

# CDISC SHARE Requirements Summary

SUMMARY OF CDISC SHARE REQUIREMENTS

NOVEMBER 2011

PREPARED BY THE CDISC SHARE LEADERSHIP TEAM

BASED ON REQUIREMENTS DOCUMENT  
VERSION 0-4, JANUARY 2011

# CDISC SHARE Requirements Summary

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# CDISC SHARE Requirements Summary

## 1.1 Introduction

This document is a high level summary of requirements collected for the CDISC Shared Health and Clinical Research Electronic Library (CDISC SHARE) in the document titled, “CDISC Share Requirements”, version 0-4, January 15, 2011. The purpose of this summary is to give readers a sense of what the metadata repository contains, and the workflow behind the administration and curation of content.

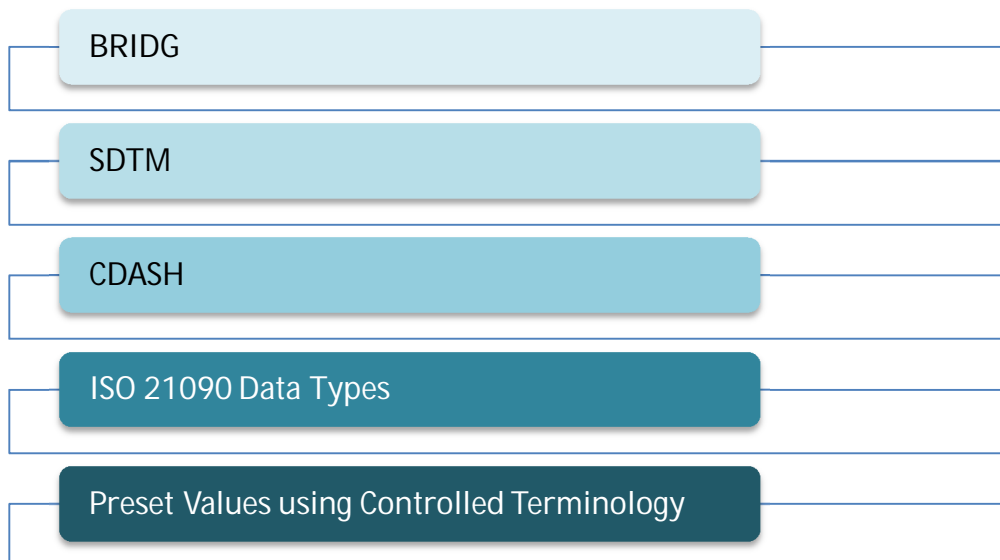
## 2.0 Requirements Related to the Metadata Model

The metadata model is the core of the CDISC SHARE system. The model will permit the range of content that CDISC has developed to be represented in a machine-readable form that can be exported into other systems. The metadata model mandates the use of the BRIDG Clinical Research Domain Analysis Model and ISO 21090 data types.

The CDISC SHARE model is described in the metadata model document titled, “CDISC SHARE Metadata Model, version 0-1, May 7, 2010”. The system will ensure that all content is consistent with the model and maintain them accordingly.

