Information Modeling Project/FHIM Meeting
Summary of Call

Date/time of call: Friday, April, 25, 2014 2:30 - 4:30 PM

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

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

- The next HIM WG call is May, 13 2014. The statement of need for group representatives has been sent out to the MB.
- Nothing new was reported for the following:
  - DAF and SDC initiatives; some mapping still needs to be done for SDC
  - CQF (Clinical Quality Framework); Rob has been unable to attend.
  - S&I Simplification WG; this meeting was canceled.
- The FHIM comparative report was submitted for comment; this will also be reviewed on the next HIM WG call.
- The FHIM team is looking to decide on the next 2 domains to go out for review and validation; we are looking at the possibility of allergies and health concerns/problems
- Ioana shared that they are mapping the FHIM Content to the S&I Frameworks Project Requirements
  - There are several repetitions of content and discussed some of the challenges.
  - 1st priority is to look across the initiatives at their common data elements; and she pointed out the need to maintain them.

Other Business

- No other business was shared.

Terminology Modeling Update and Discussion *Jay Lyle*

- NPRM comments were submitted regarding the allergic reaction value set.
- The Patient Care WG requested an addition to their Validated EDA Specification; this is being considered by the Structured Documents WG.

The Terminology WG Discussion (in place of the canceled call on Wednesday)

- Looked at the FHA-Reactions Spreadsheet.
- The IMHC items that have not been matched to VA were reviewed along with the frequency at which they were used. The group discussed multiple items and to determine whether they would be included in the VA list.

The following was concluded:

- A Problem List should be published that identifies a set of terms in SNOMED that represent all of the concepts that we need in MeDRA. This list should be validated against real life instances that we have seen from FDA, VA, IMHC etc.
    - If we use SNOMED on the critical side we do not need value sets and would rely on mapping; what is mapped goes into the reporting
- We must identify our assumptions to avoid confusion for the user as different types of users have different ideas about reporting adverse events.
- Criteria: Since FHIM is higher level and not an implementation there is room for flexibility. For recording purposes these reactions should be kept general.
    - We assume that nuances will be communicated elsewhere.
- These are reactions to an exposure and can be reported more generally assuming that they are further investigated and documented later on.
    - This may become problematic if it does not support both clinical and reporting use cases.
    - Jay will go further on the mapping of MeDRA and the group will look at this to see if there is a reasonable way to support these use cases.

- **Action item: Jay will submit an updated spreadsheet with clearly defined principles, (specificity, finding, frequency, binding), and ask for the group's comment.**
    - **Rob suggested that he apply what we've learned from MeDRA using MeDRA 2000.**

Modeling the Adverse Event Reporting Domain *Galen Mulrooney*

- The modeling of the ICH/ICSR Specification is complete.
- Galen is now creating separate models for each of the reports, he is currently working on MedWatch3500
    - Galen said that he has found little in MedWatch that is not in ICH.
    - There are things in ICH that are not needed for the 3500 report:

        - Example: Meet Expedited Criteria: this will have the cardinality of 0 and therefore will not be represented in an implementation guide.
        - For items that are in all three Medwatch forms Galen may create an intermediary class called "MedWatch Family Report"
    - It is unclear whether these forms should be modeled in the FHIM model or in the implementation models
- Galen found that he has been modeling similar constructs in 2 different ways:
    - Questions with check box answers have been modeled as Boolean values
    - Creating an enumeration (1-4) in a single field; i.e. Problem Type.
        - This is the approach that was decided to be most favorable
        - Galen will review the VAERS 2 form offline to see how to model questions that are tied to subsequent ones.
        - This approach fits into the detailed clinical model that he is adopting elsewhere in the FHIM. It also in some ways facilitates the building of FHIR resources.

- Next Steps: Galen will create generic models of the FDA, MedWatch and VAER subtypes and then publish them for the partner agencies to comment.
- This should be completed in 2-3 Terminology and Information Modeling calls.
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- On his own time Galen plans to try and generate FHIR profiles

Wrap up: The May 2nd and 9th meetings have been canceled due to CIMI and HL7 conferences.

Action Item Description	Responsible Individual	Due Date
Update Reactions Spreadsheet and send to the group	Jay	5/15/2014

Next Meeting: Friday, April 25, 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