Consolidated Clinical Document Architecture (C-CDA) for Clinical Data Exchange

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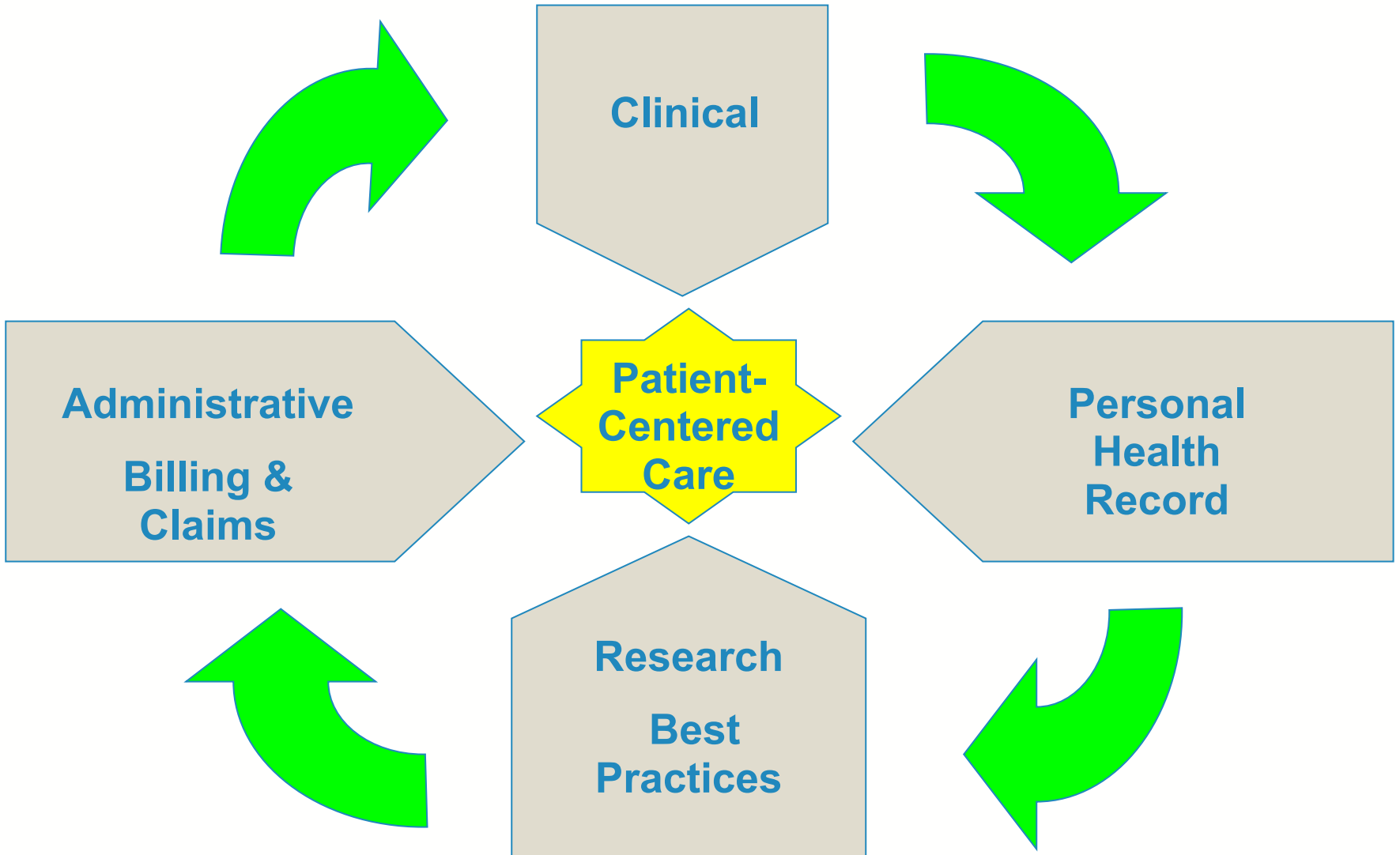
the sequoia project

Clinical Documentation Before the EHR

- Collection of Commonly used document types for various use cases
  - History & Physical
  - Consult Note
  - Operative Note/Procedure Note
  - Progress Note
  - Discharge Summary
  - Radiology/Imaging
  - Other Misc.
- Focused on narrative
- Semi-structured
- Loosely standardized content

Convergence of Data



EHR and Data Quality Challenges and Impact

- How do you interface computers and humans in the medical environment?
  - Computers “think” structured and encoded data
  - Humans “think” in sentences, paragraphs, concepts
- Data Quality challenges directly related to many aspects of a clinical workflow and the systems used
  - Data Capture, Data Storage, Data Exchange
  - Transitions of Care (ToC) is a common occurrence that if improved, benefits the patient population
    - Consistent data representation and interpretation is necessary for ToC to improve patient outcomes
    - Interoperability Exchange of the data captured and stored
    - C-CDA is the US/ONC recommended mechanism for ToC

C-CDA Provides Semantic Building Blocks!

