S&I Data Provenance Initiative

# Introduction to ISO/HL7 Standards for EHR Record Lifecycle and Lifespan

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Key Standards References

# Record Lifecycle Events

- 2004 –
  ISO 21089 – Trusted End-to-End Information Flows
  - Now in revision
- 2008 –
  HL7 EHR Lifecycle Model DSTU
- 2014 –
  ISO/HL7 10781 – EHR System Functional Model R2
  - Record Infrastructure (RI) Section
  - Includes HL7 EHR Lifecycle Model DSTU
  - Includes Records Management/Evidentiary Support (RM-ES) Functional Profile Release 1

# Actions, Actors, Record Entries

- Actions are taken:
  - To support patient health;
  - In provision of healthcare to individuals;
  - As the result of rules-based EHR System algorithms.
- Actors (i.e., patients, providers, users, systems) take Actions.
- Actions broadly encompass tasks, acts, procedures or services performed or provided.
- The EHR System captures Actions taken and creates corresponding Record Entries.
  - Action instances are documented by EHR Record Entry instances.
- Record Entries provide persistent evidence of Action occurrence, context, disposition, facts, findings and observations.

EHR-S FM Record Lifecycle and Lifespan (RI.1) Description

# Metadata, Signatures, Chronology

- Record Entries may be captured during the course of the Action or sometime thereafter.
- Actions have associated metadata including provenance
  - Who, what, when, where, why, how, under what conditions, in what context.
  - The corresponding Record Entry captures this metadata along with other Action and Record Entry related information.
- Record Entries may be encapsulated to bind Actor (individual, organization, and/or system) signatures to data and metadata content and data/time of occurrence.
- Actions and related Record Entries capture a chronology of:
  - patient health and healthcare; and
  - operations and services provided in/by a healthcare enterprise.

EHR-S FM Record Lifecycle and Lifespan (RI.1) Description

# Persistence, Indelibility, Events

- Each Record Entry serves as persistent evidence of an Action taken, enabling providers to maintain comprehensive information that may be needed for legal, business, and disclosure purposes.
- To satisfy these purposes, Record Entries must also be retained and persisted without alteration.
- Record Entries have both a lifecycle and a lifespan.
- Lifecycle Events include originate, retain, amend, verify, attest, access/view, de-identify, transmit/receive, and more.
- Lifecycle Events occur at various points in a Record Entry lifespan, always starting with a point of origination and retention (i.e., when the Entry is first created and stored).

# Pre/Post Event, Entry Content

- A Record Entry may have a pre and post Event state if content is modified.
- In this case, the original Record Entry is preserved (with signature binding) and a new Entry is created (with new signature binding).
- A Record Entry contains data and metadata, in multiple formats, following various conventions and standards.
- Record Entry Content may be:
  - Tagged and/or delimited;
  - Structured (concise, encoded, computable); or
  - Unstructured (free form, non-computable);
  - Encoded as text, document, images, audio, waveforms, in ASCII, binary or other encoding.

EHR-S FM – Sample Conformance Criteria

# 1 – Originate/Retain Record Entry

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.

↑ At Lifecycle Event Occurrence
With Event Evidence →

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.

| ISO/HL7 Standard or S&I Activity ➔<br>Vocabulary Work Underway: HL7 EHR, CBCC, Security Work Groups ➘<br>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

# Dimensions of End-to-End Flow

## Record Entry 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 destruction/deletion
2. Across Multiple Systems
   - Starting at point of origination, in Source System
   - Traversing one or more Points of Exchange
   - Ending at point of destruction/deletion, in each System

