

EHR-S-FM R2 – Record Infrastructure  
Record Entry Lifecycle Event  
Metadata on FHIR

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<http://www.hl7.org/fhir>

# FHIR Resource Index

As of 22 September 2014

## Clinical

### General:

- AdverseReaction
- AllergyIntolerance
- Condition (aka Problem)
- CarePlan
- ReferralRequest
- Procedure
- Contraindication
- RiskAssessment

## Administrative

### Attribution:

- Patient
- RelatedPerson
- Practitioner
- Organization

## Infrastructure

### Support:

- List
- Media
- Other
- Provenance
- SecurityEvent
- (Binary)

### Medications:

- Medication
- MedicationPrescription
- MedicationAdministration
- MedicationDispense
- MedicationStatement
- NutritionOrder
- Immunization
- ImmunizationRecommendation

### Entities:

- Device
- Location
- Substance
- Group

### Documents:

- Composition
- DocumentReference
- DocumentManifest

### Diagnostics:

- Observation
- DiagnosticReport
- DiagnosticOrder
- ImagingStudy
- Specimen
- DeviceObservationReport

### Workflow Management:

- Encounter
- Alert
- Supply
- Order
- OrderResponse

### Exchange:

- MessageHeader
- OperationOutcome
- Query
- Subscription

### Data Collection:

- Questionnaire
- QuestionnaireAnswers
- FamilyHistory

### Scheduling:

- Appointment
- Appointment Response
- Availability
- Slot

### Conformance:

- Conformance
- Profile
- DataElement
- OperationDefinition
- ValueSet
- Namespace
- ConceptMap

# Targets

- 30 September 2014
  - RecordLifecycleEvent FHIR Profile Proposal
  - <http://wiki.hl7.org/index.php?title=RecordLifecycleEvent> FHIR Profile Proposal
- Early December
  - Submit DRAFT Proposal

Now Underway


# Mapping to FHIR

| Requirements  | Are Fulfilled by...  |
|---|--|
| ISO/HL7 10781 EHR-S FM R2<br>Record Infrastructure (RI)<br>→ 24(+3) Record Lifecycle Events | Implementable<br>FHIR Resources  |
| <u>Basic Lifecycle Event</u>  | <ul style="list-style-type: none"><li>• SecurityEvent</li></ul>  |
| <u>Provenance Lifecycle Event</u><br>when Record Entry content is<br>originated or updated  | <ul style="list-style-type: none"><li>• SecurityEvent</li><li>• Provenance</li><li>• [other new/updated resource(s)]<br/>→ corresponding to Action Taken</li></ul> |

↑ Resources may also be indivisibly and immutably bound by one or more digital signatures in a Record Entry.

# EHR-S FM Record Lifecycle


## Pre/Post Events 1-9



| Pre Event State   | Resource @ Event              | Post Event State           |                                      |                         |                     |                     |
|---|-------------------------------|----------------------------|--------------------------------------|-------------------------|---------------------|---------------------|
|   | SecurityEvent<br>+ Provenance | Added<br>Event<br>Evidence | Retained<br>Pre Edition<br>Unaltered | Added<br>New<br>Edition | Signed as<br>Author | Signed as<br>System |
| [none]  | 1 Originate/Retain            | X                          |                                      | X                       | Opt                 | X                   |
| [Record Entry as persisted, indivisible and immutable since previous Lifecycle Event] | 2 Amend                       | X                          | X                                    | X                       | Opt                 | X                   |
|   | 3 Translate                   | X                          | X                                    | X                       |                     | X                   |
|   | 4 Attest                      | X                          | X                                    |                         | X                   | X                   |
|   | 5 Access/View                 | X                          |                                      |                         |                     |                     |
|   | 6 Output/Report               | X                          |                                      |                         |                     | X                   |
|   | 7 Disclose                    | X                          |                                      |                         |                     | X                   |
|   | 8 Transmit                    | X                          |                                      |                         |                     | X                   |
|   | 9 Receive/Retain              | X                          | X                                    |                         |                     |                     |

# EHR-S FM Record Lifecycle


## Pre/Post Events 10-18



| Pre Event State  | Resource @ Event              | Post Event State           |                                      |                         |                     |                     |
|--|-------------------------------|----------------------------|--------------------------------------|-------------------------|---------------------|---------------------|
|  | SecurityEvent<br>+ Provenance | Added<br>Event<br>Evidence | Retained<br>Pre Edition<br>Unaltered | Added<br>New<br>Edition | Signed as<br>Author | Signed as<br>System |
| [Record Entry as<br>persisted,<br>indivisible and<br>immutable since<br>previous Lifecycle<br>Event] | 10 De-Identify                | X                          | X                                    | X                       |                     | X                   |
|  | 11 Pseudonymize               | X                          |                                      |                         |                     |                     |
|  | 12 Re-Identify                | X                          |                                      |                         |                     |                     |
|  | 13 Extract                    | X                          | X                                    | X                       |                     | X                   |
|  | 14 Archive                    | X                          |                                      |                         |                     |                     |
|  | 15 Restore                    | X                          |                                      |                         |                     |                     |
|  | 16 Destroy/Delete             | X                          | [none]                               |                         |                     |                     |
|  | 17 Deprecate                  | X                          |                                      |                         |                     |                     |
|  | 18 Re-Activate                | X                          |                                      |                         |                     |                     |

