Information Modeling Project/FHIM Meeting

Summary of Call

Date/time of call: Friday, March 28, 2014 2:30 - 4:30 PM

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

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

* Steve continues to support the SDC and DAF initiatives; FHIM has not been mapped to the SDC data requirements.
* S&I has started a couple of new initiatives but so far Steve has not been asked to participate; Steve will reach out to Lauren.
* The minutes from last week’s meeting will be distributed to the group once they are complete and will have links to the Process and style guides.
* Galen will review the S&I Simplification spreadsheet that Gary has sent him to do mapping to the FHIM; the SDC and DAF initiates will not be as up to date as the rest.
* SDC is looking at potentially using FHIR as their information exchange format; no decision was made yet but they will continue to look into this.
* The S&I Clinical Quality Framework Initiative groups will take place on Thursdays at 11 am EST; Galen will participate in the first call.

**Terminology Modeling Update** *Jay Lyle*

* ICSR Vocabulary and policy were discussed on Wednesday’s call, will be discussed further on today’s call.

**Other business**

* No other business was discussed.

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

* Lise Stevens, FDA joined the call. Galen summarized that we are currently modeling the Adverse Event Reporting domain and looking to the Public Health spreadsheet that was started last year. Galen is looking at the ICSR information in the FSA requirements to model and produce implementable artifacts for electronic reporting to FDA and CDC, similar to MedWatch 3500 and the VAERS1. The following is a summary of what was discussed:
  + The ICH implementation guide is a performance profile for the ISO HL7Standard 27953. This standards has 2 parts
    - Part 1: Supports all FDA reporting
    - Part 2: Constrained for ICH
  + It deals specifically with Drugs and Biologics; it is limited to human products and doesn’t really support medical devices.
* There is no electronic version of the Medwatch3500 form that the FDA requires.
  + In order to have the ability to receive these electronic reports there must be structure as opposed to” test fields”; the ICH that the group has been looking at would be a good reference to see how this info should be structured for use.
  + MedWatch 3500b was created to be a clearer and more intuitive version for patients who intend to report to FDA.
* It was explained that, from an ISO -HL7 perspective there is no ICSR R3
  + ICSR R1- Center for Devices, closely relates to MedWatch3500
  + ICSR R2- is synonymous with the ISO 27953
  + CDER uses ICH E2B R2; this version should not be used to harmonize as it is a proprietary XML based on ICH’s standards. *(The Version Galen displayed was R2B R3, the Third Version of ICH’s specs.)*
* E2B can be used as a content specification; many of these data elements are unique with ICH reporting; trying to harmonize to an HL7 repository will be difficult.
* Lise said that we must define our scope, which will point us to the version of the ICSR that we should harmonize against.
* Galen said that the FHIM hopes to to put out implementation guides and would ask that the FDA provide their requirements for electronic reporting so that they could produce the guide and could be leveraged by the FDA.
* Lise recommends using a combination of:
  + MedWatch 3500 A, to get user facility information
  + E2B R3, as a content guideline, it will provide about 98% of the concepts
  + VAERS 1;
  + ISO 27953; can be used as a schema for the model
* Lise asked what the FHIM team would need from FDA moving forward.
  + Rob said that it is not clear what the ICH OIDs represent; it was determined that a new code system and value sets would need to be created.
    - If we were to create d an infrastructure, code system and value sets who would be the steward of this? FDA
    - FDA currently uses NCI as a repository; to transition from this to VSAC would be an enormous effort.
    - Using NCI would be ok for our purposes if we could support SVS or CTS2; Bill said that we should write up our requirements for NCI to see if they could accommodate this. These codes need to be up to date and current and need a place to go to get this information.
    - The FDA wants a robust, standardized way of electronic reporting and if it was using SNOMED than they would map it; ICH is too limited of a use case and its vocabulary isn’t all standardized.
  + Issues:
    - When dealing with a form and try to put it into a modeling construct it becomes an observation with a Boolean value. On “other”, “unknown” it would be an HL7 NullFLavor value. In terms of logical relationship, volunteered report is not a patient outcome.
    - Need a data steward and this is not an FDA concept as of now.
    - There would be many centers within FDA to do this; not staffed to do this.
    - Hope they would use the FHIM to leverage their work; could exercise the Steward role potentially on their behalf on VSAC; would be able to help with the mechanics of being sure that the value sets are up to date.
    - Are these ICSR referenced in MU activity? Lise explained that No, FDA does not contribute financial resources under ONC. They have tired several times to work with ONC before for Adverse Event Reporting and ONC seems to be most interested in Version 2 or CDA so there efforts did not go anywhere.
      * They FDA would need some sort of investment in terms of financials and find a true end to end project. Rob will speak with Lise offline to see if there is anything he can do or provide someone for her to be in touch with regarding this matter.
    - If we change the meaning of the NCI codes then we have forked the work that they have done; it would really be a FHIM view of the FDA implementation.
* Lise said that she needs Galen to help orient her on what he has done with the FHIM on Adverse Event Reporting/ Galen provided her with a brief update; he will follow up with Lise to review our superclasses.
* Lise will try and help as best she can and make herself available.

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

**Wrap up**: The meeting ended early; the discussion will reconvene next week.

**Next Meeting:** Friday, April 4, 2014 at 2:30 EDT

**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>