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Let's Build with FHIR Shorthand

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ORGANIZED BY firely

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INFERNO

mCODE™

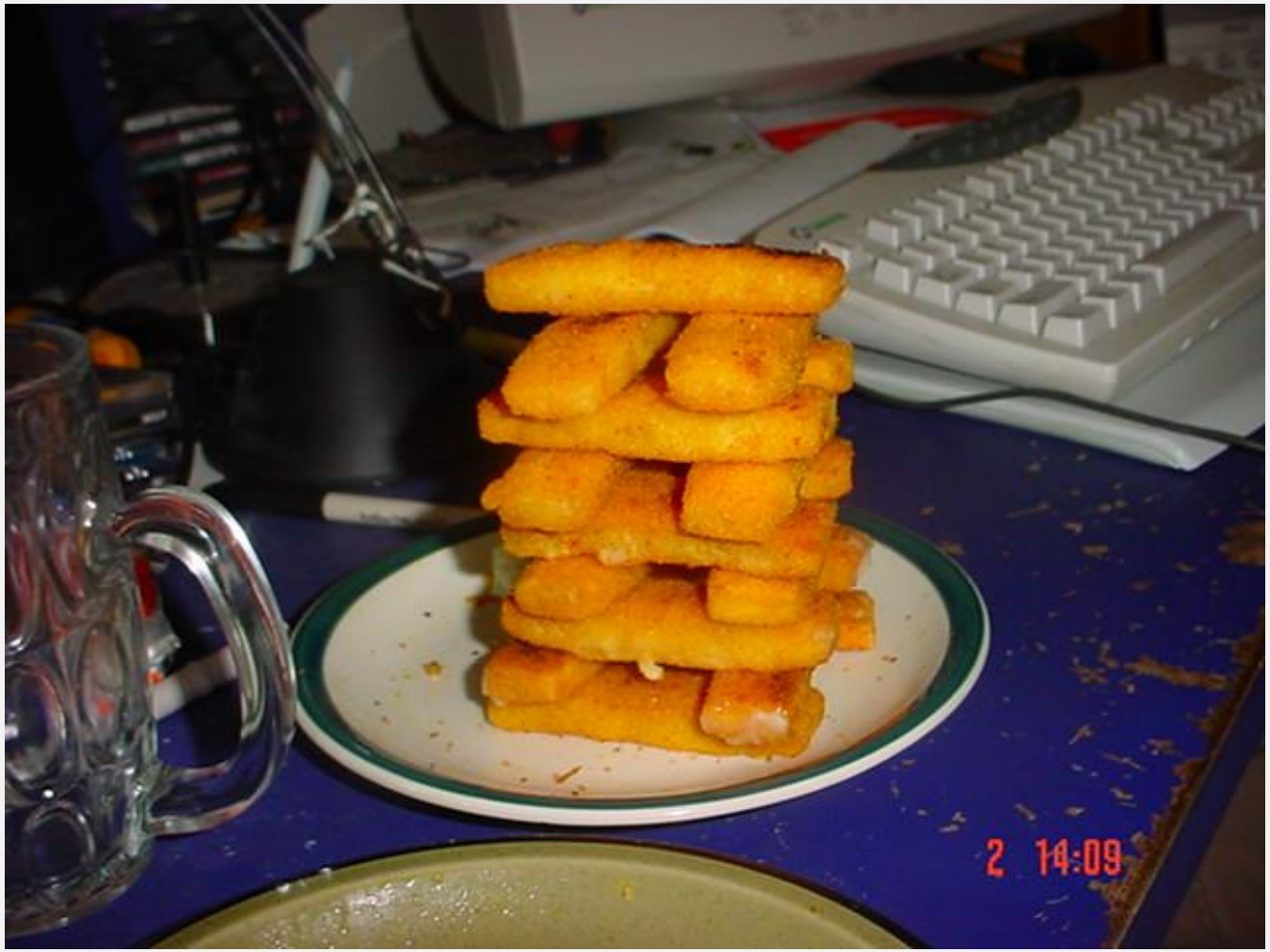
SYNTHEA

Clinical Quality Language

COVID-19 | Healthcare Coalition

Sara Alert™
Secure monitoring and reporting for public health

Let's Build with FSH



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Scenario: Adverse Events resulting from Vaccinations

Steps:

1. Create a FSH project
2. Create a value set for the type of AE
3. Create a value set for the seriousness of the AE
4. Create a value set for the grade of the AE
5. Create an extension representing the grade of the AE
6. Incorporate the above into a profile of AdverseEvent (AE)
7. Create an example of an ImmunizationAdverseEvent
8. Build an IG with all of the above using SUSHI and IG Publisher

What is an Adverse Event?

- World Health Organization (WHO)
  - Medical occurrence temporally associated with the use of a medicinal product, but not necessarily causally related
- FHIR Release 4
  - Actual or potential/avoided event causing unintended physical injury resulting from or contributed to by medical care, a research study or other healthcare setting factors that requires additional monitoring, treatment, or hospitalization, or that results in death.