# EHR-S FM Record Lifecycle

## Pre/Post Events 19-27

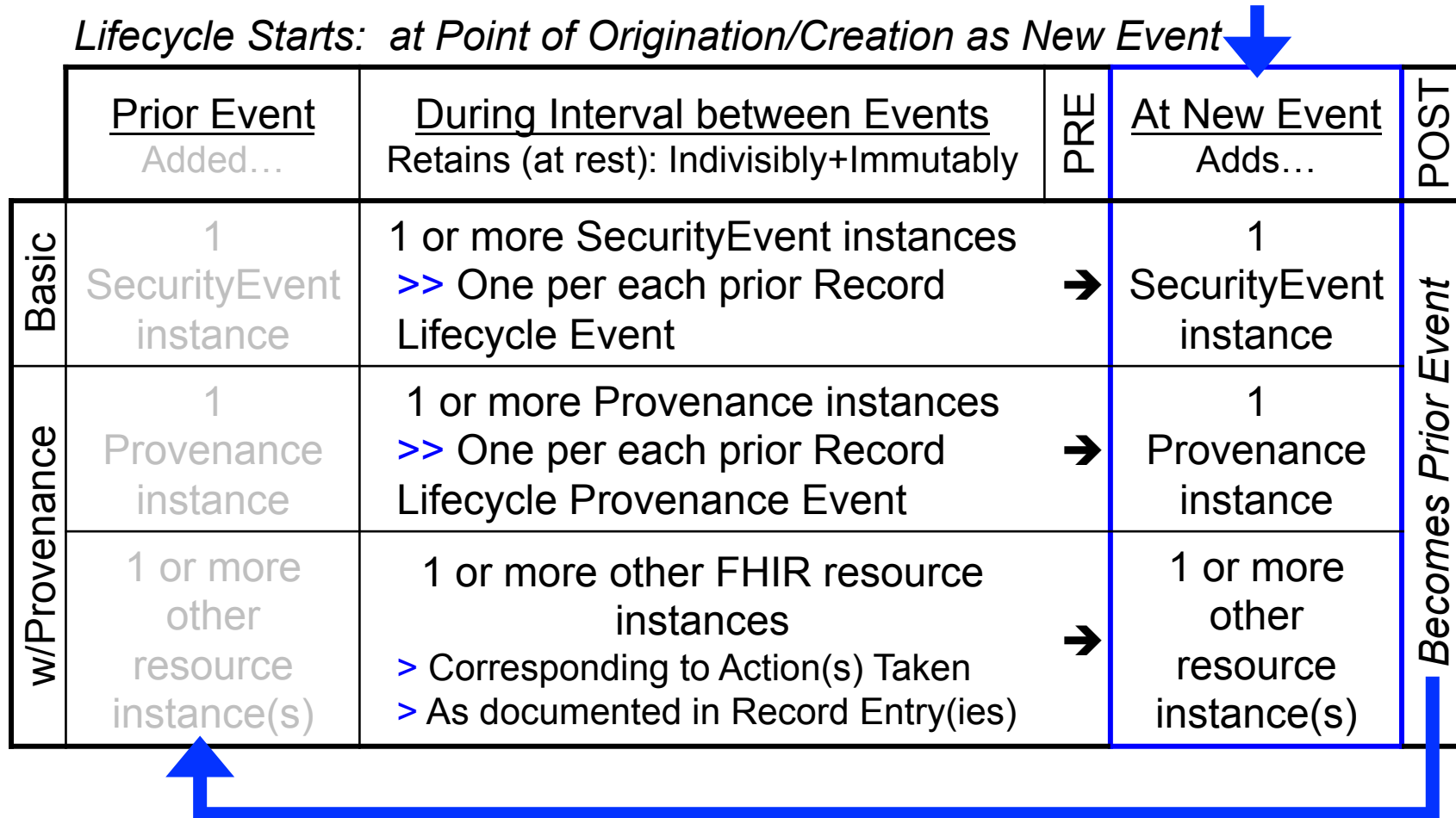


| Pre Event State   | Resource @ Event              | Post Event State           |                                      |                         |                     |                     |
|---|-------------------------------|----------------------------|--------------------------------------|-------------------------|---------------------|---------------------|
|   | SecurityEvent<br>+ Provenance | Added<br>Event<br>Evidence | Retained<br>Pre Edition<br>Unaltered | Added<br>New<br>Edition | Signed as<br>Author | Signed as<br>System |
| [Record Entry as persisted, indivisible and immutable since previous Lifecycle Event] | 19 Merge                      | X                          | X                                    | X                       |                     |                     |
|   | 20 Unmerge                    | X                          |                                      |                         |                     |                     |
|   | 21 Link                       | X                          |                                      |                         |                     |                     |
|   | 22 Unlink                     | X                          |                                      |                         |                     |                     |
|   | 23 Add Legal Hold             | X                          |                                      |                         |                     |                     |
|   | 24 Remove Legal Hold          | X                          |                                      |                         |                     |                     |
|   | 25 Verify (new event)         | X                          |                                      |                         |                     |                     |
|   | 26 Encrypt (new event)        | X                          | X                                    | ?                       |                     |                     |
|   | 27 Decrypt (new event)        | X                          | X                                    | ?                       |                     |                     |

Pre/Post Entry Content and...

# Record Entry Lifecycle

*Lifecycle Starts: at Point of Origination/Creation as New Event*








# Originate/Retain Record Entry

RM-ES will vet Record Infrastructure (RI).

With Event Evidence (RI.1.1.1.1) →  
↓ At Lifecycle Event Occurrence (RI.1.1.1)

- 1 The system SHALL provide the ability to capture (originate) a Record Entry instance corresponding to an Action instance and context.
- 2 The system SHALL capture a unique instance identifier for each Record Entry.
- 3 The system SHALL capture the signature event (e.g., digital signature) of the origination entry Author, binding signature to Record Entry content.
- 4 The system SHALL provide the ability to capture both structured and unstructured content in Record Entries.
- 5 The system SHALL provide the ability to capture Record Entries from information recorded during system downtime.
- 6 The system SHOULD provide the ability to integrate Record Entries from Information recorded during system downtime.
- 7 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.
- 8 The system SHOULD capture metadata that identifies the source of non-originated Record Entry (e.g., templated, copied, duplicated, or boilerplate information).
- 9 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), or by order of relative importance.
- 10 The system MAY capture and maintain a Record Entry encoded as a standards-based data object (e.g., HL7 Continuity of Care, other HL7 CDA R2 Document, ISO 13606 artifact).
- 11 The system MAY capture and maintain a standards-based data object to mirror (be duplicate and synchronous with) internal Record Entry representation.