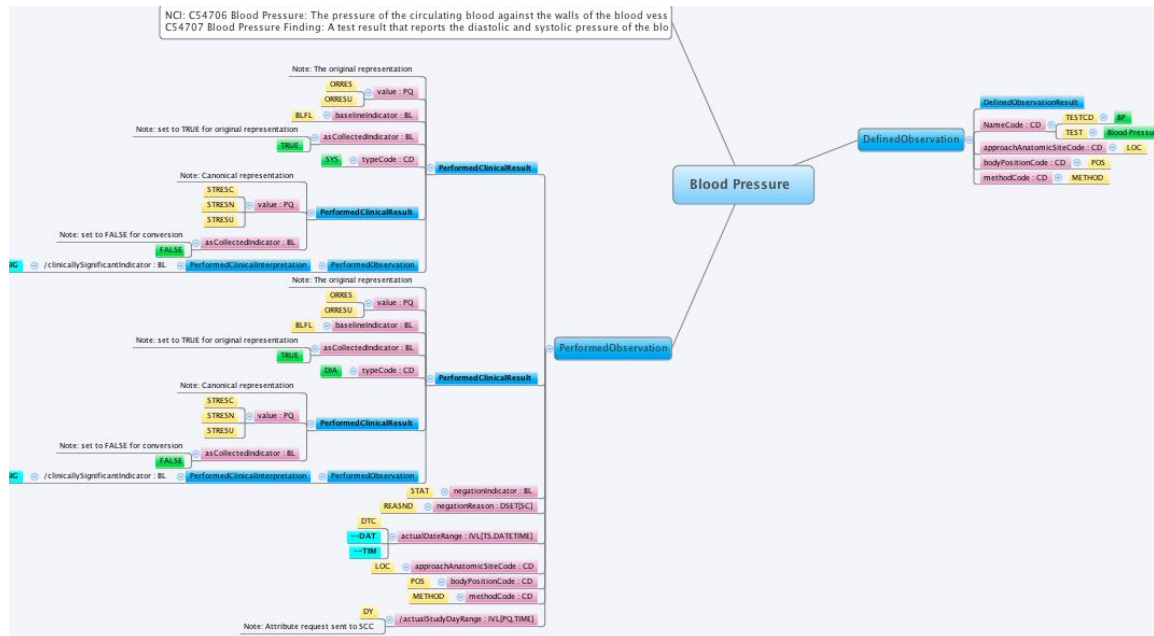
### 2.1 CDISC Share Metadata Model

The model is comprised of the following elements: the SDTM variable name, the CDASH variable name, SDTM, BRIDG mappings, and ISO 21090 data types.



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These metadata elements are linked to one another in groups called CDISC research elements. This linking and grouping is illustrated in the mind map below.



## 3.0 Requirements Related to User Management

CDISC SHARE must support effective security and appropriate roles to protect content. The CDISC SHARE system is envisioned to support multiple users and allow each user to be allocated one or more User Roles. At least one user with administrative rights (System Administrator role) will be maintained at all times. New users will be created and can be deleted within the system by the System Administrator. The system will allow a user to self-register and these self-registered users will have only Read-Only access initially. The system will ensure that spam users are not created. The system will allow a user with the System Administrator role to assign a role to a user.

### 3.1 Requirements Related to Password Management

The CDISC SHARE system will require that all users login to use any system functionality. Users will be required to login using a username and a password. Usernames will be selected by the users and will be unique. The system administrator will have the right to reset a user's password. The system will allow users to change their passwords.

### 3.2 Requirements Related to User Profiles

User profiles contain information about each user. Note that there is no requirement for any information to be entered other than email address. The information will allow other users to see who is working on particular items of work.

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The CDISC SHARE system will allow additional information to be associated with a user account (User Profile) consisting of: email address, contact details, experience and interests, current work items assigned to (maintained by the system), work items previously worked on (maintained by the system), and finally a mechanism for system notifications (via email, via a users' dashboard, others to be determined).

## 3.3 Requirements Related to User Dashboard

Users should be provided with a home page or dashboard-type mechanism to allow them to see the status of work they are involved in and other useful information pertinent to the individual concerned. The content displayed should be configurable.

When a user logs into the system the system automatically display the user dashboard. Users will be able to individually configure the dashboard. The user dashboard will display the following: current notifications, all current work items to which the user is assigned, recent updates to system content and other information to be determined.

## 3.4 Requirements Related to User Roles

The user roles and functions that each role can perform needs to be defined. The system will provide a map between a User Role and System Functions.

## 4.0 Requirements Related to Work Items and Managed Objects

The CDISC Share repository is envisioned to manage two curation processes, one for work items and one for managed objects. A work item is a proposal to create or change one or more managed objects. As a work item is developed, and if it is approved, then tasks to create or change managed objects will be created. A work item could be connected to several managed objects, for example, a work item for a new test with a coded response could be connected to at least a managed object for the concept (test and its response) and a codelist connected to the response.

Refer to the requirements document and the draft governance documents for more detailed information on workflow for work items and managed objects.

## 5.0 Requirements Related to Work Items

Work Items are the main workflow control mechanism within the CDISC SHARE environment.

### 5.1 Requirements Related to the Work Items State Machine

The state machine for Work Items is shown below. The main flow for a Work Item (this description is not exhaustive) is:

