

**Alignment**  
**ONC/AHIC/HITSP Use Cases**  
**w/HL7 EHR/PHR Models**

Chapter 1: Year 1 EHR/Lab Results Reporting

HL7 EHR Technical Committee  
EHR Interoperability Working Group  
26 December 2007

# Prepared for Presentation to...

- ANSI HITSP Foundations Committee
  - Per request of Robert Dolin, MD, FC Co-Chair (15 March 2007)
  - Per approval of EHR TC (22 October 2007)
- DHHS Office of the National Coordinator
  - Per request of John Loonsk, MD (13 November 2007)

# HL7 Electronic Health Record Technical Committee

HL7 EHR Technical Committee

# Mission

Establish requirements for:

- Functionality of EHR and PHR Systems
- Ubiquitous Record Interoperability amongst EHR and PHR Systems
- End-to-End Trust Framework for Interoperable EHR Records

# HL7 EHR TC/EHR Interoperability Working Group Projects

- “Coming to Terms” White Paper
  - Compilation and Analysis of Industry “Interoperability” Definitions
- EHR Interoperability Model
- EHR Lifecycle Model
- Alignment of ONC/AHIC/HITSP Use Cases w/HL7 EHR/PHR Models
  - Starting w/Year 1 EHR/Lab Results Reporting

# HL7 EHR/PHR Models

# HL7 EHR Technical Committee

## EHR/PHR Models

	HL7 Model	Specifies...
SYSTEMS	EHR Functional Model (EHR/FM)	Functional characteristics (functions) of Electronic Health Record <u>Systems</u> (EHR)
	PHR Functional Model (PHR/FM)	Functional characteristics (functions) of Personal Health Record <u>Systems</u> (PHR)
RECORDS	EHR Interoperability Model (EHR/IM)	Characteristics of interoperable EHR <u>Records</u>
	EHR Lifecycle Model (EHR/LM)	Key events in the EHR <u>Record</u> lifecycle

# HL7 EHR System Functional Model

## EHR/S/FM

- Normative Standard
  - Balloted/approved January 2007
  - Published March 2007
- HL7 and ANSI Approved
- Approved as ISO TC215 Work Item
- Specifies functional characteristics (functions) of EHR Systems
- Is profiled for care settings, localities and uses
  - EHR Systems conform to EHR/S/FM Profiles
- Is used as framework for CCHIT certification of EHR Systems

### Alignment Analysis:

- Specifies functions required (or likely to be invoked) by each Use Case Action
- Optionally, specifies function-related conformance criteria
- Identifies gaps (i.e., missing functions or criteria)



# HL7 PHR System Functional Model

## PHRS/FM

- Draft Standard for Trial Use
  - Balloted/approved December 2007
- Specifies functional characteristics (functions) of PHR Systems
- May be profiled for sponsors, localities and uses
  - PHR Systems conform to PHRS/FM Profiles
- Offers potential framework for CCHIT certification of PHR Systems (future)

### Alignment Analysis:

- Specifies functions required (or likely to be invoked) by each Use Case Action
- Optionally, specifies function-related conformance criteria
- Identifies gaps (i.e., missing functions or criteria)

# HL7 EHR Interoperability Model

## EHR/IM

- Draft Standard for Trial Use
  - Balloted/approved January 2007
  - Published March 2007
- Specifies characteristics of interoperable EHR records
- Establishes Common EHR Record Unit (Action Record)
- Establishes/anchors end-to-end “chain of trust” for EHR Records
  - From point of record origination
  - To each ultimate point of record access/use
  - Traversing multiple points of exchange, if applicable

### Alignment Analysis:

- Shows each Use Case Action documented by persistent Action Record, as applicable
- Shows which EHR interoperability requirements are applicable to each Use Case
- Shows how Action Records are ascribed as to: Who, What, When, Where (Action Context)
- Identifies gaps (i.e., missing interoperability characteristics or criteria)

# HL7 EHR Lifecycle Model

## EHR/LM

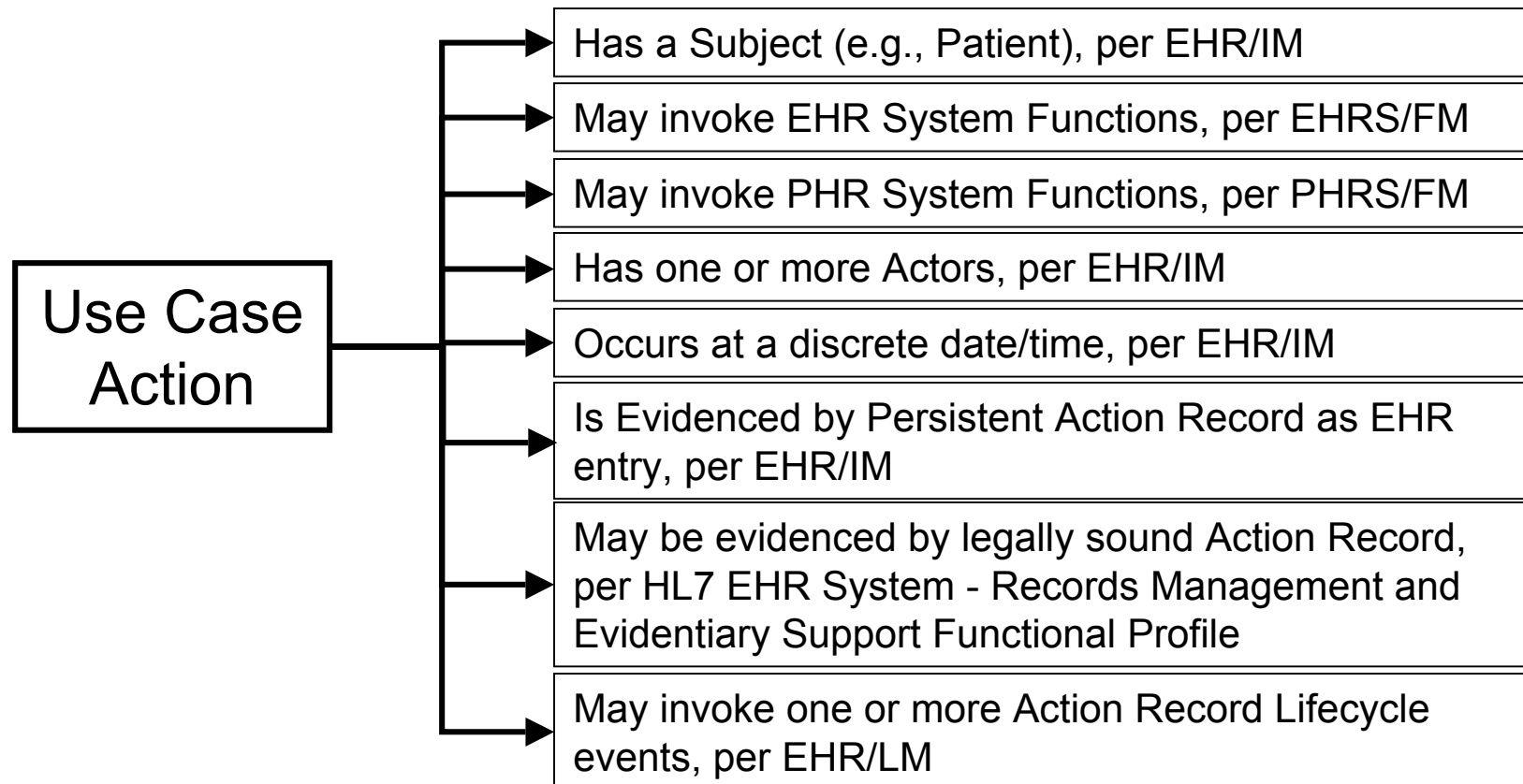
- Pending Draft Standard for Trial Use
  - In ballot December 2007
- Shows record lifecycle events within System retaining EHR records
- Shows end-to-end record lifecycle events across multiple Systems and traversing points of record exchange
- Supplements EHR Interoperability Model

### Alignment Analysis:

- Specifies EHRS lifecycle event(s) corresponding to each Use Case Action
- Identifies gaps, missing events

## Support for Use Case Actions

# Designed into HL7 Models



etc...