Terminology

- MedDRA (Medical Dictionary for Regulatory Activities)
  - Developed by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
  - Used worldwide to report clinical trial adverse events
  - Canonical URL: **http://terminology.hl7.org/CodeSystem/MDRAE**

- CTCAE (Common Terminology Criteria for Adverse Events)
  - Defines grades (levels of severity or harm) for each type of event in MedDRA
  - Five levels from mild to fatal, represented by SNOMED-CT codes

Step 0: Install SUSHI

This tutorial assumes you are running **SUSHI 1.0.1**.

To install or update SUSHI:

- Install **Node.js LTS** edition from https://nodejs.org/ *(if applicable)*
- Open a terminal and run: `npm install -g fsh-sushi`

See https://fshschool.org/docs/sushi/installation/ for additional details.

Step 1: Create a FSH Project

- Create a directory for development (e.g., **`devdays`**)
- Open a terminal and:
  - Change to your development directory (e.g., **`cd C:\workspace\devdays`**)
  - Run the command: **`sushi --init`**
- Recommended project properties:
  - Name: **`Covid19Vaccine`**
  - Id: **`devdays.letsbuildafhirspec.fsh`**
  - Canonical: **`https://fhir.devdays.com/R4/devdays-covid19-vaccine`**
  - Status: **`draft`**
  - Version: **`0.1.0`**

Step 2: Create a value set for the type of AE

First, rename **input/fsh/patient.fsh** to **input/fsh/adverse-event.fsh**, then…

Define a new value set called "MedDRA_VS"

- It should contain the set of all codes from the MedDRA code system
  - http://terminology.hl7.org/CodeSystem/MDRAE

Need help?

- See FSH 3.6: Defining Items and FSH 3.6.9: Defining Value Sets
- Consider defining an Alias for the MedDRA code system
  - See FSH 3.6.1: Defining Aliases

Step 3: Create a value set for the seriousness of the AE

Define a new value set called "AdverseEventSeriousness_VS"

- In the MedDRA/CTCAE model of AEs, seriousness only has two values:

Code	Display
non-serious	Non-serious
serious	Serious

The "serious" indication means the event resulted in disability, death, hospitalization or birth defect.

AES Code System URI: http://terminology.hl7.org/CodeSystem/adverse-event-seriousness

Step 4: Create a value set for the grade of the AE

Define a new value set called "AdverseEventGrade_VS"

- It should contain the following five codes from SNOMED-CT

Code	Display
255604002	Mild (qualifier value)
6736007	Moderate (severity modifier) (qualifier value)
24484000	Severe (severity modifier) (qualifier value)
442452003	Life threatening severity (qualifier value)
399166001	Fatal (qualifier value)

SNOMED-CT URI: http://snomed.info/sct

Step 5: Create an extension for the grade of the AE

Define a new extension called "AdverseEventGrade"

- Restrict **value[x]** to only allow **CodeableConcept**
- Bind **value[x]** to the **AdverseEventGrade_VS** value set
  - Use binding strength: **required**

Need help?

- See FSH 3.6: Defining Items and FSH 3.6.3: Defining Extensions
- Also see FSH 3.5.9: Type Rules and FSH 3.5.2: Binding Rules

Step 6: Create a profile of Adverse Event

Define a new profile called "ImmunizationAdverseEvent"

- Based on the **AdverseEvent** resource
- Further constraints to follow on next slides…

Need help?

- See FSH 3.6: Defining Items and FSH 3.6.7: Defining Profiles

Step 6a: Apply Type Constraints to AE Profile

Define the following Type rules to constrain types on AE elements:

Element/Path	Constrain Type to…
subject	Reference(Patient)
suspectEntity.instance	Reference(Immunization)

Need help?

- See FSH 3.5.9: Type Rules

Step 6b: Apply Cardinality Constraints to AE Profile

Define the following Cardinality rules to constrain occurrences of AE elements:

Element/Path	Permitted	Required	Repeating	Notes
category	yes	yes	yes	
event	yes	yes	no	
event.text	yes	yes	no	
severity	no	-	-	• Severity is not a part of the MedDRA+CTCAE model • We'll use the AdverseEventGrade extension instead

Need help?

- See FSH 3.5.3: Cardinality Rules

Step 6c: Apply Binding Constraints to AE Profile

Define the following Binding rules to constrain codes on AE elements:

Element/Path	From	Strength
event	MedDRA_VS	required
seriousness	AdverseEventSeriousness_VS	required

Need help?

- See FSH 3.5.2: Binding Rules
- *NOTE: You can refer to locally defined value sets by their name*

Step 6d: Apply Pattern Constraints to AE Profile

Define the following Assignment rules to constrain values of AE elements:

Element/ Path	Value	Value Type	Exact?
actuality	actual	code	no
category	SNOMED-CT 264519003	CodeableConcept	no

Need help?

