layout that users can directly control.

The tool runs in any modern browser and can be used on a PC, tablet or mobile device. It will also run as a standalone local fileset.

About the Winner

Dr. Bryn Lewis

Dr. Bryn Lewis developed the tool as a side project during the months of March and April. What started out as a general idea demanded to be noticed and completed. As an Australian, this was the first health IT challenge that he could enter. He enjoyed the process and hopes to participate in more challenges in the future.

Dr. Lewis plans to use the prize money to travel to the United States in September, where he will visit sites in Washington, DC, such as the nation's Capitol and the Smithsonian museum. From there, he plans to attend the 30th Annual Plenary & Working Group Meeting. Be sure to extend him a warm welcome and congratulations on his accomplishment! ■

Watch a demo version of the tool:

http://intelsoft.com.au/challenge/index.htm

Learn more details about the tool:

https://github.com/brynlewis/C-CDA_Viewer

The Care Sector: Emerging Market for HL7 Standards

HL7'S Role In Improving Information Exchange Between Care & Cure Sectors

One of the leading national healthcare IT priorities in The Netherlands is to significantly improve the electronic information exchange between institutions and organizations in the care and cure sectors.

By Bert Kabbes,
RI CMC, Chair, HL7
The Netherlands

Background

The main challenge to achieving this goal, however, is that the care sector (nursing homes, rehab institutes, elderly homes, home care organizations) is using the so called "i-Standards" as their national standard, whereas the cure sector (teaching and general hospitals) is using HL7 standards (mainly HL7 Version 2.4/2.5, Clinical Document Architecture and Version 3) as its national standard. The "i-Standards" and HL7 Version 2.4/2.5 are different in terms of reference information model, format, coding systems and data specifications as well as semantic definitions.

Objectives

The objective was to initiate and execute a project to (a) investigate the possibilities to bridge the gap between the two standards via mapping and harmonization, (b) develop syntax as well as semantic consistent translation algorithms vice versa and (c) publish an implementation guide which describes mapping on the functional level as well as the technical format level. The explicit preset condition for the project was that the mapping and harmonization solutions should not require or cause any change in the fundamentals of either of the two standards.
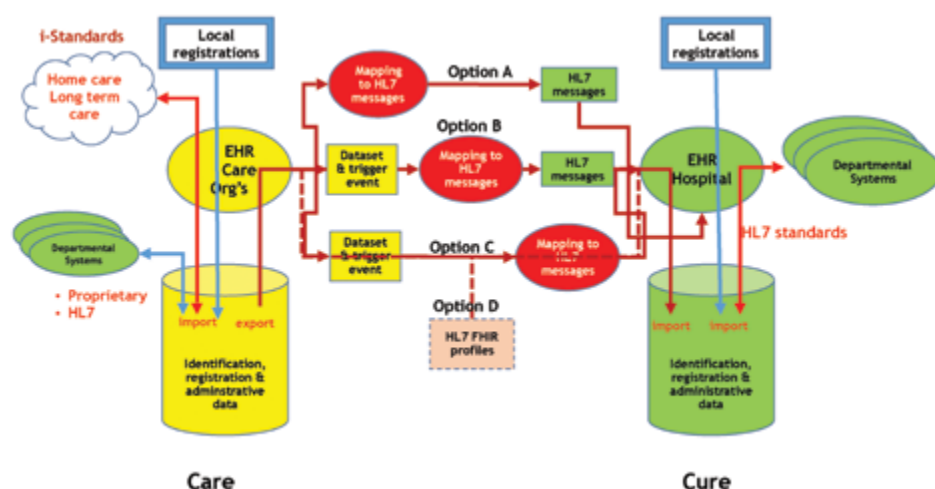
Project

The project was executed in three consecutive phases. Phase 1 was the investigation phase, in which the feasibility of the mapping and harmonization was analyzed. Based on the positive outcome of this investigation, Phase 2 was started. Phase 2 evaluated all data elements from the "i-Standards (care) and selected those which were considered to be highly relevant to exchange between the care and the cure sector. For these selected data elements, the corresponding (or alternative, or candidate) data elements in the HL7 Version 2.4 NL standard were searched and defined. In Phase 3, the mapping and harmonization solutions for the selected data elements were developed and described in terms of algorithms, coding translations, table mappings, and format translations. These mapping specifications were developed vice versa.

Results

The project was successfully executed from February through November 2015. In January 2016, the final results were published in an implementation guide, which – after some intermediate revisions by the mirror group – was balloted in February 2016 and is now an official DSTU-NL standard.

Conclusions

A total of 55 data elements from the i-Standards were defined as highly relevant for the exchange of information between care and cure organizations. Almost all of these 55 data elements did have corresponding data elements in HL7 Version 2.4. In some cases, several candidate data elements in HL7 Version 2.4 were found, some of which are still under discussion (open issues) and will be resolved

during the DSTU-phase until December 2016.

The main conclusions from the project are that (a) consistent vice versa translations via mapping are possible and have been defined, (b) without affecting the fundamentals of both standards, but that (c) tables also need to be further harmonized and (d) the wording of several semantic definitions and descriptions needs to be aligned.

The open issues as mentioned under (c) and (d) are not considered fundamental and therefore pose no barrier to begin practical pilot implementations based on the DSTU implementation guide.

International Aspects

The specific results of the project are not considered to be very relevant for international re-use, since the i-Standards are typically Dutch standards. The mapping and harmonization solutions itself from this project will therefore not be transferable to other countries.

Nevertheless, it would be very valuable to learn if the same situation exists in other countries (two different information exchange standards in the care and the cure sectors) and how these countries are approaching, or have approached, the mapping and harmonization issue. It would also be helpful to learn what the visions and priorities are with regard to the information exchange between the care and the cure sector, both on the practical level as well a the national policy level.

