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|  | Office of the National Coordinator for Health IT  Federal Health Architecture  Program Management Office |
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| FHA Federal Health Information Model  Terminology Modeling Process | |
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1. Background

This document describes the process of developing terminologies to support the Federal Health Information Model (FHIM). The FHIM, described at FHIMS.org, is a model of health information designed to support the development of interface specifications that allow communication among federal agencies and their partners. It presents a conceptual model of health information—i.e., not specific to any single technology or platform—but it also includes features that support the generation of technology-specific, implementable specifications.

1. The FHIM and Terminology Modeling

The FHIM specifies data types for each element it contains. If an element is a “coded” type, then it is incumbent on the FHIM to specify the set of values that are valid for use in that element—states of the union in an address form, for instance, or race categories for demographics. Where possible, these values are chosen from standard terminologies in order to ensure the widest possible population can understand the terms—whether because they are already known or because the standards are publicly available for reference. Standard terminologies are a necessary foundation for comparable and interoperable data, which are key requirements for today’s increasingly integrated federal health information environments.

The role of the Terminology Modeling (TM) project is to support the FHIM modeling effort by defining terminologies to support enumerated concepts in the FHIM, whether by identifying existing terminologies, modifying existing terminologies, or developing new terminologies. The information and terminology modeling efforts will collaborate closely, and their coordination requires agile and flexible processes.

In its supporting role, FHIM terminology modeling activities also serve as a forum for the harmonization of terminology requirements among a diverse FHA partner community. After federal health organization requirements are collected and interpreted, they are published to federal participants and standards development organizations. The organizations provide feedback, including terminology content clarifications, to the terminology modeling process. This process often requires adjustments to the semantics of the element, and can cause structural changes to the information model. This is why it is critical to conduct information and terminology modeling in concert.

The TM project will also provide a specific avenue for coordination with standards development organizations (SDOs). When needs are identified that are not met by existing standards, the TM team will present these needs to the appropriate SDO for resolution.

1. Process Objectives

Clarify and Confirm Model Semantics

For each coded property, a value set is needed that meets the requirements of the federal agencies and their partners. There is often ready consensus on the values that are needed. There are also many cases where consensus is harder to reach, for a variety of reasons

1. Fields are sometimes defined imprecisely, whether because their use has been imprecise or because the users rely on tacit knowledge.
2. Different agencies may have different understandings of the requirement. This may mean there are actually two requirements, or one more general requirement may subsume the other.
3. Agencies may need different levels of granularity in their concept codes, in which case the FHIM will represent the superset of both needs.
4. Sometimes, divergent understandings of a requirement result from a need that is specific to one agency. In these cases, because the FHIM is an interoperability specification, elements that are needed by only a single agency are removed from the model. Elements that are needed for interoperability but might be mistaken for an internal element are annotated to avoid confusion.

Provide values for use in FHIM-supported interactions

Once semantic values are identified, the team attempts to find an existing value set that provides these values, or a code system from which such a value set could be constructed. Failing that, values are proposed to the appropriate code system steward.

Maximize use of standards

As noted above, it is incumbent on the team to use existing standards where possible. The team begins its search with the value sets and code systems specified in the *HITSP Clinical Document and Message Terminology* (C-80, available at hitsp.org). If a system is deemed appropriate but lack values, the team may engage the system steward to add missing values. If this process requires more time than is convenient, the team may also adopt a non-standard value set in the interim.

Define value set properties

In addition to the values themselves, the team must document information about the value set, including human-readable and sometimes machine-readable definitions of the set, examples and usage notes, licensing caveats, provenance (source system, possibly value sets considered for use), and publication information (stewardship, dates, status). A list of these elements is provided in *Appendix B*.

Finally, the team also needs to specify facts germane to how the data element is associated, or “bound” to the value set.