That we can reconfigure for specific purposes

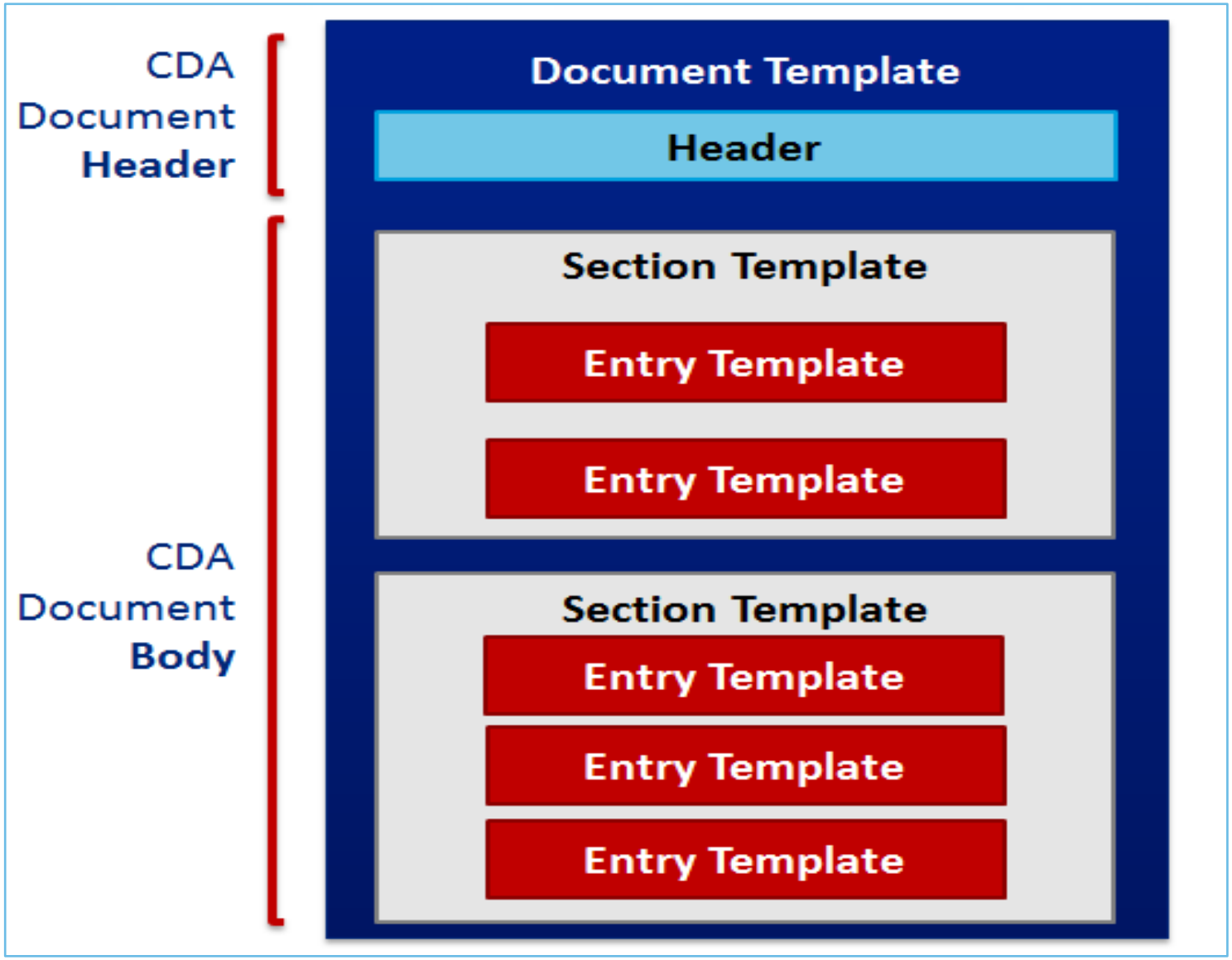
The C-CDA document defined

1. **Persistence:** **A clinical document** continues to exist in an unaltered state for a time period defined by local and regulatory requirements
2. **Stewardship:** A clinical document is maintained by an organization entrusted with its care
3. **Potential for authentication**: A clinical document is an assemblage of information that is intended to be legally authenticated
4. **Context:** A clinical document establishes the default context for its contents
5. **Wholeness:** Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document
6. **Human readability:** A clinical document is human readable to support decision making

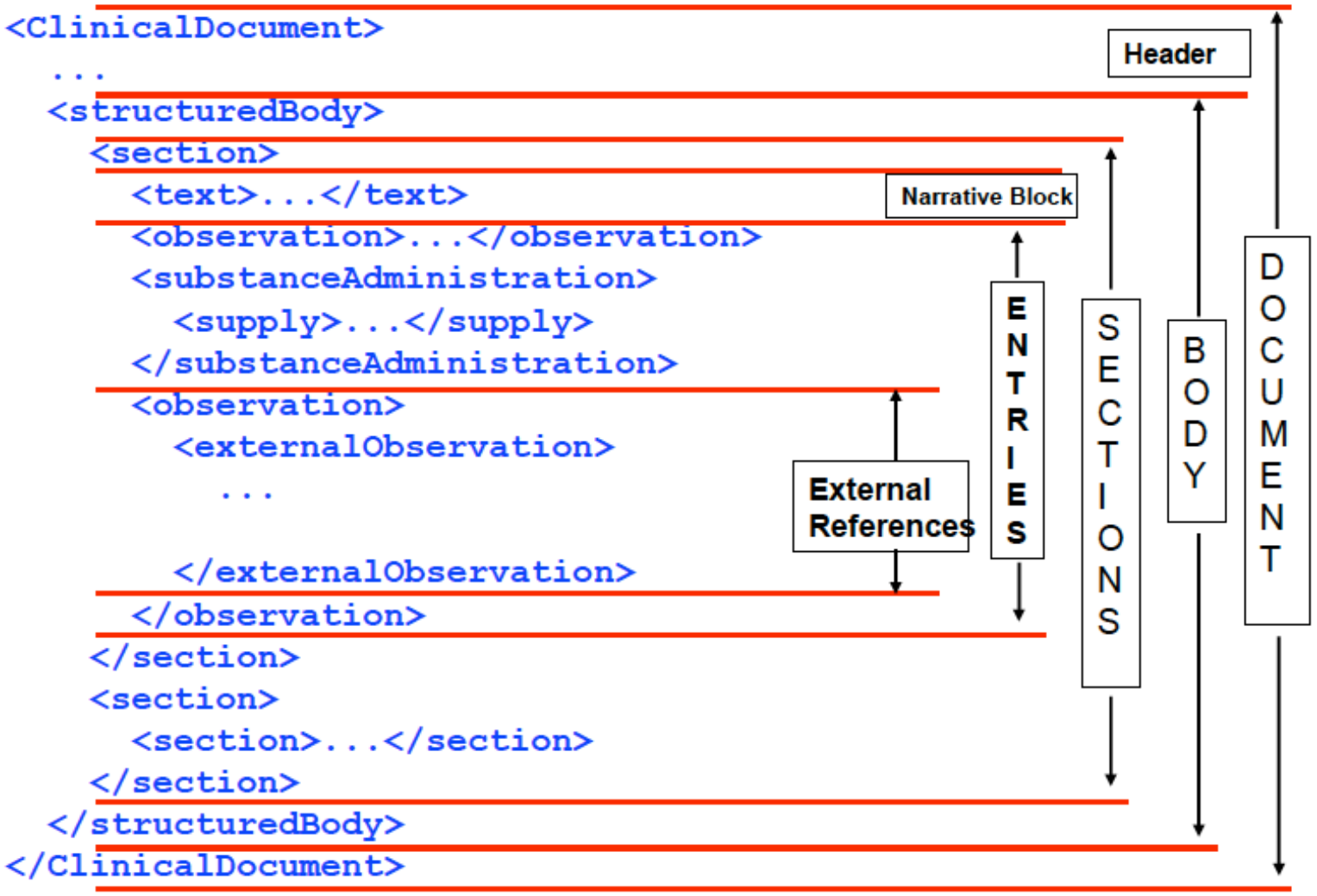
- **therefore, CDA documents are *not:***
  - data fragments, unless signed
  - birth-to-death aggregate records
  - electronic health records