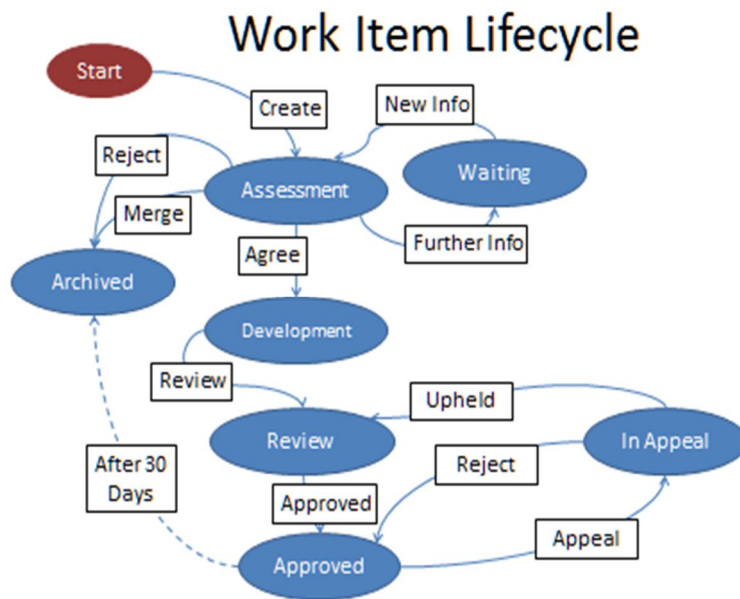
- A Work Item is created by a registered user. Attached to the Work Item can be supporting info and suggested (candidate) data elements and code lists.
- The Work Item is assessed by a Lead and Assessors. It can be approved, rejected or further information requested.
- Once approved the Work Item is worked upon by a team assembled for that purpose. Note the system makes no assumption about the techniques to be applied but will support

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a variety of such techniques. Once the team is happy with the work (after team review) then the work can be sent for public review.

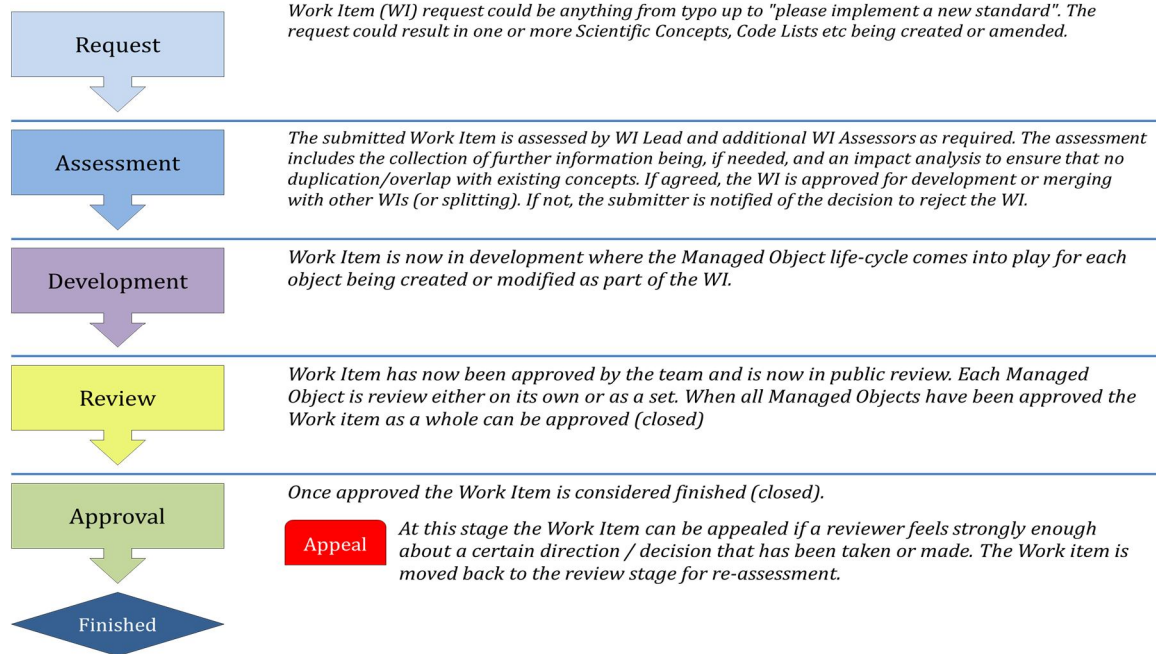
- Once all the resulting Managed Objects created or modified by the Work Item have passed review the Work Item as a whole can be approved.
- There is an appeal process for a Work Item.
- After 30 days an approved Work Item will automatically move to the archived state and no further appeals will be permitted

## 5.2 Diagram - Work Item Lifecycle



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## Work Item State Descriptions



## 5.3 Requirements Related to Creating a New Work Item

Work Item requests could be anything from a typo up to "please implement a new standard". The request could result in one or more Scientific Concepts, Code Lists, or other objects being created or amended.

The CDISC SHARE system will give users the ability to create a new work item. A work item will consist of a description of need, supporting documents, references and an optional set of candidate data elements and code lists. It is envisioned that a wiki-style notes section will hold this information. The system will allow partially created work items to be saved and completed work items to be submitted for assessment. When a work item is submitted the system will move the work item to the assessment state, notify all work allocators and add the submitting user to the Work Item Notification List (WINL).

