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

13 February 2008

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	EHRS Functional Model (EHRS/FM)	Functional characteristics (functions) of Electronic Health Record Systems (EHRS)
	PHRS Functional Model (PHRS/FM)	Functional characteristics (functions) of Personal Health Record Systems (PHRS)
RECORDS	EHR Interoperability Model (EHR/IM)	Characteristics of interoperable EHR Records
	EHR Lifecycle Model (EHR/LM)	Key events in the EHR Record lifecycle

HL7 EHR System Functional Model

EHRS/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 EHRS/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)

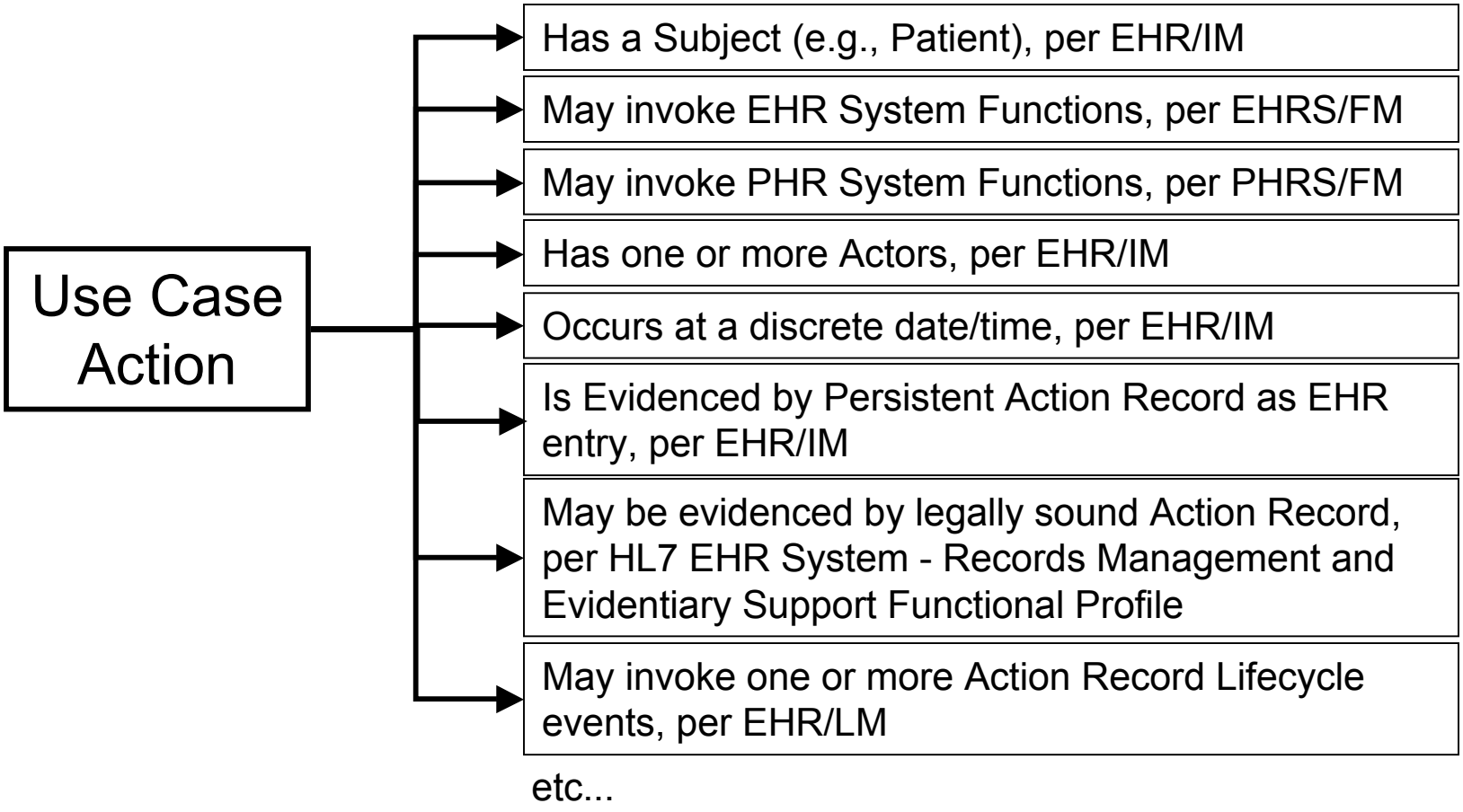
HL7 EHR Lifecycle Model

EHR/LM

• Draft Standard for Trial Use – Balloted/approved January 2008 • 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



