Section I: Best Available 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	SNOMED-CT	Final	Production	●●●●○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• SNOMED-CT may not be sufficient to differentiate between an allergy or adverse reaction, or the level of severity • **COMMENT:** The Pharmacy HIT Collaborative supports using SNOMED CT for coding reactions, intolerances, and allergic severities.	• Value Set Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4

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	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• When a medication allergy necessitates capture by medication class, NDF-RT is best available (as recommended by the HIT Standards Committee) • **COMMENT:** The Pharmacy HIT Collaborative supports using RxNorm for coding medication reactions, intolerances, and allergic severities.	• 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	SNOMED-CT	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• **COMMENT:** The Pharmacy HIT Collaborative supports using SNOMED CT for coding reactions, intolerances, and allergic severities for food substances.	• Grouping Value set: Substance-Reactant for Intolerance urn:oid:2.16.840.1.113762.1.4.1010.1. • 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	SNOMED-CT	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• **COMMENT:** The Pharmacy HIT Collaborative supports using SNOMED CT for coding reactions, intolerances, and allergic severities for environmental substances.	• 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).

I-B: 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):

• 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 • **COMMENT:** The Pharmacy HIT Collaborative supports using NPI board certification taxonomy for board for pharmacists.	• No Value Set • **No comment.**

I-C: 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):
• Feedback requested	• Problem urn:oid:2.16.840.1.113883.3.88.12.3221.7.4 (SNOMED-CT code system)

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	SNOMED-CT	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• **COMMENT:** The Collaborative supports using SNOMED CT for problems related to ICD-10 encounter diagnosis. For pharmacists providing patient care services, it is important for the pharmacists to know the reason or indication for the	• SNODENT; 2.16.840.1.113883.3.3150

medications being prescribed. ICD-10 documentation is used to validate the medication's appropriateness, including dosing, and the mitigation of adverse events. This information also improves a patients' understanding of the medications they're taking, which leads to increased medication adherence. Although ICD-10 codes may not necessarily match the indication for medication use, ICD-10 documentation for certain medications may be needed by certain payers (ICD-10 documentation is important for billing purposes). Linking the encounter diagnosis to a problem using SNOMED CT codes is a better process of more accurate medication indication matching.	

I-D: 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 Value Set(s):
• The CDC Race and Ethnicity Code Set Version 1.0, which expands upon 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. **COMMENT:** The Collaborative supports the OMB standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, Oct. 30, 1997, as well as LOINC.	• 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

I-E: 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	SNOMED-CT	Final	Production	●●●○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Some details around family genomic health history may not be captured by SNOMED-CT (recommended by the HIT Standards Committee)	For Diagnosis and Conditions: • 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

I-F: 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 4]***						

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value 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. • **COMMENT:** The Pharmacy HIT Collaborative supports using SNOMED CT.	• **No comment.**

I-G: Gender Identity, Sex, and Sexual Orientation

Interoperability Need: Representing patient gender identity

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Unknown	Unknown	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting 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. • **COMMENT:** The Pharmacy HIT Collaborative supports using SNOMED CT.	• **No comment.**

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 Male and Female, HL7 Version 3 Value Set for Administrative Gender; For Unknown, HL7 Version 3 Null Flavor	Final	Production	●●●●○	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s)
• The HIT Standards Committee recommended collecting 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.	• Administrative Gender (HL7 V3) 2.16.840.1.113883.1.11.1

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	SNOMED-CT	Final	Unknown	Unknown	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):

• The HIT Standards Committee recommended collecting 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. • **COMMENT:** The Collaborative supports the HIT Standards Committee recommendation.	• **No comment.**

I-H: 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):
• 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. • **COMMENT:** The Collaborative supports immunization coding using MVX, CVX and NDC. For tracking purposes, it will be important to code the actual product, lot number, and expiration date.	• 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	●●●●●	No	Free	N/A
Standard	National Drug Code	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• HL7 CVX codes are designed to represent administered and historical immunizations and will not contain manufacturer-specific information. • According to the HIT Standards Committee, National Drug (NDC) codes may provide value to stakeholders for inventory management, packaging, lot numbers, etc., but do not contain sufficient information to be used for documenting an administered immunization across organizational boundaries.	• 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

• **COMMENT:** The Collaborative supports immunization coding using MVX, CVX and NDC. For tracking purposes, it will be important to code the actual product, lot number, and expiration date.	