HL7 The Netherlands has defined the care sector as the major growth area for HL7 in terms of re-using all of our knowledge and experience from the cure sector as well as an opportunity to increase the HL7 membership. The Netherlands has approximately 90 hospitals whereas the care sector consists of approximately 1500 institutions and numerous home and social care organizations. This represents a potentially huge area for many years of work for vendors, standards organizations and implementers. ◼

By Catherine Chronaki, HL7 Foundation

Anne Moen, European Federation of Health Informatics

During eHealthweek, Panel Addresses Adoption of eHealth Services

A Digital Health Compass: My Data, My Decision, Our ePower

Knowledge is power. Despite extensive investments in digital health technology, navigating the health system online is still challenging for most citizens. Availability of good medical or social care services and health tools online varies inversely with the population's need. The low adoption of eHealth services and persistent disparities in health triggers a call for multidisciplinary action.

At eHealthweek 2016 held in Amsterdam, EFMI, HL7 and HIMSS Europe came together to share the vision for a personal **digital health compass**. This session discussed strategies on how to navigate in the transforming terrain of digital health ecosystems where people from all walks of life are called to play an active role. Patients living with an implanted device or coping with persistent, chronic disease such as diabetes as well as those engaged in self-care, caring for an elderly relative, a neighbor, or their child with illness, need a digital health compass.

The panel highlighted the transformative power of health data fueled by targeted open, massive and individualized delivery.

• Anne Moen presented the vision of the digital health compass, where each one of us can use our own data ("myData") for knowledge to acquire tools and decision power ("my decision") to participate in the transformation of society. Patients and families, health professionals and health informaticists should join forces with researchers and policy makers to advance digital health literacy and tap our collective expertise

("ePower") catalyzed by health data standards and open APIs.

- Petra Wilson stressed the importance of patients' access to their own data noting that, now more than ever, we should shift from discussing ownership to custodianship of data in recognition of the value and power of multiple contributors to one's health data. Personalization and mobility can help if we manage to integrate health literacy interventions every step of the way. According to Petra, as patients we need a new digital health compass because navigating the system is harder than ever due to the scarcity of health professionals and time needed to engage in one's health.

- Robert Stegwee discussed personal health records (PHRs) initiatives around the globe. A personal health record is more than a viewer and organizer of personal health information since it provides treatment support, including self-management options, facilitates exchanges of health information with healthcare providers, and supports healthy lifestyle options and the tracking of personal fitness. Despite its value and potential, Robert notes, "Not one PHR in 25 countries among six continents has reached a million users or more and the top barriers according to a recent survey include lack of leadership, few provider incentives, and non-use of standards for information exchange."

At eHealthWeek in Amsterdam, a panel discusses various eHealth initiatives around the globe.

- Ed Hammond reviewed the impact of FHIR, noting that the compass is shifting the focus from sick care to health, from provider to patient, from proprietary to shared, from competition to collaboration, from licensed to free, from site specific to mobile, and from national to global. He highlighted the drivers for HL7 FHIR, namely population health, precision medicine, data sharing, learning health, big data, new media, mobile/wearable devices, health analytics, and translational medicine. He also quoted Dr. Karen DeSalvo, the U.S. National Coordinator for Health IT, saying that "The challenge is how to bring that information together to make it usable and actionable for everybody who wants it."

- Christian Lovis stated that although immense medical knowledge is available, current misinformed decisions may affect our future health. He encouraged the audience to support strategies that enable access to knowledge and research that alleviate health disparities, stating "Setting knowledge free! And Making it matter for us!"

- Catherine Chronaki revisited the theme of the session: "My Data, My Decision, Our ePower". For the theme *My Data*, she asked the audience to imagine an app that knows our health data and helps us navigate a pharmacy without opening the boxes to review leaflets. The app would compare and suggest products for us, taking into account our medication history, allergies, and health conditions. Catherine observed that "there is much more to a patient's health data than a doctor could ever know" and it is our decision how to use this data. With increased patient focus, clinical trials involve patients every step of the way, from direct contact to actual governance. It is our choice whether we wish to donate our data for the public good. Interoperability standards help us share knowledge, collect high quality data and increase our collective "ePower".

June 2016 Event Held in Italy for the First Time

Report on the IHIC2016 Conference

By IHIC2016 Co-Chairs

Bernd Blobel,
PhD, HL7
Germany and
Professor at
University of
Regensburg

Mauro Giacomini,
PhD, HL7 Italy
and Assistant
Professor at the
University of
Genoa

General Overview

The IHIC2016 conference was the 16th in the history of the International HL7 Interoperability Conferences relating to all HL7 standards, including their development, adoption, implementation and all implications within the different types of health information systems.

For the first time ever, the conference was held in Italy at the Polytechnical School of the University of Genoa on June 13-15, 2016. It was organized by HL7 Italy in collaboration with HL7 Germany and was chaired by Professor Bernd Blobel from the University of Regensburg in Germany and Professor Mauro Giacomini from the University of Genoa in Italy. IHIC2016 was sponsored by HL7 International, HL7 Germany, HL7 Italy, DIBRIS (University of Genoa, Italy) and by the Genoa Engineering Council.

IHIC2016 attracted more than 60 attendees from academia, industry and students from 10 countries. The conference included seven tutorials, four keynote presentations, 11 presentations on full papers, four presentations of technical reports and four presentations on technical abstracts. Finally, a late afternoon workshop with 10 panelists was held on June 14, 2016.

The Joachim W. Dudeck Award is presented annually to a researcher less than 35 years of age presenting a scientific paper at this conference. The award is co-sponsored by HL7 International and HL7 Germany. This year's recipient was Abderrazek Boufahja from France. He contributed the "Model-Based Validation of HL7 CDA R2 Documents and Implementation Guides Using Gazelle ObjectsChecker and ART-DECOR®". The paper was co-authored by Dr. Kai Heitmann and Eric Poiseau.

HL7 Italy sponsored two prizes for Italian students who graduated in 2015 or 2016 with a master's thesis on standards in health informatics. The winners were:

1. Luca Douglas Magnoni from the University of Genoa, with a thesis entitled "Development and testing of a standardized terminology service by HL7 International applied to the management of semantics in laboratory reports" (Supervisor: Mauro Giacomini, Co-Supervisor: Roberta Gazzarata); and

2. Elisa Maria Zini from the University of Pavia, with a thesis entitled "Extension of the i2b2 framework for extraction of qualitative patterns from time series" (Supervisor: Cristiana Larizza, Co-Supervisors: Lucia Sacchi, Matteo Gabetta).