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

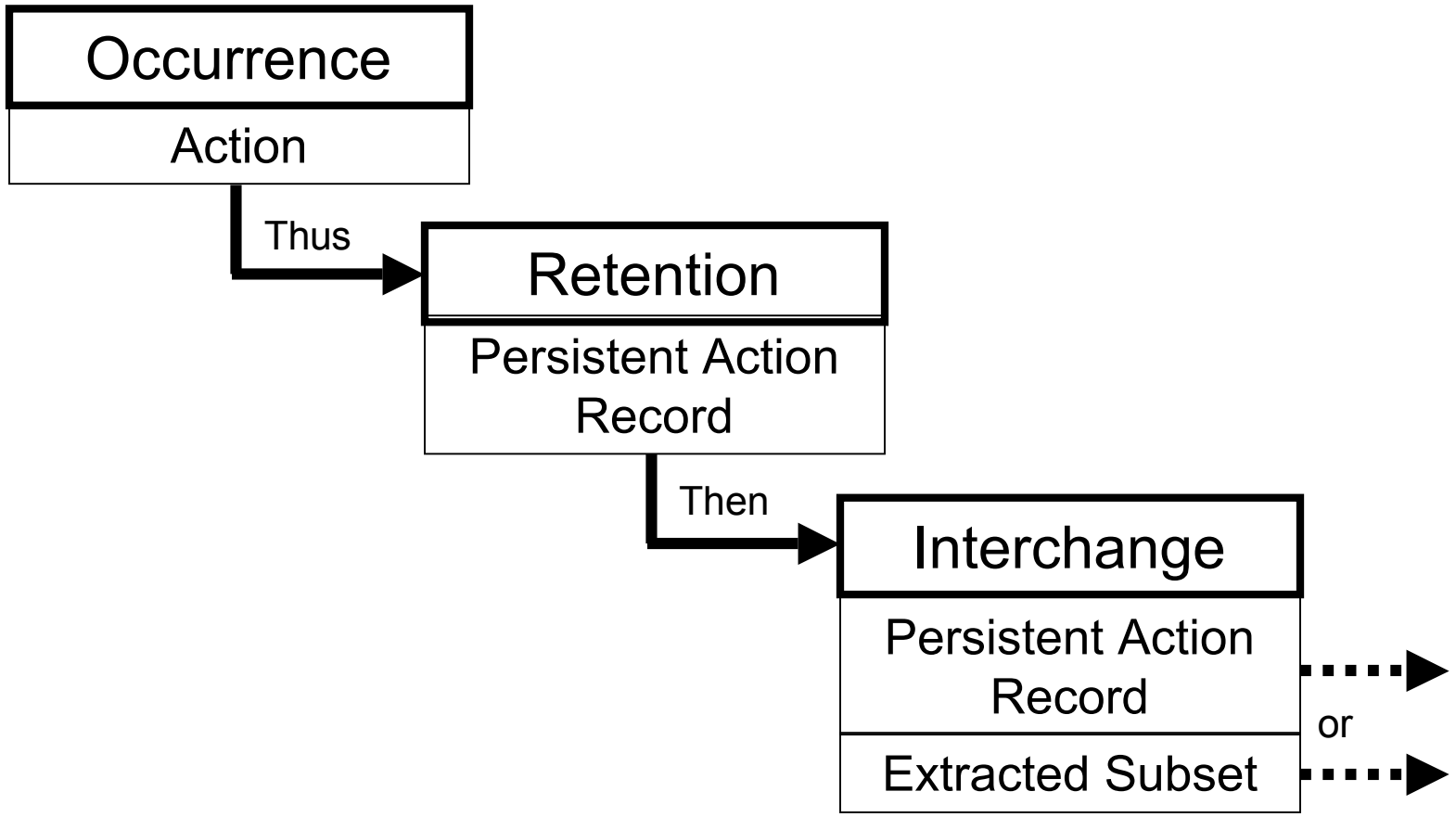
EHR Interoperability Fundamentals

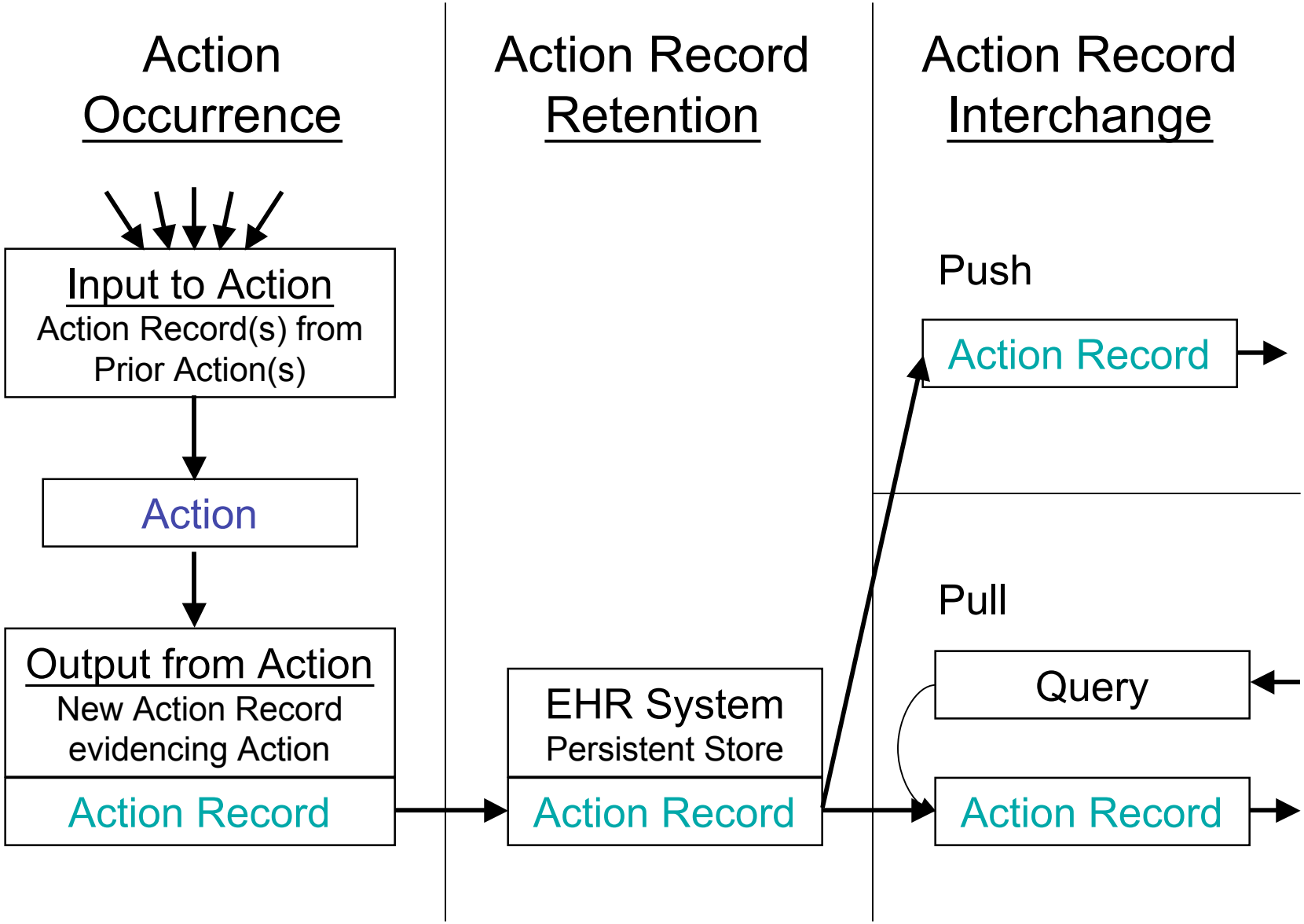
Simple Paradigm

- 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

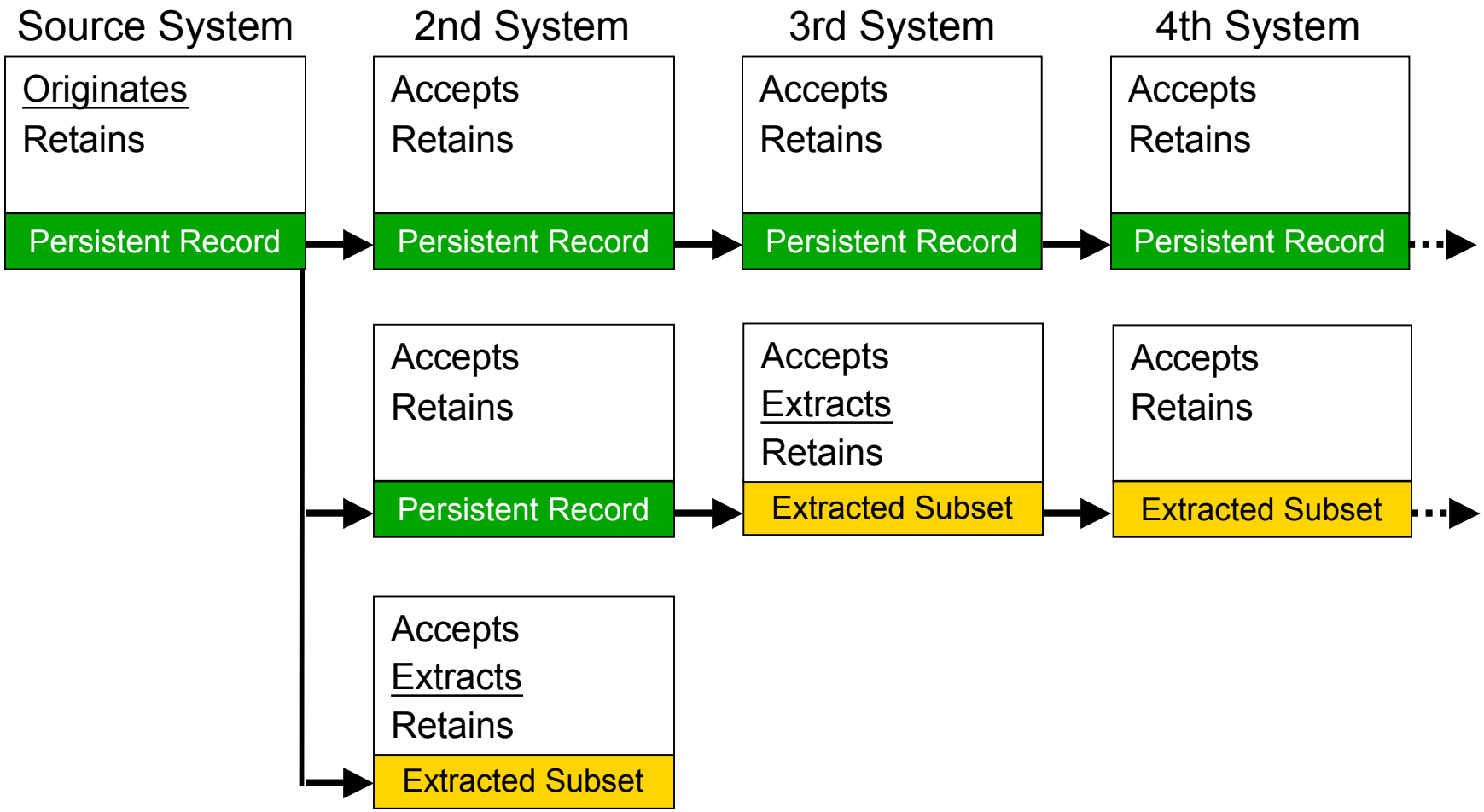
EHR Interoperability Fundamentals

Occurrence/Retention/Interchange




Action Occurrence
Action Record Retention
Action Record Interchange
Input to Action
Action Record(s) from Prior Action(s)
Action
Output from Action
New Action Record evidencing Action
Action Record
EHR System
Persistent Store
Action Record
Push
Action Record
Pull
Query
Action Record

Example Interchange Pattern
Persistent Records and Extracted Subsets



EHR Interoperability Fundamentals

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

Health(care) Delivery	**Interoperable EHR**
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

Action...	Action Record...
Occurs	Documents (evidences) Action occurrence
Has context • Who, What, When, Where	Documents Action context
Has facts • Current and historical	Documents Action facts
Has one or more Actor(s), in role(s) and participation(s) • Roles: physician, nurse, pharmacist, therapist, secretary... • Participations: perform, assist, observe, scribe...	Documents Actors, roles and participations
Is complete	Documents Action completion

Action...	Action Record...
If accountable to a Provider...	• Is persistent evidence of Action occurrence • Is retained as a persistent EHR entry • May be attested as accurate and/or complete
If consumer initiated...	• May be retained as PHR (or EHR) entry - or not

Action...	Action Record...
• Is an instance: e.g., a discrete act, task or event • Is (often) an instance of care or service provided or performed	• Is a record instance
• Is a common convention to describe acts, tasks or events occurring in health(care)	• Is a common currency for health(care) information – Spanning origination, retention, interchange and use • Is a common unit of record • Is a persistent entry in the EHR

Action...	Action Record...
Is confidential	• Is a protected unit of record • May be encrypted e.g., while “in transit” • May have embedded access controls • Is auditable as to amendment history • May be auditable as to access, “chain of trust” and custody • May be de-identified or aliased