# The Premise and A Simple Objective

A Simple Objective

# Premises

- Patient Privacy and Confidentiality of Patient Health Records are Paramount
  - Record subject controls access, use and disclosure - within legal bounds
- Health Records provide persistent, indelible evidence of Actions taken in health(care)
- Health Record Authors and Users are accountable for their specific Actions

A Simple Objective

# Premises, con't

- Health Records must be protected by an End-to-End Trust Framework
  - Traceable from Point of Record Origination to each Point of Record Access/Use
- Health Records must be interoperable between and amongst EHR and PHR Systems
- Health Records must be interoperable across, and neutral to:
  - Software products and architectures, technologies
  - Networks

A Simple Objective

# Premises, con't

- Health Records are the immediate record (documentation) of health(care) and are
  - Integral to work flow and
  - Concurrent to clinical practice
- Health(care) occurs at points along a time continuum
- Health Records document (evidence) health(care) along the same time continuum



A Simple Objective

# Ready Adoption

- Facilitate Adoption
  - Make it technology, vendor and product neutral
  - Make it easy to understand
  - Make it easy to implement by small and large alike
  - Make it easy to bring to market
  - Make it applicable to US and international alike
- Simplification Drives Adoption

A Simple Objective

# Common EHR Currency

- Establish common EHR Currency
  - A common EHR unit of record
- Simplify retention, interchange and protection to a simple common record unit
  - Not 100s of proprietary and pseudo standard formats
  - Not 1000s of message variants (see HL7 v2/v3)
- Simplify interchange triggers to key EHR lifecycle events
  - 10 or 15 record-related trigger events
  - Not 1000s of trigger event variants (see HL7 v2/v3)

A Simple Objective

# Trust Protections

- Embed Health Record trust protections, ensuring accountability and traceability
  - Consent-based use and disclosure
  - Source System and Author authentication
    - w/Digital Signature
  - Content authentication: original, amended, current
  - Access control: to Access/View Record, to Amend Record
  - Traceable Record Audit Trail encompassing:
    - Amendments, Revision History
    - End-to-End Flow and Custody
    - Lifecycle Events: originate, verify, amend, access/view, transmit/disclose, receive, de-identify/alias, archive...
  - Attestation of Record Accuracy and Completeness

A Simple Objective

# In the HITSP Context

- Be Reproducible, Applicable to all Use Cases
  - 1-day Target: Use Case narrative to complete interoperability specification in one day
- Ensure Foundational Infrastructure for all HITSP Interoperability Specifications
  - Focused on Greatest Common Denominator
  - Ensuring Common (Simple) Core
  - Extended only in the exception
    - When necessary to incorporate isolated use case requirements

# A Paradigm for Accountability The Action + Action Record

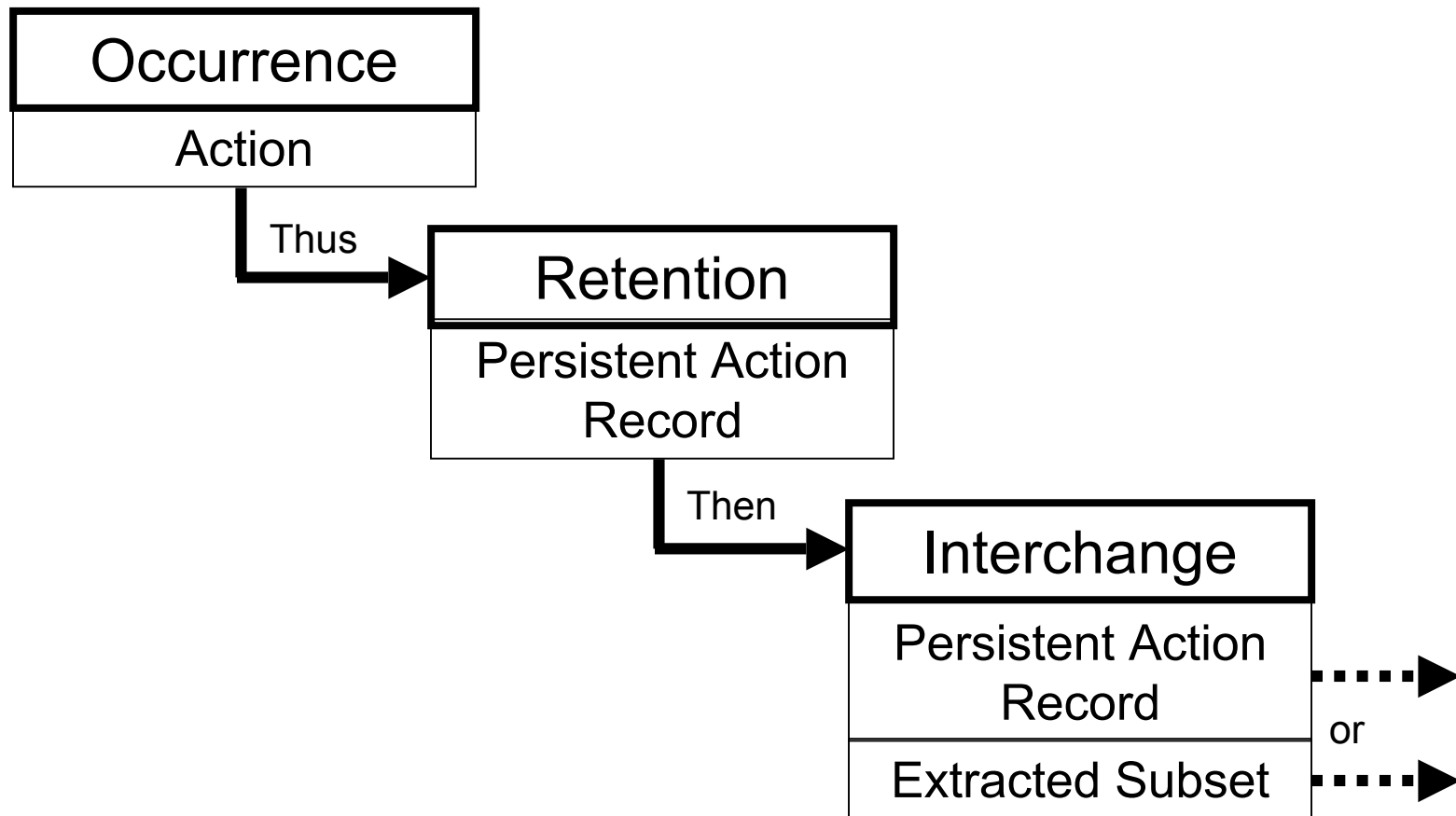
## EHR Interoperability Fundamentals

# Simple Paradigm

- Start with a discrete unit of service
  - Action
- Establish a corresponding EHR unit of record
  - Action Record
- Persist in EHR
  - Action Records = persistent entries in EHR

