**Minutes – RCRIM WG**

**FHIR Adverse Event Call 5/20/16**

ATTENDEES

1. Elaine Ayres - NIH
2. Sheila Connelly
3. Mead Walker
4. Rik Smithies
5. M’Lynda Owens
6. Wayne Kubick – HL7
7. Mitra Rocca - FDA

AGENDA

1. Introductions
2. Wiki page introduction
3. Discussion of project and review of current data elements
4. Meeting days and times – Change is needed.

MINUTES

1. Team roles reviewed. ICSR adopted for messages between pharma, device manufacturers and regulatory agencies. Interest from providers who wish to relay adverse event messages for non-regulatory purposes. We need to understand content and implementers who would use this resource. V3 ICSR serves as a good background document with use cases.

2. FDA – wants to make clear that current implementations and use of the ICSR standard are underway. Do not want the community who must provide regulatory reporting to the FDA to be confusing by work on this new resource. Note that this is a nascent project and at present will only be a draft resource – not part of the current slate of resources that will move to a normative state.

3. AHRQ has addressed the reporting of patient safety issues. What is the difference between AE and PS reporting? AE needs patient specific PII. For PS – all de-identified for common format. These two standards need harmonization. For AE, sometimes reports are submitted on the same subjects and identifiers are critical for differentiation. For ONC – had two work streams with the resulting terms entered into CADSR. A reportable condition for AHRQ may be more broad.

4. Old patient safety WG had requirements for both. There is an old DAM – there is an CDA implementation guide. Mead will look for these. May include hospital acquired infection and falls. ICSR is associated with a product, AHRQ not associated with a product.

5. The group then began looking at the actual spreadsheet of data elements and cardinality. The related spreadsheet as of today is here: 

6. Note the group agreed that this resource does not cover adverse event reporting per se. That would involve other aspects of FHIR.

Outstanding Questions:

Questions and comments below from the FMG related to FHIR Adverse Event Resource:

1. The scope should include events that happen to individual other than patients.  Specifically Practitioners and RelatedPersons, but possibly also Devices (e.g. equipment damage)
2. Timeline should be updated to inclusion in DSTU 3 rather than 2.1.  (2.1 would have been tight anyhow.  You've now got until early July 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?
4. Need to correct and update resource proposal and let Lloyd know.

Other questions:

1. Does AdverseEvent adequately reflect use for patient safety issues – e.g. is the use of the resource clear?
2. Look at cardinalities and FHIR rules for assigning cardinalities.
3. Look at order of data elements to confirm to current FHIR standards
4. Need short labels and definitions
5. Outcome – might need a codeable concept or a reference to condition (discuss this)
6. Need a context link Reference(Encounter|EpisodeOfCare) Could use Study in the future.
7. Note that the “Study” resource does not yet exist. This may represent some new work for RCRIM/BRIDG.
8. Need to look across other resources for common syntax.
9. Look at other standards for adverse events and patient safety reporting to ensure we have met all use cases.

Next call – Friday, May 27 at 10 AM ET.