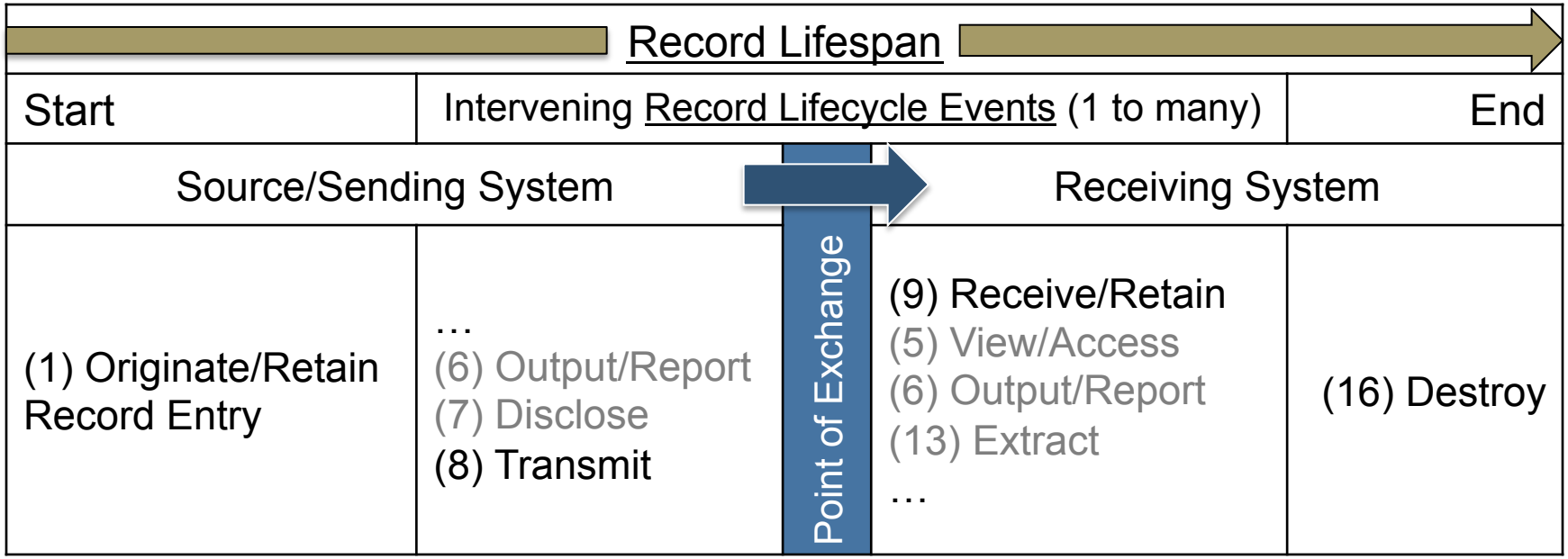
Record Lifespan – End-to-End

# Within Single System

| Record Lifespan | | |
|---|---|---|
| Start | Intervening Record Lifecycle Events (0 to many) | End |
| Source System<br>(1) Originate/ Retain Record 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<br>(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 |
| Receiving System<br>(9) Receive/Retain Record Entry | | (16) Destroy |