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

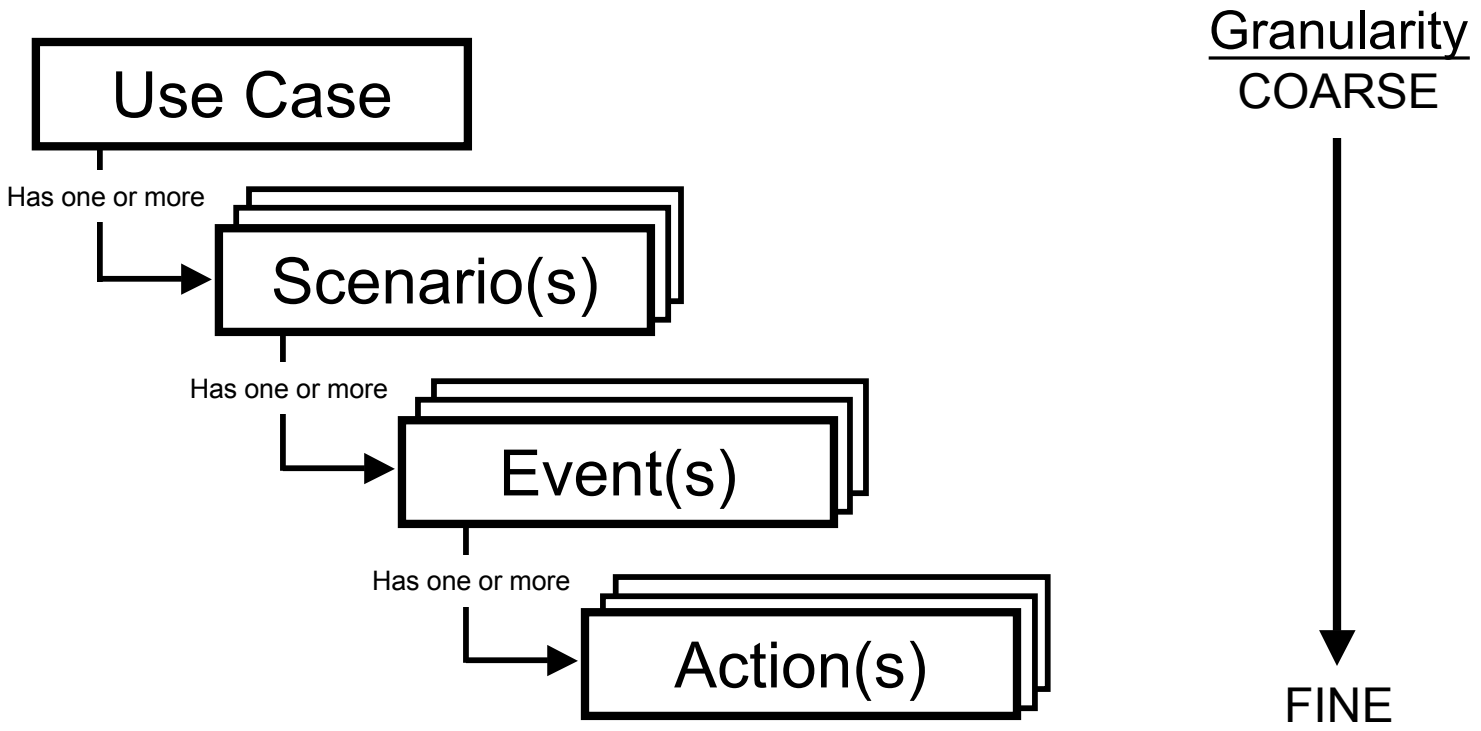
ONC/AHIC/HITSP

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

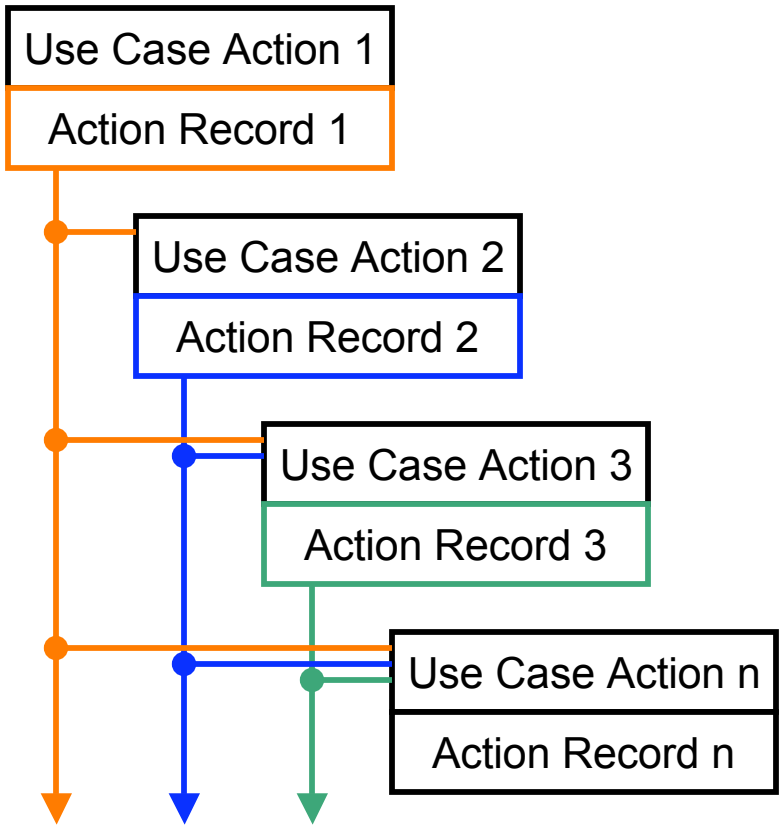
4b For purposes of the persistent EHR, an Action is often logically combined with other closely corresponding Actions. (An Action may be comprised of one or more other Actions, thus an Action Record instance may document one or more Actions.) Determine which Actions may be logically combined in a single 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
Use Case Scenario (Sum of Actions)	Action Records 1-n	X

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)