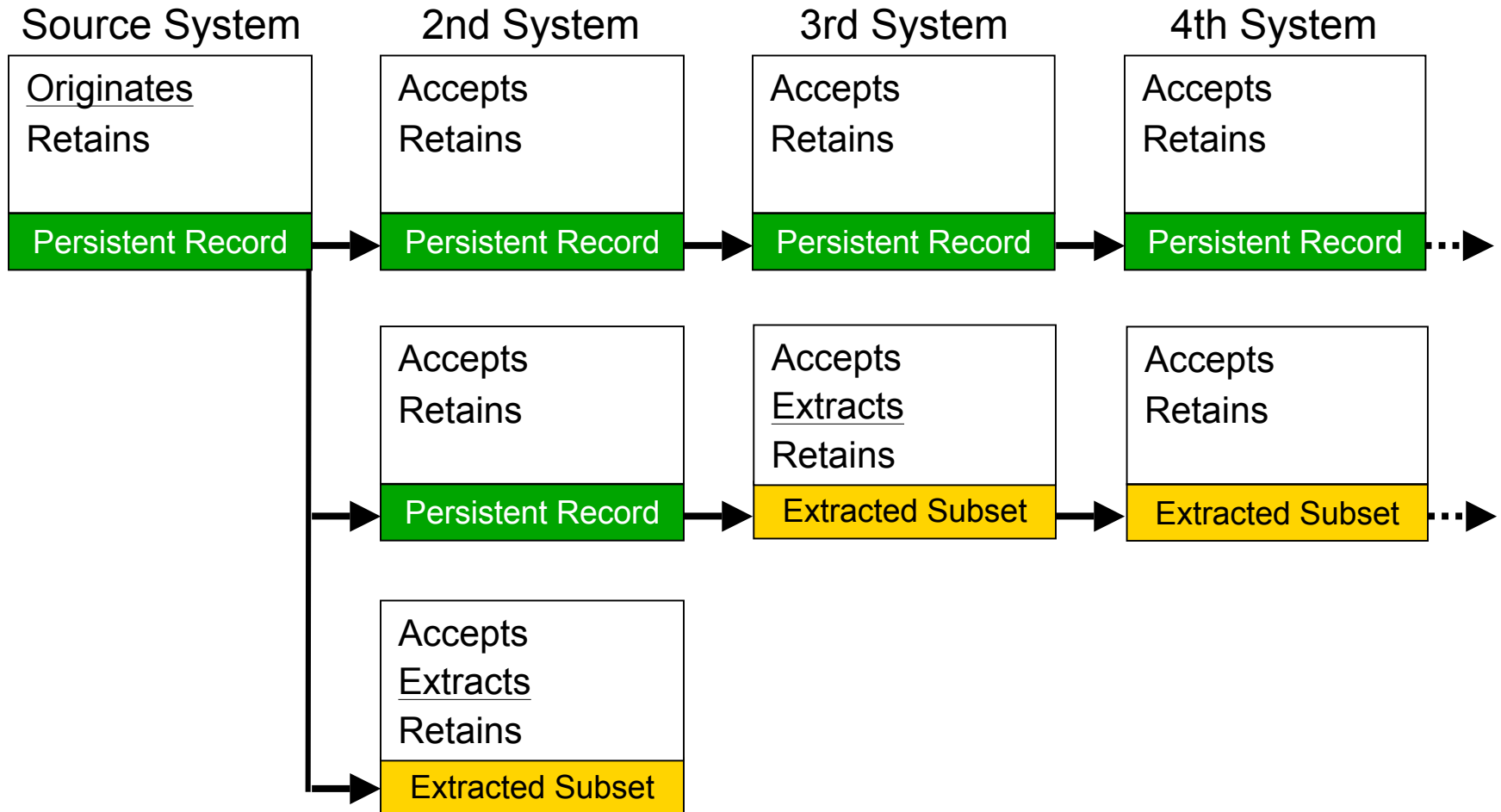
## EHR Interoperability Fundamentals

# Action/Persistence/Interchange



# Example Interchange Pattern


## Persistent Records and Extracted Subsets





# Information in Action

- All health(care) information derives from, or is attributable to, a discrete Action
- The essential context of health(care) information is indivisible from its originating Action
  - Who, What, When, Where

<b>Health(care) Delivery</b>	<b>Interoperable EHR</b>
Comprised of discrete Actions	Comprised of persistent Action Records
Action Occurs 	Action is documented by an Action Record in EHR (as Persistent Evidence of Action Occurrence)
Actions have a chronology of occurrence	Action Records have a corresponding chronology
Actions are a common unit of service in health(care)	Action Records are a common unit of record of the EHR

<b>Action...</b>	<b>Action Record...</b>
Occurs	Documents (evidences) Action occurrence
Has context <ul style="list-style-type: none"> <li>• Who, What, When, Where</li> </ul>	Documents Action context
Has facts <ul style="list-style-type: none"> <li>• Current and historical</li> </ul>	Documents Action facts
Has one or more Actor(s), in role(s) and participation(s) <ul style="list-style-type: none"> <li>• Roles: physician, nurse, pharmacist, therapist, secretary...</li> <li>• Participations: perform, assist, observe, scribe...</li> </ul>	Documents Actors, roles and participations
Is complete	Documents Action completion

<b>Action...</b>	<b>Action Record...</b>
If accountable to a Provider...	<ul style="list-style-type: none"> <li>• Is persistent evidence of Action occurrence</li> <li>• Is retained as a persistent EHR entry</li> <li>• May be attested as accurate and/or complete</li> </ul>
If consumer initiated...	<ul style="list-style-type: none"> <li>• May be retained as PHR (or EHR) entry - or not</li> </ul>

<b>Action...</b>	<b>Action Record...</b>
<ul style="list-style-type: none"> <li>• Is an instance: e.g., a discrete act, task or event</li> <li>• Is (often) an instance of care or service provided or performed</li> </ul>	<ul style="list-style-type: none"> <li>• Is a record instance</li> </ul>
<ul style="list-style-type: none"> <li>• Is a common convention to describe acts, tasks or events occurring in health(care)</li> </ul>	<ul style="list-style-type: none"> <li>• Is a common currency for health(care) information <ul style="list-style-type: none"> <li>– Spanning origination, retention, interchange and use</li> </ul> </li> <li>• Is a common unit of record</li> <li>• Is a persistent entry in the EHR</li> </ul>

<b>Action...</b>	<b>Action Record...</b>
Is confidential	<ul style="list-style-type: none"> <li>• Is a protected unit of record</li> <li>• May be encrypted e.g., while “in transit”</li> <li>• May have embedded access controls</li> <li>• Is auditable as to amendment history</li> <li>• May be auditable as to access, “chain of trust” and custody</li> <li>• May be de-identified or aliased</li> </ul>

## EHR Interoperability Fundamentals

# Sample Actions...

- Register Patient
- Admit, transfer or discharge Patient
- Patient Care
  - Examine, assess, observe
  - Plan care & set goals
  - Update problem list
  - Order diagnostics, medications or therapies
  - Provide care
  - Perform therapy or procedure
  - Administer medications
  - Provide nutrition
- Medications
  - Check allergies, interactions
  - Dispense, label
  - Renew, refill
- Specimens
  - Collect, label
  - Accession
  - Analyze, report results
- Schedule exam or appointment
- Refer Patient
- Transport Patient
- Consult w/examination

## EHR Interoperability Fundamentals

# Sample Actions, con't...

- Remind of:
  - Scheduled appointments
  - Periodic screening due
  - Immunizations due
- Notify Public Health Agency
  - Forward de-identified records
- Create Summary Record
  - e.g., CCR, CCD
- Forward Record(s) to PHR on behalf of Patient
- Perform epidemiological surveys
- Create acuity report
- Create staffing summary
- Create bed census
- Extract, report quality indicators
- Test, calibrate instrument
- Repair equipment
- Perform safety and emergency drills
- and many more...