## 5.4 Requirements Related to the Assessment State

### 5.5.1 Lead

The Work Item has been submitted, it now needs to be assessed by a Work Item Lead and additional assessors (there could be zero, one or more assessors).

The system will allow a Work Item Allocator to assign a Work Item Lead. The Work Item Lead will then add the Work Item Lead to the WINL.

### 5.5.2 Assessors

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Once a WI Lead has been assigned WI Assessors can be added. Note there is no limit placed on WI Assessors?, there can be more than one.

The system will allow the Work Item Allocator to assign users as Work Item Assessors to the Work Item. The Work Item Lead can then assign users as Work Item Assessors. These Work Item Assessors will be added to the WINL. Work Item Assessors can then add further information and comments to a Work Item.

## 5.5.3 Impact Analysis

Assessors and Leads will need support to evaluate the impact of any proposed change. The system must allow Users to see all concepts that use or are impacted by the proposed Work Item.

## 5.5.4 Further Information

There may be a need to gather further information from the submitter to help explain the need for a particular Work Item. The request for more information will be sent by the WI Lead or one of the Assessors, so the system will allow for a Work Item Lead or Assessor to request additional information from the submitter of a Work Item. When additional information is requested the system will automatically set the Work Item to the waiting stage and send an email notification to the submitter requesting further information.

## 5.5.5 Agree

The work item may be agreed upon. Consensus (not voting) among the Work Item Lead and the Assessors will move the work item to the Development State. To do this the system will allow for the Work Item Lead or an Assessor to remove an associated Managed Object from the Work Item. It will allow the Work Item Lead to approve a Work Item. When the Work Item is agreed upon, the system will set the state to Development State and associate any referenced Managed Objects with the Work Item. Finally the system will warn the user if any associated Managed Object is connected with another Work Item.

## 5.5.6 Reject

The request may be rejected. In such cases the system will allow the Work Item Lead or Assessor to reject the Work Item. When Work Item is rejected the System will set the Work Item to archived, send a notification to the submitter containing the reasons for rejection and save the reason for rejection with the Work Item.

## 5.5.7 Merge

The CDISC SHARE library will need to be able to merge Work Items when similar requests are received from multiple sources (e.g. where there is overlap in content, Managed Objects etc). Therefore the system should allow a Work Item (the Source) to be merged with another Work Item (the Destination). When Work Item (the Source) is merged with another Work Item (the Destination) the system will set the state of the Source Work Item to Archived and note the reason for merging and a reference to the Destination Work item in the Source Work Item. The system will then send a notification to the submitter containing the reasons for merging the Work Items and a reference to the destination Work Item. In addition the system will set the Work Item Lead to the Lead of the Destination Work Item. Finally the system will combine the Work Item

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Assessors and the Notification List for both Work Items and place into the Destination Work Item.

## 5.5.8 Split a Work Item

If the need emerges to split a Work Item into two Work Items, the requirements below cover the split. The Work Items would then need to be adjusted (covered by other requirements) to make them unique/different. To enable this the system shall allow a Work Item (the Source) to be split into two Work Items. When a work item is split the system will copy the entire Source Work Item into a second Copy Work Item, note the reason for splitting and a reference to the other Work Item into each of the Source and Copy Work Items and Send a System Notification to the submitter containing the reasons for splitting the Work Item and a reference to the Copy Work Item. In addition the system will set the Work Item Lead to the Lead of the Destination Work Item. Finally the system will combine the Work Item Assessors and the Notification List for both Work Items and place into the Destination Work Item.

## 5.5.9 Waiting

In this state the submitter will add further information and then re-submit the Work Item. To enable this the system will permit the submitter to add further information to a Work Item and allow a user to re-submit the Work Item containing the additional information. When a Work Item is re-submitted the system will set the state to the assessment state automatically.

## 5.5.10 Development

The Work Item is now being worked on and developed. We envision that this is where the Managed Object life cycle and state machine takes over for each of the objects being worked on or created. Managed Objects will be attached to the Work Item.

To enable these functions the system must allow for a Work Item Lead or a Work Item Assessor to allocate users (WI Members) to a Work Item and allow Managed Objects to be created by those users allocated to the Work Item. The system should allow Managed Objects associated with the Work Item to be modified by those users allocated to the Work Item and allow the Work Item to be sent for review. When a Work Item is sent for review the system will set the state to REVIEW automatically. The system shall allow an allocated user to attach a Managed Object to the Work Item and allow an allocated user to add further Candidate Data Elements and Code Lists to the Work Item.

