HL7® FHIR® DevDays

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The Vulcan Accelerator: Adventures with Adverse Events

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Who am I?

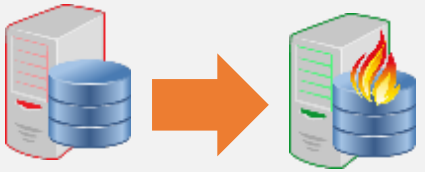
- Michelle Casagni
- Principal Health Informaticist
- The MITRE Corporation

Actively involved with HL7 FHIR Accelerators, working on FHIR standards for oncology with CodeX and adverse events with Vulcan

What is the Vulcan FHIR Accelerator?

WHY

- FHIR is an enabling technology for harmonising and processing data.
- Vulcan exists to help Clinical and Translational Research start using FHIR to manage the vast amount of data they have to work with.
- Vulcan also exists to bring Clinical and Translational Research and Clinical Care closer together through FHIR.



HOW

Vulcan:

- Creates a community
- Supports projects that have a clear and practical objective and short timescale
- Creates Implementation Guides
- Uses connectathons to test the Implementations Guides
- Provides Events & Education

SoA, RWD, ePI, AE, FHIR to OMOP, Phenotypic Data

WHO

- Over 40 members drawn from Pharma, Academic, Vendors, Regulators, SDOs.
- Operations Committee formed from Members
- Supported by Project Management Office
- International scope

What is an Adverse Event?

- Broadly, an event that has unintended effects on a patient or research participant as a result of medical care or the use of a medical product
- Clinical Research
  - “Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.” [ICH, p2]
- Clinical Care
  - An injury resulting from or contributed to by medical care rather than the underlying disease. [PSNet]

References:
ICH https://database.ich.org/sites/default/files/E2A_Guideline.pdf
PSNet https://psnet.ahrq.gov/primer/adverse-events-near-misses-and-errors

What is a Serious Adverse Event?

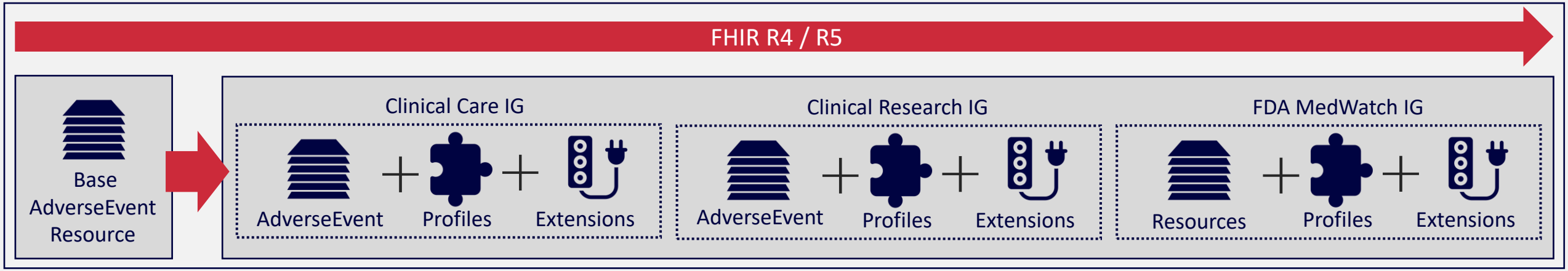
- A serious adverse event must be reported to the sponsor, clinical research organization, and regulatory agencies within a specific time frame
- An event is serious when the patient outcome results in
  - Death
  - Life-threatening
  - Hospitalization
  - Disability or Permanent Damage
  - Congenital Anomaly/Birth Defect
  - Required Intervention to Prevent Permanent Impairment or Damage (Devices)
  - Other Serious (Important Medical Events)

Reference: https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

Why are Adverse Events Tracked?

