HL7 CIC – Opening Plenary Session **Location:** Paris, France		**Date:** 11 May 2015 Monday **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

Presentations introduced by Chuck Jaffe.

- Philippe Burnel, French eHealth update
- Nicolas Canu, Chair of European HL7
    - In France the Carte Vitale was introduced in 1999 to manage patient information and identification problems. Pharmacists are very motivated to use HL7 standards; other groups are 'stuck'.
    - ICD-10 is widely used, LOINC has consensus but not actual use. Trying to find a way to use SNOMED-CT. Building services to share value sets, conceptual domains, more.
    - France has a strong initiative to protect information for privacy. Recently it was decided to use the national SSN, issued to each citizen, to access and index all patient information.
    - Transformative health care requires paradigm changes in organizations, technology and methodology. The patient must become an empowered citizen before becoming an empowered patient.
    - **Interoperability in decentralized distributed environments requires shared knowledge and skills to adequately establish cooperating systems.**
    - Interoperability is built on users' domain, to meet business objectives, to share knowledge, not on IT. The business defines naming of concepts and modeling decisions.
- John Gachago, HL7 Africa Ambassador, low and middle income countries (LMICs)
    - Lack of investment in HI education and HIT
    - Reliable infrastructure may be absent
    - Interoperability myths
    - What is in it for me?
    - Governance and policy issues
- Bobby Jefferson, Technology in LMICs, experience with Ebola outbreaks
    - Open systems must be used because they cannot be sustained if the solution requires a payment

HL7 CIC – **Location:**	Multi-group Report of Activities to Highlight Paris, France	**Date:** 11 May /2015 Monday **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

Patient Care included mention of the NI2016 showcase presentation from HL7 Nurse Group that was accepted for presentation in June 2016.

HL7 CIC – Joint Meeting with RCRIM and CBCC on Bipolar Project – Covers Substance Abuse and Mental Health **Location:** Paris, France		**Date:** 12 May 2015 Tuesday – Q1 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

Use case: prisoners released by the Criminal system now have to wait 60 days to receive substance abuse and mental health counseling.
Use case: Maternal healthcare needs post release from judicial system setting

Update from Anita: Project has been approved by TSC. James Topping has been extracting the data elements from FDA reports as part of the FDA Therapeutic Area development.

Mary Ann Slack from the FDA commented on the FDA's need for data elements. PDUFA V is a set of user-fee set of commitments with industry. Standards will facilitate efficacy analysis of new drug analysis. FDA wants to tackle this incrementally so they can get endpoints that can be used for cross-trial analysis. Approval or non-approval of a drug is the end goal of standardizing data elements.
Data elements have been synthesized and will be reviewed by the FDA before going to a clinical expert group to review them. (CERC review) Plan is to ballot in September 2015

Abstracted 220 elements from 23 trials, 55 questionnaires
Scope of the project is for Bipolar I.
This is a model of how the FDA is collecting elements to approve a drug, not a model of the condition itself. This is the set of FDA internal requirements. Want to keep the scope down to something in a reasonable timeframe, and making sure that stakeholders are engaged. Lori Simon recommended if Bipolar I and Bipolar II are done together, it would be more time-consuming upfront because most of it would already be done.

An informative DAM will be balloted. CBCC is trying to develop models that can be used for as general purpose as possible. Lot of discussion about the scope of elements needed; some of the elements may be needed for secondary analysis.

<u>Model:</u>
In the last WG meeting (January 2015) the advantages and disadvantages of a common mental health DAM vs. individual DAM for each condition was captured. After the data elements are captured the elements go to CDISC for creation.

Option 1 for separate model for each disorder
Option 2 for a combined model for mental health disorders into one model

- Common models can be harder to use because the level of abstraction is higher, and people have a harder time understanding it.
- Common models will also be harder to ballot because in ballots of changes the earlier content will also end up being reviewed and balloted.

Option 3 is a hybrid approach, where the data elements common across all areas are used across all conditions; but the elements specific to one condition will be balloted.

- But it is important to include all the common elements so that reviewers can identify with the content and not think that things are missing.

- But when they get too big and abstract, the models are not useful
- This is not an HL7 requirement for individual models.

Option 4 is for a common behavioral health model; then disease-specific condition elements can be balloted.

