



# Monthly Summary Briefing HL7 EHR Work Group (EHR-WG)

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### EHR-S FM Executive Summary

INTERNATIONAL

This executive-summary specifically address potential mHealth impacts and/or mHealth trends, which are important for VA, IPO and DOD awareness.

- The goal of the Electronic Health Record (EHR) Work Group is to support the HL7 mission of developing standards for EHR data, information, functionality, and interoperability.
  - Functional and Information Requirements for Electronic Health Records (EHR) and systems (EHRS),
  - Functional and Information Requirements for Personal Health Records (PHR) and systems (PHRS),
- An objective of the EHR Interoperability WG team is to create a clear, complete, concise, correct and consistent EHR-S FIM r3.0 in Sparx Systems Enterprise Architect tool; where, it addresses the structural issues identified by the VA negative r2.0 ballot.
- A second objective of the EHR Interoperability WG is producing a Meaningful Use profile for r2.0.
- The objective of the Resource Management Evidentiary Support (RM-ES) project team is to provide expertise on records management, compliance, and data/record integrity and related to governance to support the use of medical records for clinical care and decision-making, business, legal and disclosure purposes.



## EHR WG Meeting Participation

Meeting	Time (ET)	Relevance				
EHR-S FM Plenary	Every Tuesday 3:00 PM Eastern Phone: 770-657-9270, PC 510269# <u>LiveMeeting</u>	All things EHR, liaison with other WGs, ballot reconciliation, and development of WG documentation				
EHR Interoperability EHR-S FIM r3.0 Meaningful Use	Every Tuesday 2:00 PM Eastern Phone: 770-657-9270, PC 510269# GoTo Meeting	Directly addressing EHR-S r2.0 Interoperability concern- and-needs				
Resource Management and Evidentiary Support Standards Gap Analysis	Every Monday 12:00 Noon Eastern Phone: 650-479-3208 WebEx Code: 923-467-215, PC1519	Directly addressing EHR-S r2.0 RMES concerns and needs				

#### **Care Provision**

- 1. CP.1 Manage Clinical History
- 2. CP.2 Render Externally Sourced Information
- 3. CP.3 Manage Clinical Documentation
- 4. CP.4 Manage Orders
- 5. CP.5 Manage Results
- 6. CP.6 Manage Treatment Administration
- 7. CP.7 Manage Future Care
- 8. CP.8 Manage Patient Education & Communication
- 9. CP.9 Manage Care Coordination & Reporting

#### **Care Provision Support**

- 1. CPS.1 Record Management
- 2. CPS.2 Support Externally Sourced Information
- 3. CPS.3 Support Clinical Documentation
- 4. CPS.4 Support Orders
- 5. CPS.5 Support for Results
- 6. CPS.6 Support Treatment Administration
- 7. CPS.7 Support Future Care
- 8. CPS.8 Support Patient Education & Communication
- 9. CPS.9 Support Care Coordination & Reporting

#### **Trust Infrastructure**

- 1. TI.1 Security
- 2. TI.2 Audit
- 3. TI.3 Registry and Directory Services
- 4. TI.4 Standard Terminology and Terminology Services
- 5. TI.5 Standards-Based Interoperability
- 6. TI.6 Business Rules Management
- 7. TI.7 Workflow Management
- 8. TI.8 Database Backup and Recovery
- 9. TI.9 System Management Operations and Performance

## EHR-S FM r2.0 Dimensions and Stakeholders

#### **Population Health Support**

- 1. POP.1 Support for Health Maintenance, Preventive Care and Wellness
- 2. POP.2 Support for Epidemiological Investigations of Clinical Health Within a Population
- 3. POP.3 Support for Notification and Response
- 4. POP.4 Support for Monitoring Response Notifications Regarding a Specific Patient's Health
- 5. POP.5 Donor Management Support
- 6. POP.6 Measurement, Analysis, Research and Reports
- 7. POP.7 Public Health Related Updates
- 8. POP.8 De-Identified Data Request Management
- 9. POP.9 Support Consistent Healthcare Management of Patient Groups or Populations
- 10.POP.10 Manage Population Health Study-Related Identifiers

### **Administration Support**

- 1. AS.1 Manage Provider Information
- 2. AS.2 Manage Patient Demographics, Location and Synchronization
- 3. AS.3 Manage Personal Health Record Interaction
- 4. AS.4 Manage Communication
- 5. AS.5 Manage Clinical Workflow Tasking
- 6. AS.6 Manage Resource Availability
- 7. AS.7 Support Encounter/Episode of Care Management
- 8. AS.8 Manage Information Access for Supplemental Use
- 9. AS.9 Manage Administrative Transaction Processing

