EHRS-FM R2 – Record Infrastructure

Record Entry Lifecycle Event Metadata on FHIR

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http://www.hl7.org/fhir

FHIR Resource Index

Clinical

General:

- AdverseReaction
- AllergyIntolerance
- CarePlan
- Condition
- FamilyHistory
- Procedure
- QuestionnaireAnswers

Medications:

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

Diagnostics:

- Observation
- DiagnosticReport
- DiagnosticOrder
- ImagingStudy
- Specimen

Device Interactions:

- DeviceObservationReport

Administrative

Attribution:

- Patient
- RelatedPerson
- Practitioner
- Organization

Entities:

- Device
- Location
- Substance
- Group

Workflow Management:

- Encounter
- Alert
- Supply
- Order
- OrderResponse

Scheduling:

- Appointment (informative)
- Appointment Response (informative)
- Availability (informative)
- Slot (informative)

Infrastructure

Support:

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

Document Handling:

- Composition
- DocumentReference
- DocumentManifest

Exchange:

- MessageHeader
- OperationOutcome
- Query
- Subscription

Conformance:

- Conformance
- Profile
- ValueSet
- ConceptMap (informative)

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 ➔ Vocabulary Work Underway: HL7 EHR, CBCC, Security Work Groups ➘ Record Lifecycle Event ➘ (EHR-S FM RI.1.1.x)		ISO 21089:2004 Trusted End2End Published TR	ISO 21089:2014 Trusted End2End In development	ISO/HL7 10781 EHRS FM R2:2014 Published	ISO/HL7 16527 PHRS FM R1:2014 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 R1 2009 Published	HL7 RM-ES FP R2 In Development	HL7 Record Lifecycle on FHIR In Development	US S&I Simplification	US S&I Data Provenance
1	Originate/Retain Record Entry	X	X	X		X	X		X		X	X	X	TBD
2	Amend Record Entry	X	X	X		X	X		X		X	X	X	
3	Translate Record Entry	X	X	X		X	X		X		X	X	X	
4	Attest Record Entry		X	X		X	X		X		X	X	X	
5	View/Access Record Entry	X	X	X		X	X		X		X	X	X	
6	Output/Report Record Entry	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	
11	Pseudo-nymize Record Entry	X	X	X		X	X		X		X	X	X	
12	Re-Identify Record Entry	X	X	X		X	X		X		X	X	X	
13	Extract Record Entry	X	X	X		X	X		X		X	X	X	
14	Archive Record Entry	X	X	X		X	X		X		X	X	X	
15	Restore Record Entry		X	X		X	X		X		X	X	X	
16	Destroy Record Entry	X	X	X		X	X		X		X	X	X	
17	Deprecate/Retract Record Entry		X	X		X	X				X	X	X	
18	Re-Activate Record Entry		X	X		X	X				X	X	X	
19	Merge Record Entry		X	X		X	X				X	X	X	
20	Unmerge Record Entry		X	X		X	X				X	X	X	
21	Link Record Entry		X	X		X	X				X	X	X	
22	Unlink Record Entry		X	X		X	X				X	X	X	
23	Place Legal Hold on Record Entry		X	X		N/A	X				X	X	X	
24	Remove Legal Hold on Record Entry		X	X			X				X	X	X	
25	Verify Record Entry Content	X	X			X	X		X		X	X	X	
26	Encrypt Record Entry		X			X	X				X	X	X	
27	Decrypt Record Entry		X			X	X				X	X	X	
	Applicable Lifecycle Events ➔	15	27	24	0	25	27	4	16	0	27	27	27	?

Exchange

Now Underway

Mapping to FHIR

ISO/HL7 10781 EHR-S FM R2 Record Infrastructure (RI) → 24+3 Record Lifecycle Events	FHIR Resources
Simple Lifecycle Event	• SecurityEvent
Provenance Lifecycle Event when Record Entry content is originated or updated	• SecurityEvent • Provenance • [other new/updated resource(s)] → corresponding to Action Taken

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

EHR-S FM Record Lifecycle

Pre/Post Events 1-9

Pre Event State	Resource @ Event	Post Event State				
	SecurityEvent + Provenance	Add Event Evidence	Retain Pre Edition Unaltered	Add New Edition	Sign as Author	Sign as System
[none]	1 Originate/Retain	X		X	Opt	X
[Record Entry as persisted unaltered 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 + Provenance	Add Event Evidence	Retain Pre Edition Unaltered	Add New Edition	Sign as Author	Sign as System
[Record Entry as persisted unaltered since previous Lifecycle 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				