Fulfilled by FHIR Resource Implementation   
Lifecycle Event Metadata (who, what, when, where, why)   
Others to consider 

- 1 The system SHALL audit each occurrence when a Record Entry is originated and retained.
- 2 The system SHALL capture identity of the organization where Record Entry content is originated.
- 3 The system SHALL capture identity of the patient who is subject of Record Entry content.
- 4 The system SHALL capture identity of the individual(s) who performed the Action documented in Record Entry content.
- 5 The system SHALL capture identity of the user who entered/authored Record Entry content.
- 6 The system SHALL capture identity of the system application which originated Record Entry content.
- 7 IF the source of Record Entry content is a device THEN the system SHALL capture identity of the device.
- 8 The system SHALL capture the Action as evidenced by Record Entry content.
- 9 The system SHALL capture the type of Record Event trigger (i.e., originate/retain).
- 10 The system SHALL capture date and time of Action occurrence as evidenced by Record Entry content.
- 11 The system SHALL capture date and time Record Entry content is originated.
- 12 The system MAY capture the duration of the Action evidenced by Record Entry content.
- 13 The system MAY capture the physical location of the Action evidenced by Record Entry content.
- 14 The system SHOULD capture identity of the location (i.e., network address) where Record Entry content is originated.
- 15 The system MAY capture the rationale for the Action evidenced by Record Entry content.
- 16 The system MAY capture the rationale for originating Record Entry content.
- 17 IF Record Entry content includes templates (boilerplate information) or copied (duplicated) information THEN the system SHOULD capture the source of such content.

Individuals have specific...

# Action and Record Entry Roles

| Action Roles  | Record Entry Roles   |
|---|--|
| <ul style="list-style-type: none"><li>• Subject</li><li>• Performer</li><li>• Witness</li></ul> | <ul style="list-style-type: none"><li>• Record Target</li><li>• Author</li><li>• Recorder (Enterer?)</li><li>• Verifier</li><li>• Attester</li><li>• Informant</li></ul> |

Example – Medication Order

# Action and Record Entry Metadata

|     | Action Metadata  | Record Entry Metadata   |
|-----|--|---|
| Who | Action Subject (Patient)<br>Johnny Walker<br>Role: Subject                 | Entry Subject (Patient)<br>Johnny Walker<br>Role: Record Target         |
|     | Action Organization<br>Bay City Medical Center                             |   |
|     | Action Practitioner/<br>Performer<br>Doctor Sally Smith<br>Role: Performer | Entry Source – Author or Scribe<br>Nurse Janice Jones<br>Role: Recorder |
|     |  | Entry Source – System/Device<br>Erstwhile EHR/Device XX123456           |

Example – Medication Order

# Action and Record Entry Metadata

|       | Action Metadata   | Record Entry Metadata  |
|-------|---|--|
| What  | Action Taken<br>Medication Order for<br>Ambien 20mg PRN | Entry Origination/Retention evidenced by<br>SecurityEvent<br>Provenance<br>+ FHIR Resources related to Medication Order<br>MedicationPrescription, et al |
| When  | Action Date/Time<br>22 Aug 2014 @ 1800                  | Entry Date/Time<br>22 Aug 2014 @ 1810  |
|       | Action Duration<br>3 Minutes                            |  |
| Where | Action Physical Location<br>Ward/Room B/12              | Entry Location – IP Address<br>255.255.255.1   |
| Why   | Action Reason/Purpose<br>To Induce Sleep                | Entry Reason/Purpose<br><none entered>   |

## EHR-S FM Record Infrastructure (RI) – Lifecycle Events

# More Evidentiary Metadata

| Lifecycle Event →  | Originate<br>Retain | Amend | Attest | Translate |
|--|---------------------|-------|--------|-----------|
| Record Entry Unique ID                                       | X                   |       |        |           |
| Record Entry Content: Data, Document, Artifact ID(s)         | X                   | X     |        |           |
| Digital Signature(s) – Individual(s)                         |                     |       | X      |           |
| Digital Signature – Acting System/Device                     | Any/All             |       |        |           |
| Corresponding/linked Record Entry(ies)                       | X                   | X     |        |           |
| Pointer to Pre-Event Entry, if any: pre update/translation   |                     | X     |        | X         |
| Pointer to Post-Event Entry, if any: post update/translation |                     | X     |        | X         |
| Amendment and/or Translation Sequence                        |                     | X     |        | X         |
| Identity and version of Translation Tool(s), if any          |                     |       |        | X         |

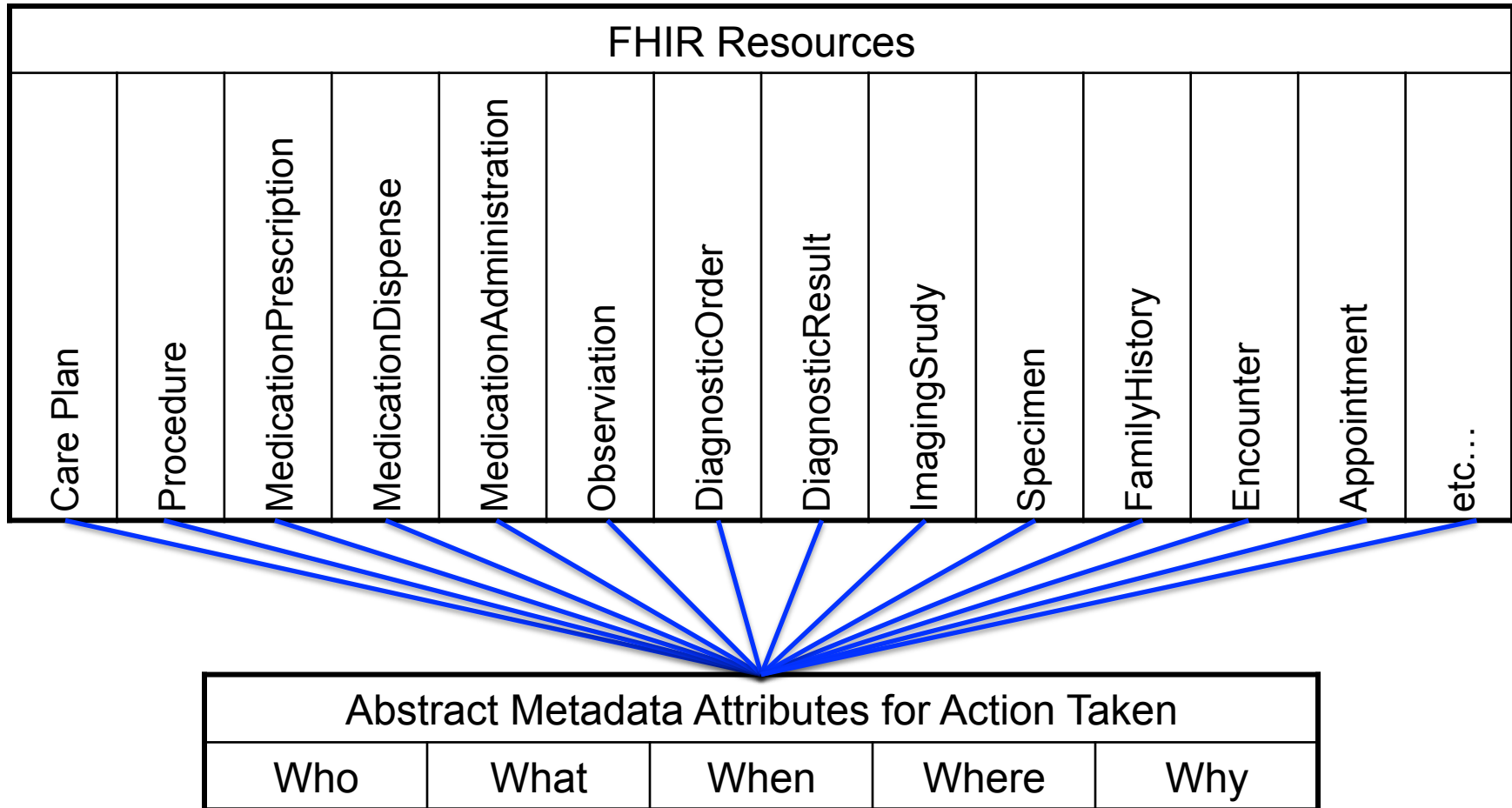
## EHR-S FM Record Infrastructure (RI) – Lifecycle Events