Binding properties:

1. Whether a binding is static or dynamic – Dynamic binding means that when the value set membership changes, such as when updated due to a code system version change, the value set used in the model reflects that change. Static means the model only uses the value set as defined in the specified value set version, and it cannot change.
2. Whether a binding allows exceptions – whether codes other than those included in the value set may be used
3. Whether an element is nullable – whether an empty value is acceptable
4. Appropriate null values – whether, if empty, a value can still communicate “flavors” of null (“other,” “not applicable,” etc.)
5. Whether a coded element might support, in addition to the standard label or designation, some other textual representation (e.g., “original text” or “displayed text”)
6. The FHIM Terminology Modeling Process

Roles

### IM Project Team

Information modeling team, consisting of domain subject matter experts, requirements analysts, and modelers. Duties include ensuring domain requirements are represented clearly for all known interoperability use cases.

### Partners

Partners include federal agency representatives as well as representatives from agency partner organizations. This task is for representatives unable to attend FHIM meetings.

### Terminology Modeling Team

Terminology modeling team, consisting of domain subject matter experts, requirements analysts, information modelers, and terminologists. Duties include ensuring that coded elements are appropriately scoped and that selected terminologies support interoperability requirements.

### VSAC Team

NLM resources responsible for maintenance and provision of the Value Set Authority Center terminology service.

### Terminology Modeler

Modeler duties include turning requirements defined by subject matter experts into implementable value sets and ensuring they are bound appropriately to the FHIM model elements.

### SDO

The Standards Development Organization responsible for defining content in a terminology system.

Terminology Authoring Process



1. Authoring Process

### G1. Prioritize Domain

Partners provide input to ONC on domain priority & sequence.

### G2. Conduct Domain Modeling Meeting

Information modeling team conducts a series of meetings to identify requirements and model the data in the FHIM.

### G3. Identify coded property

FHIM team identifies certain properties as needing encoded value ranges.

### G4. Provide property requirements

Information modeling team provides requirements for the coded element, including definition, values or example values, rules, and use cases.

### G5. Provide feedback on concept boundaries and modeling approach

The terminology modeling team assesses the requirements and ensures the request is appropriate. Alternatives might include alternate types (might it really be an ID rather than a code) or boundaries (perhaps this is two values, or perhaps two proposed values should be one).

### G6. Change Model?

If the Terminology Modeling team suggests a change to the model, the Information Modeling team will consider it.

### G7. Provide high-level analysis

The Terminology Modeling Team provides additional analysis or perspective on the requirements. This input may include a name, concept domain definition, examples, and candidate value sets or systems.

### G8. Compose scope definition & identify system

The Terminology modeler takes the requirements identified by the Information and Terminology Modeling teams and composes the core metadata elements of name, OID, scope definition, and target terminology system.

### G9. Confirm scope & system

The Terminology Modeling Team confirms the Terminology Modeler's proposals.

### G10. Agreed?

If the team disagrees, the modeler will revise the proposals.

### G11. Assess candidate assets

The modeler identifies the best candidate to meet the requirements. In addition to specific recommendations from the team, sources will include HITSP C80 VSAC, FHIR, USHIK, UMLS, PHIN VADS, NCI, and HL7 V2, V3, & FHIR.

### G12. Select best solution

The modeler selects an existing value set, existing value sets to be grouped into a superset, values from existing systems, or concepts not yet represented in any appropriate system. If the selection is an existing value set, it may be referenced (e.g., by a pointer to PHIN VADS or NCI). New value sets will be, encoded in VSAC if possible, or drafted in VSAC Collaboration if not.

### G13. Terminology Team Review

The Terminology Modeling Team reviews the modeler's proposal.

### G14. Approved?

If the Terminology Modeling team approves, the solution is proposed to the Information Modeling SMEs.

### G15. Recommend changes

If the Terminology Modeling Team does not approve, specific changes will be requested.

### G16. Make changes

The modeler implements the suggested changes.

### G17. FHIM Team Review

Once the Terminology Team approves the solution, the Information Modeling SMEs will also review it. Review will take the form of at least two meetings: one to orient SMEs to proposals and identify issues, one to approve the final publication, and intermediate meetings depending on the degree of consensus.

