HL7 RCRIM WG

FHIR AdverseEvent Resource

CALL MINUTES: Friday, April 7, 2017

Meet online at www.webex.com, meeting number: 196 412 889
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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. Review minutes from March 24 - http://wiki.hl7.org/images/4/42/FHIR_AdverseEvent_Resource_Agenda_and_Minutes_2017-03-24.pdf
2. Review of action items for current resource build: http://wiki.hl7.org/images/d/d8/Changes_to_Adverse_Event_Resource_2017_4_4.docx
3. Discussion of representation of "Past Medical History"
4. Proposed use of Adverse Event resource for Madrid Clinicians on FHIR
5. Other issues
   a. Tracking issues in G-FORGE and Zulip
6. Agenda items for Friday, April 21, at 10 AM ET.

Minutes

1. Minutes Approval:
2. Reviewed and adjusted all of the suggested changes to the current FHIR AE resource build.

Changes to Adverse Event Resource
April 7, 2017 – v2

All changes are documented in the FHIR Adverse Event meeting minutes.

1. CHANGE Seriousness to Severity with the same cardinality and same value set
2. ADD AdverseEvent.serious.criteria with cardinality of 0..1 and a value set of

   a) Serious
      a) Results in death;
      b) Is life-threatening;
      c) Requires inpatient hospitalization or causes prolongation of existing hospitalization;
      d) Results in persistent or significant disability/incapacity;
      e) Is a congenital anomaly/birth defect; or
      f) Requires intervention to prevent permanent impairment or damage (i.e., an important medical event that requires medical judgement).
      g) Bill will send one more term – for regulated products not including medical devices
   b) Non-serious

   - The element definition should read: A serious adverse event is any untoward medical occurrence that results in any of the following outcomes: death, is life threatening, requires hospitalization or prolonged hospitalization, results in a persistent or significant disability or incapacity, results in a congenital anomaly or birth defect or requires intervention to prevent permanent impairment or damage.

   - This should be searchable for serious or non-serious

~~3. ADD AdverseEvent.event – codeable concept with SNOMED CT~~

4. ADD AdverseEvent.resultingCondition – this will be a reference to Condition

5. REMOVE "reaction" as this is a subset of a type of resulting Condition

6. CHANGE name of AdverseEvent.category to AdverseEvent.kind – retain adverse event|potential adverse event as fixed with a flag – the actuality of the event.

7. Expand AdverseEvent.category to include a discrete list of broad event classifications
   a. Adverse Event
   b. Serious Adverse Event
   c. Product Problem
   d. Product Use Error
   e. Medical Device Use Error
   f. Problem with Different Manufacturer of Same Medicine
   g. Near Miss
   h. Unsafe Condition

8. AdverseEvent.event - Code using MedDRA codes such as "Fever" 10016558 or SNOMED-CT. Can be repeatable. May have SNOMED-CT in a record, but add MedDRA codes for reporting. Note levels of granularity in various terminologies…need to be described with examples.

9. CHANGE AdverseEvent.suspectEntity.causality to a backbone element – groups elements

10. CHANGE AdverseEvent.suspectEntity.causality.assessment to a codeable concept

11. ADD to AdverseEvent.suspectEntity.causality.assessment the terms defined in the WHO Uppsala Causality Assessment System: https://www.who-umc.org/media/2768/standardised-case-causality-assessment.pdf

    Note - These are applied to clinical trials, not to marketed products. – if it is a spontaneous adverse event report with a marketed project just presume causality. Also complicated by secondary use.

    Value Set Terms are (with definitions)

a) Certain
   i) Event or laboratory test abnormality, with plausible time relationship to drug intake
   ii) Cannot be explained by disease or other drugs
   iii) Response to withdrawal plausible (pharmacologically, pathologically)
   iv) Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon)
   v) Re-challenge satisfactory, if necessary

b) Probably/Likely
   i) Event or laboratory test abnormality, with reasonable time relationship to drug intake
   ii) Unlikely to be attributed to disease or other drugs
   iii) Response to withdrawal clinically reasonable
   iv) Re-challenge not required

c) Possible
   i) Event or laboratory test abnormality, with reasonable time relationship to drug intake
   ii) Could also be explained by disease or other drugs
   iii) Information on drug withdrawal may be lacking or unclear

d) Unlikely
   i) Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)
   ii) Disease or other drugs provide plausible explanations
e) Conditional/Unclassified
   i) Event or laboratory test abnormality
   ii) More data for proper assessment needed, or
   iii) Additional data under examination
f) Unassessable/Unclassifiable
   i) Report suggesting an adverse reaction
   ii) Cannot be judged because information is insufficient or contradictory
   iii) Data cannot be supplemented or verified

12. REMOVE Causality Result – Needs further discussion.

    In the regulatory environment it is a yes or no

13. REMOVE or ADD AS AN EXTENSION AdverseEvent.causality.Method (I wonder if this should be an extension…..)

    a) Probability Scale
    b) Bayesian
    c) Checklist

    ii) Assessment may be done by multiple individuals/organizations – sponsor, investigator using multiple methods.

Agenda for April 21, 2017:

7. Review minutes from April 7
8. Review of action items
9. Other issues
    a. Tracking issues in G-FORGE and Zulip
10. Agenda items for Friday, April 21, at 10 AM ET.

Additional notes: