HL7 RCRIM WG

FHIR Adverse Event Resource

CALL MINUTES: **Friday, June 3, 2016**

Attendees: 7

Present	Name	Email	Affiliation
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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 5/27/2016 - deferred.
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) Next meeting – Friday, June 10, 2016 at 10 AM ET.

Minutes

1) Approve minutes - Deferred
2) Devices – FHIR resources old – focus on UID for C-CDA using the CPM.
3) Mapping to MedWatch form – in CADSR and EVS.
    a) Mitra Rocca from FDA mapped to ICSR r2 and ICH forms (3500 and 3500A).
    b) Also mapped to ICSR r1.
    c) ICSR r2 will be used in 2017.
    d) Now registered via Diane Reeves at NCI.
    e) Mappings in CADSR – can see MedWatch mappings.
4) 2017 – Mapping of data elements
    a) human only for drugs, biologics, devices.
    b) Does not include animals.
5) Older mapping to MedWatch as well, but uses ICH version.
6) DECISION: No episode of care or encounter needed – but do need a link to study.
    a) No equivalent in ICSR.
    b) May not happen in an episode of care/encounter.
    c) Could let episode of care serve as a proxy.
    d) Do not want to match up dates.
7) DECISION: Resource does need the location of the event – e.g. care setting vs. the home.
    a) Will add a reference to the location resource or the ability to use text.
8) CDA implementation guide – check C-CDA.
    a) Examples links to study ID and how AE's are handled.
9) Status – once use only without the need for ongoing stages for specific event.
    a) Is there follow-up on an event?
    b) If the AE goes to a drug company then FDA follows up.
    c) A report might be submitted twice.
    d) This is a tracking status – in FHIR this is more like a list or plan of action.
    e) Add each resource to a list resource. (add this to usage notes)
10) Outcomes – ICH categories as possible outcomes as per e-mail from Mead Walker:
        i) 1 = recovered/resolved
        ii) 2 = recovering/resolving
        iii) 3 = not recovered/not resolved/ongoing
        iv) 4 = recovered/resolved with sequelae
        v) 5 = fatal
        vi) 0 = unknown

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

Other Questions

1) none

Action Items

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

Next Call

Friday, June 10, 2016, 10 AM ET

Agenda for Next Call

1) Approve minutes from June 3, 2016 meeting.