# More Evidentiary Metadata

| Lifecycle Event →  | Originate<br>Retain   | Amend | Attest | Disclose<br>Transmit |
|--|---|-------|--------|----------------------|
| Source of Copied Content: if copy/paste, template or boilerplate | X   | X     |        |                      |
| Event is Known Disclosure Indicator                              |   |       |        | X                    |
| Permissions associated with Record Entry Content                 | X   | X     |        | X                    |
| Entries in Event Transaction, if multiple                        | Set of Entries: <ul style="list-style-type: none"> <li>• Accessed/Viewed</li> <li>• Transmitted</li> <li>• Received</li> <li>• Extracted</li> <li>• Archived/Restored</li> <li>• Destroyed/Deleted</li> <li>• On/Off Legal Hold</li> <li>...</li> </ul> |       |        |                      |

A Potential Solution for Action Metadata

# Abstract Attributes



# Upcoming Slides...

- From the perspective of Lifecycle Event metadata:
  - Who, What, When, Where, Why
  - Additional Evidentiary Metadata



## Lifecycle Event Metadata

# Who

| Lifecycle Event Metadata | FHIR Resource                    | Resource Attribute(s)   |
|--------------------------|----------------------------------|---|
| Organization             | Provenance                       | <code>signature</code> : string 0..1  |
|                          | Provenance.Agent : 0..*          | <code>role</code> : Coding 1..1 « <code>ProvenanceAgentRole+</code> »<br><code>type</code> : Coding 1..1 « <code>ProvenanceAgentType+</code> »<br><code>reference</code> : uri 1..1                 |
| Patient                  | Provenance                       | <code>signature</code> : string 0..1  |
|                          | Provenance.Agent : 0..*          | <code>role</code> : code 1..1 « <code>ProvenanceEntityRole</code> »<br><code>type</code> : Coding 1..1 « <code>ProvenanceEntityType+</code> »<br><code>reference</code> : uri 1..1                  |
|                          | SecurityEvent.Participant : 1..* | <code>role</code> : CodeableConcept 0..* « <code>DICOMRoleId+</code> »<br><code>reference</code> : Resource(Organization Practitioner Patient Device) 0..1<br><code>requester</code> : Boolean 1..1 |
| Action - Performer       | TBD                              |   |

Distinguish Action from Record Metadata. [See Medication Order Example]  
 Action-Performer not resolved.  
 Need to add RelatedPerson to Practitioner|Patient|Device choice (per Lloyd)?

## Lifecycle Event Metadata

# Who, con't

| Lifecycle Event Metadata  | FHIR Resource                    | Resource Attribute(s)  |
|---------------------------|----------------------------------|--|
| Record - Author/<br>User  | Provenance                       | <code>signature</code> : string 0..1   |
|                           | Provenance.Agent : 0..*          | <code>role</code> : Coding 1..1 « <code>ProvenanceAgentRole+</code> »<br><code>type</code> : Coding 1..1 « <code>ProvenanceAgentType+</code> »<br><code>reference</code> : uri 1..1  |
|                           | SecurityEvent.Participant : 1..* | <code>role</code> : CodeableConcept 0..* « <code>DICOMRoleId+</code> »<br><code>reference</code> : Resource( <code>Practitioner</code>   <code>Patient</code>   <code>Device</code> ) 0..1<br><code>userId</code> : string 0..1<br><code>requester</code> : Boolean 1..1 |
| Record -<br>System/Device | Provenance                       | <code>signature</code> : string 0..1   |
|                           | Provenance.Agent : 0..*          | <code>role</code> : Coding 1..1 « <code>ProvenanceAgentRole+</code> »<br><code>type</code> : Coding 1..1 « <code>ProvenanceAgentType+</code> »<br><code>reference</code> : uri 1..1  |
|                           | SecurityEvent.Participant : 1..* | <code>role</code> : CodeableConcept 0..* « <code>DICOMRoleId+</code> »<br><code>reference</code> : Resource( <code>Practitioner</code>   <code>Patient</code>   <code>Device</code> ) 0..1<br><code>userId</code> : string 0..1<br><code>requester</code> : Boolean 1..1 |

Provenance.Agent.reference may resolve to a uri or Resource (like others)

## Lifecycle Event Metadata

# What

| Lifecycle Event Metadata | FHIR Resource               | Resource Attribute(s)  |
|--------------------------|-----------------------------|--|
| Action - Taken           | TBD                         |  |
| Record - Lifecycle Event | SecurityEvent.Event : 1..1  | <code>type</code> : CodeableConcept 1..1 « <code>SecurityEventType+</code> »<br><code>subtype</code> : CodeableConcept 0..* « <code>SecurityEventSubType+</code> »<br><code>action</code> : code 0..1 « <code>SecurityEventAction</code> »   |
|                          | SecurityEvent.Object : 0..* | <code>identifier</code> : Identifier 0..1<br><code>reference</code> : Resource(Any) 0..1<br><code>type</code> : code 0..1 « <code>SecurityEventObjectType</code> »<br><code>role</code> : code 0..1 « <code>SecurityEventObjectRole</code> »<br><code>lifecycle</code> : code 0..1 « <code>SecurityEventObjectLifecycle</code> » |

Action Taken not resolved.