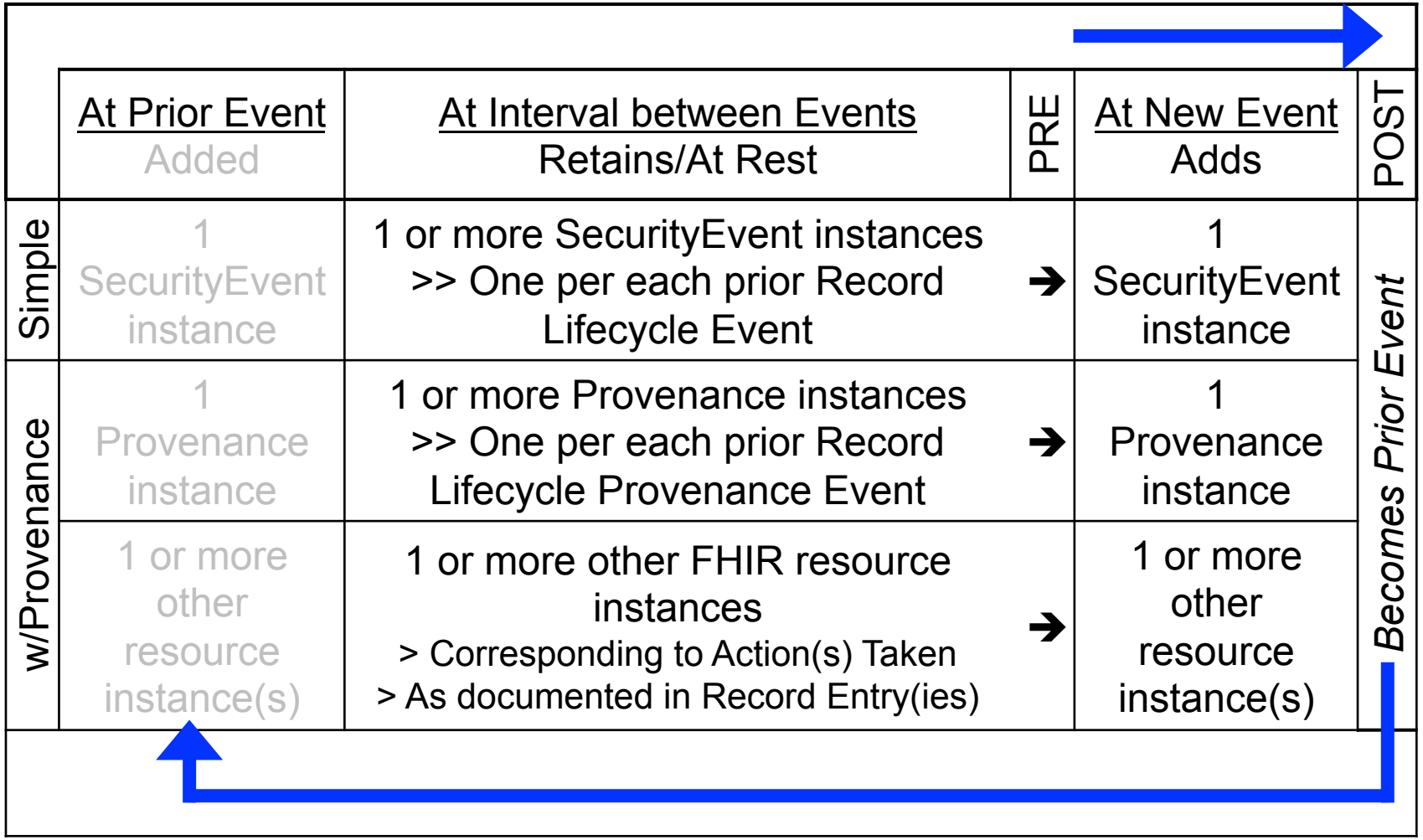
EHR-S FM Record Lifecycle

Pre/Post Events 19-27

Pre Event State	Resource @ Event	Post Event State				
	SecurityEvent + Provenance	Add Event Evidence	Retain Pre Edition Unaltered	Add New Edition	Sign as Author	Sign as System
[Record Entry as persisted unaltered 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	X				
	26 Encrypt (?)	X	X	X		
	27 Decrypt (?)	X	X	X		

Lifecycle Events

Pre/Post Record Entry w/FHIR



From ISO/HL7 10781 EHR-S FM – Sample Conformance Criteria

Originate/Retain Record Entry (RI.1.1.1)

⬇ At Lifecycle Event Occurrence

With Event Evidence➔

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.
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.

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

Event Evidence/Metadata

	Action	Corresponding Record Entry(ies)
Who	Patient, Subject of Action or Entry	User/Author Source of Entry
	Practitioner, Performer of Action	System/Device Source of Entry
	Organization of Action	
What	Action Taken	Record Lifecycle Event
When	Date/Time/Duration of Action Occurrence	Date/Time of Entry Occurrence
Where	Location of Action Taken	Device ID, Network Address of Entry Occurrence
Why	Rationale, Purpose for Action Taken	Rationale, Purpose of Entry

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

Additional Evidence or Metadata

	Action	Corresponding Record Entry(ies)
And…	N/A	Data, Document or Artifact ID
		Amendment/Translation Sequence
		Pointer to Pre-Event Entry: e.g., pre-amendment, pre-translation
		Event flagged as known Disclosure
		Permissions associated with Entry Content
		Entries in Event Transaction: e.g., set of entries viewed, entries extracted, entries to be archived or deleted.

Metadata

Who

Organization	Provenance.Agent	role : Coding 1..1 « ProvenanceAgentRole+ » type : Coding 1..1 « ProvenanceAgentType+ » reference : uri 1..1
	SecurityEvent.Participant	role : CodeableConcept 0..* « DICOMRoleId+ » reference : Resource(*Organization*|Practitioner|Patient|Device) 0..1 userId : string 0..1
Patient	Provenance.Agent	role : code 1..1 « ProvenanceEntityRole » type : Coding 1..1 « ProvenanceEntityType+ » reference : uri 1..1
	SecurityEvent.Participant	role : CodeableConcept 0..* « DICOMRoleId+ » reference : Resource(Organization|Practitioner|Patient|Device) 0..1 userId : string 0..1
Action - Performer	Provenance.Agent	role : Coding 1..1 « ProvenanceAgentRole+ » type : Coding 1..1 « ProvenanceAgentType+ » reference : uri 1..1
	SecurityEvent.Participant	role : CodeableConcept 0..* « DICOMRoleId+ » reference : Resource(*Organization*|Practitioner|Patient|Device) 0..1 userId : string 0..1