I-I: 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 4]***						

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Public comments were varied for this interoperability need. We heard 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. • **No comment.**	• **No comment.**

I-J: Lab tests

Interoperability Need: Representing numerical laboratory test results (observations)(questions)

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):
• The HIT Standards Committee recommended that 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. • Where LOINC codes do not exist, it is possible to request a new LOINC term be created. A number of factors may determine the length of time required for a new code to be created. • **COMMENT:** The Collaborative supports using LOINC and SNOMED	• A value set at this granularity level (numerical) does not exist. The list of LOINC Top 2000+ Lab Observations OID: 1.3.6.1.4.1.12009.10.2.3

CT. The Collaborative supports the HIT committee recommendations.	

I-K: 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):
• 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. • **COMMENT:** The Collaborative supports using RxNorm, NDC, and NDF-RT for patient medications.	• Grouping Value Set: Medication Clinical Drug 2.16.840.1.113762.1.4.1010.4 o Medication Clinical General Drug (2.16.840.1.113883.3.88.12.80.17) o 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 o Medication Clinical Drug (2.16.840.1.113762.1.4.1010.4) (RxNorm) o 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-L: 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):
• The case sensitive version is the correct unit string to be used for interoperability purposes per HIT Standards Committee recommendations. • Per public comments received, some issues with UCUM in the laboratory domain remain unresolved.	• Units Of Measure Case Sensitive 2.16.840.1.113883.1.11.12839 (most frequently used codes)

• 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 used in UCUM are not industry standard for the tests that use these units of measure. • **COMMENT:** The Collaborative supports the HIT committee recommendations and request that the NCPD Dosing Designations. https://www.ncpdp.org/NCPDP/media/pdf/wp/DosingDesignations-OralLiquid-MedicationLabels.pdf	

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	SNOMED-CT	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• 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) • **COMMENT:** The Collaborative supports using SNOMED CT for patient problems for medication indications.	• Problem 2.16.840.1.113883.3.88.12.3221.7.4

I-N: Preferred Language

Interoperability Need: Representing patient preferred language

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value 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
Standard	SNOMED-CT	Final	Production	●●●●●	Yes	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• **COMMENT:** THE Collaborative supports using SNOMED CT.	• SNODENT; 2.16.840.1.113883.3.3150

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):
• **COMMENT:** THE Collaborative supports using SNOMED CT, the	• **No comment**

combination of CPT-4/HCPCS, and ICD-10-PCS.	

I-P: 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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value 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 as indicated by public comments and HIT Standards Committee recommendations. • **COMMENT:** THE Collaborative supports using LOINC.	• **No comment.**

I-Q: Tobacco Use (Smoking Status)

Interoperability Need: Representing patient tobacco use (smoking status) observation result values or assertions (answers)

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• According to the HIT Standards Committee, 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. • **Comment:** The Collaborative supports using SNOMED CT.	• Current Smoking Status urn:oid:2.16.840.1.113883.11.20.9.38

I-R: 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

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):
• Per the FDA, Unique Device Identification system will be phased in over several years, with the final compliance date of September, 2020. • **Comment:** The Collaborative supports using HL7 Harmonization.	• **No comment.**

I-S: 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):
• **COMMENT:** The Collaborative supports using LOINC for recording patient vital signs.	• Vital Sign Result urn:oid:2.16.840.1.113883.3.88.12.80.62

Section II: Best Available 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. • **COMMENT:** The Collaborative supports using HL7 2.x (or later version) messaging standard.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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	Unknown	Yes	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **COMMENT:** The Collaborative recommends that consolidated CDA (C-CDA) Release 1.1 and 2.0 be included for the summary care record. For pharmacists providing patient care services, there have been joint NCPDP and HL7 standards development and implementation guides work using C-CDA Release 1.1 and current development work using C-CDA Release 2.1 for Pharmacist Care Plan. •	• **No comment.**

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
Implementation Specification	HL7 Implementation Guide: Clinical Decision Support Knowledge Artifact Implementation Guide, Release 1.3, Draft Standard for Trial Use.	Balloted Draft	Pilot	Unknown	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **COMMENT:** The Collaborative supports the use of HL 7 Implementation Guide: Clinical Decision Support Knowledge Artificial Implementation Guide, Release 1.3, Draft Standard for Trial Use.	• **No comment.**

