HL7 RCRIM WG

FHIR AdverseEvent Resource

CALL MINUTES: Friday, August 12, 2016

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

Attendees: 6

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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
3) CDISC – CDASH https://www.cdisc.org/standards/foundational/cdash

Agenda

1) Approve Minutes for 6/24/2016 and 7/1/2016
2) New Items
3) 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 Move: Sheila/Mitra
   b) 7/1/2016 Move: Sheila/Mitra
2) Pooja Babbrah – Presentation on "Biologics and Biosimilars Access and Traceability" The work presented discussed an evaluation of data flows for reporting on biosimilars. The slide deck can be found here: http://wiki.hl7.org/images/2/26/Presentation_PoojaBabbrah_BiosimilarResearch_PointofCarePartners_2016_08-12.pdf
   a) The presentation presented data flows across a variety of health care setting. It was noted that the prescription does always relate to the actual dispense. The RxFill transaction is sent to the EHR, but is not what was necessarily used by Pharmacies. It was also noted that RxFill does not capture batch and lot number which is essential information for reporting. A newer version of RxFill will address this issue. MU3 requires the actual medication used.
   b) The question of GS1 and the use of barcode for the dispense – it was noted that many ambulatory clinics may not have barcode scanner.
   c) The issue at hand: information flows do not capture biologics batch number and lot number, and these data are not getting back to the EHR. This means that there is no link back to the appropriate biologic.
   d) Currently reporting on biologics is voluntary via MedWatch. Reports may be duplicates; have inadequate or incorrect information; or an event may not be reported at all.
   e) Specialty pharmacies do report adverse events using MedWatch by patient – noting that some patients may be on multiple drugs as a confounding factor.
   f) Hospital have no standard ways to report AE's and the patient (user) may not have batch/lot (may throw packaging away).
   g) The group suggested contacting the PharmacyHIT group, NCPDP and others from the HL7 Pharmacy WG.
      i) Shelley Spiro- – Pharmacy HIT
      ii) Sue Thompson – NCPDP
      iii) Scott Robertson – Keiser
      iv) Jim McNeil - SureScripts
   h) Use of V2 – still key in the market place. This is the current state with variable implementations.
3) Next meeting will be on Friday, July 29 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

Agenda for Next Call

Friday, August 29, 2016, 10 AM ET

1) Approve minutes from August 12 meeting
2) Review spreadsheet of data elements from various sources
3) Continue to discuss scope of project