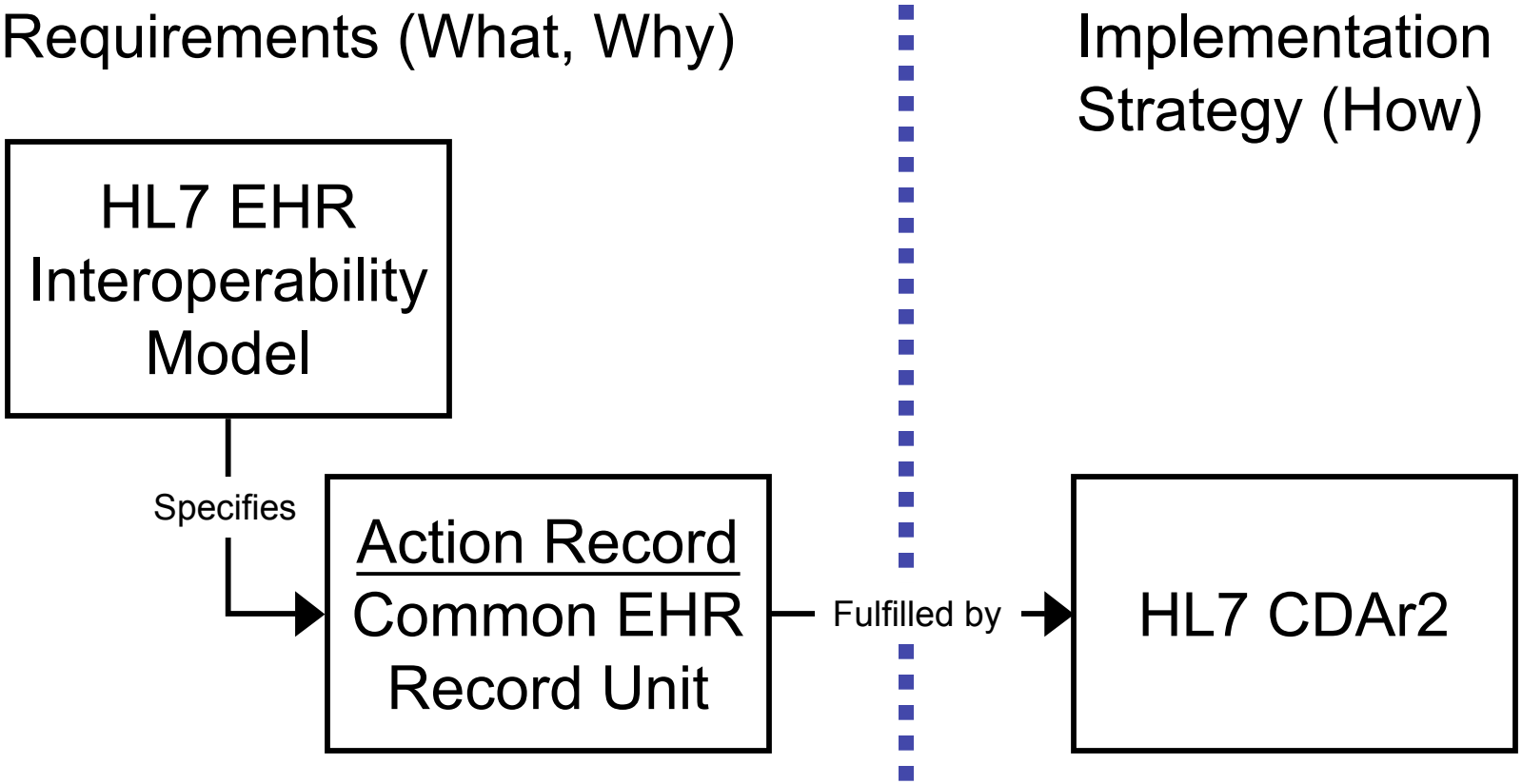
CDA Reference Profile for EHR Interoperability

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 passed ballot as a Draft Standard for Trial Use, January 2008

CDA Reference Profile for EHR Interoperability

Requirements Satisfied



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 ▪ w/Digital Signature	Included
Content authentication: original, amended, current	Included
Access control ▪ To Access/View Record, to Amend Record	Confidentiality Code (now) Discrete Attributes (future)
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...	▪ Included ▪ In development ▪ Some included, some in development
Attestation of Record Accuracy and Completeness	Included

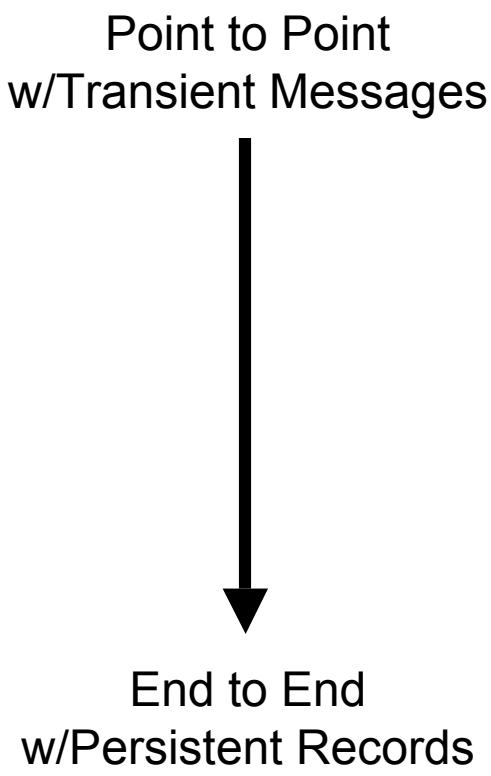
A Forward Strategy

Generations

1G - 1980s to Now

2G - Next (transitional)

3G - Goal



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 • Originated at System back-end interface, ready to transmit	Persistent Action Records • Originated at System back-end interface, ready to transmit • Digitally signed by System • Authenticate-able (traceable) to Originating System	Persistent Action Records • Originated at System front-end (often at point of care/service) • Digitally signed by Author and System • Authenticate-able (traceable) to Originating System and Author