C-CDA Design Principles

- priority is patient care, facilitate sharing of data to healthcare applications
- minimize technical barriers to implementation
- promote longevity of clinical records
- scoped by exchange, independent of transfer or storage
- enable policy-makers to control information requirements

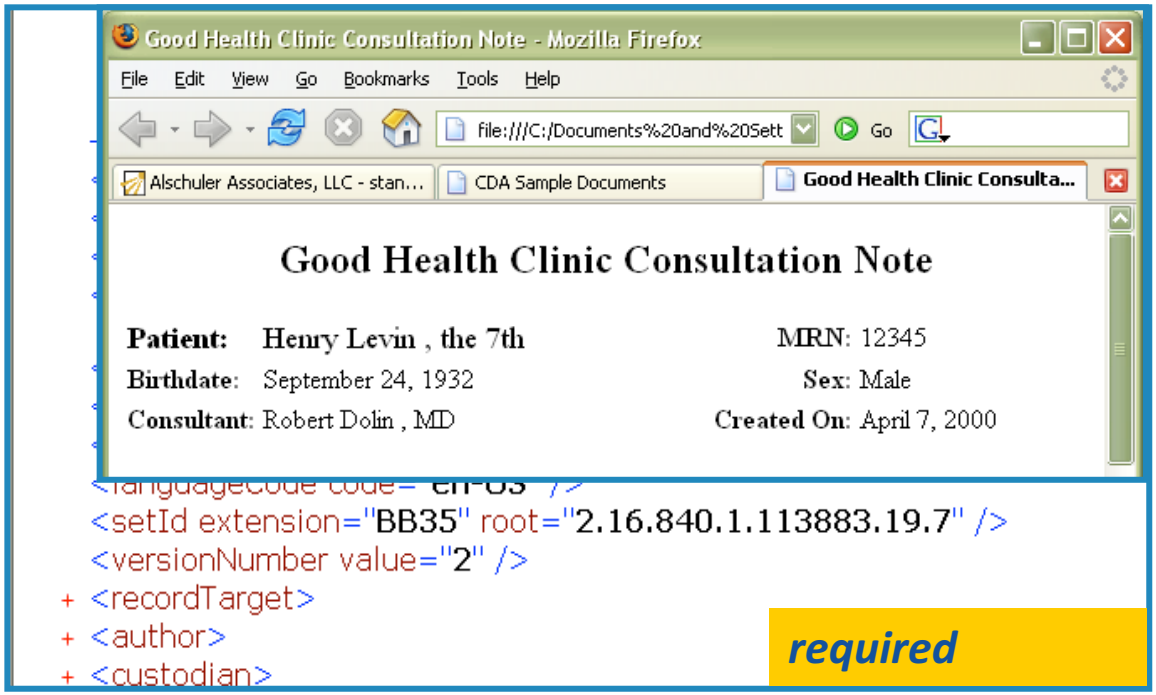


Major Components of a CDA Document



C-CDA US Realm Header: Metadata

- Identify
  - Patient
  - Provider
  - Document type…
- Sufficient for
  - Medical records management
  - Document management
  - Registry/repository
  - Record locator service
  - Store, query, retrieve