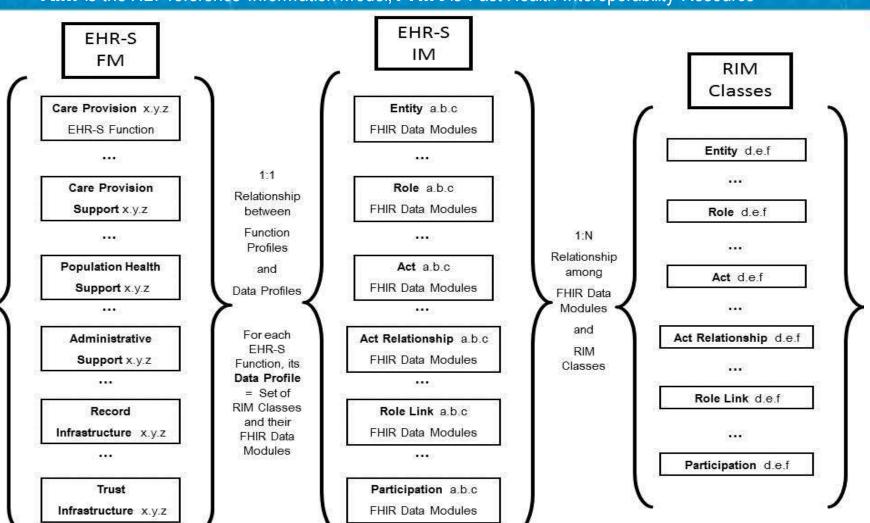
#### **Record Infrastructure**

- 1. RI.1 Record Lifecycle and Lifespan
- 2. RI.2 Record Synchronization
- 3. RI.3 Record Archive and Restore





by Stephen Hufnagel PhD; where, **RIM** is the HL7 reference Information Model, **FHIR** is Fast Health Interoperability Resource



## EHR-S FIM Anatomy Conceptual Model (Level 1)



**ISSUE**: Currently, *Managers* do not consistently correspond to <u>Data Entities</u>

other EHR or related systems **EHR-S** link External Document Care Plan **EMR Encounter Provider Patient Record Entry Partner** or Note 0..\* **EHR-S Manager Event Manager Record Manager Business Rule Trust Manager** Schedule Workflow Manager Manager Manager

### ■ EHR-S FIM Anatomy Conceptual Information Model (Level 4)



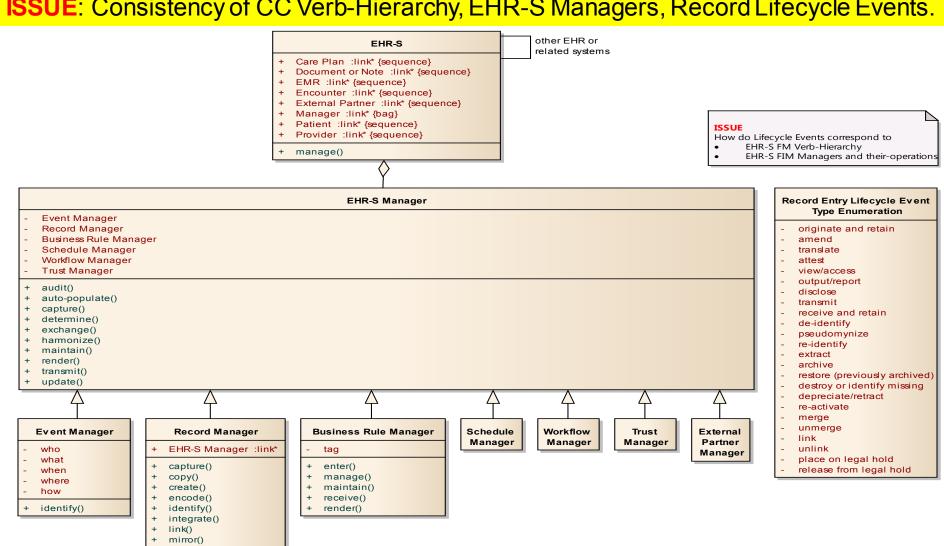
class EHR-S FIM Conceptual Information Model (4 Levels)

other EHR or related systems EHR-S **Document or Note** Care Plan **EMR** Patient Encounter **Provider** Record Entry **EHR-S** Manager link link link link link link link 0..\* Reminder or Alert Signature Event has-a List is-a is-a **Order Set** Registry Allergy, Intolerance Treatment Observation **Problem List** and Adverse History History Reaction History is-a Report Result **Immunization** Registry (Public Problem Schedule link Health Immunization) has-a Order **Observation** has-a Immunization History Treatment Order for Order for Order for **Diagnostic Test** Medication Referral Immunization Administration **Medication Administration** Order for Order for Non-medication **Immunization** Allergy, Intolerance and Adverse Reaction

### **EHR-S FIM Anatomy** Logical Manager Model (Level-2)



ISSUE: Consistency of CC Verb-Hierarchy, EHR-S Managers, Record Lifecycle Events.



record() tag() transcribe()





ISSUE: Consistency of CC Verb-Hierarchy, EHR-S Managers, Record Lifecycle Events.

