The Office of the National Coordinator for Health Information Technology

Implementing Consolidated-Clinical Document Architecture (C-CDA) for Meaningful Use Stage 2

ONC Implementation and Testing Division

April 5, 2013

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Remember how healthcare data was exchanged prior to Electronic Health Records (EHRs)?

Healthcare Data Exchange (Pre-EHRs)

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Vast amounts of patient data collected by clinicians

Medical information such as vitals, orders, prescriptions, lab notes, discharge summaries, etc. dictated or recorded by hand

All of this clinical data was stored as paper records (documents) at each point of care

If patient health records needed to be shared between providers, they usually required manual exchange (e.g. fax, "snail mail")

- **Coordination of care between providers slow, costly; patient outcomes inconsistent**
- **Duplicative healthcare services (e.g. labs imaging) frequent**

What do the 2014 Edition EHR Certification Criteria and Meaningful Use Stage 2 objectives say about Health Information Exchange?

CMS & ONC Rules: 2014 Edition EHR Certification Criteria & MU2

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ONC: Standards, Implementation Specifications & Certification Criteria (S&CC) 2014 Edition

- Specifies capabilities and functions that Complete EHRs and EHR Modules must perform electronically in order to be certified under the ONC HIT Certification Program

Reference: *ONC Health Information Technology : Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology Final Rule 170.314*

CMS: Medicare and Medicaid EHR Incentive Programs Stage 2

- outlines incentive payments (+$$$) for early adoption
- outlines payment adjustments (-$$$) for late adoption/non-compliance

Reference: *CMS Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2 Final Rule 495.6*

Meaningful Use Stage 2 Rule (MU2) Overview

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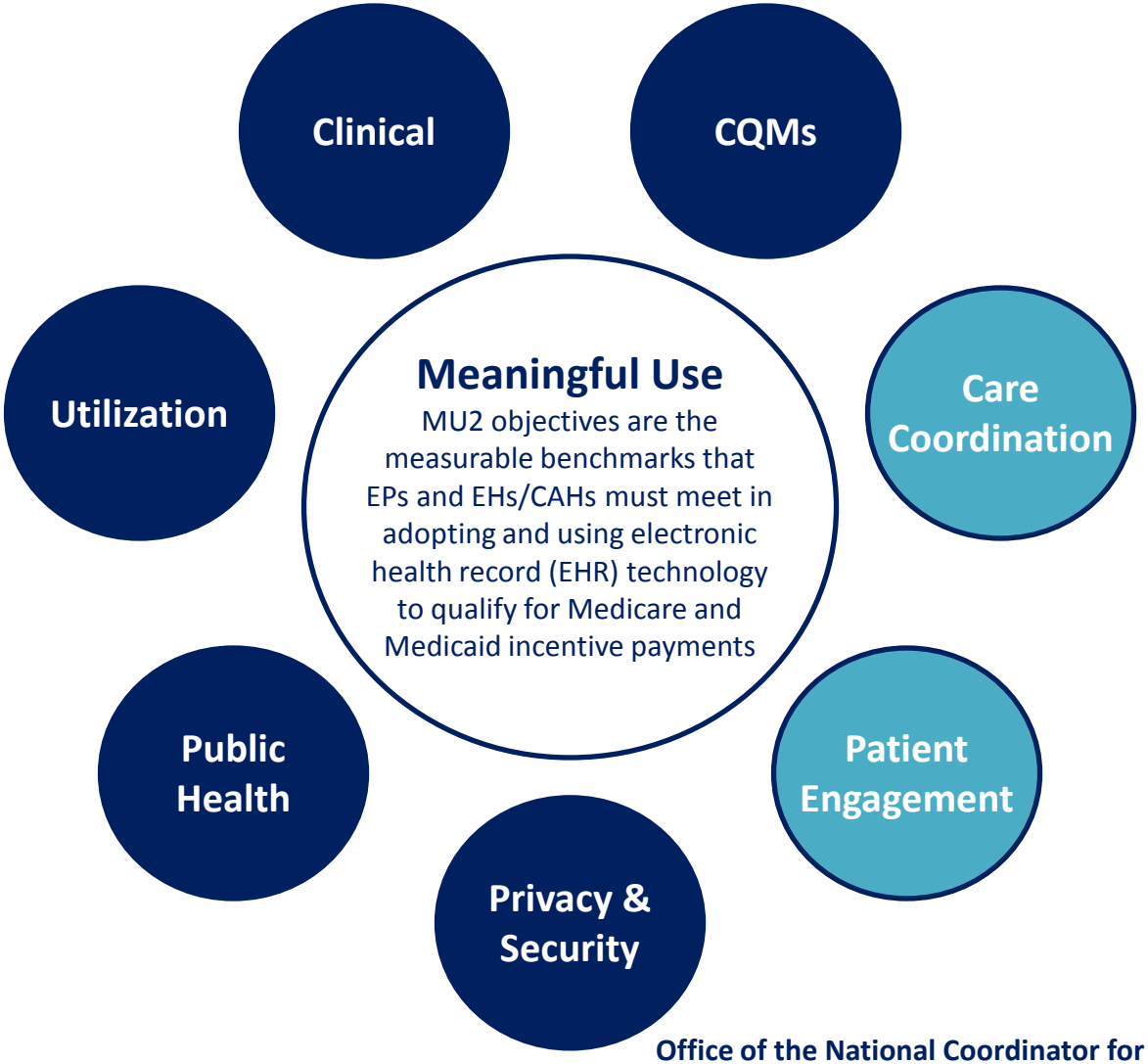

MU2 sets measurable objectives for Eligible Professionals (EPs) or Eligible Hospitals (EHs) / Critical Access Hospitals (CAHs) to obtain CMS incentives (CMS 495.6)

- MU2 objectives are categorized to reflect Health Outcomes Policy Priorities
- Pursuit of objectives within 2 of the 7 categories involve using Certified EHR Technology that has C-CDA capabilities

2014 Edition EHR Certification Criteria: Categories & Criteria

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Cert. Category	Criterion	Description	Req. Summary Type
Care Coordination *170.314(b)*	Transition of Care *170.314(b)(1)&(2)*	when transitioning a patient to another care setting, the EP or EH/CAH should provide a summary care record	Transition of Care/Referral Summary
	Data Portability *170.314(b)(7)*	when a patient transitions from provider or setting to another, a medication reconciliation should be preformed	Export Summary
Patient Engagement *170.314(e)*	View/Download/Transmit *170.314(e)(1)*	patients must be able to view & download their own medical info & also be able to transmit that info to a 3rd party	Ambulatory or Inpatient Summary
	Clinical Summary *170.314(e)(2)*	provide clinical summaries for patients for each office visit	Clinical Summary

Data Requirements Example: Transition of Care

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Cert. Category	Criterion	Description	Summary Type
Care Coordination *170.314(b)*	**Transition of Care** *170.314(b)(1)&(2)*	when transitioning a patient to another care setting, the EP or EH/CAH should provide a summary care record	**Transition of Care/Referral Summary**

Common MU Data Set

- Patient name
- Sex
- Date of birth
- Race **
- Ethnicity **
- Preferred language**
- Care team member(s)
- Medications **
- Medication allergies **
- Care plan
- Problems **
- Laboratory test(s) **
- Laboratory value(s)/result(s)
- Procedures **
- Smoking status **
- Vital signs

Criterion-Specific Data Requirements

- Provider Name & Office Contact Information (Ambulatory Only)
- Reason for Referral (Ambulatory Only)
- Encounter Diagnoses **
- Cognitive Status
- Functional Status
- Discharge Instructions (Inpatient Only)
- Immunizations **

NOTE: Data requirements marked with a double asterisk (**) also have a defined vocabulary which must be used

Vocabulary Example: Smoking Status

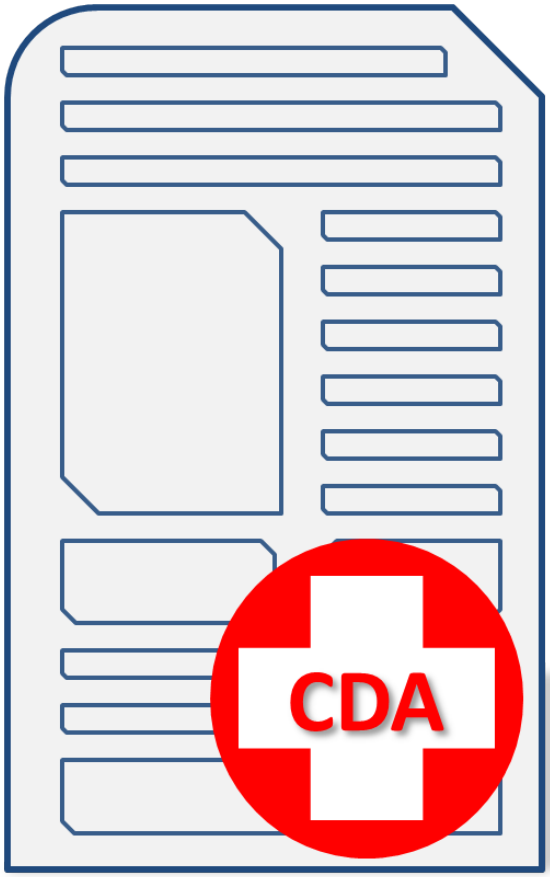
Vocabularies are used to assign a **unique value to a clinical concept**

SNOMED-CT values acceptable for "Smoking Status"	
Description	**SNOMED-CT Code**
Current every day smoker	449868002
Current some day smoker	428041000124106
Former smoker	8517006
Never smoker	266919005
Smoker, current status unknown	77176002
Unknown if ever smoked	266927001
Heavy tobacco smoker	428071000124103
Light tobacco smoker	428061000124105

By standardizing a distinct set of codes for a clinical concept, the 2014 Edition EHR Certification Criteria's use of vocabularies promotes the use of common definitions when sharing information across diverse clinical environments.

What are the purpose, functionality, usage, and structure of HL7's Clinical Document Architecture (CDA)?

Clinical Document Architecture (CDA) Overview



An international not-for-profit SDO with 2,300+ members across 500 corporations representing ~90% of IS vendors serving Healthcare.

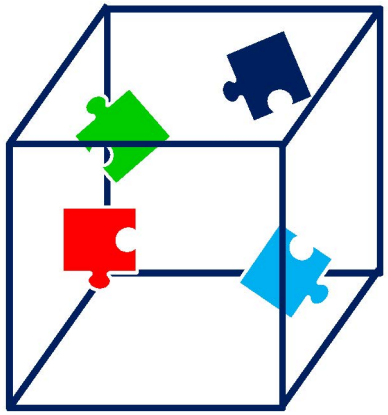
Dedicated to providing a comprehensive framework for the exchange and management of health information

CDA is a base standard which provides a common architecture, coding, semantic framework, and markup language for the creation of electronic clinical documents

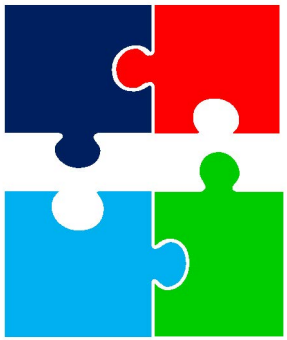
- CDA Docs are coded in Extensible Markup Language (XML)
  - HTML describes presentation, XML describes content
  - Human readable and machine interpretable
- **Templated:** standardized groupings of information organized according to clinical context
- **Object Oriented:** makes use of classes, associations, and inheritance; allows tremendous flexibility and re-use

CDA Usage

CDA defines building blocks which can be used to contain healthcare data elements that can be captured, stored, accessed, displayed and transmitted electronically for use and reuse in many formats



Sets of these CDA standardized building blocks can be arranged for whatever needs exist



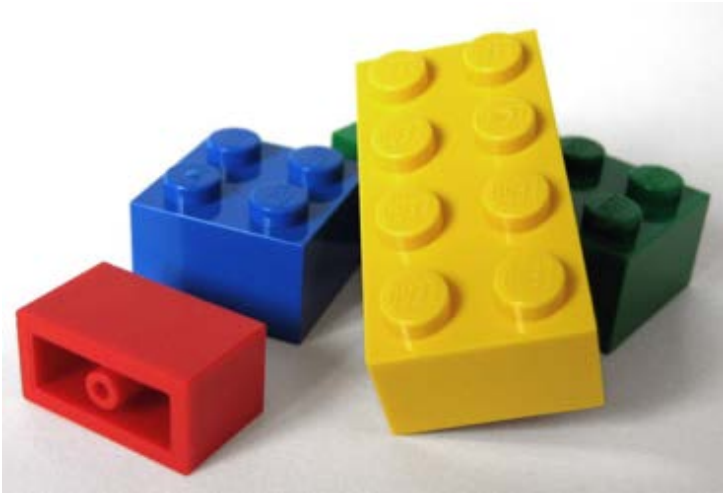
This approach offers tremendous flexibility; it allows for the creation of a comprehensive variety of clinical documents which share common design patterns and use a single base standard

Arranging (or constraining) the CDA elements in defined ways using IGs and templates produces clinical documents

e.g. a *Discharge Summary* and an *Op Note* both draw from the same CDA schema but are scoped for different use cases

CDA Purpose & Functionality

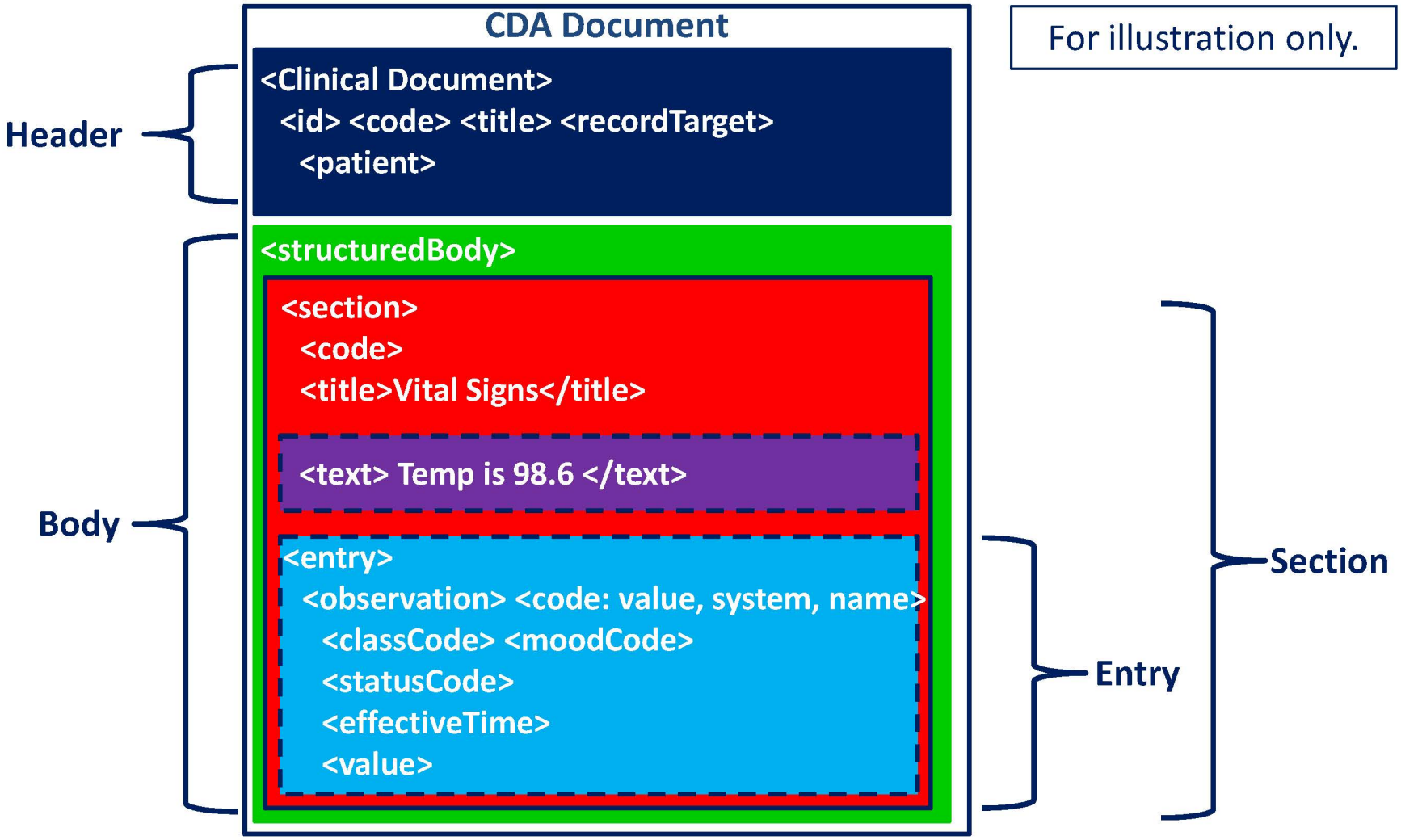
CDA defines the structure of building blocks which can be used to contain a multitude of healthcare data elements that can be captured, stored, accessed, displayed and transmitted electronically for use and reuse in many formats



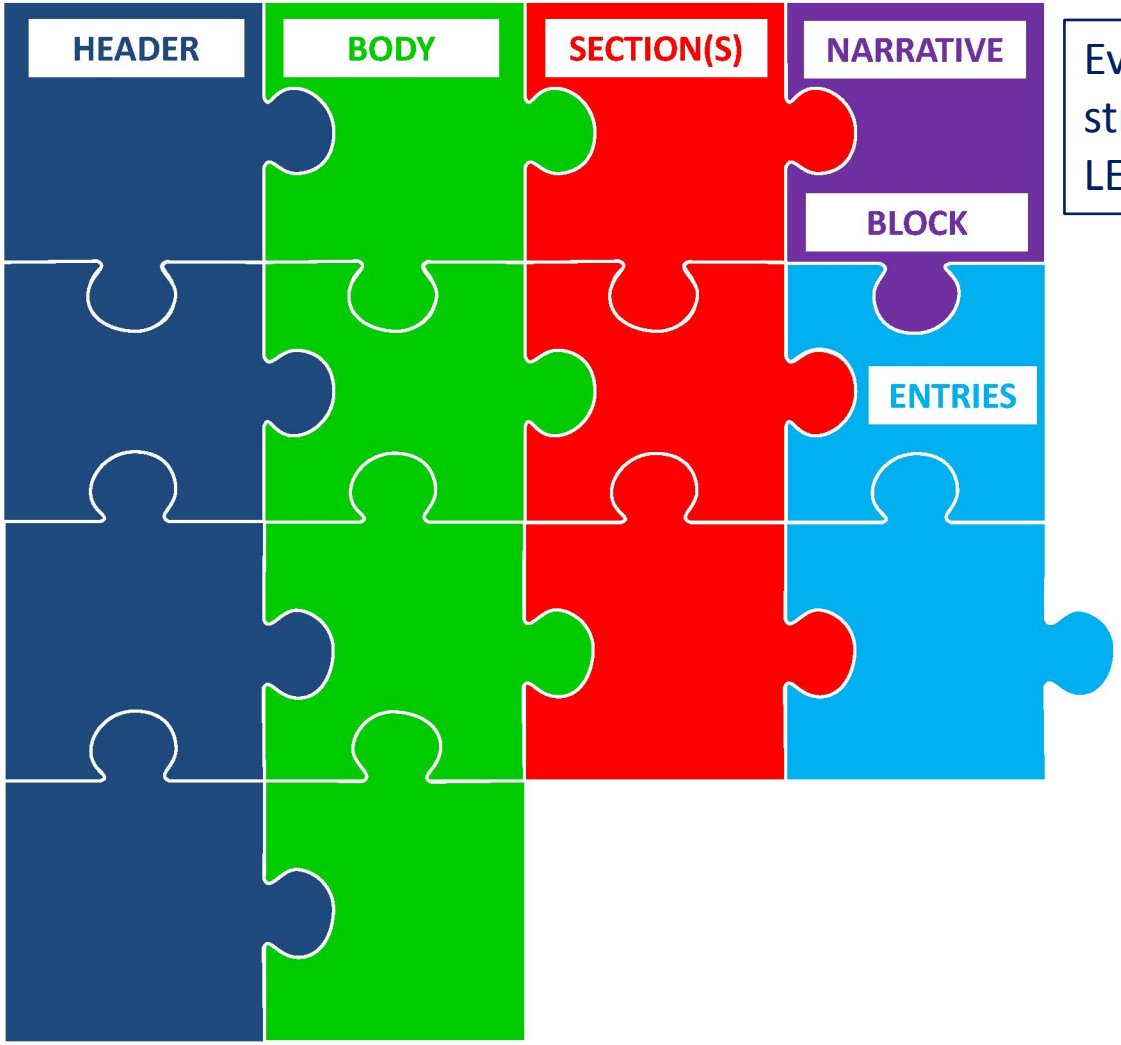
CDA *DOES NOT* specify how documents are transported, simply how critical data elements should be encoded for exchange and interoperability