- See FSH 3.5.1: Assignment Rules and FSH 3.5.1.1: Assignments with Primitive Data Types and FSH 3.5.1.3: Assignments with the CodeableConcept Data Type
- *NOTE: Technically, we should "slice" category, but that is beyond the scope of this beginner's exercise.*

Step 6e: Add AdverseEventGrade extension to the AE Profile

Add the extension using a Contains rule with a local name

- The local name should be “grade”
- The extension should be optional and non-repeating

Need help?

- See FSH 3.5.4: Contains Rules for Extensions
- *NOTE: You can reference locally defined extensions by their name*

Sanity Check: Try Compiling with SUSHI

1. Open a terminal window
2. Change to your project root directory
3. Run the command: **`sushi`**
4. Do you get error messages? What do they tell you? Try fixing them and then run SUSHI again.
5. Review the generated files in **./fsh-generated/resources**.

See https://fshschool.org/docs/sushi/running/ for additional details.

Step 7: Create an Example of an ImmunizationAdverseEvent

Your example should have the following values:

Element/Path	Value	Value Type
event	MedDRA 10002198 (display: Anaphylatcic reaction)	CodeableConcept
event.text	Anaphylaxis self-reported, self-treated by Epi pen.	string
extension[grade] .valueCodeableConcept	SNOMED-CT #6736007 (display: Moderate (severity modifier) (qualifier value))	CodeableConcept
seriousness	AES non-serious (display: Non-serious)	CodeableConcept
outcome	AEO resolved (display: Resolved)	CodeableConcept
recorder	Mary Roe (id: mary-roe)	Reference
subject	Mary Roe (id: mary-roe)	Reference
suspectEntity.instance	Immunization Profile Example (id: immunizationprofile-example)	Reference
suspectEntity.causality .assessment	AEA probably-likely (display: Probably/Likely)	CodeableConcept
date	2020-10-31	dateTime
recordedDate	2020-11-02	dateTime

Help on next slide...

Step 7 Help

- See FSH 3.6: Defining Items and FSH 3.6.4: Defining Instances
- See FSH 3.4.6: Extension Paths and FSH 3.4.5: Data Type Choice [x] Paths
- Code System URIs:
  - AES = http://terminology.hl7.org/CodeSystem/adverse-event-seriousness
  - AEO = http://terminology.hl7.org/CodeSystem/adverse-event-outcome
  - AEA = http://terminology.hl7.org/CodeSystem/adverse-event-causality-assess
- The following will be inserted automatically based on the profile:
  - actuality = #actual
  - category = SCT#264519003 "Drug reaction (qualifier value)”
- To avoid broken references in the IG Publisher, consider defining simple examples for mary-roe and immunizationprofile-example (but this is optional based on time available)

Step 8: Build an IG using SUSHI and the IG Publisher

1. Open a terminal window
2. Change to your project root directory
3. Run the command: **`sushi`**
4. Debug errors as necessary and run SUSHI again until you have 0 errors
5. Run the command: **./_updatePublisher** *(mac: **.sh**, win: **.bat**)*
6. Run the command: **./_genonce** *(mac: **.sh**, win: **.bat**)*
7. Open the generated **./output/index.html** in your browser

See https://fshschool.org/docs/sushi/running/ for additional details.

Rendered ImmunizationAdverseEvent Profile

Text Summary | Differential Table | Snapshot Table | Snapshot Table (Must Support) | All

This structure is derived from AdverseEvent

Name	Flags	Card.	Type	Description & Constraints
AdverseEvent		0..*	AdverseEvent	Medical care, research study or other healthcare event causing physical injury
extension		0..*	Extension	Extension **Slice:** Unordered, Open by value:url
adverse-event-grade		0..1	CodeableConcept	Extension **URL:** https://fhir.devdays.com/R4/devdays-covid19-vaccine/StructureDefinition/adverse-event-grade **Binding:** Adverse Event Grade Value Set (required)
actuality		1..1	code	actual | potential **Required Pattern:** actual
category		1..*	CodeableConcept	product-problem | product-quality | product-use-error | wrong-dose | incorrect-prescribing-information | wrong-technique | wrong-route-of-administration | wrong-rate | wrong-duration | wrong-time | expired-drug | medical-device-use-error | problem-different-manufacturer | unsafe-physical-environment **Required Pattern:** At least the following
coding		1..*	Coding	Code defined by a terminology system **Fixed Value:** (complex)
system		1..1	uri	Identity of the terminology system **Fixed Value:** http://snomed.info/sct
code		1..1	code	Symbol in syntax defined by the system **Fixed Value:** 264519003
event		1..1	CodeableConcept	Type of the event itself in relation to the subject **Binding:** MedDRA Value Set (required)
text		1..1	string	Plain text representation of the concept
subject		1..1	Reference(Patient)	Subject impacted by event
seriousness		0..1	CodeableConcept	Seriousness of the event **Binding:** Adverse Event Seriousness Value Set (required)
~~severity~~		~~0..0~~		
suspectEntity				
instance		1..1	Reference(Immunization)	Refers to the specific entity that caused the adverse event

Documentation for this format

Contact

- During DevDays, you can find / reach us here:
  - Via Whova App – Speaker's Gallery
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