Manage (Data)

Capture	Maintain		Render		Exchange	Determine		Manage- Data- Visibility	
Auto- Populate Enter Import Archive Backup Decrypt Encrypt Recover Restore Save	Annotate Attest Edit Harmonize Integrate Link Tag	Delete Purge	Typ - origin - amen - transla - attest - view/s - outpu - disclo - transn - receiv - de-ide - pseud - re-ide - extrac - archiv - restor - de stro - de pre - re-acti - merge - unme - link - unlink - place	access t/report se nit e and retain entify omynize ntify t e e (previously ar y or identify m ciate/retract ivate	chive d)	t Export Import Receive Transmit	Analyze	Decide	De-Identify Hide Mask Re-Identify Unhide Unmask



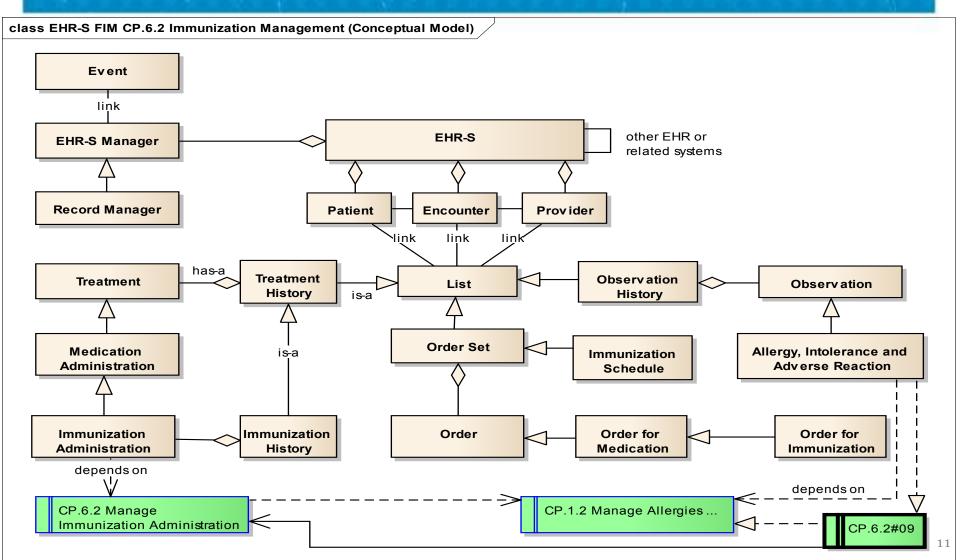
## EHR-S FIM Anatomy "Structure"

### INTERIM CONCLUSION

- We have looked at medication management, orders management and Immunization management.
- The EHR-S Conceptual Information Model (CIM) for CP.6.2 Immunization Management is generally applicable for all of the Care Provisioning (CP) section of the EHR-S FM; where,
  - minor CIM additions and modifications will likely occur as we analyze the rest of the CP section; but,
  - The Conceptual Manager Model remain to be substantially developed

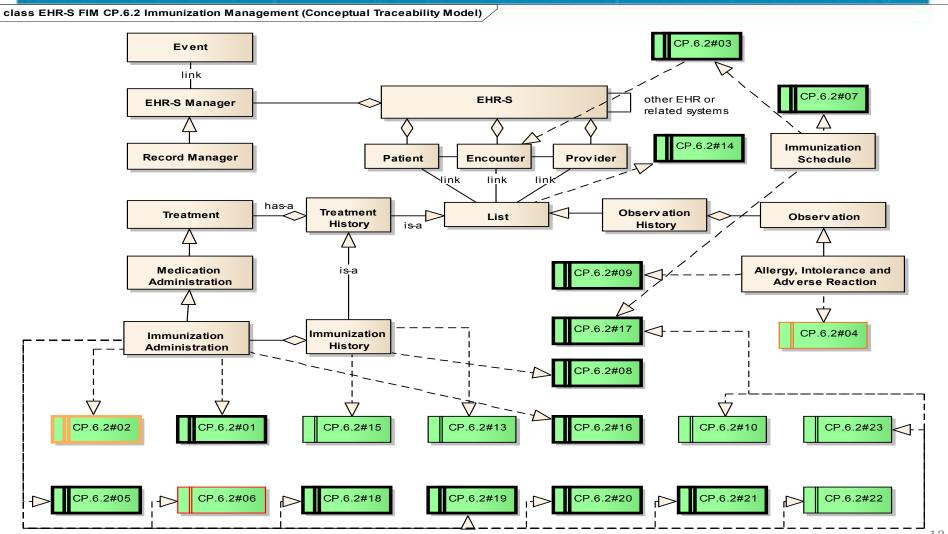
# EHR-S-FIM Physiology "Function" (Conceptual Model) CP.6.2 Immunization Management





