

**FHIMS Lab-Orders and Observation Domain  
Meeting Minutes (February 7th)  
Agenda for the next meeting (February 14th)**



**Date/time of call:**

Monday, February 7th, 2011, 10-11:30 AM (EST)

**Call:** 1-800-767-1750, **Passcode:** 84287

Microsoft Office Live Meeting

**Leadership team**

Kosta Makrodimitris, Galen Mulrooney, Cindy Vinion

Website: <https://www.projects.openhealthtools.org/sf/projects/fhims/>

**Attendees**

Neelima Chennamaraja, VA

Mike Fitch, DoD

Kosta Makrodimitris, FDA

Galen Mulrooney, VA

Anne Pollock, CDC

Cindy Vinion, NG/CDC

Steve Wagner, ONC

**Agenda**

- ALL: Galen: Modeling Information and decide on classes, patterns-granularity(30')
- ALL: Kosta-Galen-Cindy-Neelima: AAAS 2011 poster/Feb17th (15')
- ALL: Kosta-Neelima-Cindy: Discuss use case and scenarios (10')
- ALL: Kosta-Anne: International Society for Disease Surveillance cases-report(10')
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd iteration) (5')
- ALL: Lab-OO interfaces- S&I Lab, NHIN DIRECT lab, HL7 Lab-OO,(5')

# Summary of Discussion

## Modeling

- Galen: CLIA has different kinds of tests grouped together under headings. This will be modeled as super class/sub-class.
- CLIA has listed syphilis and general under diagnostic immunology. Anne believes that Syphilis is split out because it is very difficult to perform and for public health reasons. Other diagnostic immunology tests are defined by the instruments and lab capability.
  - Mike: Other than a possible need for confirmatory testing, there is nothing special about the results.
- Galen: CLIA has hematology separate while VA listed it under chemistry because of the commonality of results.
  - Anne: Flow cytometry, coagulation, and general cytometry are often under hematology.
- In VA & DoD, pathology includes cyto-pathology and anatomic pathology, including autopsy.
- Anne: we could list the CLIA immunohistology category and its test standards under blood banking as the listed tests are blood bank tests. Since blood banking is not part of the FHIMS Lab current work, those tests can be set aside.

## **See below in the Appendix latest information models concepts**

- IRA is currently working with genetic experts on modeling genetic testing; we will wait until they have something to share to add the details of genetic testing to the model.
- Histo-compatibility and cytogenetics have been added to the model. Cytogenetics are under genetics; many labs have a separate cytogenetics lab; this type of testing is also the subject of many research grants.
- HL7 has a clinical Genomics group. Ira and Kosta will share and collaborate with them in the future. The CG wiki is on <http://wiki.hl7.org/index.php?title=CG>
- Galen: The structure of the order and result data, not lab breakouts, should drive information modeling.
- Galen: In the VA, for chemistry testing only, the test ordered may not be the test performed. For example, a chemical panel may be orders and the lab may perform one test within that panel, many tests that are part of the panel, or some other tests. What actually is performed is up to the lab's procedures and processes. Some of the biological tests do have multiple results over time (e.g., a culture that is read at 12 hours and, again, at 24 hours).
  - Cindy: In public health, biological testing can also differ between the test ordered and the test performed. The orderer may order a panel or an algorithm (designed to test for or rule-out a particular agent), and the lab will perform the needed tests as defined by the protocols and procedures.
- Cindy: We should include a lab report in the model. It is usually a lab report that is returned to the orderer. The lab report may contain a range of data - from a single expert interpretation made by interpreting individual lab test results to a detailed report containing the results from each individual test.
  - Kosta: Report is certainly one of the classes needed to represent fully the results and interfaces with EHRs, repositories, between labs etc. However the 'bigger' vision is to include 4 main classes that 'interact-feed' the reports: store-analyze-process/perform-order(see the UML structure in the Appendix)
- Kosta: What is the meaning of the colors and the categories (stereotypes) on the model (e.g, procedure, observation, etc)? There is not so much consistency if we don't follow the RIM and we currently focus on HL7 2.x We need to get some more expertise and understanding of HL7 VS 3.0 and the respective normative edition.
  - Galen: The coloring and stereotypes are from the HL7 RIM.
  - Cindy: I like that the colors and stereotypes serve as a visual mapping to the RIM.
  - Anne: "Observation" is confusing on the result classes; I think of an observation being something that you observe or see; not a lab result.

