



Content Testing Program

Effective February 5, 2018

Acknowledgements

Many thanks are due to the eHealth Exchange Content Testing Workgroup members and Co-chairs, [Omar Bouhaddou](#), Chief Health Informatics Officer, InnoVet Health contractor to Department of Veterans Affairs, Veterans Health Information Exchange (VHIE/VLER Health) and [Tone Southerland](#), Director, Interoperability, IQVIA. Under the leadership of the co-chairs and Sequoia staff the workgroup members met from June 2015 – December 2016 to provide a wide breadth of input and contributions that were incorporated into this enhanced content testing program requirements and test methods.

In addition, this updated documentation incorporates suggestions for improvement from the twenty (20) organizations that helped to pilot this program in 2016. Many thanks to these organization who provided forty-five (45) document samples representing 10 distinct vendor products. The document samples were tested with the various tools under consideration at that time leading to the choice of the Sequoia/Gazelle CDA testing tooling.

Lastly, special thanks to the four organization that provided public comments November 2016 - January 2017 to further clarify and improve this documentation.

Change Log

Date	Version	Description
11/2/2015	Initial Draft v0.1	Initial rough draft
11/5/2015	Version 0.2	Added comments and fixed formatting and font issues found and updated table of contents
02/29/2016	Version 0.3	Comments received since 11/5/2015 incorporated. Added HL7 C-CDA CCD v2.1 requirements & additional clarification based on implementation FAQs tracked by the testing workgroup
4/11/2016	Version 0.4	Updated Test Methods to align with MU 2015 Edition Test Procedures and Test Data leveraged by Authorized Testing Labs
11/15/2016	Version 0.5	Updated Test Methods, test data, clinical document guidance to address pain points documented by the Testing Workgroup and findings from the April – July 2016 Pilot testing.
2017	Version 0.6	Resolved comments submitted from public comment period 11/15/2016 – 1/9/2017. Added commenters to contributor's section of this document. Clarified program requirements and cut out duplicative conformance requirements from the specifications.
02/05/2018	Version 1.0	Updated documentation to include proper linkages to historical data and also provide insights to changes that may be coming later in 2018 with the newly proposed Draft ONC US Core Data for Interoperability (USCDI) – published February 5, 2018.
08/24/2018	Version 1.1	Updated names of RECEIVE Test Case document files to align with updated ONC document samples used for Certification testing for 170.315(B)(5) Common Clinical Data Set Summary Record – Receive https://www.healthit.gov/test-method/common-clinical-data-set-summary-record-receive updated 7/30/2018.

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1 INTRODUCTION

1.1 Introduction

This Testing Documentation replaces the existing Content Test Cases used by the Product and Participant Testing Programs of the eHealth Exchange. The eHealth Exchange continues to support the content requirements and specifications defined within the prior 2011 and 2014 Edition Meaningful Use programs. In addition, the eHealth Exchange had extended testing compliance to the 2015 Edition Meaningful Use (MU3) Program Certification requirements that reference the latest Draft Standard for Trial Use (DSTU) HL7® C-CDA version 2.1 standards. These standards were published as part of the regulation in August 2015 and are referenced in the standards and implementation guides found in [Section 3](#) of this document. This content testing documentation formally deprecates the allowance of the [Bridge C32](#) content requirements previously published by the eHealth Exchange but builds upon the concepts from that documentation. It is encouraged that eHealth Exchange participants strive to support the appropriate document for their various use cases. The reality today, is that many of the eHealth Exchange participants create on-demand documents when queried and respond with a Continuity of Care Document (CCD) document type. However, there are 12 document templates in the HL7® C-CDA standards and the eHealth Exchange will begin more rigorous conformance testing for the various versions of clinical content being exchanged. All participants are encouraged to work with their implemented solutions to expand the availability of document types for the appropriate purpose and use case.

This content testing documentation adds the additional content requirements from the Transitions of Care Implementation guidance published by HL7 and the associated Meaningful Use Companion Guides. These HL7 implementation guides provide meaningful use and additional clinical guidance for information that may be exchanged by nodes among eHealth Exchange participants to address particular use cases or business needs. The eHealth Exchange participants act as nodes on the eHealth Exchange network and enable their connected stakeholders to exchange clinical document content to make use of the discovery and information exchange capabilities and rest upon a foundational set of messaging, security, and privacy services.

This document provides the methodology and scenarios that will be required for interoperability testing and exchange of content documents between eHealth Exchange participants. The outcome from the content testing program will provide a feedback loop from real world deployments to HL7 and is expected to continue to inform future documentation under development by the Structured Documents and other Workgroups within HL7.

Industry Content Pain Points

- ▶ Content in documents is highly variable
- ▶ Widely-used templates have ambiguity
- ▶ This will be an ongoing effort and there will be a gradual raising of the bar
- ▶ It is expected that this testing will provide the feedback to improve the standards at HL7 and prepare for the adoption of the US Core Data for Interoperability (USCDI)

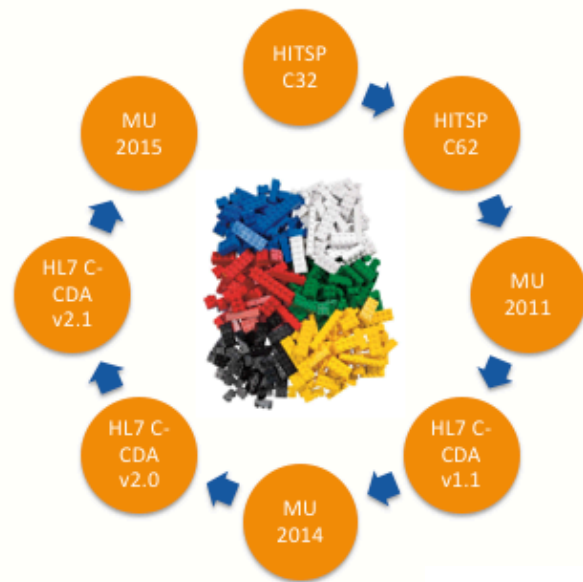
1.2 Historical Background

From 2012 – 2017 - The eHealth Exchange Content Testing Program did not require content testing if a system under test technology could be found listed in the ONC Certified Product Healthcare Listing (CHPL) <https://chpl.healthit.gov/#/search>

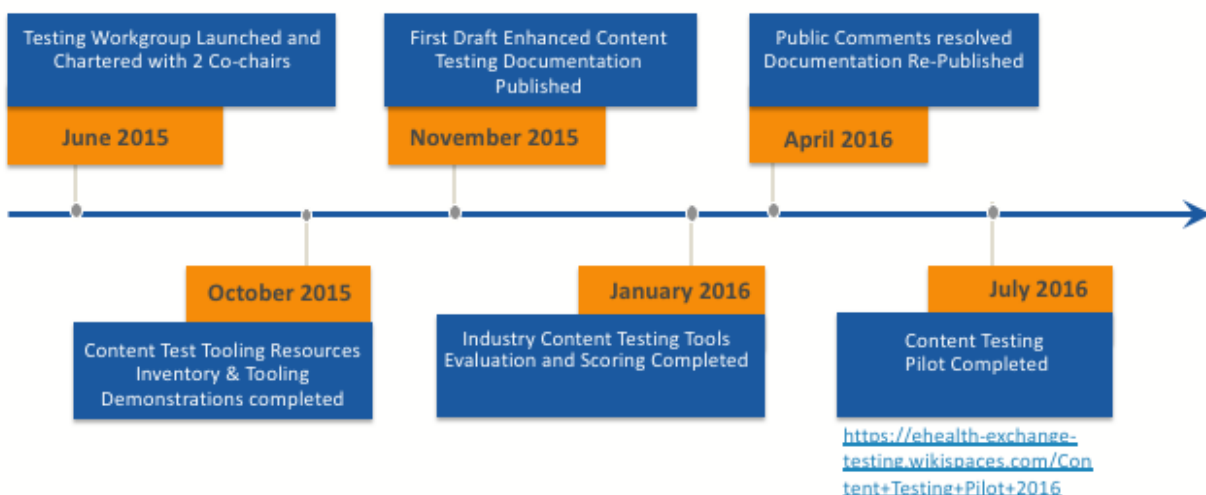
1.2.1 eHealth Exchange Content Testing Evolution