### G18. Approved?

If the Information Modeling Team approves the solution, the value set may be published.

### G19. Recommend changes

The FHIM team provides recommendations for changes.

### G20. Domain completion

If the domain is complete, it may be published for federal review.

### G21. Federal review

The value set is distributed as part of a domain publication for review by federal agencies and partners. If the value set has been published, this review will reference the publication site. Otherwise, the value set will have to be provided in the review materials.

Note that all agencies are invited to participate on FHIM calls & on the reviews at steps G13 and G17. Step G20 is a "backstop" review for stakeholders unable to attend these meetings.

### G22. Feedback?

The partners may have substantive feedback that requires the modification of a value set.

### G23. Process Complete

Terminology Specification Process



1. Specification Process

### S0. Begin specification

### S1. Approve description & name per G10

Terminology Modeling group approve draft name and scope description.

### S2. One VS or many?

Some coded elements may require more than one value set, e.g., for grouping value sets.

### S3. Handle each component value set

For each value set, follow the specification single path.

### S4. Create grouping value set

Once component value sets exist, create a grouping value set to contain them.

### S5. Existing VS or new?

Determine whether an existing value set meets the identified requirements.

### S6. Create value set in VSAC

Begin VSAC authoring process with OID, name, scope, and system.

### S7. Is system in VSAC?

Determine whether code system needed to support value set is available in VSAC.

### S8. Request code system

Request that VSAC implement the code system. This may involve securing permissions and/or content.

### S9. Add code system

VSAC adds the code system, supporting use of its contents in creating value sets.

### S10. All values encoded?

Determine whether all needed values are available in identified code system.

### S11. Approved per G14

Only request values from code system stewards if values have been approved by terminology team review.

### S12. Request values

Request that the code system steward or SDO add the required values.

### S13. Able to provide values?

Is the code system steward able to supply the requested values?

### S14. Provide values

The steward adds the needed values to the system.

### S15. Provide feedback

The code system steward informs the FHIM team why the values cannot be provided.

### S16. Manage feedback

The terminology team addresses or escalates issues as necessary.

### S17. Compose value set in VSAC

Use VSAC authoring tools to define value set.

### S18. Approval to publish per G18

The FHIM Terminology and Information modeling teams approve the value set for publication.

### S19. Publish value set in VSAC

Publish the value set in VSAC.

### S20. End of process

### S21. Is existing VS sufficiently documented?

Identify value set metadata & any extant gaps.

### S22. Document linkage; bind to provided URI

Bind the FHIM data element to the identified value set.

### S23. Escalate issue for interagency management

Encourage stewards of value sets to complete value sets documentation support for standards reuse.

Element Binding States

The following states can be inferred for the FHIM element binding. This is separate from the state of the value sets, which may pre-exist the element or may be created to support an element.



Value Set States

These are the states through which value sets move during the authoring process. Note that the early states do not distinguish whether an existing value set might be adopted. Once the content is approved, the team decides whether to create a new set or adopt an existing one.



Metadata per state

The following metadata elements should be agreed to pass milestone G10 and reach state “Definition agreed.”

* name
* definition
* default system name
* default system oid
* examples

The following metadata elements should be agreed to pass milestone G14 and reach state “Value set approved by IM team.”

* intensional definition (if intensionally defined)
* values (if extensionally defined)
* assigning authority
* binding stability
* binding strength

The following metadata elements should be agreed to pass milestone G14 and reach state “Value set approved by IM team.”

* effective date
* publication status
* url
* publication date
* publication status date

1. Appendix A: Terminology Policies

The following continue to develop. They were captured on 11/19/2013 from the FHIM Wiki, at <https://www.projects.openhealthtools.org/sf/wiki/do/viewPage/projects.fhims/wiki/HomePage>.

1. FHIM values sets shall be implementable.
   1. Publication shall be extensional. Intensional definitions may be used for authoring.
   2. They shall be provided to implementers via an open and accessible interface.

