Information Modeling Project/FHIM Meeting

Summary of Call

Date/time of call: Friday, March 14, 2014 2:30 - 4:30 PM

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| **Attendees - Agency** | **Attendees-Agency** | **Invited, but Unable to Attend** |
| Gregory Zektser- VHA | Huma Munir - VA | Krystol Shaw- DHA |
| David Bass- VHA | Steve Wagner- FHA | Sean Kopka – VHA |
| Steve Hufnagel- DOD | Caitlin Ryan-FHA | Susan Matney - 3M |
| Sean Muir - FHA | Sara Ryan - HL7 | Lynn Sanders-VHA |
| Robert Crawford – VHA | Rob McCLure - FHA | Jay Sykes - VA |
| Benton Bovee- DHA | Galen Mulrooney – FHA | Larry Shaughnesy- DHA |
| Mead Walker - HL7 | Bill Hess - FDA | Ioana Singureanu - FHA |
| Jay Lyle – FHA |  | Iona Thraen - Utah Dept of Health |

**Updates on S&I Framework integration/initiative and FHA Work** *Steve Wagner*

* The integration work with the S&I Framework has continued; there is a call scheduled to map the FHIM to MU standards. Trying to schedule a call about mapping the FHIM to all of their ongoing active domains.
* Continue support to the SDC and DAF initiatives; Galen continues with S&I Simplification initiatives
* The first FHA Health Information Modeling (HIM) WG call was Tuesday. They reviewed the type of representation needed for the call going forward; the FHA PMO will send a formal email to the Managing Board.
* Gary Dickinson had a follow-on presentation on the S&I Simplification WG and there was a review of the feedback we received on the lab and immunization domains.
* Next week’s call will include a summary of the changes/dispositions made to the Lab and Immunization domains, discussion on the FHIR, and Jay will present on terminology for Adverse Event Reporting and a review of the work done to the Modeling and Process guide.
* David asked how S&I conduct their outreach for new initiatives. Steve said it usually comes in the form of an email and instructed him to contact Lauren Thompson regarding getting his name on the distribution list.

**Terminology Modeling Update** *Jay Lyle*

* Rob provided an update on VSAC; if we submit a request saying “this is our code set and here is what we need” it would be managed pretty quickly. We want this work to be done by the end of April.
  + Next Steps: ask VSAC to create or import the value terminology systems and create value sets and make sure that everything works correctly
* Galen briefly discussed the difference between VA with LEGOs approach to terminology vs. what we are doing; the two are very different but Galen suspects there can be harmonization. David commented that it is premature to say that LEGOs is exactly the path that the VA is taking.

**Other business**

* No other business was discussed

**Modeling the Adverse Event Reporting Domain** *Galen Mulrooney*

* Galen gave a brief update on the work he has done for the Adverse Event reporting domain. He has compared the 3 Med Watch forms to VAERS and noticed that there is quite a bit of similarity; in some instances VAERS is a bit more detailed.
  + Next Galen will clean up the model and will make sub-classes of these MedWatch forms.
* Galen said that he is looking at ICSR, a standard that is broader than the MedWatch and AERS; he would like to compare those 4 forms to it.
* Meade provided an overview of the basic structure of ICH-ICSR and walked the group through its implementation guide. You can download the pdf of this Implementation Guide here: <http://www.pmda.go.jp/ich/e/1_ich_icsr_implementation_guide_v5_01.pdf>
  + ICSR is more general than the ICH. The scope of ICH is limited to human drugs.
  + MedDRA codes are used in various places; it gives a code system diagnosis analog similar to SNOMED. The FDA would like to use MedDRA for implementation; for more information please use the following link: [www.meddra.org](http://www.meddra.org)
* Galen said that ICSR has done a good portion of the work we are trying to do for Adverse Event Reporting. If FHIM could model the contents of ICSR faithfully and then generate FHIR profiles from it, do we think this would be of interest to the agencies?
  + Mead commented that there would be a value to this; there is a huge functional need for convergence of these different reporting strings but there are immense obstacles to that happening. These obstacles include:
    - Harmonizing terminologies
    - Converting to MedDRA; Who would we speak with regarding those fields that currently use MedDRA to determine what to use in the US Realm? Mead suggested the FDA Data Council but says that this list must first be developed.
  + You must concentrate on ICSR Revision 3.
  + This is a large and important subset of the over-arching public health reporting.
* Mead shared that Lise Stevens is in the processes of putting out a document that addresses US specific items, i.e. National Drug Code and things that are needed to be added to the ICH document to support VAERS. Galen commented that some sort of explicit structures that would be useful to VAERS in addition to the ICH guide might be helpful.

**Wrap up**: Steve thanked the callers for their participation and reminded them of next week’s call.

**Next Meeting:** Friday, March 21, 2014 at 2:30 EDT

| Action Item Description | Responsible Individual | Due Date |
| --- | --- | --- |
| None for this meeting |  |  |

**Information for future FHIM information and terminology modeling calls:**

1) Information Modeling (IM) project call (Every Friday)

Time of Call: 2:30 to 4:30 PM Eastern Time

Dial-in Information: 1 (773) 897-3018, Access Code: 585-151-437

Web Meeting URL: <https://global.gotomeeting.com/meeting/join/585151437>

2) Terminology Modeling calls (Every Wednesday)

Time of Call: 2:00 to 3:30 PM Eastern Time

Dial-in Information: 1 1 (773) 945-1031 Access Code: 849-124-653

Web Meeting URL: <https://global.gotomeeting.com/join/849124653>