**Office of the National Coordinator (ONC)**

**For Health IT**

**Federal Health Information Model (FHIM):**

**Terminology Value Sets for the**

**Laboratory Prototype Project**

**Whitepaper**

**April 20th, 2011**

***Release 1.0 Draft***



# TABLE OF CONTENTS

[TABLE OF CONTENTS 2](#_Toc291063946)

[Executive Summary 3](#_Toc291063947)

[1 Background 4](#_Toc291063948)

[1.1 Value Sets 4](#_Toc291063949)

[1.2 Use of HITSP Value Sets 5](#_Toc291063950)

[1.3 Terminology Binding of theFederal Health Information Model (FHIM) 6](#_Toc291063951)

[2 Laboratory Domain Prototype Project 7](#_Toc291063952)

[2.1 Terminology Binding Methodology 7](#_Toc291063953)

[Workflow Diagram 9](#_Toc291063954)

[3 Observations and Recommendations 11](#_Toc291063955)

[4 Process for terminology updates 17](#_Toc291063956)

[5 Recommendations for Terminology Working Group 21](#_Toc291063957)

[Appendix A 22](#_Toc291063958)

[Appendix B 29](#_Toc291063959)

[Appendix C- Acronyms 32](#_Toc291063960)

[Appendix D- Glossary 34](#_Toc291063961)

# Executive Summary

This paper focuses on the approach, methodology and results of binding terminology value sets to the FHIM Lab domain attributes. This is a portion of a project tasked with integrating the Federal Health Information Model (FHIM) with the Model Driven Health Tools (MDHT) and development of a prototype that demonstrates the capabilities of this integration.

A value set represents a uniquely identifiable set of valid concept representations (codes), where any concept representation can be tested to determine whether or not it is a member of the value set.[[1]](#footnote-1) Value sets constrain the allowable content for a coded attribute to ensure accuracy of recorded data and enable semantic interoperability. A number of standards organizations are actively working in the area of value sets including HITSP and HL7; however, for the purpose of this project, the terminology binding process was limited to the HITSP C80 specification.

The initial scope of the terminology portion of this project was to examine the FHIM Lab domain, identify coded attributes that could be bound to HITSP C80 value sets, enter the binding into the MDHT, identify issues/problems recognized during this process and determine what recommendations or considerations might be useful to terminology binding of value sets in the future.

The objectives of this paper include:

1. Documentation of the methodology used to bind value sets to the Lab domain
2. Results, issues and gaps identified while binding value sets to the FHIM Lab domain
3. Recommendations and process of updates from code system

# Background

## Value Sets

A value set represents a uniquely identifiable set of valid concept representations (codes), where any concept representation can be tested to determine whether or not it is a member of the value set.[[2]](#footnote-2) Value sets constrain the allowable content for a coded attribute to ensure data accuracy and enable semantic interoperability.

A value set may be defined as either extensional or intensional.

* + An extensional value set is one that contains an enumerated list of coded concepts. Size is not a limitation however; the intention is that the values in this set will probably not need to change over time or the changes will be limited.
  + An intensional value set is one that is defined by a set of rules describing a computable expression. The result of those rules is the actual list of coded concepts. These types of value sets are important in the healthcare setting where terminologies are constantly expanding and being refined. The value set can represent the most current version of the terminology without having to be manually updated as would be the case with an enumerated list.

Value set binding can be static or dynamic.

* + Static binding means that the allowed values of the value set do not change automatically as new values are added to a value set. That is, the binding is to a single version of a value set.
  + Dynamic binding means that the intent is to have the allowed values for a coded item automatically change (expand or contract) as the value set is maintained over time. This means that for dynamic binding, the binding is to the most current version of the value set in the terminology server at a given point in time.

Value Set Properties:

HL7[[3]](#footnote-3) and HITSP[[4]](#footnote-4) have defined the properties/metadata for value sets and can be referenced from CTS 2 and HITSP C80 respectively. HITSP defines the following metadata for each value set created and MDHT terminology functionality should be able to support these.

* Identifier
* Name
* Source
* URL
* Purpose – Brief description about the general purpose of the value set
* Definition – A text definition formally describing how concepts in the value set are intensionally or extensionally selected
* Version
* Type – Extensional (enumerated) or Intensional (criteria-based)
* Binding – static or dynamic
* Status
* Effective Date
* Expiration Date
* Creation Date
* Revision Date
* Code System Source
* Code System Name

## Use of HITSP Value Sets

The Healthcare Information Technology Standards Panel (HITSP) is a cooperative partnership between the public and private sectors. The Panel was formed for the purpose of harmonizing and integrating standards that will meet clinical and business needs for sharing information among organizations and systems. [[5]](#footnote-5)

The following specifications have been developed by HITSP that are relevant to this prototype project:

HITSP C 80 - Clinical Document and Message Terminology Component defines the terminologies utilized by HITSP specifications for Clinical Documents and Messages used to support the interoperable transmission of information. This specification defines 80+ value sets including those listed in section 2.2.3.6 MEASUREMENT AND LABORATORY RESULTS.

HITSP Interoperability Specification (IS 01) - The Electronic Health Records (EHR) Laboratory Results Reporting Interoperability Specification defines specific standards to support the interoperability between electronic health records and laboratory systems and secure access to laboratory results and interpretations in a patient-centric manner.[[6]](#footnote-6)

Three components of IS 01 were identified as relevent to this project; however, they do not provide value set definitions.

HITSP C35 – Lab Result Terminology Component – defines vocabulary for either message-based or document-based laboratory results reporting

HITSP C36 – Lab Result Message Component & HITSP C37 – Lab Report Document Component focus on messaging and are not applicable to terminology binding.

