HL7 RCRIM WG

FHIR AdverseEvent Resource

CALL MINUTES: Friday, July 1, 2016

Meet online at www.webex.com, meeting number: 622 569 796, password: Meeting
Phone +1 770-657-9270, passcode 7485962

Attendees: 5

Present	Name	Email	Affiliation
	Anita Walden	anita.walden@duke.edu	Duke
	Behnaz Minaei	Behnaz.Minaei@fda.hhs.gov	FDA
	Brian Peck	bpeck@epic.com	EPIC
	Claude Nanjo	cnanjo@gmail.com	
	Dianne Reeves (NIH/NCI)	reevesd@mail.nih.gov	NIH
	Ed Hammond PhD	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
	Iona Thraen	ithraen@utah.gov	VA/Dept of Health Utah
	John Kiser	john.kiser@abbvie.com	Abbvie
	Jose Costa Teixeira	jose.a.teixeira@gmail.com	
	Julie James	julie_james@bluewaveinformatics.co.uk	Blue Wave Informatics
	Konstadinos Kidos	konstadinos.kidos@baxalta.com	Baxalta
	M'Lynda Owens	Mlynda.Owens@cognosante.com	Cognosante
	Mead Walker	dmead@comcast.net	Mead Walker Consulting
	Mitra Rocca	mitra.rocca@fda.hhs.gov	FDA
	Pooja Babbrah	Pooja.Babbrah@pocp.com	Point of Care Partners
	Rashad Hasan		FDA
	Raymond Kassekert	raymond.x.kassekert@gsk.com	GSK
X	Rik Smithies	rik@nprogram.co.uk	HL7 UK
X	Sheila Connelly	sconnelly@techtalentresource.com	Technical Talent Resource
	Stella Stergiopoulos	stella.stergiopoulos@tufts.edu	Tufts University
X	Susan Terrillion (AHRQ/CQuIPS) (CTR)	Susan.Terrillion@AHRQ.hhs.gov	AHRQ
	Thomas Felix	thfelix@amgen.com	AMGEN
	Wayne Kubick	wkubick@hl7.org	CTO HL7
	William Friggle	William.Friggle@sanofi.com	Sanofi
X	William Gregory (NYC)	William.Gregory@pfizer.com	Pfizer

Project Wiki

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 6/24/2016
2) Review of analysis, HL7 FHIR W5 Report
3) Discuss other resources necessary
   a) PCOR?
   b) Quality reporting
   c) Clinical decision support
4) Begin writing resource text in the format used for other FHIR Resources. Example: http://hl7.org/fhir/allergyintolerance.html

Minutes

1) Approve minutes:
   a) 6/24/2016 Deferred due to lack of quorum
2) Review of various data sources
   a) 3500 – voluntary submission
      i) Follow-ups
   b) 3500A – mandatory submission
      i) Follow-ups depends on substance
   c) Look at global issues
3) Review of available data sources during the call:
   a) HL7 FHIR W5 Report: http://hl7-fhir.github.io/w5.html
   b) PSO Privacy Protection Center, AHRQ Common Formats, Technical Specifications - Common Formats - Hospital Version 1.2: https://www.psoppc.org/psoppc_web/publicpages/cfV1.2technicalspecifications
      i) USHIK (United States Health Information Knowledgebase) Common Format Forms: https://ushik.ahrq.gov/mdr/portals/ps?system=ps&enableAsynchronousLoading=true
   c) NCI caDSR Contexts. CDE (Common Data Elements) Browser for ONC/SDC efforts: https://cdebrowser.nci.nih.gov/CDEBrowser/. This includes common data elements for MedWatch forms and for AHRQ.
      i) CDE Browser Basics: https://wiki.nci.nih.gov/display/caDSR/1+-+CDE+Browser+Basics
   d) We did not discuss but need to look at:
      i) The IHI Global Trigger Tool for Measuring Adverse Events: http://www.ihi.org/resources/pages/tools/ihiglobaltriggertoolformeasuringaes.aspx
      ii) E2B(R3) Individual Case Safety Report (ICSR) Specification and Related Files: http://estri.ich.org/e2br3/index.htm
      iii) CIOMS (WHO/UNESCO), Reporting Adverse Drug Reactions, Definitions of Terms and Criteria for their Use: http://www.cioms.ch/publications/reporting_adverse_drug.pdf
         (1) Suspect Adverse Reaction Report Form (CIOMS Form I): http://www.cioms.ch/index.php/cioms-form-i
      iv) MedEffect Canada, Adverse Reaction and Medical Device Problem Reporting. *Canadian standards for mandatory and voluntary reporting of adverse events (Canada calls these adverse reactions):*
         (1) Reporting Adverse Reactions: http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php
         (2) MedEffect Canada Home page: www.healthcanada.gc.ca/medeffect
         (3) Canada Vigilance Program: http://www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php

4) Action items
   a) A proposed approach of looking across all common data elements was started.
      i) This process will define data elements used across both mandatory and voluntary reporting for both adverse events and patient safety events.
      ii) Additional data elements within the various reference standards will be collected to define the use of other FHIR resources (e.g. medication, observation, etc.) as the resource is developed.
   b) The group needs to begin drafting the prose that will accompany the FHIR resource data elements. These statements are to help implementers understand the resource.
      i) Match the format used for other FHIR Resources. Example: http://hl7.org/fhir/allergyintolerance.html
   c) Meetings for July 8 and July 15 were cancelled.
5) Next meeting will be on Friday, July 22 at 10 AM.

Outstanding Questions

Questions and comments from the FHIR Management Group (FMG) related to FHIR AdverseEvent 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

Other Questions

1) none

Action Items

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

Next Call

Friday, July 22, 2016, 10 AM ET

Agenda for Next Call

1) Approve minutes from June 24 and July 1 meetings
2) Review spreadsheet of data elements from various sources
3) Continue to discuss scope of project