HL7 RCRIM WG

FHIR AdverseEvent Resource

CALL MINUTES: Friday, March 10, 2017

Meet online at www.webex.com, meeting number: 196 412 889
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X	Rob Hausam	HL7 Vocab expert	

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

Agenda for March 10, 2017:

1. Review minutes from February 24
2. Basic constructs – definitions for type, changes to build
   a. Change type to eventType
   b. EventType definition and potential terminology bindings
   c. Make causality a backbone element
   d. Change seriousness to serious and code with True/False. Amend definition
3. Follow up on Vocab discussion re MedDRA
4. Other issues
   a. Tracking issues in G-FORGE and Zulip
5. Agenda items for Friday, March 24 at 10 AM ET.

Minutes

1. Minutes Approval: Move: Bill/Joe
2. Note that GFORGE does not list RCRIM or BRIDG as "owners" of any FHIR resources. Will wait until the new Biomedical Research and Regulation WG is finalized and then ask Lloyd to add. Therefore have not added any to-do items yet to G-FORGE for tracking.
3. Review Decisions
   a. Agree to use of MedDRA from a standardized terminology approach.
4. Make causality a backbone element
   a. Causality is a relationship between two things
   b. Represent event in resource
   c. Causality – link to other resources
   d. In regulatory space – there are definitions that are applied
   e. Are "causality assessment" and "causality method" redundant?
   f. Need to check E2B and MedWatch – ACTION before changing causality data elements
5. Category codes – just several buckets – use as tags in a resource with searching and querying.
   a. Use Adverse Event and Potential Adverse Event
   b. Group was fine with this categorization
   c. Make category mandatory. Use flag in background to warn that this is a modifier. aCTION

6. Seriousness vs. severity – change to Serious – use True/False. (searchable) In definition of what is serious – can put in definition. If true, it is because of (definition from Bill G.)
    a. In the regulated space (E2B – R3) – use serious yes/no. Then if serious, then meet which criteria to be classified as serious. E.g. serious – death.
    b. In MedWatch – narrative text.
    c. A summary of the definition of a serious adverse event (SAE) from ICH consensus:
        i. Any untoward medical occurrence that at any dose:
        ii. Results in death;
        iii. Is life-threatening;
        iv. Requires inpatient hospitalization or causes prolongation of existing hospitalization;
        v. Results in persistent or significant disability/incapacity;
        vi. Is a congenital anomaly/birth defect; or
        vii. Requires intervention to prevent permanent impairment or damage (i.e., an important medical event that requires medical judgement).
    d. If serious – not true or for non-serious
    e. Add serious.criteria as a placeholder. ACTION

7. Type – need a definition and then determine the terminology to describe. This is how I want to describe what occurred. Maybe type should reference condition and then eliminate reaction. Causality still remains for actual event.
    a. Retain type but change the actual|potential – include value set with actual and potential types from terminology
    b. Clinical type
8. Mapping between MedDRA and SNOMED – if needed. Many to one mapping and it is not accurate. 90 % can be mapped from MedDRA to SNOMED. Death is an exact match. But more granular events cannot be mapped. Maintenance is an issue in the map.
9. Rob Hausam will discuss with the HL7 Vocab group any issue that exist regarding the use of MedDRA and example codeable concept bindings.
10. Create condition data element with reference to condition using clinical findings or a subset of clinical findings.
    a. Resulting condition – point to condition.
    b. Or call reaction/resulting condition.
    c. Ability to show short term reaction and long term condition.
    d. Consider use cases re reaction and resulting condition. ACTION

3) ACTION ITEMS

a) Vocab group re use of MedDRA
b) Consider how to represent reaction vs. resulting condition
c) For type – propose value set bindings
d) For category – make mandatory and add a warning flag
e) For seriousness – change to serious and determine how to add category or criteria if true
f) For causality determine what current E2B and MedWatch require – determine if assessment and method are redundant.

Agenda for March 24, 2017:

1. Review minutes from March 10
2. Review of action items
3. Other issues
    a. Tracking issues in G-FORGE and Zulip
4. Agenda items for Friday, March 24 at 10 AM ET.