Record Lifespan – End-to-End

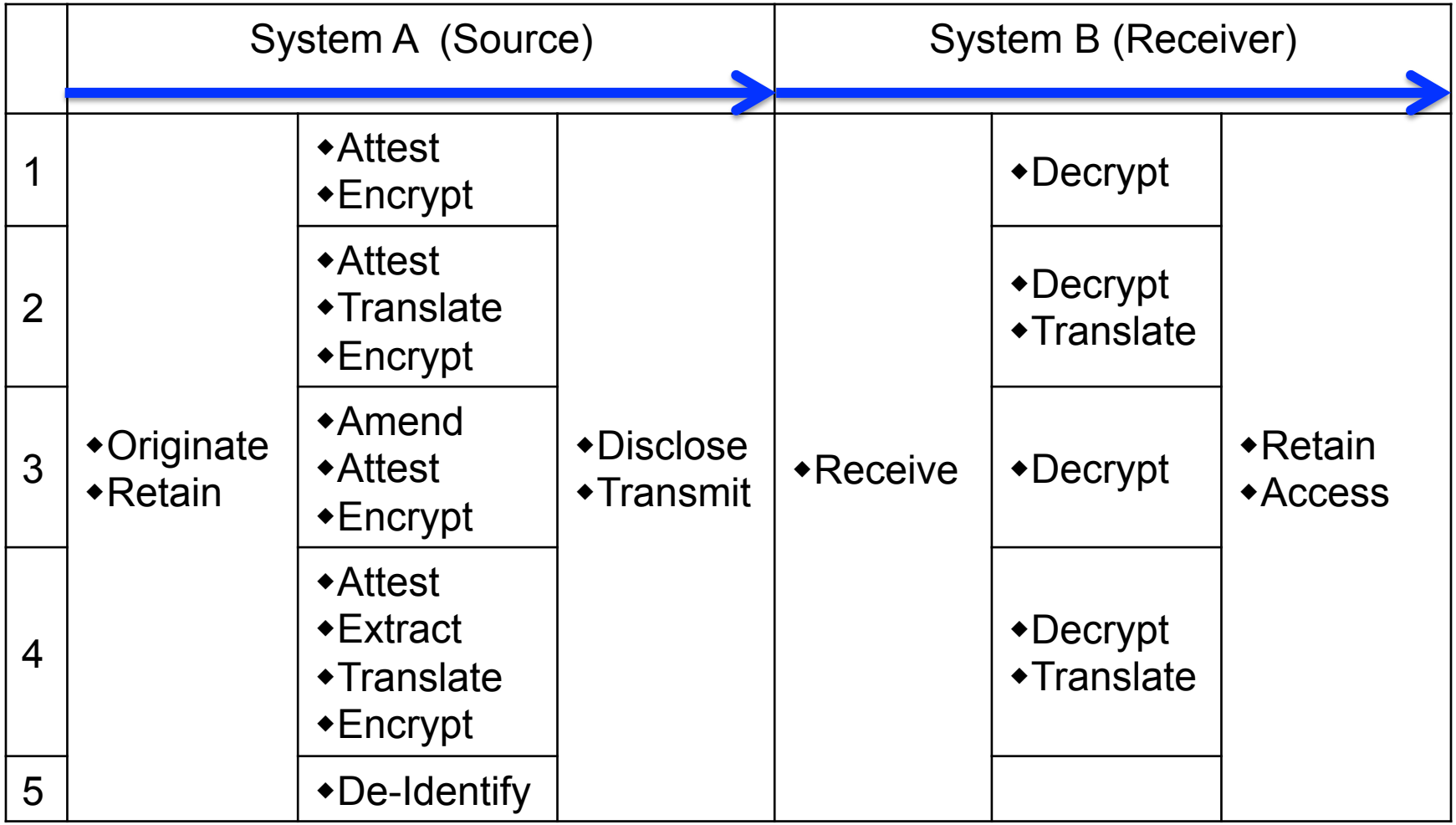
# Across Multiple Systems




Repeated at each point of exchange…

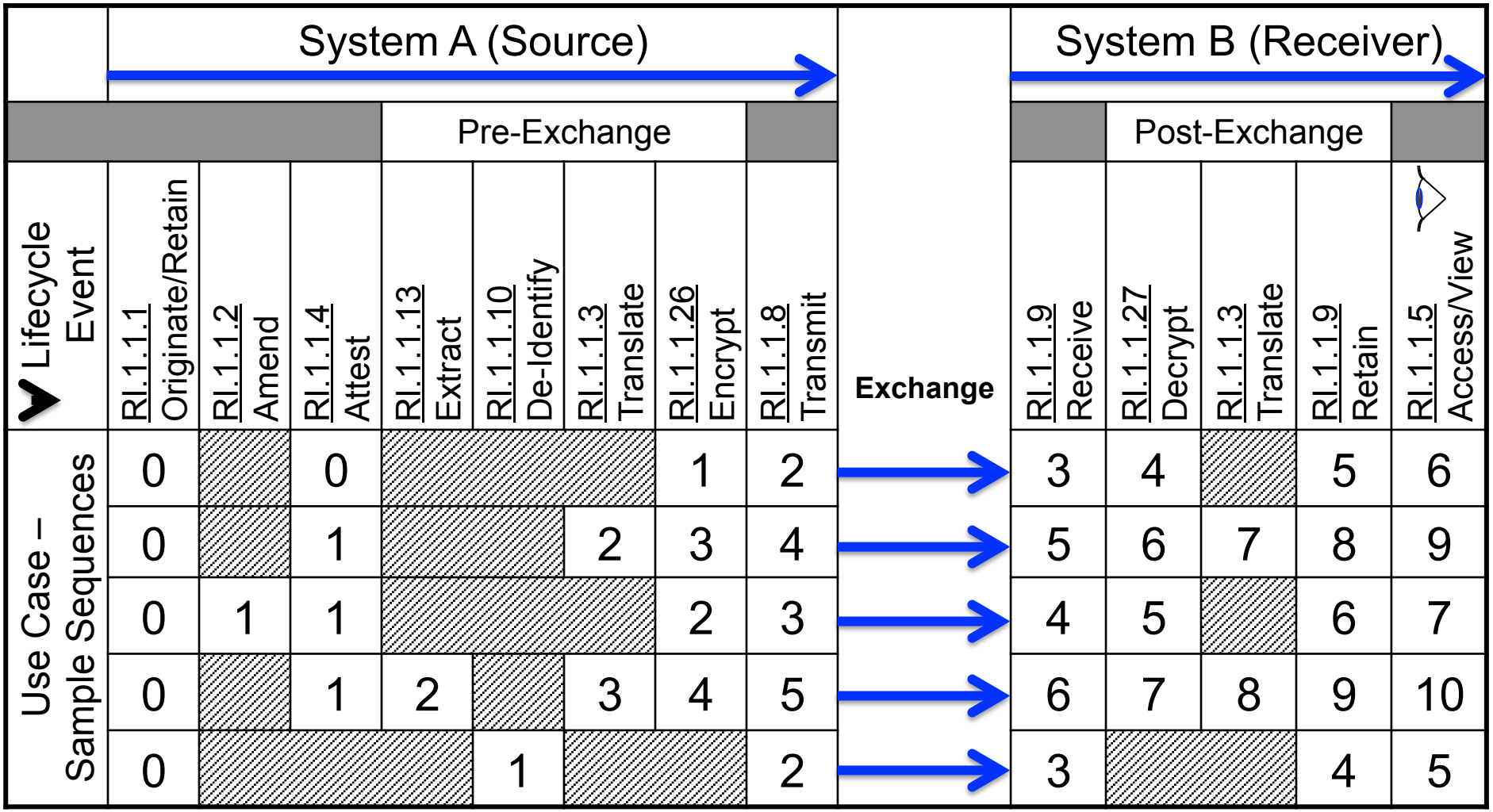
