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HL7 Clinical Genomics Weekly Call - Nov 15, 2016

Attendees

1. Bob Milius - NMDP - bmilius@nmdp.org (presiding co-chair)
2. Amnon Shabo (Shvo) - Philips - amnon.shvo@gmail.com
3. Jonathan Holt - SeqTechDX - jholt@seqtechdx.com
4. David Kreda - HMS - david.kreda@gmail.com
5. Jeremy WArner - Vanderbilt - jeremy.warner@vanderbilt.edu
6. Swapna Abhyankar - Regenstrief - sabhyank@regenstrief.org
7. Rebecca Goodwin, NLM - goodwinrm@mail.nih.gov
8. Joel Schneider - NMDP - jschneid@nmdp.org
9. Joey Yang - HFUT - jiaoyun@hfut.edu.cn
10. Shennon Lu - NLM - shennon.lu@nih.gov
11. Bowen Gong - HFUT - bowen.g.1993@gmail.com
12. Larry Babb - GeneInsight - lbabb@geneinsight.com
13. Joseph Kane - Epic - jkane@epic.com
14. Xiao Luo - USTC - l.xander.233@gmail.com
15. Tianlong Chen - USTC - wiwjp619@gmail.com
16. Perry Mar - Partners HealthCare System - pmar@partners.org
17. Jami Deckard - Regenstrief Institute, LOINC - jkdeckar@regenstrief.org
18. Joe Quinn - Optum - joseph.quinn@optum.com
19. Rosalyn Ryan, Dell, rosalyn_ryan@dell.com
20. Mollie Ullman-Cullere, OM1, mollie @OM1.com
21. Clem McDonald - NLM - clemmcdonald@mail.nih.gov
22. Bret Heale -Intermountain Healthcare - bheale@gmail.com
23. Xin Liu - BHC - xinliu215@gmail.com
24. Lynn Laakso - lynn@hl7.org
25. Xiaojia Yu -Fudan University- xiaojia.yu@yaohoo.com
26. Huanqin Dai -CDC- huanqindai@gmail.com
27. Yi Wang - USTC - panzer.wy@gmail.com
28. Gil Alterovitz
29. Eric Whitebay
30. Whitney Roark
31. Yogy

Discussion

- Brief reports (skip this week)

- Ballot Reconciliation updates
    - Ballot Reconciliation Howto
        - http://wiki.hl7.org/index.php?title=Reconciliation_HowTo
        -
    - V2 "Lite"
        - Flagged "non-negative, persuasive without mod dispositions:

        - https://docs.google.com/spreadsheets/d/11_Ci6hZzWtQcjrqVf_pNl0bAzmeuJGFrugxW3V9cZZU/
- Uploaded to the CG Document Center
    - Reconciliation Spreadsheet as of Nov 14
    - Clinical_Genomics_Coded_Reporting_Lab_US_Realm_IG (as of Nov 14)
- Update from Lynn Laakso

  Due to the confusion about the 2016SEP ballot of HL7 Version 2 Implementation Guide: Clinical Genomics Coded Reporting, Release 1 (PI ID: 1213) I did some review for its reconciliation requirements with respect to balloting the Coded Reporting material with the latest ballot of the LRI (project 1294 sponsored by OO).

  Problem:
  This one particular ballot item is particularly troubling due to two issues: while it was announced to the membership for consensus group enrollment as well as voting, it was missed (by me, with my sincere apologies) on the list of ballot items to be approved by the TSC for inclusion in the ballot. In addition, it appears the project never received Steering Division (and subsequent TSC) approval. Balloting an item without these approvals is against HL7's documented processes.

  Result(s):
  Because I left it off the TSC approval list, it missed the usual scrutiny of the PBS Metrics team looking for project approvals, as well as TSC review.

  Either of these conditions should have prevented this item from going to ballot, which renders it null and void.

  As such, the prior reconciliation for Project 1213 from its ballot in 2016SEP is not a requirement for 1294 to ballot.

  Recommendation:
  Since Project 1213 (CG Coded Reporting) has been superseded by project 1294 (updated LRI) which has specifically stated in the project description that it will consolidate the V2 IG for CG Coded reporting in addition to pharmacogenomics excluded from the prior PSS, may I suggest that project 1213 be withdrawn and its ballot records removed from active status.