[See Medication Order Example <corresponding set of Med Order resources>]

## Lifecycle Event Metadata

# When

| Lifecycle Event Metadata        | FHIR Resource              | Resource Attribute(s)          |
|---------------------------------|----------------------------|--------------------------------|
| Action - Date/ Time             | TBD                        |                                |
| Record - Date/ Time             | Provenance                 | <b>recorded</b> : instant 1..1 |
|                                 | SecurityEvent.Event : 1..1 | <b>dateTime</b> : instant 1..1 |
| Action - Duration/ Elapsed Time | TBD                        |                                |

Action Date/Time and Duration not resolved.

## Lifecycle Event Metadata

# Where

| Lifecycle Event Metadata   | FHIR Resource                     | Resource Attribute(s)  |
|----------------------------|-----------------------------------|--|
| Action - Physical Location | TBD                               |  |
| Record - Network Address   | Provenance                        | <code>location</code> : Resource(Location) 0..1  |
|                            | SecurityEvent.Participant.Network | <code>identifier</code> : string 0..1<br><code>type</code> : code 0..1 « SecurityEventParticipantNetworkType » |

Action Physical Location not resolved.  
Add "location" to SecurityEvent.Event?

## Lifecycle Event Metadata

# Why

| Lifecycle Event Metadata            | FHIR Resource              | Resource Attribute(s)                |
|-------------------------------------|----------------------------|--------------------------------------|
| Action - Reason, Rationale, Purpose | TBD                        |                                      |
| Record - Reason, Rationale, Purpose | Provenance                 | <i>reason</i> : CodeableConcept 0..1 |
|                                     |                            | <i>policy</i> : uri 0..*             |
|                                     | SecurityEvent.Event : 1..1 | <i>reason</i> : CodeableConcept 0..1 |

Action Reason not resolved.  
Add “reason” to SecurityEvent.Event?

## Lifecycle Event Metadata

# Evidentiary

| Lifecycle Event Metadata                          | FHIR Resource   | Resource Attribute(s)  |
|---|---|--|
| Digital Signature(s)                              | Provenance  | <b>signature</b> : string 0..1   |
| Record Entry ID                                   | SecurityEvent.Object : 0..*   | <b>identifier</b> : Identifier 0..1<br><b>reference</b> : Resource(Any) 0..1 |
| Record Entry Content ID(s): data, docs, artifacts | SecurityEvent.Object : 0..*,<br><b>one for each Content item</b>        | <b>identifier</b> : Identifier 0..1<br><b>reference</b> : Resource(Any) 0..1 |
| Corresponding/linked Record Entry(ies)            | SecurityEvent.Object : 0..*,<br><b>one for each linked Record Entry</b> | <b>identifier</b> : Identifier 0..1<br><b>reference</b> : Resource(Any) 0..1 |
| Amendment/Translation Sequence                    | SecurityEvent.Object : 0..*   | <b>lifecycle</b> : code 0..1 « <b>SecurityEventObjectLifecycle</b> »         |
| Pointer to Pre Event Entry, if chained            | SecurityEvent.Object : 0..*,<br><b>one to previous instance</b>         | <b>identifier</b> : Identifier 0..1<br><b>reference</b> : Resource(Any) 0..1 |

Shouldn't signature be 0..\* (System/Device + Individual)?

## Lifecycle Event Metadata

# Evidentiary, con't

| Lifecycle Event Metadata                | FHIR Resource  | Resource Attribute(s)  |
|---|--|--|
| Source of Copied Content                | SecurityEvent.Object : 0..*,<br>one for each source        | identifier : Identifier 0..1<br>reference : Resource(Any) 0..1<br>type : code 0..1 « SecurityEventObjectType »<br>role : code 0..1 « SecurityEventObjectRole »                     |
| Event is known Disclosure               | SecurityEvent.Object : 0..*                                | lifecycle : code 0..1 « SecurityEventObjectLifecycle », where lifecycle = "disclosure"   |
| Record Entry Permissions                | SecurityEvent.Participant : 1..*, one for each participant | role : CodeableConcept 0..* « DICOMRoleId+ », for role-based<br>reference : Resource(Practitioner Patient Device) 0..1<br>userId : string 0..1, for ID-based permissions           |
|   | SecurityEvent.Object : 0..*                                | sensitivity : code 0..1 « SecurityEvent.object.sensitivity »   |
| Event Transaction Entries               | SecurityEvent.Object : 0..*,<br>one for each Record Entry  | identifier : Identifier 0..1<br>reference : Resource(Any) 0..1<br>type : code 0..1 « SecurityEventObjectType »   |
| Identifier/Version of Translation Tools | SecurityEvent.Object : 0..*                                | identifier : Identifier 0..1, where identifier = Tool ID<br>type : code 0..1 « SecurityEventObjectType », where type = Trans Tool<br>name : string 0..1, where name = Tool Version |

Source of copied content: e.g., via copy/paste, template, boilerplate?  
For SecurityEvent.Participant, we have role and identifier (to support role and user-based authorization/access control).



