

HITSP Foundations Committee Harmonization Principles and Processes

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1 Executive Summary

This document describes the harmonization principles and procedures adopted by the HITSP Foundations Committee. The HITSP Foundations Committee is comprised of several subcommittees. Those subcommittees involved with harmonization efforts are described below and are referred to in this document as “the subcommittees”.

The HITSP Foundations Harmonization Subcommittee is charged with the ongoing oversight of individual Foundations harmonization projects led by various Foundations harmonization working groups. It is comprised of representatives from each HITSP-recognized Standards Development Organization, HITSP Foundations co-chairs, and other interested parties.

The HITSP Foundations Information Interchange Subcommittee is charged with addressing standards harmonization in the area of information interchange - establishing a common information interchange format and standards-based application roles and interactions in a comprehensive dynamic model. It is comprised of representatives from each HITSP-recognized Standards Development Organization, HITSP Foundations co-chairs, and other interested parties.

Principles by which the subcommittees operate are outlined in section **3 Harmonization principles**. Processes by which the subcommittees operate are detailed in section **4 Harmonization Process**.

The harmonization process has five major stages:

- **Initiate:** Proponent of a harmonization project will present to its sponsoring subcommittee, after which a harmonization working group will be formed.
- **Build:** The harmonized artifact is built by the harmonization working group.

- **Approve:** The harmonized artifact is subjected to an approval process.
- **Publish:** Approved artifacts are published.
- **Evaluate:** The harmonization process is evaluated, and then streamlined where possible.

Principles and Processes are being iteratively tested via one or more “small scale harmonization projects”, further described in section *5.1 Small Scale Harmonization Project*.

2 Subcommittee Overviews

The subcommittees involved with harmonization efforts are described below.

The HITSP Foundations Harmonization Subcommittee is charged with overseeing individual harmonization projects led by various harmonization working groups.

HITSP Foundations Harmonization Subcommittee is addressing these components of the HITSP Foundations Terms of Reference:

- Context/Information Model - establishing a common reference information model (and subordinate models) to support clinical, public health, financial, and administrative healthcare functions.
- Terminology/Content Definition - establishing common reference terminology models and data content specifications that are integrated with the information model(s).
- Methodology- establishing a common methodology/process that all standards organizations and code set maintainers will follow to achieve standards harmonization.

HITSP Foundations Harmonization Subcommittee is comprised of:

- Representatives from each HITSP-designated Standards Development Organization (SDO).
- HITSP Foundations co-chairs.
- Other interested parties.

The HITSP Foundations Information Interchange Subcommittee is charged with harmonizing standards for the exchange of healthcare information between organizations.

HITSP Foundations Information Interchange Subcommittee is addressing this component of the HITSP Foundations Terms of Reference:

- Information Interchange - establishing a common information interchange format and standards-based application roles and interactions in a comprehensive dynamic model.

HITSP Foundations Information Interchange Subcommittee is comprised of:

- Representatives from each HITSP-designated Standards Development Organization (SDO).
- HITSP Foundations co-chairs.
- Other interested parties.

Principles by which the committees operate are outlined in section *3 Harmonization principles*.

Processes by which the committees operate are detailed in section *4 Harmonization Process*.

3 Harmonization principles

Harmonization principles that guide the subcommittees include:

- **Where prior or current parallel harmonization efforts are identified, there shall be a coordinated alignment of efforts**
 - Support and build upon Consolidated Health Informatics (CHI) recommendations.
 - Support and build upon the ANSI process and HITSP foundational principles.
 - Work with NCI, NLM, and others towards common machinery for value set maintenance.
 - Draw upon existing SDO standards development frameworks for the creation of model-based standards.
 - Support and build upon HIPAA requirements.
- **Alignment of harmonized value sets and information models is not restricted to point-to-point interactions.**
 - Alignment of harmonized value sets and information models can span the spectrum of care, from data origination in an electronic health record, to point to point communication, to data reuse, etc.
- **There is expected participation from SDOs whose content is being harmonized.**
 - An SDO will appoint representation for those domains they have content they want considered in a harmonized artifact.
 - SDOs will ensure an ongoing harmonization and the use of harmonized products in their own specifications.
 - All SDOs will have an equal opportunity to participate in standards harmonization efforts.
 - SDOs will encourage changes to HITSP charter to acknowledge the Foundations processes and harmonization products.
 - The intent is for SDOs to adopt and use harmonized artifacts, as opposed to using local codes and/or models with mappings or translations. QA of mappings or translations are the responsibility of the SDO maintaining local codes and/or models.
 - If an SDO does not support all the values, while another SDO does – if there is mapping between two standards, the SDOs must determine the rules for values not supported by both.
- **Support for SDO adoption of harmonized artifacts:**
 - HITSP Foundations Harmonization Subcommittee should minimize divergence or change from existing value sets and information models when building harmonized artifacts.
 - HITSP Foundations will help identify ways to facilitate SDO adoption of harmonized artifacts.
- **The overhead potentially incurred by cross-SDO collaboration will be minimized.**
- **For HITSP-recognized harmonized artifacts:**
 - There should be a single point where change requests can be submitted.
 - There should be a single point of reference to obtain / view harmonized artifacts.
 - There should be a single consensus process for each artifact type.
 - There should be a common representational form and style guide for each artifact type.
 - There should be a common framework for reference terminology models and a common representation of value sets. There should be semantic coherence across code systems in the common framework.
 - Artifacts that participating SDOs have agreed to harmonize will become HITSP-recognized US national artifacts.
- **Value set harmonization principles:**

- Codes for a value set should be drawn from a standard reference terminology.
 - HITSP Foundations reserves the right the add values into value sets prior to the code being added into the source code system. These would be contained in an interim US national code system (with the expectation that the interim codes are replaced once adopted by the source code system).
 - Representation of **NULL** and **OTHER** will not be addressed on a per value set basis, but may be addressed as harmonization topics themselves.
 - Extensibility (e.g. whether or not local codes can be included in an instance in addition to harmonized codes) is outside the scope of HITSP Foundations, and is a decision left to the SDO and the HITSP TCs.
 - Dynamic vs. Static considerations (e.g., whether or not an instance can include codes from a value set that were added after the relevant specification was balloted) is outside the scope of HITSP Foundations, and is a decision left to the SDO and the HITSP TCs.¹
 - There will be a uniform policy for versioning harmonized artifacts, based on a predictable frequency. The frequency may vary depending on the artifact type.
- **Information model harmonization principles:**
 - When reviewing an SDO model for harmonization, only consider those portions of the model that are within the scope of the identified use cases.
 - Where models to be harmonized have the same attribute with different constraints, a harmonized model shall be represented with the broader constraint.
 - Where models to be harmonized represent an attribute differently (e.g. date/time datatype), a harmonized model will reflect the more widely used representation.
 - A harmonized model is implementation independent (i.e. is not tied to any particular implementation technology).
 - Components of a HITSP-recognized Harmonized Information Model include:
 - Data dictionary (e.g. per ISO 11179-4 rules) that defines each component.
 - UML representation.
 - Vocabulary binding rules.
 - Uni/bidirectional mapping from a harmonized model to an SDO model is the responsibility of the SDO.
 - Information interchange harmonization principles:
 - When reviewing an SDO information interchange specification for harmonization, only consider those portions that are within scope.
 - Prefer a common information interchange syntax and format.
 - Prefer a common value set for items within the working group's scope.
 - **Work will be prioritized in various ways. The end result will be a HITSP roadmap for harmonizing information and terminology standards across SDOs.**
 - Driven by HITSP.
 - Driven by national priorities such as those specified in the Health Information Technology for Economic and Clinical Health (HITECH) Act.
 - Driven by NHINs.
 - Driven by SDOs.
 - Constrained by available resources.

- **HITSP Foundations is not a Standards developer.**

Its subcommittees are developing a process to harmonize work done within and among SDOs.

¹ Except for HITSP-defined or HITSP-harmonized models and/or implementation specifications.