CDA can contain both structured and unstructured information

CDA Document Structure Example



CDA Structure: Overview



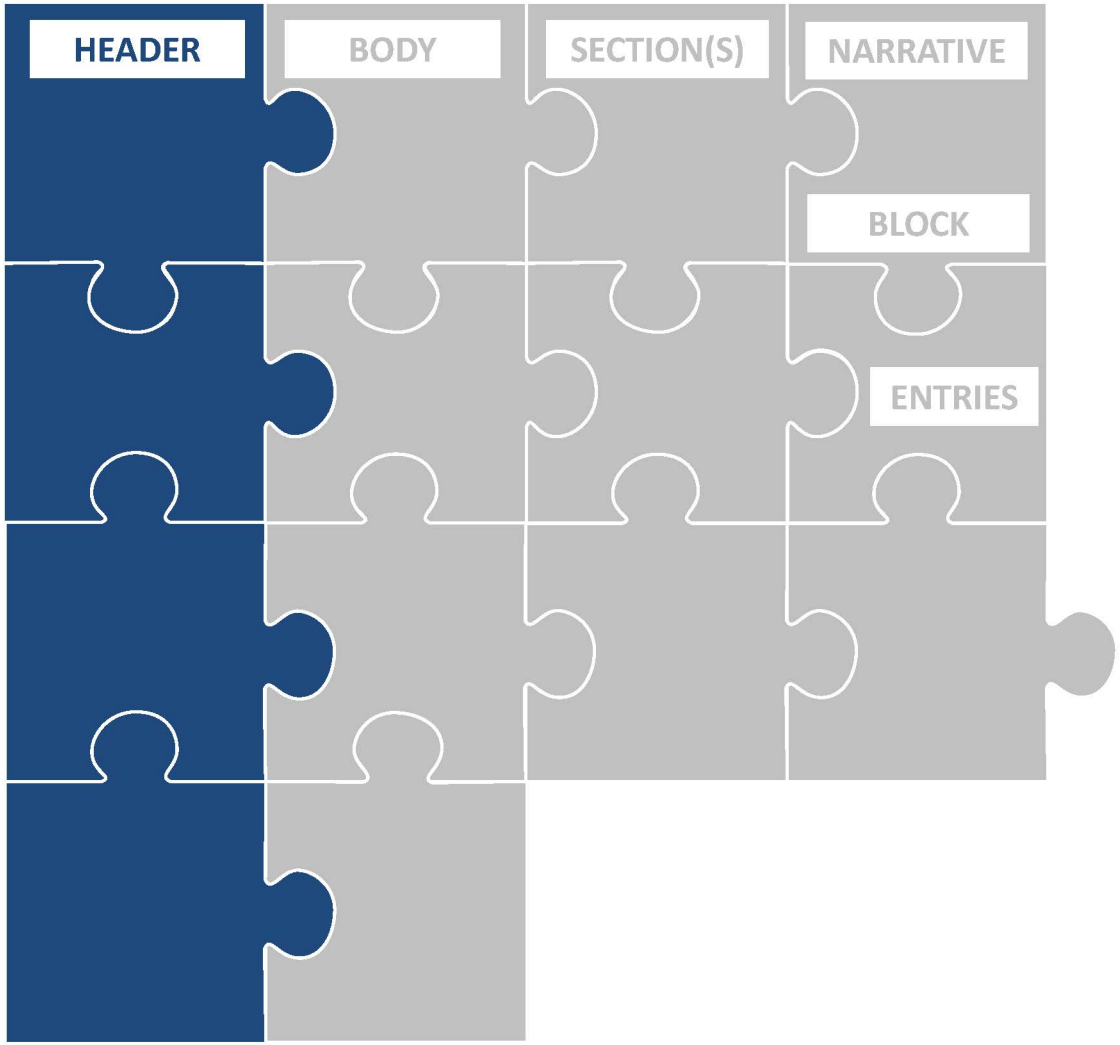
Every CDA document with a structured XML body must have AT LEAST a **Header** AND one **Section**

XML enables both human and machine readability.

The XML structure for a CDA document nests data in the following way:

» Header
» Body
» » Section(s)
» » » Narrative Block
» » » Entry(s)

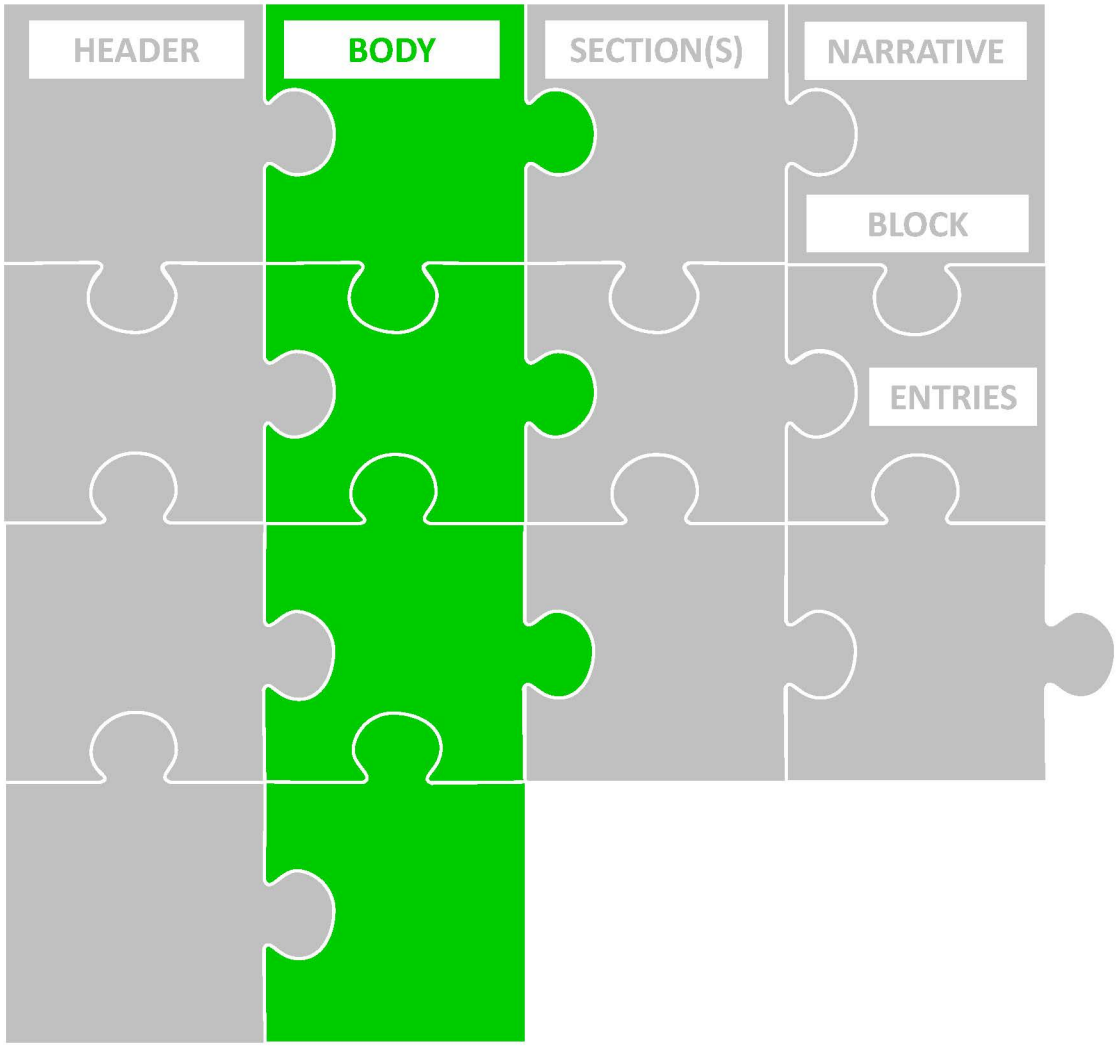
CDA Structure: Header



The **Header** sets the context for the clinical document as a whole and:

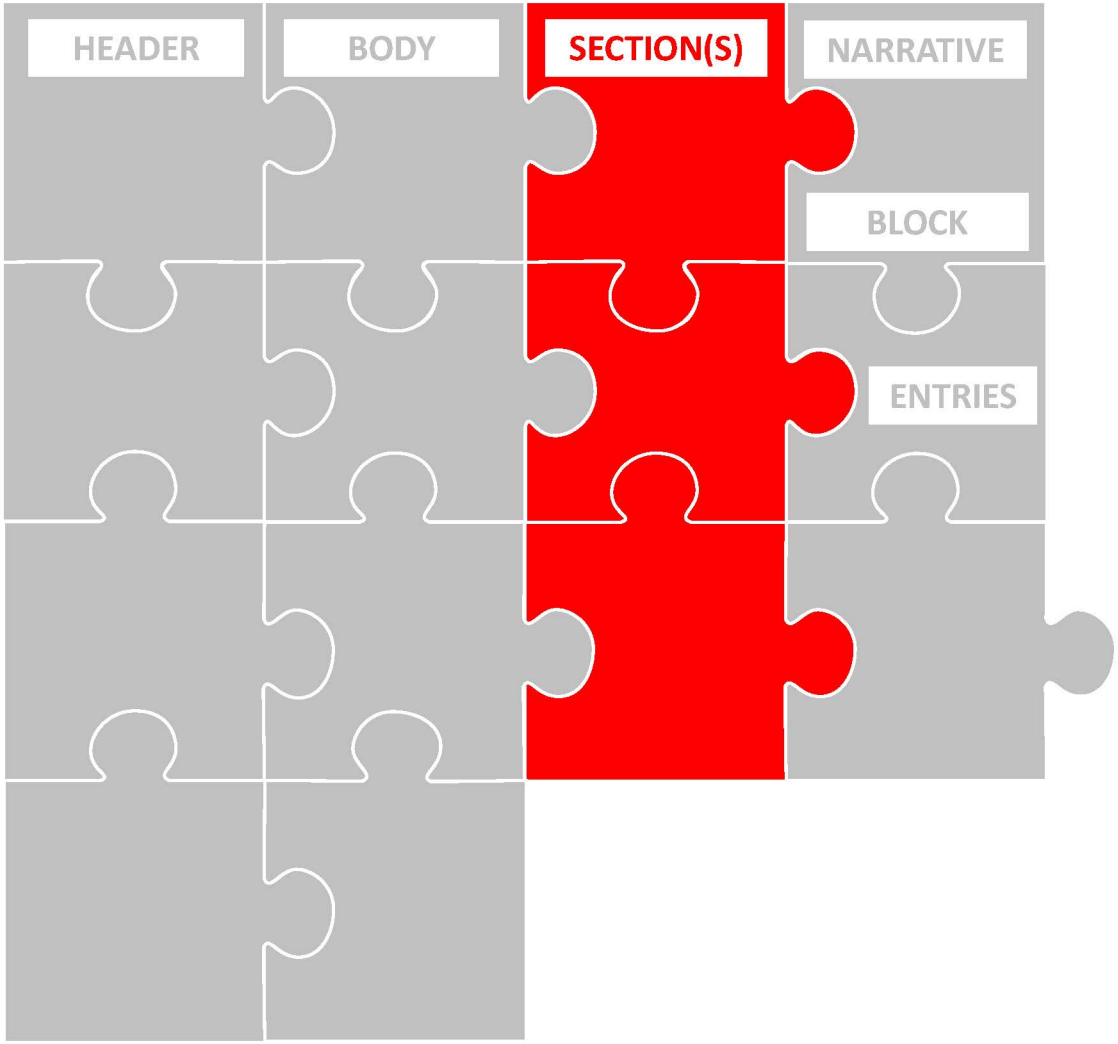
- enables clinical document exchange across and within institutions;
- facilitates clinical document management ; and
- facilitates compilation of an individual patient's clinical documents into a electronic patient record.

CDA Structure: Body



The **Body** contains the clinical report and can contain an unstructured "blob" or structured content organized in one or more **Sections**.

CDA XML Structure: Section(s)

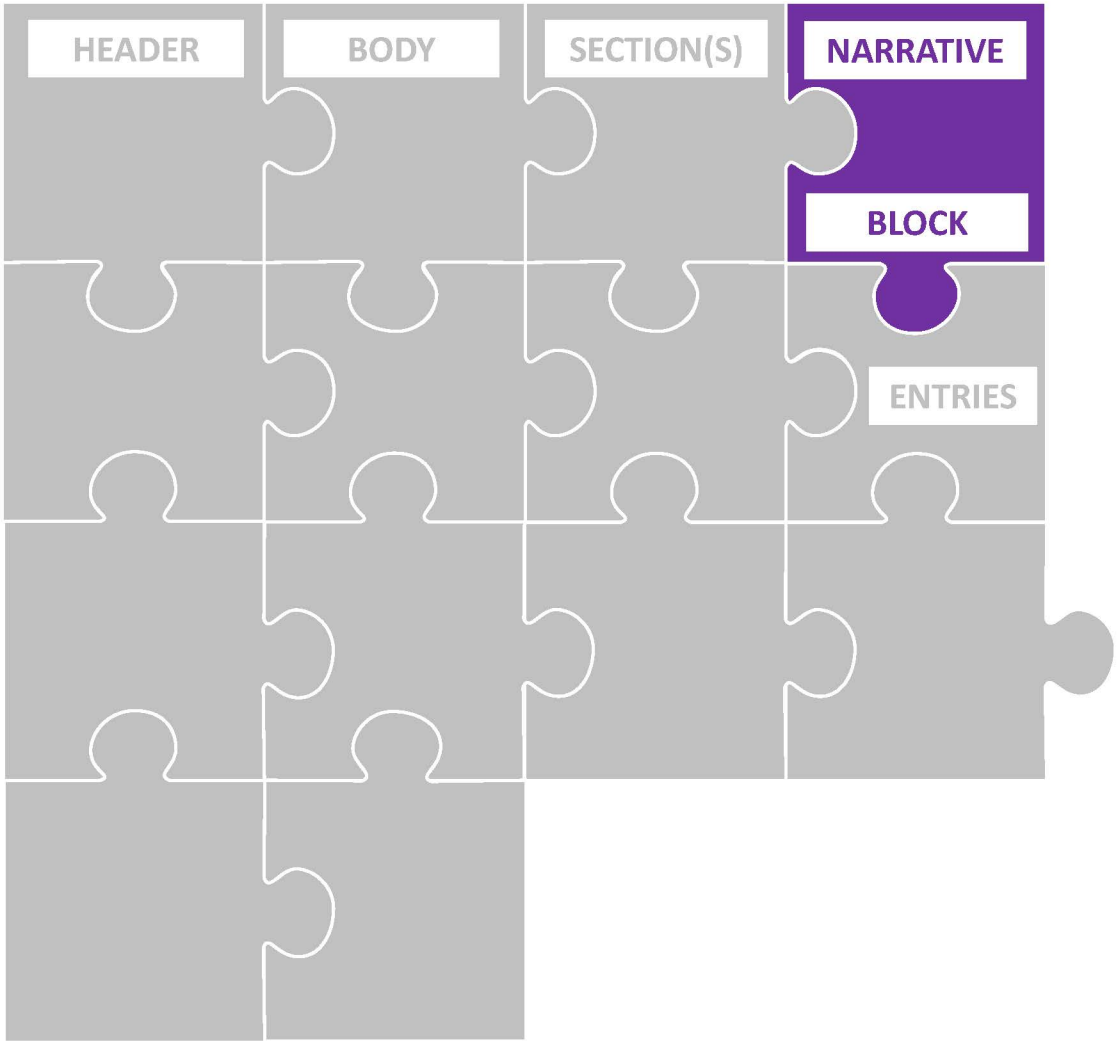


Each **Section** contains one **Narrative Block** and zero to many coded **Entries**.