C-CDA Body: Machine Processable

- Model-based computable semantics:
  - Observation
  - Procedure
  - Organizer
  - Supply
  - Encounter
  - Substance Administration
  - Observation Media
  - Region Of Interest
  - Act

```
<title>Past Medical History</title>
- <text>
  - <list>
    - <item>
        <content ID="a1">Asthma</content>
      </item>
    + <item>
    + <item>
    </list>
  </text>
- <entry>
  - <observation classCode="COND" moodCode="EVN">
      <code code="39154008"
        codeSystem="2.16.840.1.113883.6.96"
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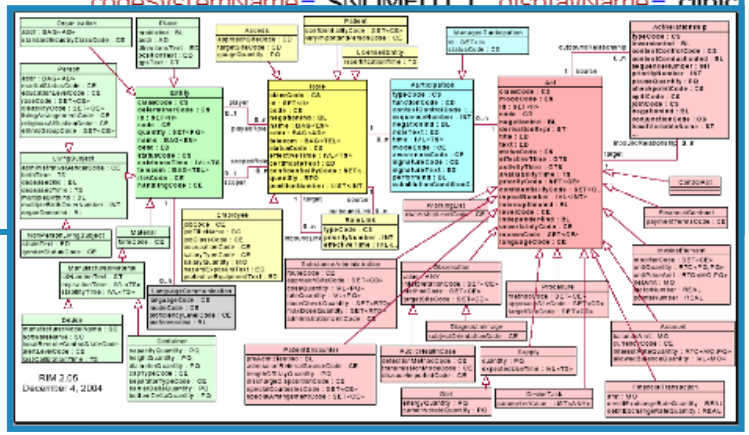
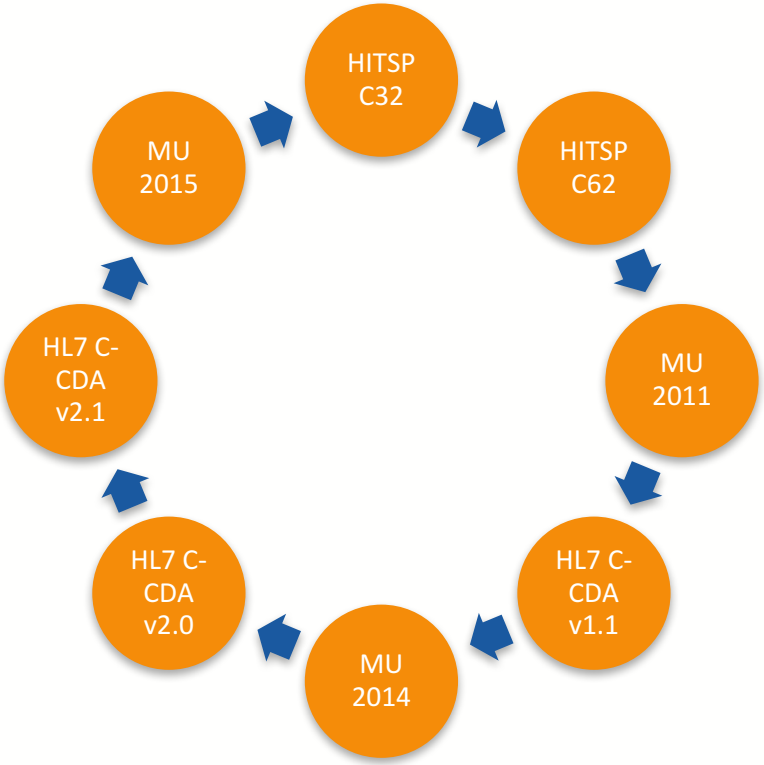


C-CDA: A Document Exchange Specification

- This is a C-CDA
- and this
- and this
- and this
- and this
- and this
- and this

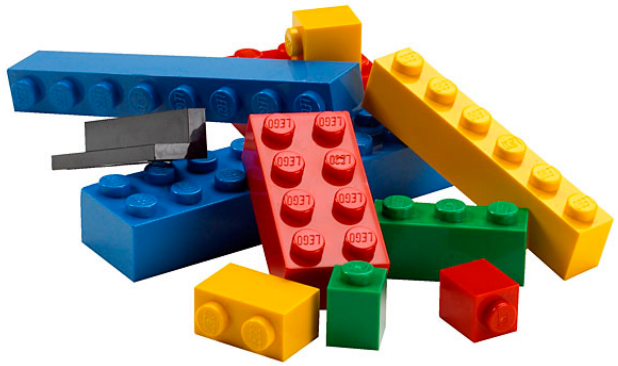
US/ONC/MU Consolidation Project (C-CDA)

- 2011 Edition/Stage 1 MU
- **2014 Edition/Stage 2 MU:**
  - HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use
  - HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm
- **2015 Edition/Stage3 MU:**
  - HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1 – Volume 1 – Introductory Material(August 2015)
  - HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm) Draft Standard for Trial Use Release 2.1- Volume 2 – Templates and SupportingMaterials(August 2015)
  - Companion Guide to HL7 Consolidated CDA R2.1 for ONC 2015 Health IT Certification Criteria
    HL7 Implementation Guide for CDA Release 2: Clinical
- Guidance on Relevant and Pertinent Data to Include Automatically Generated Patient Summaries
- HL7 Example Task Force Library
- Best Practices and Quantitative Scoring Criteria (Scorecard)



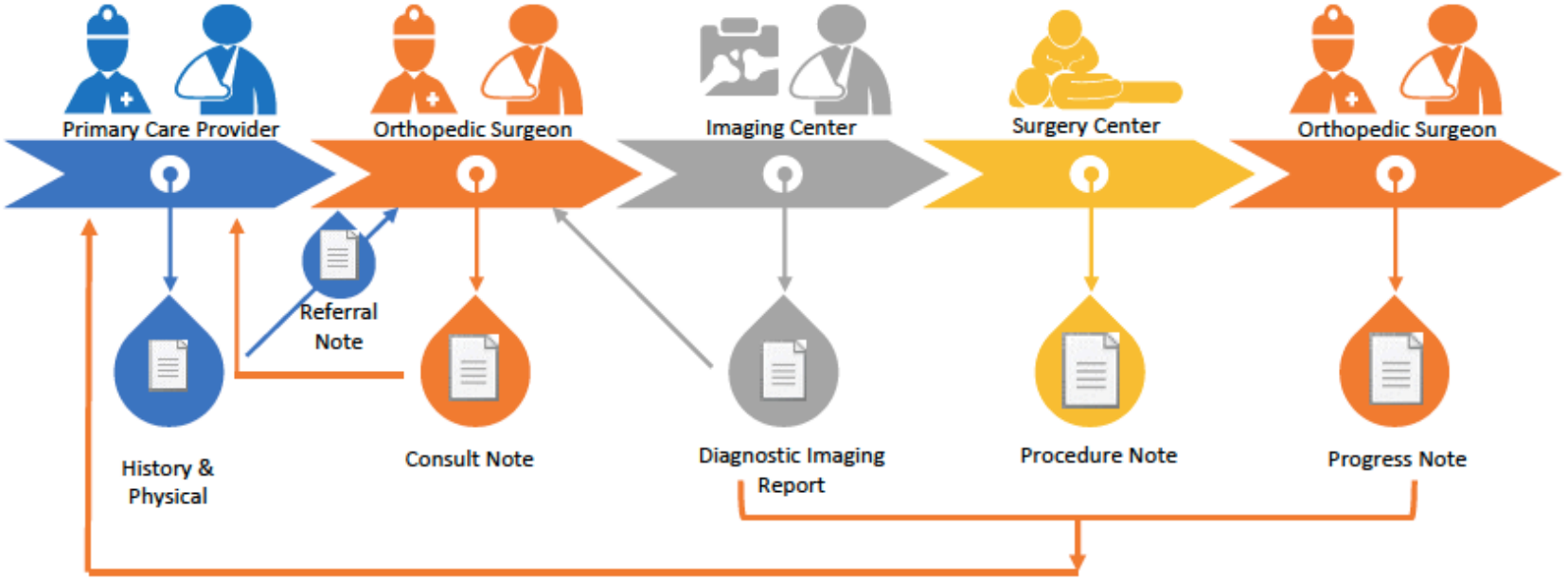
C-CDA R2.1 Document Types (12 Total)

- C-CDA R1.0/R1.1
  - Consultation Note
  - Continuity of Care Document (CCD)
  - Diagnostic Imaging Report
  - Discharge Summary
  - History and Physical
  - Operative Note
  - Procedure Note
  - Progress Note
  - Unstructured Document
- New as of C-CDA R2.0/R2.1
  - Care Plan
  - Referral Note
  - Transfer Summary



C-CDA: Exchanging the Patient's Story

- **Today, most of the clinical data exchanged by systems leverages ONLY the CCD**