## Terminology Binding of theFederal Health Information Model (FHIM)

The goal of FHIM is to produce a logical, health information model that suports semantic interoperability and that is built by harmonizing information from the individual Federal partners and standards organizations.[[7]](#footnote-7) A baseline model was created by leveraging existing UML models from the VHA, NCI and FDA and organized by “domains” which group areas of related health information.

The modeling for each domain identifies classes and attributes that support interoperability of an Electronic Health Record (EHR). Coded attributes represent information that needs to be recorded accurately and exchanged with confidence. Binding FHIM coded attributes to standard value sets was identified as the next step to enhance the modeling. The Lab domain was selected for the prototype and HITSP C80 specification was identified as the source for terminology binding.

The next section of this paper describes the methodology used by terminologist to accomplish the terminology binding.

### 

# 2 Laboratory Domain Prototype Project

## 2.1 Terminology Binding Methodology

Artifacts for this project included the FHIM Lab domain model in html and uml format, and HITSP C 80 specifications.

The left column of the table below describes the processes that were utilized by the terminology team to determine value set binding for FHIM lab domain coded attributes. The right column identifies important considerations/recommendations that were identified during our work that may be of use when completing subsequent FHIM domains.

| **Terminology Binding for Lab Domain Project** | **Considerations for Future Terminology Work** |
| --- | --- |
| The Lab domain was selected for the prototype project. |  |
| A solution was proposed for the tools to be used by the terminologist to constrain the attributes. The process for installation and configuring is still being developed and when complete it will be documented and will provide a useful guide as work continues for additional domains.  An interim process was developed by the terminology team to track all work in an excel spreadsheet. If functionality to enter terminology binding is not achieved by the end of this contract date, this spreadsheet will provide the required information to complete the binding.  GAP: A number of issues arose and functionality has not been achieved as of this date. | * The functionality must exist in MDHT for terminologists to select value sets created by SDOs and constrain attributes to value sets. * SDO approved value sets should be imported into MDHT. * A process must exist whereby the integrity of the value sets cannot be compromised. * A process must exist whereby versioning of the value sets is maintained to support the most current version. |
| Modifications to the Lab domain model were made as requirements for the prototype were identified. This created a moving-target for the terminologists. | * The modeling of the domain should be complete and align with existing standards prior to performing terminology constraining. If the model is not up-to-date, finalized and approved, it should go back to the modelers and/or SMEs prior to implementing terminology binding. * Is there a formal approval process for FHIM domain models? |
| For Lab, HITSP C80: Clinical Document and Message Terminology Component was identified as the relevent standard for this project.  HITSP IS01: Electronic Health Record (EHR) Laboratory Results Reporting   * C35 – Lab Result Terminology * C36 – Lab Result Message * C37 – Lab Report Document   These were reviewed but the focus was outside the scope of terminology binding. | * Determine the standards that the domain model will be constrained to. |
| The terminologists reviewed the Lab model including documentation metadata to understand the intent of each attribute and its place within the model.  GAP: From the perspective of an outside observer new to the model, there were many instances where we were unable to unambiguously determine the intent of the coded values based on the existing documentation. References to use cases or other artifacts will benefit during the terminology binding process as well as during any QA process that follows. | * Documentation should be sufficient for unambiguous determination of the intent and scope of the coded values. This will allow terminologists to identify if a standard value set exists. If not, then the documentation should provide adequate information to create a value set that will satisfy the attribute. * A process (formal or informal) should be in place to direct questions to modelers/SMEs for clarification of issues and documentation of resolution. |
| The terminologist identified attributes where the datatype equaled ‘code’. These attributes represent codified data of an EHR that will be exchanged or queried. Value sets define these codes and ensure harmonization and semantic interoperability across systems. | * Terminologists should be a member of the modeling process to bring expertise and minimize downstream issues. |
| With the intent of the attribute fully understood, terminologists searched identified standards (HITSP C80 for this project) to determine if a value set had been defined. Searching standard value sets should be done not only by the name of the value set but also by the defined values to ensure nothing is overlooked.  Some of the attributes in the Lab domain have explicitily enumerated codes in the documentation. For example, “drawTimeCode” is defined with the values of ‘P’ for Peak and ‘T’ for Trough. A value set can be created containing these two values and would be defined as extensional with static binding.  For Lab attributes where the documentation includes only examples of the types of codes that MIGHT be included, more information is required to make an evaluation. The terminologists must understand the intent and the scope of the data that is to be captured. Artifacts should be identified to assist in this process. Collaboration with SMEs will result in a complete, unambiguous value set that is identified from the most appropriate terminology standard. | * Functionality should exist for terminologists to create FHIM value sets and bind appropriately to FHIM attributes. * The system should be able to create a unique identifier for each value set. * A formal process should exist to develop, create, approve and manage FHIM value sets. * FHIM value sets must contain clearly defined, unique concepts. This will ensure the accuracy of the data that is captured. |
| The spreadsheet that was created by the terminologist can be used to:   * Enter binding in MDHT for identified value sets * Identify coded attributes that need clarification of the intent and scope of the values to be covered by the value set * Identify where value sets not found in HITSP C80 can be created from defined values in the documentation   The result of this work is discussed in the Observations and Recommendations section of this document. |  |

## 2.2 Workflow Diagram

The flowchart below describes the processes and decision points during the terminology binding project. The shaded processes were not steps during this discovery phase, but were identified as important considerations for the Terminology Working Group.



# Observations and Recommendations

Terminology bindings were recommended only for those attributes that had coded data types in both the Laboratory and Orders domains.

Laboratory domain contained 39 coded attributes. An applicable HITSP C80 terminology binding was found for about 22 attributes in lab domain. The list of attributes and associated value set and code system is attached in [Appendix A](#_Appendix_A:_Proposed).