II-D: 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 HIT Standards Committee noted that the NCPDP Real Time Prescription Benefit Inquiry (RTPBI) is an alternative in development that should be monitored as a potential emerging alternative. • **COMMENT:** The Collaborative supports the development of NCPDP Real Time formulary and benefit standard.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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-E: 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. • **COMMENT:** The Collaborative supports using NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 and adoption of an updated version once approved by regulation.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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: Prescription refill 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, 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. • **COMMENT:** The Collaborative supports using NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 and adoption of an updated version once approved by regulation.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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	Unknown	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. • **COMMENT:** The Collaborative supports using NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 and adoption of an updated version once approved by regulation.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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	Unknown	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. • **COMMENT:** The Collaborative supports using NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 and adoption of an updated version once approved by regulation.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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. • **COMMENT:** The Collaborative supports using NCPDP SCRIPT Standard, Implementation Guide, Version 10.6 and adoption of an updated version once approved by regulation.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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-F: 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:
• According to the HIT Standards Committee, there is no available vocabulary to capture family genomic health history. • According to the HIT Standards Committee, further constraint of this standard and implementation specification may be required to support this interoperability need. • **COMMENT:** The Collaborative supports using both the HL7 Version 3 Standard: Clinical Genomics, Pedigree and the Implementation Guide: Family History/Pedigree Interoperability, Release 1.	• **No comment.**

II-G: 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	• **No comment.**

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

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:
• **No comment.**	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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: 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	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative 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. • **COMMENT:** The Collaborative supports using both the HL7 2.5.1 and the Implementation Guide; S &I Framework Lab Results Interface Release 1 – US Realm.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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. • **COMMENT:** The Collaborative supports using HL7 Version 2.5.1 and HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Orders, et al.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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	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. • **COMMENT:** The Collaborative supports using HL7 Version 2.5.1 and HL7 Version 2.5.1 Implementation Guide: S&I Framework Laboratory Test Compendium, et al.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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-I: 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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
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:
• **COMMENT:** The Collaborative supports using the three HL7 standards proposed.	• **No comment.**

II-J: 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
1-Implementation Specification	IHE Basic Patient Privacy Consents (BPPC)	Final	Production	●●○○○	No	Free	Yes – Open
2-Implementation Specification	IHE Cross Enterprise User Assertion (XUA)	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. • **COMMENT:** The Collaborative supports using IHE Basic Patient Privacy Consents and Cross Enterprise User Authorization.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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. • **Patient Consent Information** - Identifies the patient consent information that may be required before data can be accessed.

II-K: 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 Alternative 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. • **COMMENT:** The Collaborative supports using HL7 CDA, Release 2.0, Final Edition and the Implementation Guide for CDA Release 2 – Level 3: Healthcare Association Infection Reports, Release 1, US Realm.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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
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: Reporting to Public Health Cancer Registries from Ambulatory Healthcare Providers, Release 1 - US Realm	Balloted Draft	Production	●●●○○	No	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Alternative 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 Alternative Implementation Specification	*IHE Quality, Research, and Public Health Technical Framework Supplement, Structured Data Capture, Trial Implementation*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
Emerging Alternative 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. • **COMMENT:** The Collaborative supports using HL7 CDA, Release 2.0, Final Edition and the Implementation Guide for CDA Release 2 – Level 3: Healthcare Association Infection Reports, Release 1, US Realm, and HL7 FHIR DSTU 2, Structured Data Capture Implementation Guide.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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)	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Standard	Fast Healthcare Interoperability Resources (FHIR), DSTU 2	Balloted Draft	Pilot	●○○○○	No	Free	No

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
2- Emerging Alternative 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:

• 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
• **COMMENT:** The Collaborative supports using HL7 Consolidated CDA Release 2.0; Fast Health Interoperability Resources (FHIR); and IHE Structured Data Capture Implementation.
	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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 Alternative 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*	*Unknown*	*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	• **Secure Communication** – create a secure channel for client-to- serve and server-to-server communication.