## AAAS 2011 Poster

- Steve has requested funds to print the AAAS poster. He should hear something by tomorrow (Feb 8). Unless and until he gets funding, Kosta will be paying to print the poster and will be using an FDA graphics team to do that. The poster have been printed finally in FDA by Kosta's funding.
- Kosta, Galen, Neelima, Cindy and Steve will be collaborating on the AAAS poster. Deadline to submit PowerPoint slides for the poster is Tuesday. Kosta will create the poster and send it out for review on Wednesday. We finalized the poster during the week. A snapshot is in the Appendix below. The Slide(4'x8') was uploaded in OHT.

## General Discussion

- Galen will not be available for the meeting on Friday.
- Anne: Will we be looking at one lab sending specimens to another lab, e.g., a reference lab, for additional testing as one of our use cases?
  - Galen: While our first use case and primary results will go from a lab to an EHR, this lab-to-lab use case should be one of our use cases. Lab-to-program and lab-to-repository should also be future use cases.

## Use Cases & Scenarios

- Kosta: Adding the report class or other Action(HL7-RIM) classes is not enough if we don't add enough entities and roles that should be part of the models: eg in the product-EHR-lab case you may have industry, consumer, clinic, public health agency(state-local-federal), see Appendix and graph from the poster below .
- Kosta: Sentinel is another important case that we can model in our business models since it's a nationwide important effort and involves labs and EHR's integration(LOINC loinc.org). Kosta suggested to invite Sentinel experts and leaders(Mitra Rocca) to give us an overview and discuss the concepts and cases.

<http://www.fda.gov/Safety/FDAsSentinelInitiative/ucm2007250.htm>

<http://mini-sentinel.org/>

## ISDS Discussion

The discussion was postponed for next meeting.

## S&I Framework - Lab Interface Initiative

Kosta and Cindy attended the S&I Lab Report Initiative on Thursday(Use-Case & Requirements WG). They agreed with the leadership of the WG to communicate with them by email in order to establish collaboration and leverage work and findings with them. The S&I LRI hasn't established yet a baseline for their metrics and they seek feedback in order to finalize their goals for meaningful use and adoption.