Metadata

Who, con't

Record - Author/ User	Provenance.Agent	role : Coding 1..1 « ProvenanceAgentRole+ » type : Coding 1..1 « ProvenanceAgentType+ » reference : uri 1..1
	SecurityEvent.Participant	role : CodeableConcept 0..* « DICOMRoleId+ » reference : Resource(Practitioner|Patient|Device) 0..1 userId : string 0..1
Record - System/Device	Provenance.Agent	role : Coding 1..1 « ProvenanceAgentRole+ » type : Coding 1..1 « ProvenanceAgentType+ » reference : uri 1..1
	SecurityEvent.Participant	role : CodeableConcept 0..* « DICOMRoleId+ » reference : Resource(Practitioner|Patient|Device) 0..1 userId : string 0..1

Distinguishing Action from Record Metadata

Metadata

What

Action - Taken	SecurityEvent.Event	type : CodeableConcept 1..1 « SecurityEventType+ » subtype : CodeableConcept 0..* « SecurityEventSubType+ » action : code 0..1 « SecurityEventAction »
	?	?
Record - Lifecyle Event	SecurityEvent.Event	type : CodeableConcept 1..1 « SecurityEventType+ » subtype : CodeableConcept 0..* « SecurityEventSubType+ » action : code 0..1 « SecurityEventAction »
	SecurityEvent.Object	identifier : Identifier 0..1 reference : Resource(Any) 0..1 type : code 0..1 « SecurityEventObjectType » role : code 0..1 « SecurityEventObjectRole » lifecycle : code 0..1 « SecurityEventObjectLifecycle »

Action Taken = <GAP>?

Metadata

When

Action - Date/ Time	Provenance	target : Resource(Any) 1..* period : Period 0..1
Record - Date/ Time	Provenance	recorded : instant 1..1
	SecurityEvent.Event	dateTime : instant 1..1
Action - Duration/ Elapsed Time	Provenance	period : Period 0..1

Metadata

Where

Action - Physical Location	Provenance	location : Resource(Location) 0..1
	SecurityEvent.Event	*location : Resource(Location) 0..1*
Record - Network Address	Provenance	location : Resource(Location) 0..1
	SecurityEvent.Participant.Network	identifier : string 0..1 type : code 0..1 « SecurityEventParticipantNetworkType »

Add “location” to SecurityEvent.Event?

Metadata

Why

Action - Reason, Rationale, Purpose	Provenance	reason : CodeableConcept 0..1
	SecurityEvent.Event	*reason : CodeableConcept 0..1*
Record - Reason, Rationale, Purpose	Provenance	reason : CodeableConcept 0..1
	SecurityEvent.Event	*reason : CodeableConcept 0..1*

Add “reason” to SecurityEvent.Event?

FHIR Resource

Provenance

Resource	Attribute	Description	Value Set
Provenance		Who, What, When for a set of resources	
	target : Resource(Any) 1..*	Target resources (usually version specific)	
	period : Period 0..1	When the activity occurred	
	recorded : instant 1..1	When the activity was recorded/updated	
	location : Resource(Location) 0..1	Where the activity occurred, if relevant	
	reason : CodeableConcept 0..1	Reason activity is occurring	

Create value set for “reason”?

FHIR Resource

Provenance.Agent

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

Review value sets for “role” and “type”.

FHIR Resource

SecurityEvent.Event

Resource	Attribute	Description	Value Set
SecurityEvent.Event		What was done	
	type : CodeableConcept 1..1 « SecurityEventType+ »	Type/identifier of event	<incomplete> Rest + DICOM codeset
	subtype : CodeableConcept 0..* « SecurityEventSubType+ »	More specific type/id for the event	<incomplete> Read, vread, update, delete, validate, create, history-instance, history-type, history-system, search-type, search-system, transaction + DICOM codeset
	action : code 0..1 « SecurityEventAction »	Type of action performed during the event	<incomplete>
	dateTime : instant 1..1	Time when the event occurred on source	
	location : Resource(Location) 0..1	TBD	
	reason : CodeableConcept 0..1	TBD	TBD

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

FHIR Resource

SecurityEvent.Object

Resource	Attribute	Description	Value Set
SecurityEvent.Object		Specific instances of data or objects that have been accessed	
	identifier : Identifier 0..1	Specific instance of object (e.g. versioned)	
	reference : Resource(Any) 0..1	Specific instance of resource (e.g. versioned)	
	type : code 0..1 « SecurityEventObjectType »	Object type being audited	<incomplete>
	role : code 0..1 « SecurityEventObjectRole »	Functional application role of Object	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.
	lifecycle : code 0..1 « SecurityEventObjectLifecycle »	Life-cycle stage for the object	<incomplete>

Review value sets for “type”, “role” and “lifecycle”.

FHIR Resource

SecurityEvent.Participant.Network

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	<incomplete>

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 to many individual practitioners and
  - one to many patients
- An EHR comprises
  - one to many Record Entry instances
- A Record Entry instance may comprise
  - one to many FHIR Resource instance(s)

Project Focus/Success Criteria

FHIR Enabled Lifecycle Events

Project Focus	Success Criteria
Binds (joins) FHIR Resource Instance(s) together in Record Entry Instance: • Including applicable Clinical, Administrative, Infrastructure Resources • Based on Action(s) Taken	• Complete specification of baseline Set of FHIR Resources applicable at each Record Lifecycle Event (1-24) and captured in the resulting Record Entry Instance • Allowing additional Resources to be bound in a Record Entry Instance, per Clinical, Administration and/or other context
Includes Pre- and Post-Lifecycle Event Entry States • e.g., before/after amendment or translation	• Complete specification of how both pre- and post-lifecycle event states (of FHIR Resources) are captured and preserved in one or more Record Entries

Project Focus/Success Criteria

FHIR Enabled Lifecycle Events

Project Focus	Success Criteria
Includes Action/Event Metadata	• Complete specification of Action/Event Metadata (in FHIR Resources) per Record Entry
Includes Attestation and Content Binding • With/without Digital Signature	• Complete specification of: • Attestation and/or Digital Signature bound to Record Entry content

