

An Opportunity for Compliance Assurance and Oversight in EHR-Sourced Records

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Introduction

- ISO/HL7 10781 Electronic Health Record System Functional Model, Release 2
- Normative Standard for both HL7 and ISO
- aka FM R2 or R2

R2's Record Infrastructure (RI) Section utilizes "Lifecycle Events" from ISO 21089 (now in revision)

Forward path is uncertain, "soft", and in flux

RI.1.1 24 + 3 Lifecycle Events

| Originate and Retain RI.1.1.1 | |
|------------------------------------|--|
| Receive and Retain RI.1.1.8 | |
| Amend RI.1.1.2 | |
| Verify (Added Lifecycle Event #25) | |
| Translate RI.1.1.3 | |
| Attest RI.1.1.4 | |
| View/Access RI.1.1.5 | |
| Output/ Report RI.1.1.6 | |
| Disclose RI.1.1.7 | |
| Transmit RI.1.1.8 | |
| De-Identify RI.1.1.10 | |
| Pseudo-mynize RI.1.1.11 | |
| Re-Identify RI.1.1.12 | |
| Extract RI.1.1.13 | |

| Archive RI.1.1.14 |
|---|
| Restore RI.1.1.15 |
| Destroy or Identify Record Entries as Missing RI.1.1.16 |
| Re-Activate RI.1.1.18 |
| Merge RI.1.1.19 Function |
| Unmerge RI.1.1.20 |
| Link RI.1.1.21 |
| Unlink RI.1.1.22 |
| Legal Hold RI.1.1.23 |
| Legal Hold Release RI.1.1.24 |
| Encrypt (New) |
| Decrypt (New) |

Overview

- "<u>To Verify</u>": Now available as a linchpin and critical opportunity for Record Authenticity and derivatives (Compliance and Program Integrity, Oversight)
- Upcoming ONC Workshop
- Identifying stakeholders

Action Options: Post Workshop

- HL7 gearing up-lf/How to engage
- Stakeholder engagement required
 - Advancing ONC S&I Initiative for Lab Results (LRI) which created standing for "<u>To Verify</u>"
 - FHIR Initiative with "Verify" infrastructure
- Possible topic for RMES Profile R2
- Other entities, other areas of interest?

"To evaluate the compliance of data objects with regulations, requirements, specifications, or other internally imposed conditions based on organizational policy. Contrast with validate."

- Could be automated
- Could start with a very small, minor requirement
- Could initially be voluntary (or optional with benefit(s))
- Could become increasingly complex over time
- Capability currently in progress (in nascent form) in upcoming version of FHIR* specification included in recent ballot.
- But…

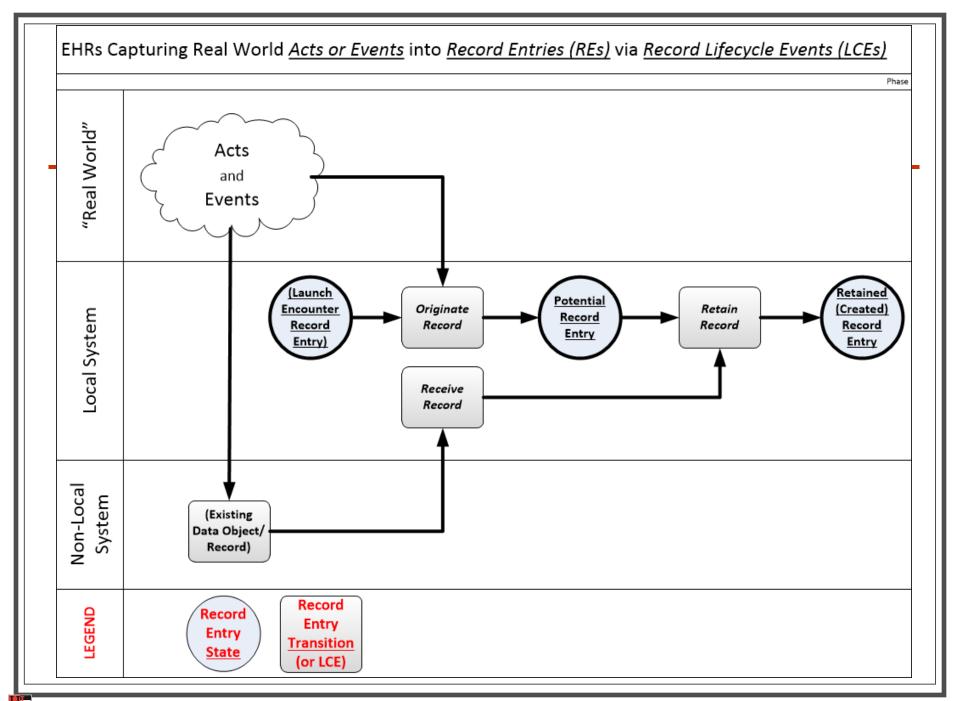
Needs...