## EHR Interoperability Fundamentals

# Quick Review

- Each (accountable)  
Action instance
- Has a corresponding  
(persistent)  
Action Record instance

# Use Case Alignment Analysis

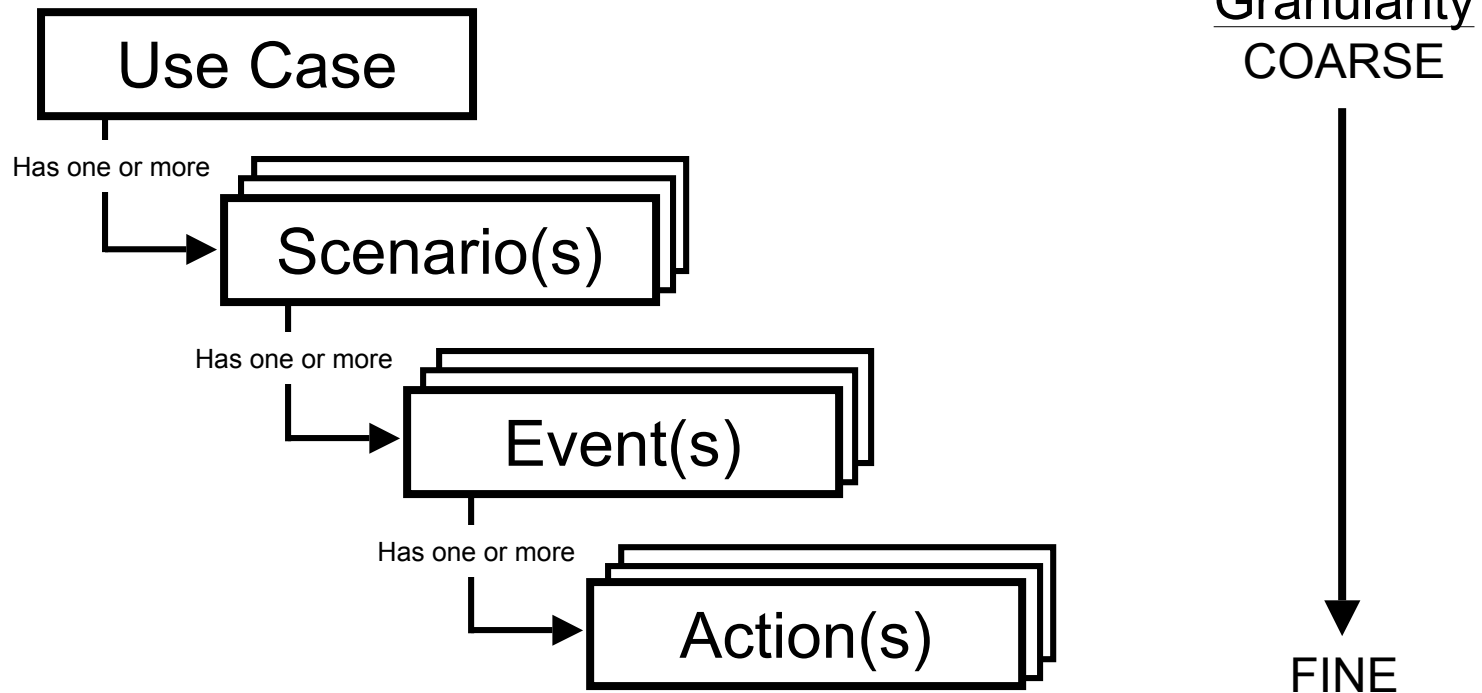
ONC/AHIC/HITSP

# Year 1 Use Cases

- Care Delivery
  - EHR/Lab Results Reporting
  - Analysis complete
- Consumer Empowerment
  - Demographics and Medication History
  - Analysis in progress
- Population Health
  - Biosurveillance
  - Analysis in progress

ONC/AHIC/HITSP

# Use Case Hierarchy



Actions occur at leaf level of each Use Case.

# Use Case Alignment Analysis

## Methodology

1 Review Use Case narrative, Scenarios, Events and Actions.

For each Use Case Action:

2a Specify which EHR system function(s) it likely invokes.

2b Specify any EHR system function(s) that are required but absent from the current EHRs/FM (a gap).

3a Specify which PHR system function(s) it likely invokes.

3b Specify any PHR system function(s) that are required but absent from the current PHRS/FM draft (a gap).

4a Many provider Actions are accountable from a clinical and medical/legal perspective and require a persistent Action Record. Determine which Use Case Actions require an Action Record, as persistent evidence of Action occurrence.

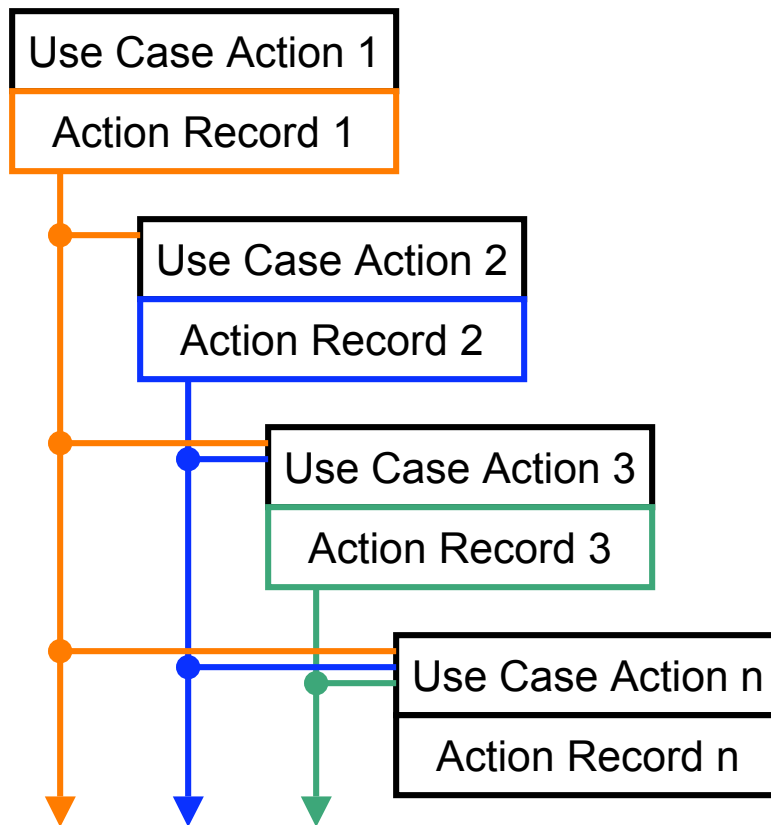
## Use Case Alignment Analysis

# Methodology, con't

- 4b For purposes of the persistent EHR, an Action is often logically combined with other closely corresponding Actions. (An Action may be comprised of one or more other Actions, thus an Action Record instance may document one or more Actions.) Determine which Actions may be logically combined in a single Action Record.
- 4c Determine, as applicable, Actions which invoke Act Record Lifecycle Events (per the EHR Lifecycle Model).
- 5 Specify which EHR Interoperability characteristics (per Act/Action Record, Section 3 of the EHR Interoperability Model) are pertinent to evidence Action occurrence – in the form of a persistent Action Record.

