

**Attendees: 10**

Present	Name	Email	Affiliation
	Anita Walden	anita.walden@duke.edu	Duke
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	Dr Ed Hammond Ph.D.	william.hammond@duke.edu	Duke
	Edward Helton (NIH/NCI)	heltone2@mail.nih.gov	NIH
X	Elaine Ayres (NIH/CC/OD)	EAYres@cc.nih.gov	NIH
	Gary Saner		Reed Technologies
X	Iona Thraen	ithraen@utah.gov	VA/Dept of Health Utah
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	Pooja Babrah		Point of Care Partners
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X	Thomas Felix		AMGEN
	Wayne Kubick		CTO HL7
	William Friggle	William.Friggle@sanofi.com	Sanofi
	William Gregory (NYC)	William.Gregory@pfizer.com	Pfizer

**Project Wiki**

[http://wiki.hl7.org/index.php?title=FHIR\\_Adverse\\_Event\\_Resource](http://wiki.hl7.org/index.php?title=FHIR_Adverse_Event_Resource)

**References**

- 1) Search the FDA Acronyms & Abbreviations Database:  
<http://www.fda.gov/AboutFDA/FDAAcronymsAbbreviations/default.htm>
- 2) FHIR Conformance Rules: <http://hl7.org/fhir/conformance-rules.html>
  - a) See 1.12.2 Cardinality

## Agenda

- 1) Approve Minutes for 5/27/2016 and 6/3/2016.
- 2) Continue discussion of outstanding questions from FHIR Management Group (FMG) related to FHIR Adverse Event Resource.
- 3) Continue review of Adverse Event (AE) data elements spreadsheet.
- 4) Continue discussion of project scope including a definition of Adverse Event (AE) for this Resource.
  - a) Discuss updates needed to the FHIR Adverse Event Resource proposal.
- 5) Review of other AE and patient safety documents that can be used for input and clarification.
  - a) Review sources for the documents referred to in the Minutes.
- 6) Next meeting – Friday, June 17, 2016 at 10 AM ET.

## Minutes

- 1) Approve minutes:
  - a) 5/27/2016 Move: Mead/Rik Abstain – 4 Negative – 0 Approve – 5
  - b) 6/3/2106 Move: Rik/Mitra Abstain – 5 Negative – 0 Approve – 4
- 2) Continued discussion of scope:
  - a) FDA – Scope concerns related to ICSR roll-out.
    - i) EMA implementing ICSR.
    - ii) CDER and CBER also planning to use with FAERS.
    - iii) Mitra has been tasked to list all related activities including ONC and Duke for building MedWatch into EPIC.
  - b) HHS planning and eval PCOR trust fund (NLM Lisa Lang).
    - i) Do a demo on the 24th.
    - ii) Not reporting in the scope.
      - (1) Can profile the resource, AND
      - (2) Create a report with this resource included.
- 3) Adverse Events Scope
  - a) Third party vendor – different treatment settings.
    - i) Draft paper available (AMGEN).
    - ii) HIT standards in treatment settings.
  - b) Project with Tufts
    - i) Direct interviews and surveys re: AE reporting in different settings.
    - ii) Characterized different systems that are involved. (AMGEN).
    - iii) Paper is submitted.
    - iv) Someone from Tufts can present data.
  - c) Vast number of resources in this arena.
    - i) Iona – chaired AE reporting for Patient Safety specific quality measures - NQF
    - ii) Harmonization is a big issue.
    - iii) Look at BRIDG model with CTCAE
      - (1) Six or seven different systems
      - (2) CDISC AE domain