For about three coded attributes (which had complete docuemtation), a suitable HITSP C80 binding was not found, however, we have suggested value sets and code systems with the definitions as below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Class** | **Class Attributes** | **Attribute documentation in FHIM** | **Possible Value Sets** | **Recommendations** |
| MeasurementWithReferenceRangeResult | **analyte** | "A substance or chemical constituent that is undergoing analysis." - Stedman's Medical Dictionary. Identifies the substance being analyzed. Examples include Sodium, Blood Urea Nitrogen, White Blood Cells. | SNOMED, LOINC | No HITSP C80 but we may be able to constrict a value set.   Value set: SNOMED - 272524002 analyte hierarchy; or LOINC  Should this be an association to analyte under ChemistryTest class? |
| Organism | **organism** | The organism identified. Since this unique identifier is a coded element, it contains both a code and a display name. | SNOMED CT | Organism hierarchy - 264395009 - microorganism (organism) |
| StainResult | **cultureCondition** | aerobic / nonaerobic condition | SNOMED or Defined values | SNOMED or Defined values: 117033003|Aerobic microbial culture (procedure) & 117034009|Anaerobic microbial culture (procedure) |

For the following three coded attributes, though a suitable HITSP C80 binding was not found. a set of defined values can be constructed mapped to a code system or added as predefined values without mapping to code system.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Class** | **Class Attributes** | **Attribute documentation in FHIM** | **Possible Value Sets** | **Recommendations** |
| AutopsyEvent | **dxClarificationCode** | Contains the Code value to indicate whether the  clinical dx insufficient (ex. Intracranial hemorrhage) did autopsy clarify the dx (ex. ruptured aneurysm) ?  '1' FOR YES; '0' FOR NO; '2' FOR CONFIRMED; | Defined values | Defined value set: '1' FOR YES; '0' FOR NO; '2' FOR CONFIRMED; |
| BacteriologyTiter | **drawTimeCode** | P' FOR PEAK;  'T' FOR TROUGH | Defined values | Defined value set:'P' FOR PEAK;  'T' FOR TROUGH |
| LabTestRequest | **referralType** | If the test was accepted as a referral from another facility, only portions of the test may need to be performed. For example, CHCS lists the following: Procedure Only, Report Only, and Outside Films. | Defined values | No HITSP definition. Can construct a defined value set. |

Some coded attributes (10 in lab domain) did not have documentation and one attribute in lab domain that needed more information to suggest the types of value set and code system (see [Appendix B](#_Appendix_B)). Based on attribute name and class we could suggest a terminology binding for six of these attributes.

|  |  |  |  |
| --- | --- | --- | --- |
| **Class** | **Class Attributes** | **Attribute documentation in FHIM** | **Recommendations** |
| Container | **containerType** | None available | Need more information about the type and scope of ‘container’ concepts. Can construct value set from **UMDNS and / or SNOMED** **UMDNS concepts:** 13-655 |Specimen Containers  14-303 |Specimen Containers, Urine **SNOMED concepts:** 433453003|Specimen container component (physical object) 434711009|Specimen container (physical object) 434746001|Specimen vial (physical object) 434822004|Specimen well (physical object) 337386000|Test tube (physical object) |
| Container | **additiveType** | None available | Some examples of additives identified from internet query: broth mixture|sodium citrate|gel separator+clot activator|sodium heparin|lithium heparin+gel separator|EDTA|acid citrate dextrose  Can construct in SNOMED CT |
| LabReferral | **statusModifier** | None available | need more information  HITSP C80 - 2.2.3.6.7 Order Control in HL7 v2.5.1 |
| LabTestRequest | **confidentialityCode** | None available | No definition from FHIM, so need to verify if Value set suggested is appropriate  HITSP C80 - 2.2.3.15.4 Clinical Specialty in HL7 |
| MeasurementWithReferenceRangeResult | **analyte** | "A substance or chemical constituent that is undergoing analysis." - Stedman's Medical Dictionary. Identifies the substance being analyzed. Examples include Sodium, Blood Urea Nitrogen, White Blood Cells. | No HITSP C80 but we may be able to constrict a value set.   Value set: SNOMED - 272524002 analyte hierarchy; or LOINC  Should this be an association to analyte under ChemistryTest class? |
| Parasite | **stage** | None available | SNOMED hierarchies: 278306005-life-cycle form (organism), 284692007-protozoal life-cycle form (organism), 284720001-helminthic life-cycle form (organism) |

In some cases, the definition of the attribute is broad or more information is needed to clarify the information that needs to be captured. Also, when referenced to HITSP C80 recommendations, more than one code system can be applied to a given attribute which is broadly defined. It is recommended that discussions between modelers, subject matter experts and terminologists can help determine which code system best meets the needs for that attribute.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Class** | **Class Attributes** | **Attribute Comments per FHIM** | **HITSP C80 recommendations** | **Value Set** | **Code System** |
| MeasurementWithReferenceRangeResult | **testCode** | An identifier code for the observation or ordered test. This can be based on local and/or universal codes. The WKLD CODE file (#64) is used to identify the observed test. It contains the VA National Laboratory Test code. Future versions may utilize LOINC codes as an additional coding system. | 2.2.3.6.1 Laboratory Observation 2.2.3.6.1.1 Laboratory Observation Identifier (formally know as Laboratory Tests Results) 2.2.3.6.1.2 Laboratory Finding Identifer (formally known a Laboratory Observation) | Laboratory Observation IdentifierValue Set, Laboratory Finding Identifer Value Set | LOINC,  SNOMED |
| StainResult | **stainType** | Contains the value results of the Smear/Prep test. | 2.2.3.6.1.1 Laboratory Observation Identifier (formerly known as Laboratory Test Results) ------------ 2.2.3.6.1.2 Laboratory Finding Identifer (formally known as Laboratory Observation) | Laboratory Observation Identifier Value Set ------------- Laboratory Finding Identifer Value Set | LOINC ------------ SNOMED CT |
| StainResult | **value** | Contains the results of the Gram Stain Test in textual format. | 2.2.3.6.1.1 Laboratory Observation Identifier (formerly known as Laboratory Test Results) ------------ 2.2.3.6.1.2 Laboratory Finding Identifer (formally known as Laboratory Observation) | Laboratory Observation Identifier Value Set ------------- Laboratory Finding Identifer Value Set | LOINC ------------ SNOMED CT |

The lab domain model in FHIM was being changed at the same time that terminology bindings were recommended. These recommendations apply to the Lab and Orders domain with changes in the model noted as of April 14, 2011.