Examples include:

- **Allergies**
- **Meds**
- **Problems**
- **Immunizations**
- **Vital Signs**

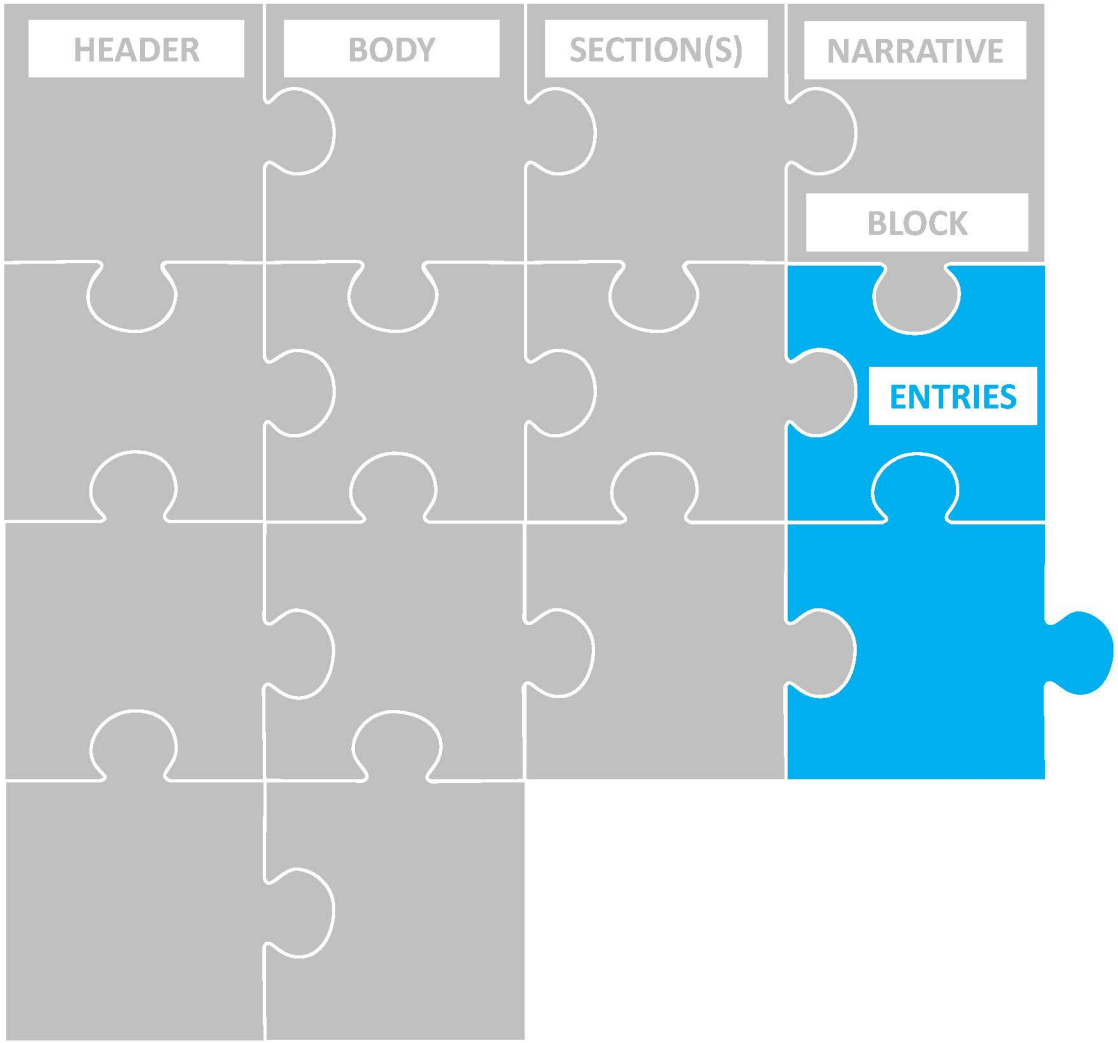
CDA XML Structure: Narrative Block(s)



Narrative Blocks allow "human-readability" of a CDA document. Within a document section, the narrative block represents content to be rendered for viewing.

The **Narrative Block** has fixed markup, and must be populated by the document originator.

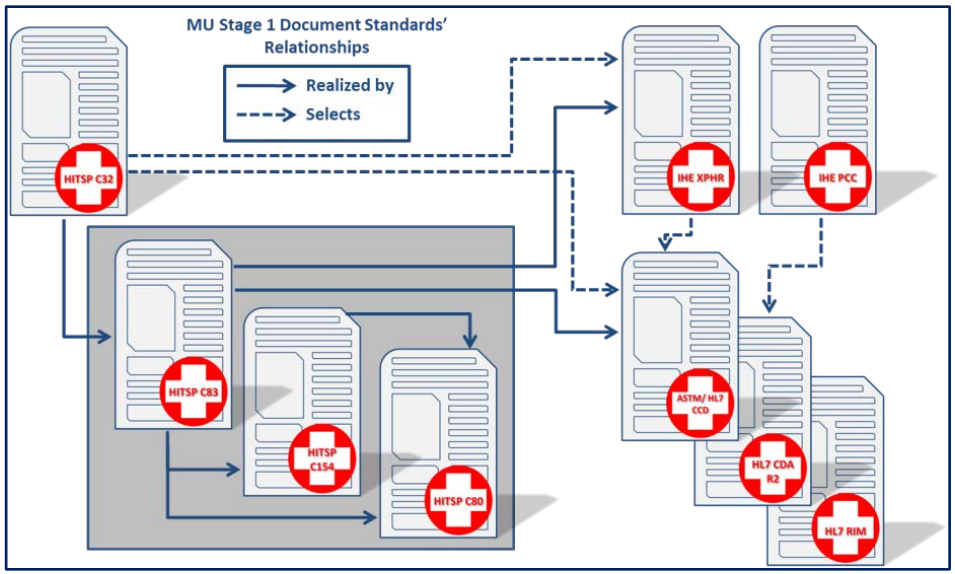
CDA XML Structure: Entries



Entries allow "machine-readability" (e.g. decision support applications). Within a document section, an entry represents structured content for further computer processing.

Why Consolidated CDA?

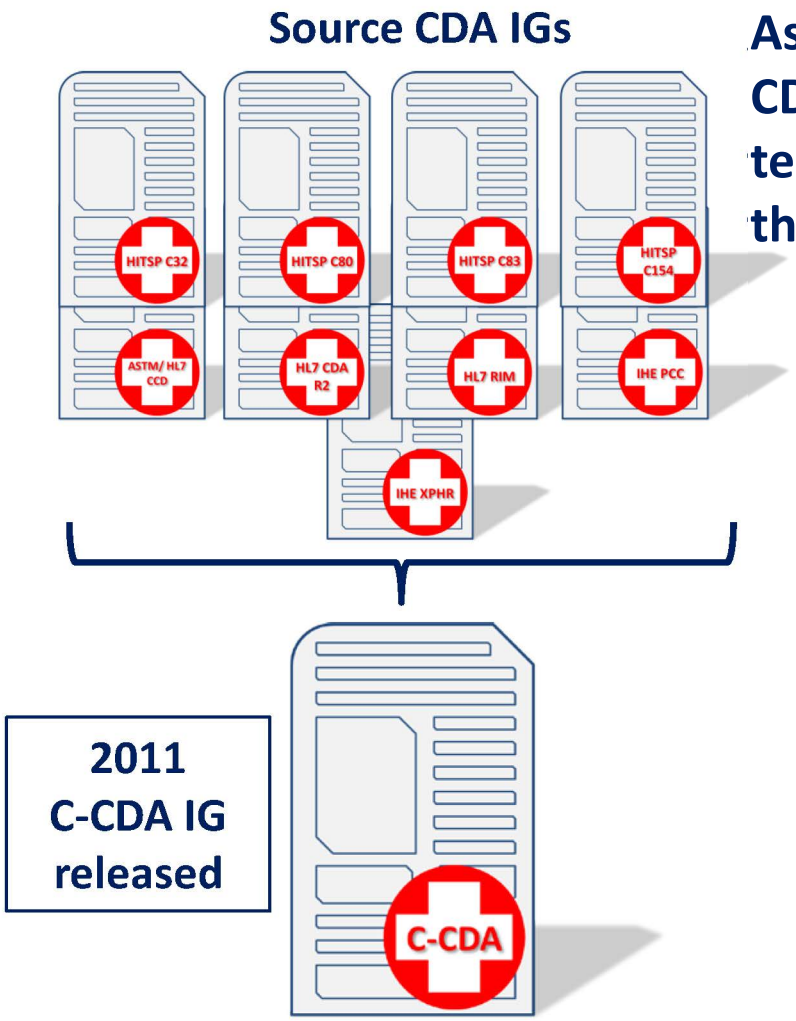
Pre-Consolidation Context



Before Consolidation, providers trying to implement a specific clinical document (e.g. *C32*) were faced with a "rabbit hole" of cross-referenced materials creating an ever growing, complex web of documentation – Consolidation was undertaken to address this issue.

- Duplicative and conflicting IGs published by different standards organizations (e.g. HITSP, HL7, IHE, Health Story); approved/balloted at different times
- Implementers faced with confusing collection of documents containing ambiguous and/or conflicting information
- C-CDA IG includes the following clinical documents (year released): Consultation Note (2008); Discharge Summary (2009); Imaging Integration and DICOM Diagnostic Imaging Reports (DIR) (2009); History and Physical (H&P) (2008); Operative Note (2009); Progress Note (2010); Procedure Note (2010); and Unstructured documents (2010)

Consolidation Process



As disparate SDOs (HL7, IHE, HITSP, etc.) developed CDA IGs, multiple approaches for documenting template requirements began to diverge threatening interoperability…

- S&I hosted a collaboration among the standards community in order to address CDA documentation issues which were hampering understanding and consistent implementation in order to:
  - examine and analyze CDA Templates across the existing documentation
  - identify and address errors, issues of ambiguity, and conflict
  - consolidate prior documentation to a new single IG and ballot (approve) through HL7
- Consolidation harmonized and balloted previous templates a single IG

C-CDA IG Purpose: Single Source for CDA Templates

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HL7 Implementation Guide for CDA R2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) July 2012

Document Templates: 9

- Continuity of Care Document (CCD)
- Consultation Note
- Diagnostic Imaging Report (DIR)
- Discharge Summary
- History and Physical (H&P)
- Operative Note
- Procedure Note
- Progress Note
- Unstructured Document

Section Templates: 60

Entry Templates: 82

Document Template	Section Template(s)		
Continuity Of Care Document (CCD)	Allergies Medications Problem List Procedures Results Advance Directives Encounters	Family History Functional Status Immunizations Medical Equipment Payers Plan of Care	Section templates in GREEN demonstrate CDA's interoperability and reusability.
History & Physical (H&P)	Allergies Medications Problem List Procedures Results Family History Immunizations Assessments	Assessment and Plan Plan of Care Social History Vital Signs History of Present Illness History of Present Illness	Chief Complaint Reason for Visit Review of Systems Physical Exam General Status

C-CDA IG Navigation

Chapter 1: Introduction

Chapter 2: General Header Template – defines a template for the header constraints that apply across all of the consolidated document types

Chapter 3: Document-Level Templates – defines each of the nine document types; defines header constraints specific to each and the section-level templates (required and optional) for each

Chapter 4: Section-Level Templates – defines the section templates referenced within the document types described

Chapter 5: Entry-Level Templates – defines entry-level templates, called clinical statements (machine readable data)

Appendices – include non-normative content to support implementers; includes a *Change Appendix summary* of previous and updated templates

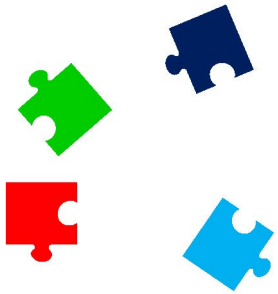
Click this link to access more information about the *HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, Release 1.1 - US Realm*

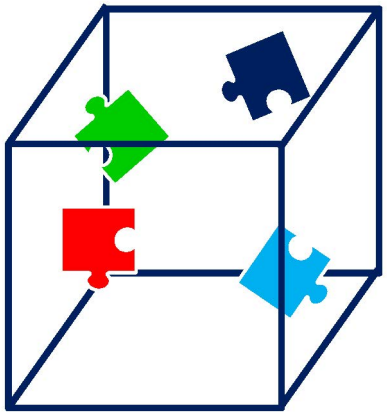
<http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258>

How is the C-CDA IG used to help providers meet applicable MU objectives?

Clinical Document Architecture (CDA) & Consolidated-CDA (C-CDA) Overview

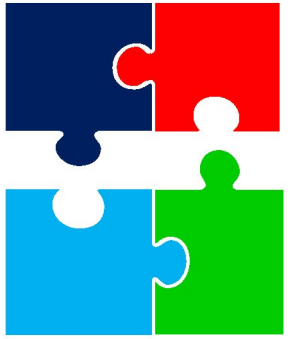
Clinical Document Architecture (CDA) is the base standard for building electronic clinical documents





Templates provide the "building blocks" for clinical documents

To help simplify implementations, commonly used templates were harmonized from existing CDA implementation guides and "consolidated" into a single implementation guide – the C-CDA Implementation Guide (IG) (07/2012)



MU Requirements Achieved via C-CDA

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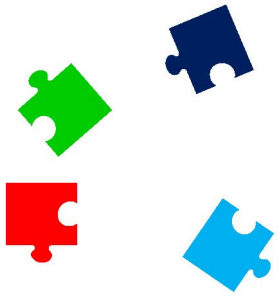
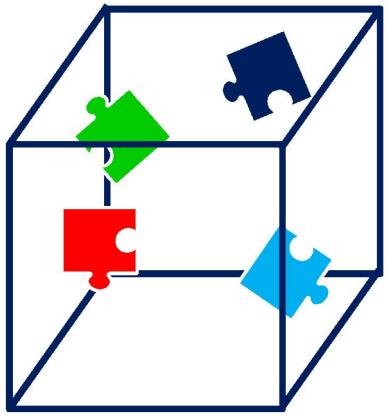
CDA standardizes the expression of clinical concepts which can be used/re-used

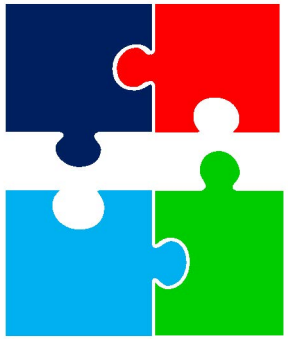
Templates are used to specify the 'packaging' for those clinical concepts

Sets of CDA templates are arranged to create a purpose-specific clinical document

MU adds data requirements, which can be layered on top of C-CDA document templates by the EP or EH/CAH to achieve MU compliance







NOTE: No single C-CDA document template contains all of the data requirements to sufficiently meet MU2 compliance – C-CDA & MU2 guidelines must be implemented together.

How can you implement clinical documents that meet both MU & C-CDA data requirements?

How to Implement a MU & C-CDA-compliant Document Overview

1. **Choose the C-CDA Document Template that best fits your clinical workflow.**

2. **Include C-CDA components defined by that Document Template**
   a) Required components
   b) Optional components appropriate for the clinical situation

3. **Add C-CDA components required to meet MU**
   a) Review which data requirements have already been met
   b) Add C-CDA components aligning to data requirements that have not yet been met

Use Case #1:
Transition of Care Criterion
(Primary Care Provider)

Use Case #1 Scenario Overview

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Scenario: A patient is experiencing severe knee pain and is referred to a Orthopedist by their Primary Care Provider (PCP). The PCP needs to generate a summary document to provide to the Orthopedist.

This use case exhibits the "Transition of Care" criterion in action:

> **§ 170.314 (b)(2) Transitions of care – create and transmit transition of care/referral summaries**

No single C-CDA Document Template includes all of the elements needed to satisfy the criterion's data requirements.

NOTE: The Document Templates within C-CDA are considered "open" templates, which means that, in addition to the required and optional Sections defined in the template, an implementer can add to the Document whatever C-CDA Sections are necessary for his purposes.

Step 1:
Pick a Document Template

Document Title	Description
Consultation Note	According to CMS evaluation and management guidelines, a Consultation Note must be generated as a result of a physician or non-physician practitioner's (NPP) request for an opinion or advice from another physician or NPP
Continuity of Care Document (CCD)	The CCD is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.
Discharge Summary	The Discharge Summary is a document that is a synopsis of a patient's admission to a hospital; it provides pertinent information for the continuation of care following discharge.

The C-CDA IG has 9 documents, but the three likely candidates for this situation are displayed above.

- Each C-CDA Document Template was designed to satisfy a specific information exchange scenario.
- Each document template defines the CDA structures to be used to document the applicable clinical information.

Best Fit Document to Scenario: CCD

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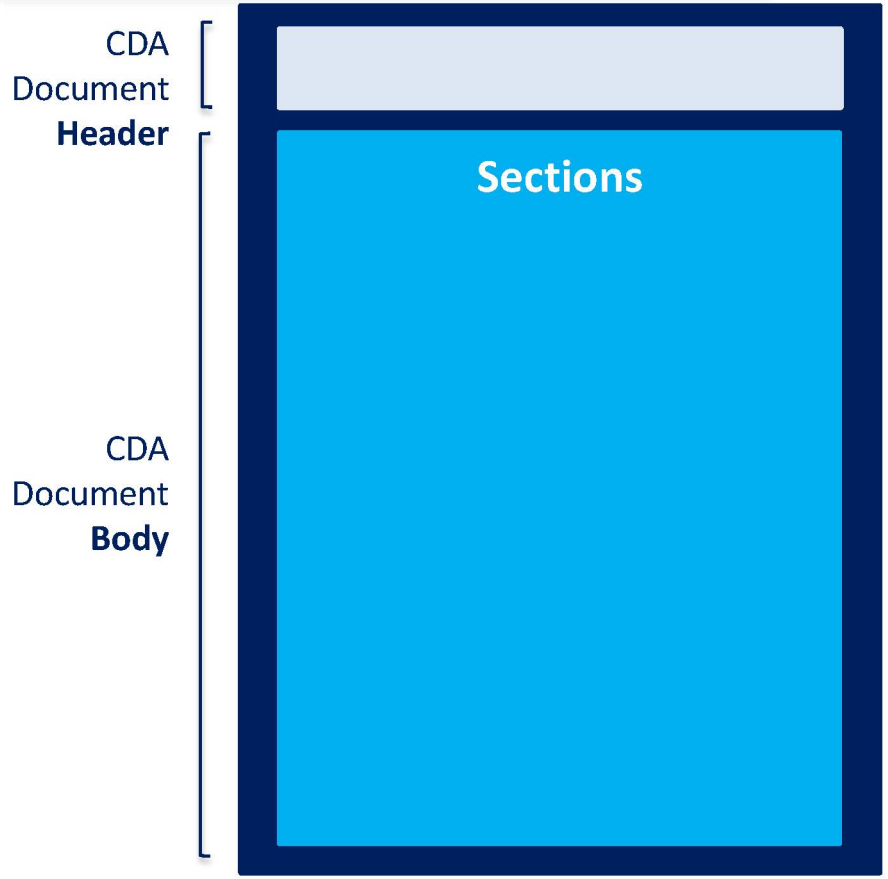
Scenario: A patient is experiencing severe knee pain and is referred to a Orthopedist by their Primary Care Provider (PCP). The PCP needs to generate a summary document to provide to the Orthopedist.

In this scenario, treatment has been provided by a PCP:

- Given that this treatment is in an ambulatory setting, a **Discharge Summary** would not be appropriate.
- Since the PCP HAS NOT been providing care at the request of another provider, a **Consultation Note** would not be appropriate.
- Given the **clinical scenario** to be described, a **Continuity of Care Document (CCD)** is the most appropriate C-CDA Document Template to use.