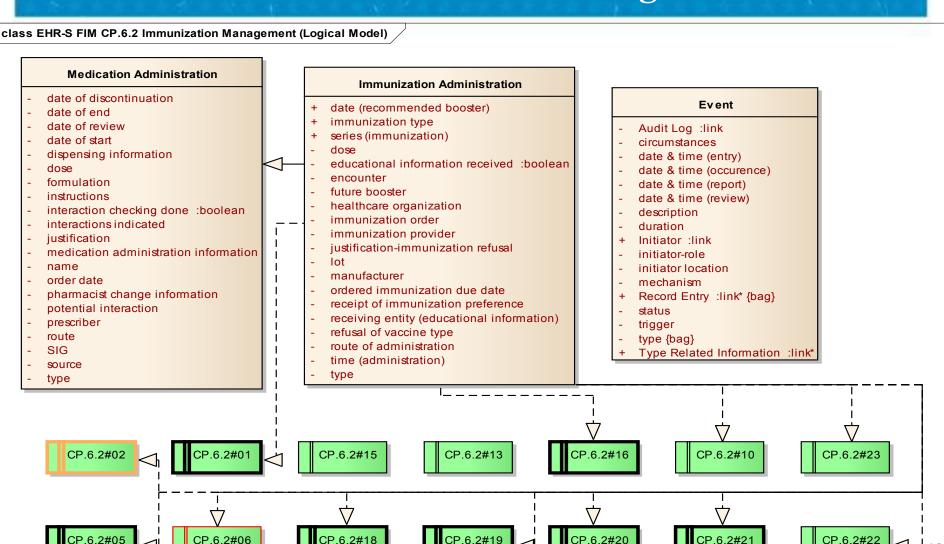
# EHR-S-FIM Physiology "Function" (Traceability Model) CP.6.2 Immunization Management





# EHR-S FIM Physiology "Function" (Logical Model) CP.6.2 Immunization Management

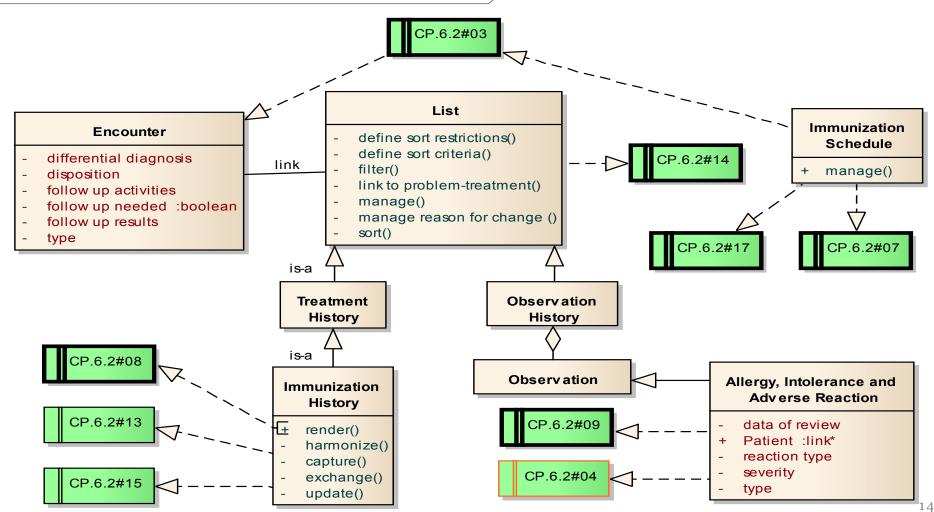




# EHR-S FIM Physiology "Function" (Logical Model) CP.6.2 Immunization Management



class EHR-S FIM CP.6.2 Immunization Management (Logical Model-2)



### **EHR-S-FIM Physiology** "Function" (Traceability Model) CP.6.2 Immunization Management Conformance Criteria

- The system **SHALL** provide the ability to capture, maintain and render immunization administration details as discrete data, including:(1) the immunization name/type, strength and dose;(2) date and time of administration;(3) manufacturer, lot number, expiration date, (4) route and site of administration; (5) administering provider; (6) observations, reactions and complications; (7) reason immunization not given and/or immunization related activity not performed; according to scope of practice, organizational policy and/or jurisdictional law."
- The system MAY auto-populate the immunization administration record as a by-product of verification of administering provider, 2. patient, medication, dose, route and time according to scope of practice, organizational policy and/or jurisdictional law.
- The system **SHALL** provide the ability to determine and render required immunizations, and when they are due, based on widely accepted immunization schedules, when rendering encounter information.
- The system SHOULD provide the ability to capture, in a discrete field, an allergy/adverse reaction to a specific immunization.
- The system **SHALL** conform to function CP.3.2 (Manage Patient Clinical Measurements) to capture other clinical data pertinent to 5. the immunization administration (e.g., vital signs).
- The system SHOULD provide the ability to link standard codes (e.g. NDC, LOINC, SNOMED or CPT) with discrete data elements 6. associated with an immunization.
- The system **SHALL** provide the ability to maintain the immunization schedule. 7.
- 8. The system **SHALL** provide the ability to render a patient's immunization history upon request for appropriate authorities such as schools or day-care centers.
- 9. The system **SHALL** conform to function CP.1.2 (Manage Allergy, Intolerance and Adverse Reaction List).
- 10. The system SHOULD transmit required immunization administration information to a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
- The system SHOULD exchange immunization histories with public health immunization registries according to scope of practice, 15 organizational policy and/or jurisdictional law.