EHR Record Lifecycle/Lifespan

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

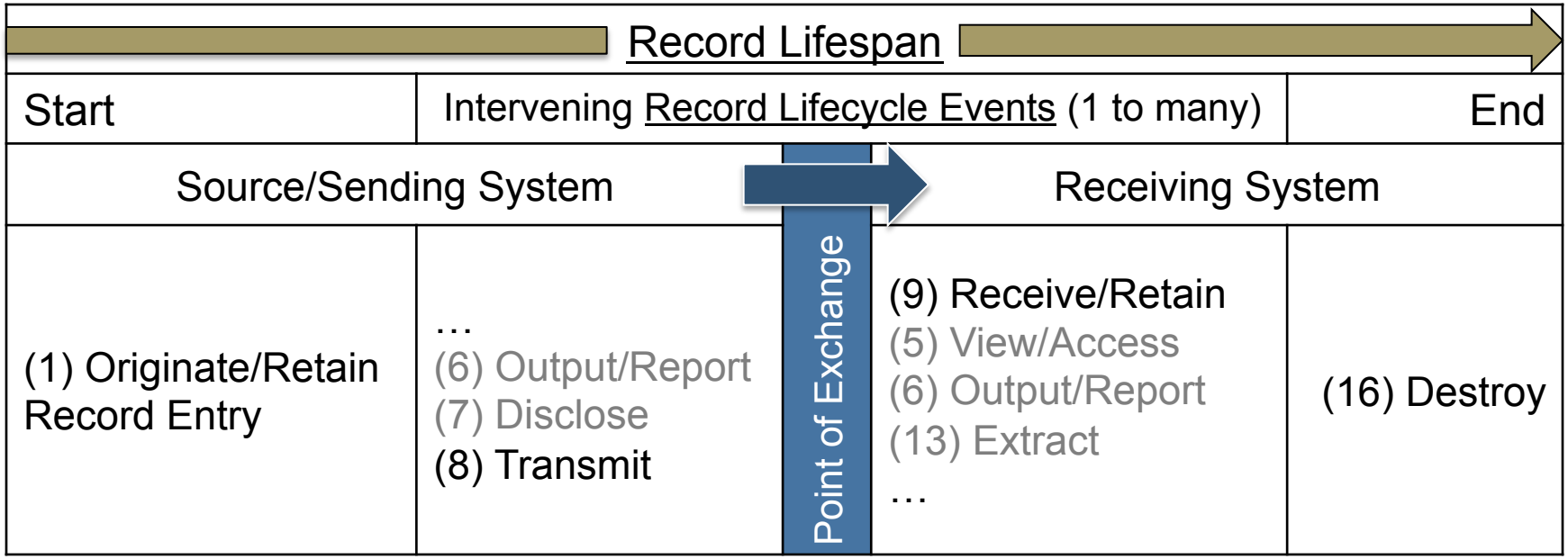
Record Lifespan – End-to-End

Within Single System

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

Record Lifespan – End-to-End

Across Multiple Systems



Repeated at each point of exchange…

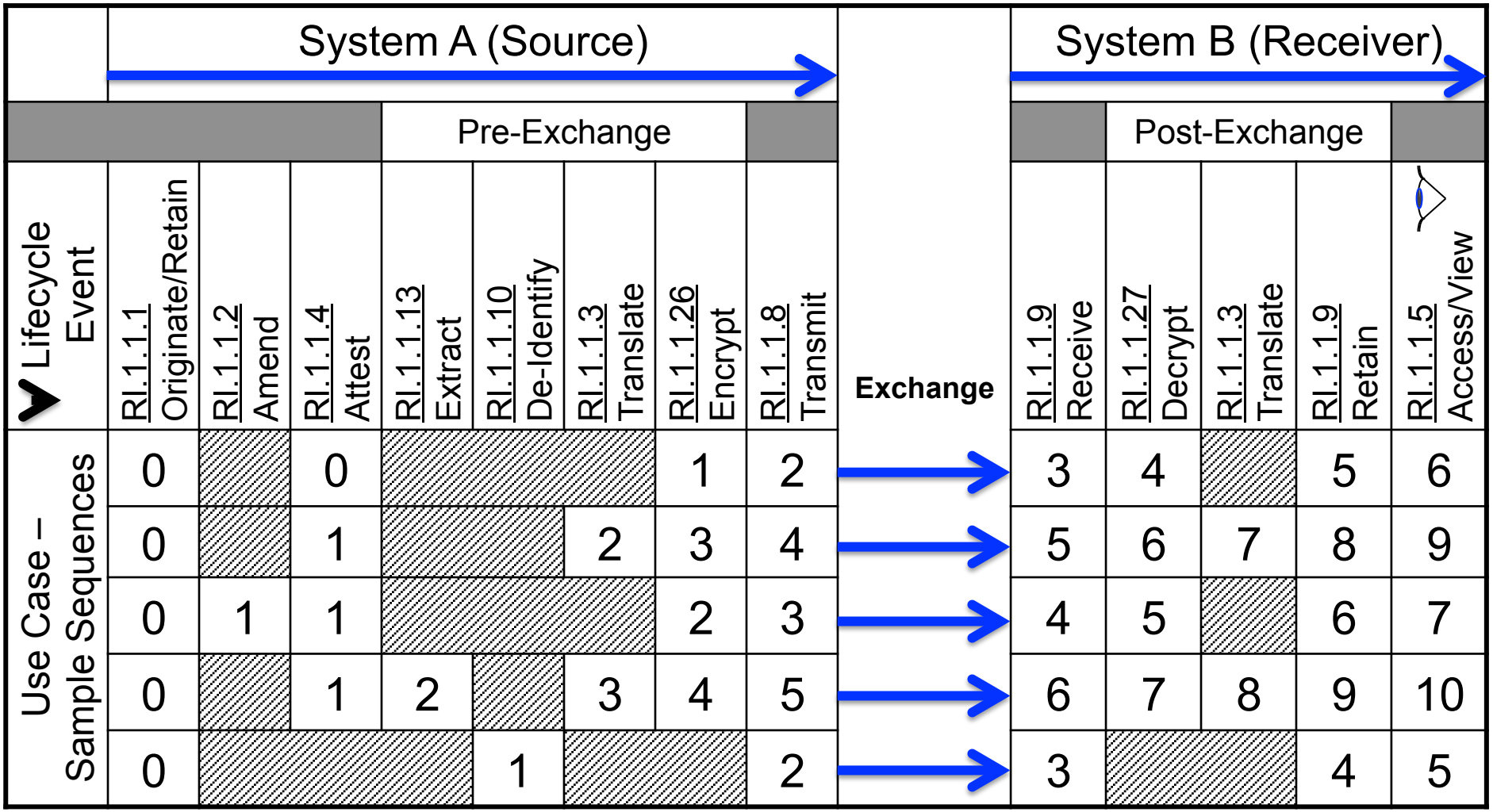
Record Lifecycle Events

Sample Sequences

	System A (Source)			System B (Receiver)		
1	◆Originate ◆Retain	◆Attest ◆Encrypt	◆Disclose ◆Transmit	◆Receive	◆Decrypt	◆Retain ◆Access
2		◆Attest ◆Translate ◆Encrypt			◆Decrypt ◆Translate	
3		◆Amend ◆Attest ◆Encrypt			◆Decrypt	
4		◆Attest ◆Extract ◆Translate ◆Encrypt			◆Decrypt ◆Translate	
5		◆De-Identify				