# Use Case Alignment Analysis

## Record Flow



As applicable, each Use Case Action produces an Action Record which is then available to inform (as input to) subsequent Action(s).

# Use Case Alignment Analysis

## Completeness

	Documented By	Complete
Action 1	Action Record 1	X
Action 2	Action Record 2	X
Action 3	Action Record 3	X
Action n	Action Record n	X
<b>Use Case Scenario (Sum of Actions)</b>	<b>Action Records 1-n</b>	<b>X</b>

Completion of each Use Case Scenario may be predicated on completion of contained Actions and Action Records.



From Requirements to Implementation  
**CDA Reference Profile for  
EHR Interoperability**

# CDA Reference Profile for EHR Interoperability

## Basics

- HL7 Clinical Document Architecture Release 2
  - Mature, deployed standard
  - Included in many HITSP Interop Specs
  - Proposed for HIPAA Claims Attachments
  - Incorporated in IHE XDS strategy
  - Readily transformed (repurposed)
    - From “Document”
    - To Action Record (Common EHR Record Unit)

# CDA Reference Profile for EHR Interoperability Profile

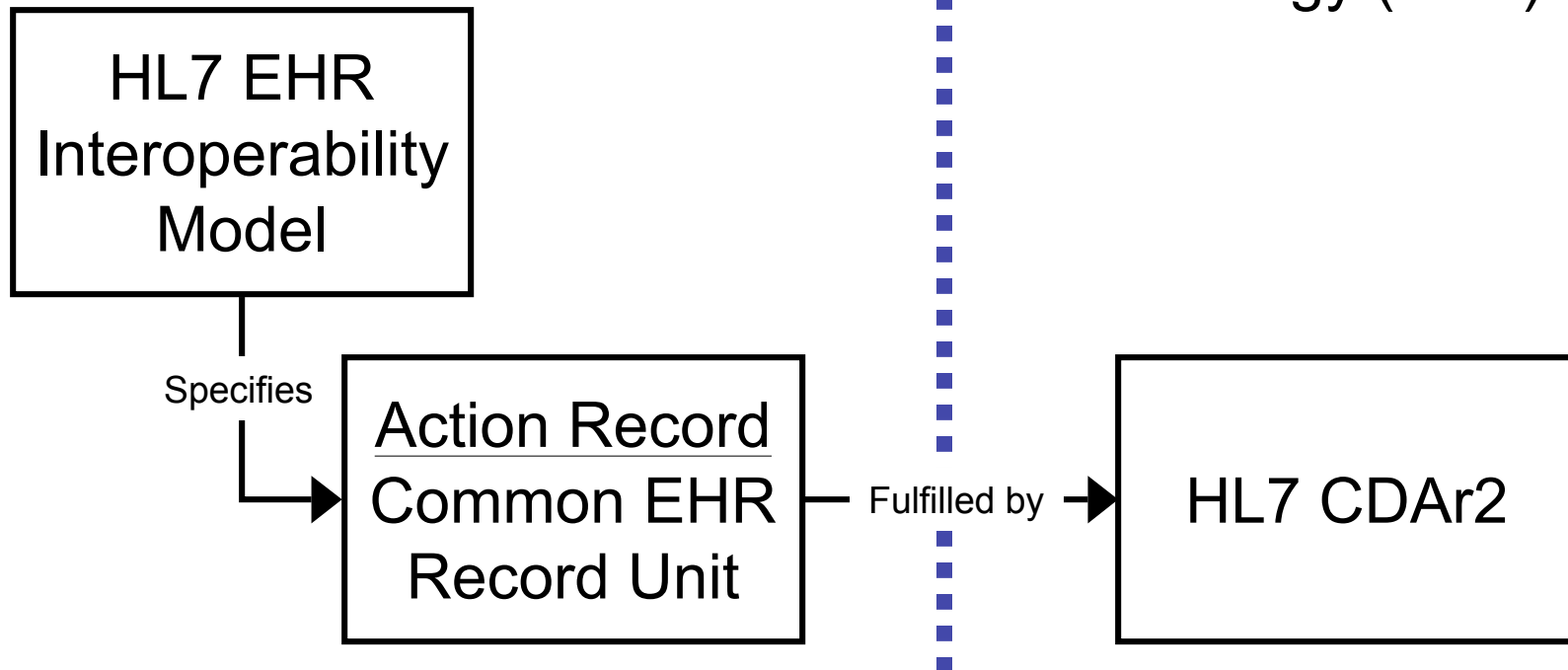
- Shows how CDAr2 meets/fulfills specific EHR interoperability requirements
  - Action Record - Common EHR Record Unit
  - HL7 EHR Interoperability Model Sections 3 & 4
- Currently
  - Profile in ballot as a Draft Standard for Trial Use

# CDA Reference Profile for EHR Interoperability

## Requirements Satisfied

Requirements (What, Why)

Implementation Strategy (How)



## CDA Reference Profile for EHR Interoperability

# Trust Protections

Privacy/Confidentiality Protection	CDAr2 Profile
Consent-based use and disclosure	In development
Source System and Author authentication <ul style="list-style-type: none"> <li>▪ w/Digital Signature</li> </ul>	Included
Content authentication: original, amended, current	Included
Access control <ul style="list-style-type: none"> <li>▪ To Access/View Record, to Amend Record</li> </ul>	Confidentiality Code (now) Discrete Attributes (future)
Traceable Record Audit Trail encompassing: <ul style="list-style-type: none"> <li>▪ Amendments, Revision History</li> <li>▪ End-to-End Flow and Custody</li> <li>▪ Lifecycle Events: originate, verify, amend, access/view, transmit/disclose, receive, de-identify/alias, archive...</li> </ul>	<ul style="list-style-type: none"> <li>▪ Included</li> <li>▪ In development</li> <li>▪ Some included, some in development</li> </ul>
Attestation of Record Accuracy and Completeness	Included

# A Forward Strategy

# Generations

1G - 1980s to Now

Point to Point  
w/Transient Messages

2G - Next (transitional)



3G - Goal

End to End  
w/Persistent Records

1G - 80s to Now	2G - Next	3G - Goal
	Action Record external to System architecture	Action Record native to System architecture
Customized Point to Point	Uniform (Back) End-to-End	Uniform (Front) End-to-End
Transient Messages <ul style="list-style-type: none"> <li>• Originated at System back-end interface, ready to transmit</li> </ul>	Persistent Action Records <ul style="list-style-type: none"> <li>• Originated at System back-end interface, ready to transmit</li> <li>• Digitally signed by System</li> <li>• Authenticate-able (traceable) to Originating System</li> </ul>	Persistent Action Records <ul style="list-style-type: none"> <li>• Originated at System front-end (often at point of care/service)</li> <li>• Digitally signed by Author and System</li> <li>• Authenticate-able (traceable) to Originating System and Author</li> </ul>