## EHR-S-FIM Physiology "Function" (Traceability Model)



### CP.6.2 Immunization Management Conformance Criteria

**ISSUE**: Consistency of Conformance Criteria (CC) across related functions, such as Medication-and-Immunization and Orders-and-Results Management.

- 12. The system SHOULD harmonize Immunization histories with a public health immunization registry according to scope of practice, organizational policy and/or jurisdictional law.
- 13. The system SHOULD capture and render immunization histories from a public health immunization registry.
- 14. The system SHALL conform to function CP.1.6 (Manage Immunization List).
- 15. The system SHOULD provide the ability to update immunization histories at the time of capturing an immunization administration.
- 16. The system **SHALL** provide the ability to render the immunization order as written (i.e., exact clinician order language) when rendering administration information.
- 17. "The system SHALL provide the ability to determine due and overdue ordered immunizations and render a notification."
- 18. The system **SHALL** provide the ability to render a patient educational information regarding the administration (e.g., Vaccine Information Statement (**VIS**)).
- 19. The system **SHALL** provide the ability to capture that patient educational information (e.g., VIS) was provided at the time of immunization administration.
- 20. The system **SHALL** provide the ability to capture documentation that patient educational information (e.g., VIS) was provided at the time of immunization administration.
- 21. The system **SHALL** provide the ability to capture the receiving entity (e.g., patient, representative, organization) when patient education information is provided at the time of immunization administration.
- 22. The system SHOULD provide the ability to capture and maintain immunization refusal reasons as discrete data.
  - 23. The system SHOULD provide the ability to capture patient preferences regarding receipt of immunization (e.g. refusal of certain vaccine types) at time of immunization administration.

# EHR-S FIM Physiology "Function" CP.6.2 Immunization Management



## Resultant Description (Scenario):

- The <u>System Manager</u> can
  - Capture, Auto-populate,
  - Maintain, Render,
  - Transmit, Exchange,
  - Harmonize, Update,
  - Determine
- The applicable data modules are
  - Immunization Administrations
  - Events, Schedules, Plans and Educational Materials

# EHR-S FIM Physiology "Function" CP.6.2 Immunization Management



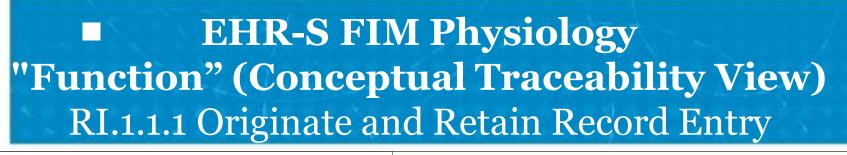
### INTERIM CONCLUSION

- Based on medication management, orders management and Immunization management functions we see a consistency-advantage in immunization-applicable data-elements
- A high level EHR-S Information Model is emerging as a set of
  - Patients, Providers, External Partners, Encounters, EMRs, Care Plans, Lists, Managers, Docs and Notes;
- A high level EHR-S Manager Model is emerging to
  - Capture, Auto-populate, Maintain, Render, Transmit, Exchange, Harmonize, Update, Determine

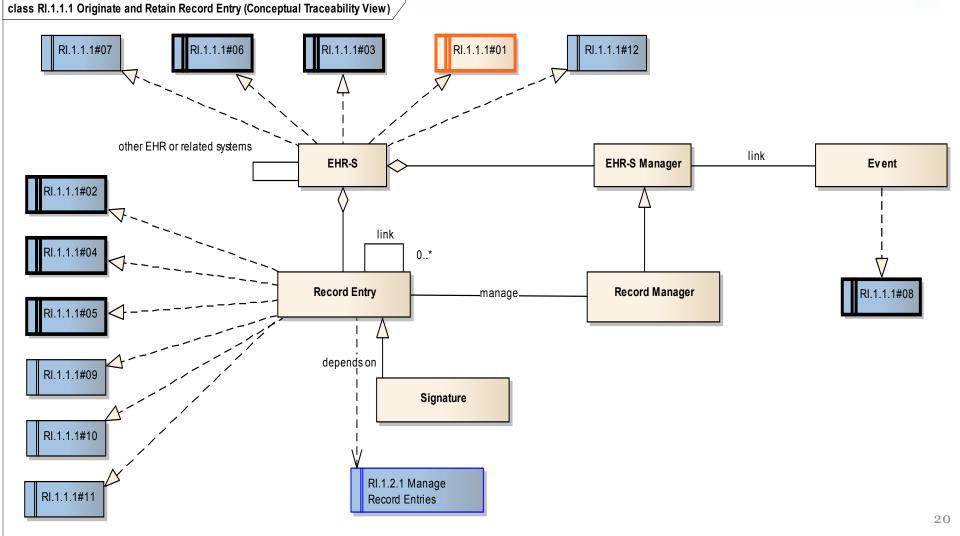




class RI.1.1.1 Originate and Retain Record Entry (Conceptual View) **EHR-S Manager** + audit() auto-populate() other EHR or related systems + capture() **EHR-S** link determine() Event exchange() + manage() harmonize() maintain() render() transmit() update() **Record Manager** link capture() copy() 0..\* depends on create() encode() RI.1.2.1 Manage **Record Entry** manage. identify() Record Entries integrate() link() mirror() record() tag() Signature transcribe()