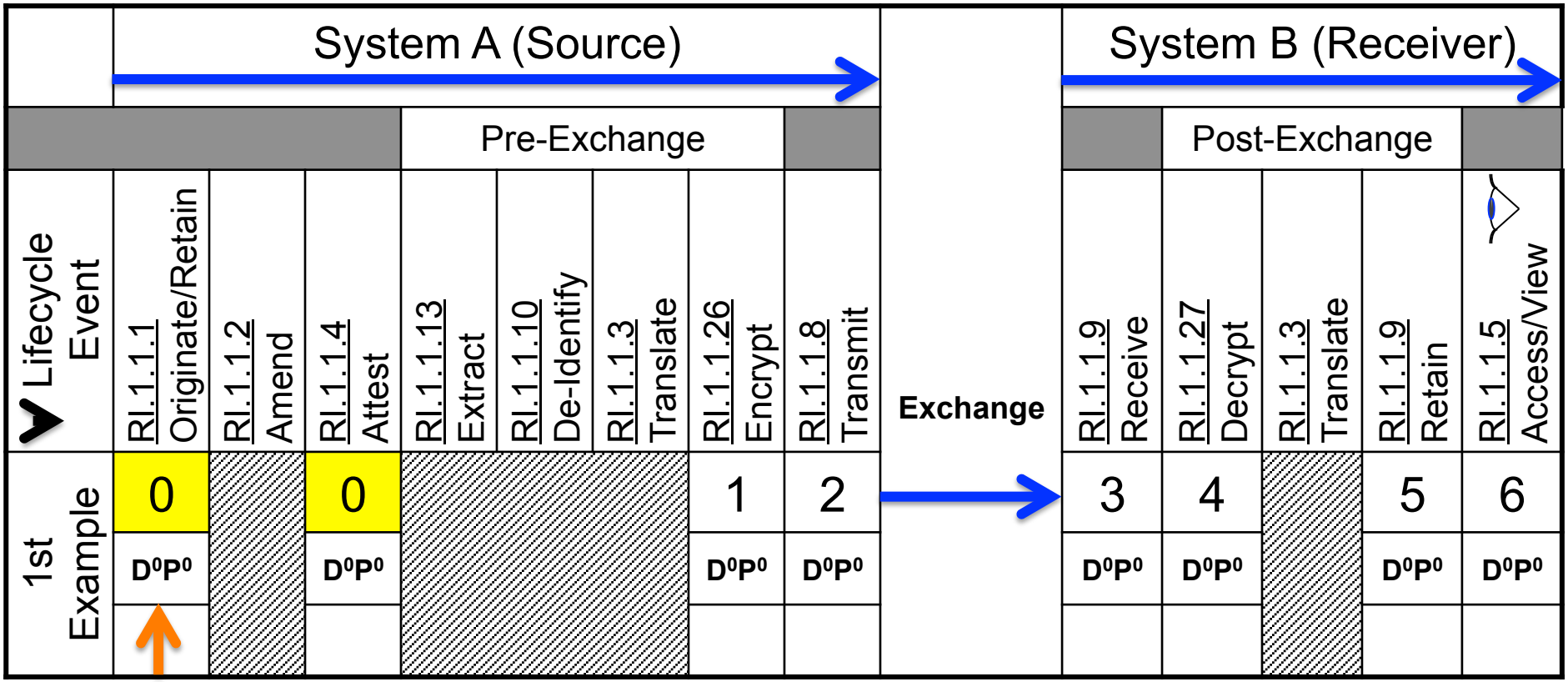
Record Lifecycle Events

Examples Du Jour



1st Example

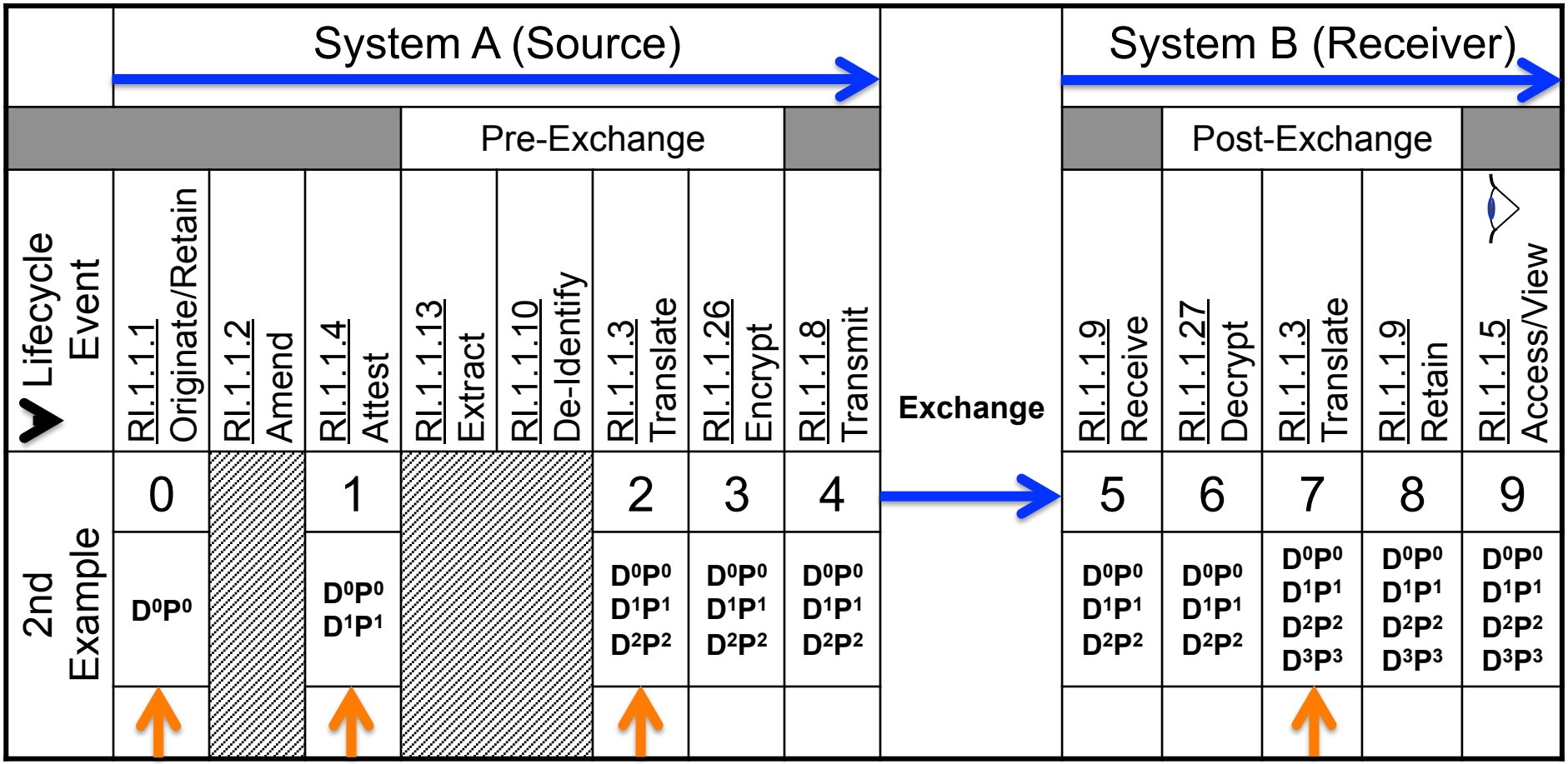
Lifecycle Event Sequences



= New Provenance Event; D^XP^X = Data/Provenance Duplets

2nd Example

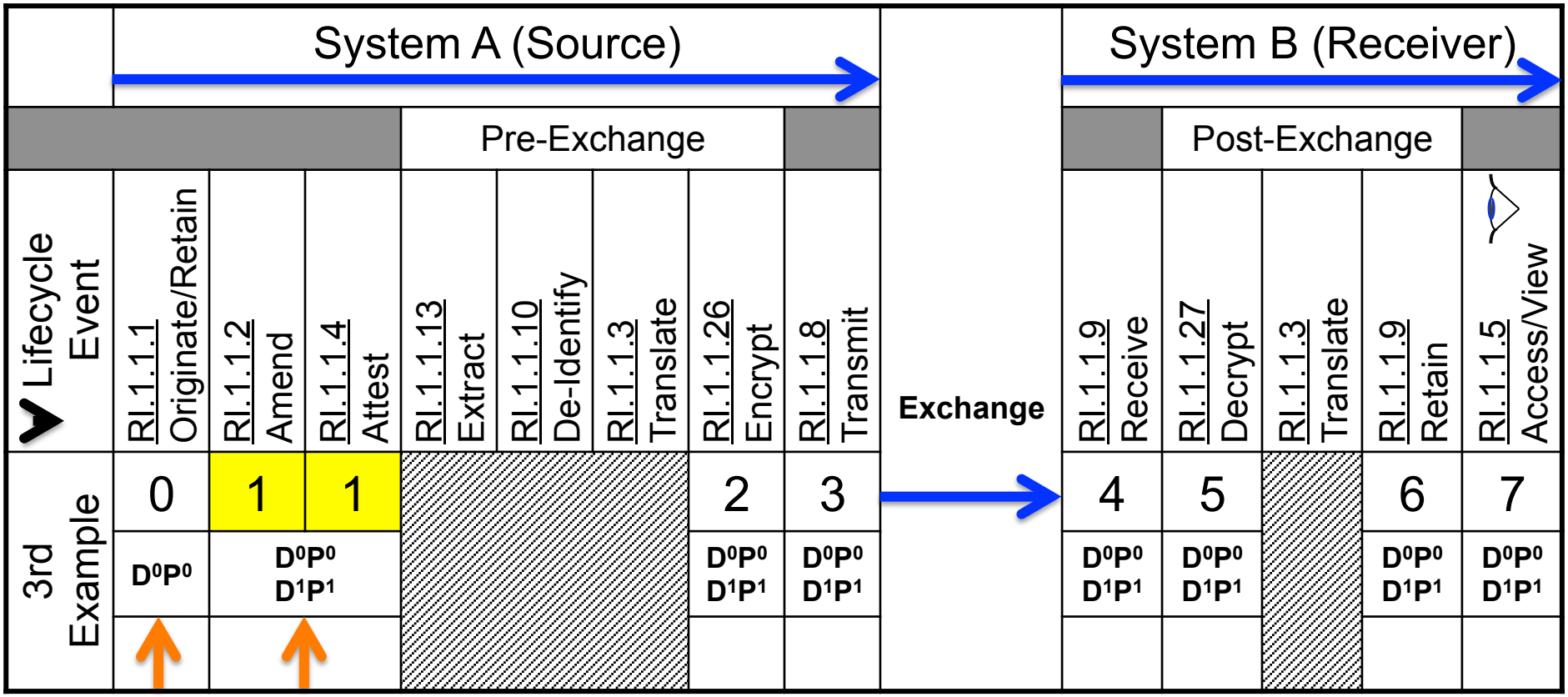
Lifecycle Event Sequences



= New Provenance Event; D^XP^X = Data/Provenance Duplets

3rd Example