A Look Back – Industry Churn

- No Content Testing Required: If Participant or Vendor's architecture is certified for MU 2011 edition, 2014 edition or 2015 edition
- If not MU certified: Required to test one or more of the following:
 - [The Basic C32 \(ONC 2011 Edition\)](#)
 - [The Bridge C32](#)
 - [The Consolidated CDA \(C-CDA\) \(ONC 2014 Edition\)](#)
- In June 2015, Coordinating Committee approves launch of Testing Workgroup (TWG) focusing on Content Testing



1.2.2 eHealth Exchange Testing Workgroup (TWG) Background and Overview



1.2.3 eHealth Exchange 2016 – Content Testing Pilot 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

1.2.4 Targeted eHealth Exchange Industry-wide Identified 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

2 USE CASE SCENARIOS FOR CONTENT

2.1 Existing eHealth Exchange Use Cases

The eHealth Exchange has various use cases in production today. For more information on the use cases supported by the eHealth Exchange please see this [presentation](#) and/or [recording](#). Some of the use cases included the following:

- **Authorized Release of Information – Consumer Access to Health Information** – Enables clinical exchange between patient and provider (e.g. via a Personal Health Record/PHR)
- **Authorized Release of Information / Disability Determination** – Social Security Administration requests claimant records electronically to make disability determinations. *Cuts down claims processes from months to days.*
- **Authorized Release of Information / Life Insurance** – Enables life insurance companies to request copies of an individual's medical records for the purpose of making a determination for life insurance benefits
- **Encounter Alerts** – Enables event notification of clinical encounters to patient associated care team members
- **Electronic Lab Reporting (in support of public health)** – Enables electronic lab reporting to public health agencies
- **Immunizations** – Enables the push of immunization data for treatment purposes (*this is not related to immunization registries*)
- **Military/Veteran Health** – DoD and VHA exchange active service members and veterans' records to provide government and private caregivers with up-to-date medical histories
- **Prescription Drug Monitoring Program (PDMP)** – Enables exchange of PDMP data
- **Quality Reporting for the End Stage Renal Disease Program – CMS** – Enables dialysis centers to send quality data to CMS to assure that individuals with End Stage Renal Disease receive the highest quality of care
- **Responder Only Profile** – Enables other networks (e.g., release of info companies, and SAAS model vendors) to respond to queries from eHealth Exchange Participants on behalf of their client
- **RSNA Image Share Use Case** – Enables organizations to share images via the eHealth Exchange with patients and providers.
- **Syndromic Surveillance** – Enables syndromic surveillance reporting to public health agencies
- **Treatment/Care Coordination** – Enables access to critical information (e.g., test results, medication history, allergy info, immunizations) and makes available to providers when a patient is transferred

Use case development requires an understanding of the business need – the issue your organization seeks to resolve or opportunity on which you intend to capitalize. Defining your need early in the process will accelerate later development efforts and provide a basis for evaluating success.

2.2 Process to Request New Use Cases

The General Performance and Service Specifications Addendum (*effective 11/19/16*) defined a new process for submitting requests for new use cases. It clarified the added flexibility of permitting Participants to voluntarily adopt other standards and specifications for new use cases. At a high level the eHealth Exchange Use Case process is as follows:

- Participants or other stakeholders should submit requests for new use cases or specifications to administrator@ehealthexchange.com, including:

- Requestor name(s) and organization(s)
 - Use Case / Specification Title
 - Brief description of the use case, identifying the applicable specifications
 - Testing approach: Identify suggested testing approach, if any (e.g. no eHealth Exchange Network testing, partner testing only, reference other authoritative testing process, etc.)
- The Coordinating Committee that governs the eHealth Exchange will consider requests for new use cases at any time throughout the year.

While the eHealth Exchange supports various transports and clinical content as required to enable the transitions of care and continuity of care process between clinicians and their patients. These testing requirements are meant to enable participants to exchange robust and meaningful clinical information with their connected stakeholders to support a variety of use cases. The expectation is that all clinical document types will be tested for conformance, so participants and their vendors can test for any innovative combination of constrained document templates, or sections or entries to support their identified use cases for the exchange of clinical data.

The following provides information that can be leveraged by participants and their vendors during use case development for their organizational implementation.

2.2.1 What is a Use Case?

A use case is an easy to understand description detailing the interaction between an actor (human, organization, system) and a system under consideration. It identifies a set of 'trading partners' as source and consumer systems and describes how they intend to use the eHealth Exchange. The use case should describe the actors and clinical data to be exchanged.

2.2.2 Why do we use them?

Use cases are developed with a goal in mind, that makes them a valuable planning tool. A well-crafted use case communicates the functional requirements that may then inform technical planning. Having the use case available prior to technical discussions helps scope the technical solution and accelerates the technical evaluation process to elaborate on the policy and procedural requirements necessary.

2.2.3 How they should help you?

Use case development requires an understanding of the business need – the issue your organization seeks to resolve or opportunity on which you intend to capitalize. Defining your need early in the process will accelerate later development efforts and provide a basis for evaluating success.

Examples:

- I need to join the eHealth Exchange
 - Not detailed enough
- Our practice/organization needs to generate and securely send summary of care records to patients' specialists to meet meaningful use transition of care criteria within this region and across care delivery locations.
 - Provides initial needed details to guide plan development, scope the effort and establish priorities.

2.2.4 Use Case Benefits

- Identifies the clinical/business need before solution development...mitigating rework and delays
- Facilitates initial scoping, project planning and effort prioritization
- Supports 'marketing and selling' your request to management – you have done your due diligence to articulate value, not just functionality
- Supports identifying the project team/stakeholders involved