- **Many documents are not created by a human but by a machine on demand when queried. Data should be exchanged using appropriate document types.**

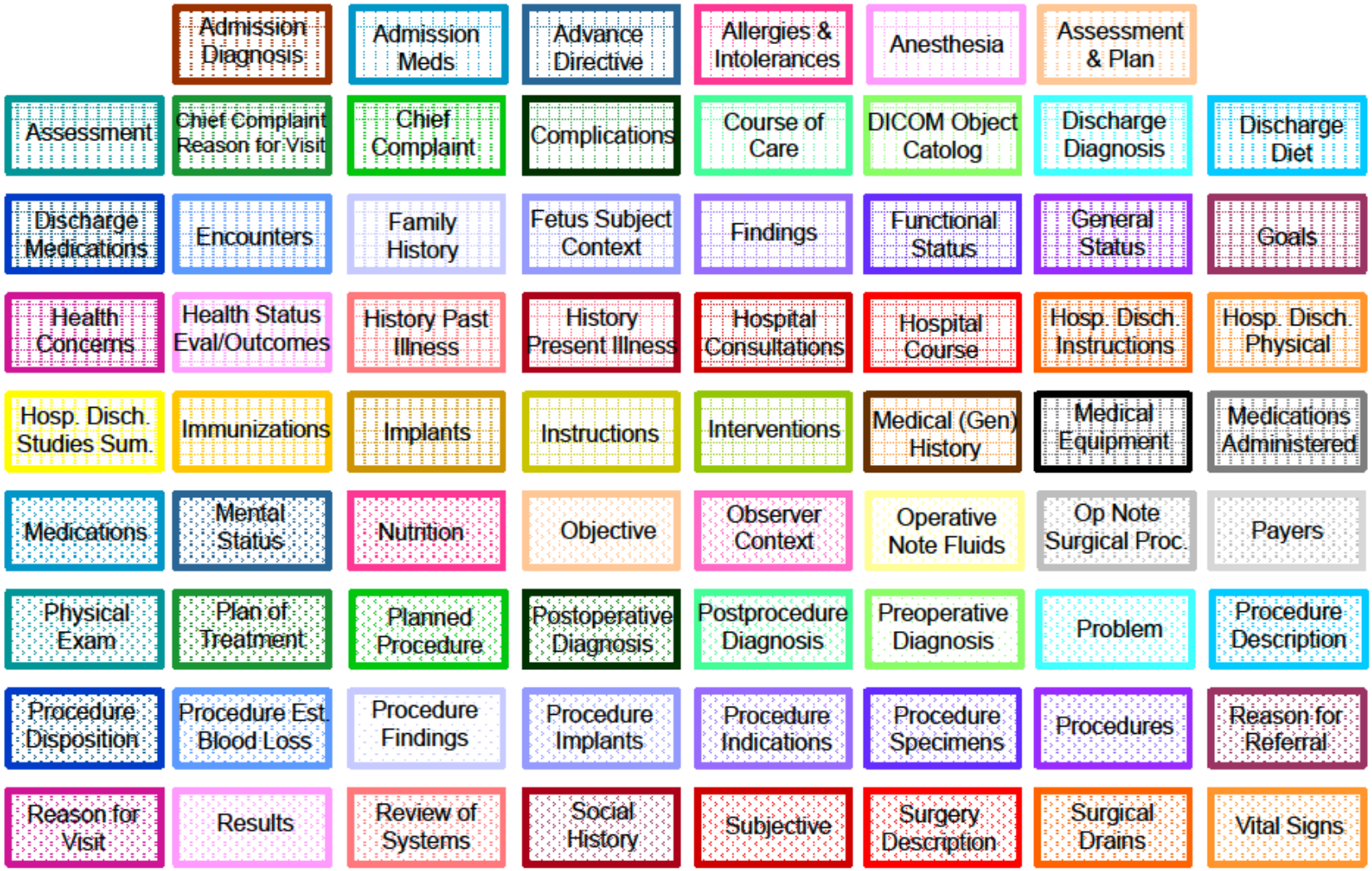


http://www.himss.org/library/c-cda-documents-building-blocks-meaningful-exchange

Why is using the right type of document important?

- Each CDA Document is designed to address a specific purpose
  - Use Cases should be reviewed to determine appropriate documents for use to support optimal patient care
  - Documents need to fit the situation
  - Share information that is relevant and pertinent
- Establish the right context for the information being shared
  - Information about multiple encounters
  - Information about a single encounter
  - Information about a service(s) within an encounter
  - Information that is related to a specific order
  - Patient generated information vs. Clinician or System generated data

70 Document Sections in C-CDA R2.1



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History & Physical

REQUIRED:

- Allergies & Intolerances
- Assessment
- Chief Complaint Reason for Visit
- Chief Complaint
- Family History
- General Status
- History Past Illness

OPTIONAL:

- Hospital Course
- Medications
- Physical Exam
- Reason for Visit
- Results
- Review of Systems
- Social History
- Vital Signs
- Assessment & Plan
- Immunizations
- Instructions
- History Present Illness
- Plan of Treatment
- Problem
- Procedures

Referral Note

REQUIRED:

- Allergies & Intolerances
- Assessment
- Medications
- Problem
- Reason for Visit

OPTIONAL:

- Advance Directive
- Assessment & Plan
- Family History
- Functional Status
- General Status
- History Past Illness
- History Present Illness
- Immunizations
- Medical Equipment
- Mental Status
- Nutrition
- Physical Exam
- Plan of Treatment
- Procedures
- Results
- Review of Systems
- Social History
- Vital Signs

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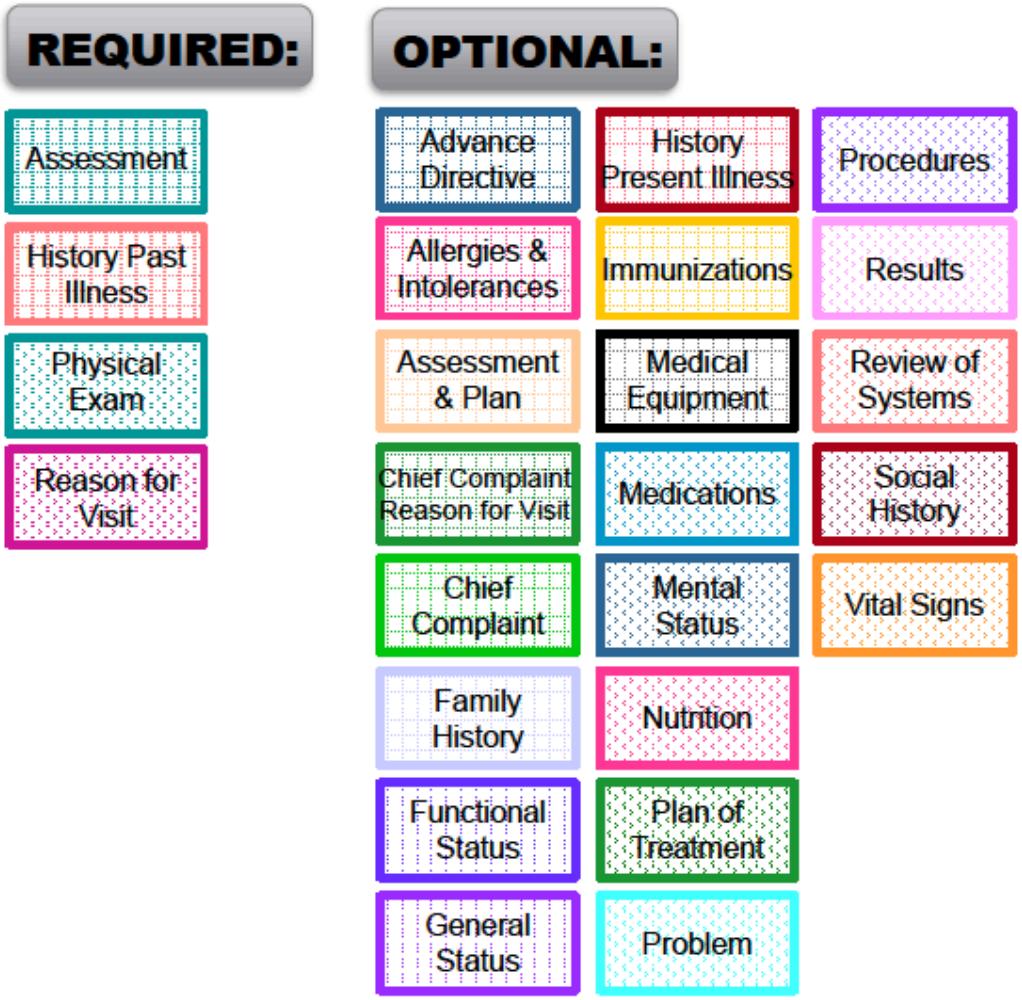
Consultation Note



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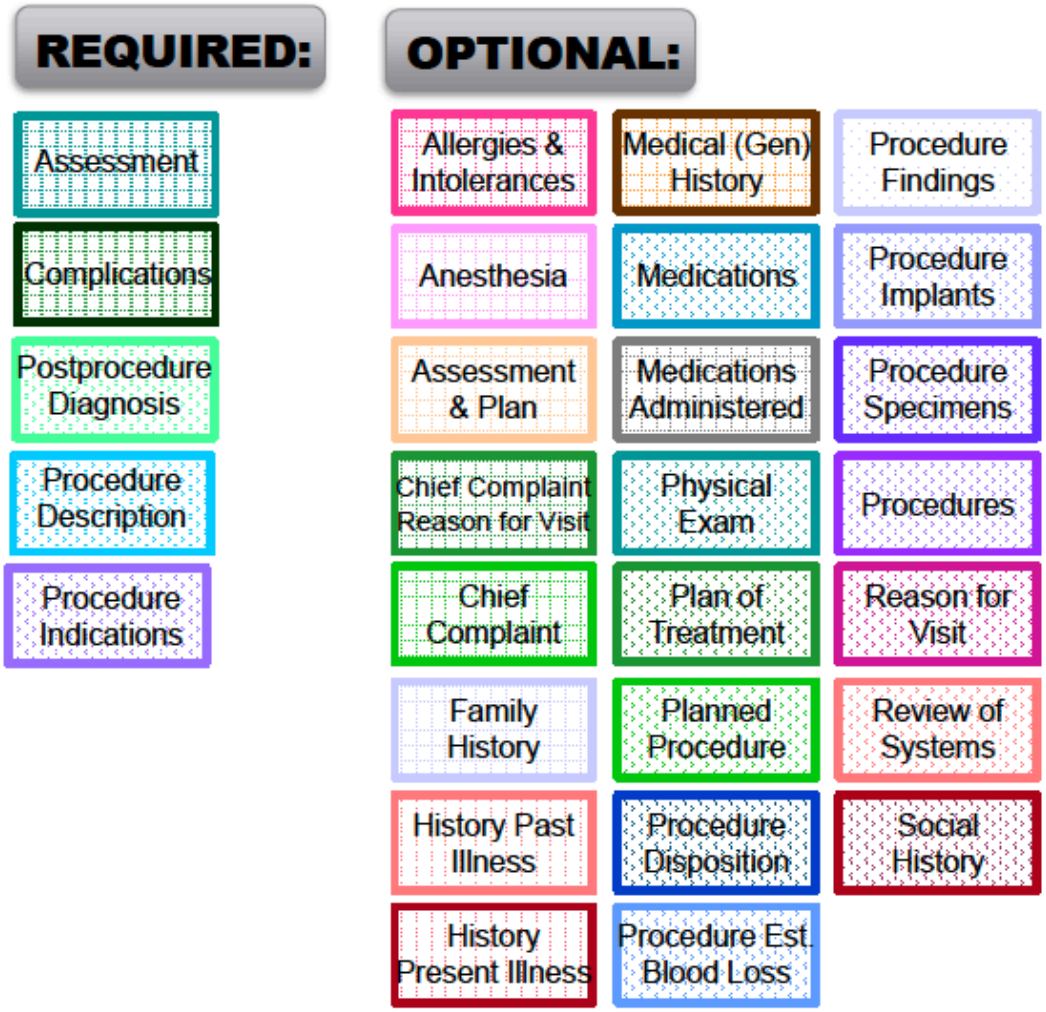
Procedure Note



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Progress Note