Step 2a: Include C-CDA components defined by the Document Template (REQUIRED)

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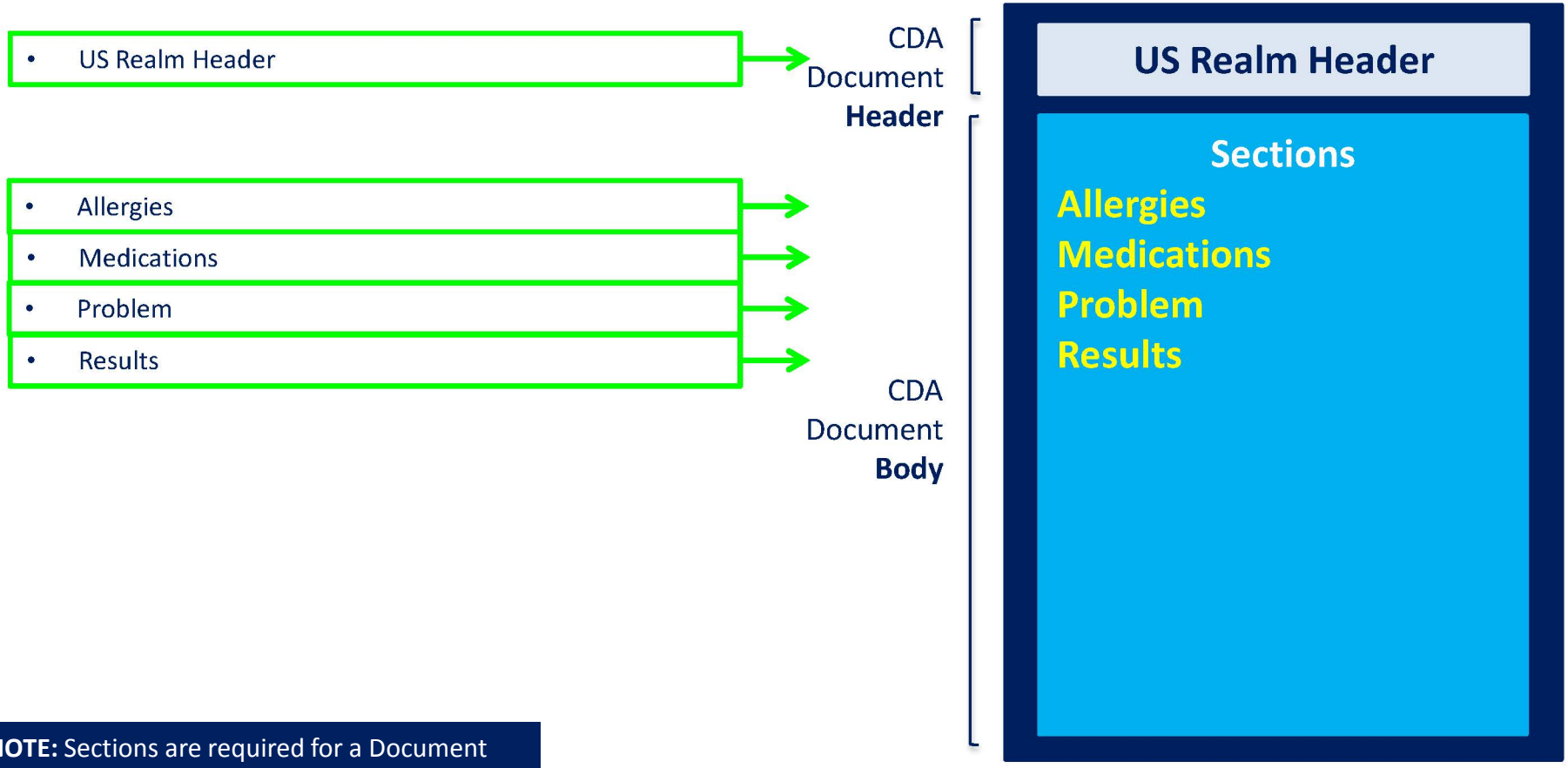
Start with the Sections required by the CCD Template in the C-CDA IG:



NOTE: Sections are required for a Document Template when the information contained in those sections will *ALWAYS BE* clinically relevant to the clinical scenario the document template is intended to describe

Step 2b: Include C-CDA components defined by the Document Template (OPTIONAL)

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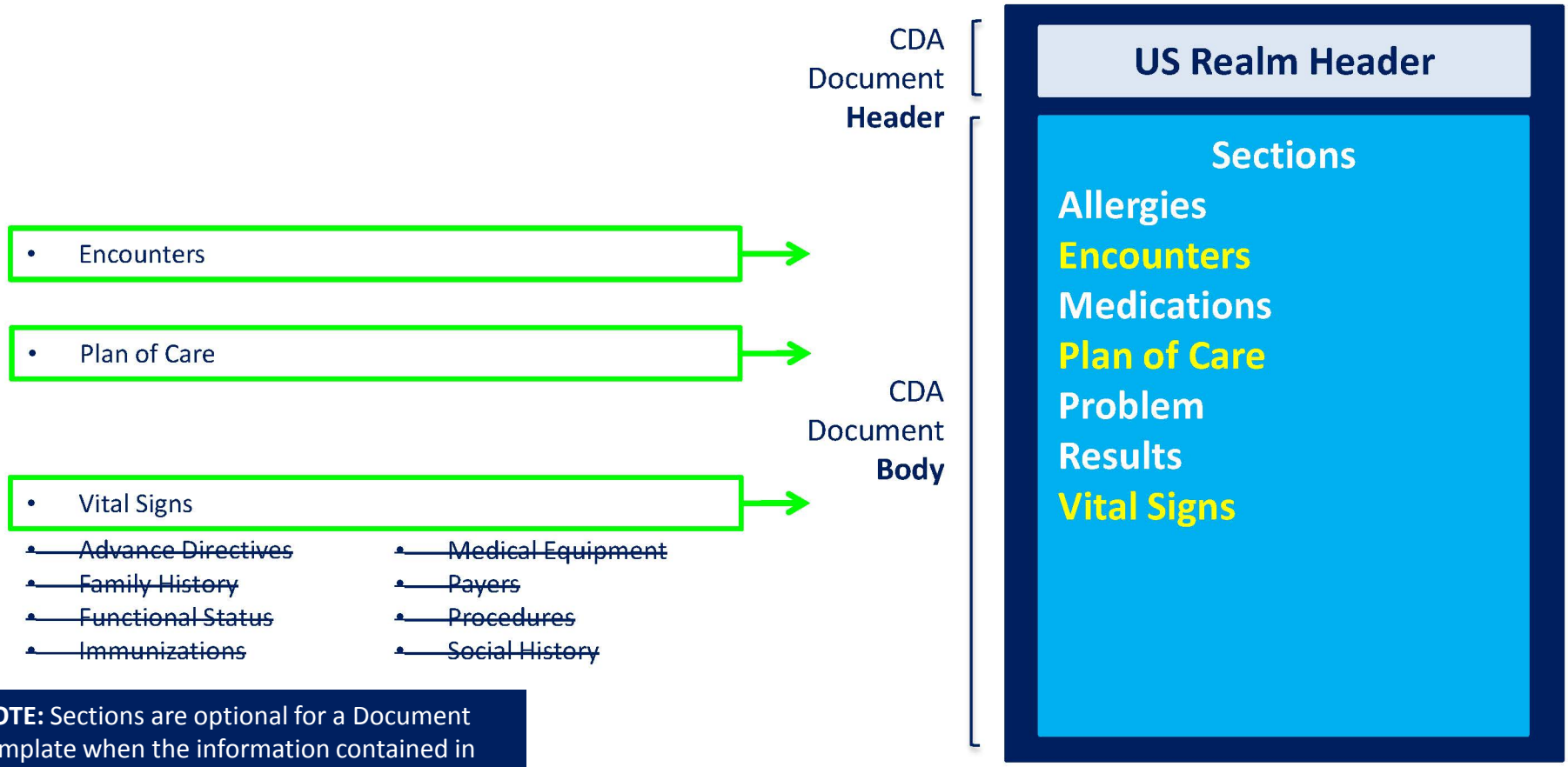
Continue by adding the *clinically relevant* Sections that are optional in the CCD Template in the C-CDA IG:



NOTE: Sections are optional for a Document Template when the information contained in those sections will *SOMETIMES BE* clinically relevant to the clinical scenario the document template is intended to describe

Step 3: Add Data Required by the 2014 Edition EHR Certification Criteria

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Cert. Category	Objective	Description	Summary Type
Care Coordination *170.314(b)*	**Transition of Care** *170.314(b)(1)&(2)*	when transitioning a patient to another care setting, the EP or EH/CAH should provide a summary care record	**Transition of Care/Referral Summary**

Common MU Data Set

- Care plan
- Care team member(s)
- Date of birth
- Ethnicity **
- Laboratory test(s) **
- Laboratory value(s)/result(s)
- Medications **
- Medication allergies **
- Patient name
- Preferred language
- Problem **
- Procedures **
- Race **
- Sex
- Smoking status **
- Vital signs

Criterion-Specific Data Requirements

- Provider Name & Office Contact Information (Ambulatory Only)
- Reason for Referral (Ambulatory Only)
- Encounter Diagnoses **
- Cognitive Status
- Functional Status
- Discharge Instructions (Inpatient Only)
- Immunizations **

NOTE: Data requirements marked with a double asterisk (**) also have a defined vocabulary which must be used

Step 3a: Review data requirements that have already been met

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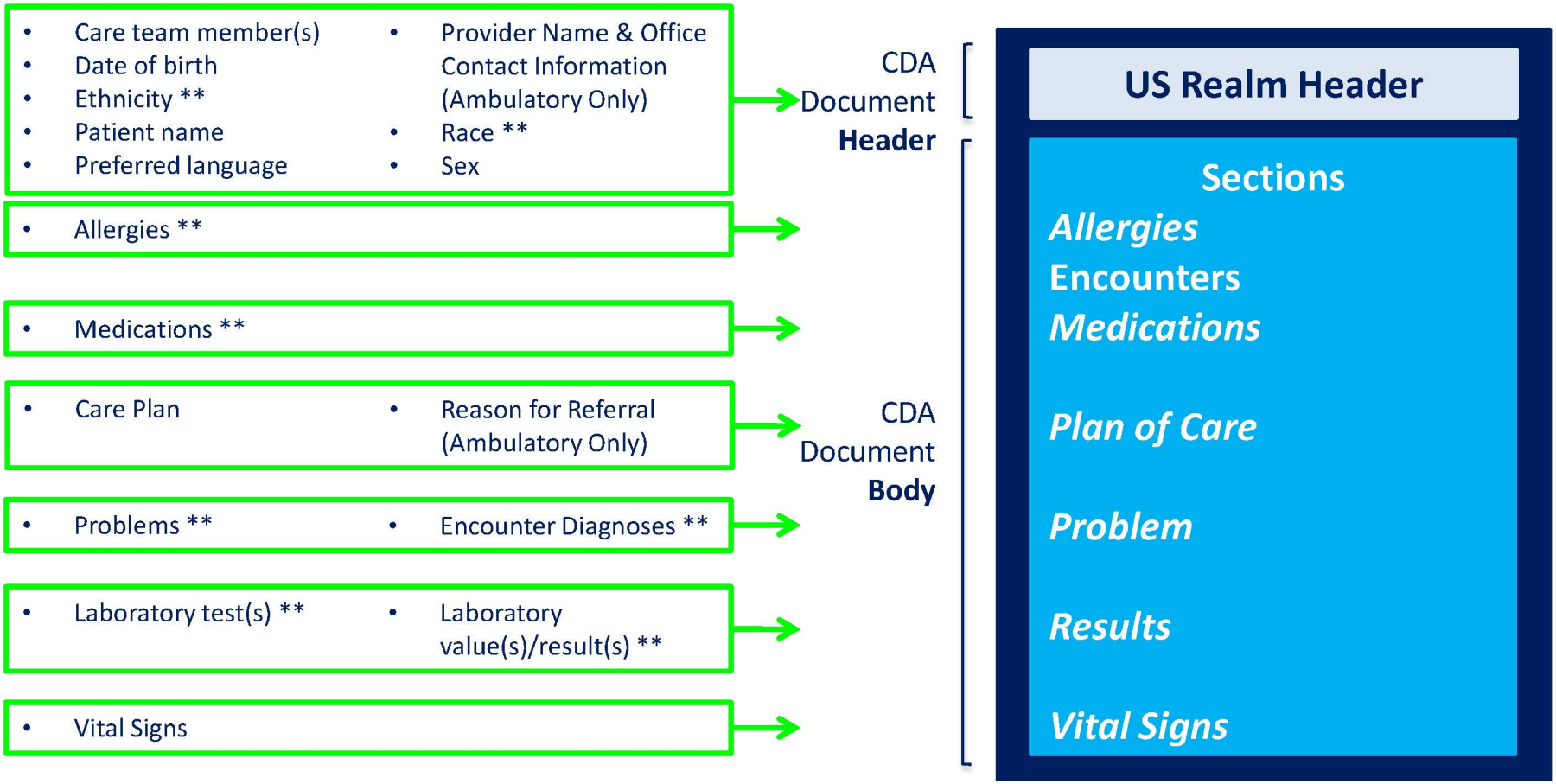
Some of the data requirements have already been met through use of the C-CDA Document Template; some may also not apply to the care setting



Step 3b: Add C-CDA components for remaining data requirements

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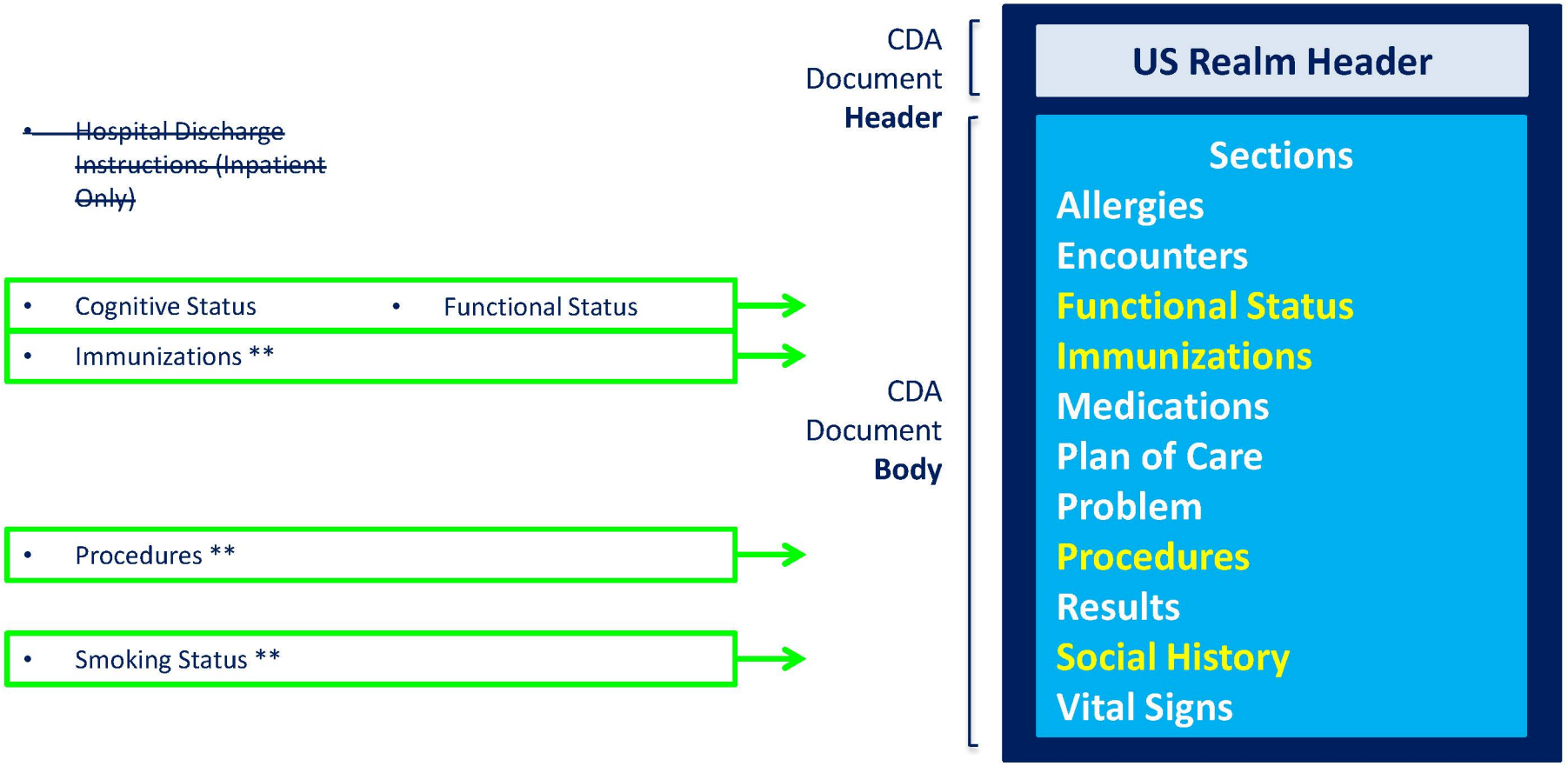
C-CDA Sections are added to the CCD to address the outstanding data requirements.



Use Case #1 Scenario Summary

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Scenario: A patient is experiencing severe knee pain and is referred to a Orthopedist by their Primary Care Provider (PCP). The PCP needs to generate a summary document to provide to the Orthopedist.

- The Continuity of Care Document (CCD) Document Template was the **best fit for the clinical workflow** in this scenario
- Many of the Transition of Care data requirements were met using the C-CDA document template.
- Additional sections were added as necessary to meet outstanding data requirements.