Record Lifecycle Events

# Sample Sequences



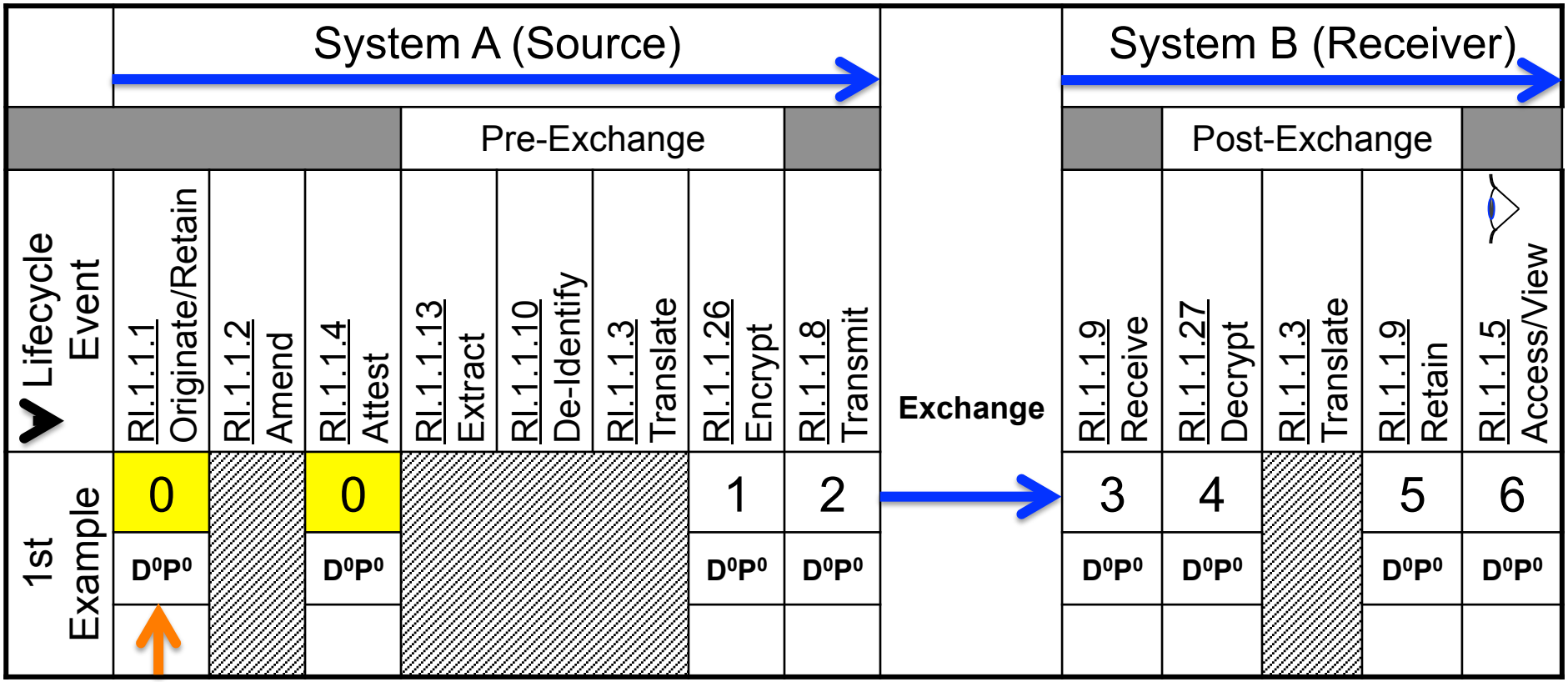
Record Lifecycle Events

# Examples Du Jour



1st Example