- iv) Accommodating current plus future data needs
  - (1) Not lack of standards
  - (2) More an issue of implementing the variety of standards
  - (3) Now batch level traceability is key for biologics – not prioritized for medical records
  - (4) Implantable devices in the surgical suite/OP – how are these included in the EHR?**
  - (5) Safety and QA with information systems per se?
    - (a) No current system or infrastructure for reporting
  - (6) HL7 ERH usability work group – Mitra is co-chair
    - (a) AHRQ has a document on EHR
    - (b) NIST also has a document
    - (c) The hope is include in EHR certification
  - (7) Biologics – immune responses – may be immediate or delayed
    - (a) Currently a snapshot with concomitant meds
    - (b) Really need a longitudinal history of events – could be a product from months ago.
- 4) Working definition required to ensure broad understanding of project scope.
  - a) At the present time the group is still considering both Adverse Events as well as Patient Safety events
  - b) Quality reporting – not in scope in broadest sense but the group agreed that AE/patient safety events that are included in quality reporting are in scope.
    - i) Establish working definition to move forward.
    - ii) Mitra provided the current FDA definitions for Drug Adverse Events and Device Adverse Events:
      - (1) **21CFRPart11, Section: 314.80 Adverse drug experience.** Any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: An adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.
      - (2) **21CFR803.3 Medical Device Reporting (or reportable event).** An event that user facilities become aware of that reasonably suggests that a device has or may have caused or contributed to a death or serious injury; or An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices: May have caused or contributed to a death or serious injury, or Has malfunctioned and that the device or a similar device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.
    - iii) Mitra will provide the updated citation for biologics.
- 5) Documentation to support scope – will continue to gather and document.
  - a) The group discussed whether to only include data from electronic health records or if the inclusion of data from other sources such as occurrence reporting systems was also in scope. The group agreed that data could originate from or be communicated to multiple systems and would not be limited to an electronic health record.
    - i) Consider how to handle use cases that may not be recorded in a system such as patient elopement or giving a baby to the wrong parent. (why are these not recorded?)
  - b) Data elements
  - c) Definitions
  - d) Use cases
  - e) Terminology bindings or examples

- 6) Continue to work with data elements on spreadsheet based on commonality between various resources.
  - a) Consider the BRIDG model: [http://www.hl7.org/implement/standards/product\\_brief.cfm?product\\_id=71](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=71)
  - b) Consider NQF Patient Safety and AE reporting measures:  
[http://www.qualityforum.org/topics/sres/serious\\_reportable\\_events.aspx](http://www.qualityforum.org/topics/sres/serious_reportable_events.aspx)

## Outstanding Questions

Questions and comments from the FHIR Management Group (FMG) related to FHIR Adverse Event Resource:

- 1) The scope should include events that happen to individual other than patients.
  - a) Specifically Practitioners and RelatedPersons
  - b) Possibly also Devices (e.g. equipment damage)
- 2) Timeline should be updated to inclusion in DSTU 3 rather than 2.1.
  - a) 2.1 would have been tight anyhow. Deadline is early July 2016 to have your resource at DSTU-level quality
- 3) For each of the "related resources", can you define what the nature of the relationship is?
  - a) Reference by name – links
  - b) Patient resource
  - c) Observation resource
  - d) Medication resources
  - e) Immunizations
  - f) Devices
- 4) Need to correct and update resource proposal and let Lloyd know.
  - a) [http://wiki.hl7.org/index.php?title=AdverseEvent\\_FHIR\\_Resource\\_Proposal](http://wiki.hl7.org/index.php?title=AdverseEvent_FHIR_Resource_Proposal)

## Other Questions

- 1) none

## Action Items

- 1) Any line items that include explicit actions are **highlighted in yellow** above.

## Next Call

**Friday, June 17, 2016, 10 AM ET**

### Agenda for Next Call

- 1) Approve minutes from June 10 meeting.
- 2) Potential presentation from Tufts/Amgen on study related to adverse events in various care settings.
- 3) Potential presentation from Point of Care Partners regarding adverse events in various care settings.
- 4) Continue to evaluate data elements across current standards.
- 5) NOTE: June 24 – Presentation from Mitra Rocca on her review of various FDA standards and other related projects for adverse event reporting.