

5.7 Other Functional Requirements

This section lists other functional requirements from the community that have not been directly traced up to a use case. Service capabilities have not been derived from these requirements at this time. These requirements are part of the Semantic Infrastructure 2.0 Roadmap and will be prioritized according to strategic objectives of CBIIT and resource availability. The following areas are included:

- [Tools Artifact Search and Access](#)
- [Tools Artifact Authoring](#)
- [Artifact Governance and Lifecycle Management](#)
- [Artifact Analysis](#)
- [Search and Access Services](#)
- [Administer Services and Specifications](#)
- [Analyze Services](#)
- [Plug-ins, Loaders and Miscellaneous Development Tools](#)
- [Forms Editor](#)
- [Knowledge Manager](#)

Tools Artifact Search and Access

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Search for content to include in a model or form by leveraging the existing semantic structure of the ISO 11179 data elements to find related or similar items.

Download data element and form artifacts in various formats: XML, Excel, Resource Description Framework (RDF).

Retrieve a model in UML, XML/XMI, or Web Ontology Language (OWL) format.

Tools Artifact Authoring

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Create ISO 11179 data element from concepts and Value sets in Reference Information Model (RIM) or other terminology.

Add metadata to existing item to reflect context of use, such as alternate names or definitions, reference documents.

Ability to add or modify assertions of equivalence between items such as asserting that an existing common data element (CDE) is equivalent to a RIM-based data element.

Extend existing models.

Add semantic annotations to services.

Constraining and extending models will be in accordance with user defined business rules.

Artifact Governance and Lifecycle Management

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Allow curators to set the status of forms according to user defined business rules.

Allow curators to set the status of data elements according to user defined business rules.

Perform impact analysis when changing a data element, value set or model to see where it is used and determine if other changes to other artifacts are needed.

Artifact Analysis

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Support comparison of models in easy to use user interfaces.

Support comparison of value sets and alignment of like items.

Support comparison of forms so users can compare items side-by-side (Question by question).

Support comparison of ISO 11179 data elements.

Search and Access Services

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Search for a service by finding those that contain particular models or parts of models (classes, associations, data elements, value sets or concepts) by name or identifier.

Administer Services and Specifications

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Annotate service descriptions with data and service semantics to support search and discovery across services, such as finding a service that supports registering a patient on a clinical trial, or creating a new protocol.

Validate conformance to a particular model including analysis of whether class definitions, associations and concept annotations are consistent with the base model.

Extend existing services to include newly created model, forms or data elements.

Analyze Services

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Execute service queries to find services that can be combined, where the output of one service is an appropriate input to another.

Execute service queries to find services that transform data from one format into another input format matching that required for use with another service.

Plug-ins, Loaders and Miscellaneous Development Tools

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Support loading of data elements and value sets from Excel spreadsheets and ensure there is no duplication with existing content.

Support deriving data elements and value sets from Excel spreadsheet data.

Forms Editor

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Allow curators to create and manage collections of downloadable forms.

Export forms in Clinical Document Architecture (CDA) format.

Export forms in Operational Data Model (ODM) format.

Export forms in caDSR-compatible format so that vendors who have made their product compatible with caDSR forms can still use caBIG® forms in their systems.

Import forms from caDSR format so users can add RIM-derived data elements to existing forms.

Allow curators to organize questions on forms and value sets according to the workflow defined by an existing institutional form.

Allow curators to copy forms to create new form content.

Allow curators to reuse Question/Answer sets from form to form.

Allow curators to reuse and manage modules independently of forms.

Allow curators to download forms in XML or Excel format.

Allow curators to specify default values for questions.

Allow curators to specify repeating groups of questions.

Provide a platform-independent export of the form so that it can be consumed by other forms software.

Include the meaning of each of the values in the value set on the form.

Allow curators to record what token is being persisted in the data for a particular value set which could be different from the values in the value set, for example record a Medical Dictionary for Regulatory Activities (MedDRA) Code associated with a particular Common Terminology Criteria for Adverse Events (CTCAE) term.

Provide notification when viewing a form if the data element or value set has changed since the form was created.

Allow curators to monitor changes to forms.

Provide search for forms that use a particular model.

Provide search for forms that use a particular value set.

Provide search for forms that use a particular value or set of values.

Provide search for forms that use a particular data element.

Provide search for forms that use a particular set of class associations.

Provide search for forms that use a particular module.

Provide search for forms that collect data dealing with a particular RIM class or terminology concept.

Provide the ability to support complex ISO 21090 datatypes on forms so that the values needed to populate the attributes of the datatypes can be captured.

Provide support for questions on forms that are based on a calculation or derivation from other questions on the form.

Provide information and ability to search Forms based on the form owner, dates created or modified and by whom modified.

Provide search for forms using a particular class or set of classes.

Provide the ability for curators to search for forms in all workflow statuses, but hide draft content from the casual user (for example, ability to "Publish" or "Not Publish" forms).

Provide the ability to search for forms that are part of a particular protocol.

Provide the ability to search for forms that pertain to a particular trial type.

Provide the ability to print the form.

Provide the ability to view the form as it will look when rendered.

Provide the ability to attach reference document to the form.

Provide the ability to include form, module and question instructions on the form.

Provide the ability to specify whether form contents are mandatory, optional or conditional.

Provide the ability to author new question text or use standard question text.

Provide the ability to search for forms that pertain to a disease.

Provide the ability to transform spreadsheet data into RDF stores.

Knowledge Manager

[Link to related Semantic Infrastructure 2.0 Roadmap page](#)

Provide the ability to transform models represented in ISO 11179 into RDF stores.

Provide the ability to transform relational databases into RDF stores.