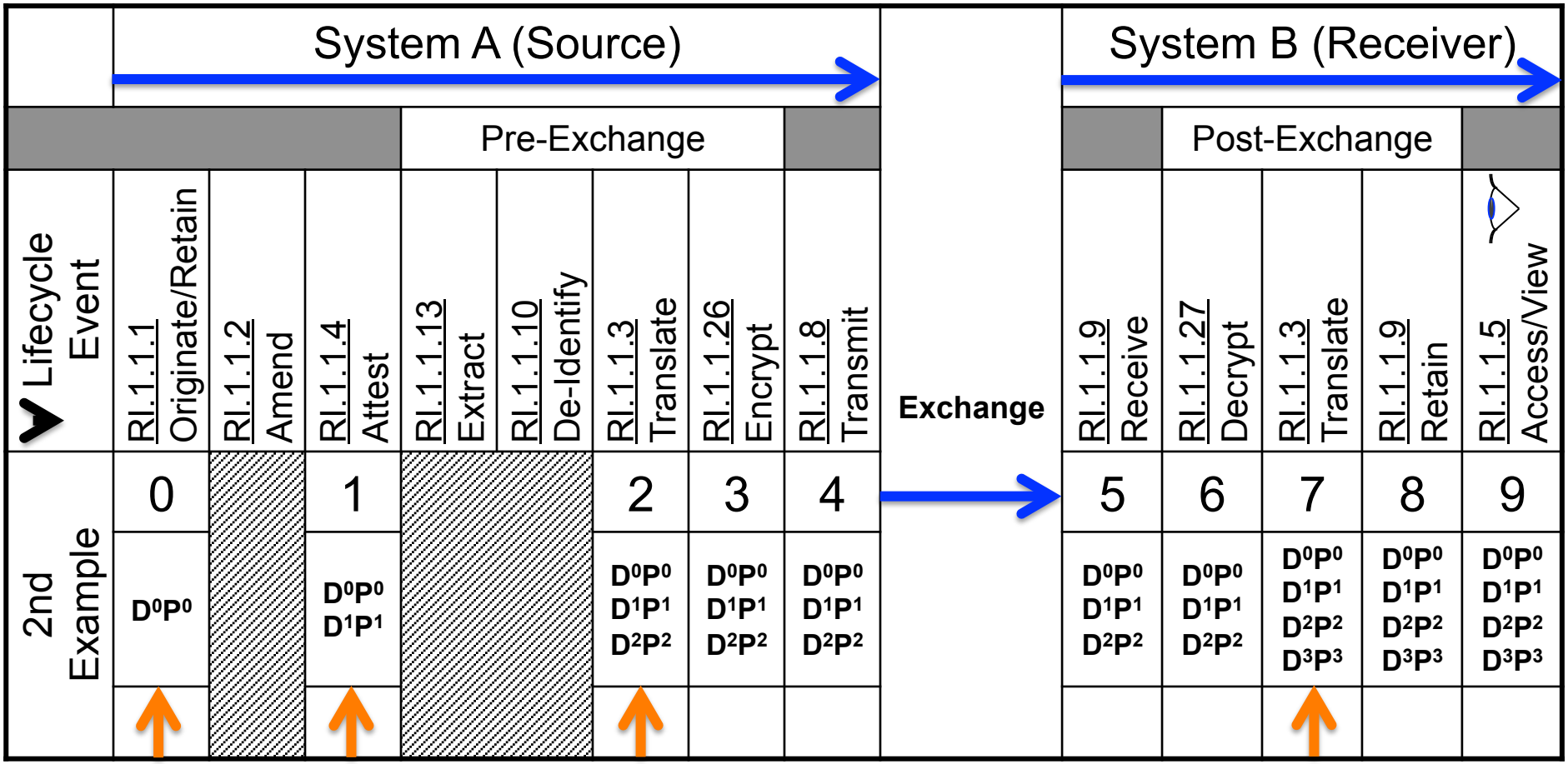
# Lifecycle Event Sequences




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

2nd Example