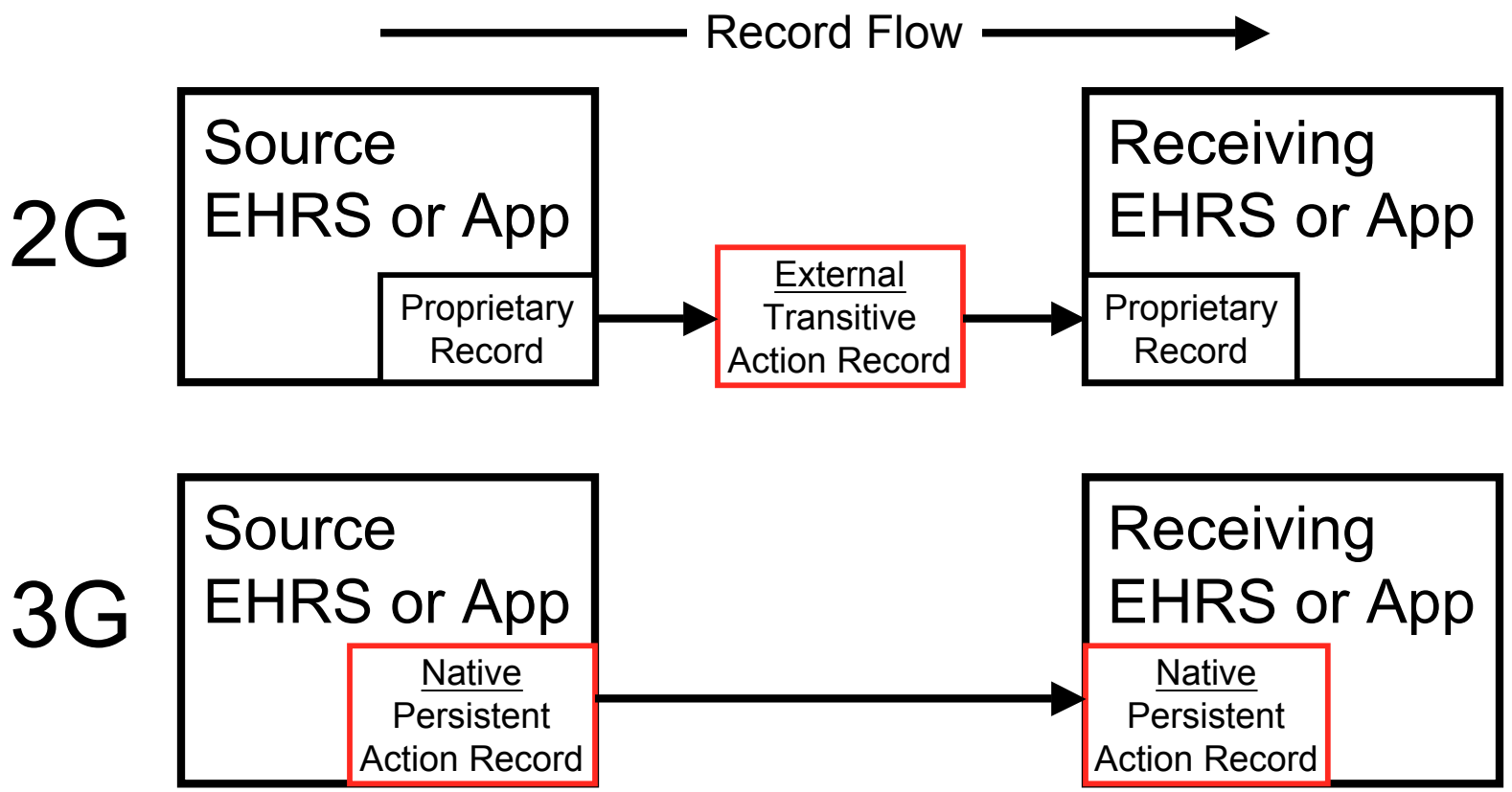
Health Information Capture, Retention and Exchange

