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

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Project Wiki

References
1) Search the FDA Acronyms & Abbreviations Database:
http://www.fda.gov/AboutFDA/FDAAcronymsAbbreviations/default.htm
   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/cfV1.2technicals specifications
      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/ihiglobaltriggertoolformeasuringaees.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
         (1) Suspect Adverse Reaction Report Form (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
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.

**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