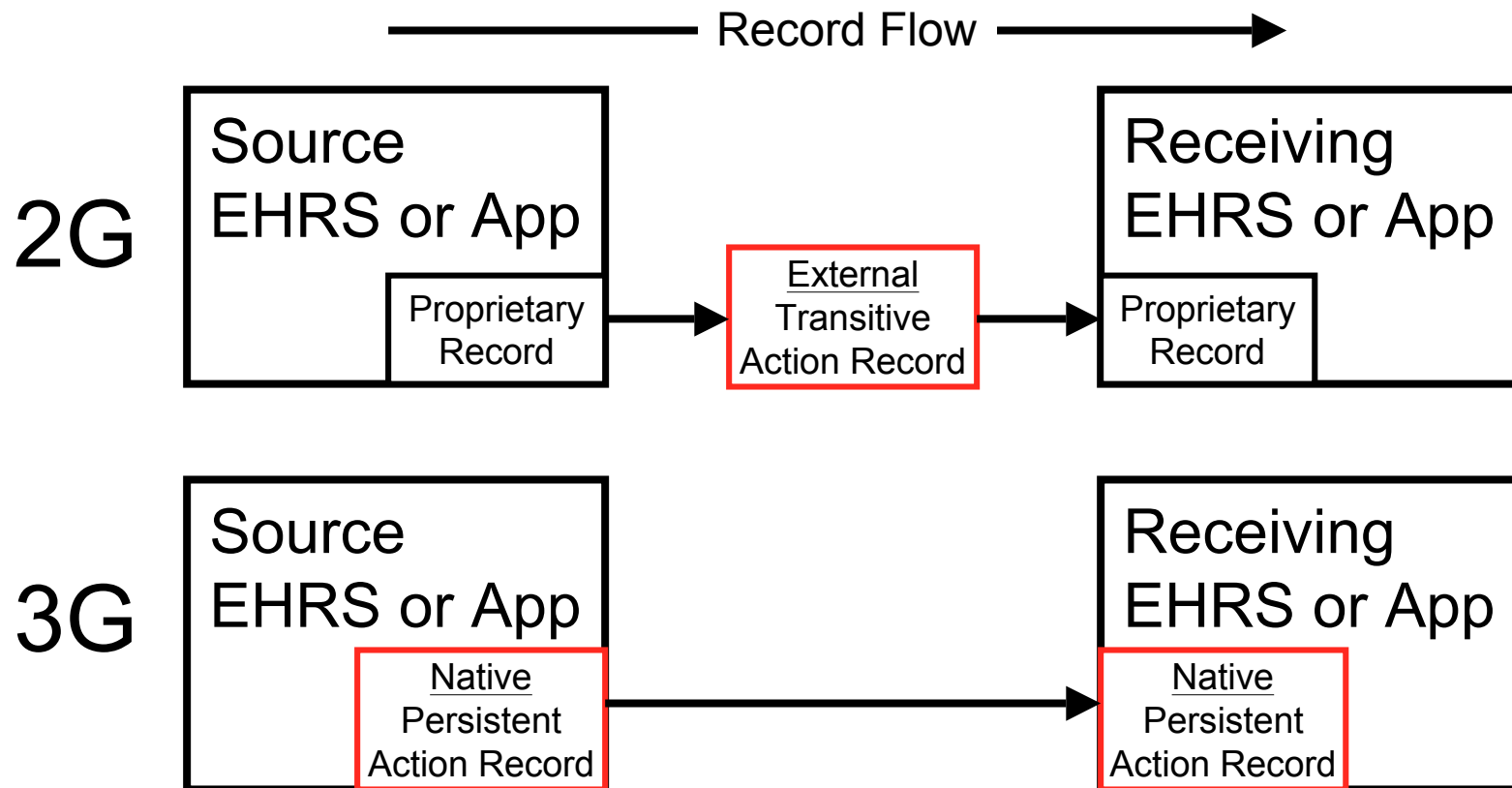
# Health Information Capture, Retention and Exchange

## The Transition Forward

1G - 80s to Now	2G	3G - Goal
Transitive, Volatile, Lossy	→	Persistent, Indelible, Lossless
Incomplete	→	Complete, As Originated
Piecemealed, Fragmentary	→	Whole, Uniform
Divergent Implementations	→	Common Currency, Consistent Exchange