applicable, and determine which transport methods are acceptable for submitting ELR as there may be jurisdictional variation or requirements. • **COMMENT:** The Collaborative supports using HL7 Version 2.5.1; HL7 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm) et al; and HL7 2.5.1 Implementation Guide: Electronic Laboratory Reporting to Public Health, Release 2 (US Realm), Draft Standard for Trial Use, Release 1.1.	• **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 (examples – 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 at: http://www.cdc.gov/nchs/nhcs/how_to_participate.htm for information on participation. • **COMMENT:** The Collaborative supports using HL7 CDA, Release 2.0, Final Edition and HL7 Implementation Guide for CDA R2: National Health Care Services, Release 1 – US Realm.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Implementation Specification	HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4	Final	Production	●●●●●	Yes	Free	Yes
Emerging Alternative 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. • **COMMENT:** The Collaborative supports using HL7 Version 2.5.1; HL7 2.5.1 Implementation Guide for Immunization Messaging, Release 1.4 and 1.5.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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	Final	Production	●●●●○	Yes	Free	Yes
Emerging Alternative Implementation Specification	*PHIN Messaging Guide for Syndromic Surveillance: Emergency Department, Urgent Care, Inpatient and Ambulatory Care Settings, Release 2.0*	*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. • **COMMENT:** The Collaborative supports using HL7 Version 2.5.1 and PHIN Messaging Guide for Syndromic Surveillance: Emergency Department and Urgent Care Data Release 1.1.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – SAML, Kerberos). • **User Role** – identifies the role asserted by the individual initiating the transaction. • **Purpose of Use** - Identifies the purpose for the transaction.

II-L: 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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **COMMENT:** The Collaborative supports using proposed HL7 CDA editions noted above.	• **No comment.**

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 Implementation Guide for CDA® Release 2: Quality Reporting Document Architecture – Category I, DSTU Release 2 (US Realm)	Balloted Draft	Production	●●●●○	Yes	Free	Yes

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Emerging Alternative Implementation Specification	*HL7 CDA® R2 Implementation Guide: Quality Reporting Document Architecture - Category I (QRDA I) DSTU Release 3 (US Realm)*	*Balloted Draft*	*Pilot*	●○○○○	*Yes*	*Free*	*Yes*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **COMMENT:** The Collaborative supports using proposed HL7 CDA editions noted above.	• **No comment.**

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

[See Question 6]

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

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 • **COMMENT:** The Collaborative supports using Fast Healthcare Interoperability Resources (FHIR).	• **No comment.**

II-N: 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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
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:
• **COMMENT:** The Collaborative supports using HL7 CDA, Release 2.0, Final Edition and the Consolidated HL7 Implementation Guide: Data Segmentation for Privacy (DS4P), Release 1.	• **No comment.**

II-O: 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 Alternative 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*	*Unknown*	*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. • **COMMENT:** The Collaborative supports using HL7 Consolidated CDA Release 1.1 (HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1 – US Realm).	• **No comment.**

Section III: Best Available 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 Alternative Standard	*Applicability Statement for Secure Health Transport v1.2*	*Final*	*Pilot*	●○○○○	*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 Alternative Standard	*Fast Healthcare Interoperability Resources (FHIR) DSTU 2*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
3, 4 - Emerging Alternative 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"	• **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

between two parties and may vary based on the trust community(ies) to which parties belong. • 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. • **COMMENT:** The Collaborative supports using the above standards proposed for "push" of clinical health information. The Collaborative strongly believes that it is vitally important to include pharmacists in this interoperability element.	• **Sender Signature** – details that are necessary to identity of the individual sending the message • **Secure Communication** – create a secure channel for client-to- serve 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
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
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.	• **Secure Communication** – create a secure channel for client-to- serve 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.

• **COMMENT:** The Collaborative supports using the above standards proposed for "push" of clinical health information. The Collaborative strongly believes that it is vitally important to include pharmacists in this interoperability element.	• **Authorization Enforcer** – specified policies access control. • **Credential Tokenizer –** encapsulate credentials as a security token for reuse (examples – 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-B: Clinical Decision Support Services

Interoperability Need: Providing patient-specific assessments and recommendations based on patient data for clinical decision support

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	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, Draft Standard for Trial Use	Balloted Draft	Pilot	●○○○○	No	Free	No
2-Emerging Alternative Implementation Specification	*IHE- GAO (Guideline Appropriate Ordering)*	*Balloted Draft*	*Pilot*	●○○○○	*No*	*Free*	*No*
3-Emerging Alternative 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:
• **COMMENT:** The Collaborative supports using HL7 Version 3 Standard: Decision Support Service, Release 2 and the HL7 Implementation Guide.	• **No comment.**

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:
• **COMMENT:** The Collaborative supports using HL7 Implementation Guide: Service-Oriented Architecture Implementations of the Context-aware Knowledge Retrieval (Infobutton) Domain, Release 1 and the HL7 Version 3 Implementation Guide (Infobutton), Release 4.	• **No comment.**

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 Alternative 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. • **No comment.**	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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. • **No comment.**	• **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 (examples – SAML, Kerberos)..