2.2.5 Use Case Elements

- Use case name: a brief summary of your use case
 - Patient referral from PCP to Specialist
- Goal: what is your end goal?
 - To attest to meaningful use, transition of care criteria
- Story: How do you intend to use the eHealth Exchange?
 - Perspective: a provider referring a patient to a specialist
 - Context: the referring provider has made the determination that it is clinically and legally appropriate to send a referral and summary of care to a specialist.
 - Story:
 - Dr. Jones (the referring provider) searches for a patient in the practice EHR and initiates a referral message. The referral reason is described in the message. In some cases, the referral is directed to a specific specialist, and in other case to a specialist practice. Dr. Jones attaches a summary of care for reference, and then sends the referral.
 - Dr. Smith (the specialist) sees the new referral in his/her local practice EHR. If this is a new patient for the practice, a new patient is created in the EHR. The core referral and the various documents are imported into the new patient's chart.
 - *Reference: The Direct Project, User Stories*
 - <http://wiki.directproject.org/Primary+care+provider+refers+patient+to+specialist+including+summary+care+record>
 - Actors: who are the sources and consumers, e.g. people, roles, organizations?
 - People = Dr. John, Nurse Thompson
 - Roles = Case Manager, Triage Nurse
 - Organizations = Hospital ABC, Medical Associates of XYZ
 - When describing the organization include size indicators, e.g. number of beds, providers, visits per month
- **Actors:** What are the source and intermediary systems and consumers?
 - When describing systems include vendor names and system versions
 - The eHealth Exchange gateway is typically an intermediary system
- **Data to exchange:** What data do you intend to exchange?
 - CCDS data set (all data that may be required for exchange as part of MU2/2014 Edition or MU3/2015 Edition)
 - Patient name
 - Sex
 - Date of birth
 - Race**
 - Ethnicity**
 - Preferred language
 - Care team member(s)
 - Allergies**
 - Medications**
 - Care plan
 - Problems**
 - Laboratory test(s)**
 - Laboratory value(s)/result(s)**
 - Procedures**
 - Smoking status**
 - Vital signs

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

2.2.6 Use Case Guidance

- Limit the use case to 1-2 page(s)

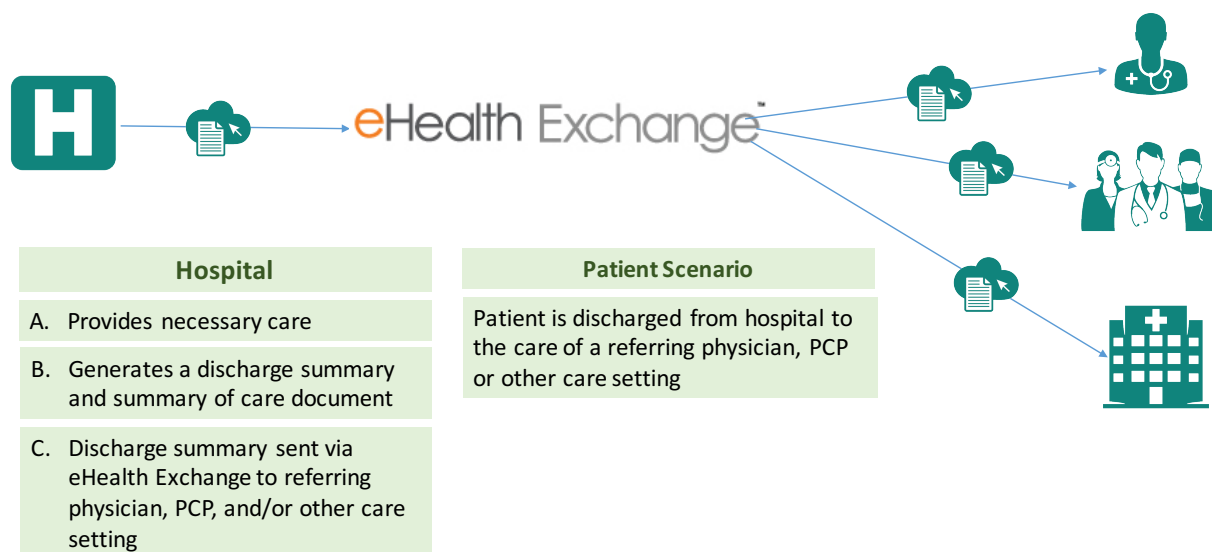
- Engage your clinical and business leaders early
- Align to business objectives, e.g. meaningful use criteria
- Complete all identified elements, but in 2 phases:
 - Part 1 – Name, Perspective, Context, Story
 - Part 2 – Actors, Data to Exchange
- Do not describe technical connectivity (i.e. S/MIME vs. XDS vs. XCA), rather tell the story of how you will use the solution once built
- Do not make the use case too general – select a well-defined area of focus and add in appropriate data

Some examples use cases can be found in the tables and diagrams below:

Table 1: Hospital Discharge Use Cases

Use Case	Type of Transaction	Care Setting	To Care Setting
1.1	Hospital discharge summary	Hospital	Referring physician and/or PCP
1.2	Hospital discharge summary	Hospital	Other care settings (i.e. Skilled Nursing Facility (SNF))
1.3	Hospital discharge summary	Hospital	Hospital
1.4	Hospital ED visit summary	Hospital	Referring physician and/or PCP

2.2.7 SAMPLE Use Case 1: Hospital Discharge



This use case describes the situation where a patient is discharged from a hospital and their care is transitioned by to another care setting or referred to another care provider. The health information systems of the two provider organizations should be able to successfully transfer a notification of the patient discharge. The notification may include important patient data elements that facilitate the effective transfer of the patient's care from the first provider organization to the second.

1. Communicate a patient discharge to an external organization
2. Like a transition of care
3. Transport is tested separately from content requirements

Goals:

To be able to electronically send a discharge for a patient from a hospital encounter from a care provider Sender to care provider Receiver with the appropriate patient demographic, administrative and clinical data to ensure a smooth transition of care.

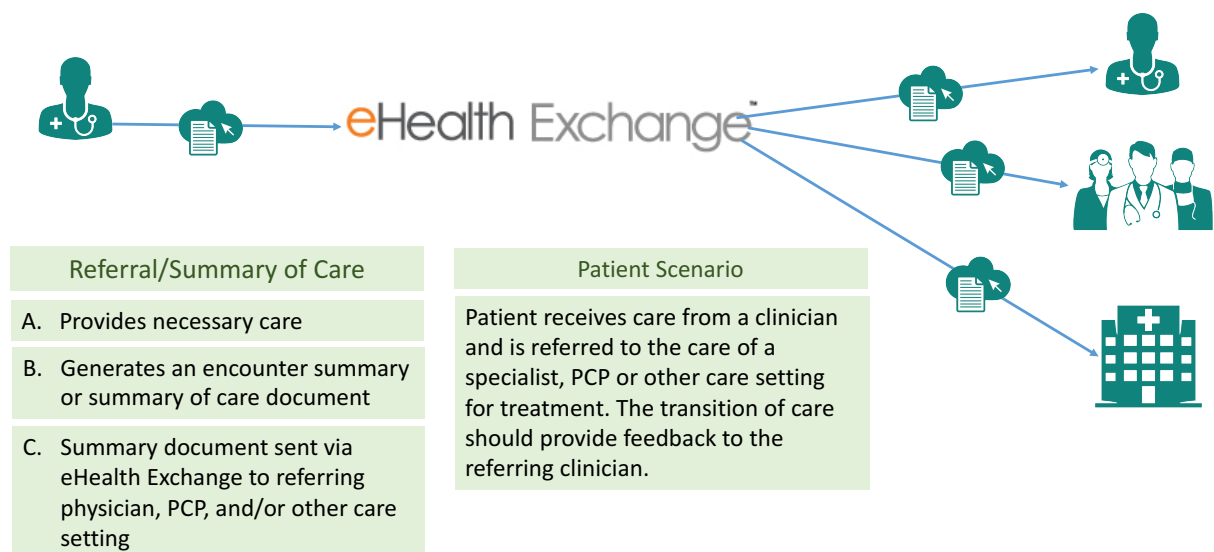
Document templates that can be leveraged:

- Continuity of Care Document (CCD)
- Hospital Discharge Summary

2.2.8 SAMPLE Use Case 2: Patient Referral/Transition of Care

Table 2: Patient Referral/Transition of Care Use Cases

Use Case	Type of Transaction	Care Setting	To Care Setting
2.1	Referral – Summary of care record	PCP	Specialist
2.2	Consult note – Summary of care record	Specialist	PCP
2.3	Referral – Summary of care record	PCP or specialist	Hospital



This use case describes the situation where a patient's care is transitioned or referred to another care provider. The health information systems of the two provider organizations should be able to successfully transfer a notification of the patient referral. The notification may include important patient data elements that facilitate the effective transfer of the patient's care from the first provider organization to the second.

1. Communicate a patient referral to an external organization

2. A transition of care
3. Transport is tested separately from content requirements but can include provider to provider referral

Goals:

To be able to electronically send a referral for a patient from a care provider Sender to a care provider Receiver with the appropriate patient demographic, administrative and clinical data to ensure a smooth transition of care.

Documents templates that can be leveraged:

- Care Plan
- Consultation Note
- Continuity of Care Document (CCD)
- Progress Note
- Referral Note
- Transfer Summary

3 REFERENCED STANDARDS AND IMPLEMENTATION GUIDES

3.1 REQUIRED Standards and Implementation Guides – Effective 1/11/2017

These requirements were approved by the eHealth Exchange Coordinating Committee and passed the formal change management process with the following timeline:

Formal Change Process Milestones

Approval Milestones	Target Dates
Present to CC for Review (Draft):	11/15/2016 - Completed
CC Approval:	11/15/2016 - Completed
Participant Input (Post draft to eHealth Exchange Wiki):	11/15/2016 - Completed
Participant Input (Webinar to review):	12/2/2016 - Completed
30-day notice to Participants:	12/2/2016 - Completed
Objection Period Ends:	1/10/2017 - Completed
New Content Testing Program Requirements	EFFECTIVE DATE: 1/11/2017
Comment Resolution	2/5/2018
Testing Workgroup Feedback Loop to HL7/ONC	Ongoing
Production Content Testing Program Launch	2/5/2018
eHealth Exchange Informational Call - Announcing Launch	2/5/2018

HL7 Standard or Implementation Guide	Short Name	URL
HL7 CDA R2 Basic Requirements	CDA R2 Basic	https://gazelle.ihe.net/cda/cda-basic-req.pdf
HITSP Summary Documents Using HL7 Continuity of Care Document	HITSP C32	http://www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=e1b99525-a1a5-48f6-a958-4b2fc6d7a5c7
HL7/ASTM Implementation Guide for CDA® R2 – Continuity of Care Document (CCD®) Release 1 (April 2007)	HL7 CCD	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=6
HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 (US Realm) Draft Standard for Trial Use (July 2012)	HL7 C-CDA R 1.1	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258
HL7 Implementation Guide: S&I Framework Transitions of Care Companion Guide to Consolidated-CDA for Meaningful Use Stage 2, Release 1 – US Realm (September 2014)	2014 Edition Stage 2 MU Guide	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=374
HL7 CDA R2 Implementation Guide: Consolidated CDA® Templates for Clinical Notes (US Realm) DSTU Release 2.1 (with errata) (May 2018)	HL7 C-CDA R 2.1 Volume 1	http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=168 Volume 1 provides narrative introductory and background material pertinent to this implementation guide, including information on how to understand and use the templates in Volume 2.
Companion Guide to HL7 Consolidated CDA R2.1 for ONC 2015 Health IT Certification Criteria (March 2017)	2015 Edition Stage 3 MU Guide	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=408 HL7 is developing a Companion Guide for C-CDA Release 2.1 and the Testing Workgroup intends to update this document once it becomes publicly available. In the meantime, we recommend developers follow the guidance provided by the HL7 CDA Example Task Force for implementation of the C-CDA Release 2.1 standard.
Best Practices and Quantitative Scoring Criteria (Scorecard)	Scorecard Rubrics	http://www.hl7.org/documentcenter/public/wg/structure/C-CDA%20Scorecard%20Rubrics%203.pptx https://github.com/siteadmin/site-content/raw/master/C-CDA-Scorecard-Rubrics.docx
NIH National Library of Medicine hosted Value Set Authority Center	VSAC	https://vsac.nlm.nih.gov/welcome
2015 Edition Common Clinical Data Set – 45 CFR 170.102	CCDS	https://www.healthit.gov/sites/default/2015Ed_CCG_b4-CCDS-summary-record-create.pdf https://www.healthit.gov/sites/default/files/2015Ed_CCG_CCDS.pdf https://www.healthit.gov/sites/default/files/ccds_reference_document_v1_1.pdf

ONC Regulations can be found at: <https://www.healthit.gov/policy-researchers-implementers/standards-and-certification-regulations>

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3.2 Optional – Best Practice Guidance Standards and Implementation Guides

These specifications and implementation guides are NOT REQUIRED but are offered here for industry awareness of best practices:

HL7 Standard or Implementation Guide	Short Name	URL
HL7 CDA® R2 Implementation Guide: Data Provenance, Release 1 – US Realm (September 2014)	HL7 Data Provenance Implementation Guide (DPROV)	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=420
HL7 Implementation Guide for CDA® Release 2: Clinical Guidance on Relevant and Pertinent Data to Include Automatically Generated Patient Summaries	HL7 Relevant and Pertinent Guide	http://wiki.hl7.org/index.php?title=Relevant_and_Pertinent http://www.hl7.org/implement/standards/product_brief.cfm?product_id=453
HL7® Example Task Force Library	HL7 Samples	http://hl7-c-cda-examples.herokuapp.com/ http://wiki.hl7.org/index.php?title=CDA_Example_Task_Force
Draft U.S. Core Data for Interoperability (USCDI) 1/5/2018	Draft USCDI	https://www.healthit.gov/sites/default/files/draft-uscdi.pdf

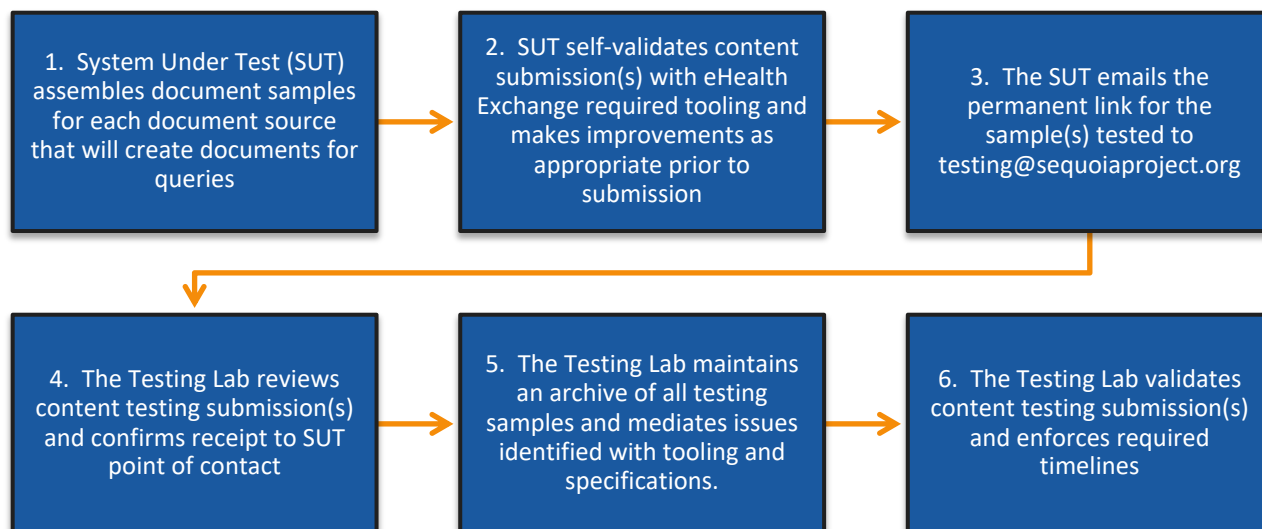
4 TESTING APPROACH

4.1 Testing Process

The testing approach will include a business process and technical process to facilitate the required testing of eHealth Exchange participants. The general process is outlined below:

1. Submission Form Completion (describes the participant's content, data limits included in each section, terminology coding, reports inclusion, etc.)
2. Testing
 - Focus is on HITSP C32, HL7 C-CDA Release 1.1 and HL7 C-CDA Release 2.1 document templates
 - Product Vendors create samples based on Test Procedure test data referenced in Appendix D or Participants SUT will provide sample(s) with self-created testing data.

The testing process will proceed as follows:



1. System Under Test (SUT) submits C-CDA document with appropriate test data.
2. SUT self-tests with prescribed testing tooling and makes improvements as appropriate prior to submission
 - a. Repeat until all Errors reported by the testing tool(s) are eliminated
 - b. Warnings from the tooling should be reviewed by SUT for potential improvement
 - c. If SUT finds inappropriate error(s) or warning(s), please report each issue separately with details in an email to testing@sequoiaproject.org
3. The SUT emails the permanent link for the sample(s) for each document source to testing@sequoiaproject.org
4. The Testing Lab reviews submission form and content testing C-CDA submission(s) for completeness
 - a. If submission is complete, the testing lab confirms receipt and tracks testing completion date
5. The Testing Lab maintains an archive and mediates issues with HL7 and the tooling vendor as required
6. The Testing Lab validates the submission(s) with testing tools as prescribed by the testing program

4.2 Template Driven Testing

HL7 templates are used to constrain and verify conformance to profiled/modeled HL7 C-CDA. A template is an expression of a set of constraints on the RIM which is used to apply additional constraints to a portion of an instance of data expressed in terms of some other Static Model. Templates are used to further define and refine these existing models within a narrower and more focused scope.

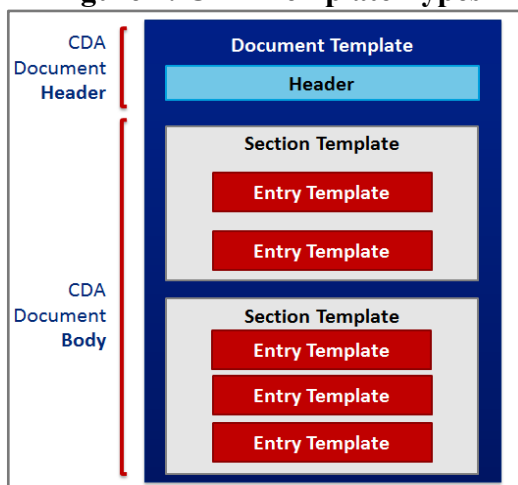
Each template is identified with a `templateID`, a globally unique identifier.¹ CDA is the most widely adopted implementation of HL7 v3. It is used for exchanging information in the form of documents. CDA has three levels:

- level 1 is a single human-readable document,
- level 2 can include multiple documents and
- level 3 can include structured information.

Each CDA document has a common header and a variable body part. Templates are used widely in HL7 CDA to constrain the generic CDA model. Conformance statements within the referenced HL7 guides are presented as constraints from Trifolia Workbench, a template repository. An algorithm converts constraints recorded in Trifolia to a printable presentation within the HL7 C-CDA standards specifications. Each constraint is uniquely identified by an identifier at or near the end of the constraint (e.g., CONF:1198-16823). The digits in the conformance number before the hyphen identify which implementation guide the template belongs to and the number after the hyphen is unique to the owning implementation guide. Together, these two numbers uniquely identify each constraint. These identifiers are persistent but not sequential.

Templates are declared at the document, section, and entry level of CDA documents. The C-CDA Implementation Guide defines an initial set of commonly used clinical documents whose contents are harmonized, thus ensuring semantic interoperability across current and future document models. Templates capture specific uses and can represent professional society recommendations, national clinical practice guidelines, and standardized data sets. Templates are designed to create standardized clinical documents that are specifically intended to support clinical workflows in various use cases.

Figure 2: CDA Template Types



Document-level templates: These templates constrain fields in the CDA header and define containment relationships to CDA sections. For example, the Continuity of Care Document (CCD)

template contains patient summary data defined by the ASTM Continuity of Care Record (CCR) represented in the C-CDA XML format. Understanding the purpose of a template helps to ensure that implementations support the inclusion of clinical information that is relevant to the intended use. In the case of the CCD, the clinical content is limited to the most relevant patient data captured during one or more encounters to ensure continuity of patient care. Similarly, the Problem Observation entry template captures a single problem or diagnosis for the patient and is limited to information about the problem or diagnosis, such as the diagnosis or observation date and the code representing the diagnosis or observation.

Templates are available in different types that reflect levels of a CDA document. Starting at the top of a document, the **header template** describes the scope and intended use of the document. The header includes the metadata, or data about the document data, that details contextual information, such as who created the document, encounter or event time and location, and patient demographics. In the broadest sense, header templates are documents with no defined body content.

Content comprising the document body and additional constraints on the header are expressed within **document templates** that define the clinical information contained based on the purpose for the document. Document templates include constraints on the CDA header and indicate contained section-level templates.

Each document-level template contains the following information:

- Scope and intended use of the document type
- Description and explanatory narrative
- Template metadata (e.g., templateId)
- Header constraints (e.g., document type, template id, participants)
- Required and optional section-level templates

Contents of the document body are comprised of **section and entry templates**. These templates specify standardized patterns used to express clinical concepts and provide the basis for reusability of CDA documents. Document templates include section and entry templates as needed, but the section and entry templates are not limited to a certain document. For example, the same Medications section may be used in more than one type of document, as in the case of the CCD and Consultation Note.

The Section-level templates constrain fields in the CDA section and define containment relationships to CDA entries that revolve around a common clinical concept, such as Procedures or Encounters. The Procedures section template captures information relative to patient procedures detailed in the entry templates that specify the procedure.

The **entry-level templates** constrain the CDA clinical statement model in accordance with real-world observations and acts. The **entry-level templates** represent individual clinical statements through coded data elements, such as a specific medication or procedure. Entries are very specific templates intended to capture an event, action, or observation relative to the clinical concept captured in the Section. Each **document template** defines a collection of required and optional sections as well as the entries within sections. Figure 2 depicts the template types in the CDA document.

Lastly, there are also **Other templates** that exist to establish a set of constraints that are reused in the CDA document. These other templates are only used within another template, rather than on their own as a complete clinical statement. For example, US Realm Date and Time (DTM.US.FIELDDED) includes a set of common constraints for recording time. This template is referenced several times with other templates used in the testing documentation.

¹ Benson, Tim. *Principles of Health Interoperability HL7 and SNOMED*. 3rd ed. London: Springer-Verlag; 2016.

4.3 Assessing C-CDA Documents for Meaningful Use

The majority of eHealth Exchange participants provide some form of the Continuity of Care Document (CCD) type when exchanging clinical data.

This section details the body constraints for select CDA documents and results of the assessment. The US Realm Clinical Document Header **SHALL** be required for all document templates. Considerations are provided below for implementations of the Consolidated CDA General Header, Section and Entry template requirements for encounter and care team information.

ONC TOC Consolidated CDA IG Chapter References

Table 3: Initiative Consensus Recommendations and Consolidated CDA(C-CDA) IG Chapters

MU Data Requirement	Consensus Recommendations	C-CDA IG (Release 1.1) Chapter	C-CDA IG (Release 2.1) Chapter
Patient Name; Sex; Date of Birth; Race; Ethnicity; Preferred Language	Header element: Record Target	2.2.1	Volume 2 Section 1.1
Provider Name & Contact Information [participating in the encounter]; Date and Location of Visit or Hospitalization; Care Team Members [participating in the encounter]	Header element: Component Of Encompassing Encounter	2.2.13	Volume 2 Section 1.1
Provider Name & Contact Information [performing the service event]; Care Team Members [performing the service event]	Header element: Documentation Of Service Event	2.2.11	Volume 2 Section 1.1
Medication Allergies	Allergies Section	4.2	Volume 2 Section 2.4.1
Functional Status; Cognitive Status	Functional Status Section	4.14	Volume 2 Section 2.20
Discharge Instructions or Clinical Instructions	Hospital Discharge Instructions Section (inpatient settings) or Instructions Section	4.23 or 4.28	Volume 2 Section 3.4
Immunizations	Immunizations Section	4.27	Volume 2 Section 2.32.1
Medications	Medications Section (entries required) or Hospital Discharge Medications (inpatient settings)	4.33 or 4.24	Volume 2 Section 2.38
Care Plan, including goals and instructions; Future Scheduled Tests and Appointments; Referrals to Other	Plan of Care Section or Assessment and Plan Section	4.39 and/or 4.4	Volume 2 Section 2.48

Providers; Diagnostic Test(s) Pending			
Problems	Problems Section (entries required)	4.44	Volume 2 Section 2.53.1
Procedures	Procedures Section (entries required)	4.52	Volume 2 Section 2.61.1
Reason for Referral	Reason for Referral Section	4.53	Volume 2 Section 2.62
Reason for Visit or Hospitalization	Reason for Visit or Chief Complaint or Chief Complaint and Reason for Visit	4.54 and/or 4.7	Volume 2 Section 2.63
Laboratory Test(s); Results of Laboratory Test(s)	Results Section (entries required)	4.55	Volume 2 Section 2.64.1
Smoking Status	Social History Section	4.57	Volume 2 Section 2.66
Vital Signs	Vital Signs Section	4.60	Volume 2 Section 2.70.1

4.4 Outstanding Questions

1. How do we ensure the tested systems are realistic? (similar to what is implemented in production and include fully populated C-CDA document?)
2. How do we measure value gained to ensure improvements and that the content is good and drives data sharing, usage, and patient outcomes?
3. What should be required for each Participant on the eHealth Exchange to ensure data quality monitoring once moved into production as new stakeholders are connected to their exchange gateways?
 - inside the organization?
 - using real patient data, during production?

Additional FAQs and Pain Points are being tracked as a separate Appendix to this document in collaboration with HL7, the federal agencies and Carequality for suggested improvements to documentation. (See [Appendix A](#)).

5 TEST PROCEDURES

5.1 Test Case: TC: Common Clinical Data Set (CCDS) summary record - Create

The system under test will create a document sample with their own representative test data expected to be exchanged from each source system. A source system is defined as any technology that will package/create a document that could provide within responses to a query from another eHealth Exchange participant. This test method will validate that the system under test (SUT) can create a source document in accordance with the standards and guidance referenced in [chapter 3](#) of this document. It is recommended that health IT developers and providers follow the guidance provided in these Implementation and Companion Guides that include industry best practice guidance for consistent implementation of the HITSP C32/CCD, C- CDA Release 1.1 and C-CDA Release 2.1 standards, including mapping Common MU Data Set elements into the C-CDA standard.

In addition, the document created will be scored for vocabulary conformance to the required vocabulary standards (and value sets). These value sets and vocabulary standards can be found referenced to the 2014 or 2015 ONC requirements here: <https://www.healthit.gov/policy-researchers-implementers/meaningful-use-stage-2-0/2015-standards-hub>

and a new expansion file for download can be found at the NIH National Library of Medicine hosted Value Set Authority Center here: <https://vsac.nlm.nih.gov/welcome>

5.1.1 Testing Requirements

All **current Validated vendors and Participants in production** will be required to test in 12 months from February 5, 2018 program launch date.

Required for Vendors and Participants

- Create Test Cases (Using Supplied Test Data – No PHI please)

All **New Vendors seeking Product Validation and Participants** wishing to onboard to the eHealth Exchange will be required to provide one or more content samples as follows:

- All Vendors will be required to provide samples for testing for each version of HL7 specification they support (HITSP C32, HL7 C-CDA R1.1 or R2.1)
- All Vendors will be required to provide samples of each document type they support for their customers on an ongoing basis as new documents are added (CCD, Discharge Summary, Progress Note, etc.)

5.1.2 Data Entry

- a) *SUT creates a document sample that includes the Common Clinical Data Set (CCDS) summary record information in order to create a patient document with the necessary information in the Health IT Module*

5.1.3 Create

- a) *Using the Health IT Module, the user facilitates the creation of a document sample record formatted in accordance with the standards specified in [section 3](#) of this document.*

5.1.4 Self-Test

- a) *Applicant performs self-testing to remediate all errors possible with each sample against the Sequoia tooling found at <https://gazellecontent.sequoiaproject.org/EVSCClient/home.seam>*
- b) *Applicant has the ability to fix the errors and resubmit to testing@sequoiaproject.org.*

5.1.5 Email Permanent Link

- a) *Applicant emails the permanent link ID for each document source testing result to testing@sequoiaproject.org.*

5.1.6 Repeat steps 1-4 for each document source sample

Applicant has the ability to fix the errors after initial testing and resubmit within the 18 months after initial testing testing@sequoiaproject.org.

5.2 Test Case: TC: Common Clinical Data Set (CCDS) summary record - Receive

This test case is ONLY REQUIRED by Vendors. This test case will enable the system under test to receive a document summary formatted in accordance with standards adopted in [section 3](#) of this document.

Required for Vendors ONLY

- Receive Test Cases (HITSP C32, R1.1 and R2.1 Documents)

5.2.1 Receive: SUT downloads the Sequoia-supplied CCDS.xml documents

- a) *SUT uses the Health IT Module to receive the downloaded Continuity of Care Document (CCD) - MU HITSP C32C83 4Sections RobustEntries NoErrors.xml*
- b) *SUT uses the Health IT Module to receive the downloaded R1.1 CCD – 170.315_b5_toc_amb_ccd_r11_sample1_v8.xml; and*
- c) *SUT uses the Health IT Module to receive the downloaded R2.1 CCD – 170.315_b5_toc_amb_ccd_r21_sample2_v11.xml; and*
- d) *SUT uses the Health IT Module to receive the downloaded R2.1 Referral Note (RN) - 170.315_b5_toc_amb_rn_r21_sample2_v11.xml*

APPENDIX A: C-CDA IMPLEMENTATION FAQs

Index	Questions	Best Practice Guidance	Category
1	How does a CCDA implementer differentiate in the structured entries between different sub-sections of the Results section, like lab (chemistry/hematology, radiology, pathology, etc.? This is particularly important if the receiver needs to parse out the different sub-sections and present them to a user in different tabs of their GUI.	<p>One participant reported that in their production HIE:</p> <p>"They prefer to have partners put clinical notes into the results section and for all results provide an identifier, that allows them to differentiate between lab/pathology/cardiology/radiology/clinical notes/vascular. They use those entry sections to help parse the data into clinical result subsections so that the data is easier to traverse, filter and sort.</p> <p>Implementers should review the various HL7 published Implementation and Companion Guides for additional guidance. In addition, the Carequality Content Workgroups are working on additional guidance that will be incorporated into this appendix and/or moved to an online FAQ in the future.</p>	C-CDA - Results Section
2	Where do I include clinical notes in a summary of care document - e.g., encounters, procedures, results sections?	<p>The 2.1 Companion Guide will be published with updated guidance for where to include clinical notes.</p> <p>The current documentation package leverages heavily the work already published by HL7 and ONC.</p> <p>One participant reported they preferred to have the clinical notes in the results section of the C-CDA CCD so that entry sections could be used to identify the data in a discrete way. They stated "This is not available to us in the encounters section as the specifications are defined today.</p>	General - Notes
3	When I issue a query for a date range what sections in a summary of care document should the range be applied against?	<p>A Gateway is expected to pass along date ranges to underlying EHR systems and they are to respond for all sections as appropriate.</p> <p>Per the new guidance from the 2014 TOC documentation published by HL7 in September 2014, this should be applied to the document header information pertaining to the overall document rather than at a section level.</p> <p>In addition, two organizations gave differing guidance as follows:</p> <p>Organization #1 - Date range is relevant to all sections as long as historical data is available except for allergies, problems and medications. For allergies, problems and medications-all active data should be pulled regardless.</p> <p>Organization #2 - Provide two document types as follows:</p> <p>Patient Level documents We send back the last 3 months of data for procedures, results, and encounters. That date range is based on feedback from clinical users and our customers. This is used to limit the amount of data stored in the patient-level document because that negatively impacts the usability of the document. If more data is required, it is sent through an encounter-level document.</p> <p>Encounter Level documents We include all procedures, results, and notes for that encounter.</p> <p>Both document types All allergies, active medications, and problems are always included as of the document generation date.</p>	General - Data limits
4	Is a summary of care or continuity of care document based on a single encounter, multiple encounters, episode of care?	<p>There is no correct answer to this question if you consider various document types such as History and Physical, Discharge Summary, Referral, etc. This information will be requested from all product vendors and participants during the testing program.</p> <p>Carequality is working toward additional guidance on this front that will be updated in the future when this is pulled from being an appendix to an online FAQ.</p>	General - CCD

5	Do I use the summary of care or continuity of care document like a table of contents referring to specific other documents for the detailed clinical notes? other documents might be a discharge summary, operative note, progress lab, labs? Or, can on include clinical notes/reports inside the CCD health summary?	<p>Implementers can choose what document types are supported by their organization and how data is populated as long as it conforms to the document template requirements. Two organizations provided the following feedback:</p> <p>Organization #1 responded with: We send back the last 3 months of data for procedures, results, and encounters. That date range is based on feedback from clinical users and our customers. This limits the data that is stored in the patient-level document because it negatively impacts the usability of the document. If other organizations need more data, this is provided through an encounter-level document.</p> <p>Organization #2 responded with: We provide all clinical data in the C-CDA/CCD. This includes lab, pathology, clinical documents, radiology, cardiology, etc. All this data is supplied in the results section of the CCD.</p> <p>As to leveraging the CCD to refer to other specific documents, this would be allowed since this is an open template.</p>	General - Notes
6	How do I handle external references that may cross security contexts?	The use case needs further clarification for proper guidance.	General - Links
7	For a query, how do I deem what is the minimal necessary information required to satisfy a request?	If the Purpose of Use is "Treatment" all data that is available should be provided. Organizations should work with their clinical users to ensure that data provided is usable within the workflow provided.	General - data limits
8	How is embedded formatting handled within text elements?	For the clinical notes, it depends on the formatting. eHealth Exchange staff will gather various formatting used during the new content testing program and provide further guidance to address examples received.	General - Notes
9	What consistency should be enforced between the narrative block and the structured entries?	<p>There SHALL be absolute consistency between the narrative block and structured entries. Otherwise there will be either missed or duplicate information based on how the receiving entity is using that clinical document (i.e. parsing, style sheet, importing, etc.)</p> <p>One organization responded with: We will always include all allergies, active medications, and problems as of the document generation date.</p>	General - Narratives
10	What date ranges or max number of occurrences should be applied to each section of the CCD?	At a minimum, it is expected that all allergies, active medications and problems as of the document generation date be included. Although, it depends on use case (i.e. authorization for disability vs. treatment). Some organizations choose to provide multiple years for what is available within the organizational repository.	General - data limits
11	How do we prevent duplicative information within the CCD? How do we deal with the presence of duplicate information within the CCD?	<p>Duplicate data should be removed from a single source. Across multiple sources it may be safest to present all the information for the clinician to allow them to make a determination.</p> <p>Consideration could also be given to the IHE RECON profile from the Patient Care Coordination (PCC) domain. http://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_RECON.pdf.</p>	General - CCD dup data
12	What happens when the CCD is simply too large due to "excessive" amounts of data contained therein-- for instance, what if everything is simply "stuffed" into the summary of care section? Should the summary of care section, as a matter of best practice, be advised to serve as an index into other sections/areas that contain the relevant data?	Normally, this can be solved for by reducing the date range. However, this is just as much an issue when separate documents are issued within a date range.	General - CCD size