<http://jira.siframework.org/wiki/pages/viewpage.action?pageId=4194700>

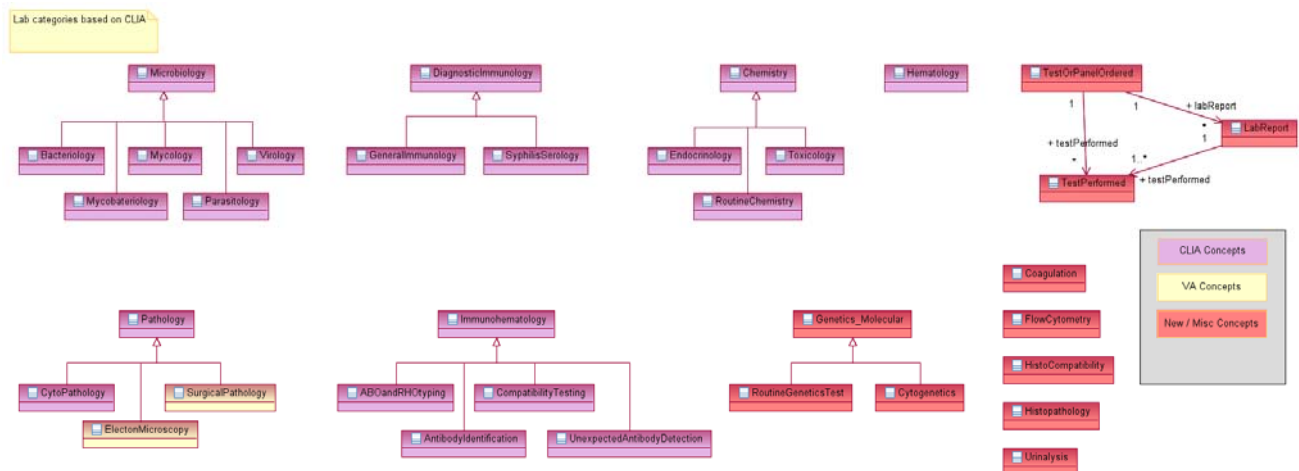
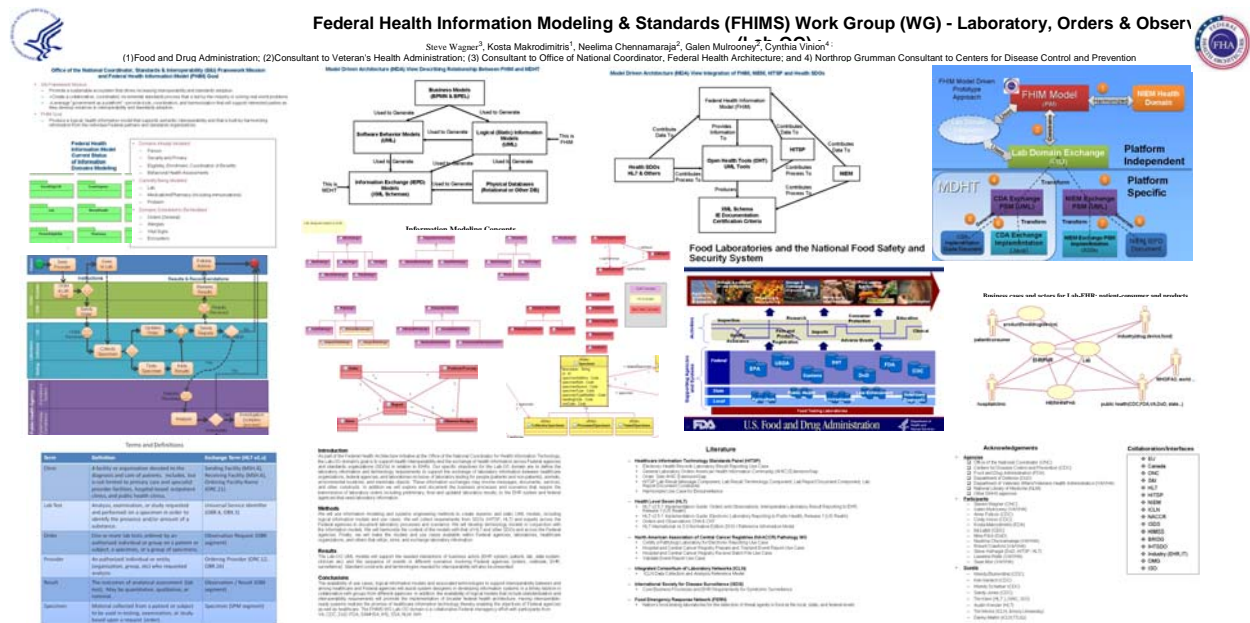
## NEWS /RESOURCES