The high level scientific papers were published in a special edition of the European Journal for Biomedical Informatics (EJBI) entitled "Interoperability is more than just technology". Technical reports and abstracts were published in locally printed proceedings books (ISBN 9788894180602).

Scientific details of the conference

The scientific presentations were divided into four sessions, each with its own keynote presentation as well as presentations on the scientific papers, technical reports and technical aspects.

The first session was entitled "Paradigm Changes in Healthcare and Resulting Interoperability Challenges" with the keynote by Bernd Blobel on the needs of an architectural approach to interoperability.

The second session concerned the general HL7 perspectives and began with a keynote by Riccardo Bellazzi from Italy about data integration strategies to meet big data challenges through decision support methods.

After this session, a workshop was held in which multi-stakeholder experts presented and discussed their differing perspectives on the perceived and experienced gaps and bridging opportunities between the regulatory and

A Digital Health Compass: My Data, My Decision, Our ePower

- The panelists agreed that digital health literate people from all walks of life can engage with health professionals, researchers and policymakers to advance health and wellness, as well as shape precision medicine, population health initiatives, and personal self-care efforts. Barriers and challenges should not be underestimated; thus, culture, education, skills, costs, and perceptions of power and role are essential for multidisciplinary action. Active discussion followed, starting with the question asking whether patients should be given access to their examination data before the data has been reviewed by their physician. The panelists agreed that patients could be given to the right to decide according to personal preferences and desire for engagement.

The active attendance at the panel at the eHealthweek, along with the inspiring discussions that followed, encourage us to continue our cooperation in this space with the digital health compass initiative as well as elaborate on the concept and specific tools to advance the vision. The dialogue will continue. We will meet in Lisbon (eHealth summer week), Munich (MIE2016), Athens (eHealthForum) and Oslo (eHIN & ETC) later this year to understand how advancement in health informatics, digital health standards and digital health literacy can give rise to the vision of the digital health compass, and ensure that research and policy roadmaps align every step of the way. ■

For more information

Presentation

http://www.slideshare.net/chronaki/in-search-of-a-digital-health-compass-my-data-my-decision-our-power

Interview

https://soundcloud.com/techtalkscentral/ttc-277-the-digital-health-compass

Report on the IHIC2016 Conference (continued)

clinical world on medicinal product identification (see page 28 for openMedicine article). An interactive discussion with the audience addressed how implementation of IDMP standards and openMedicine project recommendations may help reinforce these bridges.

The third session was devoted to Clinical Document Architecture (CDA®) related contributions. HL7 International's Dr. W. Ed Hammond gave a keynote presentation on the elusive search for interoperability.

The last session centered on terminology, ontology and classification issues and was introduced by a keynote from Libor Seidl of HL7 Czech Republic. This presentation considered the relationship between HL7 specifications and terminology standards.

Conclusion

The IHIC2016 conference was a success both in terms of scientific quality – brainstorming, exploring present and future applications and development of standards—as well as connecting scientists and technical individuals from all pertinent areas in the wider health IT industry. We welcome suggestions for future IHIC meetings, especially on issues related to present and future standards development and their application in health informatics. ■

openMEDICINE

openMedicine Workshop Report

Does IDMP Fit the Purpose of Bridging Clinical Practice with Regulatory Oversight?
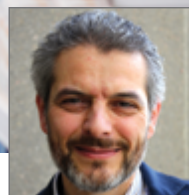
By Giorgio Cangioli, Chair, HL7 Italy

Christof Gessner, Chair, European Strategic Advisory Board; Past Chair, HL7 Germany

Catherine Chronaki, Secretary General, HL7 Foundation

openMEDICINE (www.open-medicine.eu) is a European project funded by the Horizon 2020 research and innovation program.

Its goal of advancing unique identification of medicinal products and thereby patient safety in cross-border settings. *openMedicine* aims to deliver:

(a) common data models for identification and description of medicinal products based on the ISO IDMP (Identification of Medicinal Products) standards;

(b) a common vocabulary for unambiguous description of medicinal products;

(c) rules to guarantee safe identification of medicinal products in prescriptions for cross-border dispensing; and

(d) a roadmap for post-project actions.

The European Medicines Agency (EMA) has validated ISO IDMP and, along with United States Food and Drug Administration (FDA), actively participates in the creation of the relevant implementation guides in ISO and HL7. The EMA is committed to establishing a single European Database of Medicinal Products by 2018. *openMedicin*e reaches out to EU member states including their health ministries, national agencies and stakeholders to raise awareness and discuss what steps are needed in order to roll out implementation of ISO IDMP as well as the implications for eHealth.

openMedicine has launched a series of workshops across European member states in an effort to gain insight on the current gaps and bridging opportunities between the regulatory and clinical worlds as well as the ways the implementation of

ISO/IDMP (Identification of Medicinal Products) standards can help. Thus far, workshops were organized in Madrid, Spain (May 22, 2016), Genoa, Italy (June 14, 2016) and in Lisbon (June 29, 2016). More workshops are planned in the Den Haag in the Netherlands, Brussels in Belgium, Athens in Greece, Stockholm in Sweden, and Warsaw in Poland.

The *openMedicine* workshop in Genoa, Italy, took place during IHIC2016 and was hosted by HL7 Italy and the University of Genoa. HL7 Italy Chair Giorgio Cangioli welcomed the participants and introduced the objectives of the workshop and the project as a whole. Giovanni Ferretti, from the Italian drug regulatory body called AIFA, offered the vision of the Italian regulators toward equivocal identification of medicinal products across their lifecycle. He also introduced ISO/IDMP and the plans of AIFA, in coordination with EMA, toward its implementation. HL7 International Board Secretary Dr. W. Ed Hammond continued with the vision of the standards organizations and HL7 in particular. During his presentation, he highlighted the role of HL7 in establishing the Joint Initiative Council for Global Health Information Standardization.

Catherine Chronaki and Jos Devlies moderated a panel comprised of HL7 affiliate leaders and representatives of Italian regions including: Christof Gessner, Gematik, Immediate past Chair HL7 Germany; Bert Kabbes, D&A Medical Group BV and Chair, HL7 the Netherlands; Stefan Sabutsch, ELGA, Chair HL7 Austria; Libor Seidl, Chair HL7 Czech Republic; Paolo Invernizzi, Lispa/Regione Lombardia, Italy; Stefano Dalmiani, FTGM CNR/Regione Toscana, Italy.