REQUIRED:

- Assessment

OPTIONAL:

- Allergies & Intolerances
- Assessment & Plan
- Chief Complaint
- Instructions
- Interventions
- Medications
- Nutrition
- Objective
- Physical Exam
- Plan of Treatment
- Problem
- Results
- Review of Systems
- Subjective
- Vital Signs

Care Plan

REQUIRED:

- Goals
- Health Concerns

OPTIONAL:

- Health Status Eval/Outcomes
- Interventions

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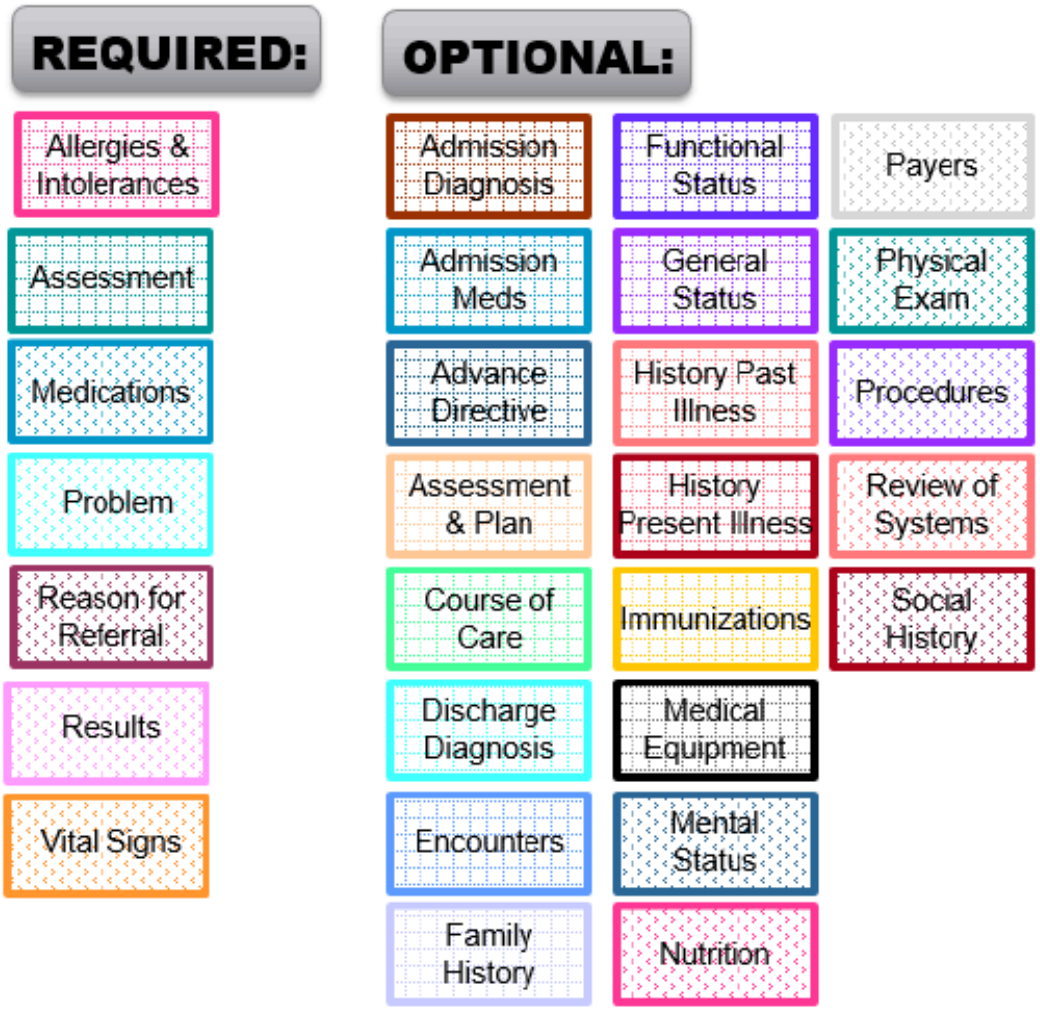
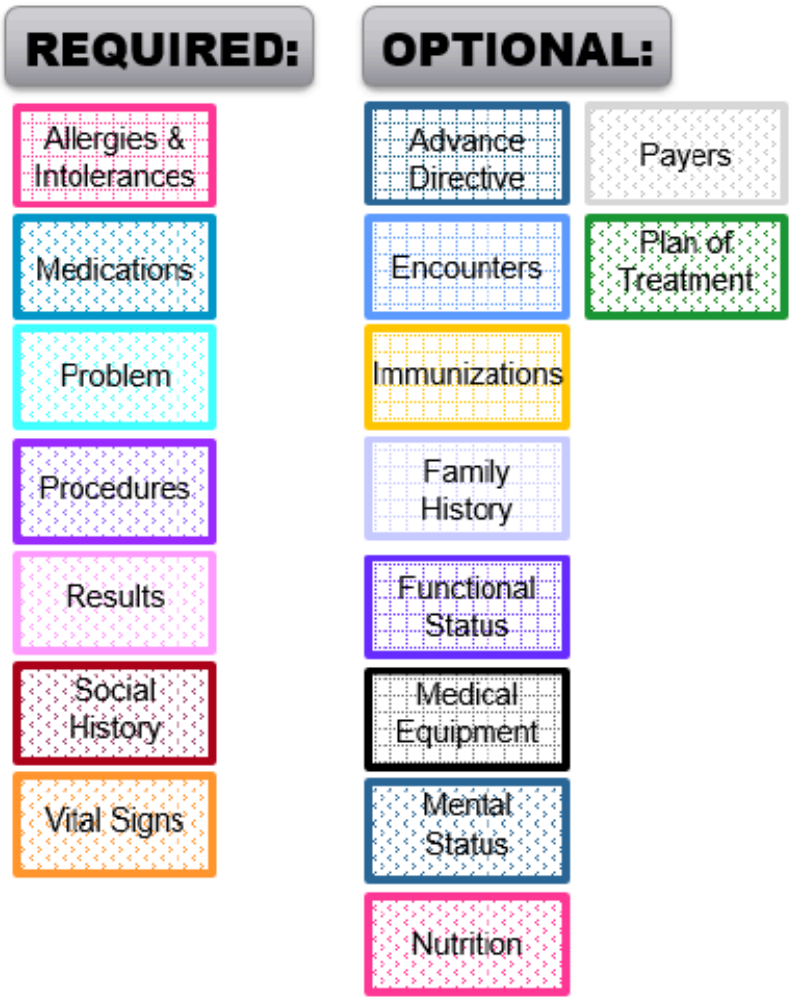
Transfer Summary



CCD



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What is the Sequoia Project Doing to Improve C-CDA Content Exchanged?

2016 - Content Testing Pilot/Program Completed

eHealth Exchange Content Testing Pilot April – July 2016

- 20 Organizations Participated in the Pilot with 10 different vendor architectures
  - All 20 Organizations had one or more documents fail
- 45 Sample Documents Received (9 C32s, 27 R1.1, 9 R2.1)
- 5 testing tools were evaluated and scored
- Testing Documentation published for 3rd round of public comment
  - November 2015
  - April 2016
  - December 2016

Industry-wide Content Pain Points

Optionality:
More than one way to do things and inconsistent implementations across vendors

Terminology:
Inconsistent terminology usage

Specification Ambiguity

Complexity:
The C-CDA standard is difficult to understand and consume and is lacking in clearly documented examples

Data Quality Challenges and Impact

Terminology: Inconsistent terminology usage

- Coding issues (>1,000,000 terms spread across multiple vocabularies (RxNorm, ICD-10, SNOMED, LOINC, CPT with overlap between concepts)
- How to manage terminologies with conceptual overlap?
  - Differences around code system mappings, including some creation of duplicates
- UCUM errors are common
- How to handle consistency of meta-information for class and type codes?

Data Quality Challenges and Impact Cont'd

Optionality: More than one way to do things and inconsistent implementations across vendors

- How to deal with unstructured or free-text information when terminologies are not used?
- How to deal with missing information?