*This has been PHIN VADS (phinvads.cdc.gov/), but we plan to begin using VSAC (vsac.nlm.nih.gov) when it is available..*

1. FHIM values sets shall follow standards where possible.
   1. The authors shall document preferred systems for domains, starting with HITSP C-80.
   2. Clinical concepts shall be taken from SNOMED CT, or a SNOMED CT extension.
      1. Where we modify an existing value set that does not use SCT, we will migrate the included contents into SCT.
2. FHIM values sets shall be versioned.
   1. Following PHIN VADS practice, a value set shall have a single OID, and versions shall have serial numbers.
      1. Proposed scheme: use the OID for dynamic assignment, and append the version number to the OID for static assignment. This may work internally, but it may not be consistent with CTS2.

*This approach may not support other key platforms, and is subject to change.*

1. FHIM may use externally defined value sets, but they will be managed as external value sets.
   1. Sets maintained by other organizations may meet our requirements. We may choose to bind to these value sets statically, in order to avoid uncontrolled change, or dynamically, in order to leave the burden of maintenance to the external group.
   2. Externally maintained sets that partially meet our requirements may be leveraged in the authoring process, but the resulting set is a FHIM value set. No linkage to its source is required, except as a historical record of the authoring process.
2. Dates
   1. We go beyond the HITSP recommendation and adopt the ISO 8061 specification, recording dates as text strings of the form "YYYY-MM-DDThhmmss,ff” (see <http://en.wikipedia.org/wiki/ISO_8601> for more information).
3. Completeness
   1. Some value sets may not be complete. These will be useful as examples, or as “starter sets.” They will be clearly identified.
4. Relationships
   1. Properties may require different subsets of the value domain in different use cases. If there are no structural differences in a property in the different cases, the information model will represent a single property, which will have a single value set. This value set will contain values for all contexts or use cases.
      1. There may be cases (e.g., microbiology labs requiring "microorganisms" not "species") where a new class is desirable despite a lack of structural difference.
      2. For supersets, subsequent modeling efforts (e.g., messaging guides) may further constrain these value sets.
      3. We will investigate the possibility of subsetting value sets in an MDHT formalism that recognizes context or use.
   2. Other relationships (other than subsets) are delegated to the source system.
5. Stewardship
   1. As steward, FHIM will prepend PHIN VADS “codes” for value sets with “FHA,” for “Federal Health Architecture.”
   2. FHIM value sets will be given OIDs from the FHA root.
6. Backward compatibility
   1. Backward compatibility is a valuable property, but the FHIM is modeling the future state, and will not be constrained to current patterns where those patterns don’t meet requirements.
   2. Where backward compatibility can be achieved without compromising other design principles, it will be supported.
7. Mixing systems
   1. A value set shall draw concepts from a single code system.
   2. In cases where values from different systems are required in different use cases, a “grouping” value set will include value sets constructed from the respective systems. Use cases may constrain the binding to a specific member value set.
8. Null values
   1. Null values are values from the Null values system, and will not be included as proper values in FHIM value sets.
   2. "Nullable" is a property of the information model, to be captured during IM analysis.

*Whether null flavor values are part of a coded datatype or represent another element—and therefore whether the TM group is responsible for defining allowable values—is TBD*

1. New values
   1. FHIMS will use an FHA Extension of SNOMED CT as the preferred venue for publishing new clinical concept codes, where the domain is appropriate. [Probably via NLM, not a FHIM-managed extension]
2. Status
   1. Unless otherwise indicated, status shall follow the HL7 V3 state machine. Refinements may be supported in a domain-appropriate status modifier.
3. Extensibility
   1. Extensibility is a model binding property, not a value set property.
   2. We prefer to model the value sets broadly, and have implementers map to the standards, than to allow locally defined codes.
4. Value set names
   1. Value set names shall represent the semantics of their content. Names of applications or programs will only be used when the rationale for selection is unknown.
   2. When a FHIM value set is based on another value set, the existing name will be preserved if it doesn’t break other policies
5. Appendix B: Value Set Data Elements