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

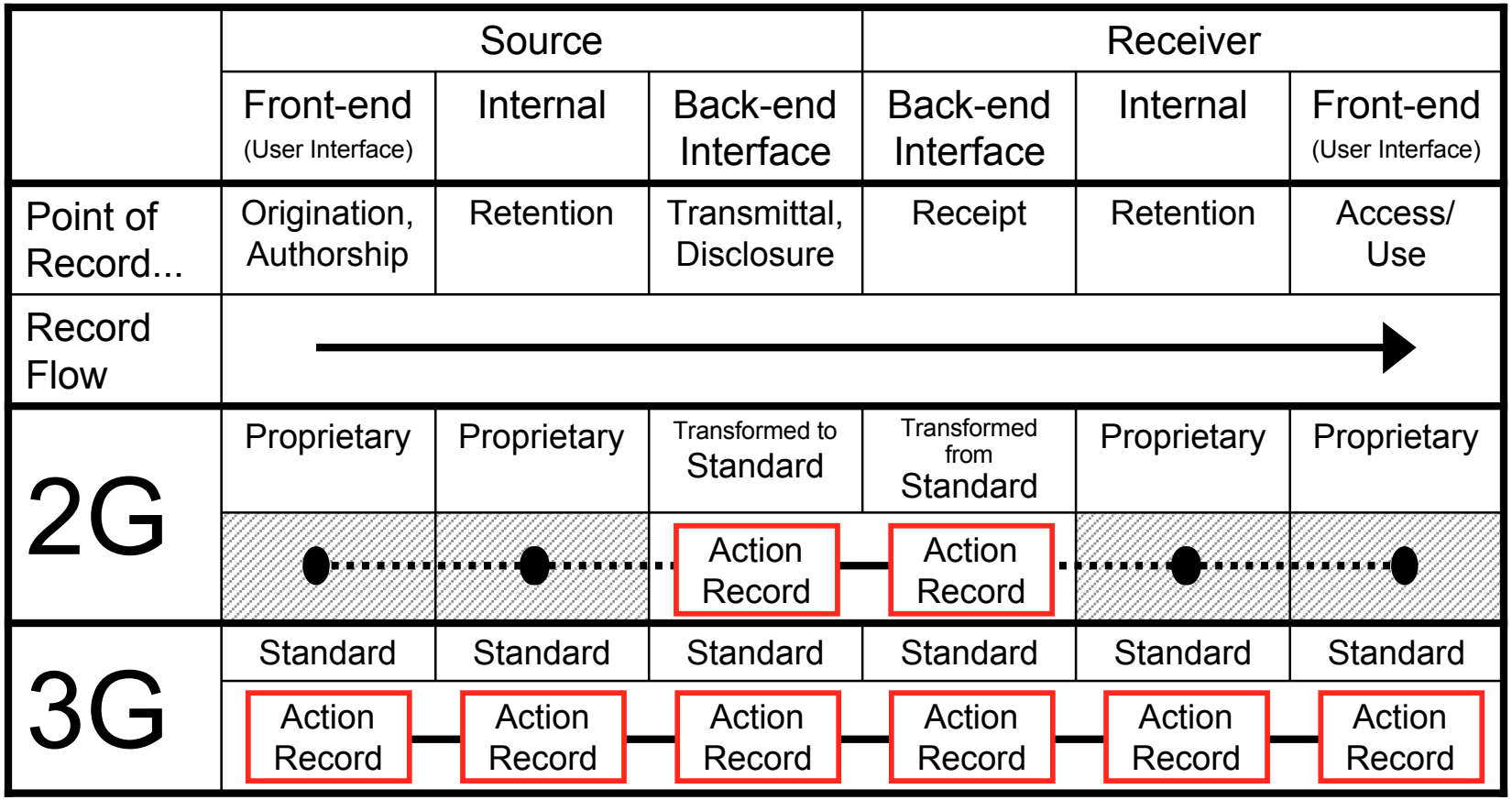
Transition Strategy

External to Native



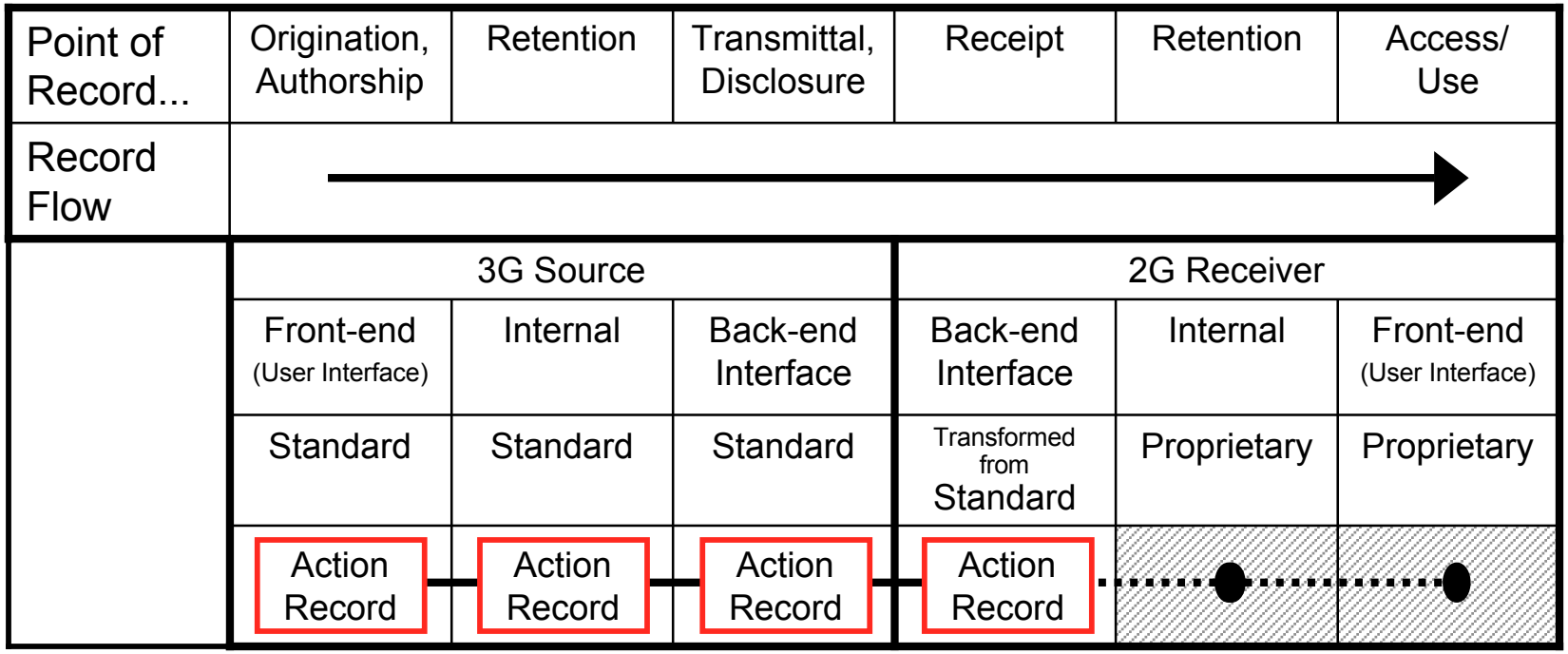
Transition Strategy

Record Flow



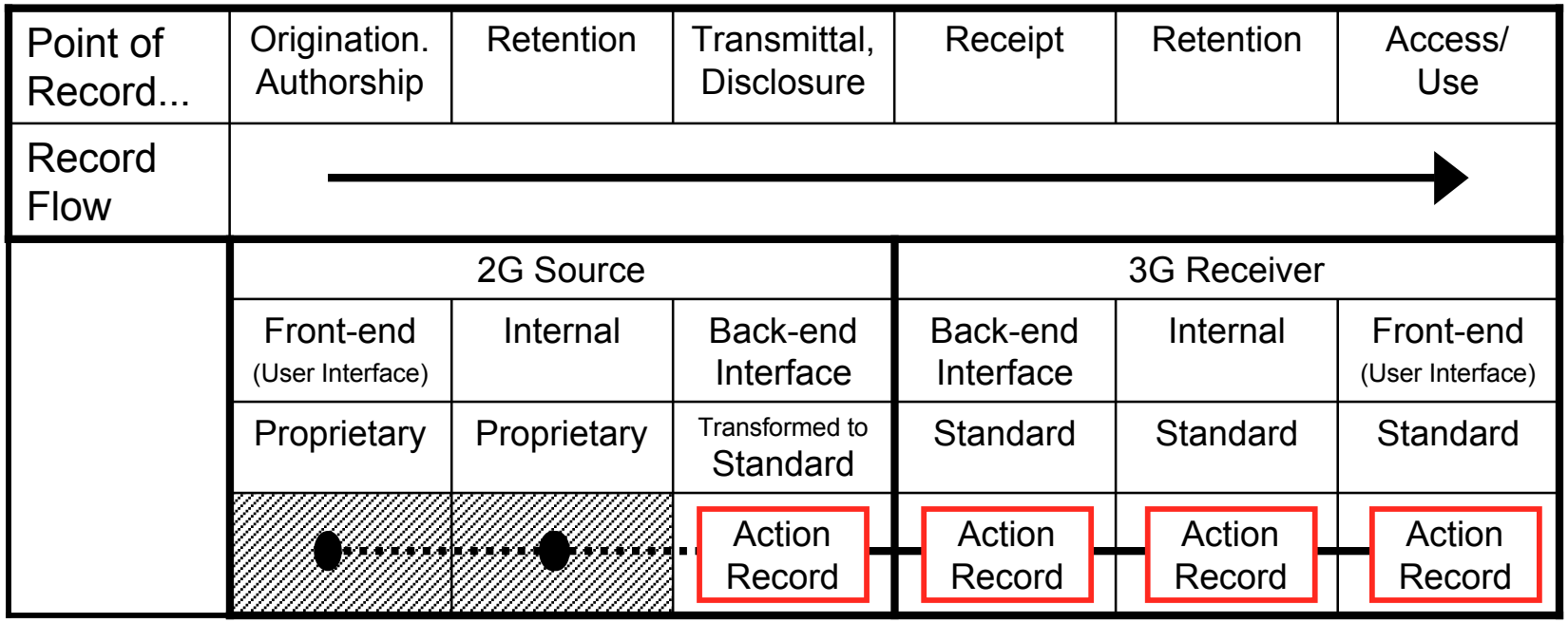
Transition Strategy

3G to 2G Record Flow



Transition Strategy

2G to 3G Record Flow



Action Record...	2G	3G
Is uniquely identifiable, as to: • Record Subject • Action	At point of record transmittal: • Asserted by System • Digitally signed by System	At point of record origination: • Captured in native Action Record • Digitally signed by Author and System
Has a context: • Who - Record Subject • Who - Record Author • Who - Action Participants • What - Action • When - Date, Time, Duration • Where - Location		
Is persistent As EHR entry	N/A	Yes, as native Unit of Record (Action Record)

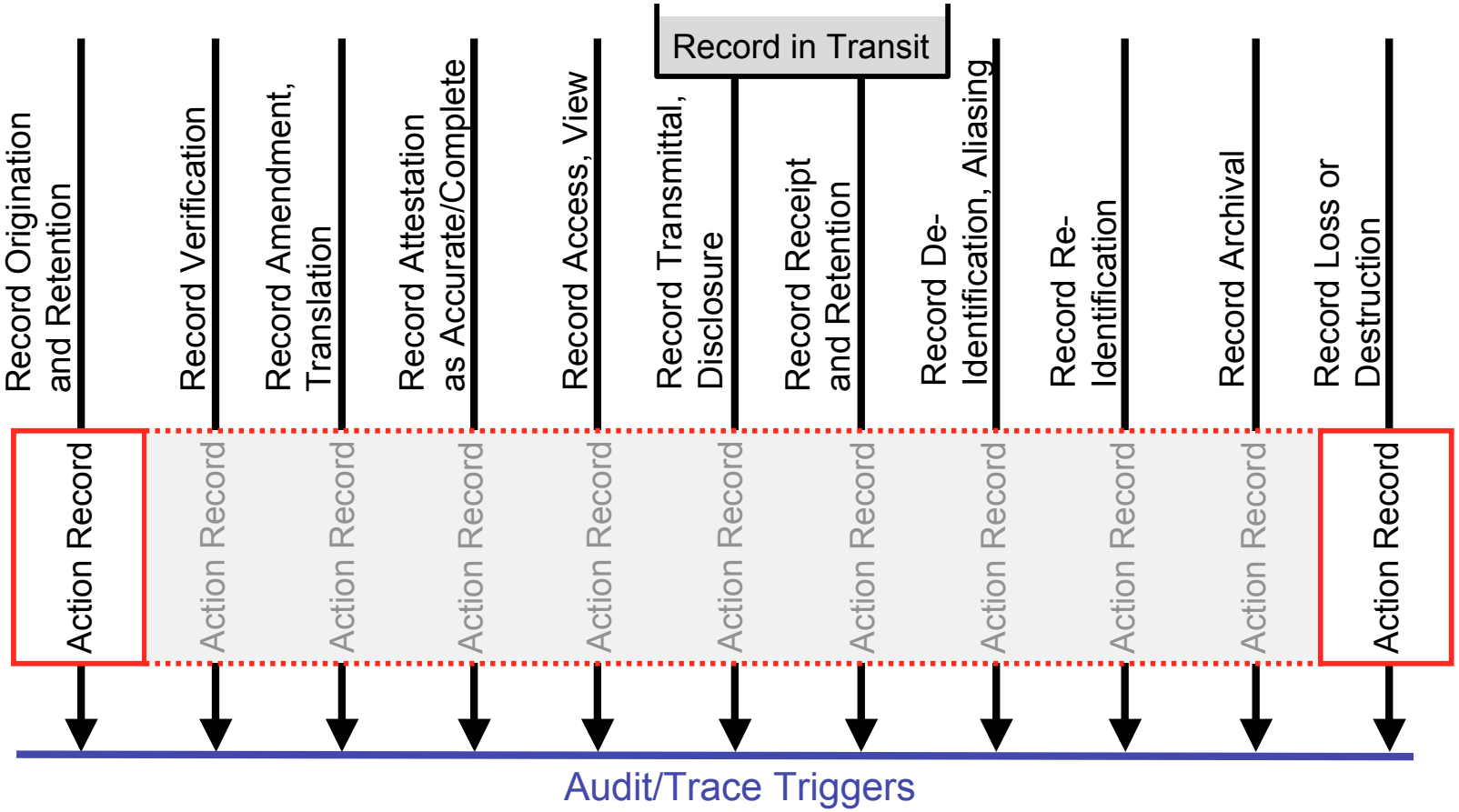
Action Record...	2G	3G
Is indelible	From point of originating System digital signature on	From point of originating Author's digital signature on
May be accessed or viewed: e.g., to recall Action context + facts	No (interface artifact only)	Yes, as native Unit of Record (Action Record)
Is authenticated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

Action Record...	2G	3G
Is accessible, based on access control rules: • Record access/view • Record amendment	As asserted by Originating System Based on: • Established business rules • Patient/Consumer or Provider request May be: • Role based • Person or organization specific Coverage: • Confidentiality code, limiting access to whole record or section (see CDAr2 Reference Profile) • Fine grained, constraining access to specific record attributes	

Action Record...	2G	3G
May be attested as to accuracy	Asserted by System, based on algorithm	• Attested by Author, and/or • Asserted by System, based on algorithm
May be attested as to completeness		
Incorporates audit/trace log, showing: • Amendments and revision history • "Chain of trust" and custody • Points in record lifecycle	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

HL7 EHR TC/EHR Interoperability Working Group

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