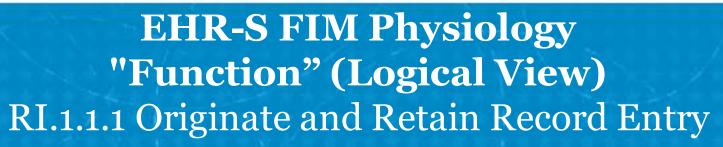






# Conformance Criteria (CC) **RI.1.1.1 Originate and Retain Record Entry**

- 1. RI.1.1.#01 The system **SHALL** provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.
- 2. RI.1.1.1#02 The system **SHALL** capture a unique instance identifier for each Record Entry.
- 3. RI.1.1.1#03 The system **SHALL** conform to <u>function TI.2.1.1.1</u> (Originate/Retain Record Entry Audit Trigger), including specified metadata.
- RI.1.1.1#04 The system SHALL capture the signature event (e.g., digital signature) of the origination entry Author, binding signature to Record Entry content.
- 5. RI.1.1.1#05 The system **SHALL** provide the ability to capture both structured and unstructured content in Record Entries.
- 6. RI.1.1.1#06 The system **SHALL** provide the ability to capture Record Entries from information recorded during system downtime.
- 7. RI.1.1.1#07 The system SHOULD provide the ability to integrate Record Entries from Information recorded during system downtime.
- 8. RI.1.1.1#08 The system **SHALL** provide the ability to capture date/time an Action was taken or data was collected if different than date/time of the Record Entry.
- 9. RI.1.1.1#09 The system SHOULD capture metadata that identifies the source of non-originated Record Entry (e.g., templated, copied, duplicated, or boilerplate information).
- 10. RI.1.1.1#10 The system MAY provide the ability to tag unstructured Record Entry content to organize it according to need, for example, in a time-related fashion or by application-specific groups (such as photographs, handwritten notes, or auditory sounds)
- 11. RI.1.1.#11 The system MAY capture and maintain a Record Entry encoded as a standards-based data object (e.g., HL7 Continuity of Care or other HL7 CDA R2 Document).
- 12. RI.1.1.1#12 The system MAY capture and maintain a standards-based data object to mirror (be duplicate and synchronous with) internal Record Entry representation.





class RI.1.1.1 Originate and Retain Record Entry (Logical View) Record Entry Lifecycle Event **Event-Status Enumeration Event Type Enumeration** Event Type Enumeration Audit Log: link active advanced directive completed circumstances adverse reaction amend archive deactive date & time (entry) allergy date & time (occurence) CDS Alerts attest erroneously captured CDS reminders de-identify pending date & time (report) date & time (review) depreciate/retract CDS update destroy or identify missing description clinical document or note disclose duration discharge extract Initiator :link encounter link initiator-role intolerance initiator location medication (pharmacist change) Record Entry Manager merge Record Entry originate and retain mechanism medication (prescription dispensing) System Manager :link\* Alert-Notification Record Entry :link\* {bag} medication (prescription filling) output/report link Content place on legal hold medication history (external source) status capture() content type pseudomynize trigger order copy() destroved :boolean re-activate type {bag} other create() Event :link (sequence) re-identify Type Related Information: link\* procedure encode() format receive and retain record-entry identify() + manage() instance identifier release from legal hold registry integrate() language/ code restore (previously archived) reminders & alerts link() link lifecycle event type translate report mirror() Record Entry: link\* {bag} transmit signature record() Signature :link unlink surgical tag() source transfer unmerge 0..\* transcribe() state view/access tag {bag}

translated :boolean

version

+ manage()

type-of

Signature

+ Record Entry :link\* {bag}

manage

depends on

RI.1.2.1 Manage Record

Entries

# EHR-S FIM Physiology "Function" RI.1.1.1 Originate and Retain Record Entry



### **Resultant Description (Scenario):**

- The EHR-S <u>System Manager</u> can
  - Capture, Create, Copy,
  - Record, Transcribe, Identify,
  - Link, Tag, Encode, Mirror, Integrate
- The applicable data modules are
  - Record-Entry
    - structured or unstructured-data link-to associated
      - Event-Metadata and Signature

# EHR-S FIM Physiology "Function" RI.1.1.1 Originate and Retain Record Entry



### INTERIM CONCLUSION

we have only looked at the RI.1.1.1 function; yet,

- we see that the emergence of common <u>Record-Entries</u>,
   <u>Events</u>, <u>Record Entries</u> and a <u>Record Entry Manager</u>
- which can Capture, Create, Copy, Record, Transcribe, Identify, Link, Tag, Encode, Mirror, Integrate
  - structured-data or unstructured-data and link-to
  - associated <u>Event-Metadata</u> and <u>Signature</u>.