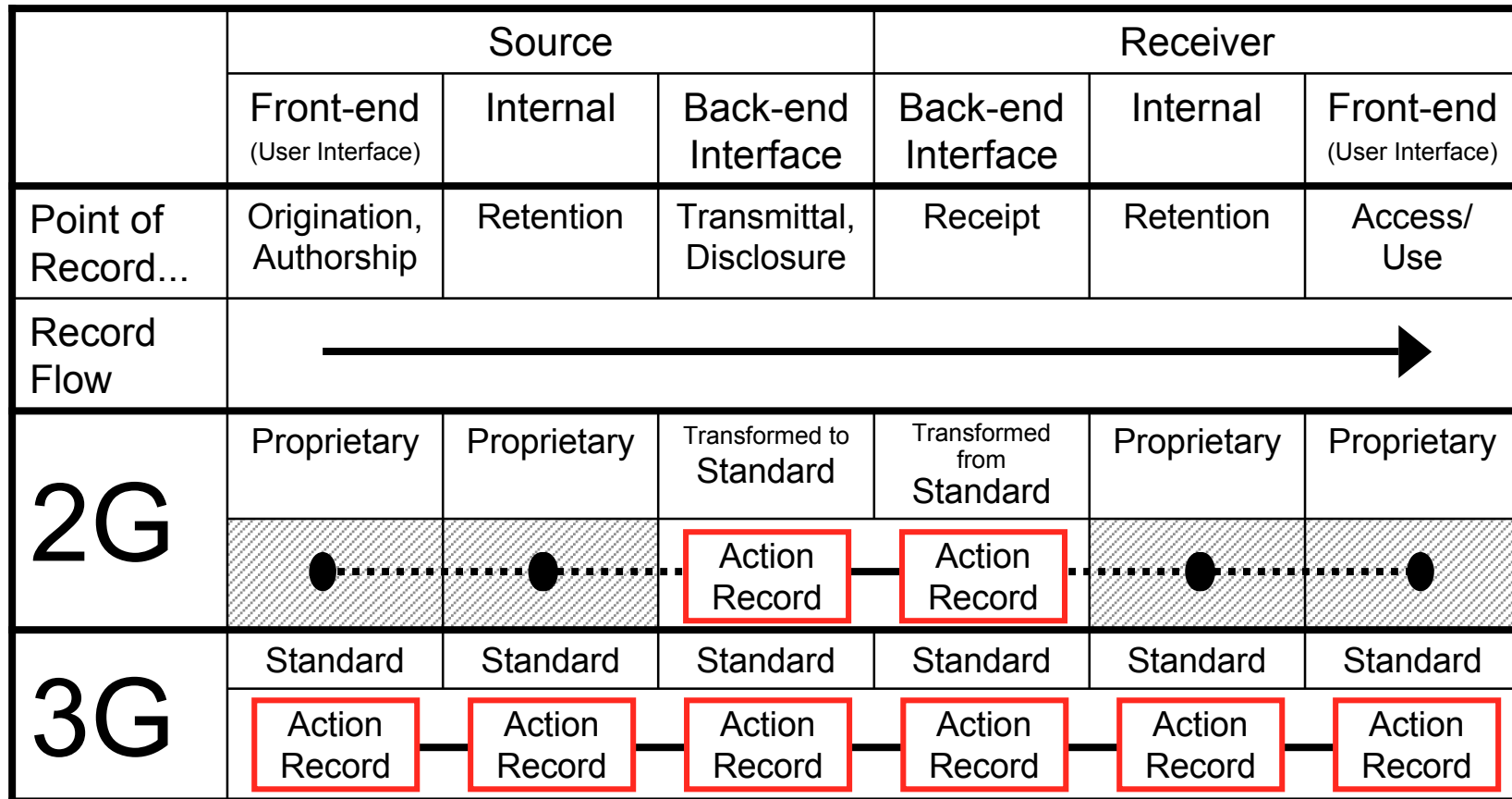
# Transition Strategy

## External to Native



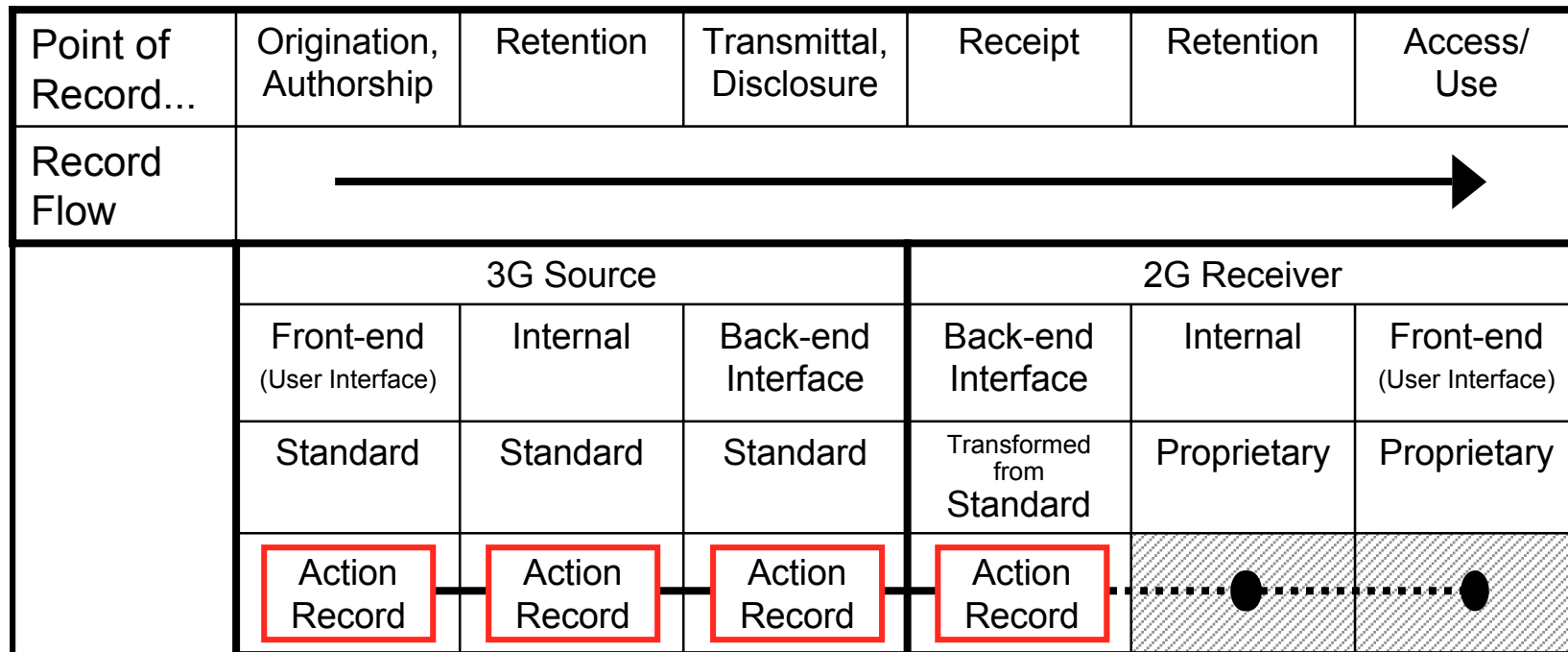
# Transition Strategy

## Record Flow



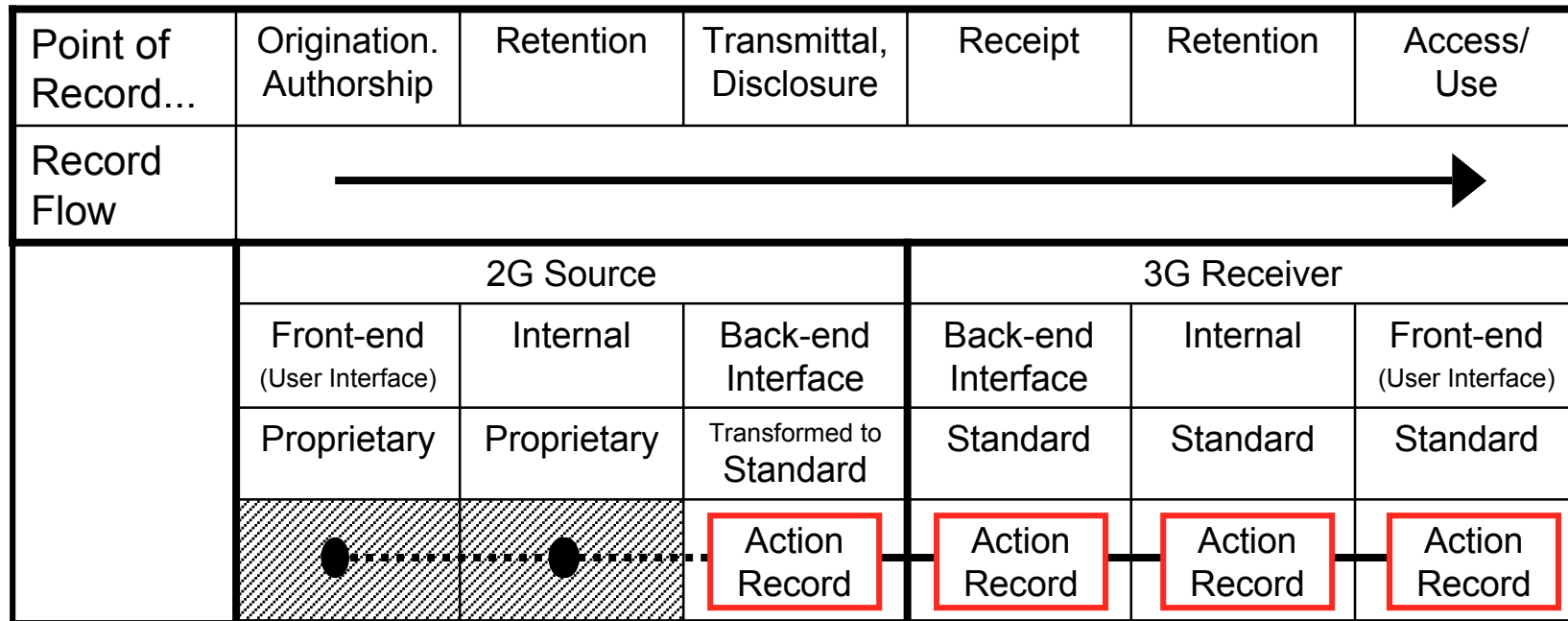
# Transition Strategy

## 3G to 2G Record Flow



# Transition Strategy

## 2G to 3G Record Flow



<b>Action Record...</b>	<b>2G</b>	<b>3G</b>
<p>Is uniquely identifiable, as to:</p> <ul style="list-style-type: none"> <li>• Record Subject</li> <li>• Action</li> </ul>	<p>At point of record transmittal:</p> <ul style="list-style-type: none"> <li>• Asserted by System</li> <li>• Digitally signed by <u>System</u></li> </ul>	<p>At point of record origination:</p> <ul style="list-style-type: none"> <li>• Captured in native Action Record</li> <li>• Digitally signed by <u>Author</u> and <u>System</u></li> </ul>
<p>Has a context:</p> <ul style="list-style-type: none"> <li>• Who - Record Subject</li> <li>• Who - Record Author</li> <li>• Who - Action Participants</li> <li>• What - Action</li> <li>• When - Date, Time, Duration</li> <li>• Where - Location</li> </ul>		
<p>Is persistent As EHR entry</p>	<p>N/A</p>	<p>Yes, as native Unit of Record (Action Record)</p>