III-D: 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

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 Alternative 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 following URL provides links to relevant FHIR Resource, Practitioner - http://www.hl7.org/implement/standards/fhir/practitioner.html • FHIR Resources are in various stages of maturity. Please refer to the FHIR website for updates on specific profiles and their progress. • **COMMENT:** The Collaborative supports using IHE IT Infrastructure Technical Framework Supplement, Healthcare Provider Directory, Trial Implementation.	• **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 (examples – 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. • **User Details** - identifies the end user who is accessing the data.

III-E: 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 Alternative 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:
• **COMMENT:** The Collaborative supports using the above proposed NwHIN Specification and IHE Document Metadata Subscription.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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-F: 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
1,2-Implementation Specification	IHE-PIX (Patient Identifier Cross-Reference)	Final	Production	●●●●○	No	Free	Yes
2- Emerging Alternative 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. • **COMMENT:** The Collaborative supports using IHE-XDS, PDQ, and PIX.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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. • **COMMENT:** The Collaborative supports using all of the above-proposed standards for this interoperability element, and especially FHIR when it becomes available. The Collaborative also strongly believes it is important for pharmacists, as providers, should have access to queries for clinical information. They should not to be limited or excluded from queries.	• **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. o May be required to authorize any exchange of patient information o May be required to authorized access and use of patient information o 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

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. • **COMMENT:** The Collaborative supports using all of the above-proposed standards for this interoperability element, and especially FHIR when it becomes available. The Collaborative also strongly believes it is important for pharmacists, as providers, should have access to queries for clinical information. They should not to be limited or excluded from queries.	• **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. o May be required to authorize any exchange of patient information o May be required to authorized access and use of patient information o May be required to be sent along with disclosed patient information to o 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-G: 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:
• **COMMENT:** The Collaborative supports using IHE IT Infrastructure Technical Framework Supplement, Care Services Discovery, Trial Implementation.	• **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: Projected Additions to the ISA

The following tables represent projected additions to the ISA. They represent different and additional interoperability needs for which there may be "best available" standards or implementation specifications which have not yet been reviewed through the ISA's comment process. ONC seeks feedback from stakeholders as to whether the proposed interoperability needs and/or standards are accurate and would be beneficial additions to the ISA. See additional questions in Section V for specific areas where feedback is requested.

Projected Vocabulary/Code Set/Terminology Standards and Specifications:

Family Health History

Interoperability Need: Representing patient family health history observations (questions)

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):
• **COMMENT:** The Collaborative supports using LOINC.	• Problem Type 2.16.840.1.113883.3.88.12.3221.7.2 (LOINC code system)

Gender Identity, Sex and, Sexual Orientation

Interoperability Need: Representing patient gender identity observations (questions)

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting 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. • **COMMENT:** The Collaborative supports using LOINC.	• LOINC code: 76691-5 Gender identity

Interoperability Need: Representing patient sex (at birth) observations (questions)							
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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting 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. **COMMENT**: The Collaborative supports using LOINC.	• One LOINC code: 76689-9 Sex assigned at birth

Interoperability Need: Representing patient-identified sexual orientation observations (questions)							
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**Federally Required**	**Cost**	**Test Tool Availability**
Standard	LOINC	Final	Unknown	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• The HIT Standards Committee recommended collecting 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. **COMMENT:** The Collaborative supports using LOINC.	• LOINC code: 76690-7 Sexual orientation.

Health Care Provider

Interoperability Need: 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	Unknown	●●○○○	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• **COMMENT:** The Collaborative supports using SNOMED CT.	• Healthcare Provider Taxonomy (HIPAA): 2.16.840.1.114222.4.11.1066 • HL7 Participation Function

	• Subjects role in the care setting (SNOMED-CT)

Lab Tests

Interoperability Need: Representing numerical laboratory test order observations (questions/what will be tested)

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):
• The HIT Standards Committee recommended that 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. • Where LOINC codes do not exist, it is possible to request a new LOINC term be created. A number of factors may determine the length of time required for a new code to be created. • 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. • **COMMENT:** The Collaborative supports using LOINC.	• A value Set at this granularity level (numerical) does not exist. Use Universal Lab Orders OID: 1.3.6.1.4.1.12009.10.2. (if need be, the rest of LOINC)

Interoperability Need: Representing categorical laboratory test result observation values (answers)

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):
• The HIT Standards Committee recommended that 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. • **COMMENT:** The Collaborative supports using SNOMED CT.	• **No comment.**

Nursing

Interoperability Need: Representing nursing assessments

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	LOINC	Final	Production	Unknown	No	Free	N/A
Standard	SNOMED-CT	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value 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). • **COMMENT:** The Collaborative supports using LOINC and SNOMED CT.	• **No comment.**