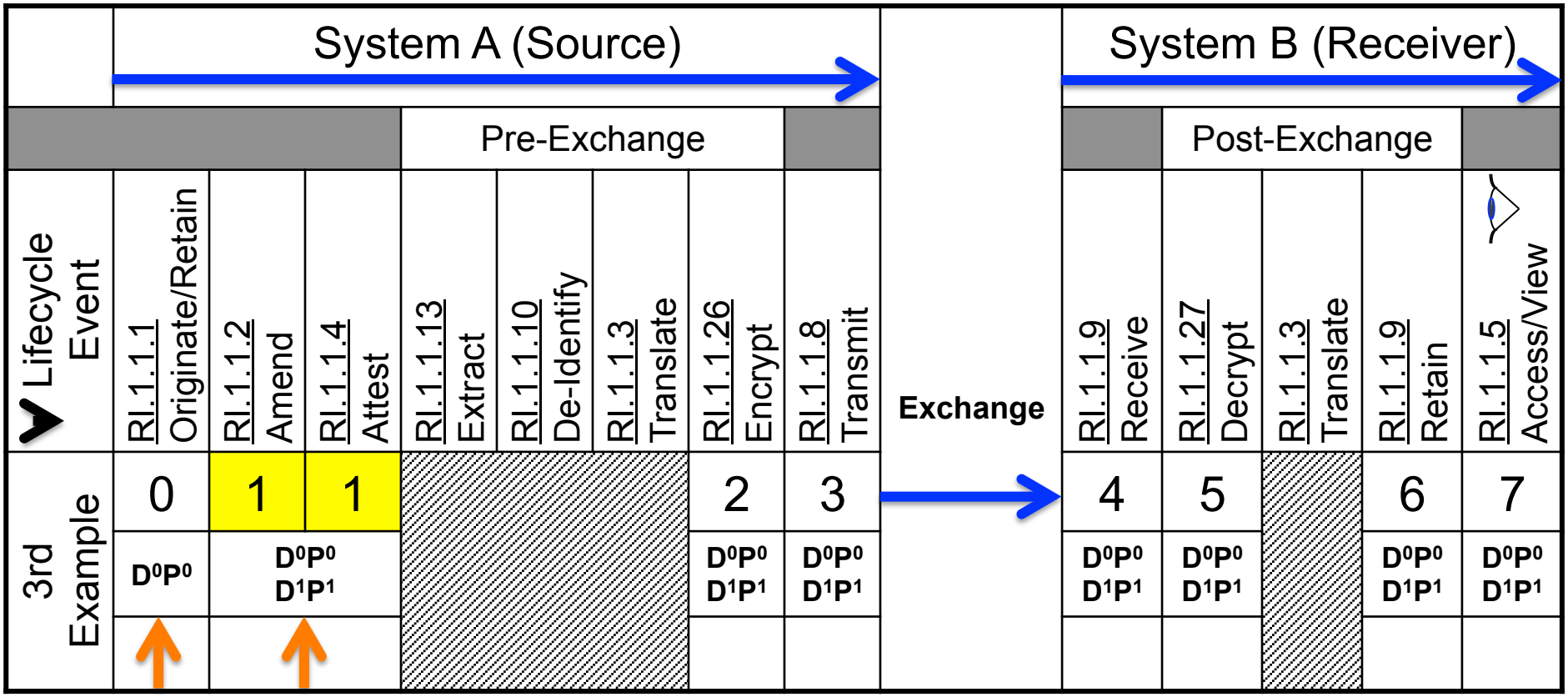
# Lifecycle Event Sequences




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

3rd Example

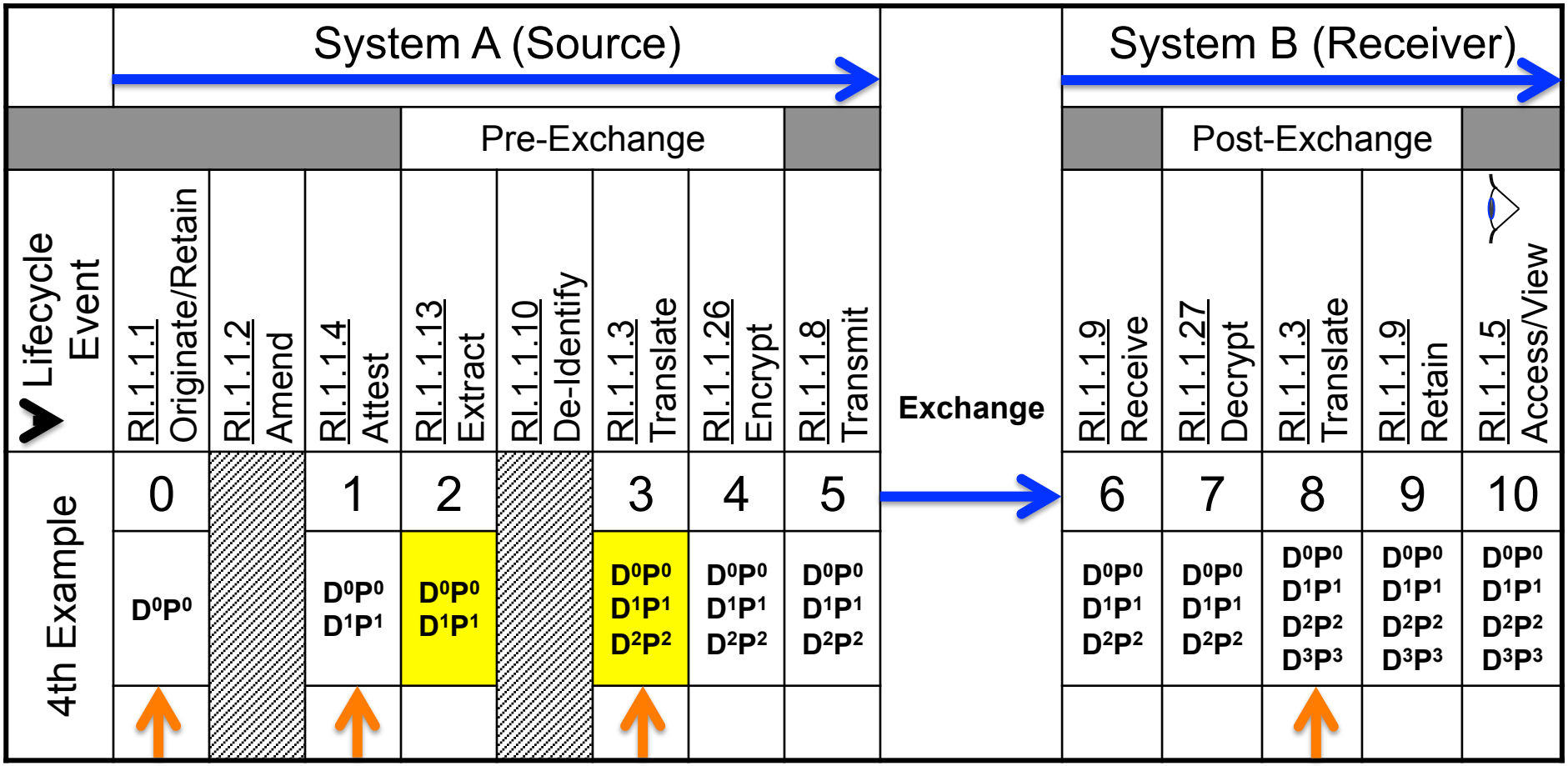
# Lifecycle Event Sequences




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

4th Example

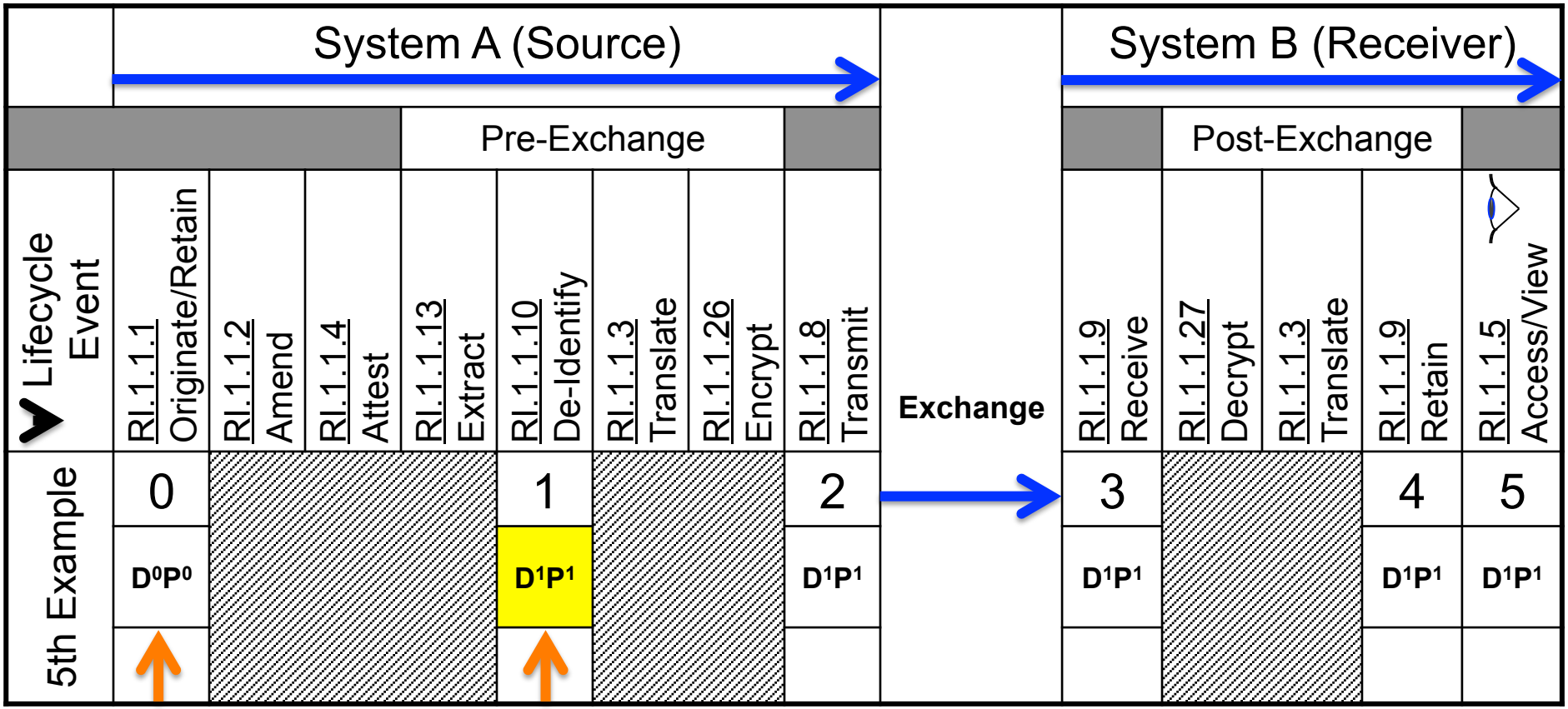
# Lifecycle Event Sequences




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

5th Example

# Lifecycle Event Sequences




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