# Upcoming Slides...

- From the perspective of FHIR Provenance and SecurityEvent resources:
  - Targeted Resource Attributes, some with Code/Value Sets
  - Resource Notes, Comments and Proposals

## FHIR Resource

# Provenance

| Resource   | Resource Attribute                        | Description                                 | Value Set |
|------------|---|---|-----------|
| Provenance |   | → Who, What, When for a set of resources    |           |
|            | <b>target</b> : Resource(Any) 1..*        | Target resources (usually version specific) |           |
|            | <b>period</b> : Period 0..1               | When the activity occurred                  |           |
|            | <b>recorded</b> : instant 1..1            | When the activity was recorded/updated      |           |
|            | <b>location</b> : Resource(Location) 0..1 | Where the activity occurred, if relevant    |           |
|            | <b>reason</b> : CodeableConcept 0..1      | Reason activity is occurring                |           |
|            | <b>signature</b> : string 0..1            | Base64 signature (DigSig) - integrity check |           |
|            | <b>policy</b> : uri 0..*                  | Policy or plan the activity was defined by  |           |

Create value set for “reason”? [Galen, Diana P-M]

## FHIR Resource

# Provenance.Agent

| Resource         | Resource Attribute                          | Description   | Value Set   |
|------------------|---|---|---|
| Provenance.Agent |   | → Person, organization, records, etc. involved in creating resource |   |
|                  | role : Coding 1..1 « ProvenanceAgentRole+ » |   | <confirm><br>Enterer, performer, author, verifier, attester, informant, source, cc, application, daemon |
|                  | type : Coding 1..1 « ProvenanceAgentType+ » |   | <confirm><br>Practitioner, organization, software, record, document                                     |
|                  | reference : uri 1..1                        |   |   |

Provenance.Agent.reference may resolve to a uri or Resource (like others)  
Review value sets for “role” and “type”.

## FHIR Resource

# SecurityEvent.Event

| Resource            | Resource Attribute  | Description                               | Value Set   |
|---------------------|---|---|---|
| SecurityEvent.Event |   | → What was done                           |   |
|                     | <b>type</b> : CodeableConcept 1..1 « SecurityEventType+ »       | Type/identifier of event                  | <confirm><br>Rest + DICOM codeset   |
|                     | <b>subtype</b> : CodeableConcept 0..* « SecurityEventSubType+ » | More specific type/id for the event       | <confirm><br>Read, vread, update, delete, validate, create, history-instance, history-type, history-system, search-type, search-system, transaction + DICOM codeset |
|                     | <b>action</b> : code 0..1 « SecurityEventAction »               | Type of action performed during the event | <confirm><br>C) Create; R) Read/view/print; U) Update; D) Delete; E) Execute.   |
|                     | <b>dateTime</b> : instant 1..1                                  | Time when the event occurred on source    |   |
|                     | <b>location</b> : Resource(Location) 0..1                       | TBD                                       |   |
|                     | <b>reason</b> : CodeableConcept 0..1                            | TBD                                       | TBD   |

Review value sets for “type”, “subtype” and “action”.  
Add “location” and “reason” and value set for “reason”.

## FHIR Resource

# SecurityEvent.Source

| Resource             | Attribute  | Description                                   | Value Set   |
|----------------------|--|---|---|
| SecurityEvent.Source |  | → Application systems and processes           |   |
|                      | site   | Logical source location within the enterprise |   |
|                      | identifier   | The id of source where event originated       |   |
|                      | type : CodeableConcept 1..1 « SecurityEventSourceType+ » | The type of source where event originated     | <confirm><br>1) User Device; 2) Data Interface; 3) Web Server; 4) Application Server; 5) Database Server; 6) Security Server; 7) Network Device; 8) Network Router; 9) Other. |
|                      | location : Resource(Location) 0..1                       | TBD   |   |

[This sub-resource not currently referenced by Lifecycle Event metadata.]  
 Why not “location” resource instead of site, identifier and type?  
 Review value set for “type”.

## FHIR Resource

# SecurityEvent.Object

| Resource             | Resource Attribute                                  | Description                                      | Value Set   |
|----------------------|---|--|---|
| SecurityEvent.Object |   | → Specific instances of data or objects accessed |   |
|                      | <b>identifier</b> : Identifier 0..1                 | Specific instance of object (e.g. versioned)     |   |
|                      | <b>reference</b> : Resource(Any) 0..1               | Specific instance of resource (e.g. versioned)   |   |
|                      | <b>type</b> : code 0..1 « SecurityEventObjectType » | Object type being audited                        | <confirm><br>1) Person; 2) System Object; 3) Organization; 4) Other.  |
|                      | <b>role</b> : code 0..1 « SecurityEventObjectRole » | Functional application role of Object            | <confirm><br>1) patient; 2) location; 3) report; 4) resource; 5) master file; 6) user; 7) list; 8) doctor; 9) subscriber; 10) guarantor; 11) security user entity; 12) security user group; 13) security resource; 14) security granularity definition; 15) practitioner; 16) data destination; 17) data reposition; 18) schedule; 19) customer; 20) job; 21) job stream; 22) table; 23) routing criteria; 24) query. |

For “type”, need “EHR record entry” as specific value.  
Review value set for “role”.

## FHIR Resource

# SecurityEvent.Object, con't

| Resource             | Resource Attribute  | Description                               | Value Set   |
|----------------------|---|---|---|
| SecurityEvent.Object | <b>lifecycle</b> : code 0..1 «<br><b>SecurityEventObjectLifecycle</b> »       | Life-cycle stage for the object           | <confirm><br>1 OriginationCreation; 2) Import/ Copy from original; 3) Amendment; 4) Verification; 5) Translation; 6) Access/Use; 7) De-identification; 8) Aggregation, summarization, derivation; 9) Report; 10) Export/ Copy to target; 11) Disclosure; 12) Receipt of disclosure; 13) Archiving; 14) Logical deletion; 15) Permanent erasure/Physical destruction |
|                      | <b>sensitivity</b> : code 0..1<br>« <b>SecurityEvent.object.sensitivity</b> » | Policy-defined sensitivity for the object | <confirm><br>L) Low; M) Moderate; N) Normal; R) Restricted; U) Unrestricted; V) Very restricted.  |
|                      | <b>description</b> : string 0..1  | Instance-specific descriptor for Object   |   |

SecurityEvent.Object.lifecycle must reference RI.1.1.1-27.x.  
 Review value sets for “lifecycle” and “sensitivity”.

## FHIR Resource

# SecurityEvent.Participant

| Resource                  | Resource Attribute  | Description                                       | Value Set |
|---------------------------|---|---|-----------|
| SecurityEvent.Participant |   | → A person, a hardware device or software process |           |
|                           | <b>role</b> : CodeableConcept 0..* « DICOMRoleId+ »           | User roles (e.g. local RBAC codes)                |           |
|                           | <b>reference</b> : Resource(Practitioner Patient Device) 0..1 | Direct reference to resource                      |           |
|                           | <b>userId</b> : string 0..1                                   | Unique identifier for the user                    |           |
|                           | <b>requester</b> : Boolean 1..1                               | Whether user is initiator                         |           |

Review value set for “role”.