This is a specific use case in the FDA drug application review process. The real question is the interoperability goals of what you are trying to achieve. Are you trying to get information from a special setting, and what are you trying to achieve from the poll process?

Anita: We are trying to scope down the problem, but also trying to keep the big picture in mind to harmonize mental health model with functional profile so that implementation will have the elements.

Lori Simon: The interest of CBCC is to develop a model for mental health that is broad and reusable as possible. The FDA need for data is one use case for the use of mental health data. As you understand more and more uses of the data, that can shape the scope of the model.

- The approach is to gather as much data as possible.

Mead: If you want to model the content that is used over and over in one place, and then show the specifics in the same model, then managing it becomes tricky and takes a lot of work. The common model can change over time, and keeping the model coordinated and doing continuous refactoring is a challenge. Separate models can lead to a lack of alignment. That is a real danger. Post-hoc harmonization is a lot of work.

Lori Simon: pointed out that the data elements are the same, but the responses/values to the elements are different.

AMS: Do we maintain one information model and subset it each time we create a DAM? We're talking about an information model with a functional model. This becomes a management issue for the model.

Is it really an option to look at the elements in each type of model and see if the purposes of the models are so different? Or is there plenty of opportunity for reuse and overlap. Is this a federated model that has different parts with the need for governance?

Building views is important to consider – values of the elements and the setting of how the elements are used represent two views to consider.

For the General Anxiety Disorder project can we start moving in the direction of a general model?
For the Bipolar disorder we will continue as an individual model in order to meet the September ballot timeline.

CBCC: CBCC can continue by looking at a common model across conditions while CIC continues with their work in order to meet their timelines. CBCC is balloting in September as well.

1. Look for common elements for reuse
2. GAD – continue to move along as before, and CBCC will come to Anita to get our input. CBCC can then engage CIC. It will take too much time to harmonize all the content right now.
3. CIC will continue on and work with CBCC on areas of commonality.

We will meet again at the WGM in September. And include the BRIDG model in the discussion in September.

AMS: What made the decision for me is the fact that both the common and specific models are changing. It's just too hard to keep two changing models in alignment.

For October WGM – meet again Tuesday Q4

HL7 CIC – Update on the Max Tool – Presentation by Michael van der Zel **Location:** Paris, FR		**Date:** 12 May 2015 Tuesday – Q4 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

For October WGM – meeting again while in Atlanta

HL7 CIC – Trauma Project/EMS Project Updates – Presentation by Jay Lyle, Clay McMann, Other on Team **Location:** Paris, FR		**Date:** 13 May 2015 Wednesday – Q1 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

For October WGM – meet in Atlanta Wednesday Q1, with the need for a second contiguous Quarter to cover both projects. Either Q1/Q2 or Q3/Q4.

HL7 CIC – Joint Meeting with BRIDG, OO, CTG **Location:** Paris, FR		**Date:** 13 May 2015 Wednesday – Q2 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

BRIDG update – Ballot reconciliation for BRIDG v4.0 ongoing at the meeting, along with an Architectural review of the model.

- Request made for SMEs to help reconcile the comments received from HL7 voters
- Need a set of principles or governance to keep models aligned
- Answer sets are not described in BRIDG

Each module should be driven by the domain experts. The real challenge is to integrate the domains.
BRIDG is now a stakeholder in specimen discussions – and will provide additional scope and use cases.

The BRIDG WG will set up calls and invite people to participate to resolve negative ballots for BRIDG 4.0

HL7 CIC – Trauma Registry Symposium **Location:** Paris, FR		**Date:** 13 May 2015 Wednesday – Q3 & Q4 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

Non-HL7 experts from Europe invited to participate in this session to present on and discuss issues related to Trauma Registries. Speakers highlighted registry issues such as standards for the registry and other issues.

HL7 CIC – CIC Business Meeting **Location:** Paris, FR		**Date:** 14 May 2015 Thursday – Q1 **Time**	
Facilitator		**Note taker(s)**	Dianne Reeves
Attendee	**Name**	**Affiliation**	
Quorum Requirements Met:			

PLEASE ✓ YOUR NAME AND UPDATE INFORMATION

Name		Affiliation	E-mail Address	MON 11 May		TUES 12 May				WED 13 May				THURS 14 May			
Last	First			Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
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Beeler	George	Beeler Consulting	woody@beelers.com														
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