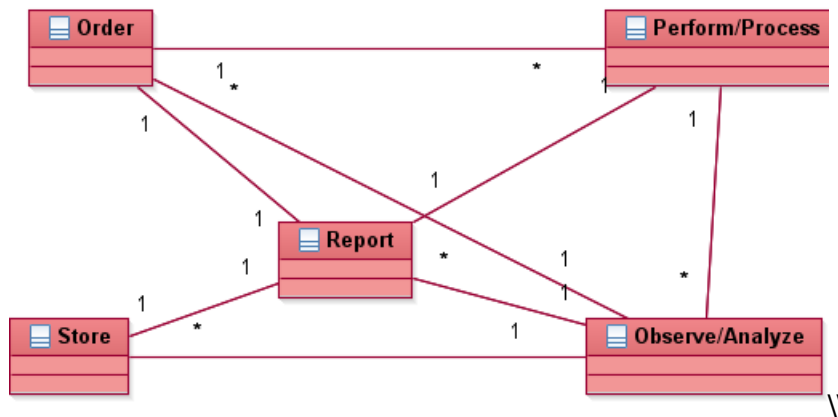
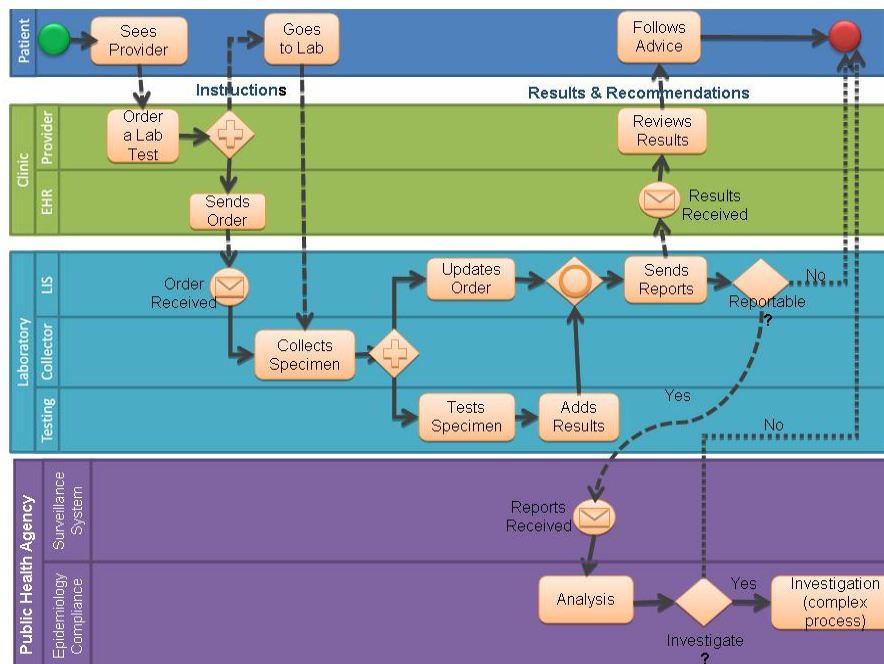
- AAAS meeting in DC (Feb 17-21 2011) <http://www.aaas.org/meetings/>
- HIMSS meeting in Orlando, FL <http://www.himssconference.org/>

## **Agenda Next Call: February 14th 2011**

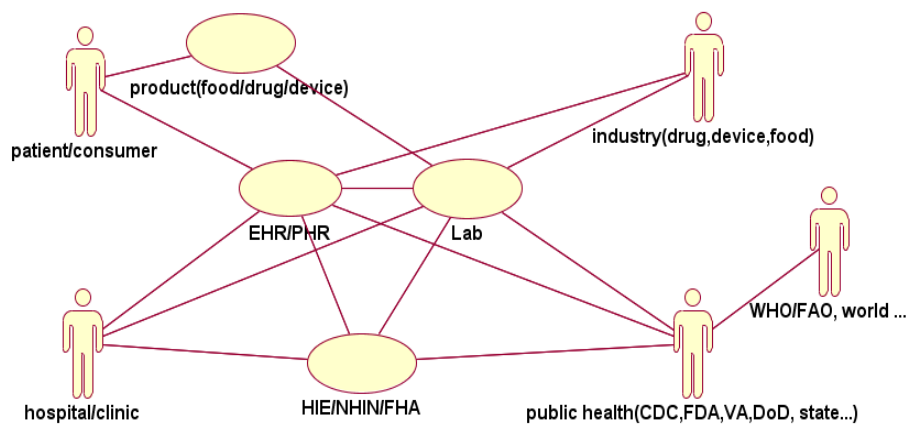
- ALL-Galen: Modeling Information and decide on classes, patterns-granularity(30')
- ALL-Kosta-Cindy S&I LRI communication and strategies
- ALL-Kosta-Neelima-Cindy-Ira : Discuss use case and scenarios (10')
- ALL-Kosta-Anne: International Society for Disease Surveillance cases-report(10')
- ALL: Milestones-Plans-Risks for modeling & use cases(3rd iteration) (5')
- ALL:Lab-OO interfaces-participation S&I Lab, NHIN DIRECT lab, HL7 Lab-OO,(5')