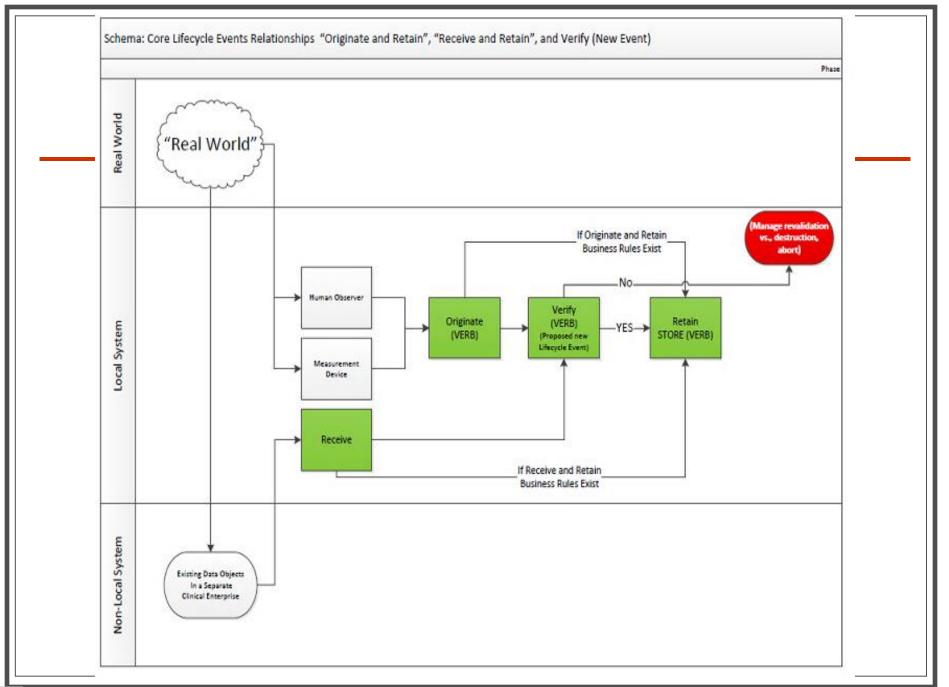
- Advocates/End-users
- Use Case(s)
- Home Health, DME as CMS interest areas

Launch opportunity

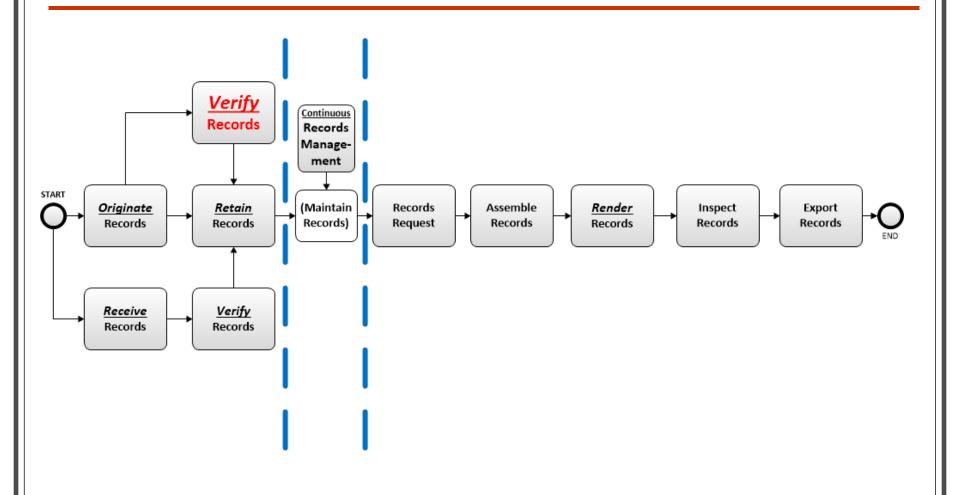
ONC Workshop: Using the Lab Results Interface (LRI) Implementation Guide as a "demonstration of current capacities"

Signal vendors: Building better EHRs as best option

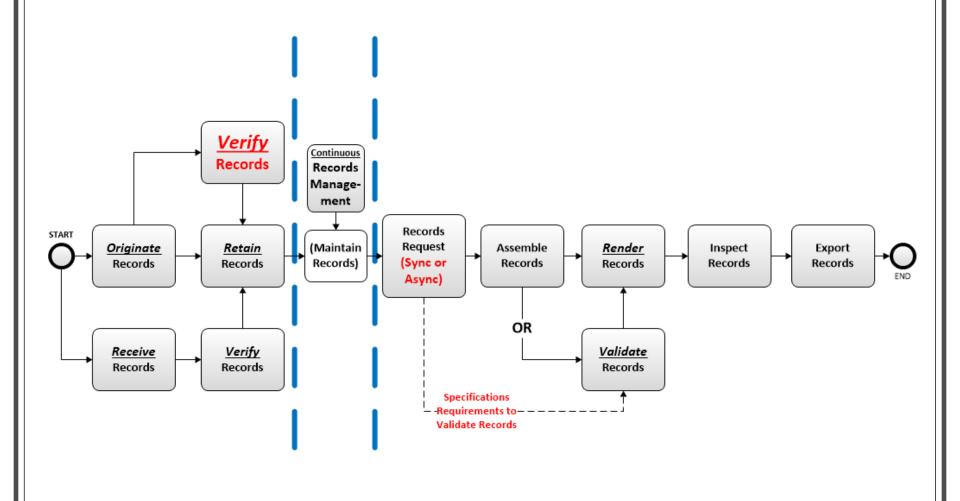




"To Verify" in Context of "Export"



Future: "To Validate" for "Export"



Summary

- Lab Results Implementation Guide established the "existence" of LCE "To Verify" as an operational requirement for Received Records (labs)
- FHIR is incorporating "To Verify" as an implementable function referencing End-User specific "Record Specifications" as a Resource Type.
- End Users of EHR-sourced Records can establish "Record Specifications"

"Specification" Potential Examples

Machine-readable specifications to be verified

- Elementary: Yes vs. No: "Clinician (or org) has attested to compliance with applicable documentation guidelines as indicated at (end-user website here...)
- Basic: EHR verifies that this Record Entry
 Origination event does (or does not) incorporate
 Record Specification (XYZ) for (End-Use ABC)
- 3. Minimal: EHR verifies that this Record Entry
 Origination event does/does not capture and
 attribute all authors per Record Specification (DEF)

Discussion, Questions

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