Changes to Adverse Event Resource
April 4, 2017

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

1. CHANGE Severity to Serious – use True/False. Make searchable
2. ADD a definition of a serious adverse event (SAE) from ICH consensus:
   Any untoward medical occurrence that at any dose:
   i. Results in death;
   ii. Is life-threatening;
   iii. Requires inpatient hospitalization or causes prolongation of existing hospitalization;
   iv. Results in persistent or significant disability/incapacity;
   v. Is a congenital anomaly/birth defect; or
   vi. Requires intervention to prevent permanent impairment or damage (i.e., an important medical event that requires medical judgement).

3. ADD AdverseEvent.serious.criteria as a placeholder.

4. ADD AdverseEvent.event – codeable concept with SNOMED CT

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

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

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

8. 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.type - Code using MedDRA codes such as "Fever" 10016558.

9. CHANGE AdverseEvent.causality to a backbone element

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

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

Terms are (with definitions)

1. Certain
   - Event or laboratory test abnormality, with plausible time relationship to drug intake
   - Cannot be explained by disease or other drugs
   - Response to withdrawal plausible (pharmacologically, pathologically)
   - Event definitive pharmacologically or phenomenologically (i.e. an objective and specific medical disorder or a recognized pharmacological phenomenon)
   - Re-challenge satisfactory, if necessary
2. Probably/Likely
   - Event or laboratory test abnormality, with reasonable time relationship to drug intake
   - Unlikely to be attributed to disease or other drugs
   - Response to withdrawal clinically reasonable
   - Re-challenge not required
3. Possible
   - Event or laboratory test abnormality, with reasonable time relationship to drug intake
   - Could also be explained by disease or other drugs
   - Information on drug withdrawal may be lacking or unclear
4. Unlikely
   - Event or laboratory test abnormality, with a time to drug intake that makes a relationship improbable (but not impossible)
   - Disease or other drugs provide plausible explanations
5. Conditional/Unclassified
   - Event or laboratory test abnormality
   - More data for proper assessment needed, or
   - Additional data under examination
6. Unassessable/Unclassifiable
   - Report suggesting an adverse reaction
   - Cannot be judged because information is insufficient or contradictory
   - Data cannot be supplemented or verified

7. REMOVE Causality Assessment

8. REMOVE Causality Result

9. AdverseEvent.causality.Method (I wonder if this should be an extension…..)

   a. Probability Scale
   b. Bayesian
   c. Checklist