As a part of this deliverable, we have also included FHIM\_Terminology bindings table in FHIM\_Terminology bindings.xls that gives details about the bindings, recommendations about value sets and code systems and also pending questions.

# Process for terminology updates

Every code system has updates where the codes or semantics of the ontology are changed. For an information model to represent the most accurate information, the value set represented by the code system needs to be up to date. Hence, a process will be required where the most up to date versions of code systems are available to those FHIM attributes that have terminology bindings.

There are a few options how these updates can be obtained.

**Option 1 – Value set updates without use of terminology service provider.**

For the attributes that have dynamic terminology bindings, the value set from a code system can be constructed with every updated version. This would involve creation of definitions for the dynamic set and also execution of the definitions with updated versions outside of a terminology service provider against each code system individually perhaps using API calls against each code system or using data files from each code system. This option would also involve FHIM having to keep track of the update schedule which varies by every code system.



**Option 1 – Value set updates from code systems directly**

**Option 2 – Value set updates through a terminology service provider.**

A terminology service provider can be used for updates from code systems for value sets both with dynamic and static bindings.

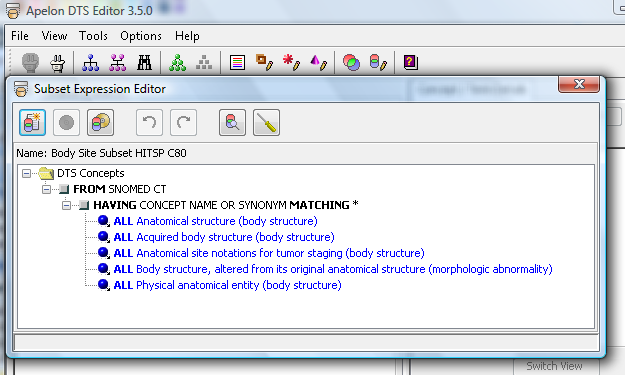
The definitions of the dynamic value sets can be stored and with every updated version, the definitions are re-executed to construct the latest value set. The value sets in many cases as referred in HITSP C80 recommendations and also as suggested by terminologists for lab domain in Section 3 can be created as “Subsets” through the terminology service provider. A subset is a set of concepts in a code system that is created using specific inclusion and exclusion criteria. These subsets can be created using a terminology service provider using the definitions for dynamic bindings on value sets for FHIM attributes.

An example of subset creation is described below.

Many FHIM attributes have a terminology binding as recommended in HITSP C80 that refers to the value set “Body Site”. In HITSP C80, this value set is intentionally defined from the SNOMED CT code system with the following definition:

*Anatomical Structure (91723000) hierarchy or Acquired body structure (body structure) (280115004) or Anatomical site notations for tumor staging (body structure) (258331007) or Body structure, altered from its original anatomical structure (morphologic abnormality) (118956008) or Physical anatomical entity (body structure) (91722005)*

In DTS subset editor, this definition can be constructed to create a Body system subset as follows:



When the subset is executed, the resulting value set contains all the concepts needed in the value set as defined in the HITSP C80 Body Site value set definition. This subset can then be exported to a flat file in formats like .txt or .csv for use in FHIM or Java API calls can be made against the DTS subset database to extract the concepts.

When new code system versions are available, the definitions in subset editor remain the same but are executed against the new version to get the latest concepts in the subset.

Since all code systems are obtained through a single terminology service provider, the methodology of extraction of updated content for use in FHIM remains uniform. In addition, with any updated version of a code system involved, the subset definitions are re-executed by the terminology service and made available to FHIM without FHIM having to manage the updates from each code system individually.



**Option 2 – Value set updates using Terminology service provider**

For static value sets, though there are no definitions to construct subsets, a similar methodology of content updates can be used where with updated versions of the code systems, the static value sets are exported as flat file or using API calls and made available to FHIM.

# Recommendations for Terminology Working Group

In order to recommend terminology bindings, documentation for attributes provided better insight of what data the modeler intended to capture rather than relying on the context (class and domain package) of the attribute and its data type. Hence it is recommended that all attributes especially the coded data types have up to date documentation and examples where applicable before terminology bindings are assigned.

The [methodology and considerations](#_Terminology_Binding_Methodology) and [workflow diagram](#_Workflow_Diagram) in Section 2 can be a reference for assigning terminology bindings to attributes in other FHIM domains.

From the observations made while assigning terminology bindings in the lab and orders domain, it is recommended that a methodology be developed by the Terminology Working Group to address attributes that do not have applicable HITSP C80 recommendations.

* Should an attempt be made to map these to code systems?
* If attributes cannot be mapped to a code system or are specific predefined values, should they be maintained in a terminology maintenance service?

For code systems either referred by HITSP C80 or outside of HITSP C80, there are a few other questions that might help determine the approach in assigning and maintaining terminology bindings such as:

* Should a subset in the code system be created for reusability and ease of maintenance? (as described in Section 4 – option 2)
* Should a terminology update service be used for updates from code systems?

During the process of assigning terminology bindings, we questioned whether the attributes in some classes can have a different data type. Our preliminary review of the FHIM model in lab domain identified some attributes that can have a coded data type to best represent the information captured in the attribute. For example, can the attributes “preOperativeDiagnosis” and “postOperativeDiagnosis” in the class “PathologyObservationEvent” be a code rather than a string. Our concern is that important data that needs to be exchanged may not be consistently captured if the data type is not coded. For such attributes, discussion between modelers, subject matter experts and terminologists can be a valuable step in representing information in FHIM and interaction of FHIM with other agencies.