13	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?	<p>The eHealth Exchange Testing Workgroup members strongly advocated to these concepts, as labels, which were mapped to metadata properties as follows:</p> <p>Date of Service - serviceStartTime Title - title Document Type - typeCode Service Location - authorInstitution List of Services - eventCode Practice Type - practiceSettingCode Document Author – authorPerson Format Code - formatCode</p> <p>Additional Guidance is also provided within the 2017 Content Testing Documentation.</p> <p>Vendors don't typically allow for a user to pick and choose specific documents or filters.</p>	General - metadata
14	Some provider comments recently are: It is just a CCD.... where is the narrative? Where are the operative and procedure notes?	<p>In the past, some have sent these narratives/notes as separate C62/Unstructured documents. The issue is that few have implemented such capability to exchange/request C62/Unstructured Documents. As a result, the practical outcome is these items are "stuffed" in the most common document type exchanged Continuity of Care Document (CCD). This connects to pain point above related to excessive size. In some organizations, the C62 was prohibited as a matter of policy. Meaningful Use does not allow for this document type so this has been a matter of confusion as this may well be more related to certification type issues.</p> <p>A point of clarification is the distinction between structured entries and narratives in CCD.</p>	General - Notes
15	How do we encourage the industry to move beyond the use of the CCD document type of C-CDA R1.1? What would encourage the use of the other document types? Relates to the question above on where is the narrative?	<p>CCD Summary information (allergy, meds, etc....) is fairly discrete in terms of information. The patient's story is best told when the appropriate document type is used for the encounter or episode of care. Since the notes constitute 80% of the overall content, and most EHR's don't structure those notes "adequately". Some other issues may well be 2.0 backward compatibility issues to 1.1 is prohibitive. 2.1 solves many of those and therefore may be the next "jump" to be implemented. The end of 2016 and the finalization of the rules making may ease this. The ONC no longer supports 2.0 testing (removed 9/2015) and now has tools only for 2.1. However, until the industry has time to digest the various HL7 C-CDA guidance documentation and time be given to implementers to perform robust testing to validate structure and content, then it is going to be hard to move folks forward. Consistency is going to be a motivation for all.</p>	General - other CCDA templates
16	How do we handle versioning?	The use of proper document template OIDs will help with handling multiple versions such as HL7 R1.1 vs HL7 R2.1 etc.	General - versioning
17	How do we handle consistency of meta-information for class and type codes?	The guidance in the testing documentation provides a high level of linkage to requirements from the combined C-CDA R1.1, C-CDA R2.1 and associated companion guides. In addition, clarification has been added in section 4.3 .	QD - doc class code
18	Too many documents response to queries. What is the best set of filters (metadata constraints) in order to reduce the size of the query response?	<p>relates to discussions above on serviceStartTime, but extends into createTime and also needs to be related to the presence of On-Demand Document Entries. It is suggested to use serviceStartTime/serviceStopTime, ClassCode, MimeType</p> <p>Allowing the user to query by date range will help constrain the relevant document. Making the data more manageable once it is received (i.e. parsing, rendering, sorting, filtering, etc) will also make it more useful.</p> <p>See the related TWG Wiki: http://exchange-specifications.wikispaces.com/share/view/76356099</p>	QD response

19	How do systems handle query response for content and/or document types that a Content Consumer cannot handle? What is done to prevent errors from happening for content that a Consumer cannot handle? Are content that cannot be handled filtered out of the query responses before display?	Today most participants of the eHealth Exchange can handle C32, and R1.1 /R2.1 of CCDA-CCD. With improved testing tooling, it is expected that content will continue to improve and expand to various document types being supported by eHealth Exchange participants.	QD response
20	Lack of basic understanding and consistent implementation on service start and stop (to/from) for a query?	This typically presents itself more for those participants leveraging technology that assembles on-demand document creation from a wide variety of data aggregated for a patient from HL7 feeds. In this situation, the document data SHALL honor the service start and stop time values, if they are specified in the request. (Please note prior discussion thread by the eHealth Exchange Specification factory with additional information on this topic can be found at (http://exchange-specifications.wikispaces.com/share/view/54214588))	Query for Doc
21	Is there general recognition that it is not programmatically feasible to determine whether or not the content of an On-Demand Document Entry has previously been retrieved? This is sometimes a surprise to Community implementations where some endpoints wish to determine from query response whether or not to retrieve content.	All participants should expect that repetitive queries for a patient to an end-point could result in the same data being provided in queries.	RD response
22	Has there been any use of metadata (submission sets attribute/folder) to associate, for instance a C62 (unstructured document) with a C32? [This is not the same as the XDS Submission Set attribute provided as part of the QD process]	Not at this time. It is expected that further considerations will be tested for in the future content testing program proposed. Testing for a security boundary issues with external references such as URL/URI/external link will need to be considered? How would the security boundaries be applied/re-applied?	same as #6
23	We are also interested in how to get participant test systems to a place where they are better ready to test with each other after they complete the current eHealth Exchange testing conducted within the Developers Integration Lab (DIL) testing environment. For instance, how much of certification is happening with harnesses or limited systems & does it really test the actual software/systems that would be used	More rigorous production testing will continue to be implemented to help quickly identify any configuration or networking issues that may be specific to the production setup. The current plan is to receive C-CDA documents during the enhanced content testing program. The samples received during the enhanced content testing will have reported errors and issues identified with an imposed timeline for defect correction by participants. In the future, transport and content testing will be improved with the testing tooling.	Testing
24	How do systems support Unstructured Document? Are systems capable of opening the package and displaying the wrapped content?	It is expected that Unstructured Document types will at least be able to be rendered in a human readable form to clinicians and use the metadata with the unstructured information to make it more usable for the clinician.	Unstructured CCDA

APPENDIX B: TESTING TOOLS CHOSEN – ART DÉCOR/IHE GAZELLE

Gazelle is a test bed aimed to test the interoperability of eHealth information systems. It is developed by IHE Europe with the support of several other IHE countries (USA, Japan, Korea, and Australia). The development was initiated in 2006 with a team of developers at INRIA and continued with the team moving to Kereval. The development of the Gazelle Test Bed is the second generation of Test Management tooling that IHE developed.

The first-generation tooling was initiated in 2002 with the development of a tool called “Kudu” based on Postgresql and PHP. This first-generation tool allowed IHE to structure the connectathon process and to improve the quality and auditability of the testing performed during the connectathon.

In 2006, with the growth in the number of participant to the connectathon, it became clear that the tool had to move to a more robust platform in order to support the load and the scalability of a large project. The choice of Java and Jboss was then made and a development team was established at INRIA Rennes.

In 2011 the Gazelle Test Bed project reached maturity and it was decided to move the development team to a company specialized in testing (Kereval in Rennes) in order to offer a more robust software development environment and deploy a quality management compatible with the certification requirement of ISO 17025 and Guide 65.

During the pilot phase held April – June 2016, multiple tooling offerings were vetted with static documents to determine requirements coverage and gaps for the overall level of testing outlined within this testing document. The Sequoia Project chose the Art Décor/IHE Gazelle Tooling for this testing program. You can find more information about this tooling here: <https://gazelle.ihe.net/>

Sequoia worked with IHE Services in Europe during 2017 to implement the bundled Art Décor with the IHE Gazelle tooling for the US Realm C-CDA Conformance Testing. This same tooling is used in countries worldwide as part of the IHE International Scheme Testing. The tooling was first piloted in April 2015 by IHE Services in Europe and then by Sequoia in 2016 with several enhancements to usability being made over the course of the pilots. The tooling covers the HL7 CCD/C32, HL7 C-CDA R1.1 and R2.1 versions. Testing of this tool has shown it reports on warnings and errors not found by other testing tooling. (<https://gazelle.ihe.net/cda/cda-basic-req.pdf>)

APPENDIX C: EHEALTH_EXCHANGE_CONTENT_TESTING_SURVEY_SUBMISSION _FORM_V5.0.PDF

Please find the PDF of this form here:

http://sequoiaproject.org/wp-content/uploads/2018/02/eHealth_Exchange_Content_Testing_Survey_Submission_Form_2017-10-06.pdf

This PDF will be turned into an online form to allow for more streamlined data gathering at a later date. eHealth Exchange members will be informed with the online form is available.

APPENDIX D: RECEIVE TEST CASE XML FILES

FOR VENDORS ONLY: Receive Test Case XML Files

The following files can be found at:

<https://sequoiaproject.org/ehealth-exchange/testing-overview/content-testing/>

CCD/C32: MU_HITSP_C32C83_4Sections_RobustEntries_NoErrors.xml

HL7 C-CDA R1.1: 170.315_b5_toc_amb_ccd_r11_sample1_v8.xml

HL7 C-CDA R2.1 CCD: 170.315_b5_toc_amb_ccd_r21_sample2_v11.xml

HL7 C-CDA R2.1 RN: 170.315_b5_toc_amb_rn_r21_sample2_v11.xml