## EHR-S FIM NEXT-STEP Traceability

**ISSUE**: EHR-S FM r2.0 traceability to UML Model Elements, FHIR & FHIM Is essential to guarantee a clear, complete, concise, correct and consistent EHR-S FIM r3.0

- Workbook 1: Class attributes & operations mapped-to EHR-S FM r2.0 Functions and LOCAL CCs
- Workbook 2 Class attributes & operations mapped to EHR-S FIM r3.0 Functions and GLOBAL CCs
- Workbook 3 EHR-S FM r2.0 Functions and CCs mapped-to EHR-S FIM r3.0 Functions and CCs
- Workbook 4 EHR-S FM r2.0 Functions and LOCAL Conformance Criteria (CC)
- Workbook 5 EHR-S FIM R3.0 Functions and UNIVERSALConformance Criteria (CC)
- Workbook 6 EHR-S FIM UML-Model mapped-to FHIR (optional)
- Workbook 7 EHR-S FIM UML-Model mapped-to FHIM (Federal Health Information Model) (optional)
- Workbook 8 FHIR mapped-to FHIM (Federal Health Information Model) (optional)
- Workbook 9 Master Data Dictionary (DD) (If we use FHIR or FHIM, they already have an DD)
- ISSUE: Can the Traceability-Matrices and DD be efficiently done directly in Sparx EA?

# EHR-S FIM NEXT-STEP FHIR (Fast Healthcare Interoperability Resources)

**ISSUE**: EHR-S FM r2.0 Implied Information Model is Ad-Hoc; where, FHIR & FIM Information Model & Data Dictionary are Configuration Managed.

### FHIR Administrative

- Attribution: Patient, RelatedPerson, Practitioner, Organization
- Resources: Device, Location, Substance, Group
- Workflow Management: Encounter, Alert, Supply, Order, OrderResponse
- Financial: Coverage

#### FHIR Clinical

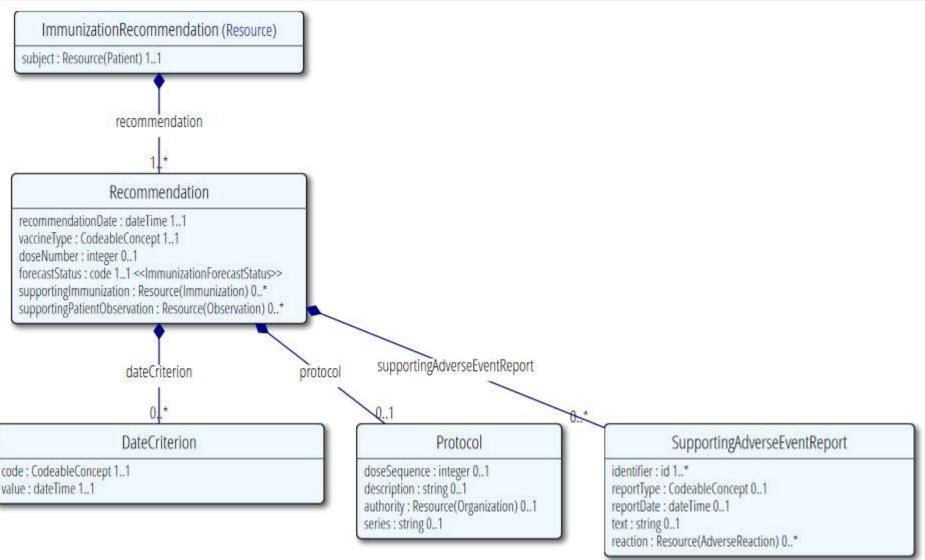
- General: AdverseReaction, AllergyIntolerance, CarePlan, FamilyHistory, Condition, Procedure, Questionnaire
- Medications: Medication, MedicationPrescription, MedicationAdministration, MedicationDispense,
- MedicationStatement, Immunization, ImmunizationProfile
- Diagnostic: Observation, DiagnosticReport, DiagnosticOrder, ImagingStudy, Specimen
- Device Interaction: DeviceCapabilities, DeviceLog, DeviceObservation

### FHIR Infrastructure

- Support: List, Media, Other, DocumentReference, (Binary)
- Audit: Provenance, SecurityEvent
- Exchange: Document, Message, OperationOutcome, Query
- Conformance: Conformance, ValueSet, Profile

### FHIR

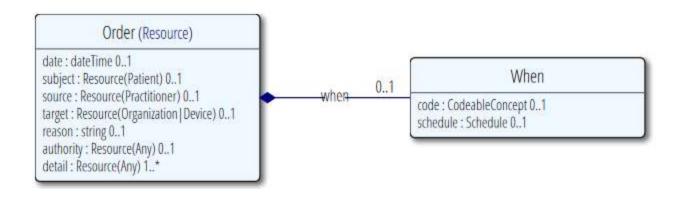
Immunization Recommendation http://www.hl7.org/implement/standards/fhir/