Interoperability Need: Representing outcomes for nursing

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Other ANA-recognized terminologies should be converted to LOINC for comparison across health systems and/or transmission. • **COMMENT:** The Collaborative supports using LOINC.	• **No comment.**

Interoperability Need: Representing patient problems for nursing

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
Standard	SNOMED-CT	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Other ANA-recognized terminologies should be converted to SNOMED-CT for comparison across health systems and/or transmission. • **COMMENT:** The Collaborative supports using SNOMED CT.	• **No comment.**

Interoperability Need: Representing nursing 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	SNOMED-CT	Final	Production	Unknown	No	Free	N/A

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• Other ANA-recognized terminologies should be converted to SNOMED-CT for comparison across health systems and/or transmission. • **COMMENT:** The Collaborative supports using SNOMED CT.	• **No comment.**

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):

• **No comment.**	• **No comment.**

Tobacco Use (Smoking Status)

Interoperability Need: Representing patient tobacco use (smoking status) observations (questions)

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

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Value Set(s):
• 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]. • **COMMENT:** The Collaborative supports using LOINC.	• One LOINC code: 72166-2 "Tobacco smoking status NHIS"

Projected Content/Structure Standards and Specifications:

Admission, Discharge and Transfer

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. • **COMMENT:** The Collaborative supports using NCPDP SCRIPT Standard, Implementation Guide, Version 10.6.	• **Secure Communication** – create a secure channel for client-to- serve 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 (examples – 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.

Care Plans

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	Unknown	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **COMMENT:** The Collaborative supports using HL 7 CDA Release 2.0 and CDA R2 Implementation Guide proposed above.	• **No comment.**

Clinical Decision Support

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 Alternative Implementation Specification	*IHE: Guideline Appropriate Ordering (GAO)*	*Balloted Draft*	*Pilot*	*Unknown*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **No comment.**	• **No comment.**

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 Alternative Implementation Specification	*IHE: Clinical Decision Support Order Appropriateness Tracking (CDS-OAT)*	*Balloted Draft*	*Pilot*	*Unknown*	*No*	*Free*	*No*

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **COMMENT:** The Collaborative supports using IHE: Clinical Decision Support Order.	• **No comment.**

Images

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	Unknown	No	Free	No

Limitations, Dependencies, and Preconditions for Consideration:	Applicable Security Patterns for Consideration:
• **No comment.**	• **No comment.**

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:
• **COMMENT:** The Collaborative supports using IHE-PCD.	• **No comment.**

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
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
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:
• **No comment.**	• **No comment.**

Interoperability Need: Pre-population of research case report forms from electronic health records

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 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
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	Final	Production	●●●○○	No	Free	N/A
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
Standard	CDISC Shared Health And Research Electronic Library (SHARE)	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:
• **No comment.**	• **No comment.**

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
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. • **COMMENT:** The Collaborative supports using IHE-RFD; HL7 CDA, and CDISC as proposed above.	• **No comment.**

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:
• **No comment.**	• **No comment.**

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

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability
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:
• **COMMENT:** The Collaborative supports using IHE-RFD, DSC, CPRC, and CDISC.	• **No comment.**

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
Implementation Specification	IHE-RFD (Retrieve Form for Data Capture)	Final	Production	●●●●○	No	Free	N/A
Standard	CDISC Clinical Data Acquisition Standards Harmonization (CDASH)	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:
• **COMMENT:** The Collaborative supports using IHE RFD; CDISC, and HL7 CDA.	• **No comment.**

Interoperability Need: Registering a clinical trial

Type	Standard/Implementation Specification	Standards Process Maturity	Implementation Maturity	Adoption Level	Federally Required	Cost	Test Tool Availability

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:
• **No comment.**	• **No comment.**

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. **COMMENT:** The Collaborative supports using HL7 CDA Release 2 Implementation Guide Data Provenance.	• **No comment.**

Projected Standards and Specifications for Services:

"Push" Exchange

Interoperability Need:	Push communication of vital signs from medical devices						
Type	**Standard/Implementation Specification**	**Standards Process Maturity**	**Implementation Maturity**	**Adoption Level**	**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. • **COMMENT:** The Collaborative supports using ISO/IEEE Health Informatics – Medical/health device communication standards.	• **No comment.**

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:**
• **COMMENT:** The Collaborative supports using EHRS-IIS Interoperability Enhancement, Version 1.2 and IIS Standard WSDL.	• **No comment.**