The panel reflected on the perceived and experienced gaps between the regulatory and the clinical world. As HL7 affiliates described the regulatory situation in their countries and its links to care, it became evident that the situation varies substantially. This creates significant challenges for the adoption of ISO/IDMP across Europe. Each country has a regulatory agency responsible for market authorization of medicinal products and pharmacovigilance. There are standardization activities around medication information (patient medication plan, ePrescription, patient summaries/referrals/discharge letters, medication documentation, etc.), but they are not usually related to standardization in the regulatory areas.

In most countries there are also medicinal product dictionaries (MPD) which are "intermediate" databases managed by companies that obtain the drug list from the national regulator and deliver value-added content and services to clinical users by annotating and/or masking out part of the provided information, such as the marketing authorization number. Panelists called for more transparency related to changes made by the MPDS. Ideas included keeping original information and the development of mapping rules.

Data exchange between the clinical and pharmaceutical domains also involves mapping since they differ in the standards they use. For example, the sections of IDMP/SPOR (substance, product, organization and referential) vary in maturity. The "R" section addresses vocabularies for concepts that are also important for clinical care, e.g. dose forms, routes of administration, and units of measure. However, there seems to be a gap in how the clinical and regulatory realms address their terminology needs. Affiliates agreed that more coordination on the selected value sets is essential.

A lively debate followed regarding how openMedicine recommendations on the implementation of IDMP may help bridge these gaps. In particular, the implications and potential impact of implementing IDMP at the European level for ePrescription/eDispensation at national and regional levels was discussed. Participants commented on the opportunities, challenges, and costs of the pending roll-out of IDMP.

The participating affiliates agreed that collaborative activities are necessary to fully engage HL7 affiliates in the process of realizing the benefits of IDMP rollout in a coherent and consistent way across Europe.

For more information, please visit the *openMedicine* website: www.open-medicine.eu. ■

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Partners in Interoperability ™

How FHIR Can Drive Progress on Today's Interoperability Challenges

Partnering for Interoperability: A Meeting of Minds

By Wayne Kubick, PhD, HL7 International Chief Technology Officer

One of the more interesting aspects of HL7's Fast Healthcare Interoperability Resources (FHIR®) standard is its ability to attract the attention of a much wider range of stakeholders than the traditional technical standards development community of HL7.

This was apparent at the first *Partners in Interoperability* workshop in Washington, DC last April. The event brought together senior decision makers from the clinician, payer and biopharmaceutical communities to exchange ideas on how to make more progress toward a mutual goal of using FHIR to achieve "an interoperable healthcare system that leads to better patient care and improved outcomes."

The *Partners* workshop was designed as a non-technical forum for business leaders to explore business objectives that could be met by FHIR and discuss how to work together to remove common barriers to change. The workshop alternated between presentations from senior government and industry leaders and breakout sessions for each of the three communities, which had somewhat differing levels of historical involvement with FHIR:

- For clinicians, who have been involved with FHIR from the earliest days, discussion focused on resolving key informatics problems like sharing patient information across organizations and developing better point-of-care decision support to improve outcomes. This track was facilitated by Russ Leftwich of InterSystems.

- For payers, who now recognize the importance of FHIR in the age of MACRA, the focus was on how to improve patient care and increase healthcare value under the new payment models. This track was facilitated by Rosalyn Ryan of Dell.

- For the Biopharmaceutical industry, which is just beginning to gain exposure to FHIR, the focus was on how the availability of FHIR APIs from EHR systems can expand secondary uses of healthcare data to improve clinical research and drug safety processes. This track was facilitated by HL7 International CTO Wayne Kubick.

The meeting commenced with welcoming talks from HL7 International CEO Dr. Charles Jaffe and Grahame Grieve, father and Product Director of FHIR. They were followed by an entertaining and informative FHIR tutorial presented by Dave Shaver of Corepoint Health.

Participants then attended the first breakout session to discuss the opportunity space for FHIR and what types of progress might be possible in each area.

The afternoon began with a panel discussion from Steve Posnack of the ONC, Doug Fridsma of AMIA, and Micky Tripathi of the Argonaut Project. The panel explored the current state of interoperability.

It was followed with subsequent breakouts to discuss the types of change management that would be necessary to successfully adopt FHIR in each area.

Day 2 commenced with encouraging case studies of successful FHIR implementations from Greg Barnowsky of Blue Cross, Dr. Stan Huff of Intermountain Healthcare, and Beverly Buckta and Chrissy Johnson of Pfizer.

It was then followed by a session that reinforced the extraordinary opportunity of FHIR with observations on what's holding us back by Rahul Dubey of AHIP, Dr. Michael Hodgkins of the AMA and Dr. Taha Kass-Hout of FDA on the precision medicine initiative.

The final breakout concluded with a dialogue on how to collaborate to move forward in each area. This yielded plans for additional workshops in July for the Clinicians and Payers to help further define requirements in these areas. There was also a spurt of energy and interest from Biopharma in becoming more engaged in the FHIR community, including exploring participation in upcoming FHIR connectathons.

While each of the tracks demonstrated substantial progress toward meeting goals during the meeting, it was also gratifying to see the robust exchange of dialogue between the various participants of each community as they intermingled during lunch and breaks.

Clearly, the meeting had thus achieved perhaps its most important goal – a common recognition that we're on the cusp of making incredible breakthroughs toward improving interoperability through FHIR, and that we truly are all in this together as partners. In this sense, *Partners in Interoperability* achieved a meeting of the minds on the importance of FHIR.

The march will continue at the next *Partners in Interoperability* summit in October 2016. ◼

HL7 Welcomes New Members

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- PEO DHMS - DoD/VA Interagency Program Office

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- Rhode Island Quality Institute
- PCPI
- University of Texas School of Biomedical Informatics

Using FHIR to Address Telehealth Challenges

A Fully Functional HL7 FHIR Based Ontology for Telehealth Data Management and Exchange

We have developed an HL7 FHIR based ontology to support clinical and telehealth data storage and exchange in a scalable and low maintenance cost manner.