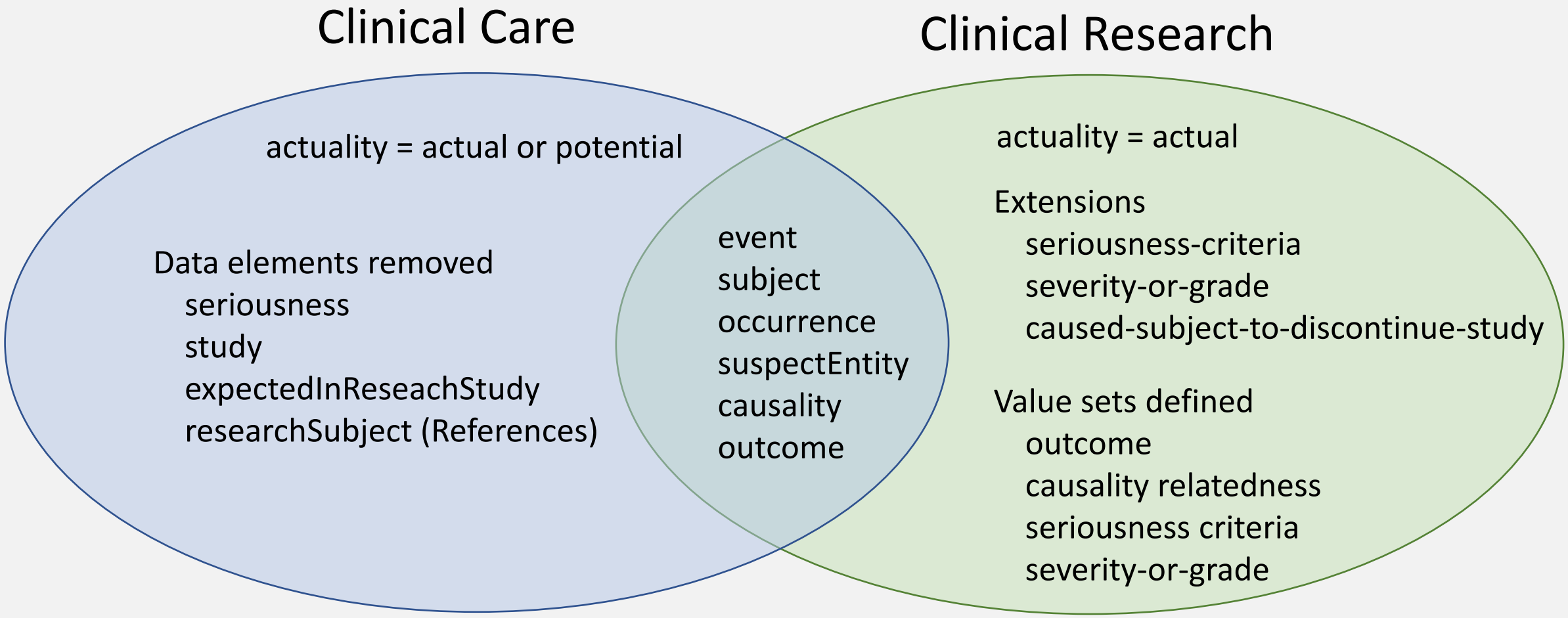
- Clinical Care
  - Meet business requirements for safety concerns and incident reporting
  - Include factors that surround the event
    - What happened?
    - Was it prevented?
    - How was it resolved or managed?
- Clinical Research
  - Evaluate as part of the process for the research study
  - Determine if surfacing as potential confounder or potential side-effect of study treatment
  - Report serious adverse events to respective health authorities

How is the AdverseEvent FHIR Resource Used?



- Base AdverseEvent Resource is used to further profile data elements to meet specific use cases
- Implementation Guides (IG) are under development to define separate profiles specifically for the two use cases due to their context complexities

What are the Differences between the Adverse Event Profiles?



Clinical Care Example (Procedure Mishap)

Mrs. Jones is a 68-year-old female scheduled for a **routine colonoscopy** in an outpatient surgery center on 8-May-2021. Her current medical history included hypertension for which she took Cozaar 50 mg daily, and Naproxen 500 mg daily for her osteoarthritis.

The patient followed the usual bowel preparation routine (polyethylene glycol solution) and the procedure began with the introduction of the endoscope by the gastroenterologist, Dr. Colon. The ascending and transverse colon showed no significant findings but the presence of a .5 cm sessile adenoma in the sigmoid colon merited removal. The **gastroenterologist performed a polypectomy with electrocautery** and completed the procedure.

Mrs. Jones was discharged two hours after the procedure. One the second day after the procedure the patient experienced symptoms of **fever, localized abdominal pain, localized peritoneal signs and leukocytosis.** Upon examination by Dr. Colon, Mrs. Jones was found to have an **electrocoagulation injury to the bowel wall that caused a transmural burn and localized peritonitis** without evidence of perforation on radiographic studies. Her postpolypectomy electrocoagulation syndrome was **managed with intravenous hydration, antibiotics, and nothing by mouth until the symptoms subsided**.

Data Element	Values
actuality	actual
category	Procedure-mishap
event	fever, localized abdominal pain, localized peritoneal signs and leukocytosis
subject	Mrs. Jones
occurrence	10-May-2021
suspectEntity	polypectomy with electrocautery
causality	Probably-likely
resultingEffect	electrocoagulation injury to the bowel wall that caused a transmural burn and localized peritonitis
outcome	Transient abnormality with full recovery (finding)
mitigatingAction	postpolypectomy electrocoagulation syndrome was managed with intravenous hydration, antibiotics, and nothing by mouth until the symptoms subsided

Clinical Care Example (Wrong Patient, No Harm Event)

Arnold Bear, a 70-year-old male patient hospitalized for an elective hip replacement is inadvertently **given a capsule containing 3,000 IU of Vitamin D intended for a patient in the adjacent room**.