<b>Action Record...</b>	<b>2G</b>	<b>3G</b>
Is indelible	From point of originating <u>System</u> digital signature on	From point of originating <u>Author's</u> digital signature on
May be accessed or viewed: e.g., to recall Action context + facts	No (interface artifact only)	Yes, as native Unit of Record (Action Record)
Is authenticated	At point of original record transmittal, by <u>System</u>	At point of record origination, by <u>Author</u>
Is authenticate-able, as to source and author • By any record recipient, downstream from point of origination	Yes, to <u>Originating System</u>	Yes, to <u>Originating Author and System</u>

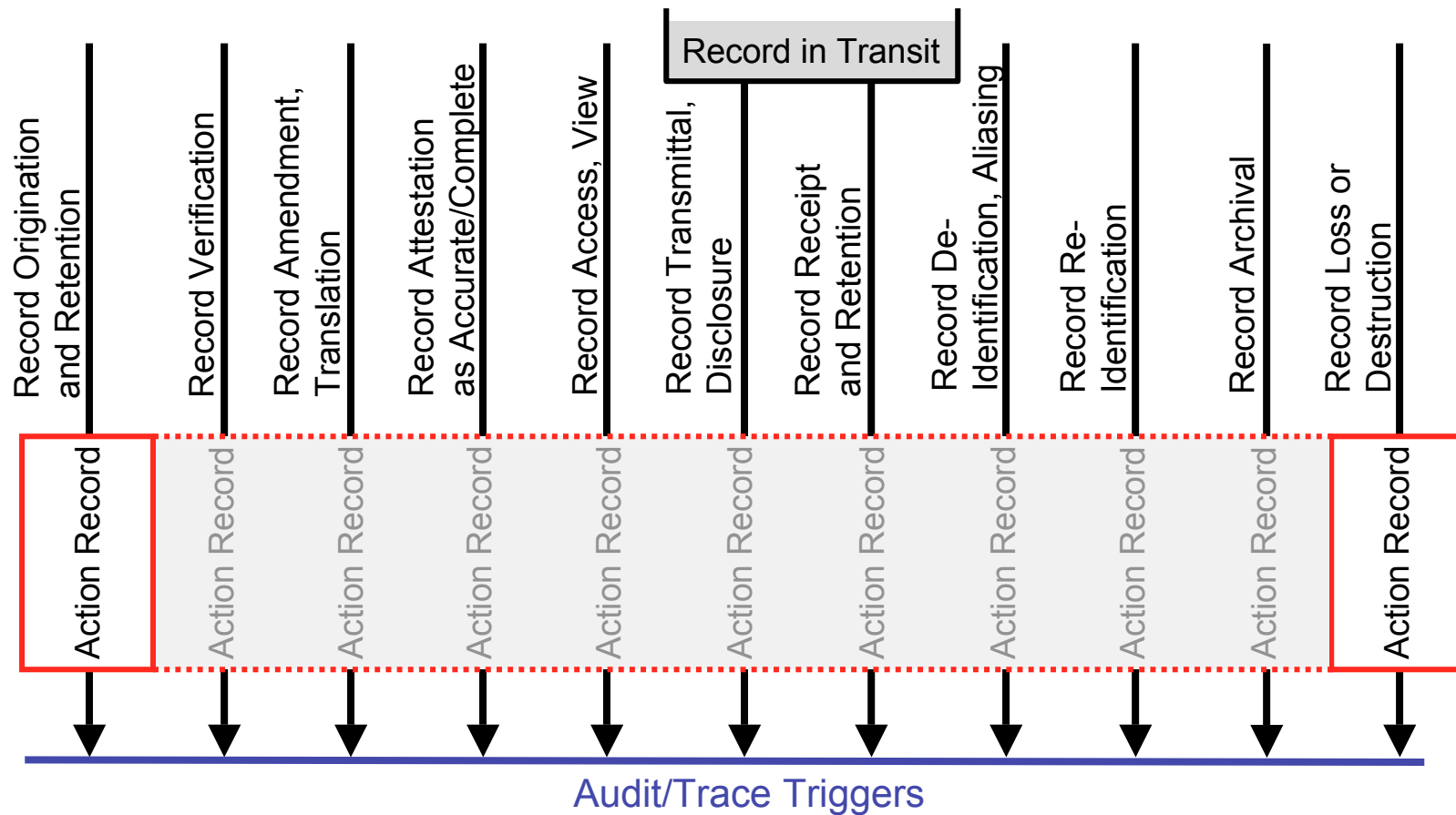
<b>Action Record...</b>	<b>2G</b>	<b>3G</b>
<p>Is accessible, based on access control rules:</p> <ul style="list-style-type: none"> <li>• Record access/view</li> <li>• Record amendment</li> </ul>	<p>As asserted by Originating System</p> <p>Based on:</p> <ul style="list-style-type: none"> <li>• Established business rules</li> <li>• Patient/Consumer or Provider request</li> </ul> <p>May be:</p> <ul style="list-style-type: none"> <li>• Role based</li> <li>• Person or organization specific</li> </ul> <p>Coverage:</p> <ul style="list-style-type: none"> <li>• Confidentiality code, limiting access to whole record or section (see CDAR2 Reference Profile)</li> <li>• Fine grained, constraining access to specific record attributes</li> </ul>	



<b>Action Record...</b>	<b>2G</b>	<b>3G</b>
May be attested as to accuracy	Asserted by System, based on algorithm	<ul style="list-style-type: none"> <li>• Attested by Author, <u>and/or</u></li> <li>• Asserted by System, based on algorithm</li> </ul>
May be attested as to completeness		
<p>Incorporates audit/trace log, showing:</p> <ul style="list-style-type: none"> <li>• Amendments and revision history</li> <li>• “Chain of trust” and custody</li> <li>• Points in record lifecycle</li> </ul>	Asserted by System at back-end record origination	Maintained and updated within native Action Record

## Audit/Trace Triggers

# EHR Record Lifecycle



## Actions and Action Record Content

# Who Specifies?

- SDOs, using consensus ballot
- Accreditation and governance bodies
- Professional societies
- Provider organizations
- and others...

- 
- Based on national, regional or local requirements
  - Potentially catalogued in public registries
    - e.g., NIST registry of EHRs/FM Profiles

## HL7 EHR Technical Committee

# References

- ONC/AHIC/HITSP Use Case Alignment with HL7 EHR/PHR Models
  - Chapter 1, Year 1 EHR/Lab Results Reporting Use Case
- HL7 EHR System Functional Model
- HL7 PHR System Functional Model
- HL7 EHR Interoperability Model
- HL7 EHR Lifecycle Model
- HL7 Implementation Guide for CDA Release 2: Reference Profile for EHR Interoperability
- HL7 “Coming to Terms” White Paper
- HL7 EHR System - Records Management and Evidentiary Support Functional Profile

# Alignment Continues

- Teams formed, analysis underway
  - Year 1 Consumer Empowerment
    - Demographics and Medication History
  - Year 1 Population Health
    - Biosurveillance
- Anticipated in 2008
  - Year 2 Use Cases (x4)

HL7 EHR Technical Committee

# Resources

- EHR TC
  - <http://www.hl7.org/ehr>