Integrated Care Data Challenges

Integrated care links multiple levels of care management together and provides coordinated services, including telemedicine. In order for care to be integrated, professionals across the continuum of care from different organizations and health systems must collaborate on the prevention and management of chronic disease and co-morbidity for their patients.

In this context, multiple challenges arise with regards to data management, due to the disparity of the types of data that need to be managed, including clinical record data, bio-signals, derived features, subjective reports and provenance information. The solutions must be designed for multiple data and information sources as well as multiple access points. Additionally, they must provide the flexibility to meet the needs not only of standard EHR systems but also of PHRs and telehealth systems.

Data Management Scaffolding Framework: The Role of Ontology

We envision a framework applicable to integrated care data management which minimizes maintenance points, adheres to current state of the art standards, provides single point of extension and relies on Linked Data principles. This translates to a reusable, cost effective, scalable and sustainable solution, with the ability to reuse the stored information for a learning health system.

Core components of our framework are the underlying ontology that not only describes the domain entities but also acts as a roadmap for restful web service communication API and the persistent storage server that holds not only the actual data but also the current version of the ontology.

By Vasilis Kilintzis, PhD, Postdoctoral Researcher, Laboratory of Computing and Informatics Group, Aristotle University of Thessaloniki, Greece;
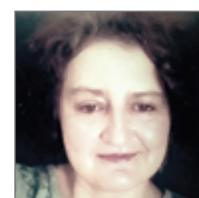
Ioanna Chouvarda, PhD, Assistant Professor, Laboratory of Computing and Informatics Group, Aristotle University of Thessaloniki, Greece

Figure 1 Snapshot class hierarchy along with the visualization of the developed HL7 FHIR based ontology.

The ontology acts as the data model of the domain and also contains the actual medical record data related to the disease in scope. In addition, it provides the roadmap upon which web services endpoints are automatically deployed. Finally, it defines the rules that, once applied, ensure that the stored information is valid and meaningful and allows the incorporation of additional domain knowledge to allow for decision support.

Building on Top of HL7-FHIR OWL Classes

We ensured that HL7 Fast Healthcare Interoperability Resources (FHIR®) was consistently applied in order to facilitate interoperability while preserving flexibility by taking the following two steps:
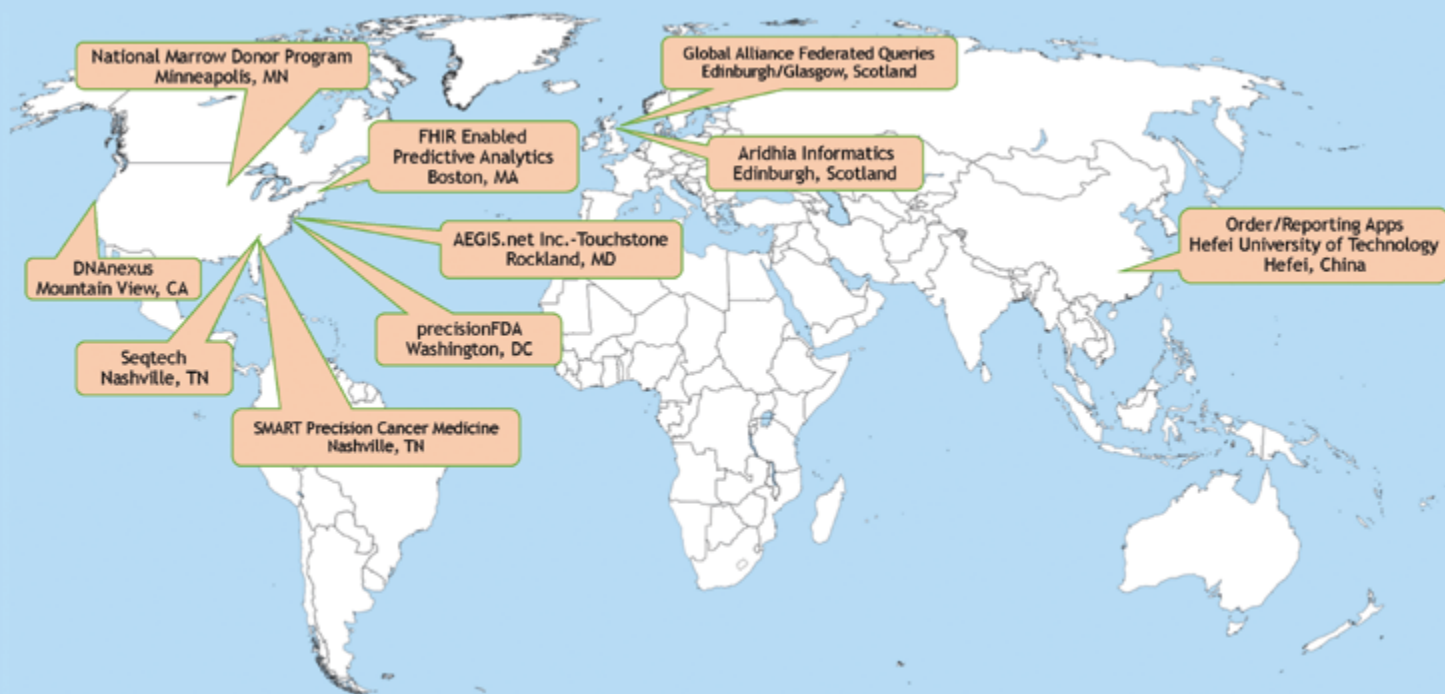
- HL7 FHIR primitive and complex data types were used **as containers of all the data represented/stored in our ontology.** This was achieved by developing a stand-alone Resource Description Framework (RDF) vocabulary representing the data types alongside their validation rules**.** In this reusable vocabulary, the various FHIR data types are represented as distinct Ontology Web Language (OWL) classes. To represent any primitive value, one needs only to instantiate the relevant class and assign it a value using the *rdf:value* property. Each FHIR data type is defined as a subclass of *fhir:PrimitiveType*. Additional property restrictions are defined per class, in order to constrain the literal values on the *rdf:value* property to the relevant XSD data types.

- The appropriate HL7 FHIR resources were selected and defined in RDF/OWL in order to use them as parent classes of all our domain specific entities. The ontology is the common place for the entities definition and the actual data stored. The domain entities were defined as OWL classes while the actual recorded, reported, extracted and computed data were stored as ontology instances of the aforementioned classes. The decision to create classes for each domain entity was based

on the need of restricting accepted values on specific resources (such as observation) in an equivalent way with the HL7 FHIR profiles. The ontology classes were grouped based on the conceptual relation and the common shared properties.

An Application Scenario

The WELCOME project (http://www.welcome-project. eu/) develops a technical solution for integrated care of, and self-management by, patients suffering from chronic obstructive pulmonary disease with co-morbidities (chronic heart failure, diabetes, anxiety and depression). In this scenario, an application server is consuming the web services offered by the framework to provide EHR data related functionality to an end user. ◼

Available Online:

Visualization of the aforementioned ontologies can be found in http://medilomi. med.auth.gr:8000/, while the ontologies can be accessed in the following links in order to view documentation or download as rdf/xml:

http://lomi.med.auth.gr/ ontologies/FHIRPrimitiveTypes/

http://lomi.med.auth.gr/ ontologies/FHIRComplexTypes/

http://lomi.med.auth.gr/ ontologies/FHIRResources/

http://lomi.med.auth.gr/ ontologies/WELCOME_entities/

Contact Email: ioannach@certh.gr

A Fleet of Pilots on FHIR Goes Global

FHIR Genomics Pilots Taking Off for Precision Medicine

At the May 2016 HL7 Fast Healthcare Interoperability Resources (FHIR®) Connectathon in Montreal, many people participated in both the connectathon track and tutorial devoted to FHIR Genomics.

By
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Business School,
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FHIR Genomics consists of FHIR profiles and resources that are used to describe genomics data, including linkages to other FHIR resources (see "Piloting Precision Medicine via Connectathon: FHIR Genomics" in the May 2016 issue of *HL7 News*).

FHIR Genomics has been cited by the White House Office of the National Coordinator (ONC), the Precision Medicine Task Force (September 2015), and the National Institutes of Health's (NIH) Precision Medicine Cohort Program (November 2015) as a standard for advancing precision medicine for point-of-care needs. Interest in

precision medicine, combined with an increasing focus on achieving breakthroughs in clinical data interoperability and the popularity FHIR has already achieved among healthcare IT vendors, makes this an opportune time to incorporate genomics into FHIR. As a result, many organizations are piloting FHIR Genomics around the globe – in China, Scotland, and the United States (see map). While interest will surely grow as a result of the HL7 Clinical Genomics Work Group's work to prepare FHIR Genomics for the September 2016 FHIR Standard for Trial Use 3 (STU3) ballot, the array of pilots is already impressive. Here's a sampling from a fleet of pilots:

SMART Precision Cancer Medicine – Vanderbilt University

Jeremy Warner, MD, MS, and the Medical Director of the Vanderbilt Cancer Registry at Vanderbilt University in Nashville, TN, discussed the SMART Precision Cancer Medicine (PCM) prototype, which began development in late summer of 2014. This prototype visualizes genomic information in real-time and compares somatic mutations detected for a specific patient and diagnosis with comparable population level data. PCM is open-source and is designed to help clinicians determine where individual patients fall on the population-level scale of genetic somatic mutations. Warner states that the app can be used on any SMART on FHIR-enabled EHR that supports the FHIR Genomics extensions and is designed to be able to evolve in parallel as knowledge bases expand. The pilot is ongoing and is now focusing on expanding the visualization capabilities for complex genomic data, as well as possibly expanding to include other data streams.

Jeremy Warner, MD, MS, Assistant Professor of Medicine and Biomedical Informatics – Vanderbilt University

"Working with HL7 and the FHIR group has been highly collaborative and has resulted in rapid turnaround and enhancement of the FHIR Genomics standards. The pilot illustrated the challenges of representing new medical data in particular the large number of nomenclatures, terminologies, and web resources available for use. Defining a standard ultimately means constraining against scope creep, and this is an ongoing process."

Federated Queries SMART on FHIR Server – Global Alliance for Genomics and Health

In the summer of 2015, the Global Alliance for Genomics and Health (GA4GH) began the exploratory phase of a project designed to test the emerging standards for federated analysis of genomic data. The project is led by the Stratified Medicine Scotland Innovation Centre and Aridhia Informatics, out of Glasgow and Edinburgh, Scotland. In the Proof of Concept statement for GA4GH in July 2015, Aridhia Informatics Chief Technology Officer Rodrigo Barnes explained that federated analysis refers to the ability to perform distributed analysis on data that is not physically shared. It allows diverse and widespread groups to collaborate and share data in the form of a virtual data set comprised of information and/or data from multiple sites. Some of the current standards come from GA4GH for pure genomic data sets, but will also begin to incorporate HL7 FHIR and FHIR Genomics in order to test combined clinical and genomic data sets. Participating organizations include:

- University of California, Santa Cruz
- Royal Melbourne Hospital & Biogrid Australia
- Beijing Institute of Genetics, Chinese Academy of Science
- EMC R&D – Skolkovo, Russia
- Wellcome Trust Centre for Human Genetics – Oxford, England
- Harvard/MIT – Cambridge, MA
- Australia – Health Intersections

The exploratory phase is complete and the proof of concept phase began in August of 2016.

Rodrigo Barnes, CTO – Aridhia Informatics

"As part of funding from the Scottish Government to establish a precision medicine ecosystem, SMS-IC is extending its informatics capability to add better support for HL7 FHIR and FHIR Genomics. As part of this work Aridhia is designing a set of components that provide portable, standards-based interfaces that facilitate the integration of genomics in clinical workflows. Throughout 2017, we expect to test this approach with a number of exemplar programmes in oncology and neurology and look forward to reporting back when we have some concrete results."

FHIR Genomics Pilots Taking Off for Precision Medicine

Diagnostic Order/Reporter Apps — Hefei University of Technology

In November 2015, developers at Hefei University of Technology in China began work on the Diagnostic Order/Reporter. Bowen Gong, a software engineer at Hefei Institute of Technology described the structure and functions of the apps. He explained that the Order/Reporter consists of two SMART on FHIR applications which allow clinicians to place an order requesting genomic testing through the Diagnostic Order app. Companies and labs receive the orders and submit the reports through the Reporter app. All test results are stored on the SMART on FHIR platform and are available for other applications to access for research purposes. The development work on the apps is completed and the apps are being deployed as a VM image running on the server. The project is scheduled for completion in November 2016.

Bowen Gong, Software Engineer – Hefei University of Technology

"The FHIR Genomics provide lots of standards for EHR and genomics, which I think can be useful in gene therapy. The SMART platform provides a unified way for gene and medical information gathering, processing and researching. The experience with FHIR is interesting and delightful. I learned a lot about EHR and genomic information standard, and the newest developments of medical/EHR."

Touchstone — AEGIS.net, Inc.

AEGIS.net Inc. began the Touchstone Project in May 2015. AEGIS.net Lead Consultant Richard Ettema provided some background and details about the project. He explained that Touchstone is an Infrastructure as a Service and Testing as a Service solution which provides a mechanism for assessing a test system's conformance and interoperability using published standards and specifications. Touchstone uses the FHIR DSTU2 TestScript resource in order to allow the use of test cases written by business users, rather than just tests written in complex code by developers. Ettema stated that Touchstone will also provide monitoring for the implementation of standards, and the quality of vendors and implementers by storing all test results confidentially but providing access to general statistics.

The system was first deployed in September of 2015 and supports the HL7 FHIR versions DSTU 2.0, DSTU 2.1, and STU 3 Candidate. AEGIS.net began working with the FHIR Genomics group prior to the January 2016 FHIR Connectathon. AEGIS covered two of the eight FHIR Genomics testing scenarios at that time, and at the May 2016 Connectathon they covered all eight FHIR Genomics scenarios. The FHIR Genomics test suite is currently available 24 hours per day to allow all participants to test as needed.

The Touchstone service will be publicly available on an ongoing basis for interoperability and conformance testing for the HL7 FHIR specification and standard.

Richard J. Ettema, Lead Consultant, Touchstone – AEGIS.net, Inc. Rockville, MD

"At the Connectathon 12 event, we were able to provide test definitions for all eight of the FHIR Genomics test scenarios. This was due again to Gil (Alterovitz)'s and the HL7 Clinical Genomics Work Group's enthusiastic support of testing in Touchstone. A major lesson learned from this experience is that in order to provide valuable and relevant testing scenarios for a problem domain, it is critical to have support from the domain stakeholders and subject matter experts."

Local HL7 FHIR Specification-Based Website – Seqtech Diagnostic, LLC

Seqtech Diagnostic, LLC has developed a local HL7 FHIR specification website to provide payload validation. Jonathan Holt, DO, MS, FACMG, Executive VP, Chief Medical Officer and Chief Informatics Officer at Seqtech Diagnostic, discussed the company's current products including a tumor profile for cancer, a pharmacogenomics product, and a food testing product. Recently, the company has been focusing primarily on food testing. He added that the company is now experimenting with packaging HL7 FHIR bundles as base64 encoded JSON files and plans to send them to customers along with a PDF containing interpretive results. These projects are ongoing.

Development of HLA Genotyping Reporting with FHIR – National Marrow Donor Program/Be the Match

Bob Milius, Senior Data Analyst at the National Marrow Donor Program(NMDP)/Be the Match, provided an update on how the organization is using FHIR. They are looking at HL7 FHIR as a data exchange standard to report human leukocyte antigen (HLA) genotyping results. The project involves mapping the Histoimmunogenetics Markup Language (HML) to FHIR. Milius explained that HML is a technical implementation of reporting principles outlined in the Minimum Information for Reporting Next Generation Sequence Genotyping (MIRING). The organization uses HML to exchange HLA typing data. The goal of the project is to implement the MIRING principles in FHIR so NMDP's partnering transplant centers and typing labs can use FHIR to report the HLA genotyping information for patients and donors. Milius states that the organization has begun the initial mapping of HML to FHIR and is also working on setting up a FHIR server based on the HAPI open source server as seen at https://github.com/jamesagnew/hapi-fhir. This pilot began in January of 2016 and is ongoing.

FHIR-Based Predictive Analytics: A Family History/Genetics Pilot – Massachusetts General Hospital

Brett Johnson, researcher at Boston Children's Hospital, discussed a pilot utilizing FHIR to enable predictive analytics. He explained that Dana Farber Cancer Institute (DFCI), Intermountain Healthcare, Cerner, Massachusetts General Hospital, and SysBioChem LLC are collaborating on the design of a harmonized system to integrate genetic/risk assessment and family history based HL7 FHIR files into the electronic health record (EHR). The project is initially focusing on developing a translator for FHIR to Version 3 for the web service at DFCI, but has led to increased interest in developing a data model that can be shared between organizations. The model may then be used for predictive analytics by adding corroborated risk information and may evolve to include a SMART app. Johnson stated that this data model "will provide the basis for a functional, validated prediction model that will serve as a testable pilot for integrating genetic and clinical data for use by all stakeholders."

FDA precisionFDA – precisionFDA Server

As part of President Obama's Precision Medicine Initiative, the Food and Drug Administration (FDA) is working on its precisionFDA initiative. The precisionFDA platform, developed with the support of DNAnexus, is a portal for research and development that allows users to test, pilot, and validate approaches for processing the genomic data collected through Next Generation Sequencing (NGS) techniques. The precisionFDA work on FHIR will enable communication of genomics/sequencing test metrics such that apps can integrate this for use by providers and consumers. Learn more on precisionFDA at: https://precision.fda.gov/about

Conclusion

The organizations involved in these pilots have expressed satisfaction with their trial experiences with FHIR Genomics. It is likely that they will continue these projects and that new organizations will initiate pilot studies in the coming months, both as interest in precision medicine continues to increase and FHIR STU3 provides for a larger set of structured genomics data and a more comprehensive set of resource interlinkages. ■

HL7 International is partnering with the 3rd European Congress on eCardiology and eHealth to bring together cardiovascular clinicians, healthcare professionals, eHealth experts and technology developers in Berlin on October 26-28, 2016.