- What if there is content in one section but not the other?
- When a query for a date range is used, what sections in a summary of care should the range be applied against?

Data Quality Challenges and Impact Cont'd

Complexity: The C-CDA standard is difficult to understand and consume; lack of clearly documented examples

- How to reconcile machine readable entries and the human readable portion when information conflicts?
- How does one package multiple documents that are related? other documents might be a discharge summary, operative note, progress lab, labs?
- What is the minimal set of metadata that a Content Consumer should display from a query response to help providers have sufficient information to choose from the returned list?
- How do we handle versioning (C32, HL7 C-CDA R1.1 or R2.1) and conflicting guidance?

Data Quality Challenges and Impact Cont'd

Specification Ambiguity

- Where to include clinical notes in a summary of care document - e.g., encounters, procedures, results sections?
- When a query is issued for a date range, what sections in a summary of care should the range be applied against?
- Lack of basic understanding and consistent implementation on service start and stop (to/from) for a query?
- Is a summary of care or continuity of care document based on a single encounter, multiple encounters, episodic of care?
- How are external references handled that may cross security contexts?
- How is embedded formatting handled within text elements?

Sequoia Project Content Testing Objectives

Develop
testing requirements to test and validate Health IT Modules

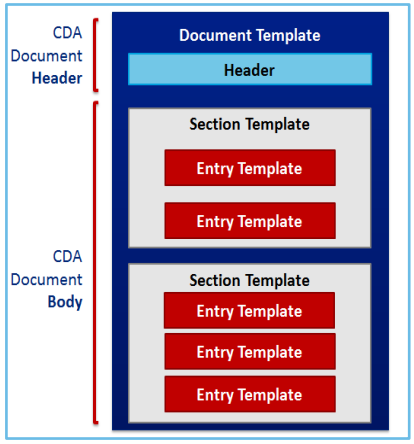
Create
review and approve testing documentation, checklists and Use Cases

Determine
interoperability testing requirements to enable robust testing of information exchange among participants

https://ehealth-exchange-testing.wikispaces.com/Documentation+for+Comment

What is the Enhanced Content Testing Program?

- Focused on HITSP C32/CCD, HL7 Consolidated CDA (C-CDA) R1.1 and R2.1
- Enhanced Testable Assertions
- Meaningful Use (MU) requirements/Transitions of Care
- Enhanced test cases and procedures