## FHIR Resource

# SecurityEvent.Participant.Network

| Resource                          | Resource Attribute                                       | Description  | Value Set |
|-----------------------------------|--|--|-----------|
| SecurityEvent.Participant.Network |  | → Logical network location for application activity      |           |
|                                   | identifier : string 0..1                                 | Identifier for the network access point of a user device |           |
|                                   | type : code 0..1 « SecurityEventParticipantNetworkType » | The type of network access point                         | <confirm> |

Review value set for “type”.

# Record Entry and FHIR Resources

- An EHR System manages a persistent EHR comprising Record Entries for
  - One or more provider organizations,
  - One or more individual practitioners, and
  - Many patients
- An EHR comprises
  - Many Record Entry instances
- A Record Entry instance may comprise
  - One or more FHIR Resource instance(s)
  - With signature bindings

## Project Focus/Success Criteria

# FHIR Enabled Lifecycle Events

| Project Focus  | Success Criteria  |
|--|---|
| <p>Binds (joins) FHIR Resource Instance(s) together in Record Entry Instance:</p> <ul style="list-style-type: none"><li>• Including applicable Clinical, Administrative, Infrastructure Resources</li><li>• Based on Action(s) Taken</li></ul> | <ul style="list-style-type: none"><li>• Complete specification of baseline Set of FHIR Resources applicable at each Record Lifecycle Event (1-27) and captured in the resulting Record Entry Instance</li><li>• Allowing additional Resources to be bound in a Record Entry Instance, per Clinical, Administrative and/or other context</li></ul> |
| <p>Includes Pre- and Post-Lifecycle Event Entry States</p> <ul style="list-style-type: none"><li>• e.g., before/after amendment or translation</li></ul>   | <ul style="list-style-type: none"><li>• Complete specification of how both pre- and post-lifecycle event states (of FHIR Resources) are captured and preserved in one or more Record Entries</li></ul>  |

Project Focus/Success Criteria

# FHIR Enabled Lifecycle Events

| Project Focus   | Success Criteria   |
|---|--|
| Includes Action/Event Metadata  | <ul style="list-style-type: none"><li>• Complete specification of Action/Event Metadata (in FHIR Resources) per Record Entry</li></ul>   |
| Includes Attestation and Content Binding <ul style="list-style-type: none"><li>• With/without Digital Signature</li></ul> | <ul style="list-style-type: none"><li>• Complete specification of:<ul style="list-style-type: none"><li>• Attestation and/or Digital Signature bound to Record Entry content</li></ul></li></ul> |

# Dimensions of End-to-End Flow

## Record Lifespan

### 1. Within Single System


- Starting at point of origination, in Source System
- Starting at point of receipt, in Receiving System
- Ending at point of deletion

### 2. Across Multiple Systems

- Starting at point of origination, in Source System
- Traversing one or more Points of Exchange
- Ending at point of deletion, in each System

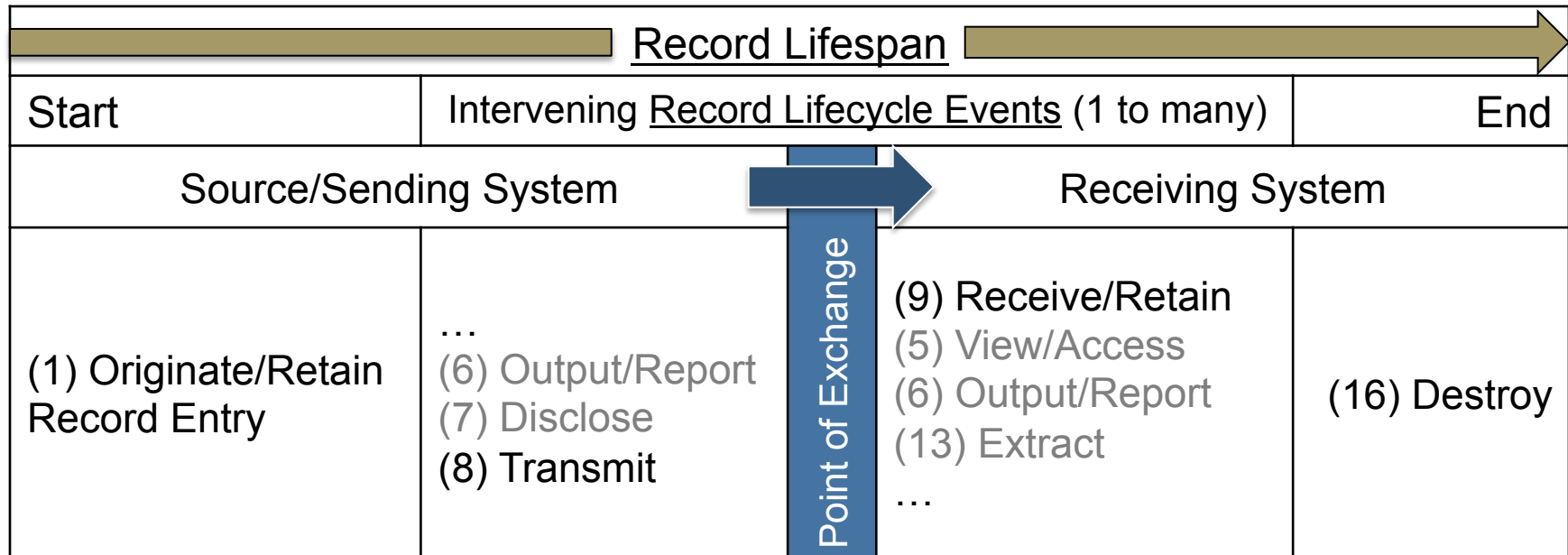
## Record Lifespan – End-to-End

# Within Single System

| Record Lifespan  |   |              |
|---|---|--------------|
| Start   | Intervening Record Lifecycle Events (0 to many)   | End          |
| <u>Source System</u><br>(1) Originate/<br>Retain Record<br>Entry                                    | (2) Amend<br>(3) Translate<br>(25,4) Verify, Attest<br>(5) View/Access<br>(6) Output/Report<br>(7) Disclose<br>(8) Transmit<br>(10) De-Identify<br>(11) Pseudo-nymize<br>(12) Re-Identify<br>(13) Extract | (16) Destroy |
| <u>Receiving System</u><br>(9) Receive/Retain<br>Record Entry                                       | (14,15) Archive, Restore<br>(17,18) Deprecate/Retract, Re-Activate<br>(19,20) Merge, Unmerge<br>(21,22) Link, Unlink<br>(23,24) Place, Remove Legal Hold<br>(26,27) Encrypt, Decrypt                      | (16) Destroy |

Record Lifespan – End-to-End

# Across Multiple Systems



Repeated at each point of exchange...