CDA Document **Header**

CDA Document **Body**

US Realm Header

Sections

- Allergies
- Encounters
- Functional Status
- Immunizations
- Medications
- Plan of Care
- Problem
- Procedures
- Results
- Social History
- Vital Signs

Rendered CCD Example

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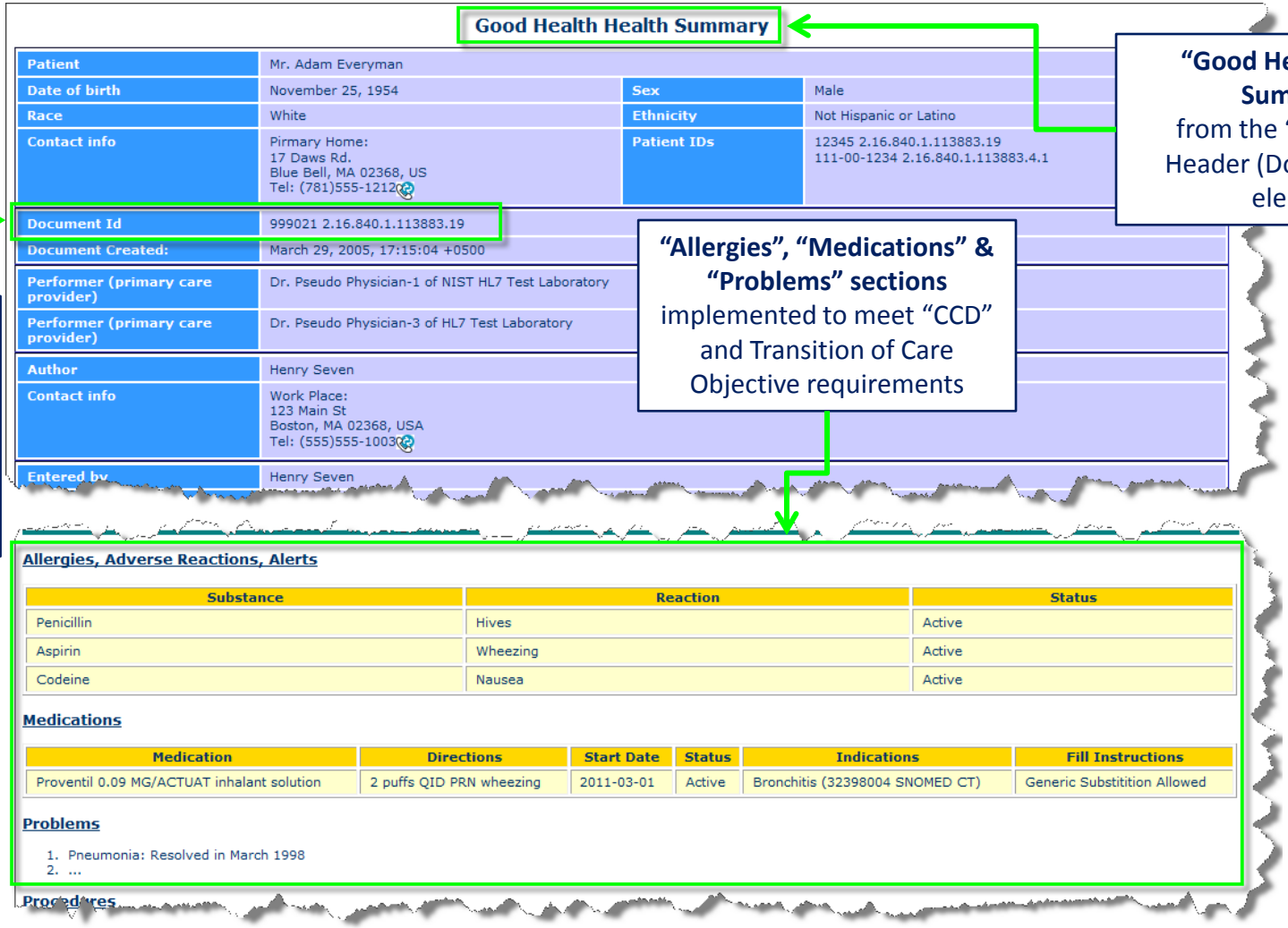

Good Health Health Summary

Patient	Mr. Adam Everyman		
Date of birth	November 25, 1954	**Sex**	Male
Race	White	**Ethnicity**	Not Hispanic or Latino
Contact info	Pirmary Home: 17 Daws Rd. Blue Bell, MA 02368, US Tel: (781)555-1212	**Patient IDs**	12345 2.16.840.1.113883.19 111-00-1234 2.16.840.1.113883.4.1
Document Id	999021 2.16.840.1.113883.19		
Document Created:	March 29, 2005, 17:15:04 +0500		
Performer (primary care provider)	Dr. Pseudo Physician-1 of NIST HL7 Test Laboratory		
Performer (primary care provider)	Dr. Pseudo Physician-3 of HL7 Test Laboratory		
Author	Henry Seven		
Contact info	Work Place: 123 Main St Boston, MA 02368, USA Tel: (555)555-1003		
Entered by	Henry Seven		

Allergies, Adverse Reactions, Alerts

Substance	Reaction	Status
Penicillin	Hives	Active
Aspirin	Wheezing	Active
Codeine	Nausea	Active

Medications

Medication	Directions	Start Date	Status	Indications	Fill Instructions
Proventil 0.09 MG/ACTUAT inhalant solution	2 puffs QID PRN wheezing	2011-03-01	Active	Bronchitis (32398004 SNOMED CT)	Generic Substitition Allowed

Problems

1. Pneumonia: Resolved in March 1998
2. ...

Procedures

"Good Health Health Summary" from the "U.S. Realm" Header (Document Title element)

"Document ID" from the "U.S. Realm" Header (Document ID element)

"Allergies", "Medications" & "Problems" sections implemented to meet "CCD" and Transition of Care Objective requirements

"Good Health Health Summary" – Sample CCD. "CCD.sample.xml" file. C-CDA R2 July 2012 via HL7.

Use Case #2: View/Download/Transmit Criterion (Orthopedist)

Use Case #2 Scenario Overview

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Scenario: The Orthopedist, after consulting with the patient, schedules surgery to be performed and provides an ambulatory summary to the patient including the care plan to be followed leading up to the surgery.

This use case exhibits the "View/Download/Transmit" criterion in action:

§ 170.314 (e)(1) View, download, and transmit to 3rd party

No single C-CDA Document Template covers all of the data requirements to successfully meet this criterion using only the template's baseline required components.

NOTE: The Document Templates within C-CDA are considered "open" templates, which means that, in addition to the required and optional Sections defined in the template, an implementer can add to the Document whatever C-CDA Sections are necessary for his purposes.

Step 1:
Pick a Document Template

Document Title	Description
Consultation Note	According to CMS evaluation and management guidelines, a Consultation Note must be generated as a result of a physician or non-physician practitioner's (NPP) request for an opinion or advice from another physician or NPP
Continuity of Care Document (CCD)	The CCD is a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters.
Discharge Summary	The Discharge Summary is a document that is a synopsis of a patient's admission to a hospital; it provides pertinent information for the continuation of care following discharge.

The C-CDA IG has 9 documents, but the three likely candidates for this situation are displayed above.

- Each C-CDA Document Template was designed to satisfy a specific information exchange scenario.
- Each document template defines the CDA structures to be used to document the applicable clinical information.

Best Fit Document to Scenario: Consultation Note

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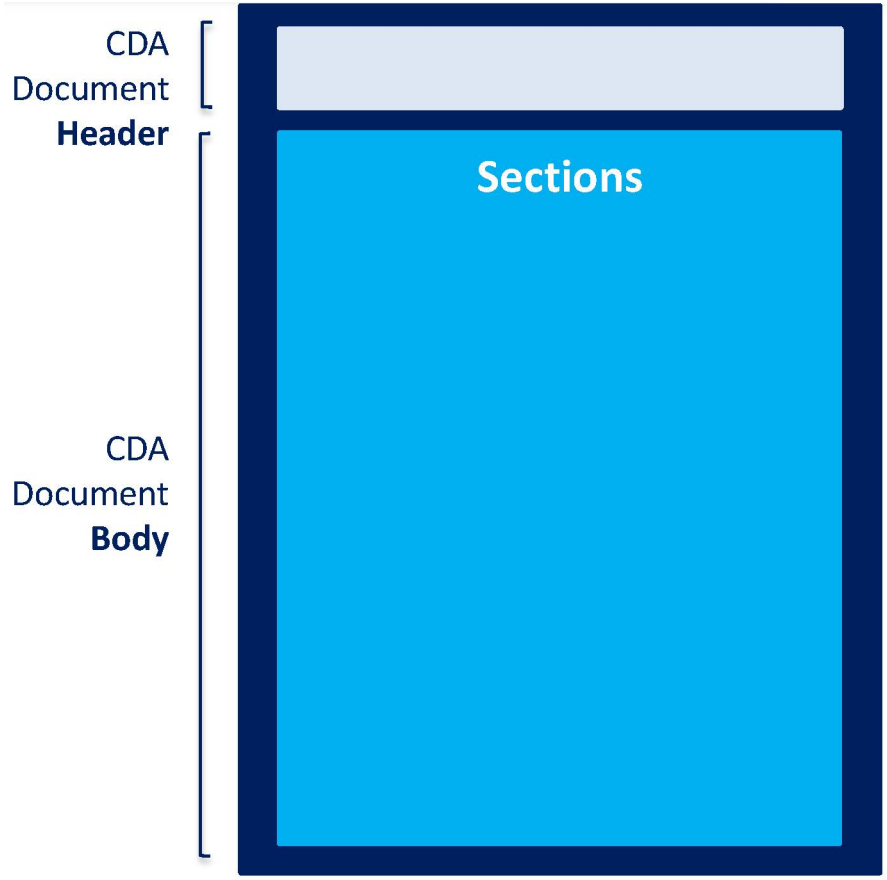
Scenario: The Orthopedist, after the consultation with the patient, schedules surgery to be performed and provides an ambulatory summary to the patient including the care plan to be followed leading up to the surgery.

In this scenario, treatment has been provided by a PCP:

- Given that this treatment is in an ambulatory setting, a **Discharge Summary** would not be appropriate.
- The **Continuity of Care Document (CCD)** is intended to summarize a full episode of care, and as such may be too cumbersome for this scenario.
- Since the Orthopedist is providing care at the request of the PCP, a **Consultation Note** is the best fit for the clinical workflow



Step 2a: Include C-CDA components defined by the Document Template (REQUIRED)

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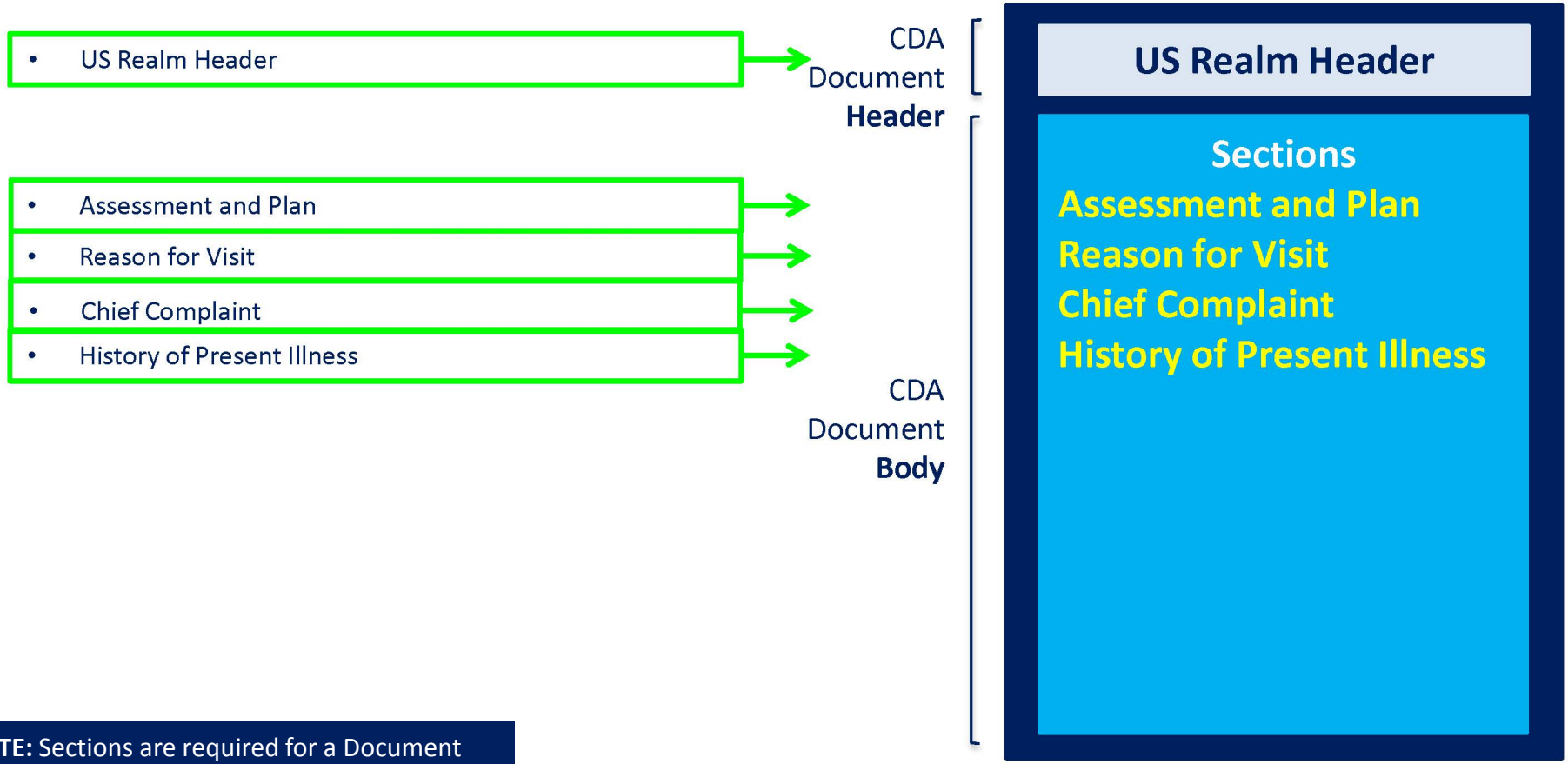
Start with the Sections required by the CCD Template in the C-CDA IG:



NOTE: Sections are required for a Document Template when the information contained in those sections will *ALWAYS BE* clinically relevant to the clinical scenario the document template is intended to describe

Step 2b: Include C-CDA components defined by the Document Template (OPTIONAL)

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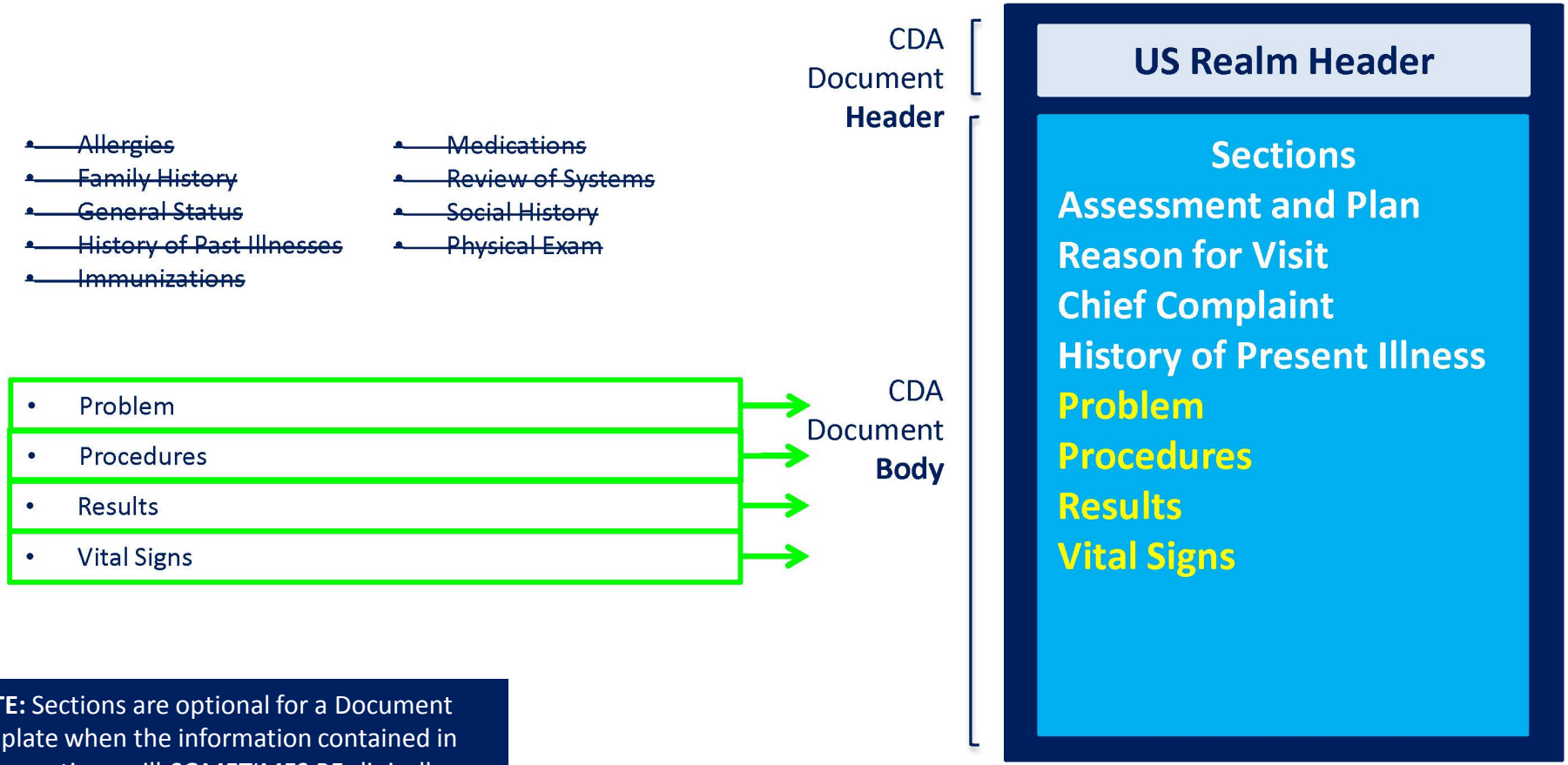
Continue by adding the *clinically relevant* Sections that are optional in the Consultation Note Template in the C-CDA IG:



NOTE: Sections are optional for a Document Template when the information contained in those sections will *SOMETIMES BE* clinically relevant to the clinical scenario the document template is intended to describe

Step 3: Add Data Required by the 2014 Edition EHR Certification Criteria

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Cert. Category	Criterion	Description	Summary Type
Patient Engagement *170.314(e)*	View/Download/Transmit *170.314(e)(1)*	patients must be able to view & download their own medical info & also be able to transmit that info to a 3rd party	Ambulatory or Inpatient Summary

Common MU Data Set

- Care plan
- Care team member(s)
- Date of birth
- Ethnicity **
- Laboratory test(s) **
- Laboratory value(s)/result(s)
- Medications **
- Medication Allergies **
- Patient name
- Preferred language
- Problems **
- Procedures **
- Race **
- Sex
- Smoking status **
- Vital signs

Criterion-Specific Data Requirements

- Admission & Discharge Dates (Inpatient Only)
- Admission & Discharge Locations (Inpatient Only)
- Discharge Instructions (Inpatient Only)
- Provider Name & Office Contact Information (Ambulatory Only)
- Reason(s) for Hospitalization (Inpatient Only)

NOTE: Data requirements marked with a double asterisk (**) also have a defined vocabulary which must be used

Step 3a: Review data requirements that have already been met

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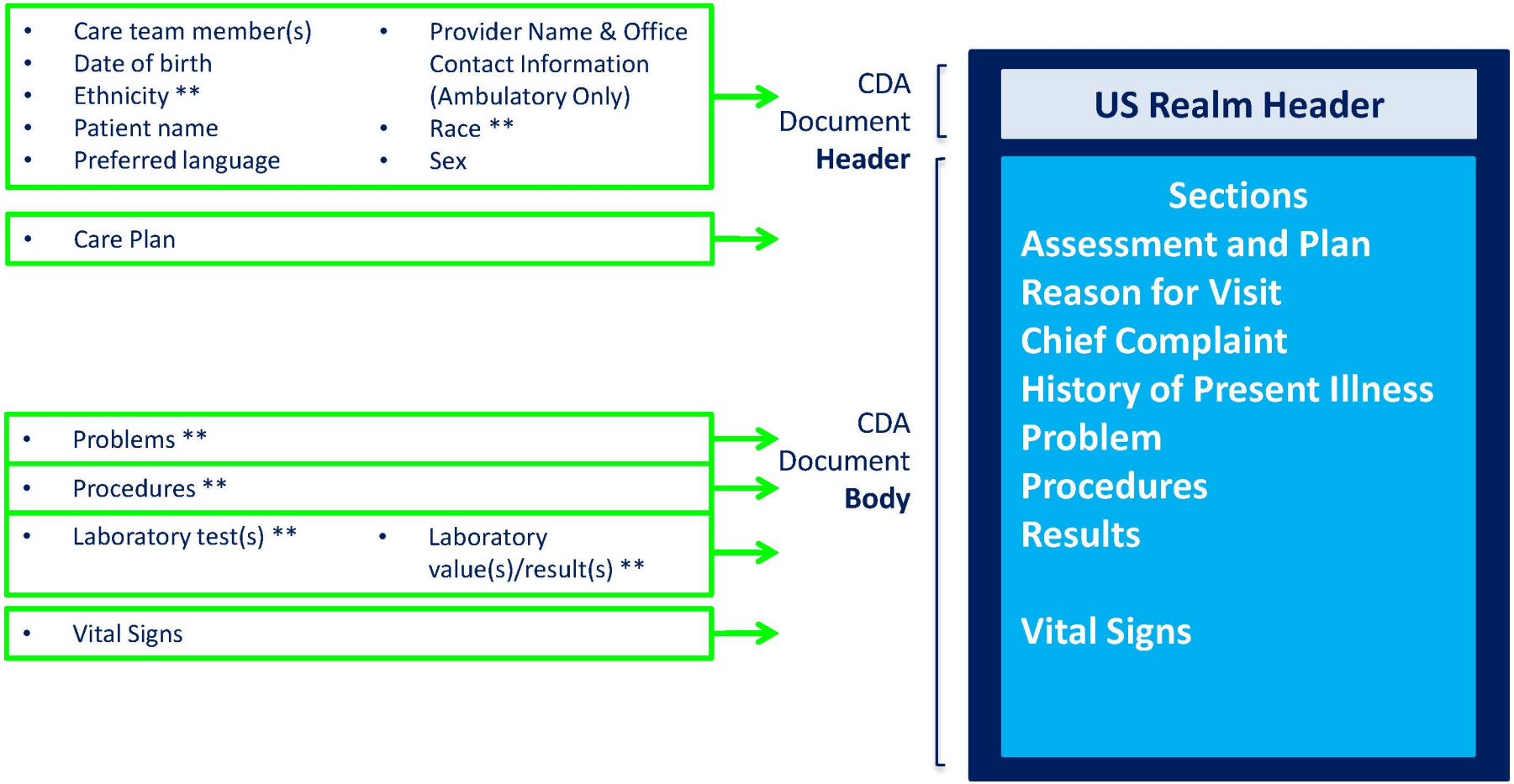
Some of the data requirements have already been met through use of the C-CDA Document Template; some may also not apply to the care setting



Step 3b: Add C-CDA components for remaining data requirements

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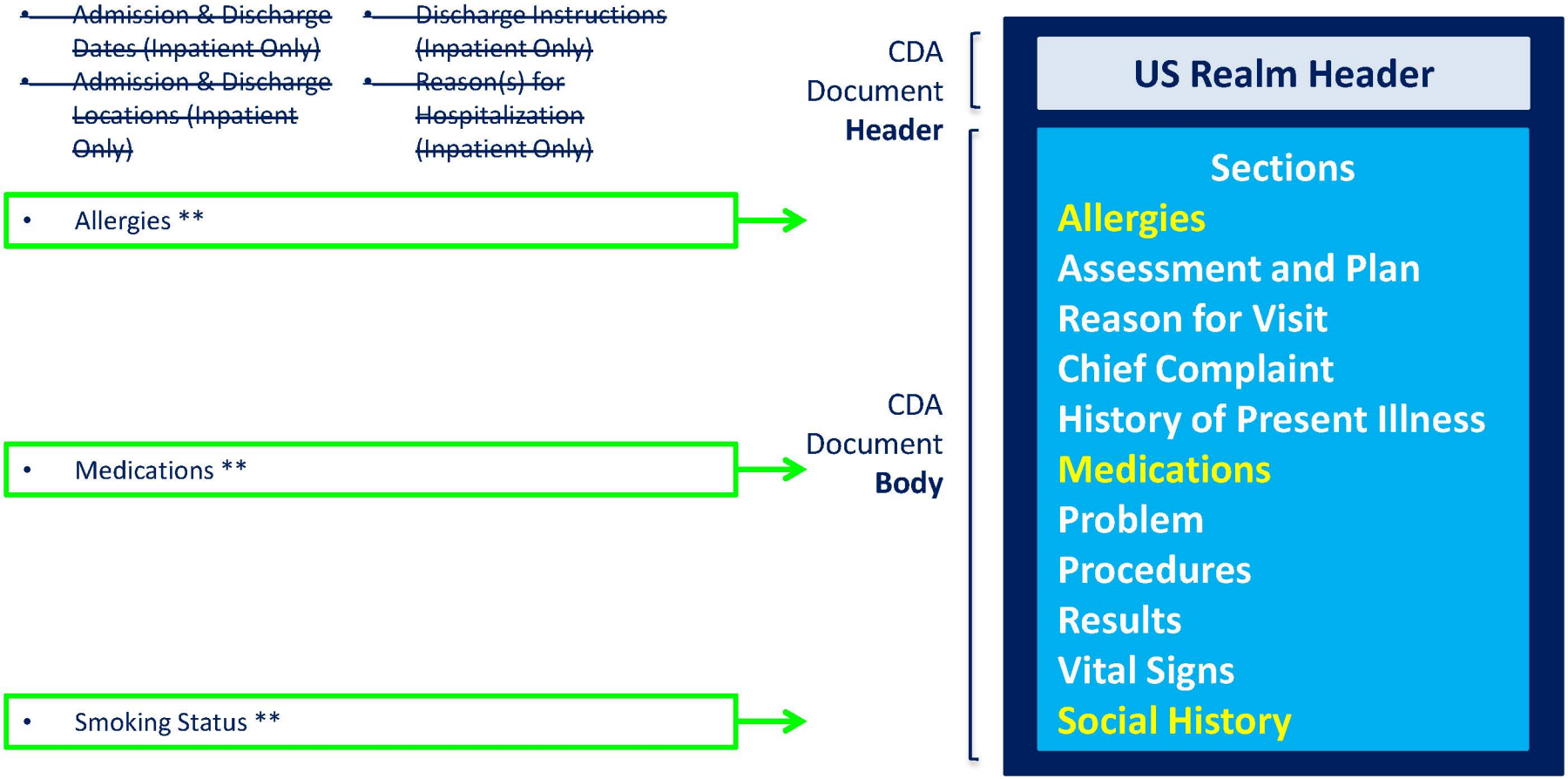
C-CDA Sections are added to the Consultation Note to address the outstanding data requirements.



Use Case #2 Scenario Summary

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Scenario: The Orthopedist, after the consultation with the patient, schedules surgery to be performed and provides an ambulatory summary to the patient including the care plan to be followed leading up to the surgery.

- The Consultation Note Document Template was the **best fit for the clinical workflow** in this scenario
- Many of the View/Download/Transmit data requirements were met using the C-CDA document template.
- Additional sections were added as necessary to meet outstanding data requirements.

CDA Document **Header**

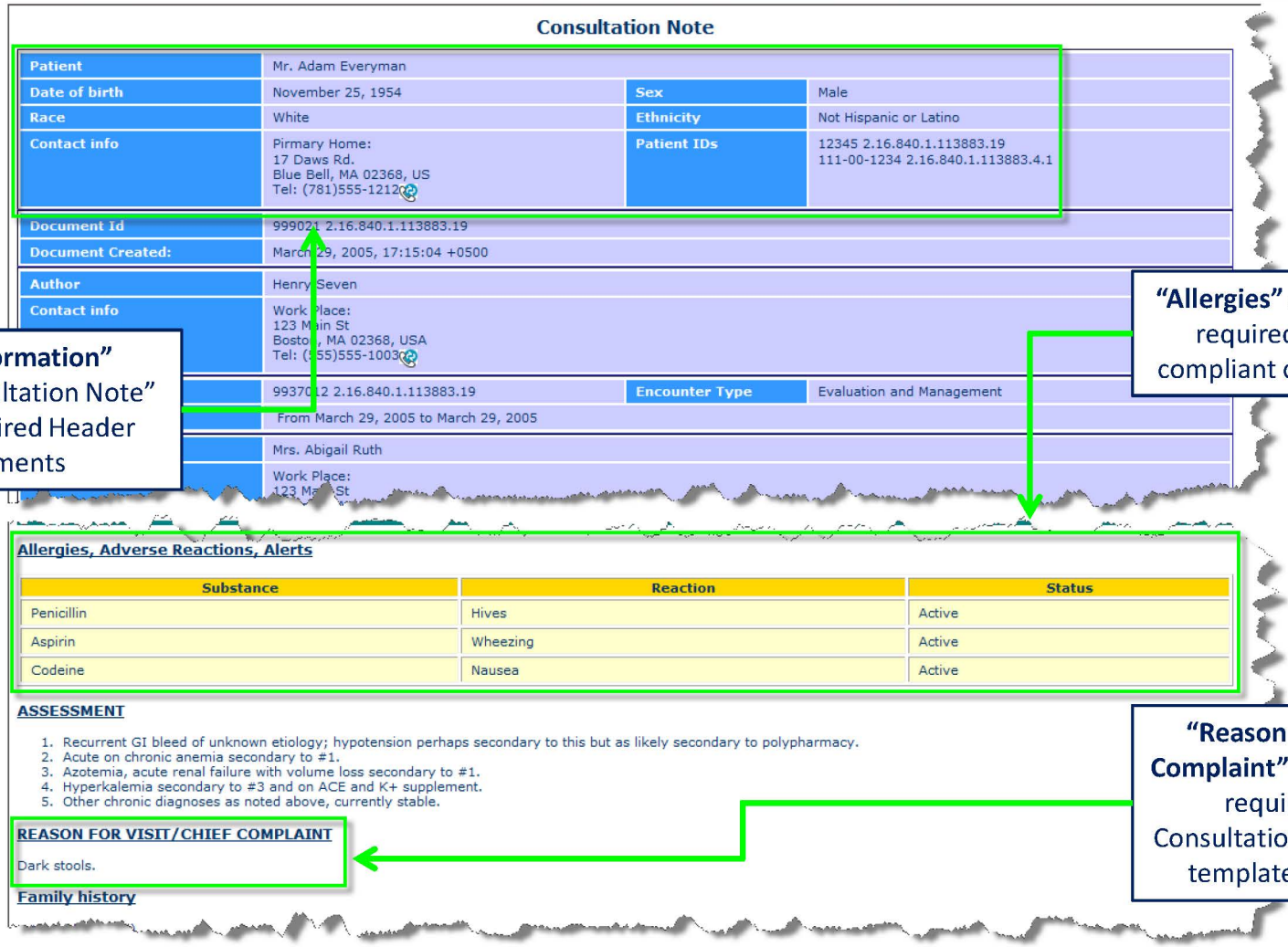
CDA Document **Body**

US Realm Header

Sections

- Allergies
- Assessment and Plan
- Reason for Visit
- Chief Complaint
- History of Present Illness
- Medications
- Problem
- Procedures
- Results
- Vital Signs
- Social History

Rendered Consultation Note Example



Consultation Note

Patient	Mr. Adam Everyman		
Date of birth	November 25, 1954	Sex	Male
Race	White	Ethnicity	Not Hispanic or Latino
Contact info	Pirmary Home: 17 Daws Rd. Blue Bell, MA 02368, US Tel: (781)555-1212	Patient IDs	12345 2.16.840.1.113883.19 111-00-1234 2.16.840.1.113883.4.1
Document Id	999021 2.16.840.1.113883.19		
Document Created:	March 29, 2005, 17:15:04 +0500		
Author	Henry Seven		
Contact info	Work Place: 123 Main St Boston, MA 02368, USA Tel: (555)555-1003		
	9937012 2.16.840.1.113883.19	Encounter Type	Evaluation and Management
	From March 29, 2005 to March 29, 2005		
	Mrs. Abigail Ruth		
	Work Place: 123 Main St		

Allergies, Adverse Reactions, Alerts

Substance	Reaction	Status
Penicillin	Hives	Active
Aspirin	Wheezing	Active
Codeine	Nausea	Active

ASSESSMENT

1. Recurrent GI bleed of unknown etiology; hypotension perhaps secondary to this but as likely secondary to polypharmacy.
2. Acute on chronic anemia secondary to #1.
3. Azotemia, acute renal failure with volume loss secondary to #1.
4. Hyperkalemia secondary to #3 and on ACE and K+ supplement.
5. Other chronic diagnoses as noted above, currently stable.

REASON FOR VISIT/CHIEF COMPLAINT

Dark stools.

Family history

"Patient Information" from the "Consultation Note" template required Header data elements

"Allergies" section template required by ALL MU2-compliant clinical document

"Reason for Visit/Chief Complaint" section template required to meet Consultation Note document template requirements

"Consultation Note" – Sample Consultation Note. "Consults.sample.xml" file. C-CDA R2 July 2012 via HL7.

Learn More about C-CDA

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Access the S&I Framework Wiki for the latest version of the Companion Guide to Consolidated-CDA for Meaningful Use Stage 2

http://wiki.siframework.org/Companion+Guide+to+Consolidated+CDA+for+MU2

How are C-CDA capabilities tested and certified?

A few things you should know if you certified to the 2011 Edition

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The 2014 Edition Standards & Certification Criteria Final Rule made important changes to the way products are certified in the ONC HIT Certification Program.

The C-CDA has been adopted as the content standard for criteria which involve creation of care summaries.

- The C-CDA's template structure can support the formatting of a care summary including all of the data elements that CMS proposed be available for inclusion in a care summary.

ONC has defined a Common MU Data Set and provided a descriptive label in the form of a "summary type" for each set of data and vocabulary requirements corresponding to a certification criterion.

- The Common MU Data Set includes the data requirements that are common to ALL of the criteria which involve care summaries.
- Individual criteria might include data requirements that are specific or unique to that criterion
- The summary type definitions are intended to help clarify discussions of the care summary criteria, and don't imply a required document template, new standards, or regulatory meaning.

Testing and certification roadmap

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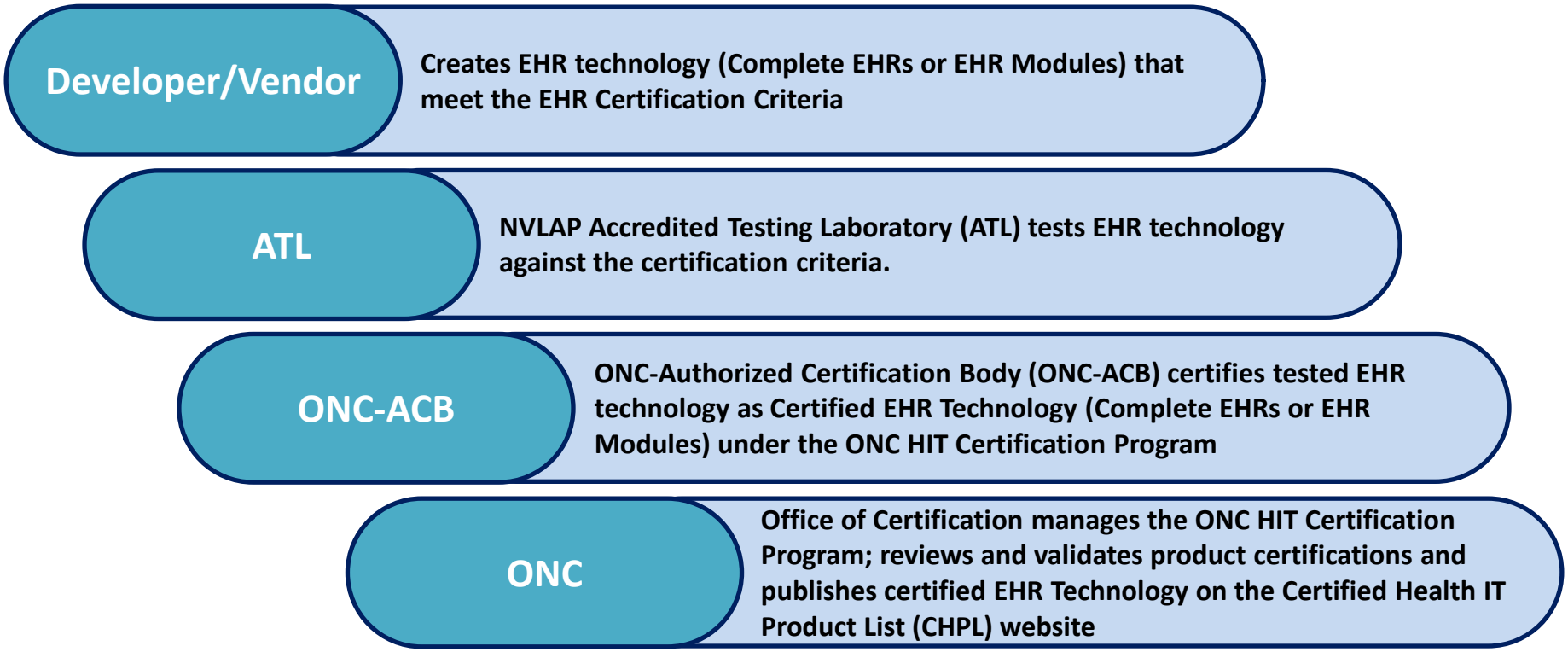

Vendors and developers should contact their ATL and ONC-ACB early in the development process for important information about the testing and certification process.

- For a list of ATLs and ONC-ACBs, please visit the Certification Bodies and Testing Laboratories section of ONC's website.

How your testing process is designed

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The exact testing and certification process will differ depending on the vendor's product and the ATL and ONC-ACB each vendor elects to use.

The testing and certification process has been designed to allow ATLs and ONC-ACBs to customize testing and certification for each EHR technology.

- This ensures that ATLs and ONC-ACBs can make sure that each product is adequately tested for and certified to conformance to the relevant standards and certification criteria.

The test method which ATLs and ONC-ACBs use for testing and certification against the 2014 Edition EHR Certification Criteria has been developed by ONC in cooperation with NIST.

- The 2014 Edition Test Method includes test procedures, test data, and test tools.
- Access the 2014 Edition Test Method on ONC's website.

Testing, certification, and the scope of certification criteria

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EHR Technology must satisfy ALL of the capabilities identified within a certification criterion to be certified.

§ 170.314(b)(2) TOC – create and transmit transition of care/referral summaries.

(i) Create
(ii) Transmit

Criterion

	EHR A		EHR B		EHR C	
	Create	Transmit	Create	Transmit	Create	Transmit
Tested	✓	✗	✗	✓	✓	✓
Certified	✗		✗		✓	

Testing an EHR Technology's ability to create and transmit a C-CDA

Test Flows for creating and transmitting a C-CDA

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The test flow described on the following slides focuses on how C-CDA creation is tested.

For more on transport, including Direct specifications, please visit ONC's website:

- Information on Direct
- Resources for TOC and VDT

For a detailed FAQ on how EHR Technology can rely upon a HISP/HIE for C-CDA creation and transmission, please visit ONC's YouTube channel:

- Meaningful Use Education Module: Transitions of Care

Creating and transmitting a C-CDA: Test Flow Overview

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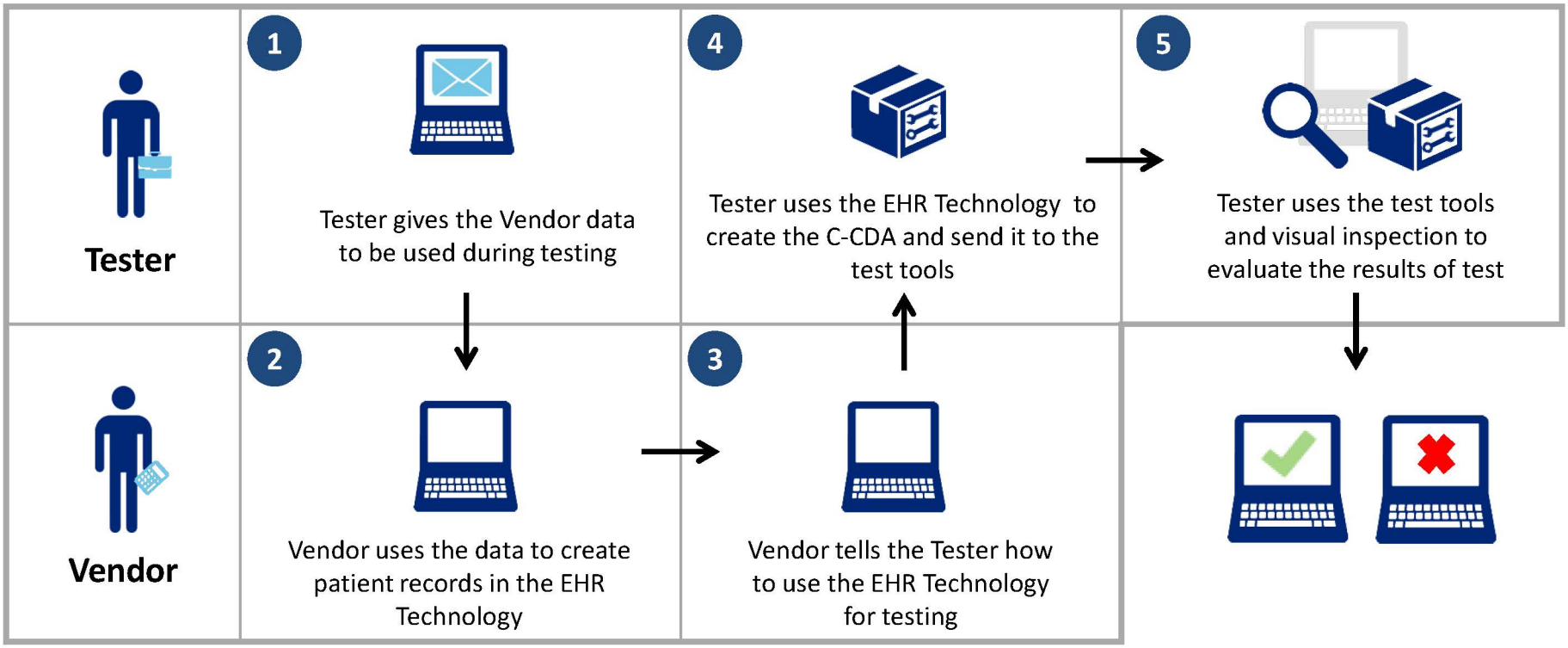
ONC's test procedures establish a general test flow around which ATLs build test scripts.



Creating a C-CDA: Test Flow Steps 1, 2 and 3 – Set Up

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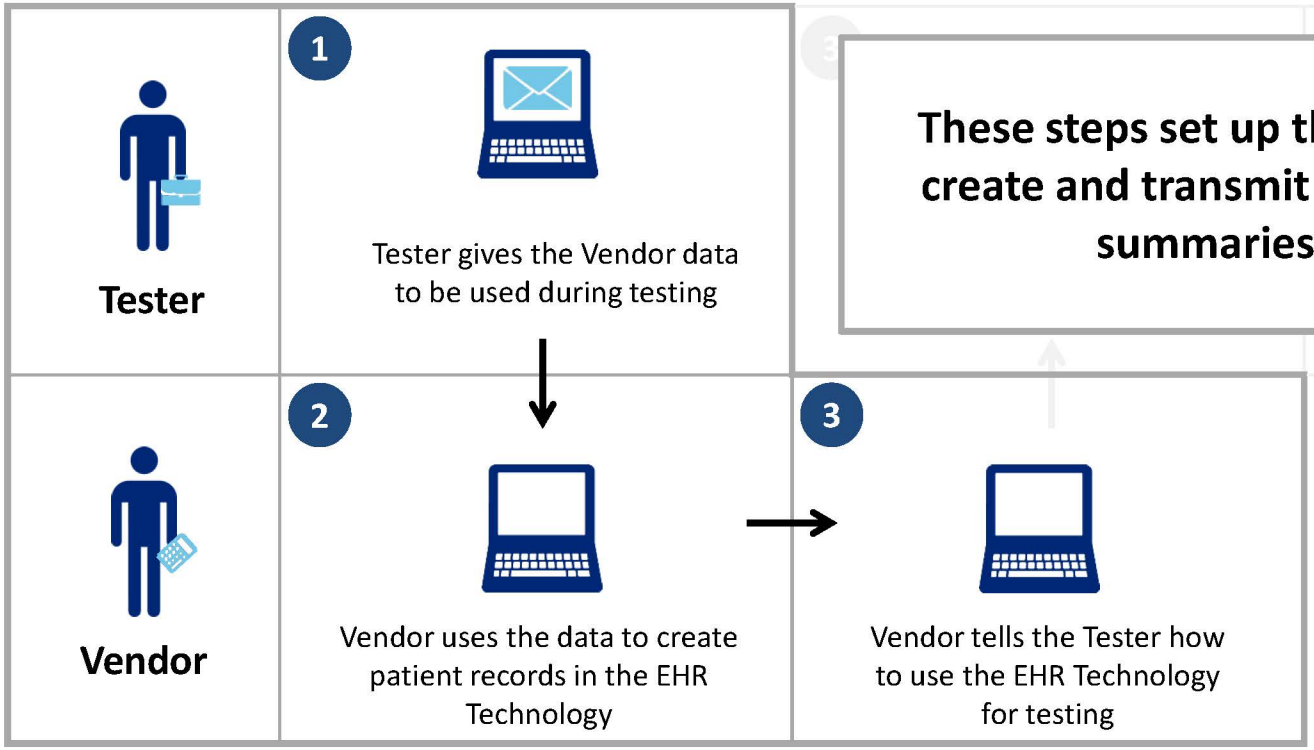
Testers and Vendors will set up the EHR Technology to test its ability to create and transmit a C-CDA.



These steps set up the EHR Technology to create and transmit the C-CDA formatted summaries for the test.

Creating a C-CDA: Test Flow Step 4 – Create and Transmit

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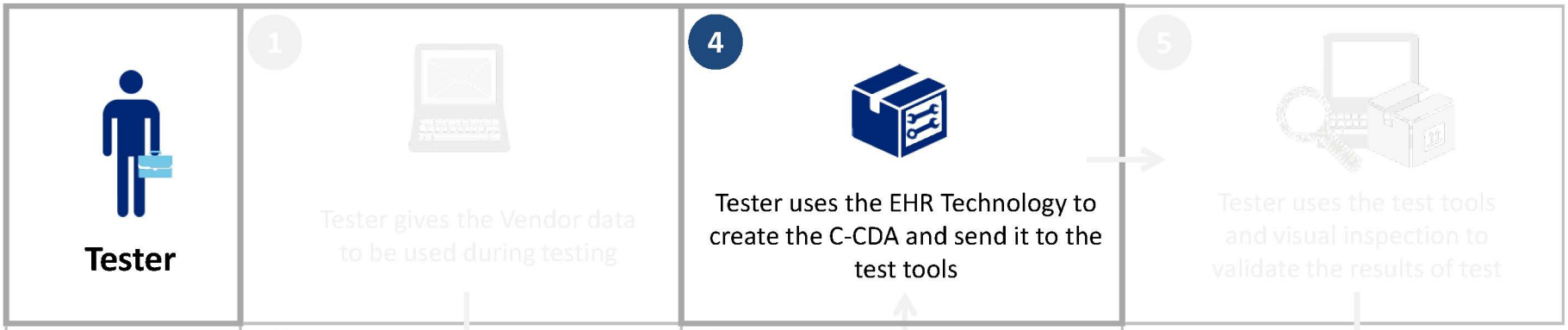
Testers will execute the test procedure steps for creating and transmitting the C-CDA using the EHR Technology as well as ONC-supplied Test Tools and Data.



After the EHR has been set up, the Tester will use the EHR Technology to create the C-CDA and send it to the test tools.

- Testers can use test scripts provided by the ATL to perform the Test Procedure steps required for creating and transmitting the C-CDA.
- Testers are responsible for verifying that the data was entered and used correctly both directly (through visual inspection) and indirectly (using the Test Tools).

Creating a C-CDA: Test Flow Step 5 - Validation

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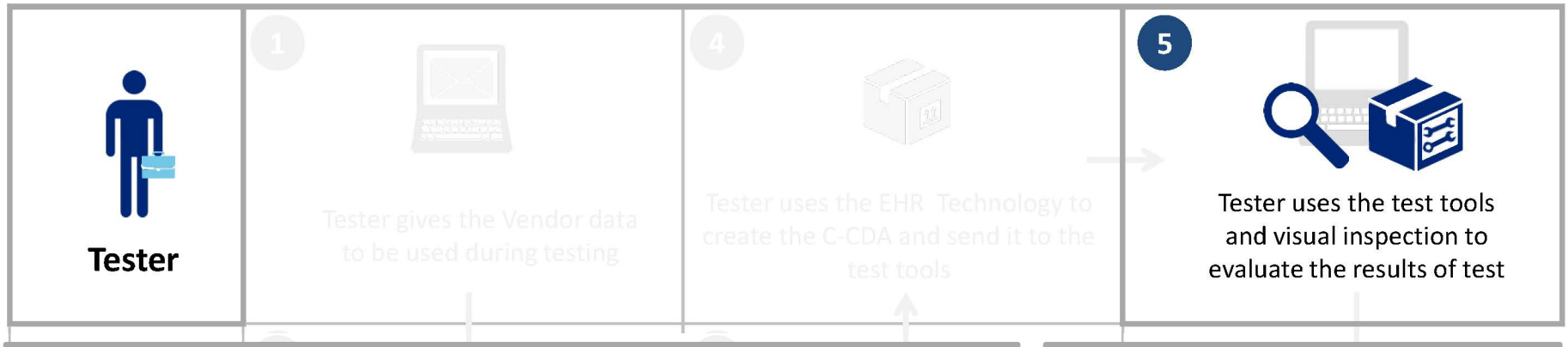
Once the Tester has used the EHR Technology to create and transmit the C-CDA, they will evaluate the results of the test using visual inspection and the test tools.



Test Tools

- Use of the Transport Testing Tool (TTT) to verify that the C-CDA was transmitted successfully and constructed properly
  - For more on the TTT, visit http://ttt.transport-testing.org/ttt
- Use of the Direct Certificate Discovery Tool (DCDT) to verify that the EHR can successfully publish certificates to be discovered and discover published certificates before transmitting the C-CDA
  - For more on the DCDT, visit http://code.google.com/p/direct-certificate-discovery-tool

Visual inspection

- Validation that the content of documents created is correct and complete
- Validation that the content of transmitted documents is correct and complete
- Specific visual inspection steps will be provided by ATLs

Validation Methods: Test Tools

ONC provides the Direct Certificate Discovery Tool and the Transport Testing Tool to automatically validate some of the test results.

The **Direct Certificate Discovery Tool** will verify that the EHR can successfully publish certificates and discover published certificates.

- For more on the DCDT, visit http://code.google.com/p/direct-certificate-discovery-tool

The **Transport Testing Tool** has several capabilities:

- It validates C-CDA templates, and, where appropriate, vocabularies and value sets required by the standard
- During testing, the TTT acts as a HISP by sending and receiving Direct messages
- For more on the TTT, visit http://ttt.transport-testing.org/ttt

The Transport Testing Tool's C-CDA validation capabilities will be discussed in greater detail at the end of the presentation.

Validation Methods: Visual Inspection

Testers will use guidelines provided by individual ATLs to perform visual inspection to validate other test results.

Visual inspection guidelines will be provided by each ATL.

- Visual inspection will make sure that the content of documents created by the EHR is correct and complete.
- Visual inspection will also make sure that the content of documents received by the TTT is correct and complete.
- Visual inspections steps will vary by ATL to make sure that validation is customized for each vendor and EHR Technology being tested and certified.

Testing an EHR's ability to receive, display, and incorporate a C-CDA

Receiving and incorporating a C-CDA: Test Flow Overview

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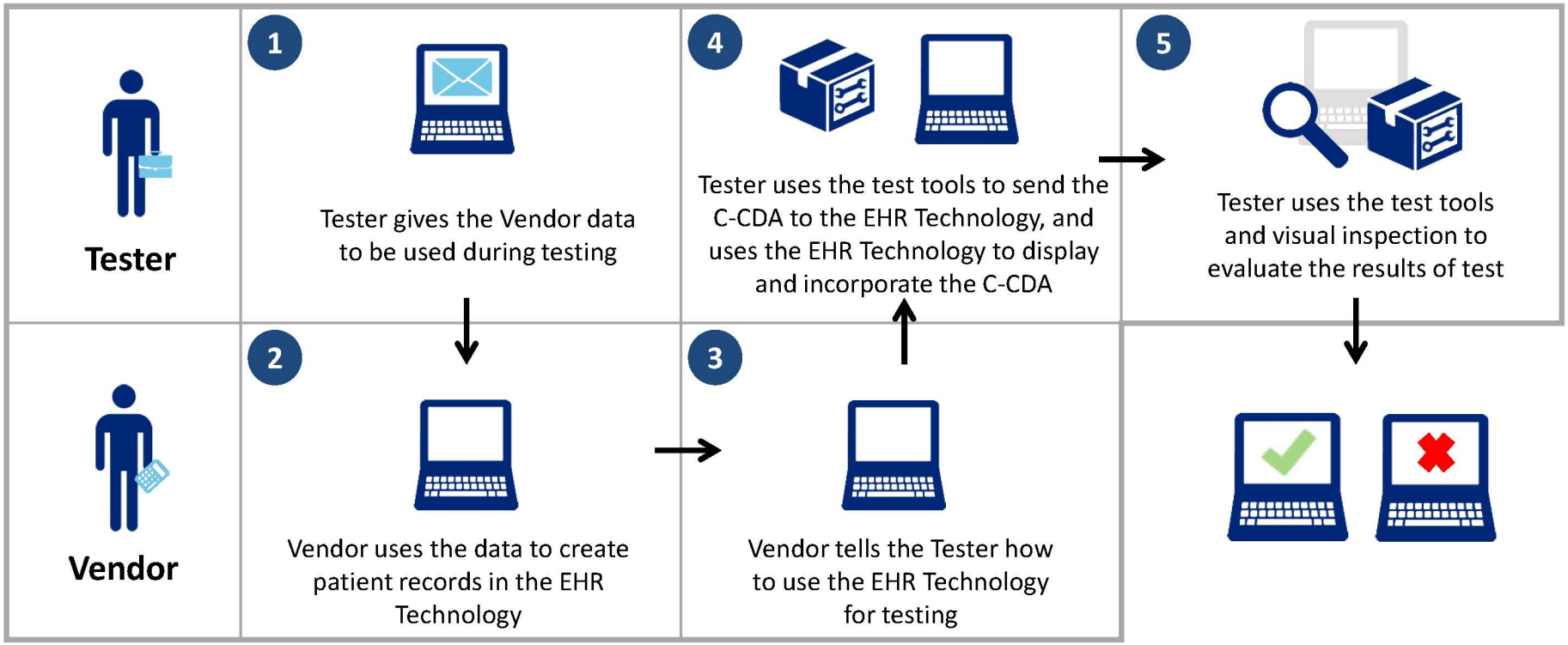
ONC's test procedures establish a general test flow around which ATLs build test scripts.



Receiving a C-CDA: Test Flow Steps 1, 2 and 3 – Set Up

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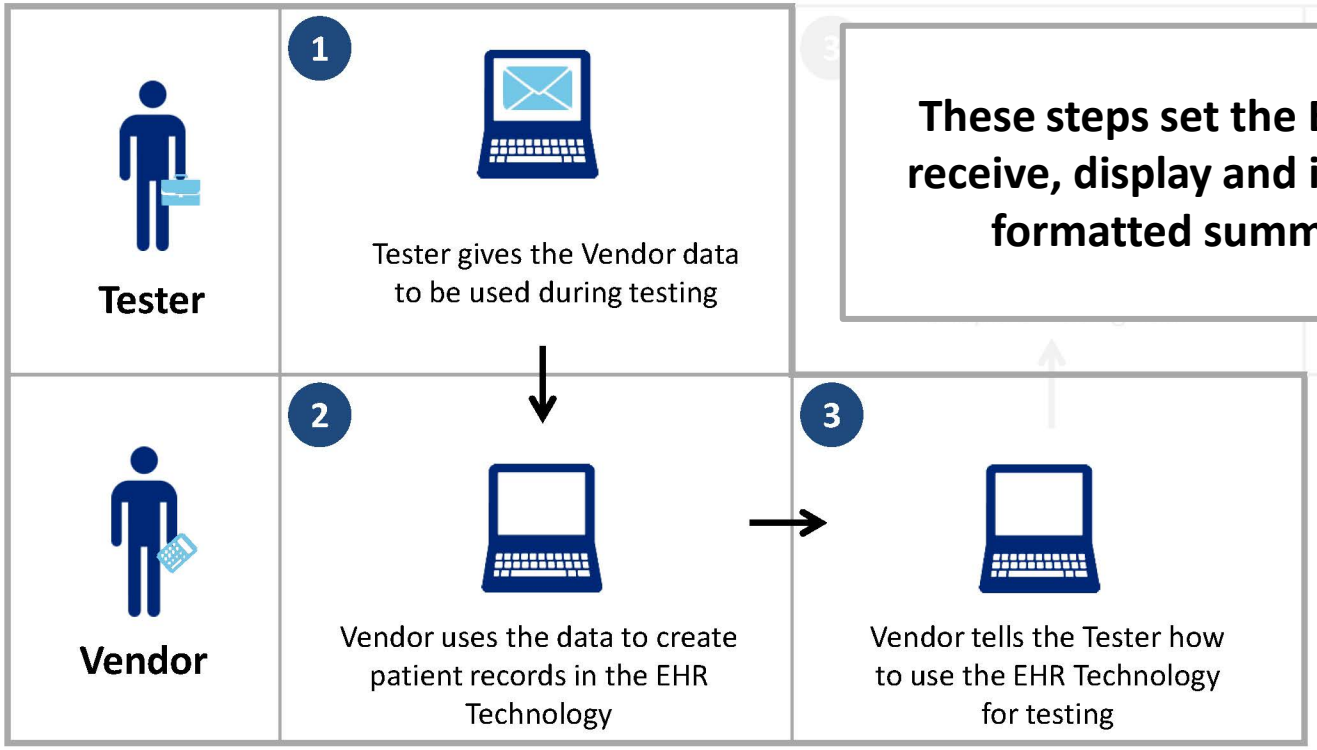
The set up steps for receiving, displaying, and incorporating a C-CDA are very similar to the set up steps for creating and transmitting a C-CDA.



These steps set the EHR Technology up to receive, display and incorporate the C-CDA formatted summaries for the test.

This makes sure that the EHR Technology contains a patient record for the test tools-transmitted C-CDA to match.

Receiving a C-CDA: Test Flow Step 4 – Receive and incorporate

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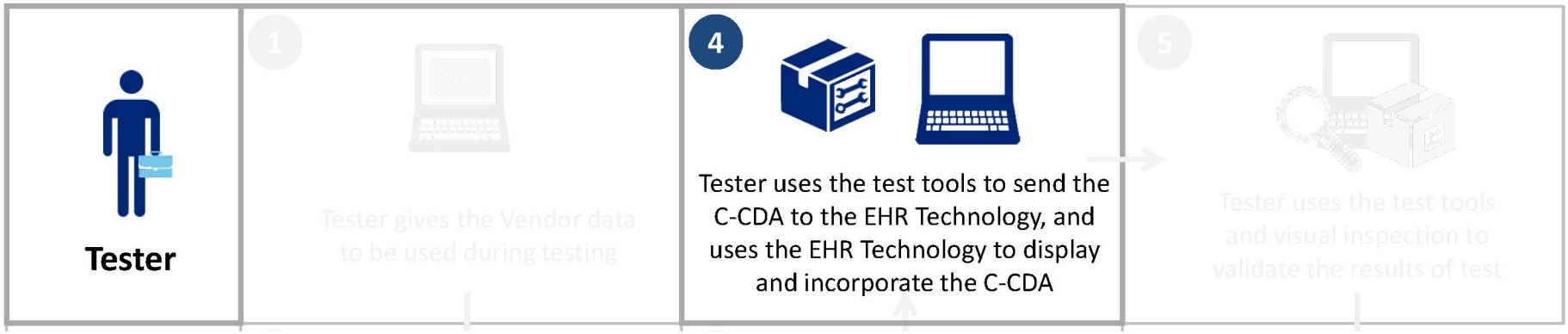
Instead of using the EHR Technology to send the C-CDA to the Transport Testing Tool, Testers will use the Transport Testing Tool to send the C-CDA to the EHR Technology.



After using the test tools to send the C-CDA to the EHR Technology being tested, the Tester will access the EHR Technology and display and incorporate the received C-CDA.

- Testers can use test scripts provided by the ATL to perform the Test Procedure steps required for creating and transmitting the C-CDA.
- Testers will use directly verify (using visual inspection) that the data was received and incorporated correctly.
- Testers will indirectly validate (using the test tools) that the EHR confirmed receipt of the C-CDA by sending an MDN.

Receiving a C-CDA: Test Flow Step 5 - Validation

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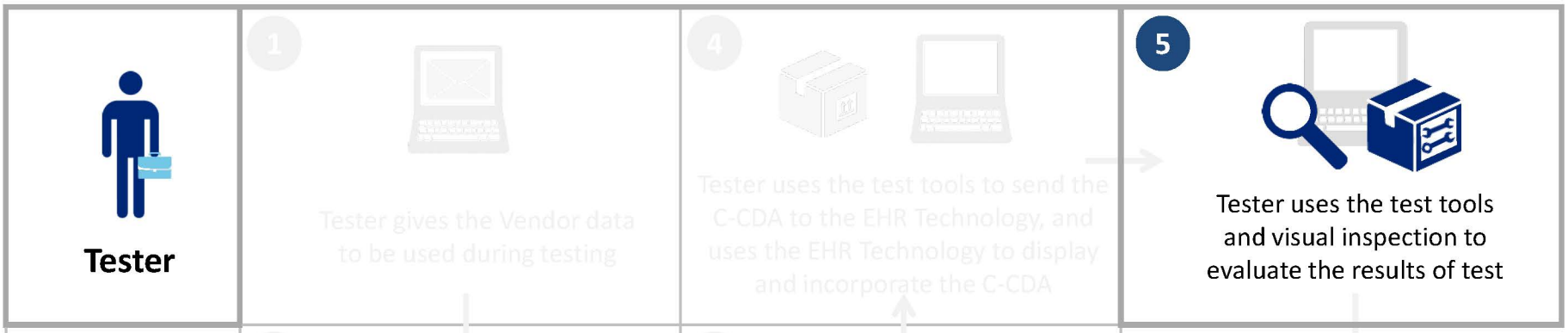
Once the Tester has used the EHR Technology to receive, display and incorporate the C-CDA, they will validate the results of the test using visual inspection and the test tools.



Test Tools

- Verification that the Transport Testing Tool (TTT) received a Message Delivery Notification (MDN) from the receiving EHR
  - For more on the TTT, visit http://ttt.transport-testing.org/ttt
- Use of the Direct Certificate Discovery Tool (DCDT) verifies that the EHR can successfully publish certificates to be discovered and discover published certificates before receiving the C-CDA
  - For more on the DCDT, visit http://code.google.com/p/direct-certificate-discovery-tool

Visual inspection

- Validation that the content of received documents is correct and complete
- Verify that summaries and the data they contain are
  - Matched to the right patient
  - Incorporated correctly
- Specific visual inspection steps will be provided by ATLs

Example:
Transition of Care Criterion
(Primary Care Provider)

Roles in the Testing Process

ONC's Test Method is constructed to emulate realistic clinical workflows.

Testers play the role of EHR users and use test data and tools to test the conformance of EHR technology to the required standards and certification criteria.

Vendors use test data to set up the EHR for the test and provide the Tester with information about how to use their EHR to perform the test.

Testing: Step One - Set Up

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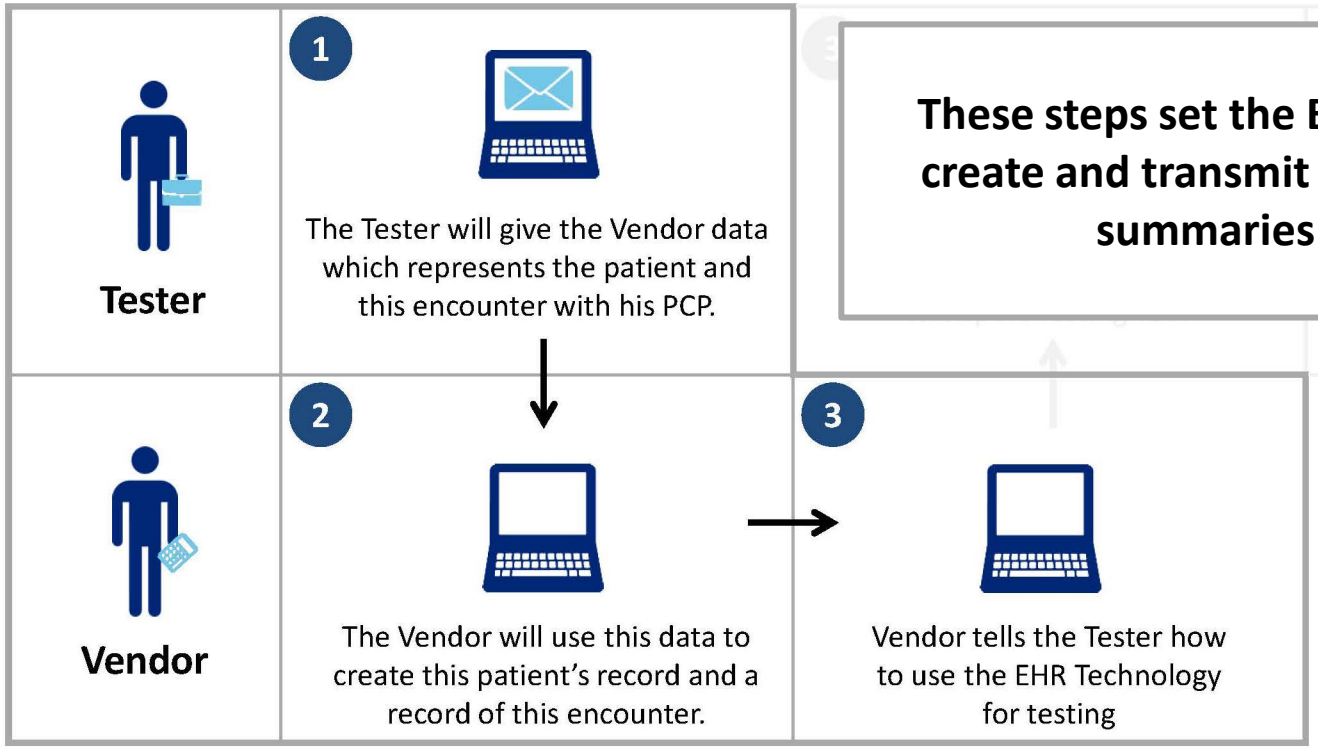
Scenario: A patient is experiencing severe knee pain and is referred to a Orthopedist by their Primary Care Provider (PCP). The PCP needs to generate a summary document to provide to the Orthopedist.



These steps set the EHR Technology up to create and transmit the C-CDA formatted summaries for the test.

Testing: Step 2 - Creating the C-CDA

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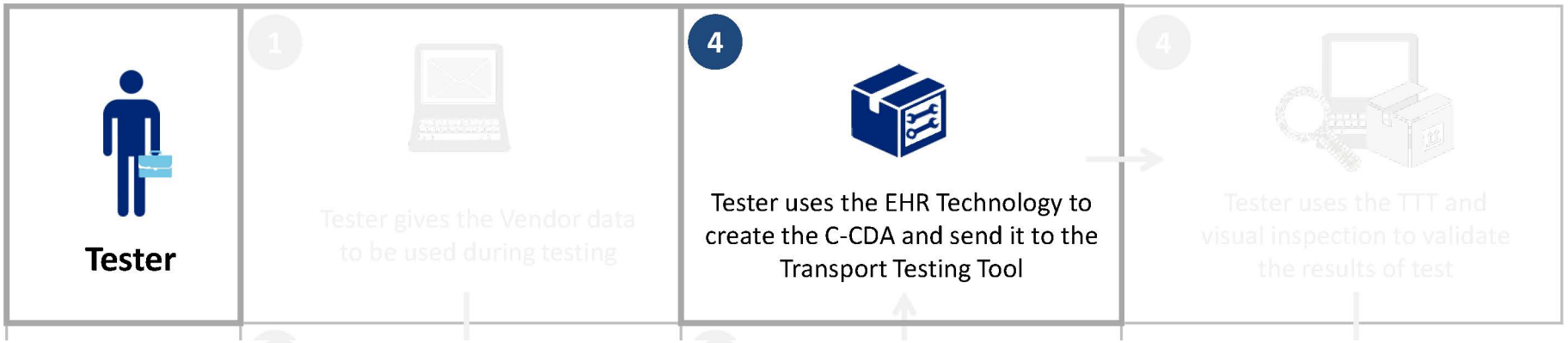
The patient's PCP uses their EHR Technology to create a summary document for this patient's referral to an Orthopedist.



After the EHR has been set up, the Tester will use the EHR Technology to create a C-CDA formatted referral summary for this patient from his PCP to an Orthopedist.

The Tester plays the part of an authorized user who:

- Uses the EHR Technology to create the C-CDA formatted summary.

Testing: Step 3 - Transmitting the C-CDA

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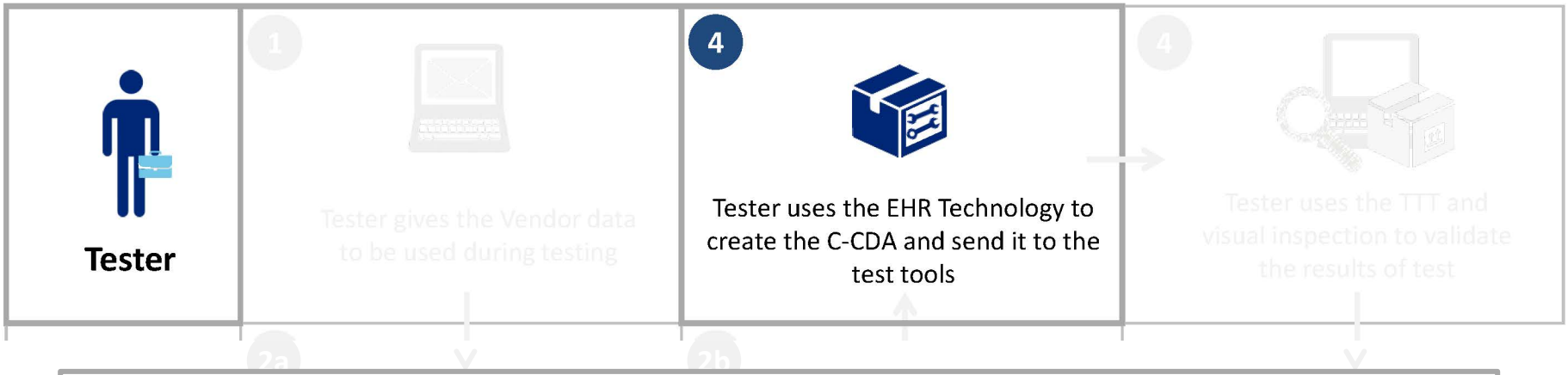
The patient's PCP uses their EHR Technology to transmit a referral summary for this patient from his PCP to an Orthopedist.



After the Tester has created a C-CDA formatted referral summary, they will use the EHR Technology to send the summary to the Transport Testing Tool, which plays the part of the Orthopedist's EHR.

- Testers will use visual inspection steps defined by the ATL to make sure that test data was entered and used correctly.

Testing: Step 4 - Validation

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The Orthopedist's EHR receives the referral summary.

Playing the role of an authorized user of the Orthopedist's EHR Technology, the Tester will use the Transport Testing Tool to receive the referral summary and validate the results of the test.

Test Tools

- Use of the Transport Testing Tool (TTT) to verify that the C-CDA was transmitted successfully and constructed properly
  - For more on the TTT, visit http://ttt.transport-testing.org/ttt
- Use of the Direct Certificate Discovery Tool (DCDT) to verify that the EHR Technology can successfully publish certificates to be discovered and discover published certificates before transmitting the C-CDA
  - For more on the DCDT, visit http://code.google.com/p/direct-certificate-discovery-tool

Visual inspection

- Validation that the content of documents created is correct and complete
- Validation that the content of transmitted documents is correct and complete
- Specific visual inspection steps will be provided by ATLs

Care Summary
Testing and Certification FAQs

What types of C-CDA errors does the Transport Testing Tool validator check for?

The Transport Testing Tool validates Consolidated CDA templates and where appropriate, vocabularies and value sets required by the standard.

- Where appropriate, the Transport Testing Tool validates vocabularies and value sets required by 2014 Edition EHR Certification Criteria which may override the C-CDA standard.
- The Transport Testing Tool does **NOT** require documents to adhere to or assert conformance with any Document Template.
- For each data requirement associated with a particular 2014 Edition EHR Certification Criterion, the Transport Testing Tool checks for the presence of appropriate corresponding C-CDA Section and/or Entry Templates.

The TTT validates Consolidated CDA templates

templateId assertions in CDA are indicators that an element conforms to a corresponding template definition.

Wherever the Transport Testing Tool finds a templateId assertion, it will attempt to validate that the element properly conforms to the indicated template.

- This includes the General Header Template, Document templates, Section templates, and Entry templates

```
        <!--
*********************************************************
Advanced Directives (entries optional)
*********************************************************
-->
        <component>
           <section>
              <!-- Advance Directives Section (entries optional) -->
              <templateId root="2.16.840.1.113883.10.20.22.2.21"/>
              <code code="42348-3" displayName="Advance Directives" c
              <title>ADVANCE DIRECTIVES</title>
              <text>
```

The TTT validates vocabularies and value sets from the standard

Value Sets such as Language, Ethnicity, Smoking Status are validated by the TTT tool.

Vocabularies are also validated per the standard as applicable.

- Note: There are value sets and vocabularies required per 2014 Edition EHR Certification Criteria which are different than the C-CDA standard. In these cases the 2014 Edition EHR Certification Criteria takes precedence and will be used for value sets and vocabulary validations.
  - Examples of these include Race, Ethnicity, Language value sets which are different than C-CDA standard.
  - Also Vocabulary requirements for Problems, Medications, Results and Immunizations are validated per the regulation.

The TTT does NOT require documents to adhere to or assert conformance with any Document Template.

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It is important to understand what the TTT does NOT do.

While the Consolidated CDA Implementation Guide defines 8 structured document templates, the TTT does **NOT**:

- Require a templateId asserting conformance with a Document Template from the Consolidated CDA Implementation Guide
- Require ANY templateId asserting conformance with a document template

*NOTE: If conformance with a document template is asserted, TTT **WILL** validate that the document conforms to the indicated template.

- Both examples below would pass validation

```
<!-- US General Header Template -->
<templateId root="2.16.840.1.113883.10.20.22.1.1"/>

<!-- Continuity of Care Document (CCD)/HITSP C32 templateId -->
<templateId root="2.16.840.1.113883.10.20.22.1.2"/>

<!-- CONF 5363 -->
<id extension="Test CCDA" root="1.1.1.1.1.1.1.1.1"/>
```

```
-- US General Header Template -->
emplateId root="2.16.840.1.113883.10.20.22.1.1"/>

-- No Document Template followed -->

-- CONF 5363 -->
d extension="Test CCDA" root="1.1.1.1.1.1.1.1.1"/>
```

The TTT checks for appropriate Section and Entry templates matching each data requirement.

When providing a C-CDA document to the TTT, the user selects which 2014 Edition EHR Certification Criterion that document relates to.

- For each data requirement associated with that criterion, the TTT searches for the presence of an appropriate C-CDA Section and/or Entry that could address that data requirement.
    - A validation error is reported if no appropriate Section and/or Entry can be found for a given data requirement.

*NOTE: To access the full reference of acceptable C-CDA templates for each data requirement, review the mapping at the following location: MDHT Requirements.xlsx

The Transport Testing Tool has been updated

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NIST is using a new domain for the Transport Testing Tool.

The new address is: http://ttt.transport-testing.org/ttt

Be sure to complete the following in order to use the updated tool at the new domain:

- Re-register user addresses in order to send Direct messages to the TTT
  - The domain name is “ttt.transport-testing.org”
- Download and re-install the public cert and Trust Anchor for the new domain to make sure the EHR Technology being tested can communicate with the new domain

Testing and Certification Resources

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Your ATL and ONC-ACB are your best resource for specific questions about testing and certification.

ONC publishes FAQs about the certification criteria and standards:

- Regulatory FAQs (General)

CMS has published an FAQ about Transition of Care requirements for Meaningful Use.

- CMS FAQ 7699

ONC's website has additional guidance about the Certification program's structure and the Test Method.

- Access the 2014 Edition Test Method on ONC's website.
- Questions can also be submitted to ONC.Certification@HHS.gov

Standards FAQs

Your ATL and ONC-ACB are your best resource for specific questions about testing and certification.

Additional resources on the standards referenced by the criteria involving care summaries are available:

- C-CDA Implementation
- Direct & XDR/XDM Specifications
- SOAP Specification

Q & A

Thank you for your participation

This concludes today's training concerning "Implementing CDA".

For more information about these and other related topics, visit the ONC website

http://www.healthit.hhs.gov