4 Harmonization Process

This section describes the harmonization process used by the subcommittees. Harmonization processes are tightly coupled with harmonization principles – the two are iteratively reviewed and revised as processes are tested and refined over time.

The intent is to define harmonization processes such that they can serve as a template for a project plan for any harmonization project. All harmonization projects will be tracked with a project plan built from said template.

4.1 Initiate a project (i.e. create Harmonization Working Group)

Requests for new harmonization projects or for revisions to existing harmonization artifacts shall be presented to the appropriate subcommittee (known as the sponsoring subcommittee), who will then assist in the creation of a Harmonization Working Group. The real harmonization work is carried out by the Harmonization Working Group, following the process defined by the subcommittees. All Harmonization Working Groups are open, and the artifacts they produce will be subject to approval by HITSP-member SDOs.

NOTE: While anyone can propose a harmonization project, there are logistical factors that often determine whether or not a Harmonization Working Group will be formed. In particular, there needs to be an identifiable working group leader, and there needs to be sufficient direct participation from the affected SDOs.

NOTE: The HITSP Foundations Harmonization Subcommittee is not a standards developer. Identified terminology or information model gaps should be communicated to the SDOs. In order to ensure that identified gaps don't wind up being implemented differently by different SDOs, HITSP Foundations Harmonization Subcommittee could be a forum / model for pre-reconciliation.

- Project coordination will be managed by HITSP staff
- Sponsor of proposed harmonization project will present a draft description to sponsoring subcommittee, including:
 - Overview of project, including high level scope and need being addressed.
 - Existing code sets, if known.
 - Existing collaboration/harmonization efforts, if known.
 - Suggested actions.
 - Forward / backward compatibility issues if this is a proposed change to an existing harmonized artifact.
 - Describe the benefits of the proposed artifact(s).
- The sponsoring subcommittee will formally notify all HITSP members (all SDOs, non-SDO stakeholder organizations, governmental bodies, consumers) of an intent to harmonize and call an organizational meeting.
- The organizational meeting will be held to identify level of interest and participants. Presuming sufficient interest and SDO participants, a Harmonization Working Group will be formed. The Harmonization Working Group will further clarify the objectives and harmonized artifacts to be built.
- The Harmonization Working Group will identify a project lead (to collect use cases, to manage the project template, etc).
- The Harmonization Working Group will operate under standard HITSP committee guidelines. All meetings will be announced in advance. Key discussions, decisions and attendance will be documented. All decisions will be by consensus or failing that by two-thirds vote of members.
- The Harmonization Working Group, once formed, will report back to its sponsoring subcommittee before proceeding on to the next step.

4.2 HITSP Foundations Harmonization Working Group

4.2.1 Determine project scope

- The Harmonization Working Group will perform background research as a necessary part of scope determination.
 - In accordance with the ONC Contract, for value sets, the HITSP Foundations Harmonization Subcommittee will start with, and give priority to, the CHI recommendations.
 - Review existing HITSP referenced standards and value sets.
 - Identify HIPAA requirements
 - Review prior and current parallel efforts
 - Identify existing mappings and collaborative activities
 - Assess broad impact of various options to the SDOs.
- The Harmonization Working Group will further clarify the scope and objectives, identify use cases to be supported, and define the harmonized artifacts to be built.
 - Review relevant HITSP use cases.
 - Review relevant SDO use cases.
- The Harmonization Working Group will record their work in a HITSP Foundations project plan template.
- The Harmonization Working Group will report back to its sponsoring subcommittee before proceeding on to the next step.

4.2.2 Build harmonized artifact

4.2.2.1 Establish baseline decisions

- For value sets, determine if you're building a code system, a value set drawn from one or more existing code systems, or enhancing an existing code system or value set. This item is not necessarily applicable to pilot projects of the HITSP Foundations Information Interchange Committee.
 - What is/are the code system(s)?
 - What cross-mappings will be built?
 - Enumerated (e.g. Sex Structure, Marital Status) vs. Criteria-based (e.g. Body Structure)? (see section **5.4 Definitions** for definitions) Heuristics to guide decision making include:
 - Rate of expected change: low favors enumerate, high favors criteria-based.
 - Volume of concepts: low favors enumerate, high favors criteria-based.
 - Sensitivity/Specificity: Greater sensitivity and specificity requirements favor enumeration.
 - HITSP (e.g. Sex Structure) vs. Non-HITSP (e.g. Race/Ethnicity, MIME types, VA/KP SNOMED Problem List subset) stewardship? (see section **5.4 Definitions** for definitions) This item is not necessarily applicable to pilot projects of the HITSP Foundations Information Interchange Committee. Heuristics to guide decision making include:
 - Preponderance of use / existing steward: if everyone is already using a non-HITSP maintained value set, they may be no need to change anything.
 - Versioning requirements?
 - Display name requirements? (HITSP-recognized value sets typically harmonize on codes rather than display names. Display names from the code system(s) are typically shown with the value set, but SDOs are not bound to them. In some cases, there may be a need to harmonize both on the codes and the display names).
 - Determine the steward for the value set.
- Populate "Baseline Decisions" tab in HITSP Foundations project plan template.
- The Harmonization Working Group will report back to its parent committee before proceeding on to the next step.

4.2.2.2 Create metadata

HITSP Foundations will use the metadata documentation methodology used by the Data Architecture Tiger Team.

NOTE: HITSP Foundations anticipates that metadata will evolve over time, as the number of harmonized artifacts grow, in order to support discoverability.

- HITSP Harmonization Subcommittee assigns OIDs to artifacts (or registers pre-existing OIDs).
 - HITSP OID: 2.16.840.1.114443.
 - HITSP Foundations OID: 2.16.840.1.114443.1.
 - HITSP Foundations sex structure value set OID: 2.16.840.1.114443.1.1
 - HITSP Foundations marital status value set OID: 2.16.840.1.114443.1.2
 - HITSP Foundations body structure value set OID: 2.16.840.1.114443.1.3
 - HITSP Foundations person name use value set OID: 2.16.840.1.114443.1.4
 - HITSP Foundations person name part qualifier value set OID: 2.16.840.1.114443.1.5
 - HITSP Foundations person name part type value set OID: 2.16.840.1.114443.1.6
 -
- Populate “Metadata” tab in HITSP Foundations project plan template.

4.2.2.3 Build the artifact

- The actual harmonized artifact is built.
- Building a harmonized information model:
 - Often most efficient is to first convert source models into a canonical UML (to resolve ambiguity, to support traceability, etc), and then compare the UML models.
 - Components to build include data dictionary, UML model, vocabulary binding.
- Update “Metadata” tab in HITSP Foundations project plan template.
- The Harmonization Working Group will report back to its sponsoring subcommittee before proceeding on to the next step.

4.2.2.4 Create cross-mappings or translations

Per [principles](#), these are the responsibility of the SDO. The repository will be able to hold cross-mappings.

4.3 Approve harmonized artifact

In the process outlined below, approval of harmonized artifacts is occurring without a full membership ballot of any of the affected SDOs. This raises some logistic issues, which are addressed partially in this section, and partially in section 5.2 *Facilitating SDO adoption of harmonized artifact*.

It is recognized that changes to information model fragments can have a more significant structural impact on an SDO (e.g. may require a formal vote of the SDO in order to approve incorporation of said changes into their standard), and therefore this section lays out a general approval process, along with special considerations for different artifact types.

- What needs approval?
 - Value Sets:
 - New value sets

- Changes to enumerations in enumerated value sets where HITSP is the steward. (These changes include those arising due to changes in source code system, such as where a code in a value set is retired).
 - Changes to the criteria of criteria-based value sets where HITSP is the steward.
 - Changes to value sets with a non-HITSP steward do not require HITSP approval.
 - Information Models:
 - New models
 - Changes to the UML model, data dictionary, binding rules of existing model
 - Information Interchange Specifications:
 - Syntax
 - Format
 - Content
 - Dynamic Model items
- Upon completion of the steps outlined in section **4.2 HITSP Foundations Harmonization** Working Group, its sponsoring subcommittee will initiate the artifact approval process, which involves formally notifying the SDOs (with a response from each SDO, confirming that they have been notified) of the new artifact, and giving them a chance to comment on it.

NOTE: The guiding presumption is that the Harmonization Working Group is the authoritative source of technical harmonization. Therefore all SDOs with interest in the subject matter should participate in the working group phase. The sponsoring subcommittee may, based on input from its members and formal comments from SDOs, determine that the artifact needs further work and refer it back to the Harmonization Working Group. The sponsoring subcommittee will not make technical changes to artifacts.

- The sponsoring subcommittee will formally notify all HITSP member SDOs of its intent to publish a harmonized artifact within 60 days. These notifications will occur at a regularly specified frequency. Any SDO through its primary representative may submit a comment during this period. Such comments will be dispositioned by the sponsoring subcommittee and/or the Harmonization Working Group, until they are resolved.

NOTE: Disposition will seek to resolve the comment to the submitter's satisfaction. However, decisions will be made by consensus and failing that by two thirds approval of voting members of the sponsoring subcommittee (HITSP-member SDO representatives, HITSP Foundations co-chairs).

- Final approval of all of the subcommittees' harmonized artifacts rests with the HITSP Panel.

4.4 Publish harmonized artifact

The final publication process has not yet been determined. For now we are publishing in:

- United States Health Information Knowledgebase (USHIK) [<http://ushik.ahrq.gov>] [Contact: "Noah Stromer" <noah.stromer@gmail.com>]
- National Cancer Institute's Cancer Data Standards Repository (caDSR) [http://ncicb.nci.nih.gov/NCICB/infrastructure/cacore_overview/cadsr] [Contact: "George Komatsoulis" <komatsog@mail.nih.gov>]

Per [principles](#), there is a uniform policy for versioning harmonized artifacts of a particular type, based on a predictable frequency.

A “**release**” is a compilation of approved additions, deletions, or criteria changes to the harmonized artifact, since the prior release. The date of every change (e.g. every addition or deletion from a value set) is captured. These changes are gathered together, at a frequency to be determined, and published. Such

publication constitutes a new release of the harmonized artifact. Releases are identified by (at least) date/time.

NOTE: Value set releases will reference the current version of the source code system. This should not imply however that the value set version needs to be communicated. In fact, source code systems should adhere to good vocabulary practices (e.g. don't reuse codes, don't mutate the meaning of a code, clearly indicate retired vs. active codes) so that users can trust received codes without worrying about the value set release.

4.5 Evaluate harmonization process

Per [principles](#), HITSP needs to minimize the overhead of cross-SDO collaboration. In order to do this, HITSP should iteratively review, refine, and streamline the process. Changes to the process can be approved similarly to how artifacts themselves are approved.

- Was there a need to deviate from the defined principles or processes?
- Is there a need to modify the defined principles or process?

5 Appendix

5.1 Small Scale Harmonization Project

The subcommittees are defining a process for harmonizing artifacts across SDOs. To iteratively test and refine the process, the subcommittee is undertaking a small scale harmonization project, that has a limited scope, but that will test the end to end process.

The objectives of the project are to:

- Develop and prototype a process for harmonizing standards (both fields and vocabulary) across SDOs.
- Based on the prototype, enable a determination of level of effort and timelines for addressing other domains (building and maintaining).
- Develop a process that is scalable (e.g. that can be extended to all domains of interest).
- Develop a process that is maintainable.
- Make recommendations for organization to implement terminology standards for the United States.
- Complete the prototype and prototype analysis in 3-6 months.

Because the objectives of the small scale harmonization project are as much about process as about product, the initial domain will be very limited. The intent is to iteratively develop a sustainable process that results in a harmonized product that SDOs will use in the construction of their own standards. By keeping the initial domain very limited, we should be able to explore a number of process options without getting bogged down in detailed mapping exercises.

- Model
 - Name
 - Date of birth
 - Marital status
 - Gender
- Terminology
 - Marital status
 - Gender
 - Procedure body site
- Information Interchange

- A query/response interchange
- A provider directory service specification
- Methodology / process
- Organizational requirements to implement method and process.

5.2 Facilitating SDO adoption of harmonized artifacts

It should be noted that while the subcommittees facilitate the development of harmonized artifacts, it is outside the subcommittees' scope to enforce SDO adoption of such artifacts or implement an adoption timeline. Rather, in an effort to facilitate adoption, the subcommittees, in collaboration with SDOs, have developed this section, which we believe will ultimately be pulled out and used as the starting point of a HITSP-wide document that delves into adoption strategy in more detail.

It should also be noted that harmonized artifacts often represent a target, where an interim and/or migration strategy may be needed before they can be adopted, either by an SDO, or within a HITSP Interoperability Specification. The demographics information model fragment illustrates this point in that, for instance, it differs from demographics representation in HITSP/C32. It is anticipated that future SDO specifications will evolve towards the harmonized artifact, leading HITSP ISs there too.

5.2.1 Things HITSP can do to facilitate adoption

- Ensure that the harmonized artifact meets the requirements for the stated use case, and addresses the requirements of the participating stakeholder SDOs.
- Provide adequate time to vet proposed changes within an SDO before seeking their approval.
- Use harmonized value sets in HITSP Interoperability Specifications.
- Establish collaboration between HITSP Foundations and HITSP IRT to proactively identify and harmonize artifacts so that cross-HITSP discrepancies are avoided in Interoperability Specifications.
- Support multiple value sets where necessary to support legitimate divergence of use cases.
- Ensure that a clear forward / backward compatibility statement accompanies a change request for an existing harmonized artifact.
- Request periodic reports from the SDOs regarding progress towards and obstacles thwarting adoption.
- Provide a single point of reference where implementers can grab harmonized value sets.
- Define a prioritization process for creating harmonized artifacts that reflects real world needs. (For instance, work on existing overlaps already present in existing HITSP Interoperability Specifications).
- Where a reference terminology serves as the source terminology for a HITSP-recognized US Realm value set, establish a service level agreement with the source terminology that addresses:
 - Value set maintenance process (e.g. based on revisions to the source terminology);
 - Value set publication process;
 - Resolution of mapping gaps and ambiguities (e.g. to support the needs of an SDO transitioning from their existing code system).
- Provide a transition plan for the industry to move to a common information interchange format.

5.2.2 Things an SDO can do to facilitate adoption

- Consider a harmonized artifact as a target that should be adopted over time.
- Inconsistencies with the harmonized artifact, or additional SDO requirements not met by the harmonized artifact, should be raised with HITSP Foundations as a change request.
- When binding a field in an SDO specification to a HITSP-recognized US Realm value set, consider a DYNAMIC binding, so that the value set can evolve without the need to re-ballot the SDO specification.
- Interim/transition strategies include
 - Publish SDO-sanctioned mappings and translations from the SDO artifact to the HITSP-recognized US Realm artifact as part of the SDO specification.

- Use a constrained view or a subset of a harmonized artifact. In this case, it will help to also publish SDO-sanctioned "down-translation" rules. For instance, if a HITSP-recognized US Realm value set has 10 codes and an SDO is only using 7 of them, when mapping to the SDO specification from some other standard, the SDO can give guidance around what to do with the other 3 codes – map them to null, roll them up to one of the 7, etc.
- Where the SDO is using model components or values not present in the HITSP-recognized US Realm artifact, it will help to publish SDO-sanctioned bi-directional mapping rules. In addition, the SDO should bring new requirements forward in an effort to resolve inconsistencies.

5.3 References

- CHI Demographics recommendations
[http://www.whitehouse.gov/omb/egov/documents/demo_full_public.doc]
- CDC/NIH/Federal collaborations [Tim Morris Director of Shared Services at the CDC.
tom1@CDC.GOV].
- NCI CaBIG: [<http://cdebrowser.nci.nih.gov/CDEBrowser/>]
- OASIS Code List Representation [<http://www.oasis-open.org/committees/codelist>]
- USHIK : [<http://ushik.ahrq.gov>]

5.4 Definitions

- **Application Role:** A collection of communication responsibilities intended to be implemented as an atomic group. Communication responsibilities are identified as the interactions that the system is able to send or receive.
- **Coding system:** A coding system is a scheme for representing concepts using (usually) short concept identifiers to denote the concepts that are members of the system; defines a set of unique concept codes. Examples of coding systems are ICD-9, LOINC and SNOMED.
- **Dynamic model:** A framework for specifying the event triggers, application roles, and interactions of information interchanges.
- **Envelope:** A wrapper that completely encloses data for distribution; it typically includes information about the sender and recipient, the specific standard and version of the payload
- **Event trigger:** The real world event that initiated an information interchange
- **Harmonization Working Group:** A group of people working on a HITSP Foundations harmonization project. (See section *4.1 Initiate a project (i.e. create Harmonization Working Group)* for details).
- **Harmonized artifact:** A harmonized artifact is any unit of consensus that is the focus of a Harmonization Working Group project. Artifacts include value sets, information model fragments, information interchange formats, etc.
- **Information interchange:** The electronic exchange of data (in a standard format) between two systems
- **Information model fragment:** An information model fragment is a portion of a larger reference information model that is the subject of Harmonization Working Group activities. Typically,

Harmonization Working Groups will harmonize on small models, but each of these small models retain the ability to be coalesced into a larger unified reference information model.

- **Interaction:** a single, one-way information flow that supports a communication requirement expressed in a scenario; identifies the abstract structure of message content exchanged between sending and receiving application roles
- **Integrated vs. Federated terminology:** These terms refer to the spectrum of harmonized terminology solutions used to fulfill interoperability requirements, where on the one side (the “integrated” side) there is a single code system, managed by a single organizational entity, from which all subsets are drawn, and on the other side (the “federated” side) there are multiple code systems that in total fulfill the requirements. The federated code systems are independently maintained, but ideally work closely together in an effort to manage redundancy and consistency. **Semantic coherence** across the code systems in a federated network factors heavily in to the ability to integrate, where the more divergent the code system models, the more complex and costly the integration.
- **Release:** A release is a compilation of approved additions, deletions, and/or criteria changes to a harmonized artifact, since the prior release. These changes are gathered together, at a frequency to be determined, and published. Such publication constitutes a new release of the harmonized artifact. Releases are identified by (at least) date. (See section **4.4 Publish harmonized artifact** for details on release management).
- **Standards Development Organization (SDO):** One of four categories of HITSP membership, as defined in the HITSP Charter, Jan 5, 2006. HITSP membership categories include (a) “Standards development organizations” (SDOs); (b) “Non-SDO stakeholder organizations”; (c) “Governmental bodies”; (d) “Consumers”.
- **Steward:** The governing body having the right to accept or reject proposed changes to a harmonized artifact. HITSP or a non-HITSP organization can be a steward.
- **Value set:** A vocabulary domain that has been constrained to a particular realm and coding system.
 - An **ENUMERATED** value set (aka an **EXTENSIONAL** value set) is one that is comprised of an explicit listing of the set of codes. Versioning occurs if values are added or deleted. SDOs typically have **STATIC** bindings to **ENUMERATED** value sets.
 - A **CRITERIA-BASED** value set (aka an **INTENSIONAL** value set) is one that is defined by a computable expression that can be resolved to an exact list of codes (e.g. “all SNOMED CT concepts that are descendants of the SNOMED CT concept Diabetes Mellitus”). Versioning occurs if the criteria changes. SDOs typically have **DYNAMIC** bindings to **CRITERIA-BASED** value sets.
- **Value set binding:** Specifies the relationship between a field in an SDO’s specification and a referenced HITSP-recognized US Realm value set.
 - A **STATIC** value set binding relates a field in an SDO’s specification to a particular version of a value set.
 - A **DYNAMIC** value set binding relates a field in an SDO’s specification to a particular value set, without mention of a particular version.
- **Vocabulary domain:** The set of all concepts that can be taken as valid values in an instance of a coded attribute or field; a constraint applicable to coded values.