We participate and [present posters](#) relevant to our projects on next Sunday Feb-20  
Federal Health Information Modeling & Standards (FHIMS) Work Group (WG) -  
Laboratory, Orders & Observations (Lab-OO) : Information Exchanges and Electronic  
Health Records (EHR)





## Business cases and actors for Lab-EHR: patient-consumer and products





## Action Items

Start Date	Priority	Action Item	Status
11/22/10	Low	7) Wendy-Kosta-Galen-Cindy: Clarify Specimen-Sample filler and placer order number, test identifier, placer group number and universalServiceIdentifier. The Pathology Laboratory uses specs from DICOM (Supplement 122) to describe the various units (specimen, accession number, etc) in workflow.	In process
11/22/10	Low	8) Kosta-Steve: Services Aware Interoperability Framework and Lab-OO FHIMS relevance (Lab-OO HI7 domain has done some work, Cindy)	In process
11/15/10	High	9)Mike, Cindy, Galen: Finalize definitions for and use of different identifiers & numbers in lab domain - filler order number, placer order number, group number, test identifier, etc.	In process
11/8/10		10) Need to discuss different scenarios involving different people (ward clerk, nurses, physicians, physician's assistants, interns, etc) and who those people would be in a data exchange.	Not started
11/8/10	Low	11)Tim (ICLN) to determine if they would like to participate in FHIMS.	In process
11/1/10	Low	12)Cindy will update sample accessioning scenarios.	In process
11/1/10	Med	13)Anne will write up lab processes to include as additional scenarios.	In process
11/1/10		14)Cindy to identify and contact FBI person from LRN National Meeting for participation in the FHIMS Lab calls when we start doing Chain of Custody, slated for phase 2.	Not started
11/1/10	Med	15) Kosta/Cindy to transform flowchart of outpatient scenario to BPMN. The first BPMN 1.2 draft is done and need to review and add data objects.	In process
10/25/10	Low	16)Keep in touch with Ted Klein and get material and links Update 11/1: Ted waiting for approval to release draft version of volume V	In process
10/25/10	Med	17)Contact laboratory experts, LIMS admins, HL7 OO WG Update 11/1: HL7 OO WG information shared with interested participants	In process
11/09/10	Med	18)Kosta to present relevant material for Automated Laboratory Management, FERN, eLEXNET . Kosta may invite some experts for Medical Countermeasures from the FDA agency and collaborating contractors.	In process
11/08/10	Low	19)Galen to update weekly the FHIMS Lab-OO model and collaborate with Kosta to update about changes from baseline(map .xls-overview)	In process (recurring)
11/17/10	Low	20)Kosta-Galen-Cindy-Steve-Neelima to prepare and design a FHIMS-Lab-OO poster accepted for AAAS meeting in DC(Feb-20th 2011)	In process
11/17/10	Low	21)Kosta to invite CFSAN statisticians to present possible scenario for lab collaboration with CDC (sample hygiene-diseases)	In process
11/17/10	Low	22)Kosta to prepare sample use case for FDA/ORA lab automation and model in BPMN(draft completed). Present and organize library of BPMN cases.	In process
11/17/10	High	23) Kosta-Cindy-Galen-Steve: Plans and documentation of modeling efforts and cases during the next 3 meetings as the end of the 2 <sup>nd</sup> iteration of the Lab-OO. Schedule and plan the 3 <sup>rd</sup> iteration Jan-April 2011	In process

## Completed/Not Tracked Action Items

Start Date	Priority	Action Item	Status
11/8/10		6)Tim (ICLN) to discuss with DHS the sharing of the Actionable Data Elements spreadsheets with definition.	Completed
11/1/10	Low	5) Cindy to share meeting information for the next meeting when it is sent by the co-chairs(ICLN).	Completed
11/1/10	Low	4) Cindy to send flow chart PDF to Anne Pollock	Completed
10/25/10	Low	3) Kosta-Galen will organize the OpenHealthTools shared project space for Lab-OO, Update 11/1: Steve working on organizing the OpenHealth tools project space	Completed
10/25/10	High	2) Prepare for FHA leadership meeting to present FHIMS domains process (Steve-Sean presented,Nov-2010)	Completed
10/25/10	Low	1) Initiate a dictionary of terms and definitions for Lab (Cindy, draft)	Completed