Information Modeling Project/FHIM Meeting
Summary of Call

Date/time of call: Friday, April, 18, 2014 2:30 - 4:30 PM

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

Updates on S&I Framework integration/initiative and FHA Work   *Steve Wagner*
- No updates were given for the SDC or DAF Initiatives
- Galen reported that there was a new Privacy and Security WG; the timing is opportune as we plan to refresh the Privacy and Security model for FHIM
    o This WG is looking at data provenance not just clinical but record management as well;
    o Galen expects there to be overlap between our work and what they are doing.
- The S&I Simplification WG had asked Galen to map its data spreadsheet and have provided him with their latest version; Ioana will take on this task as Galen travels.
    o Galen asked Gary to validate that this would still be valuable as many of these initiatives are complete; Gary feels that it is worthwhile so that we have coverage with the tooling that they are working on.

Terminology Modeling Update   *Jay Lyle*
- The group continued to work on the reaction lists provided by the VA and Intermountain Healthcare; the FDA has also provided their SNOMED values.
    o There is a fair amount of overlap between the VA and Intermountain lists;
        ▪ They will use VA's list as a baseline and use the list they received from Intermountain as needed.

- The group will revise their draft comment for the NPRM to say that there are better lists than what is suggested in the NPRM and provide an example for them to take into consideration.

Other business
- No other business was shared.

Modeling the Adverse Event Reporting Domain *Galen Mulrooney*
- He has finished modeling the E2B (R3) from ICH;
- Galen refactored the model to reflect last week's conversation and walked the group through those updates.
- We examined the Characterization of the Drug Role and looked at the hierarchy that was created.
  - o It was first decided that SuspectedProduct and ConcomitantProduct should be modeled as roles not observations;
  - o After discussing combination drugs and common products the hierarchy was collapsed; combining the subclasses for SuspectedProduct and ConcomitantProduct
    - ▪ For the purpose of this model; if someone wants to know if this is a device, a drug, or both they will have to review the term.
- The group discussed the addition of an "action taken" attribute within AbstractProductRole. The ICH only deals with drugs; now that we have made these broader some of the fields do not make sense.
  - o This is ok for our purposes as this will be the top level of the FHIM that will not have vocabulary bound to it; we will need clear implementation templates with distinct, associated value sets.
- Information that is independently obtained from the user should be captured here if there is no terminological core.
- Galen reviewed the ICSR Mapping Spreadsheet that was sent to the group.
  - o Has coverage on every data element in the ICSR with the exception of a couple;
  - o Next Galen will fill in the fields for MedWatch and VAERS forms;
  - o Once the domain is complete he will create a FHIR resource for one of them and try to implement it.
- The Data Elements Spreadsheet was reviewed; there are 196 so far with the definitions filled in. Galen asked that the terminology group look at the codes and concepts he has found in the specification.
  - o Galen will not create value sets for things that the FDA is not concerned with at the MedWatch level.
  - o The goal for next week is to complete modeling of MedWatch and VAERS;
- Mapping the PHRI spreadsheet to the FHIM; Galen said that this he expects this to be fairly easy as PHRI maps to ICSR but noted that there are about 100 items that are not in ICH.

Action Item Description	Responsible Individual	Due Date
None for this meeting		

Wrap up: Galen ended the discussion early as it was the Friday before a holiday. He noted that the May 2nd an d May 9th meetings will be canceled due to scheduling conflicts.

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