- Designed to enable interoperability and assure specification compliance
- Implementation-hardened by years of operations and documented pain points that continue to be coordinated with HL7 for inclusion in future documentation:
  - HL7 Implementation Guides/Companion Guides
  - Improved Scorecard Rubrics
    - (Quantitative Scoring Criteria)
  - HL7 C-CDA Companion Guide for MU Guidance for R2.1
  - Relevant & Pertinent Documentation Publication
  - HL7 CDA Example Search



Process for Creating Consistent & Robust HL7 C-CDAs

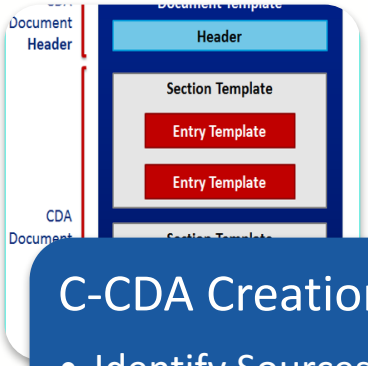
Content Priorities

- Clinicians
- Business Office
- Others

Data Mapping	SUT	HL7 C-CDA CCD	
Patient Gender	0	UN	"Administrative Gender" value
	1 (="Male")	M	
	2 (="Female")	F	
"Continuing"	1 (-"Yes")	active	"Problem Observation"
	2 (="No")	inactive	

Data Mapping

- SDO Requirements
- Vendor specific data model overlay
- Semantic Interoperability Transformation



C-CDA Creation

- Identify Sources
- System Configuration
- Value Sets
- Internal/External transformation

Enhanced Content Testing - Milestones

Milestone Descriptions	Target Date	Status
Present to CC for Review/approval	11/15/16	Completed
Participant Input (Post draft to eHealth Exchange Wiki)	11/15/16	Completed
Participant Input Informational Call (Review documentation)	12/02/16	Completed
30 day notice to Participants	12/02/16	Completed
30+ day Objection Period Ends	01/09/17	Completed
Target Effective Date	01/10/2017	Completed
eHealth Exchange Tooling Implementation/Training	Q2/2017	Not Started
Testing Workgroup Feedback to HL7/ONC	Ongoing	Ongoing

Content Testing Future Timeline

- Public Comment of Updated Documentation through December 2016
- Testing Tooling chosen for Production Content Testing by February 2017
- Production Content Testing to begin Q2/2017
  - All New participants will be required to test Content
  - Existing Production Participants will have 12 months to test content
  - Errors Encountered with Initial testing will have to be corrected within 18 months of initial testing report
- Enable continuous improvements to clinical content exchanged
- Ongoing Feedback to HL7 from industry to improve standards

Questions/Thank You!