Mr. Bear experiences **no symptoms and has no conditions which would be affected by Vitamin D intake**. The inadvertent administration of **Vitamin D is documented in his medication administration record** and in a clinical note in his record. An **incident report is completed** in the hospital's incident reporting system.

Data Element	Values
actuality	actual
category	wrong-patient
event	Administered 3,000 IU of Vitamin D
subject	Arnold Bear
occurrence	03-Nov-2020
suspectEntity	Administered 3,000 IU of Vitamin D
causality	certain
outcome	Transient abnormality unnoticed by the patient (finding)
resultingEffect	
mitigatingAction	The inadvertent administration of Vitamin D is documented in his medication administration record and in a clinical note in his record. An incident report is completed in the hospital's incident reporting system

Clinical Research Example (Serious Adverse Event)

Patient SCHJO on **Research Study XYZ**, Study ID XYZ-123, Subject number XYZ-123-002. SCHJO was enrolled in the study on 12-Jun-2021 taking **Study Medication ABC** 10 mg orally daily every morning for atrial fibrillation to prevent thromboembolism. On 2-Dec-2021, the subject XYZ-123-002 was **hospitalized** with a **Gastrointestinal (GI) bleed**. The investigator was notified of the event on the day of admission when the patient presented with vomiting a large amount of coffee-ground like hematemesis. The investigator **stopped the study drug** because the event was "**Possibly related**" to the study drug. The patient's hemoglobin dropped to 6.5 g/dL and received 2 units of PRBCs. The patient had an upper endoscopy that showed a moderate amount of bleeding from the esophagus. The site was cauterized, and the patient had no further bleeding after the procedure. The GI bleed **resolved** within one week after discontinuation of study drug and the patient was discharged on 9-Dec-2021 in good condition.

Data Element	Values
actuality	actual
event	Gastrointestinal hemorrhage [10017955]
subject	Patient SCHJO, Subject number XYZ-123-002
occurrence	2-Dec-2021 to 9-Dec-2021
seriousness	serious
seriousness-criteria	death = false life-threatening = true hospitalization = true disability or permanent damage = false congenial anomaly/birth defect = false required intervention = true other medically important event = false
severity-or-grade	severe
suspectEntity	Study Medication ABC, 10 mg orally daily
causality	Possibly related
outcome	Recovered/resolving
study	Research Study XYZ, Study ID XYZ-123
mitigatingAction	Drug withdrawn

Clinical Research Example (Non-Serious Adverse Event)

Patient MOUMIC on **Research Study DISNEY**, Study ID DUCK-828, Subject number DUCK-828-012. MOUMIC was enrolled in the study on 21-Jan-2022 taking **Study Medication MMX** 20 mg subcutaneously daily every morning for diabetes. At visit 3 on 21-Feb-2022, the patient stated that he had started to experience **intermittent headaches** on 1-Feb-2022 that were **mild**. They occurred once a week and resolved with Tylenol but were still ongoing. The investigator said the headaches were "**UNLIKELY RELATED**" to study drug. The action taken with the study treatment was the "**DOSE NOT CHANGED**" and the outcome was noted to be "**NOT RECOVERED/NOT RESOLVED**".

Data Element	Values
actuality	actual
event	Headache [10019211]
subject	Patient MOUMIC, subject number DUCK-828-012
occurrence	1-Feb-2022
seriousness	Non-serious
seriousness-criteria	
severity-or-grade	Mild
suspectEntity	Study Medication MMX, 20mg daily
causality	Unlikely related
outcome	Not recovering/not resolved
study	Research Study DISNEY Study ID DUCK-828
mitigatingAction	Dose not changed

Summary

- Adverse Event concept is different in clinical care and clinical research
- Hard to resolve these differences to accommodate in a single FHIR resource
- Adverse Event resource being profiled specifically for each use case
- Vulcan Adverse Events Project Team
  - Developed an Adverse Event Clinical Research IG – balloting in September 2023
  - Provided Patient Care Work Group a draft IG for Adverse Event Clinical Care

Contact and Related Links

- Michelle Casagni
  - Email: mcasagni@mitre.org
- Vulcan Program Management Office
  - Email: Vulcan@hl7.org
- Vulcan Adverse Events Project Page
  - https://confluence.hl7.org/display/VA/Adverse+Events
- Adverse Event Implementation Guides
  - https://confluence.hl7.org/display/PC/AdverseEvent+Implementation+Guides
- Adverse Event Use Cases
  - https://confluence.hl7.org/display/PC/Adverse+Event+Use+Cases

Q&A

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