Current/Emerging Projects Related to...

# EHR-S FM Record Infrastructure

- EHR Record Lifecycle Event Metadata using HL7 Fast Health Interoperable Resources (FHIR) – [this project](#)
- S&I Data Provenance
- S&I esMD
- S&I Simplification
  - S&I Use Case Requirements Analysis
  - Use Case Authoring Tool (UCAT) Development
- HL7 Functional Model Framework
  - Next Releases of EHR-S FM (R3), PHR-S FM (R2), Lab FM (?)
- HL7 Vocabulary Harmonization: EHR, Security, CBCC WGs
- Functional Profile Development: RM-ES R2, MU FP, PH FPs
- ISO 21089 Revision, Trusted End-to-End Information Flows
- ISO 13606 Revision, EHR Communication
- Others: HSPC?



| ISO/HL7 Standard or S&I Activity →           | ISO TC215 – Stds. Infrastructure Frame In development | ISO 21089:2004 Trusted End to End Published TR | ISO 21089:2014 Trusted End to End In development | ISO/HL7 10781 EHRS FM R2:2014 Published | ISO/HL7 16527 PHRS FM R2 In development | ISO 19669 – Re-Usable Use Case In development | ISO 13606 – EHR Communication In Revision | HL7 EHR Lifecycle Model DSTU:2008 Published | HL7 RM-ES FP R2 In Development | HL7 Record Lifecycle on FHIR In Development | US S&I Simplification | US S&I Data Provenance |
|--|---|--|--|---|---|---|---|---|--------------------------------|---|-----------------------|------------------------|
| Record Lifecycle Event ↓ (EHR-S FM RI.1.1.x) |   |  |  |   |   |   |   |   |                                |   |                       |                        |
| 1 Originate/Retain Record Entry              | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 2 Amend Record Entry                         | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 3 Translate Record Entry                     | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 4 Attest Record Entry                        | X   |  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 5 View/Access Record Entry                   | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 6 Output/Report Record Entry                 | Exchange  | X  | X  | X                                       | X                                       | X   | X   | X   | X                              | X   | X                     |                        |
| 7 Disclose Record Entry                      |   | X  | X  | X                                       | X                                       | X   | X   | X   | X                              | X   | X                     |                        |
| 8 Transmit Record Entry                      |   | X  | X  | X                                       | X                                       | X   | X   | X   | X                              | X   | X                     |                        |
| 9 Receive/Retain Record Entry                |   | X  | X  | X                                       | X                                       | X   | X   | X   | X                              | X   | X                     |                        |
| 10 De-Identify Record Entry                  |   | X  | X  | X                                       | X                                       | X   | X   |   | X                              | X   | X                     | X                      |
| 11 Pseudo-nymize Record Entry                | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 12 Re-Identify Record Entry                  | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 13 Extract Record Entry                      | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 14 Archive Record Entry                      | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 15 Restore Record Entry                      | X   |  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 16 Destroy Record Entry                      | X   | X  | X  | X                                       | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 17 Deprecate/Retract Record Entry            | X   |  | X  | X                                       | X                                       | X   |   |   | X                              | X   | X                     |                        |
| 18 Re-Activate Record Entry                  | X   |  | X  | X                                       | X                                       | X   |   |   | X                              | X   | X                     |                        |
| 19 Merge Record Entry                        | X   |  | X  | X                                       | X                                       | X   |   |   | X                              | X   | X                     |                        |
| 20 Unmerge Record Entry                      | X   |  | X  | X                                       | X                                       | X   |   |   | X                              | X   | X                     |                        |
| 21 Link Record Entry                         | X   |  | X  | X                                       | X                                       | X   |   |   | X                              | X   | X                     |                        |
| 22 Unlink Record Entry                       | X   |  | X  | X                                       | X                                       | X   |   |   | X                              | X   | X                     |                        |
| 23 Place Legal Hold on Record Entry          | X   |  | X  | X                                       | N/A                                     | X   |   |   | X                              | X   | X                     |                        |
| 24 Remove Legal Hold on Record Entry         | X   |  | X  | X                                       | N/A                                     | X   |   |   | X                              | X   | X                     |                        |
| 25 Verify Record Entry Content               | X   | X  | X  |   | X                                       | X   |   | X   | X                              | X   | X                     |                        |
| 26 Encrypt Record Entry                      | X   |  | X  |   | X                                       | X   |   |   | X                              | X   | X                     |                        |
| 27 Decrypt Record Entry                      | X   |  | X  |   | X                                       | X   |   |   | X                              | X   | X                     |                        |
| Applicable Lifecycle Events →                | 27  | 15   | 27   | 24                                      | 25                                      | 27  | 4   | 16  | 27                             | 27  | 27                    | ?                      |

TBD

Longer Term...

# Project Segments/Leads

|   |  | Leads   |
|---|--|---|
| 1 | <a href="#">ISO/HL7 10781 EHR-S FM R2</a><br>RI – Record Infrastructure<br><a href="#">RM-ES – Records Management/<br/>Evidentiary Support</a> | Gary Dickinson, Reed Gelzer, MD,<br>Josh Mandel, Diana Warner |
| 2 | TI – Trust Infrastructure  | TBD   |
| 3 | CP – Care Provision  | TBD   |
| 4 | CPS – Care Provision Support   | TBD   |
| 5 | AS – Administrative Support  | TBD   |
| 6 | POP – Population Health Support  | TBD   |
| 7 | <a href="#">ISO/HL7 16527 PHR-S FM R1</a><br>PH – Personal Health<br>S – Supportive<br>II – Information Infrastructure                         | John Ritter, et al.   |

## EHR-S FM Record Lifecycle Events on FHIR

# Links

- HL7 EHR Interop Wiki:
  - [http://wiki.hl7.org/index.php?title=EHR\\_Interoperability\\_WG](http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG)