Draft 2017 Interoperability Standards Advisory

Office of the National Coordinator for Health IT

Public Comment Version

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The Draft 2017 Interoperability Standards Advisory represents the Office of the National Coordinator for Health Information Technology's current assessment of the heath IT standards landscape. It is for informational purposes only. It is non-binding and does not create nor confer any rights or obligations for or on any person or entity.

Introduction to the Draft 2017 Interoperability Standards Advisory

The Interoperability Standards Advisory (ISA) process represents the model by which the Office of the National Coordinator for Health Information Technology (ONC) will coordinate the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by industry to fulfill specific clinical health IT interoperability needs.

The Draft 2017 Interoperability Standards Advisory remains focused on clinical health information technology (IT) interoperability and its updates and improvements are due largely to recommendations received from public comments and the Health IT Standards Committee. For historical background on the ISA please review prior Interoperability Standards Advisory publications.

At a high-level, the most substantial changes between the 2016 and the Draft 2017 ISA are largely related to the ISA's content and framing. This includes the following:

1) The beginning transition of the ISA from a stand-alone document to a Web-based resource with greater interactive potential.
2) The discontinued use of the label "best available" as an overall concept for the ISA. This change, at the recommendation of the Health IT Standards Committee, seeks to address feedback that stakeholders may perceive varied standards and implementation specifications associated with an interoperability need as "best" despite known limitations or low adoption levels. Further, that the ISA serves as a way to "identify" standards and implementation specifications and should be as inclusive as possible in order to increase public awareness about a standard or implementation specification's applicability to an interoperability need. Thus, a determination as to whether one standard listed in the ISA may be more "fit for purpose" than another (for the same interoperability need) could be reflected by referenced industry experience and the ISA's associated informative characteristics.
3) Where applicable, the addition of "Applicable Starter Set(s)" alongside appropriate code sets in Section I.
4) Links to active projects listed in ONC's Interoperability Proving Ground as a way to indicate their use of an ISA-listed standard or implementation specification to showcase ongoing implementations.
5) Better representation of the pairing of standards for observations (i.e., questions) and standards for observation values (i.e., answers).

The Draft 2017 ISA includes revisions and additional descriptive text for several of the six informative characteristics.

Per the process first established with the publication of the 2015 ISA, this document represents the Draft ISA for 2017. The comment period on this version will open in August upon publication and run to mid-October, 2016. Based on public comments, the Draft 2017 ISA will be revised and the Final 2017 ISA will be published in December 2016. Your continued feedback and engagement is critical to improve and refine the ISA.

Scope

The standards and implementation specifications listed in this Draft 2017 ISA focus explicitly on clinical health IT systems' interoperability. Thus, the ISA's scope includes electronic health information created in the context of treatment and subsequently used to accomplish a purpose for which interoperability is needed (e.g., a referral to another care provider, public health reporting). The Draft 2017 ISA does **not** include within its scope administrative/payment oriented interoperability purposes or administrative transaction requirements that are governed by HIPAA and administered by the Centers for Medicare & Medicaid Services (CMS).

The ISA is not exhaustive but it is expected that future ISAs will continue to incrementally include a broader range of clinical health IT interoperability needs. When more than one standard or implementation specification

is listed it is intended to prompt industry dialogue as to whether one standard or implementation specification is necessary or if the industry can efficiently interoperate more than one. It may also reflect the fact that there is an ongoing transition from the use of one standard towards a new version or even next-generation approach.

As noted in prior ISAs, a standard listed in one section is not intended to imply that it would always be used or implemented independent of a standard in another section. To the contrary, it will often be necessary to combine the applicable standards from multiple sections to achieve interoperability for a particular clinical health information interoperability need.

Purpose

The Interoperability Standards Advisory is meant to serve at least the following purposes:

1) To provide the industry with a single, public list of the standards and implementation specifications that can best be used to fulfill specific clinical health information interoperability needs.
2) To reflect the results of ongoing dialogue, debate, and consensus among industry stakeholders when more than one standard or implementation specification could be used to fulfill specific clinical health information interoperability need.
3) To document known limitations, preconditions, and dependencies as well as known security patterns among referenced standards and implementation specifications when they are used to fulfill a specific clinical health IT interoperability need.

The ISA is designed to provide clarity, consistency, and predictability for the public regarding the standards and implementation specifications that could be used for a given clinical health IT interoperability purpose.

Stakeholders who administer government programs, procurements, and testing or certification programs with clinical health IT interoperability components are encouraged to look first to the ISA in order to more fully inform their goals. In that regard, standards and implementation specifications in the ISA and their associated informative characteristics are also available to help more fully inform policymaking. In this case, a standard or implementation specification's reference in the ISA may serve as the initial basis for industry or government consideration and action. While the ISA itself is a non-binding document, standards and implementation specifications listed in the ISA may be considered for rulemaking or other Federal requirements. However, those decisions would be made on a case-by-case basis by the administering organization.

ISA Structure

The ISA is organized and structured into four sections.

- *Section I – Vocabulary/Code Sets/Terminology* Standards and Implementation Specifications (i.e., "semantics").
- *Section II – Content/Structure* Standards and Implementation Specifications (i.e., "syntax").
- *Section III – Standards and Implementation Specifications for Services* (i.e., the infrastructure components deployed and used to fulfill specific interoperability needs)
- *Section IV* – Questions and Requests for Stakeholder Feedback

Within each section specific "interoperability need" subheadings are listed and followed by the table illustrated below. Each interoperability need may have one or more standards and/or implementation specifications associated with it. Each standard and implementation specification has six informative characteristics (first introduced in the Draft 2016 ISA) attributed to it in order to provide added context.

When known, an "emerging" standard or implementation specification is also listed and is shaded in a lighter color and italicized for additional emphasis. In addition, for vocabulary standards, where there may be one

standard used to represent the "observation" or question being asked, and one standard used for the "observation value" or answer these are listed in distinct rows.

The Draft 2017 ISA also includes links within the limitations, dependencies and preconditions to ONC's Interoperability Proving Ground (IPG) to showcase real-world implementations of standards listed within the ISA. Please note: when accessing links to the IPG, all projects for the selected standard will be listed, including those that may be demonstrating use of the standard for different interoperability needs. In addition, IPG entries are self-reported by stakeholders, so the quality and accuracy of the data may vary across entries.

Interoperability need: [Descriptive Text]

Standard/ Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	Final	Production	●●●●○	Yes	Free	Yes
Standard for observation values	Final	Production	●●●●○	No	Free	Yes
Emerging Standard	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Section I: Applicable Value Set(s) and Starter Set(s):** **Sections II & III: Applicable Security Patterns for Consideration:**
• Where standards listed for an interoperability need have active projects listed on ONC's Interoperability Proving Ground, a link to that standard will be provided in this section. Please note, all projects for the standard will be listed, including those that may be demonstrating use of the standard for different interoperability needs.	• Descriptive text

The following describes the ISA's six informative characteristics in greater detail. This detail is meant to better inform stakeholders about the maturity and adoptability of a given standard or implementation specification and provides definition for the terms and symbols used throughout the ISA. These definitions remain similar in nature to those presented in the 2016 ISA, but have been modified slightly to provide additional clarity as requested by public comments. Stakeholders should consider all six characteristics together to gain insight into the level of maturity and adoptability of the standards and implementation specifications provided within the ISA.

#1: Standards Process Maturity

This characteristic conveys a standard or implementation specification's maturity in terms of its stage within a particular organization's approval/voting process.

- ***"Final"*** – when this designation is assigned, the standard or implementation specification is considered "final text" or "normative" by the organization that maintains it.
- ***"Balloted Draft"*** – when this designation is assigned, the standard or implementation specification is considered to be a Draft Standard for Trial Use (DSTU), Standard for Trial Use (STU), or in a "trial implementation" status by the organization that maintains it and has been voted on or approved by its membership as such. This designation does not include standards and implementation guides that are unofficial drafts and early "works in progress".
- ***"In Development"*** – when this designation is assigned, the standard or implementation specification is currently in development. It also includes those that are in the midst of being balloted. This designation is generally reserved for "emerging standards."

#2: Implementation Maturity

This characteristic conveys a standard or implementation specification's maturity based upon its implementation state. Where available, a link to published maturity assessments based on known published criteria about the standards is also provided. *[See Question 3, Section IV]*

- ***"Production"*** – when this designation is assigned, the standard or implementation specification is being used in production to meet a health care interoperability need.
- ***"Pilot"*** – when this designation is assigned, the standard or implementation specification is being used on a limited scale or only as part of pilots to meet a health care interoperability need.

#3: Adoption Level

This characteristic conveys a standard or implementation specification's approximate, average adoption level in health care within the United States. Presently, it is based on ONC's analysis of several factors, including, but not limited to: 1) whether and/or how long a standard or implementation specification has been included in regulation for health IT certification (if applicable) or another HHS regulatory or program requirement; 2) feedback from subject matter experts and 3) public comments.

The adoption level also considers the variety of stakeholders and stakeholder groups that would use the standard and implementation specification to address the specified interoperability need and attempts to display it as such, with the understanding that the designation is a generality and not a pre-defined measured value. Where available, annotated references or links to publicly available documentation known about adoption levels for listed standards is also provided. *[See Question 4, Section IV]*

The following scale is used to indicate the approximate, average adoption level among the stakeholders that would use a standard or implementation specification to meet the specified interoperability need:

- "*Feedback requested*" Indicates that we do not have a known status for the current level of adoption in health care.
- ●○○○○ Indicates low adoption.
- ●●○○○ Indicates low-medium adoption.
- ●●●○○ Indicates medium adoption.
- ●●●●○ Indicates medium-high adoption.
- ●●●●● Indicates high or widespread adoption.

#4: Federally Required

This characteristic (provided as a "*Yes*" or "*No*") conveys whether a standard or implementation specification has been adopted in regulation, referenced as a federal program requirement, or referenced in a federal procurement (i.e., contract or grant) for a particular interoperability need. Where available, a link to the regulation has been provided.

#5: Cost

This characteristic conveys whether a fee is involved to purchase, license or obtain membership for access or use of the recommended standard or implementation specification.

- "*$*" – when this designation is assigned, it signifies that some type of payment needs to be made in order to obtain the standard or implementation specification. Where known, the estimated cost for access will be provided.
- "*Free*" – when this designation is assigned, it signifies that the standard or implementation specification can be obtained without cost. This designation applies even if a user account or license agreement is required to obtain the standard at no cost.

#6: Test Tool Availability

This characteristic conveys whether a test tool is available to evaluate health IT's conformance to the standard or implementation specification for the particular interoperability need. Where available, a link will be provided to the publicly available test tool. *[See Question 5, Section IV]*

- *"Yes"* – When this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is free to use. Where available, a hyperlink pointing to the test tool will be included.
- *"Yes*[$]*"* – When this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and has a cost associated with its use. Where available, a hyperlink pointing to the test tool will be included.
- *"Yes – Open"* – When this designation is assigned, it signifies that a test tool is available for a standard or implementation specification and is available as open source with rights to modify. Where available, a hyperlink pointing to the test tool will be included.
- *"No"* – When this designation is assigned, it signifies that no test tool is available for a standard or implementation specification.
- *"N/A"* – When this designation is assigned, it signifies that a test tool for the standard or implementation would be "not applicable."

Section I: Vocabulary/Code Set/Terminology Standards and Implementation Specifications

I-A: Allergies

Interoperability Need: Representing Patient Allergic Reactions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• SNOMED CT® may not be sufficient to differentiate between an allergy or adverse reaction, or the level of severity • For use of SNOMED CT®, codes should generally be chosen from the Clinical finding axis • See LOINC projects in the Interoperability Proving Ground.	• SNOMED CT Value Set Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 • There is an 'Adverse Clinical Reaction' set in Value Set Authority Center (VSAC) created by Federal Health Interoperability Modeling and Standards (FHIMS) which can be considered a candidate as a starter set.

Interoperability Need: Representing Patient Allergens: Medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	RxNorm	Final	Production	●●●●○	Yes	Free	N/A
Standard	NDF-RT	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• When a medication allergy necessitates capture by medication class, NDF-RT should be used.	• Grouping Value Set: Substance-Reactant for Intolerance urn:oid:2.16.840.1.113762.1.4.1010.1. The codes from the following value set should be selected in the following order of preference: NDF-RT -> RxNorm -> UNII -> SNOMED CT® • Medication Drug Class (2.16.840.1.113883.3.88.12.80.18) (NDFRT drug class codes) • Clinical Drug Ingredient (2.16.840.1.113762.1.4.1010.7) (RxNORM ingredient codes

Interoperability Need: Representing Patient Allergens: Food Substances

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	UNII (Unique Ingredient Identifier)	Final	Feedback requested	Feedback requested	No	Free	N/A
Standard	SNOMED CT®	Final	Feedback requested	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Feedback requested	• Grouping Value set: Substance-Reactant for Intolerance urn:oid:2.16.840.1.113762.1.4.1010.1. • Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT® substance codes) • Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII ingredient codes)

Interoperability Need: Representing Patient Allergens: Environmental Substances

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	UNII	Final	Feedback requested	Feedback requested	No	Free	N/A
Standard	SNOMED CT®	Final	●●●○○	Production	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Feedback requested	• Grouping Value set: Substance-Reactant for Intolerance urn:oid:2.16.840.1.113762.1.4.1010.1. • Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT® substance codes). • Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII ingredient codes)

I-B: Encounter Diagnosis

Interoperability Need: Representing Patient Medical Encounter Diagnosis

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED CT®	Final	Production	●●●●○	Yes	Free	N/A
Standard	ICD-10-CM	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Use of SNOMED CT® codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event. • Systems should be able to handle older code sets, such as ICD-9, as legacy content still exists and may be used for analysis/decision support/quality measurement needs as retroactive analysis is often required. • A mapping from SNOMED CT® to ICD-10-CM is available from the National Library of Medicine.	• Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED CT® code system) • Recommended starter set: CORE Problem List Subset urn:oid: 2.16.840.1.113762.1.4.1018.240

Interoperability Need: Representing Patient Dental Encounter Diagnosis

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNODENT	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Code System:
• Feedback requested	• OID 2.16.840.1.113883.3.3150

I-C: Family Health History

Interoperability Need: Representing Patient Family Health History

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Some details around family genomic health history may not be captured by SNOMED CT® • See LOINC projects in the Interoperability Proving Ground.	For Diagnosis and Conditions: • Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 (LOINC® code system) • Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED CT® code system) For genomic data: • Gene Identifier: HGNC Value Set • Transcript Reference Sequence Identifier: NCBI vocabulary • DNA Sequence Variation Identifier: NCBI vocabulary • DNA Sequence Variation: HGVS nomenclature

Interoperability Need: Representing Patient Family Health History Observations

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	--	--	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):Applicable Value Set(s) and Starter Set(s):
• Feedback requested • See LOINC projects in the Interoperability Proving Ground.	• Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 (LOINC® code system)

I-D: Functional Status/Disability

Interoperability Need: Representing Patient Functional Status and/or Disability

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	***[See Question 7, Section IV]***	--	--	--	--	--	--

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Public comments were varied for this interoperability need. We heard the strongest support for SNOMED CT® and ICF standards, but at this time do not have enough information to warrant inclusion of either standard for this interoperability need. • LOINC® and SNOMED CT® are the preferred vocabularies for this area.	• Feedback requested

I-E: Health Care Provider

Interoperability Need: Representing Care Team Member (Health Care Provider)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	National Provider Identifier (NPI)	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• For the purpose of recording a care team member, it should be noted that NPPES permits, but does not require, non-billable care team members to apply for an NPI number to capture the concept of 'person'. • Some care team members may not have an NPI and may not wish to apply for one as noted above. • NPI taxonomy may not have sufficient enough detail to describe all roles associated with an individual's care team	• No Value Set

Interoperability Need: Representing Provider Role in Care Setting							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	SNOMED CT®	Final	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Feedback requested.	• Healthcare Provider Taxonomy (HIPAA): 2.16.840.1.114222.4.11.1066 • HL7 Participation Function • Subjects role in the care setting (SNOMED CT®)

I-F: Imaging (Diagnostics, interventions and procedures)

Interoperability Need: Representing Imaging Diagnostics, Interventions and Procedures							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC®	Final	Production	●●●○○	No	Free	N/A
Standard	DICOM	Final	Production	●●○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Radlex and LOINC® are currently in the process of creating a common data model to link the two standards together to promote standardized indexing of radiology terms.	• Feedback requested

I-G: Immunizations

Interoperability Need: Representing Immunizations – Historical

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Standard Code Set CVX—Clinical Vaccines Administered	Final	Production	●●●●●	Yes	Free	N/A
Standard	HL7 Standard Code Set MVX -Manufacturing Vaccine Formulation	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. • When an MVX code is paired with a CVX (vaccine administered) code, the specific trade named vaccine may be indicated providing further specificity as to the vaccines administered.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • MVX: entire code set

Interoperability Need: Representing Immunizations – Administered

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Standard Code Set CVX—Clinical Vaccines Administered	Final	Production	●●●●●	Yes	Free	N/A
Standard	National Drug Code	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information.	• CVX: Vaccines Administered 2.16.840.1.113762.1.4.1010.6 • RxNorm: Vaccine Clinical Drug 2.16.840.1.113762.1.4.1010.8 • RxNorm: Specific Vaccine Clinical Drug urn:oid:2.16.840.1.113762.1.4.1010.10

I-H: Industry and Occupation

Interoperability Need: Representing Patient Industry and Occupation

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	***[See Question 8, Section IV]***	--	--	--	--	--	--

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Public comments were varied for this interoperability need. Stakeholders have conveyed the strongest support for National Institute for Occupational Safety and Health (NIOSH) list, which includes an Industry and Occupation Computerized Coding System (NIOCCS), U.S. Department of Labor, Bureau of Labor Statistics, Standard Occupational Classification, and National Uniform Claim Committee Health Care Taxonomy (NUCC) codes standards, but at this time do not have enough information to warrant inclusion of either standard for this interoperability need.	• Feedback requested

I-I: Lab tests

Interoperability Need: Representing Laboratory Tests

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●○○	Yes	Free	N/A
Standard for observation values	SNOMED CT®	Final	Feedback requested	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Laboratory test and observation work in conjunction with values or results which can be answered numerically or categorically. If the value/result/answer to a laboratory test and observation is categorical that answer should be represented with the SNOMED CT® terminology. • A single lab test with a single result will have the same LOINC® term for its order and result answer, but a panel order will have an order LOINC® term and multiple result LOINC® terms for each result in the panel. • A single lab test with a single result may have the same LOINC® code for the order and the result or may have a more specific code in the result (for example if the order code was method less or did not declare the system property). A panel order will have an order LOINC® code and multiple result LOINC® terms for each result in the panel. • See LOINC projects in the Interoperability Proving Ground.	• The list of LOINC® Top 2000+ Lab Observations is a starter set represented by OID: 1.3.6.1.4.1.12009.10.2.3

I-J: Medications

Interoperability Need: Representing Patient Medications

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	RxNorm	Final	Production	●●●●●	Yes	Free	N/A
Standard	National Drug Code (NDC)	Final	Production	●●●○○	No	Free	N/A
Standard	National Drug File – Reference Terminology (NDF-RT)	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The use of NDC in conjunction with RxNorm can help minimize gaps in representing medications, including compounded products, over -the-counter medications, and herbals. • NDF-RT allows for representing classes of medications when specific medications are not known. • Immunizations are not considered medications for this interoperability need. • RxNorm is often used for the exchange of information; however, it may not be available for export and import by end users.	• Grouping Value Set: Medication Clinical Drug 2.16.840.1.113762.1.4.1010.4 ○ Medication Clinical General Drug (2.16.840.1.113883.3.88.12.80.17) ○ Medication Clinical Brand-specific Drug (2.16.840.1.113762.1.4.1010.5) (RxNorm). • Grouping Value Set: Clinical Substance 2.16.840.1.113762.1.4.1010.2 ○ Medication Clinical Drug (2.16.840.1.113762.1.4.1010.4) (RxNorm) ○ Unique Ingredient Identifier - Complete Set (2.16.840.1.113883.3.88.12.80.20) (UNII) • Substance Other Than Clinical Drug (2.16.840.1.113762.1.4.1010.9) (SNOMED CT®).

I-K: Numerical References & Values

Interoperability Need: Representing Units of Measure (For Use with Numerical References and Values)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	The Unified Code for Units of Measure	Final	Production	●●●○○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The case sensitive version is the correct unit string to be used for interoperability purposes. • Per public comments received, there may be some limitations with UCUM in the laboratory domain remain unresolved. • The abbreviations used for a few of the units of measure listed in the UCUM standard are currently on lists of prohibited abbreviations from the Institute for Safe Medication Practice (ISMP). • Some abbreviations for units of measure include symbols which may be in conflict with other HL7 standards. • Some abbreviations for units are nonstandard for human understanding.(For example, if a result for a White Blood Cell count is 9.6 x 103/µL, the UCUM recommendation for rendering this value in a legacy character application is 9.6 x 10*3/uL. Because the "*" is a symbol for multiplication in some systems.) This recommendation may result in errors either by the information system or the human reading the result. • Some other abbreviations uHIPAA Security regulations that are specific to healthcare used in UCUM are not industry standard for the tests that use these units of measure. • UCUM is a syntax for representing units of measure for use with numerical references and values. It is not an enumerated set of codes.	• Units Of Measure Case Sensitive 2.16.840.1.113883.1.11.12839 (most frequently used codes) • Table of Example UCUM Codes for Electronic Messaging" published by the Regenstrief Institute, Inc. Value set is made available at http://loinc.org/usage/units and identified by the OID 1.3.6.1.4.1.12009.10.3.1

I-L: Nursing

Interoperability Need: Representing Nursing Assessments

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Assessments are represented as question/answer (name/value) pairs. They are not represented in other terminologies. • LOINC® should be used for the assessment/observation questions and SNOMED CT® for the assessment/observation answers (value sets, choice lists). • See LOINC projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Representing Nursing Interventions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• LOINC® should be used for the assessment/observation questions and SNOMED CT® for the assessment/observation answers (value sets, choice lists). • See LOINC projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Representing Outcomes for Nursing

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Other ANA-recognized terminologies should be converted to LOINC® for comparison across health systems and/or transmission. • See LOINC projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Representing Patient Problems for Nursing

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Other ANA-recognized terminologies should be converted to SNOMED CT® for comparison across health systems and/or transmission.	• Feedback requested

Interoperability Need: Representing nNursing Interventions and Observations (Observations are Assessment Items)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observation values	SNOMED CT®	Final	Production	Feedback requested	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Other ANA-recognized terminologies should be converted to SNOMED CT® for comparison across health systems and/or transmission.	• Feedback requested

I-M: Patient Clinical "Problems" (i.e., conditions)

Interoperability Need: Representing Patient Clinical "Problems" (i.e., Conditions)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	Uknown	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• The use of SNOMED CT® for this interoperability need, codes should generally be chosen from three axes: Clinical finding, Situation with explicit context, and Event. • Depending on the patient problem, more than one SNOMED CT® code may be required to accurately describe the patient problem (e.g., left leg fracture requires the use of two SNOMED CT® codes) • SNOMED CT® supports the combination of codes (post-coordination) to generate new meaning. Codes from other axes can be used in post-coordination. The need to pick multiple codes may be seen as a disadvantage. This can be avoided if post-coordination is limited to the backend, exposing a single code for users to pick. • See LOINC projects in the Interoperability Proving Ground.	• Problem 2.16.840.1.113883.3.88.12.3221.7.4 • Starter Set: CORE Problem List Subset urn:oid: 2.16.840.1.113762.1.4.1018.240

I-N: Preferred Language

Interoperability Need: Representing Patient Preferred Language (Presently)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	RFC 5646	Final	Production	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• RFC 5646 encompasses ISO 639-1, ISO 639-2, ISO 639-3 and other standards related to identifying preferred language	• Language urn:oid:2.16.840.1.113883.1.11.11526 (based off RFC 4646. This will be updated to reflect RFC 5646)

I-O: Procedures

Interoperability Need: Representing Dental Procedures Performed

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Code on Dental Procedures and Nomenclature (CDT)	Final	Production	●●●●○	Yes	$	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Feedback requested	• Feedback requested

Interoperability Need: Representing Medical Procedures Performed

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A
Standard	the combination of CPT-4/HCPCS	Final	Production	●●●●●	Yes	$	N/A
Standard	ICD-10-PCS	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• ICD-10-PCS is only for Inpatient Procedures. Outpatient Procedures are not coded in ICD-10-PCS.	• Feedback requested

I-P: Race and Ethnicity

Interoperability Need: Representing Patient Race and Ethnicity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct 30, 1997	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Code System ~~Value Set(s)~~:
• The CDC Race and Ethnicity Code Set Version 1.0, which expands upon and can be rolled up to the OMB standards may help to further define race and ethnicity for this interoperability need as it allows for multiple races and ethnicities to be chosen for the same patient. • The high-level race/ethnicity categories in the OMB Standard may be suitable for statistical or epidemiologic or public health reporting purposes but may not be adequate in the pursuit of precision medicine and enhancing therapy or clinical decisions. • LOINC® provides observation codes for use in the observation / observation value pattern for communicating race and ethnicity.	• Race (5 codes): Race Category Excluding Nulls urn:oid:2.16.840.1.113883.3.2074.1.1.3 • Race (extended set, 900+codes): Race urn:oid:2.16.840.1.113883.1.11.14914 • Ethnicity: Ethnicity urn:oid:2.16.840.1.114222.4.11.837 • Ethnicity (extended set, 43 codes): Detailed Ethnicity urn:oid:2.16.840.1.114222.4.11.877

I-Q: Research

Interoperability Need: Representing Analytic Data for Research Purposes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CDISC Controlled Terminology for Regulatory Standards Hosted by NCI-EVS	Final	Production	●●●●●	Yes	Free	N/A
Standard	CDISC Controlled Terminology for CDISC Therapeutic Area Standards Hosted by NCI-EVS	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Controlled Terminology for Medical Devices Hosted by NCI-EVS	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Feedback requested	• Feedback requested

I-R: Sexual Orientation and Gender Identity

Interoperability Need: Representing Patient Gender Identity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Feedback requested	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Feedback requested	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Collect discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine. • See LOINC projects in the Interoperability Proving Ground.	• Gender identity. LOINC® code: 76691-5 • Male. SNOMED CT® code: 446151000124109 • Female. SNOMED CT® code: 446141000124107 • Female-to-Male (FTM)/Transgender Male/Trans Man. SNOMED CT® code: 407377005 • Male-to-Female(MTF)/Transgender Female/Trans Woman. SNOMED CT® code: 407376001 • Genderqueer, neither exclusively male nor female. SNOMED CT® code: 446131000124102 • Additional gender category or other, please specify. HL7 Version 3 code: OTH • Choose not to disclose. HL7 Version 3 code: ASKU

Interoperability Need: Representing Patient Sex (At Birth)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●●●	No	Free	N/A
Standard for observation values	For Male and Female, HL7 Version 3 Value Set for Administrative Gender; Unknown , HL7 Version 3 Null Flavor	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s)
• Collect discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a report by The Fenway Institute and the Institute of Medicine. • Precision medicine requires an increased focus to document granular, specific information about the patient that aids in targeted delivery of healthcare to the patient. There are other ways to determine gender outside of traditional approaches. *[See Question 9, Section IV]* • See LOINC projects in the Interoperability Proving Ground.	• LOINC® code: 76689-9 Sex assigned at birth • Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1 • ONC's 2015 Edition certification requirements reference the following value set for birth sex that use a combination of HL7 Version 3 (V3) Standard value set for Administrative Gender and NullFlavor: (1) Male. M (2) Female. F (3) Unknown. nullFlavor UNK

Interoperability Need: Representing patient-identified sexual orientation

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Feedback requested	Feedback requested	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Feedback requested	Feedback requested	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Collect discrete structured data on patient gender identity, sex, and sexual orientation following recommendations issued in a **report** by The Fenway Institute and the Institute of Medicine. • See LOINC projects in the Interoperability Proving Ground.	• LOINC® code: 76690-7 Sexual orientation • ONC's 2015 Edition certification requirements reference the following value set for sexual orientation. Codes from (i) through (iii) are SNOMED CT® and (iv) through (vi) are from HL7 Version 3: (i) *Lesbian, gay or homosexual.38628009* (ii) *Straight or heterosexual. 20430005* (iii) *Bisexual. 42035005* (iv) *Something else, please describe. nullFlavor OTH* (v) *Don't know.* nullFlavor UNK (vi) *Choose not to disclose.* nullFlavor ASKU

I-S: Social Determinants *[See Questions 10 and 11, Section IV]*

Interoperability Need: Representing Financial Resource Strain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 76513-1 • LOINC® answer list ID LL3266-5

Interoperability Need: Representing Level of Education

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 63504-5 • LOINC® answer list ID LL1069-5

Interoperability Need: Representing Stress

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 76542-0 • LOINC® answer list LL3267-3

Interoperability Need: Representing Depression

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 55757-9 • LOINC® code 44250-9 (with LOINC® answer list ID LL358-3 • LOINC® code 44255-8 (with LOINC® answer list ID LL358-3) • LOINC® code 55758-7 (with applicable UCUM unit of measure)

Interoperability Need: Representing Physical Activity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 68515-6 • LOINC® code 68516-4 • With applicable UCUM unit of measure

Interoperability Need: Representing Alcohol Use

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® codes 72109-2, • LOINC® code 68518-0 (with LOINC® answer list ID LL2179-1) • LOINC® code 68519-8 (with LOINC® answer list ID LL2180-9) • LOINC® code 68520-6 (with LOINC® answer list ID LL2181-7) • LOINC® code 75626-2

Interoperability Need: Representing Social Connection and Isolation

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 76506-5, • LOINC® code 63503-7 (with LOINC answer list ID LL1068-7) • LOINC® code 76508-1 • LOINC® code 76509-9 • LOINC® code 76510-7 • LOINC® code 76511-5 (with LOINC answer list ID LL963-0) • LOINC® code 76512-3

Interoperability Need: Representing Exposure to Violence (Intimate Partner Violence)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 76499-3 • LOINC® code 76500-8 (with LOINC® answer list ID LL963-0) • LOINC® code 76501-6 (with LOINC® answer list ID LL963-0) • LOINC® code 76502-4 (with LOINC® answer list ID LL963-0) • LOINC® code 76503-2 (with LOINC® answer list ID LL963-0) • LOINC® code 76504-0

I-T: Tobacco Use (Smoking Status) *[See Question 12, Section IV]*

Interoperability Need: Representing Patient Tobacco Use (Smoking Status) Observation Result Values or Assertions

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard for observations	LOINC®	Final	Production	●●●●●	No	Free	N/A
Standard for observation values	SNOMED CT®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• There are limitations in SNOMED CT® for this interoperability need, which include not being able to capture severity of dependency, level of use, quit attempts, lifetime exposure, and use of e-Cigarettes. • LOINC® includes codes that support recording smoking status in the CDC's preferred (and sometimes required) responses (e.g. Tobacco smoking status NHIS[76691-5]) and other kinds of observations (e.g. Have you smoked at least 100 cigarettes in your entire life [PhenX] [63581-3] or How old were you when you first started smoking cigarettes every day [PhenX] [63609-2]. • See LOINC projects in the Interoperability Proving Ground.	• LOINC® code 72166-2 "Tobacco smoking status NHIS" • Current Smoking Status urn:oid:2.16.840.1.113883.11.20.9.38 • ONC's 2015 Edition certification requirements reference the following value set for smoking status. Codes from SNOMED CT® : (1) Current every day smoker. 449868002 (2) Current some day smoker. 428041000124106 (3) Former smoker. 8517006 (4) Never smoker. 266919005 (5) Smoker, current status unknown. 77176002 (6) Unknown if ever smoked. 266927001 (7) Heavy tobacco smoker. 428071000124103 (8) Light tobacco smoker. 428061000124105

I-U: Unique Device Identification

Interoperability Need: Representing Unique Implantable Device Identifiers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Unique device identifier as defined by the Food and Drug Administration at 21 CFR 830.3	Final	Production	●○○○○	Yes	Free	N/A
Implementation Specification	HL7 Harmonization Pattern for Unique Device Identifiers	Final	Production	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020. • See UDI projects in the Interoperability Proving Ground.	• Feedback requested

I-V: Vital Signs

Interoperability Need: Representing Patient Vital Signs

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC®	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• Vital Sign Result urn:oid:2.16.840.1.113883.3.88.12.80.62

Section II: Content/Structure Standards and Implementation Specifications

II-A: Admission, Discharge, and Transfer

Interoperability Need: Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to Other Providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1 (or later) ADT message	Final	Production	●●●●●	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• A variety of transport protocols are available for use for ADT delivery. Trading partners will need to determine which transport tools best meet their interoperability needs. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Sending a Notification of a Patient's Admission, Discharge and/or Transfer Status to the Servicing Pharmacy							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Census Message" transaction allows for long-term and post-acute care settings to notify the servicing pharmacy of a patient's admission, discharge and/or transfer status. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-B: Care Plan

Interoperability Need: Documenting Patient Care Plans							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), Draft Standard for Trial Use, Release 2.1	Balloted Draft	Pilot	Feedback requested	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

Interoperability Need: Documenting, Planning and Summarizing Care Plans for Patients with Cancer							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 CDA® R2 Implementation Guide: Clinical Oncology Treatment Plan and Summary, Release 1	Balloted Draft	Pilot	Feedback requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA projects in the Interoperability Proving Ground.	• Feedback requested

II-C: Clinical Decision Support

Interoperability Need: Shareable Clinical Decision Support							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1-Standard	HL7 FHIR Profile: Quality, Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
2-Standard	HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU Release 1.1	Balloted Draft	Production	●●○○○	No	Free	Yes
3-Standard	HL7 Version 3 Standard: Decision Support Service, Release 2.	Balloted Draft	Pilot	●○○○○	No	Free	No
3-Implementation Specification	HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use.	Balloted Draft	Pilot	Feedback requested	No	Free	No
1-Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), Release*	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See FHIR projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Provide Access to Appropriate Use Criteria

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), Release*	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Emerging Implementation Specification	*IHE: Guideline Appropriate Ordering (GAO)*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE: Guideline Appropriate Ordering (GAO) specification is being incorporated into the CQF content listed above it. • See FHIR and IHE projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Communicate Appropriate Use Criteria with the Order and Charge to the Filling Provider and Billing System for Inclusion on Claims.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Implementation Specification	*IHE: Clinical Decision Support Order Appropriateness Tracking (CDS-OAT)*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

II-D: Clinical Quality Measurement

Interoperability Need: Sharing Quality Measure Artifacts for Quality Reporting Initiatives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Standard	HL7 V3: Representation of the Health Quality Measures Format (eMeasure), DSTU Release 2.1	Balloted Draft	Pilot	●●●●○	No	Free	Yes
2-Standard	HL7 FHIR Profile: Quality, Release 1	Balloted Draft	Pilot	●○○○○	No	Free	Yes
3-Standard	HL7 Cross-Paradigm Specification: Clinical Quality Language, Release 1, STU Release 1.1	Balloted Draft	Production	●●○○○	No	Free	Yes
1-Implementation Specification	HL7 V3 Implementation Guide: Quality Data Model (QDM)-based Health Quality Measure Format (HQMF), Release 1 – US Realm	Balloted Draft	Pilot	●●●●○	No	Free	Yes
1-Emerging Implementation Specification	*HL7 Version 3 Implementation Guide: Clinical Quality Language (CQL)-based Health Quality Measure Format (HQMF), Release 1 - US Realm*	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Emerging Implementation Specification	*HL7 FHIR Implementation Guide: Clinical Quality Framework (CQF on FHIR), Release*	*In Development*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See FHIR projects in the Interoperability Proving Ground.	• Feedback requested

II-E: Clinical Quality Reporting

Interoperability Need: Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture - Category III (QRDA III), DRAFT Release 1	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category III (QRDA I) DSTU Release2 (US Realm)*	*In Development*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA and QRDA projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Reporting Patient-level Quality Data to Federal Quality Reporting Initiatives

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3 (US Realm)	Balloted Draft	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release43 (US Realm)*	*In Development*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA and QRDA projects in the Interoperability Proving Ground.	• Feedback requested

II-F: Data Provenance

Interoperability Need: Establishing the Authenticity, Reliability, and Trustworthiness of Content Between Trading Partners.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 CDA® Release 2 Implementation Guide Data Provenance, Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This implementation specification is focused on data provenance representation for CDA R2 implementations and the use of CDA templates. • See CDA projects in the Interoperability Proving Ground.	• Feedback requested

II-G: Drug Formulary & Benefits

Interoperability Need: The Ability for Pharmacy Benefit Payers to Communicate Formulary and Benefit Information to Prescribers Systems

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP Formulary and Benefits v3.0	Final	Production	●●●●●	Yes	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• NCPDP Formulary and Benefits v3.0 does not provide real-time patient-level benefit information. • The NCPDP Real Time Prescription Benefit Inquiry (RTPBI) is an alternative in development that should be monitored as a potential emerging implementation specification.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-H: Electronic Prescribing

Interoperability Need: A Prescriber's Ability to Create a New Prescription to Electronically Send to a Pharmacy

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●●	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "New Prescription" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • Allows the pharmacist to notify the prescriber about the status of a prescription in three cases: (1) To notify the prescriber of a dispensed prescription, (2) to notify the prescriber of a partially dispensed prescription, and (3) to notify a prescriber of a prescription not dispensed. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: A Prescriber's Ability to Grant a Refill Request to the Pharmacy

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●●○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Refill Request" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • Allows the pharmacist to request approval for additional refills of a prescription beyond those originally prescribed. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Allows the Pharmacy to Respond to Prescriber with a Change on a New Prescription

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	Feedback requested	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The RX message allows a Pharmacist to request a change of a new prescription or a "fillable" prescription. • See NCPDP projects in the Interoperability Proving Ground.	• Secure Communication – create a secure channel for client-to-server and server-to-server communication. • Secure Message Router – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • Authentication Enforcer – centralized authentication processes. • Authorization Enforcer – specified policies access control. • Credential Tokenizer – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • Assertion Builder – define processing logic for identity, authorization and attribute statements. • User Role – identifies the role asserted by the individual initiating the transaction. • Purpose of Use - Identifies the purpose for the transaction

Interoperability Need: Cancellation of a Prescription

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	Feedback requested	Yes	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Cancel" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • Notifies the pharmacy that a previously sent prescription should be cancelled and not filled. • Send the prescriber the results of a prescriptions cancellation request. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Pharmacy Notifies Prescriber of Prescription Fill Status

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	Feedback requested	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The "Fill Status" transaction is best suited for this interoperability need. • Both the prescriber and the receiving pharmacy must have their systems configured for the transaction in order to facilitate successful exchange. • Allows the pharmacist to notify the prescriber about the status of a prescription in three cases: (1) To notify the prescriber of a dispensed prescription, (2) to notify the prescriber of a partially dispensed prescription, and (3) to notify a prescriber of a prescription not dispensed • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: A Prescriber's Ability to Obtain a Patient's Medication History

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide, Version 10.6	Final	Production	●●●○○	Yes	$	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Both the "Medication History Request" and "Medication History Response" transactions need to be implemented for interoperability purposes. • Both the prescriber and the receiving pharmacy or pharmacy benefits manager (PBM) must have their systems configured for the transaction in order to facilitate successful exchange. • See NCPDP projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Allows Prescriber to Respond to a Prior Authorization for a Medication Electronically to the Payer/Processor.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide v2013071.	Final	Production	●●●○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See NCPDP projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Prior Authorization Cancel Request							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	NCPDP SCRIPT Standard, Implementation Guide v2013071.	Final	Production	●●●○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See NCPDP projects in the Interoperability Proving Ground.	• Feedback requested

II-I: Family health history (clinical genomics)

Interoperability Need: Representing Family Health History for Clinical Genomics							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 Version 3 Standard: Clinical Genomics; Pedigree	Balloted Draft	Production	●○○○○	Yes	Free	No
Implementation Specification	HL7 Version 3 Implementation Guide: Family History/Pedigree Interoperability, Release 1	Balloted Draft	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• There is no available vocabulary to capture family genomic health history. • Further constraint of this standard and implementation specification may be required to support this interoperability need	According to HIMSS, the following value sets may be considered: • Gene Identifier: HGNC Value Set • Transcript Reference Sequence Identifier: NCBI vocabulary • DNA Sequence Variation Identifier: NCBI vocabulary • DNA Sequence Variation: HGVS nomenclature

Interoperability Need: Representing Patient Family Health History Observations							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC®	Final	Production	●●●○○		Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s) and Starter Set(s):
• See LOINC projects in the Interoperability Proving Ground.	• Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 (LOINC® code system)

II-J: Images

Interoperability Need: Medical Image Formats for Data Exchange and Distribution

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Digital Imaging and Communications in Medicine (DICOM)	Final	Production	●●●●●	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Use Image Acquisition Technology Specific Service/Object Pairs (SOP) Classes	• Feedback requested

Interoperability Need: Format of Medical Imaging Reports for Exchange and Distribution

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Digital Imaging and Communications in Medicine (DICOM)	Final	Production	●●●●●	No	Free	No
Implementation Specification	PS3.20 Digital Imaging and Communications in Medicine (DICOM) Standard – Part 20: Imaging Reports using HL7 Clinical Document Architecture.	Final	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Format of Radiology Reports for Exchange and Distribution							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	IHE Management of Radiology Report Templates (MRRT)	Balloted Draft	Pilot	Feedback requested	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

II-K: Laboratory

Interoperability Need: Receive Electronic Laboratory Test Results							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 2.5.1	Final	Production	●●○○○	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1—US Realm [HL7 Version 2.5.1: ORU_R01] Draft Standard for Trial Use, July 2012	*Balloted Draft*	Production	●○○○○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Ordering Labs for a Patient

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●○○○	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders from EHR, Release 1 DSTU Release 2 - US Realm	*Balloted Draft*	Pilot	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. • Note that the implementation specification has been harmonized with the most current suite of Lab US Realm Implementation Guides and is scheduled for update in the HL7 January 2017 Ballot Cycle • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Support the Transmission of a Laboratory's Directory of Services to Health IT.

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●○○○	No	Free	No
Implementation Specification	HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium Framework, Release 2, DSTU Release 2	Balloted Draft	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 Laboratory US Realm Value Set Companion Guide, Release 1, September 2015, provides cross-implementation guide value set definitions and harmonized requirements. • Note that the current version has been harmonized with the most current suite of Lab US Realm Implementation Guides and is scheduled for update in the HL7 January 2017 Ballot Cycle • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-L: Medical Device Communication to Other Information Systems/Technologies

Interoperability Need: Transmitting Patient Vital Signs from Medical Devices to Other Information Systems/Technologies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-PCD (Patient Care Device Profiles)	Final	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested • Recommend adding the link to the guidance developed by FDA CDRH and CBER: • Design Considerations and Pre-Market Submission Recommendations for Interoperable Medical Devices to the footnote on page 68 http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm482649.pdf • See IHE projects in the Interoperability Proving Ground.	• Feedback requested

II-M: Patient Education Materials

Interoperability Need: A Standard Mechanism for Clinical Information Systems to Request Context-Specific Clinical Knowledge Form Online Resources

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2.	Final	Production	●●●●○	Yes	Free	No
Implementation Specification	HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.	Final	Production	●●●○○	Yes	Free	No
Implementation Specification	HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.	Final	Production	●●●○○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

II-N: Patient Preference/Consent

Interoperability Need: Recording Patient Preferences for Electronic Consent to Access and/or Share their Health Information with Other Care Providers

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE Basic Patient Privacy Consents (BPPC)	Final	Production	●●○○○	No	Free	Yes – Open

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• These profiles operate in conjunction with the IHE XDS, XCA, and XDR profiles • IHE BPPC may not support management of patient privacy across governmental jurisdictions which may have different regulations regarding access to patient data by providers, patients, governmental entities, and other organizations. • Along with security tokens and consent documents, security labels that are the critical third part of the Attribute-Based-Access-Control and SLS should be mentioned as well. Security Labels are used in CDA, FHIR, as well as the IHE Document Sharing (e.g. XDS), as described on the FHIR security page at http://hl7-fhir.github.io/security-labels.html • See IHE projects in the Interoperability Proving Ground.	• **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction. • **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.

II-O: Public Health Reporting

Interoperability Need: Reporting Antimicrobial Use and Resistance Information to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® Release 2 – Level 3: Healthcare Associated Infection Reports, Release 1, U.S. Realm.	Final	Production	●○○○○	Yes	Free	No
Emerging Implementation Specification	*HL7 Implementation Guide for CDA Release 2 – Level 3: NHSN Healthcare Associated Infection (HAI) Reports Release 2, DSTU Release 2.1*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This is a national reporting system to CDC. Stakeholders should refer to implementation guide for additional details and contract information for enrolling in the program. • See CDA projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Reporting Cancer Cases to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	Yes	Free	No
2-Implementation Specification	HL7 Implementation Guide for CDA® Release 2: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm	Balloted Draft	Production	●●○○○	Yes	Free	Yes
1-Emerging Implementation Specification	*HL7 CDA ® Release 2 Implementation Guide: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1, DSTU Release 1.1 – US Realm*	*Balloted Draft*	*Pilot*	●○○○○	Yes	*Free*	*No*
Emerging Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Implementation Specification	*HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting cancer reporting data as there may be jurisdictional variation or requirements. Some jurisdictions may not support cancer case reporting at this time. • See CDA projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Case Reporting to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1- Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
1-Implementation Specification	**IHE IT Infrastructure Technical Framework, Volume 1 (ITI TF-1): Integration Profiles, Section 17: Retrieve Form for Data Capture (RFD)**	**Final**	**Production**	●●●○○	**No**	**Free**	**Yes**
2-Standard	HL7 electronic Initial Case Report HL7 C-CDA STU: HL7 Version 3 Clinical Document Architecture (CDA), Release 2 format.	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Standard	Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
2- Emerging Implementation Specification	*HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
2 – Emerging Standard	*HL7 FHIR STU 3*	*In Development*	*Pilot*	*N/A*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• Electronic case reporting is not wide spread and is determined at the state or local jurisdiction.
• Structured Data Capture Implementation Guide does not currently restrict vocabulary to standard vocabulary sets
• Some additional implementation guides related to public health reporting follow. Reporting is often captured under a specialized registry with associated standards when not specified as a separate measure. These include:
  ○ Early Hearing Detection and Intervention (EHDI)
  ○ Office of Populations Affairs (OPA) Family Planning Reporting IHE Profile
• See FHIR projects in the Interoperability Proving Ground.
	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication.
	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.
	• **Authentication Enforcer** – centralized authentication processes.
	• **Authorization Enforcer** – specified policies access control.
	• **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos).
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Electronic Transmission of Reportable Lab Results to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●○○○	Yes	Free	No
Implementation Specification	HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification	Final	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*HL7 Version 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1*	*Balloted Draft*	*Pilot*	*Feedback requested*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements. • Note the Public Health Profile as specified in the *HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Results Interface Implementation Guide, Release 1 DSTU Release 2 - US Realm* is harmonized with the Lab US Realm suite of Implementation Guides and improves on the ELR emerging implementation specification. Both are scheduled for revision in the HL7 January 2017 • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Sending Health Care Survey Information to Public Health Agencies

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	HL7 Implementation Guide for CDA® R2: National Health Care Surveys (NHCS), Release 1 - US Realm	Balloted Draft	Pilot	●○○○○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• This is a national reporting system to CDC. Stakeholders should refer to the National Health Care Survey Program. • See CDA projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Reporting Administered Immunizations to Immunization Registry

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4	Final	Production	●●●●●	Yes	Free	Yes
Implementation Specification	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5	Final	Production	●○○○○	Yes	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting immunization registry data as there may be jurisdictional variation or requirements. • HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.5 – Addendum is also available. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Reporting Syndromic Surveillance to Public Health (Emergency Department, Inpatient, and Urgent Care Settings)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	HL7 2.5.1	Final	Production	●●●●●	Yes	Free	No
Implementation Specification	PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1 and Conformance Clarification for EHR Certification of Electronic Syndromic Surveillance, Addendum to PHIN Messaging Guide for Syndromic Surveillance	Final	Production	●●●●○	Yes	Free	Yes
Emerging Implementation Specification	*PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0 and Erratum to the CDC PHIN 2.0 Implementation Guide, August 2015; Erratum to the CDC PHIN 2.0 Messaging Guide, April 2015 Release for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings*	*Final*	*Pilot*	●○○○○	*Yes*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	**Applicable Security Patterns for Consideration:**
• Stakeholders should refer to the health department in their state or local jurisdiction to determine onboarding procedures, obtain a jurisdictional implementation guide if applicable, and determine which transport methods are acceptable for submitting syndromic surveillance data as there may be jurisdictional variation or requirements. • An Erratum to the CDC PHIN 2.0 Implementation Guide was issued in August, 2015. Implementers should refer to this guide for additional information and conformance guidance. • See HL7 V2 projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-P: Representing clinical health information as a "resource"

[See Question 13, Section IV]

Interoperability Need: Representing Clinical Health Information as "Resource"

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	Yes
Emerging Standard	*HL7 FHIR STU 3*	*In Development*	*Pilot*	*N/A*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• HL7 defines a "resource" as an entity that: has a known identity (a url) by which it can be addressed; identifies itself as one of the types of resource defined in the FHIR specification; contains a set of structured data items as described by the definition of the resource type; and, has an identified version that changes if the contents of the resource change • See FHIR projects in the Interoperability Proving Ground.	• Feedback requested

II-Q: Research

Interoperability Need: Submission of Analytic Data to FDA for Research Purposes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CDISC Study Data Tabulation Model (SDTM)	Final	Production	●●●●●	Yes	Free	Yes
Standard	CDISC Analysis Dataset Model (ADaM)	Final	Production	●●●○○	Yes	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Production	●●●●●	No	Free	Yes
Standard	CDISC Dataset-XML (ODM-Based)	Final	Production	●○○○○	No	Free	N/A
Standard	CDISC Define-XML (ODM-Based)	Final	Production	●●●●●	No	Free	N/A

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CDISC Standard for the Exchange of Non-clinical Data (SEND)	Final	Production	●○○○○	Yes	Free	N/A
Standard	Study Data Tabulation Model Implementation Guide for Medical Devices (SDTMIG-MD)	Final	Production	●○○○○	No	Free	N/A
Standard	Therapeutic Area Standards (to complement the aforementioned CDISC foundational standards that apply across all therapeutic areas)	Final	Production	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback Requested	• Feedback requested

Interoperability Need: Pre-population of Research Forms from Electronic Health Records

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Shared Health And Research Electronic Library (SHARE)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	No
Implementation Specification	IHE-CRD (Clinical Research Document)	Balloted Draft	Production	●●○○○	No	Free	N/A

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE-XUA (Cross-Enterprise User Assertion)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-ATNA (Audit Trail and Node Authentication)	Final	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-DEX (Data Element Exchange)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Implementation Specification	HL7 FHIR DSTU 2, Structured Data Capture (SDC) Implementation Guide	Balloted Draft	Pilot	●○○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	IHE- RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●○○○	No	Free	N/A
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Production	●●●●●	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Stakeholders should review 21CFR11 for more details. • See IHE projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Integrate Healthcare and Clinical Research by Leveraging EHRs and other Health IT Systems while Preserving FDA's Requirements							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	CDISC Protocol Representation Model (PRM)	Final	Production	●○○○○	No	Free	Yes
Standard	CDISC Study/Trial Design Model (SDM)	Final	Production	●○○○○	No	Free	N/A
Implementation Specification	IHE-RPE (Retrieve Protocol for Execution)	Balloted Draft	Production	●●○○○	No	Free	N/A
Implementation Specification	IHE-CPRC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Submit Adverse Event Report from an Electronic Health Record to Drug Safety Regulators							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	IHE-DSC (Drug Safety Content)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Implementation Specification	IHE- CPRC (Clinical Research Process Content)	Balloted Draft	Production	●●○○○	No	Free	N/A
Standard	CDISC Protocol Representation Model (PRM)	Final	Production	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Complete Disease Registry Forms and Submit to Reporting Authority (ACC)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Implementation Specification	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Registering a Clinical Trial

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	CDISC Clinical Trial Registry (CTR-XML)	Balloted Draft	Pilot	●○○○○	No	Free	N/A
Standard	CDISC Operational Data Model (ODM)	Final	Pilot	●●●●●	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

II-R: Segmentation of sensitive information

Interoperability Need: Document-Level Segmentation of Sensitive Information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1	Final	Pilot	●○○○○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See CDA projects in the Interoperability Proving Ground.	• Feedback requested

II-S: Summary care record

Interoperability Need: Support a Transition of Care or Referral to Another Health Care Provider

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	HL7 Clinical Document Architecture (CDA®), Release 2.0, Final Edition	Final	Production	●●●●●	No	Free	No
Implementation Specification	Consolidated CDA® Release 1.1 (HL7 Implementation Guide for CDA® Release 2: IHE Health Story Consolidation, DSTU Release 1.1 - US Realm)	Balloted Draft	Production	●●●●●	Yes	Free	Yes
Emerging Implementation Specification	*HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes (US Realm), DraftStandard for Trial Use, Release 2.1*	*Balloted Draft*	*Pilot*	*Feedback requested*	*Yes*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• There are several specific document templates within the C-CDA implementation specification. Trading partners will need to ensure that their systems are capable of supporting specific document templates. • See CDA and CCDA projects in the Interoperability Proving Ground.	• Feedback requested

Section III: Standards and Implementation Specifications for Services

III-A: "Push" Exchange

Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Individuals and Systems

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1- Standard	Applicability Statement for Secure Health Transport v1.1 ("Direct")	Final	Production	●●●●●	Yes	Free	Yes
2 - Emerging Standard	*Applicability Statement for Secure Health Transport v1.2*	*Final*	Production	●●●○○	*Yes*	*Free*	*Yes*
1, 2, 3 - Implementation Specification	IG for Direct Edge Protocols	Final	Production	●●○○○	Yes	Free	Yes
1, 2 - Implementation Specification	IG for Delivery Notification in Direct	Final	Production	●●●○○	Yes	Free	Yes
1, 2, 3 - Implementation Specification	XDR and XDM for Direct Messaging Specification	Final	Production	●●●●○	Yes	Free	Yes
3 – Standard	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●●	Yes	Free	Yes
4 - Emerging Standard	*Fast Healthcare Interoperability Resources (FHIR) DSTU 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
3, 4 - Emerging Implementation Specification	*IHE-MHD (Mobile Access to Health Documents*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. • For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong. The leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange). • The reference to FHIR for this interoperability need is in relation to the transport services that are conformant to the "RESTful FHIR API" • The MHD supplement is based on FHIR DSTU1.1. The IHE MHD committee is currently working to update the MHD profile and planning to release it to implementers in first quarter calendar year 2016. • See Direct, FHIR, and IHE projects in the Interoperability Proving Ground.	• **System Authentication** - The information and process necessary to authenticate the systems involved • **Recipient Encryption** - the message and health information are encrypted for the intended user • **Sender Signature** – details that are necessary to identity of the individual sending the message • **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.

Interoperability Need: An Unsolicited "Push" of Clinical Health Information to a Known Destination Between Systems

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1- Standard	SOAP-Based Secure Transport Requirements Traceability Matrix (RTM) version 1.0 specification	Final	Production	●●●○○	Yes	Free	Yes
1- Standard	Applicability Statement for Secure Health Transport v1.1 ("Direct")	Final	Production	●●●●●	Yes	Free	Yes
2 - Emerging Standard	*Applicability Statement for Secure Health Transport v1.2*	*Final*	*Production*	●●●○○	*Yes*	*Free*	*Yes*
2- Implementation Specification	IHE-XDR (Cross-Enterprise Document Reliable Interchange)	Final	Production	●●●●○	No	Free	Yes
1 - Implementation Specification	NwHIN Specification: Messaging Platform	Final	Production	●●●○○	No	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Levels	Federally Required	Cost	Test Tool Availability
1- Implementation Specification	NwHIN Specification: Authorization Framework	Final	Production	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The IHE-XDR implementation specification is based upon the underlying standards: SOAP v2, and OASIS ebXML Registry Services 3.0 • The NwHIN Specification: Authorization Framework implementation specification is based upon the underlying standards: SAML v1.2, XSPAv1.0, and WS-1.1. • "Direct" standard is based upon the underlying standard: Simple Mail Transfer Protocol (SMTP) RFC 5321 and for security uses Secure/Multipurpose Internet Mail Extensions (S/MIME) Version 3.2 Message Specification, RFC 5751. • For Direct, interoperability may be dependent on the establishment of "trust" between two parties and may vary based on the trust community(ies) to which parties belong. The leading trust communities to enable communication amongst the most users include DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange). • See Direct and IHE projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer** – encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Push Communication of Vital Signs from Medical Devices

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Levels	Federally Required	Cost	Test Tool Availability
Standard	ISO/IEEE 11073 Health informatics - Medical / health device communication standards.	Final	Pilot	●○○○○	No	$	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• ISO/IEEE 11073 is a suite of standards for various medical devices.	• Feedback requested

III-B: Clinical Decision Support Services

Interoperability Need: Providing Patient-Specific Assessments and Recommendations Based on Patient Data for III-B Clinical Decision support

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Levels	Federally Required	Cost	Test Tool Availability
1- Standard	HL7 Version 3 Standard: Decision Support Service, Release 2.	Balloted Draft	Pilot	●○○○○	No	Free	No
1- Implementation Specification	HL7 Implementation Guide: Decision Support Service, Release 1.1, US Realm, DraftStandard for Trial Use	Balloted Draft	Pilot	●○○○○	No	Free	No
1- Standard	QICore/QuICK, DraftStandard for Trial Use	Balloted Draft	Pilot	●○○○○	No	Free	No
1- Standard	CQL, Draft Standard for Trial Use	Balloted Draft	Pilot	●○○○○	No	Free	No
1- Standard	CDS on FHIR, Draft Standard for Trial Use	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Emerging Implementation Specification	*IHE- GAO (Guideline Appropriate Ordering)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
3-Emerging Implementation Specification	*IHE-CDS-OAT (Clinical Decision Support – Order Appropriateness Tracking)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• Feedback requested

Interoperability Need: Retrieval of Contextually Relevant, Patient-Specific Knowledge Resources from Within Clinical Information Systems to Answer Clinical Questions Raised by Patients in the Course of Care

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Standard	HL7 Version 3 Standard: Context Aware Knowledge Retrieval Application. ("Infobutton"), Knowledge Request, Release 2.	Final	Production	●●●○○	Yes	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1.	Final	Production	●●●●○	Yes	Free	No
1-Implementation Specification	HL7 Version 3 Implementation Guide: Context-Aware Knowledge Retrieval (Infobutton), Release 4.	Final	Production	●●●●○	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

III-C: Image Exchange

Interoperability Need: Exchanging Imaging Documents Within a Specific Health Information Exchange Domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	IHE Cross Enterprise Document Sharing for Images (XDS-I.b)	Final	Pilot	●○○○○	No	Free	Yes
1,2-Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	No
1,2-Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No
2-Emerging Implementation Specification	*IHE – MHD-I (Mobile Access to Health Documents for Imaging)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need. • See IHE projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Interoperability Need: Exchanging Imaging Documents Outside a Specific Health Information Exchange Domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE Cross Community Access for Imaging (XCA-I)	Final	Pilot	●○○○○	No	Free	Yes
Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need. • See IHE projects in the Interoperability Proving Ground.	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos)..

III-D: Healthcare Directory, Provider Directory

Interoperability Need: Listing of Providers for Access by Potential Exchange Partners

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	Yes
2-Emerging Standard	*Fast Healthcare Interoperability Resources (FHIR), DSTU 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• The IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory (HPD), Trial Implementation was proposed, but not adopted for CEHRT 2015. The Health IT community has recognized the value of the underlying data elements and structure of that standard. The standard has met with limited adoption due to other concerns with the API. Work is underway in FHIR workgroups to reconcile FHIR resources with the data requirements of Provider/Healthcare Directories in order to offer a Healthcare Directory resource as part of FHIR. http://argonautwiki.hl7.org/index.php?title=Implementation_Guide • FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. • See IHE and FHIR projects in the Interoperability Proving Ground	• Feedback requested

III-E: Public Health Exchange

Interoperability Need: Query/Response for Immunization Reporting and Exchange

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	EHR-IIS Interoperability Enhancement Project Transport Layer Protocol Recommendation Formal Specification, Version 1.2	Final	Production	●○○○○	No	Free	No
Implementation Specification	IIS Standard WSDL	Final	Production	●○○○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• Feedback requested	• Feedback requested

III-F: Publish and Subscribe

Interoperability Need: Publish and Subscribe Message Exchange

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	NwHIN Specification: Health Information Event Messaging Production Specification	Final	Production	●○○○○	No	Free	No
2-Emerging Implementation Specification	*IHE Document Metadata Subscription (DSUB), Trial Implementation*	*Balloted Draft*	*Pilot*	●●●○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication. • **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery. • **Authentication Enforcer** – centralized authentication processes. • **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos). • **Assertion Builder** – define processing logic for identity, authorization and attribute statements. • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

III-G: Query

Interoperability Need: Query for Documents Within a Specific Health Information Exchange Domain

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1-Implementation Specification	IHE-XDS (Cross-enterprise document sharing)	Final	Production	●●●●○	No	Free	Yes
1,2-Implementation Specification	IHE-PDQ (Patient Demographic Query)	Final	Production	●●●●○	No	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
1,2-Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes
2- Emerging Implementation Specification	*IHE – MHD (Mobile Access to Health Documents)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• IHE-PIX and IHE-PDQ are used for the purposes of patient matching and to support this interoperability need.
• The MHD supplement is based on FHIR DSTU1.1. The IHE MHD committee is currently working to update the MHD profile and planning to release it to implementers in first quarter calendar year 2016.
• See IHE projects in the Interoperability Proving Ground.
	• **Secure Communication** – create a secure channel for client-to-server and server-to-server communication.
	• **Secure Message Router** – securely route and enforce policy on inbound and outbound messages without interruption of delivery.
	• **Authentication Enforcer** – centralized authentication processes.
	• **Authorization Enforcer** – specified policies access control.
	• **Credential Tokenizer –** encapsulate credentials as a security token for reuse (e.g., – SAML, Kerberos).**Message Interceptor Gateway** – provide a single entry point solution for centralization of security enforcement for incoming and outgoing XML WebService messages.
	• **System Authentication** - The information and process necessary to authenticate the systems involved
	• **User Authentication** – The identity information and process necessary verify the user's identity
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Purpose of Use** - Identifies the purpose for the transaction.
	• **Patient Consent Information** - Identifies the patient consent information that:
	  ○ May be required to authorize any exchange of patient information
	  ○ May be required to authorized access and use of patient information
	  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply
	• **Security Labeling** – the health information is labeled with security metadata

Interoperability Need: Query for Documents Outside a Specific Health Information Exchange Domain							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
1-Implementation Specification	IHE-XCA (Cross-Community Access)	Final	Production	●●●●○	No	Free	No
Implementation Specifications	the combination of IHE-XCPD (Cross-Community Patient Discovery) and IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	No
Implementation Specification	NwHIN Specification: Patient Discovery	Final	Production	●●●○○	No	Free	No
Implementation Specification	NwHIN Specification: Query for Documents	Final	Production	●●●○○	No	Free	No
Implementation Specification	NwHIN Specification: Retrieve Documents	Final	Production	●●●○○	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• IHE-PIX and IHE-XCPD are used for the purposes of patient matching and to support this interoperability need.
• See IHE projects in the Interoperability Proving Ground.
	• **System Authentication** - The information and process necessary to authenticate the systems involved
	• **User Authentication** – The information and process necessary to authenticate the end user
	• **User Details** - identifies the end user who is accessing the data
	• **User Role** - identifies the roles and clearances asserted by the individual initiating the transaction for purposes of authorization. E.g., the system must verify the initiator's claims and match them against the security labels for the functionalities that the user attempts to initiate and the objects the user attempts to access.
	• **Purpose of Use** - Identifies the purpose for the transaction, and for the purposes for which the end user intends to use the accessed objects
	• **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.
	  ○ May be required to authorize any exchange of patient information
	  ○ May be required to authorized access and use of patient information
	  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply
	• **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.
	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.

Interoperability Need: Data Element Based Query for Clinical Health Information

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No
Emerging Standard	*HL7 FHIR STU 3*	*In Development*	*Pilot*	*N/A*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:

• The following URL provides links to relevant FHIR resources http://www.hl7.org/implement/standards/fhir/resourcelist.html
• FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress.
• See FHIR projects in the Interoperability Proving Ground.
	• **System Authentication** - The information and process necessary to authenticate the systems involved
	• **User Details** - identifies the end user who is accessing the data
	• **User Role** – identifies the role asserted by the individual initiating the transaction.
	• **Purpose of Use** - Identifies the purpose for the transaction.
	• **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.
	  ○ May be required to authorize any exchange of patient information
	  ○ May be required to authorized access and use of patient information
	  ○ May be required to be sent along with disclosed patient information to advise the receiver about policies to which end users must comply
	• **Security Labeling** – the health information is labeled with security metadata necessary for access control by the end user.
	• **Query Request ID** - Query requesting application assigns a unique identifier for each query request in order to match the response to the original query.

III-H: Resource Location

Interoperability Need: Resource Location Within the US

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery (CSD), Trial Implementation	Balloted Draft	Pilot	●○○○○	No	Free	Yes

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• See IHE projects in the Interoperability Proving Ground.	• **System Authentication** - The information and process necessary to authenticate the systems involved • **User Details** - identifies the end user who is accessing the data • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

Section IV: Questions and Requests for Stakeholder Feedback

As with the previous Interoperability Standards Advisories (ISA), posing questions has served as a valuable way to prompt continued dialogue with stakeholders to improve the ISA. Your feedback on the questions posed below is critical and we encourage answers to be submitted as part of the current public comment process.

General

1. For each standard and implementation specification there are six assessment characteristics, for which detailed information has been received and integrated. However, some gaps remain. Please help complete information that is missing or noted "feedback requested . Additionally, assessing the adoption and maturity of standards is an ongoing process, so please continue to provide feedback if you believe something has changed or is not correct.
2. The table beneath the standards and implementation specifications includes limitations, dependencies, and preconditions. Given the enhancements made, please comment on accuracy and completeness and where information gaps remain, forward applicable content.
3. For the Implementation Maturity characteristic for the standards and implementation specifications, ONC plans to publish a link, where available, to published maturity assessments based on known published criteria. Please help identify any publications that are publically available and provide the hypertext links to those resources.
4. For the Adoption Level characteristic for the standards and implementation specifications, ONC plans to publish reference annotations or links to publicly available documentation known about adoption levels for listed standards. Please help identify any publications that are publicly available and provide the hypertext links to those resources.
5. For the Test Tool Availability characteristic for the standards and implementation specifications, ONC plans to publish references, where available, a to the publicly available test tool. Please help identify any publicly available test tools.

Section I: Vocabulary/Code Set

6. Within the Section I tables, Value Sets have been selected to substitute for what otherwise references Security Patterns in Sections II and III. Please review and provide feedback on placement, accuracy and the completeness of the selected value sets.
7. For subsection I-D: Functional Status/Disability, the Health Information Technology Standards Committee recommends using SNOMED®/LOINC® observation paring for this interoperability need. Do you support this approach?
8. For subsection I-H: Industry and Occupation, there continues to be varied opinion on the standards or implementation specifications to be sited in these areas. Please review and provide feedback on what should be included and/or whether these areas should be removed.
9. For subsection I-R: Sexual Orientation and Gender Identity, Interoperability Need: Representing patient sex (at birth), what are the appropriate genetic identifiers or gender determinants (e.g., gonadal sex, karyotype sex) for potential inclusion in the ISA.
10. For subsection I-S: Social Determinants please help identify the adoption level of LOINC® for each of the Interoperability Needs.
11. Are there additional psychosocial Interoperability Needs with corresponding standards that should be included in the ISA?

12. For subsection I-T: Tobacco Use (Smoking Status), because of the current limitations, what surveys, instruments or tools are being used to collect tobacco use information that is more complete that the current coding methodologies?

Section II: Content / Structure

13. For the existing interoperability need, "representing clinical health information as a resource", public comments expressed this may not be the best language to describe this area. Please provide feedback on whether or not this is correct or recommend alternative language that better describes this interoperability need.
14. Opinions vary in the way (messaging vs. transport) the ISA should represent FHIR. Please review and provide feedback on the manner FHIR should be represented.

Appendix I: Sources of Security Standards

15. Are there other authoritative sources for Security Standards that should be included in Appendix I?

Appendix I – Sources of Security Standards and Security Patterns

[See Question 15, Section IV]

In this Draft 2017 Interoperability Standards Advisory, a structure to capture necessary security patterns associated with interoperability needs is represented (see Section III-A and III-F for examples). To address public comments that requested a distinct security standards section the list below provides a number of sources to which stakeholders can look in order to find the latest applicable security standards. Note that this list is not meant to be exhaustive.

- Security Pattern Catalog http://www.munawarhafiz.com/securitypatterncatalog/index.php
- ASTM: http://www.astm.org/Standards/computerized-system-standards.html
- Information Organization for Standardization (ISO) Information Security Standards: http://www.27000.org/
- National Institute for Standards and Technology (NIST) Special Publications 800 Series: http://csrc.nist.gov/publications/PubsSPs.html
- NIST's Federal Information Processing Standard (FIPS): http://www.nist.gov/itl/fipscurrent.cfm
- ISO IT Security techniques – evaluation criteria for IT security, ISO/EC 15408 series: http://standards.iso.org/ittf/PubliclyAvailableStandards/index.html
- ISO/TR 21089:2004(en) -Health informatics — Trusted end-to-end information flows: https://www.iso.org/obp/ui/#iso:std:iso:tr:21089:ed-1:v1:en
- NIST Special Publication: 800-63-2. Electronic Authentication Guideline. August 2013. http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf
- FIPS PUB 202. SHA-3 Standard: Permutation-Based Hash and Extendable-Output Functions. August 2015. http://dx.doi.org/10.6028/NIST.FIPS.202
- NIST SP 1800-a-e. Securing Electronic Health Records on Mobile Devices. July 2015. https://nccoe.nist.gov/projects/use_cases/health_it/ehr_on_mobile_devices and https://nccoe.nist.gov/library/nist-sp-1800-1a-e-securing-ehrs-mobile-devices-all-volumes-plus-template-and-manifest-files
- Fair Information Practice Principles (FIPPs). http://www.nist.gov/nstic/NSTIC-FIPPs.pdf
- HIPAA Security regulations that are specific to healthcare: http://www.hhs.gov/hipaa/for-professionals/security/index.html
- NIST Special Publication 800-30, rev 1: http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-30r1.pdf
- OpenID Connect 1.0 http://openid.net/specs/openid-connect-core-1_0.html
- OAUTH 2.0 https://tools.ietf.org/html/rfc6749
- User-Managed Access (UMA) Profile of OAuth 2.0 https://docs.kantarainitiative.org/uma/rec-uma-core.html

- IHE - Cybersecurity Standards: https://www.us-cert.gov/Information-Sharing-Specifications-Cybersecurity
- IHE - Consistent Time http://wiki.ihe.net/index.php/Consistent_Time
- IHE – Audit Trail and Node Authentication http://wiki.ihe.net/index.php/Audit_Trail_and_Node_Authentication
- IHE – Enterprise User Authentication http://wiki.ihe.net/index.php/Enterprise_User_Authentication
- IHE - Cross-Enterprise User Assertion (XUA) http://wiki.ihe.net/index.php/Cross-Enterprise_User_Assertion_(XUA)
- IHE – Document Digital Signature http://wiki.ihe.net/index.php/Document_Digital_Signature
- IHE – Basic Patient Privacy Consents -- http://wiki.ihe.net/index.php/Basic_Patient_Privacy_Consents
- IHE – Document Encryption http://wiki.ihe.net/index.php/Document_Encryption
- IHE – Access Control http://wiki.ihe.net/index.php/ITI_Access_Control_White_Paper

Appendix II - Revision History

Summary Level Description of Changes between the 2016 ISA and the Draft 2017 ISA

ISA Area	Summary Level Description of Revision History	Revision History, Expanded
Table of Contents	Minor changes were made.	• Additions were made to the Table of Contents reflecting additions of subsections, removal of a section, etc.
Executive Summary	This section was removed.	• Combined into a new section called "Introduction to the Draft 2017 Interoperability Standards Advisory"
Introduction to the Draft 2017 Interoperability Standards Advisory	New information added to the 2017 Draft ISA is explained.	• This section describes the major differences between 2016 and 2017. • Discussion on how ONC is placing the ISA online and making it more interactive • Describes the move away from the concept of "Best Available" • Describes the addition of "Applicable Starter Sets.". • Discussion about observation and observation values as now reflected in the ISA. • In the Limitations, Dependencies, and Preconditions for Consideration field, there will now be links to the Interoperability Proving Ground that will point to projects using the referenced standard(s).
Scope	Enhanced the description of the scope.	• Content from other sections were moved into this section.
Purpose	Additional information was added.	• A discussion about anticipated use of the ISA by stakeholders and how it relates to regulation.
The Draft 2016 Interoperability Standards Advisory	This section was removed.	• Contents of this section were moved into other areas.
ISA Structure	Name changed from Sections of the Sections. Updates to the content were made.	• Changes were made in the following descriptions of the characteristics: o Standards Process Maturity - added "In Development" o Implementation Maturity - added links to published maturity assessments to known published criteria about that standards (if known and/or available) o Adoption Levels - links will be provided, when available, of known documentation about adoption levels for the listed standards or implementation specifications o Costs – Where known, estimated costs for access will be given. o Test Tool Available – Where available, at link will be provided to the publicly available test tools.
Projected Additions to the ISA	This section was removed for the Draft 2017 ISA. Likely will be used for the Final 2017 ISA.	• Advanced the Projected Additions in 2016 ISA into the appropriate sections and subsections in the Draft 2017 ISA.
Questions and Requests for Stakeholder Feedback	The questions were updated.	• The questions offered, were structured to solicit feedback on changes made to the Draft 2017 ISA and to assist in addressing recommendations where disposition is pending. These are found within Section IV.

ISA Area	Summary Level Description of Revision History	Revision History, Expanded
Revision History	Updates were made to the Revision History content as needed.	• Routine updates to the Revision History content.
Responses to Comments Requiring Additional Consideration	An appendix has been added to indicate those comments unable to be represented in the current Draft 2017 ISA released, e.g., more time and/or consideration needed.	• The current state of the Draft 2017 ISA reflects substantive amount of the Public Comments yet several remain, e.g., more exploration required, more time to properly address; potential redirection to SDOs, etc.

Additions/Enhancements/Deletions by Sub-section Between the 2016 ISA and the Draft 2017 ISA

Section	Description	Added Enhanced Deleted
I-A: Allergies	Under the Interoperability Need: "Representing patient allergic reactions" added a standard, Applicable Value Set(s) and Starter Set(s), and clarifying notes.	Added
I-A: Allergies	Under the Interoperability Need: "Representing patient allergens: food substances" several applicable Value Sets and Starter Sets were added.	Enhanced
I-B Encounter Diagnosis	Under the Interoperability Need: "Representing patient medical encounter diagnosis" additional information was provided in the Limitations, Dependencies, and Preconditions for Considerations field.	Enhanced
I-B: Encounter Diagnosis	Under the Interoperability Need: "Representing patient medical encounter diagnosis" a starter set was provided Applicable Value Set(s) and Starter Set(s) field.	Enhanced
I-B: Encounter Diagnosis	Under the Interoperability Need: "Representing patient dental encounter diagnosis" the standard SNOWMED was deleted.	Deleted
I-B: Encounter Diagnosis	Under the Interoperability Need: "Representing patient dental encounter diagnosis" the standard SNOWDENT was added.	Added
I-C: Family Health History	An additional Interoperability Need: " Representing patient family health history observations" and corresponding standard was added.	Added
I-D: Functional Status/Disability	Under the Interoperability Need: Representing patient functional status and/or disability a note in the Limitations, Dependencies, and Preconditions for Considerations field was added.	Enhanced
I-I: Lab tests	Under the Interoperability Need: "Representing laboratory tests" some additional information was provided in the Limitations, Dependencies, and Preconditions for Considerations field.	Enhanced

Section	Description	Added Enhanced Deleted
I-K: Numerical References & Values	Under the Interoperability Need: "Representing units of measure (for use with numerical references and values)" some edits were made to the information in the Limitations, Dependencies, and Preconditions for Considerations field.	Enhanced
I-L: Nursing	"Nursing" subsection was added.	Added
I-L: Nursing	Five interoperability needs along with corresponding standards and other information was added.	Added
I-M: Patient Clinical "Problems" (e.g., conditions)	Under the Interoperability Need: "Representing patient clinical "problems" (i.e., conditions)" LOINC® was added along with the Applicable Value Sets and Starter Sets and information in the Limitations, Dependencies, and Preconditions for Considerations field.	Added
I-O: Procedures	Under Interoperability Need "Representing medical procedures performed" additional information was added in the Limitations, Dependencies, and Preconditions for Considerations field.	Enhanced
I-P: Race and Ethnicity	Additional Applicable Value Sets were given.	Enhanced
I-Q: Research	Added the subsection "Research" with corresponding Interoperability Need, standards, implementation specifications, and other information	Added
I-R: Sexual Orientation and Gender Identity	The subsection name had changed.	Enhanced
I-R: Gender Identity, Sex and Sexual Orientation	LOINC® was added to three Interoperability Needsalong with the Applicable Value Set(s) and Starter Set(s) and other notes in the Limitations, Dependencies, and Preconditions for Considerations field.	Added
I-S: Social Determinants	Added the subsection "Social Determinants" with corresponding Interoperability Needs, standards and other information.	Added
I-T: Tobacco Use (Smoking Status)	LOINC® standard was added along with information in the Limitations, Dependencies, and Preconditions for Considerations field and the Applicable Value Set(s) and Starter Set(s).	Added
II-A: Admission, Discharge, and Transfer	Added Interoperability Need "Admission, discharge and/or transfer status to the servicing pharmacy" with corresponding standard.	Added
II-B: Care Plan	Added the Interoperability Need: "Establishing the authenticity, reliability, and trustworthiness of content between trading partners" with corresponding standard and related information.	Added
II-C: Clinical Decision Support	Added two additional Interoperability Needs with corresponding Implementation Specifications and other related information.	Added
II-D: Clinical Quality Measure	Created a new subsection "Clinical Quality Measure" with one Interoperability Need and corresponding standards, implementation specifications and related information.	Added

Section	Description	Added Enhanced Deleted
II-E: Clinical Quality Reporting	Under the Interoperability Need: "Reporting Aggregate Quality Data to Federal Quality Reporting Initiatives" added an Emerging Implementation Specification.	Added
II-F: Data Provenance	Added subsection "Data Provenance" with an Interoperability Need, corresponding standard and other related information.	Added
II-H: Electronic Prescribing	Added three Interoperability Needs with related standards and other information.	Added
II-H: Electronic Prescribing	Modified the names of some of the original Interoperability Needs and made some edits to the information.	Enhanced
II-I: Family Health History	Added one Interoperability Need along with corresponding standard and other related information.	Added
II-J: Images	Added one Interoperability Need along with corresponding standard and other related information.	Added
II-L: Medical Device Communication to Other Information Systems/Technologies	Created a new subsection II-J: Medical Device Communication to Other Information Systems/Technologies with an Interoperability Need, corresponding standard and other related information.	Added
II-Q: Research	Added the subsection "Research" along with seven Interoperability Needs including corresponding standards, implementation specifications, and other related information	Added
III-A: "Push" Exchange	Added an Interoperability Need with corresponding standard and other related information.	Added
III-B: Clinical Decision Support Services	Under the Interoperability Need; "Providing patient-specific assessments and recommendations based on patient data for clinical decision support" three standards were added.	Added
III-D: Healthcare Directory, Provider Directory	Name of subsection changed.	Enhanced
III-D: Healthcare Directory, Provider Directory	Additional information was added to the Limitations, Dependencies, and Preconditions for Considerations field.	Enhanced
III-E: Public Health Exchange	New subsection was added along with an Interoperability Need, corresponding standards and other related information.	Enhanced
Old IV: Projected Additions to ISA	Most of the proposed additions in the 2016 ISA were added to their respective areas in this draft and the section was deleted from the Draft 2017 ISA.	Deleted
IV: Questions and Requests for Stakeholder Feedback	Questions have been updated.	Enhanced
Appendix I	Name changed and also sources of Security Standards and Security Patterns were updated.	Added
Appendix II	Revision History updated.	Added
Appendix III	Updated the Comments Regarding Additional Considerations.	Added

Appendix III – Responses to Comments Requiring Additional Consideration

ONC has reviewed all of the comments that were submitted as part of the public comments process and has incorporated many of the recommendations into this current version. In some cases, feedback provided may have been out of scope of the ISA or where additional exploration may be needed for consideration in future ISA drafts. To acknowledge these areas, and recognize the time and effort required for stakeholders to submit thoughtful public comments, ONC has attempted to address as many of these recommendations as possible in the statements below. What is provided reflects a mix of new and pending considerations received as part of the 2016 ISA and 2017 ISA development process.

Overarching

- Several comments were received during the 2016 and 2017 ISA review around inclusion of EHR Functional Model elements within the ISA. ONC will explore, with stakeholder and Health IT Standards Committee feedback whether or not this is feasible and if these should be included in future updates
- As described in the executive summary, the scope of the ISA has been limited to clinical health IT interoperability needs. As we work to update the ISA, we will explore adding various purposes to its scope. At this time, payment and administrative standards will not be included. CMS maintains a list of standards for this purpose that can be referenced: https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/StatutesandRegulations.html
- Further, the ISA does not attempt to represent how these standards can help support providers in meeting legal requirements for maintaining patient health records for their business needs.
- Several commenters suggested addition of use case development and management of information flows. Doing so would not be in alignment with the purpose of the ISA and is not addressed.
- We received requests to include standards related to transfer on pregnancy, birth information, newborn nursery, newborn screening, and related topics. ONC will continue to explore inclusion of these standards for future ISA updates.
- We also received requests to include standards for preventive health schedules. ONC may need additional information in this area, but will explore inclusion of these in future ISA updates.
- Requests were made to distinguish between "eligible providers" for Meaningful Use and "non-eligible providers". The ISA focuses on the representation of standards and implementation specifications that can be used to achieve interoperability needs.
- Specific requests were received during the 2016 and 2017 ISA review regarding variance in adoption level for specific settings. We will continue to work with these organizations to evolve the way adoption levels are reflected and substantiated.
- The ISA does not directly address primary and secondary use but is beginning to add standards related to research interoperability needs.
- The ISA does not currently address "end-to-end chain of trust", health record capture, retention, auditing, or other standards associated with this concept. Similar to functional models, ONC will explore inclusion in future ISA updates.
- ONC does not plan to provide more granularity on implementation maturity levels at this time. Nor does ONC intend to provide a direct assessment as to the "readiness" of standards to be used within the ISA. Instead, the current characteristics are provided to allow for stakeholders to make their own informed decisions as to whether a standard or implementation specification will meet their needs.
- ONC does not currently have the capacity to publish testing results surrounding how well standards support interoperability needs identified in the ISA. ONC encourages other organizations to build upon the information provided in the ISA to provide additional value such as this.
- ONC does not intend to provide contact information for each of the SDOs with standards referenced within the ISA. However, a URL for each standard or implementation specification is provided, which may provide contact information or at least a link to the SDO home page whereby stakeholders could contact the SDO if needed.
- ONC has received and is pursuing interests to enhance the distinction of certain information as well as enhanced capability. Representative interests include:
    - Ability to filter standards by those required in regulation.
    - Ability to filter standards by any of the characteristics ONC captures on them.
    - Ability to add an "Accredited SDO" characteristic to each standard. Also, an "Audited Standard" characteristic.
    - Addition of characteristics showing the extent standards are backwards compatible to the previous versions and also showing how compatible standards are to comparable standards.

- Addition of Privacy Patterns and Standards
- Addition of specific FHIR Profiles for specific interoperability needs
- Ability to provide detailed criteria related to how we break the tie between two standards. Additionally, showing the score between the two standards.

Making the ISA not only the platform for listing the standards but also getting feedback on them as far as adoption levels, ease of implementation, links to successful pilots or implementation, and other information (part of what is driving the interactive, dynamic ISA we are developing for December)

Section I

- ONC will continue to monitor areas where a known standard has not yet become evident (e.g.., industry and occupation, and functioning status/disability, etc.) and will attempt to include relevant standards in future ISA updates.

Section II

- ONC will consider adding implementation guides, such a best practices for documenting referrals to community resources, if deemed appropriate, in future ISA updates.
- ONC will follow progress on projects related to care planning, and include resulting standards and implementation specifications in future ISA updates.
- ONC will continue to monitor industry activities surrounding genomic standards and current developments in FHIR profiles in this area. We will include them in future ISA updates as appropriate.
- ONC received comments around the IHE Radiology Domain's Suite of Profiles, but at this time did not have enough information to warrant inclusion for many of them. ONC will continue to explore inclusion for future ISA updates.
- A request was received regarding adding Nutrition/Diet Orders and other related dietary implementation information. ONC will analyze for inclusion in future ISA updates.
- A request was received regarding inclusion of "legacy data standards". ONC will continue to explore inclusion of this for future ISA updates.
- ONC will consider, for future ISA updates, adding "Privacy Patterns for Consideration", but do not have sufficient information to provide these at this time.

Section III:

- N/A