# Appendix A: Proposed HITSP C80 binding

Attributes in Lab domain with proposed HITSP C80 terminology binding

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Classifiers/Classes** | **Class Attributes** | **Attribute documentation in FHIM** | **HITSP C80 recommendations** | **Value Set** | **Code System** |
| AnatomicMeasurement | **bodySite** | This property indicates the organ or structure that is being measured, e.g., the Brain. Note that this property will require an extensive effort by the terminology team to define fully. | 2.2.3.2 BODY SITE | Body Site Value Set | SNOMED CT |
| AnatomicMeasurement | **measurementType** | Identifies the kind of measurement that is contained in the measurement value such as weight, length, or volume. | 2.2.3.6.6 Unit of Measure | Unit of Measure Code system | Unified Code for Units of Measure (UCUM) |
| AntibioticSensitivityObservationEvent | **interpretation** | Interpretation of the susceptibility of the identified organism to the test antibiotic. i.e., I=Intermediate, MS=Moderately Susceptible, R=Resistant, S=Susceptible. In addition, N=Not Tested may occasionally used when an antibiotic that would commonly tested was not for some reason. | 2.2.3.6.3 Result Normalcy Status | Result Normalcy Status Value Set | HL7 Observation Interpretation |
| AutopsyEvent | **autopsyType** | Anatomical areas of the body the autopsy is performed on.  This can be as broad as a full autopsy or grouping of the body region such as chest, trunk, head. lower body. | 2.2.3.2 BODY SITE | Body Site Value Set | SNOMED CT |
| BiologicalEntitySpecimenCollection | **bodySite** | The location on the patient's body from which the specimen was obtained. | 2.2.3.2 BODY SITE | Body Site Value Set | SNOMED CT |
| LabReferral | **priority** | A code (e.g., routine, emergency), specifying the urgency under which the order is requested to happen. | 2.2.3.6.10 Order Priority | Order Priority Code System Table | HL7 V2.5.1 |
| LabReferral | **status** | A code specifying the **status of the order.** Valid status codes should reflect the HL7 state machine, e.g., Active, Held, Canceled, Aborted, New, Nullified, Obsolete). | 2.2.3.6.8 Order Status | Order Status Code System Table | HL7 V2.5.1 |
| LabTestPromise | **priority** | **This field has been retained for backward compatibility only.** It is not used. Previously priority (e.g., STAT, ASAP), but that information is carried as the sixth component of OBR-27-quantity/timing. | 2.2.3.6.10 Order Priority | Order Priority Code System Table | HL7 V2.5.1 |
| LabTestPromise | **status** | Identifies the status of the Lab Test Promise act. | 2.2.3.6.8 Order Status | Order Status Code System Table | HL7 V2.5.1 |
| LabTestRequest | **labTestOrPanelOrdered** | Lab test or panel of tests ordered | 2.2.3.6.2 Laboratory Order | Laboratory Order Value Set | LOINC |
| MaterialSpecimenCollectionEvent | **collectionSite** | The location on the patient's body from which the specimen was obtained. | 2.2.3.2 Body Site | Body Site Value Set | SCT |
| MeasurementWithReferenceRangeResult | **interpretation** | Provides an automated indication of the result, based upon "normal" values as indicated by the reference range. Examples include High, Low, Critically High, Critically Low, etc. | 2.2.3.6.3 Result Normalcy Status | V3 Result Normalcy Value Set | HL7 V3 - Observation Interpretation |
| MeasurementWithReferenceRangeResult | **status** | Identifies the status of an investigative procedures performed in the laboratory. | 2.2.3.6.4 Result Status  2.2.3.6.4.1 HL7 V2.5 2.2.3.6.4.2 HL7 V3 | V2 Result Status Value Set and V3 Result Status Value Set | HL7 v 2.5.1 - Result Status |
| MeasurementWithReferenceRangeResult | **testCode** | An identifier code for the observation or ordered test. This can be based on local and/or universal codes. The WKLD CODE file (#64) is used to identify the observed test. It contains the VA National Laboratory Test code. Future versions may utilize LOINC codes as an additional coding system. | 2.2.3.6.1 Laboratory Observation 2.2.3.6.1.1 Laboratory Observation Identifier (formally know as Laboratory Tests Results) 2.2.3.6.1.2 Laboratory Finding Identifer (formally known a Laboratory Observation) | Laboratory Observation IdentifierValue Set, Laboratory Finding Identifer Value Set | LOINC,  SNOMED |
| SpecimenCollectionEvent | **collectionMethod** | This attribute captures the method by which the specimen was obtained from the patient's body; e.g., needle stick, thin needle aspirate. | 2.2.3.6.14 Specimen Collection Method | Specimen Collection Method | Code System Name Specimen Collection Method Code System Source Health Level Seven (HL7) Version 2.5.1 |
| SpecimenCollectionEvent | **specimenSourceSite** | "Specifies the source from which the specimen was obtained. For example, in the case where a liver biopsy is obtained via a percutaneous needle, the source would be ‘liver.’" - HL7 V2 | Body Site Value Set | Body Site Value Set | SNOMED CT |
| SpecimenCollectionEvent | **specimenSourceSiteModifier** | "Specifies the source from which the specimen was obtained. For example, in the case where a liver biopsy is obtained via a percutaneous needle, the source would be ‘liver.’" - HL7 V2 | Body Site Value Set | Body Site Value Set | SNOMED CT |
| SpecimenCollectionPromise | **status** | Identifies the status of the coded value. | 2.2.3.6.8 Order Status | Order Status Codes Value Set | HL7 Version 2.5.1 - Order Status |
| SpecimenCollectionRequest | **bodySite** | The location on the patient's body from which the specimen was obtained. | 2.2.3.2 BODY SITE | Body Site Value Set | SNOMED CT |
| SpecimenCollectionRequest | **collectionMethod** | This attribute captures the method by which the specimen was obtained from the patient's body; e.g., needle stick, thin needle aspirate. | 2.2.3.6.14 Specimen Collection Method | Specimen Collection Method | Code System Name Specimen Collection Method Code System Source Health Level Seven (HL7) Version 2.5.1 |
| StainResult | **stainType** | Contains the value results of the Smear/Prep test. | 2.2.3.6.1.1 Laboratory Observation Identifier (formerly known as Laboratory Test Results) ------------ 2.2.3.6.1.2 Laboratory Finding Identifer (formally known as Laboratory Observation) | Laboratory Observation Identifier Value Set ------------- Laboratory Finding Identifer Value Set | LOINC ------------ SNOMED CT |
| StainResult | **value** | Contains the results of the Gram Stain Test in textual format. | 2.2.3.6.1.1 Laboratory Observation Identifier (formerly known as Laboratory Test Results) ------------ 2.2.3.6.1.2 Laboratory Finding Identifer (formally known as Laboratory Observation) | Laboratory Observation Identifier Value Set ------------- Laboratory Finding Identifer Value Set | LOINC ------------ SNOMED CT |