  The Coded Reporting material from CG, in whatever condition (any changes applied in response to prior ballot comments) the WG feels is current, may be included in the Project ID 1294 LRI ballot as "starting over" within the larger context of the whole LRI. I also embrace Hans' recommendation to include all ballot comments not yet addressed into the January ballot reconciliation process.

- **Where we stand on the ballot**

- As of noon on Nov 14 the tally was 49 affirmative and 15 negatives which means the ballot passes easily (only need 39 affirmatives to pass). We expect more of the negative withdrawals to trickle in, but regardless the ballot has passed.

- **Background on the proposed new version of V2 Clinical Genomics coded reporting Lite.**
  - Overview of the larger changes in the revised HL7 V2 clinical genomics coded reporting lite are as follows

    1) Remove the option for multiple coded values in a OBX-5 (to accommodate strong objections

    2) Remove of the cross references approach to linking content from one part of the ballot to another. Instead related content complex variants will be included in the hierarchy below the complex variant

    3) Inclusion of a new panel (glossary) that defines for each haplotype what variants the laboratory defines to be its constituents. This is mostly intended for star alleles but could have other purposes.(Section 5)

    4) Merge description of discrete structured variants with discrete simple variants in one panel. (For many good reasons described in the document)

    5) New algorithm of defining the dot notation of OBX-4 but did not make it normative because there might be simpler rules that would work for this particular hierarchy and the exact dot notation is not as important since we have dropped the cross reference linkage to the OBX-4 content.

    6) Slight revision of the order of the sections to accommodate the other changes.

    7) Made the table of Coding systems an appendix

    8) The examples will also be moved to an appendix in the final LRI forma
  - Also made many little changes in response to the many good suggestions from the balloters
- **Proposed motion (**wording suggested by Hans Buitendjik, co-chair of O&O)
  - Adopt all proposed dispositions, accept the materials as-is, recognizing that this effectively still a re-ballot of the materials in context now of the full LRI IG, thus accept ballot comments on all aspects of the CG material, rather than waiting a ballot round, and include all ballot comments not yet addressed into the January ballot reconciliation process.
  - Motion by Clem McDonald, Second by Jonathan Holt
  - Discussion (see below)
    - Gil suggests that we reexamine the old PSS and update its scope before we incorporate it into the LRI, define exactly what it is; we cannot vote away process
    - Mollie - old V2 is no longer relevant, need to be flexible
    - David - what is the control we have in tucking this into the LRI effort?
      - Bob - per LRI PSS, CG is a co-sponsor, which will have formal content review prior to ballot
    - Jonathan - A lot of work has already been done which can be rolled into LRI, without needing to re-create a PSS. Gil's comments about procedure could also be directed at the lack of proper process for FHIR, so it seems like stalling the process. We

do need to have better transparency and follow proper procedures in the future. We HAVE spent a lot of time discussing V2 lite and PGx.

- Vote
  - Abstain -
    - David Kreda,
    - Yi Wang,
    - Gil Alterovitz,
    - Tianlong Chen,
    - Larry Babb,
    - Bowen,
    - Joel Scheider,
    - Joe Quinn,
    - Xin Liu,
    - Xiao Luo,
    - Xiaojia Yu,
    - Rosalyn Ryan,
    - Yogy,
    - Joe Quinn
  - Nay - 0
  - Yea -
    - Jonathan Holt,
    - Eric Whitebay,
    - Mollie Ullman-Cullere,
    - Bret Heale,
    - Jami Deckard,
    - Joseph Kane,
    - Perry Mar,
    - Rebecca Goodwin,
    - Shennon Lu,
    - Swapna Abhyankar,
    - Clem McDonald,
  -
- Jonathon suggests that we work on DMP, and be clear on our process in the future.
  - Clinical Genomics Decision Making Process document
- Dave Hamill wants to work with us and OO on next PSS and/or LRI PSS update. He will contact CG co-chairs, Hans (who will identify others in OO), and Clem.

- FHIR
  - https://docs.google.com/spreadsheets/d/17fqbTWKrIvPysZXIhlhLX4proKpv95inFQGVNO54axk/
  - No time for update

- DAM
  - no time for update
- Other
  - none