These elements are captured for each value set defined. Not all are required, and sets that have not been published may not have values in several fields relating to the publication process. Publication is limited to those elements supported by the publication platform (PHIN VADS or VSAC). Equivalent elements from the Model Driven Health Tools (MDHT) platform, CDC PHIN VADS site, HITSP C-80 document, and CTS2 specification are listed.

| **Group** | **Property** | **Definition** | **MDHT** | **PHIN VADS** | **HITSP** | **CTS2** |
| --- | --- | --- | --- | --- | --- | --- |
| Definition | valueSetDefinition | text definition of value set semantics | definition | description | Definition | ValueSetCatalogEntry.resourceSynopsis |
| Definition | valueSetExamples | a set of 3-5 example values to illustrate the description |  |  |  |  |
| Definition | valueSetIntensionalDefinition | formal intensional definition of set |  |  |  | ValueSetDefinitionEntry |
| Definition | valueSetType | Intensional, enumerated or grouping | type |  | Type |  |
| Definition | valueSetView | guides or domains for publication |  | views |  |  |
| Identification | valueSetId | OID for value set |  |  | Identifier | ValueSetCatalogEntry.about |
| Identification | valueSetName | human-readable name of value set | fullName | Name | Name | ValueSetCatalogEntry.valueSetName |
| Identification | valueSetVersionNumber | serial integer to append to value set OID | version | version | Version | ValueSetDefinition.documentURI |
| Publication | valueSetFileUrl | URL for value set in PHIN VADS |  |  | URL |  |
| Publication | valueSetVersionEffectiveDate | version effective date (YYYYMMDD) | effectiveDate | version effective date | Effective Date | ValueSetDefinition.officialActivationDate |
| Publication | valueSetVersionExpirationDate | version expiration date (YYYYMMDD) | expirationDate | version expiration date | Expiration Date |  |
| Source | sourceValueSetComment | explanation of FHIM divergence from source set |  |  |  |  |
| Source | sourceValueSetName | name of the value set on which the FHIM set is based |  |  |  |  |
| Source | sourceValueSetOID | OID of the value set on which the FHIM set is based |  |  |  |  |
| Source | sourceValueSetVersion | version of the value set on which the FHIM set is based |  |  |  |  |
| Source | valueSetDefaultSystemName | name of default system for value set | codeSystem |  | Code System Name |  |
| Source | valueSetDefaultSystemOID | OID of default system for value set | codeSystem |  |  |  |
| Source | valueSetAssigningAuthority | text name of authority defining value set | source |  | Source |  |
| Usage | valueSetGroup | [multiple] tag for grouping (by domain, use, organization) |  | PHIN vocabulary groups | Purpose |  |
| Usage | valueSetLicenseRequirements | text license requirements for value set |  |  |  |  |
| Usage | valueSetUsageNotes | special cases or conditions of use |  |  |  |  |
| Usage | valueSetVersionCompleteness | "complete" or "incomplete" |  |  |  |  |
| Workflow | valueSetVersionProcessingStatus | status for purpose of FHIMS: in process, FHIM review, SME review, CDC review, published, withdrawn | status |  |  |  |
| Workflow | valueSetVersionProcessingStatusDate | date on which status is assigned | statusDate |  |  |  |
| Workflow | valueSetVersionPublicationComments | note to accompany release |  | version description |  |  |
| Workflow | valueSetVersionPublicationDate | version publication date (YYYYMMDD) | revisionDate |  | Revision Date | ValueSetDefinition.officialReleaseDate |
| Workflow | valueSetVersionPublicationStatus | status as published in PHIN VADS: proposed, published, retired |  | version status | Status | ValueSetCatalogEntry.status |
| Workflow | valueSetVersionPublicationStatusDate | date on which status is assigned |  | version status date |  | ChangeDescription.changeDate |

Note: Three HITSP-defined properties are not included.

* Binding: this is independent from the value set, as one value set may be bound to multiple model elements.
* Creation Date: we have effective and publication dates, and internally we have status dates. “Creation” was not an event of interest.
* Code System Source: meaning unclear.