The HL7 Foundation is co-organizing this event with the e-Cardiology working group of the European Society of Cardiology. A session on eMedication connected to the openMedicine project and a session titled *The Impact of Patient Summaries on the Practice of Medicine: What to Expect from eStandards* take place on October 28.

In addition, attendees can visit three departments of telemedicine in the Charité Hospital on October 26.

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Upcoming International Events

Date	Event	URL	Location
September 17-23, 2016	HL7 30th Annual Plenary & Working Group Meeting	www.HL7.org/events/wgm092016	Baltimore, Maryland
October 25-26, 2016	eHealth Forum 2016	www.ehealthforum.org	Athens, Greece
October 26-28, 2016	eCardiology eHealth	www.e-cardiohealth.com	Berlin, Germany
November 15-16, 2016	EHiN-FH 2016	www.ehin.no	Oslo, Norway
December 11-14, 2016	Connected Health Conference	www.pchaconference.org/	Washington, DC
January 14-20, 2017	HL7 January Working Group Meeting	www.HL7.org	San Antonio, Texas
February 19-23, 2017	HIMSS17	www.himssconference.org	Orlando, Florida
February 21-23, 2017	HEALTHINF 2017	www.healthinf.biostec.org	Porto, Portugal
May 6-12, 2017	HL7 May Working Group Meeting	www.HL7.org	Madrid, Spain
May 22-24, 2017	Medical Informatics World Conference 2017	www.medicalinformaticsworld.com	Boston, Massachusetts

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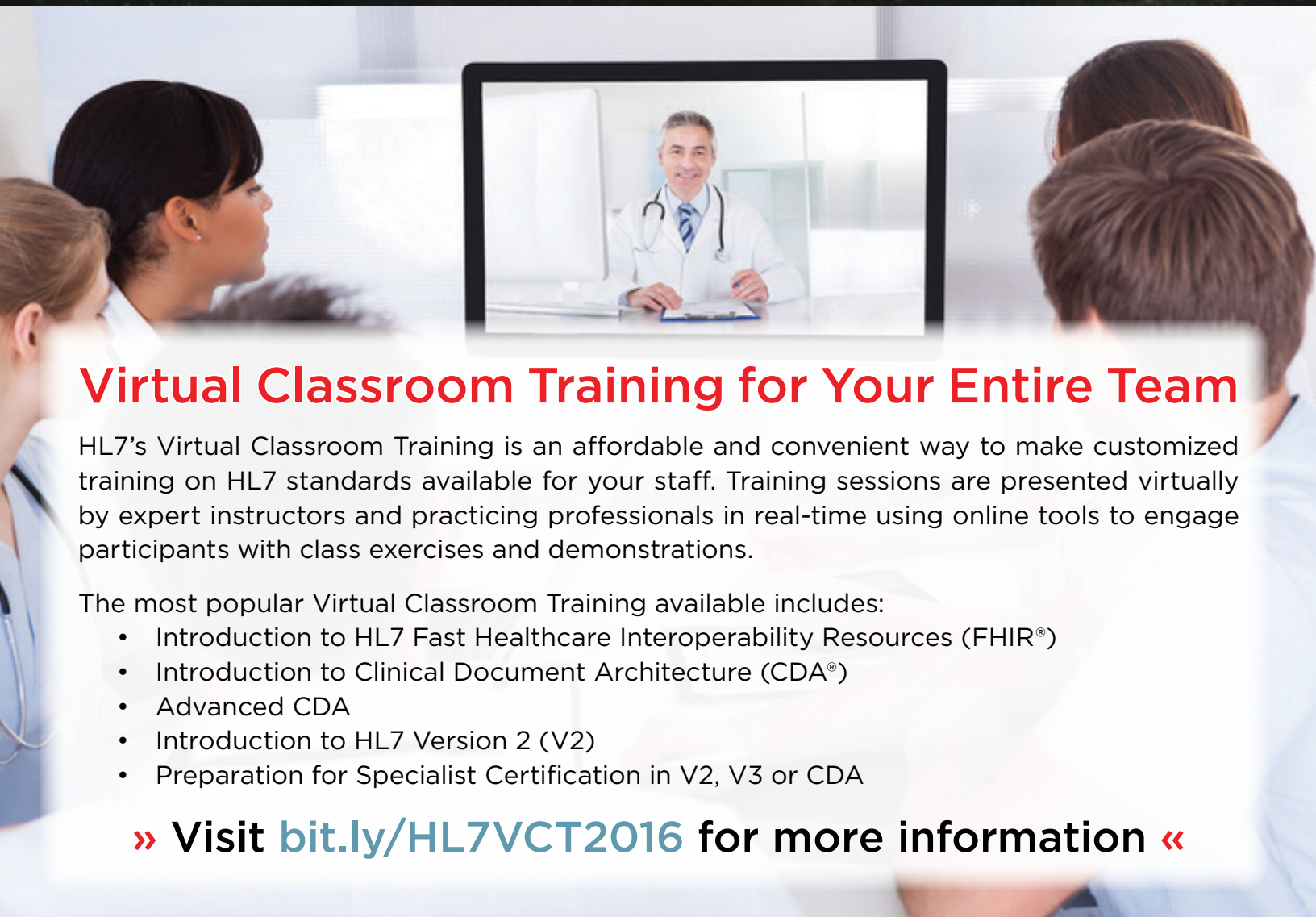
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Upcoming Working Group Meetings

September 17-23, 2016
30th Annual Plenary &
Working Group Meeting

Hyatt Regency
Baltimore Inner Harbor

Baltimore, Maryland

January 14-20, 2017
Working Group Meeting

Hyatt Regency San Antonio on
the Riverwalk

San Antonio, Texas

May 6-12, 2017
Working Group Meeting

Madrid Marriott Auditorium
Hotel & Conference Center

Madrid, Spain

September 9-15, 2017
31st Annual Plenary &
Working Group Meeting

Hyatt Regency La Jolla at
Aventine

San Diego,
California

September 29 -
October 5, 2018
32nd Annual Plenary &
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Hyatt Regency
Baltimore Inner Harbor

Baltimore, Maryland

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