# Appendix B: Attributes with missing documentation

Attributes in lab domain with missing documentation

|  |  |  |  |
| --- | --- | --- | --- |
| **Class** | **Class Attributes** | **Attribute documentation in FHIM** | **Recommendations** |
| AutopsyEvent | **serviceCode** | Contains the code set that identifies the reason for autopsy service performed. | More information needed |
| Container | **containerType** | None available | Need more information. Can construct value set from **UMDNS and / or SNOMED** UMDNS 13-655 |Specimen Containers  14-303 |Specimen Containers, Urine **SNOMED** 433453003|Specimen container component (physical object) 434711009|Specimen container (physical object) 434746001|Specimen vial (physical object) 434822004|Specimen well (physical object) 337386000|Test tube (physical object) |
| Container | **containerCondition** | None available | need more information |
| Container | **additiveType** | None available | examples of additives: broth mixture|sodium citrate|gel separator+clot activator|sodium heparin|lithium heparin+gel separator|EDTA|acid citrate dextrose (source:internet) Can construct in SNOMED CT |
| LabReferral | **statusModifier** | None available | need more information  HITSP C80 - 2.2.3.6.7 Order Control in HL7 v2.5.1 |
| LabTestRequest | **confidentialityCode** | None available | No definition from FHIM, so need to verify if Value set suggested is appropriate  HITSP C80 - 2.2.3.15.4 Clinical Specialty HL7 |
| MeasurementWithReferenceRangeResult | **method** | None available | Need more information for value set bindings |
| Parasite | **stage** | None available | SNOMED hierarchies: 278306005-life-cycle form (organism), 284692007-protozoal life-cycle form (organism), 284720001-helminthic life-cycle form (organism) |
| ReferenceRangeCriterion | **criterion** | None available | No documentation for value set bindings |
| RelatedLabPromise | **relatedPromiseCategory** | None available | No documentation for value set bindings |
| ShippingContainer | **tempuratureMethod** | None available | Unit of measure? No documentation for value set bindings |

# Appendix C- Acronyms

|  |  |
| --- | --- |
| BRIDG Model | Biomedical Research Integrated Domain Group Model |
| CDA | Clinical Document Architecture |
| CIM | Computationally Independent Model |
| CPM | Common Product Model |
| CTS 2 | Service Functional Model Specification, Common Terminology Services, Release 2 |
| DSTU | Draft Standard for Trial Use |
| EHR | Electronic Health Record |
| FHIM | Federal Health Information Model |
| HITSP C 80 | Component 80 - Clinical Document and Message Terminology Component |
| HITSP IS 01 | Interoperability Specification 01 - Electronic Health Record (EHR) Laboratory Results Reporting |
| HL7 | Health Level Seven International |
| HL7 EHR S-FM | HL7 Electronic Health Record System Functional Model |
| HL7 ISCR | HL7 Individual Case Safety Report |
| HL7 RIM | HL7 Reference Information Model |
| ISO | International Organization for Standardization |
| LOINC | Logical Observation Identifiers Names and Codes |
| MDA | Model Driven Architecture |
| MDHT | Model Driven Health Tools |
| OID | Object Identifier |
| ONC | Office of the National Coordinator for Health IT |
| SDO | Standards Development Organizations |
| S&I Framework | Standards and Interoperability Framework |
| SNOMED-CT | Systematized Nomenclature of Medicine- Clinical Terms |
| SPL | Structured Product Labeling |
| UML | Universal Modeling Language |
| VHIM | Veterans Affairs Health Information Model |
| XML | Extensible Markup Language |