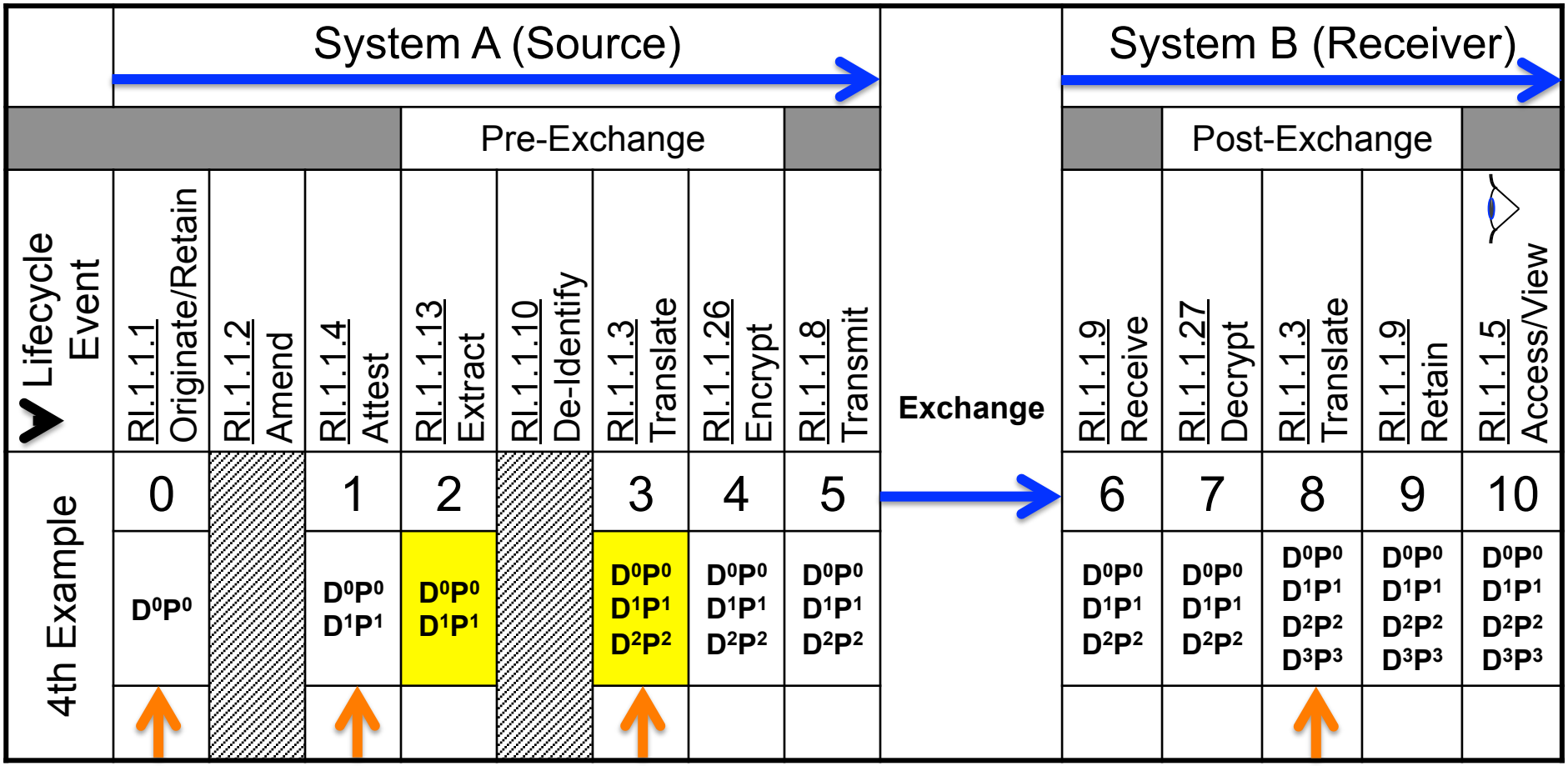
Lifecycle Event Sequences



↑ = New Provenance Event; D^XP^X = Data/Provenance Duplets

4th Example

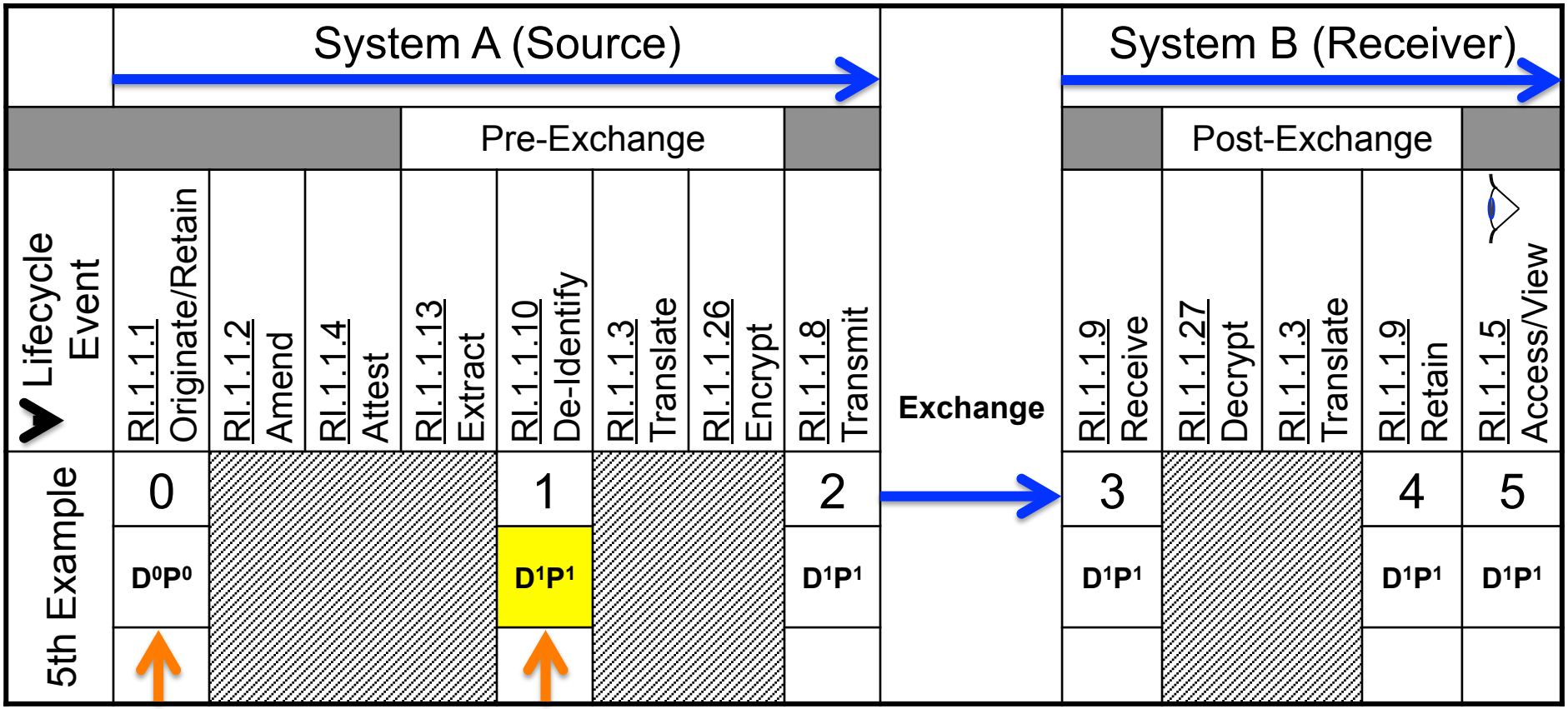
Lifecycle Event Sequences



= New Provenance Event; D^XP^X = Data/Provenance Duplets

5th Example

Lifecycle Event Sequences



= New Provenance Event; D^XP^X = Data/Provenance Duplets

Longer Term…

Project Segments/Leads

		Leads
1	ISO/HL7 10781 EHR-S FM R2 RI – Record Infrastructure RM-ES – Records Management/ Evidentiary Support	Gary Dickinson, Reed Gelzer, MD, 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	ISO/HL7 16527 PHR-S FM R1 PH – Personal Health S – Supportive II – Information Infrastructure	John Ritter, et al.

Links

- HL7 EHR Interop Wiki:
  - http://wiki.hl7.org/index.php?title=EHR_Interoperability_WG