### Order Resource http://www.hl7.org/implement/standards/fhir/

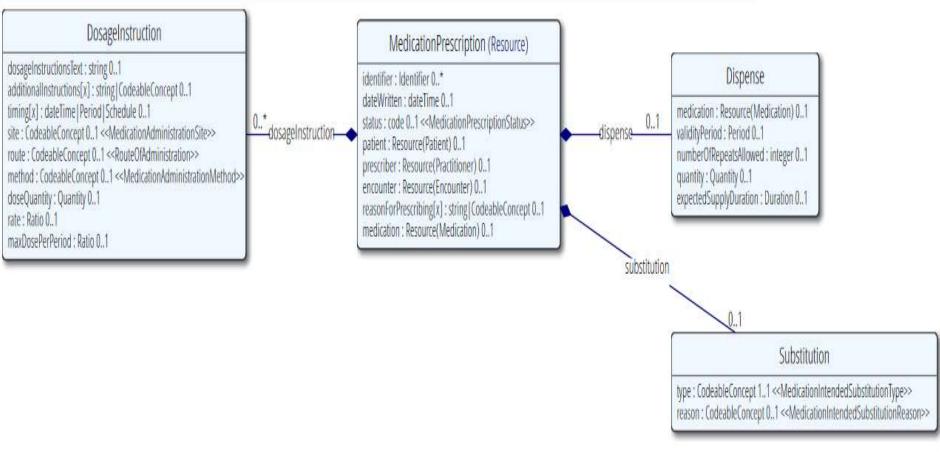
FHIR



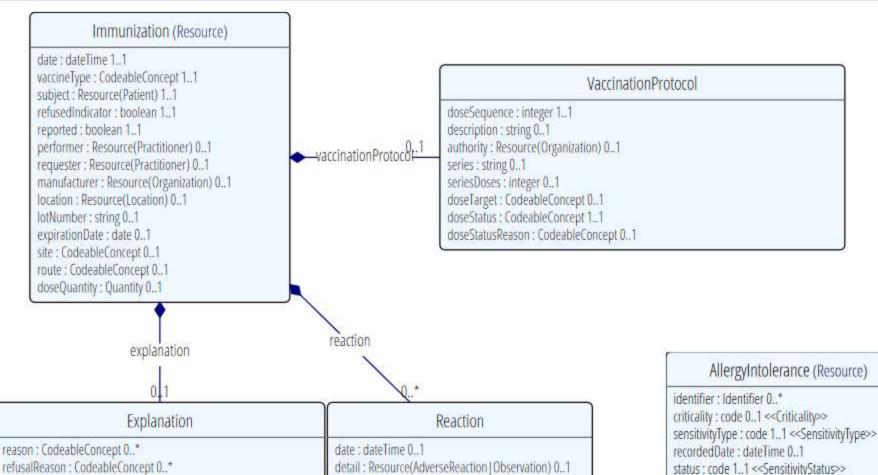


## Medication Prescription http://www.hl7.org/implement/standards/fhir/

FHIR



### FHIR **Immunization Resource** http://www.hl7.org/implement/standards/fhir/



refusalReason: CodeableConcept 0..\*

detail: Resource(AdverseReaction | Observation) 0..1

reported: boolean 0..1

subject: Resource(Patient) 1..1

recorder: Resource(Practitioner | Patient) 0..1 substance: Resource(Substance) 1..1 reaction: Resource(AdverseReaction) 0..\*

sensitivityTest: Resource(Observation) 0..\*

# FHIR Medication Administration http://www.hl7.org/implement/standards/fhir/

#### MedicationAdministration (Resource)

identifier: Identifier 0..\*

status: code 1..1 << MedicationAdministrationStatus>>

patient: Resource(Patient) 1..1

practitioner: Resource(Practitioner) 1..1 encounter: Resource(Encounter) 0..1

prescription: Resource(MedicationPrescription) 1..1

wasNotGiven: boolean 0..1

reasonNotGiven: CodeableConcept 0..\* << MedicationAdministrationNegationReason>>

when Given: Period 1..1

medication: Resource(Medication) 0..1 administrationDevice: Resource(Device) 0..\* dosage 0..\*

#### Dosage

timing: Schedule 0..1

site : CodeableConcept 0..1 << MedicationAdministrationSite>> route : CodeableConcept 0..1 << RouteOfAdministration>>

method: CodeableConcept 0..1 << MedicationAdministrationMethod>>

quantity: Quantity 0..1 rate: Ratio 0..1

maxDosePerPeriod: Ratio 0..1

### Federal Health Information Model (FHIM) http://www.fhims.org/content/420A62FD03B6\_root.html



BehavioralHealth AdverseEventRepo... Allergies AudiologyAndSpee... Assessment CarePlan ClinicalDecisionSup... ClinicalDocument Consultation Dental

BloodBank **Dietetics EnrollEligCOB** Encounter HealthConcern HomeBasedPrimar... Imaging **Immunization** Lab OncologyRegistry Orders PatientEducation Person Pharmacy Provider Radiology **Prosthetics PublicHealthReporting** SecurityAndPrivacy SocialWork SpinalCord Surgery VitalSigns WomensHealth

Common **Datatypes** 

FHA Federal Health Information Model (FHIM)

FHIM modeling complete FHIM modeling in progress Color Key Unchanged from the VHIM