# Appendix D- Glossary

|  |  |
| --- | --- |
| Biomedical Research Integrated Domain Group Model | The Biomedical Research Integrated Domain Group (BRIDG) Model is a collaborative effort engaging stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management Technical Committee (RCRIM TC), the National Cancer Institute (NCI) and its Cancer Biomedical Informatics Grid (caBIG®), and the US Food and Drug Administration (FDA). The BRIDG model is an instance of a Domain Analysis Model (DAM). The goal of the BRIDG Model is to produce a shared view of the dynamic and static semantics for the domain of protocol-driven research and its associated regulatory artifacts. (http://www.bridgmodel.org) |
| Clinical Document Architecture | The HL7 Clinical Document Architecture (CDA) is an XML-based markup standard intended to specify the encoding, structure and semantics of clinical documents for exchange. http://en.wikipedia.org/wiki/Clinical\_Document\_Architecture |
| Computationally Independent Model | A model which is not geared to any specific operating system or computer language (fhims.org) |
| Common Product Model | The Common Product Model (CPM) will be an overarching domain information model relating to the HL7 v3 modeling of any kind (or instance) of a 'product'. The definition of the term product is intentionally kept loose at this point, but will definitely include:  Medication, incl. vaccines  Devices used in medical services  Anything else a person can be exposed to (wiki.HL7.org) |
| Constraint | A constraint is an expression of a business rule applied to an Information Exchange. It can restrict the values that appear within the exchange in a variety of different ways, and appear in both HITSP Specifications and in the standards those specifications select. (Source: HITSP) |
| Draft Standard for Trial Use | Draft standards are released as Draft Standards for Trial Use (DSTFU) to allow implementers to test the standards. At the end of the trial period the standard may be balloted, revised or withdrawn. |
| Dynamic Binding | A dynamically bound value set has its definitions fixed, but the values in the set may vary as new versions of the code system on which they are based are released. Intensional value sets are often dynamically bound. (Source: HITSP) |
| Electronic Health Record | The Electronic Health Record (EHR) is a longitudinal electronic record of patient health information generated by one or more encounters in any care delivery setting. Included in this information are patient demographics, progress notes, problems, medications, vital signs, past medical history, immunizations, laboratory data and radiology reports. The EHR automates and streamlines the clinician's workflow. The EHR has the ability to generate a complete record of a clinical patient encounter - as well as supporting other care-related activities directly or indirectly via interface - including evidence-based decision support, quality management, and outcomes reporting. (source: HIMSS) |
| Encoded | Information, such as diseases, procedures, and/or demographic data may be coded into discrete categories, identified by codes which may be numeric, alphabetic or a combination of these. In computer-based systems, this eases retrieval and simplifies analysis. In healthcare, 'encoded' may refer to clinical conditions or interventions coded into specific coding systems for administrative, financial, and other analyses. Among the most common coding systems are the International Classifications of Diseases (see ICD) and Current Procedural Terminology (see CPT). Another approach to coding is atomic coding, which involves assigning a value to each position in the code. (A simple example would be "35yoF " meaning "35 year old female.") Such coding systems, of which SNOMED is the most well known, are more flexible than hierarchical classifications, but may be more difficult to use. (Source: HITSP) |
| Extensible Markup Language | Extensible Markup Language (XML) is a set of rules for encoding documents in machine-readable form. (Source: HITSP) |
| Extensional Value Set | [Adapted from HL7 Version 3 Core Principals] An extensional value set definition is an enumeration of all of the concepts within the value set. Value sets defined by extension are composed of explicitly enumerated sets of concept representations (with the code system in which they are valid). The simplest case is when the value set consists of only one code. (Source: HITSP) |
| Federal Health Information Model | FHIM is a modeling initiative focused on producing a logical, health information model that supports semantic interoperability among federal agencies and their health information exchange partners. The model is built by harmonizing information from federal partners and standards development organizations (SDOs) and presenting it in logical and conceptual views based on specialized health domains.  This logical model uses the HL7 Reference Information Model (RIM) as its reference model and is designed to support multiple Office of Interoperability and Standards initiatives, including CONNECT and the S&I Framework. FHA and its stakeholders also use the FHIM to view and analyze information exchanges that have been identified by federal partners and SDOs, and the FHIM model is also used to support the development of National Information Exchange Model (NIEM) compliant information exchanges by the S&I Framework. |
| Harmonization | Harmonization is the name given to the effort by industry to replace the variety of product standards and other regulatory policies adopted by nations, in favor of uniform global standards. Usually used to in the context of trade agreements, harmonization has recently been adopted by the United States government to refer to information technology standards. (Source: HITSP) |
| HITSP Component 80 - Clinical Document and Message Terminology Component | The Clinical Document and Message Terminology Component defines the vocabularies and terminologies utilized by HITSP specifications for Clinical Documents and Messages used to support the interoperable transmission of information. (Source: HITSP) |
| HITSP Interoperability Specification 01 - Electronic Health Record (EHR) Laboratory Results Reporting | The Electronic Health Records Laboratory Results Reporting Interoperability Specification defines specific standards to support the interoperability between electronic health records and laboratory systems and secure access to laboratory results and interpretations in a patient-centric manner. (Source: HITSP) |
| Health Level Seven International | Founded in 1987, Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services. http://www.hl7.org/ |
| HL7 Electronic Health Record System Functional Model | The HL7 EHR System Functional Model provides a reference list of over 160 functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Functional Model, through the creation of Functional Profiles, enables a standardized description and common understanding of functions sought or available in a given setting (e.g. intensive care, cardiology, office practice in one country or primary care in another country). Source: http://www.hl7.org/ehr/downloads/index\_2007.asp) |
| HL7 Individual Case Safety Report | The HL7 Individual Case Safety Report (ICSR) is a Health Level Seven (HL7) standard for the exchange of adverse event or product problem reports to public health, patient safety, healthcare quality improvement organizations or regulatory authorities. Release 1 of the standard supports reporting for drugs, therapeutic biologics, blood derivatives, devices and vaccines. Release 2 of the standard is being balloted to support other product types such as foods, food additives, dietary supplements, cosmetics and veterinary drugs. (HL7.org) |
| HL7 Reference Information Model | The Reference Information Model (RIM) is the cornerstone of the HL7 Version 3 development process. An object model created as part of the Version 3 methodology, the RIM is a large, pictorial representation of the HL7 clinical data (domains) and identifies the life cycle that a message or groups of related messages will carry. It is a shared model between all domains and, as such, is the model from which all domains create their messages. The RIM is an ANSI approved standard. http://www.hl7.org/implement/standards/rim.cfm |
| Intensional Value Set | [Adopted from HL7 Version 3 Core Principals] An intensional value set definition is a set of rules that can be resolved (ideally computationally) to an exact list of concept representations at a particular point in time. (Source: HITSP) |
| Interoperability | Interoperability is the ability of health information systems to work together within and across organizational boundaries, in order to advance the effective delivery of health care for individuals and communities. (Source: HITSP) |
| International Organization for Standardization | ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards. ISO is a non-governmental organization that forms a bridge between the public and private sectors. On the one hand, many of its member institutes are part of the governmental structure of their countries, or are mandated by their government. On the other hand, other members have their roots uniquely in the private sector, having been set up by national partnerships of industry associations.  http://www.iso.org/iso/home.html |
| Logical Observation Identifiers Names and Codes | LOINC laboratory terms set provides a standard set of universal names and codes for identifying individual laboratory and clinical results, and allows users to merge clinical results from many sources into one database for patient care, clinical research, or management. (Source: HITSP) |
| Model Driven Architecture | Model-driven architecture (MDA) is a software design approach for the development of software systems. It provides a set of guidelines for the structuring of specifications, which are expressed as models. Model-driven architecture is a kind of domain engineering, and supports model-driven engineering of software systems. It was launched by the Object Management Group (OMG) in 2001 (Wikipedia) |
| Model Driven Health Tools | The Model-Driven Health Tools (MDHT) Project focuses on the development and promotion of model-driven Health Information standards within the standards community by providing a unified set of modeling tools for standards organizations and standard implementers to design, publish, and implement standards such as Clinical Document Architecture all from a UML model. https://www.projects.openhealthtools.org/sf/projects/mdht/ |
| Object Identifier | In computing, an object identifier or OID is an identifier used to name an object (compare URN). Structurally, an OID consists of a node in a hierarchically-assigned namespace, formally defined using the ITU-T's ASN.1 standard. (wikipedia) |
| Office of the National Coordinator for Health IT | The Office of the National Coordinator for Health Information Technology (ONC) is at the forefront of the administration’s health IT efforts and is a resource to the entire health system to support the adoption of health information technology and the promotion of nationwide health information exchange to improve health care. ONC is organizationally located within the Office of the Secretary for the U.S. Department of Health and Human Services (HHS). http://healthit.hhs.gov/portal/server.pt/community/healthit\_hhs\_gov\_\_home/1204 |
| Public Health Conceptual Data Model | The purpose of the Public Health Conceptual Data Model is to document the information needs of public health so that the Centers for Disease Control and Prevention (CDC) and its state and local partners in public health can: •Establish data standards for public health, including data definitions, component structures (such as for complex datatypes), code values, and data use; • Collaborate with national health informatics standards setting bodies to define standards for the exchange of information among public health agencies, and healthcare providers; •Construct computerized information systems that conform to established data and data interchange standards for use in the management of data relevant to public health. (cdc.gov) |
| Standards and Interoperability Framework | The S&I Framework is the mechanism by which ONC will manage the implementation of specifications and the harmonization of existing health IT standards to promote interoperability nationwide. The S&I Framework supports the entire specification lifecycle, from identifying the need for specifications through to creating/harmonizing standards and testing for compliance. The Framework functions within each phase of the specification process by coordinating efforts among public and private sector stakeholders as they work together to: develop content and technical specifications; develop reusable tools and services; and unite stakeholders around common healthcare challenges. |
| Standards Development Organizations | A standards organization, standards body, standard-developing organization (SDO), or standard-setting organization (SSO) is any organization whose primary activities are developing, coordinating, promulgating, revising, amending, reissuing, interpreting, or otherwise maintaining technical standards that address the interests of a wide base of users outside the standard-developing organization. (wikipedia) |
| Static Binding | The values in the value set are fixed until a new version of the value set is released. Extensional Value Sets are typically statically bound. When an intensional value set is statically bound, the version of the code system being used must be specified before the members of the value set can be computed. (Source: HITSP) |
| Systematized Nomenclature of Medicine- Clinical Terms | A structured nomenclature and classification of the terminology used in human and veterinary medicine developed by the College of Pathologists and American Veterinary Medical Association. Terms are applied to one of eleven independent systematized modules. (Source: HITSP) |
| Structured Product Labeling | The Structured Product Labeling (SPL) is a document markup standard approved by Health Level Seven (HL7) and adopted by FDA as a mechanism for exchanging product information. (fda.gov) |
| Terminology Binding | A formally expressible connection between an information model representation and a terminology representation of a clinical statement represented in an EHR (Source: OpenEHR) |
| Universal Modeling Language | An ISO ( International Standard) specification, graphical visualisation language for modelling objects. It's a refinement of earlier Object Oriented Design and Object Oriented Analysis methodologies. It consists of a series of symbols and connectors that can be used to create process diagrams and is often used to model computer programs and workflows. |
| Veterans Affairs Health Information Model | The VHA Health Information Model (VHIM) is the authoritative enterprise information model for Veterans Health Administration (VHA), representing the structure and content of all shared information that is exchanged across the enterprise. http://www.va.gov/VHIM/ |

1. Service Functional Model Specification, Common Terminology Services, Release 2 (CTS 2), Version 1.1 (DSTU) [↑](#footnote-ref-1)
2. Service Functional Model Specification, Common Terminology Services, Release 2 (CTS 2), Version 1.1 (DSTU) [↑](#footnote-ref-2)
3. Service Functional Model Specification, Common Terminology Services, Release 2 (CTS 2), Version 1.1 (DSTU) [↑](#footnote-ref-3)
4. HITSP Clinical Document and Message Terminology Component (HITSP C80), Version 2.0, Section 2.1.1 Value Set Metadata [↑](#footnote-ref-4)
5. <http://www.hitsp.org/#c> [↑](#footnote-ref-5)
6. <http://wiki.hitsp.org/docs/IS01/IS01-1.html> [↑](#footnote-ref-6)
7. FHA Presentation to HHS DAWG Dec 2010\_IM Project\_FHIM v1.pdf [↑](#footnote-ref-7)