## 5.5.11 Review

The Work Item is now in the review state. The review is done on each of the Managed Objects that are attached to the Work Item. We need all the Managed Objects to be approved and then the Work Item as a whole can be moved to approved status. Note there is no actual voting on the Work Item as a whole; this is done on the individual Managed Objects.

To enable this functionality the system should allow the Work Item Lead to place the Work Item in to the Development state and allow a Work Item Lead to approve the Work Item. When the Work Item is approved the Work Item shall be moved to the approved state. The system will only permit a Work Item to be moved to the approved state when all the Managed Objects linked to the Work Item are in Pre-Production or Production state.

## 5.5.12 Approved

Once approved the work is finished. However, someone could appeal the decision to close the work.

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On entering the approved state an appeal timeout will start. The appeal timeout will be configurable [default value 30 days]. The system shall allow for a user to lodge an appeal regarding the decision to approve a Work Item (Work Item Appeal). When an appeal is raised the Work Item state will be set to appeal, users involved will be notified and the appeal timeout cancelled. And finally if the appeal timeout expires the Work item state will be set to archived.

## 5.5.13 In Appeal

The appeal against closing the Work Item can be rejected. To accomplish this the system must allow a Work Item Appeal to be rejected and when rejected the system will set the Work Item state to the approved state.

## 5.5.14 Uphold Appeal

The appeal against closing the Work Item can be upheld. The Work Item is then moved back to the Review state. The system will allow a Work Item Appeal to be upheld and will set the Work Item state to the Review state. Note: need to work out the process for Managed Objects.

## 5.5.15 Archived State

In this state the Work Item has been archived and can no longer be modified. The only action permitted is viewing it. So the requirement is that the system will allow a Work Item to be viewed.

## 5.5.16 In All States

The system will alert all users within the WINL when the Work Item changes state and permit any user associated with the Work Item to amend the Work Item Notes. The system shall permit a Work Item Allocator to manage (Add, Delete, Replace) Work Item Leads and Work Item Assessors for Work Items. The system will permit a Work Item Lead to manage Work Item Assessors and Work Item Members for Work Items.

## 5.5.17 Audit

The audit trail will consist of: who performed the action, what, why and when the action was performed. Further the audit trail will be maintained for the following system actions: when a user logs in and out of the system, when a user account is modified, when a user is added to or removed from a Work Item. When a work item is created, a requirement is deleted, when a work item changes, new content is added to a work item, when content is modified in a work item there will be a system that does not obscure the previous entry or entries. When a managed Object is created, when new content is added to a Managed Object, when content is modified within a Managed Object. The system will allow for the audit trail to be viewed by the User, by type of event, date/time range, by Work Item, Managed Object and others to be determined.

## 6.0 Requirements Related to Object Management

This section is about the state model for the objects that CDISC SHARE will manage. What goes on in each state is described in the following sections.

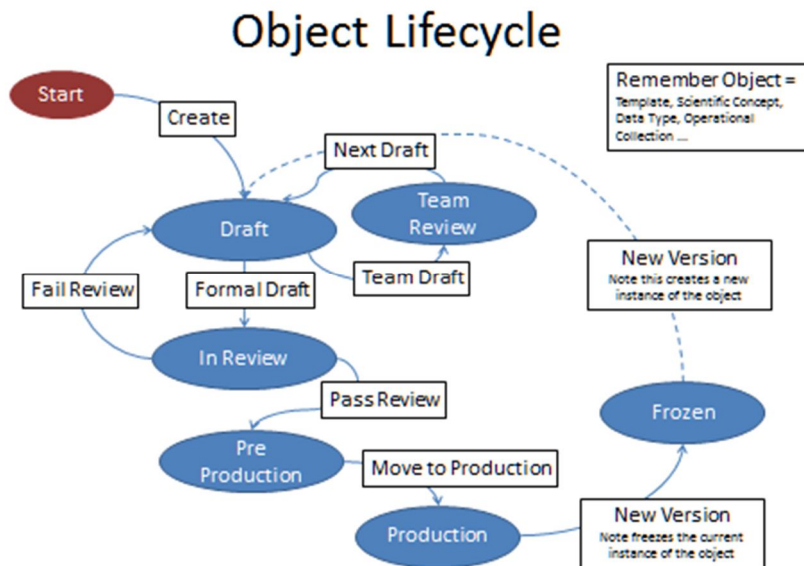
Also note that while ISO 21090 entities are managed by the system because CDISC SHARE will constrain the use of attributes, BRIDG is not a managed object. BRIDG forms part of the metadata model but is used as-is without constraints or modifications.

To support this the system will manage objects of the following types: ISO 21090 Data Type Definition (Data Type), Code List, Code List Subset, Concept Template, CDISC Concepts,

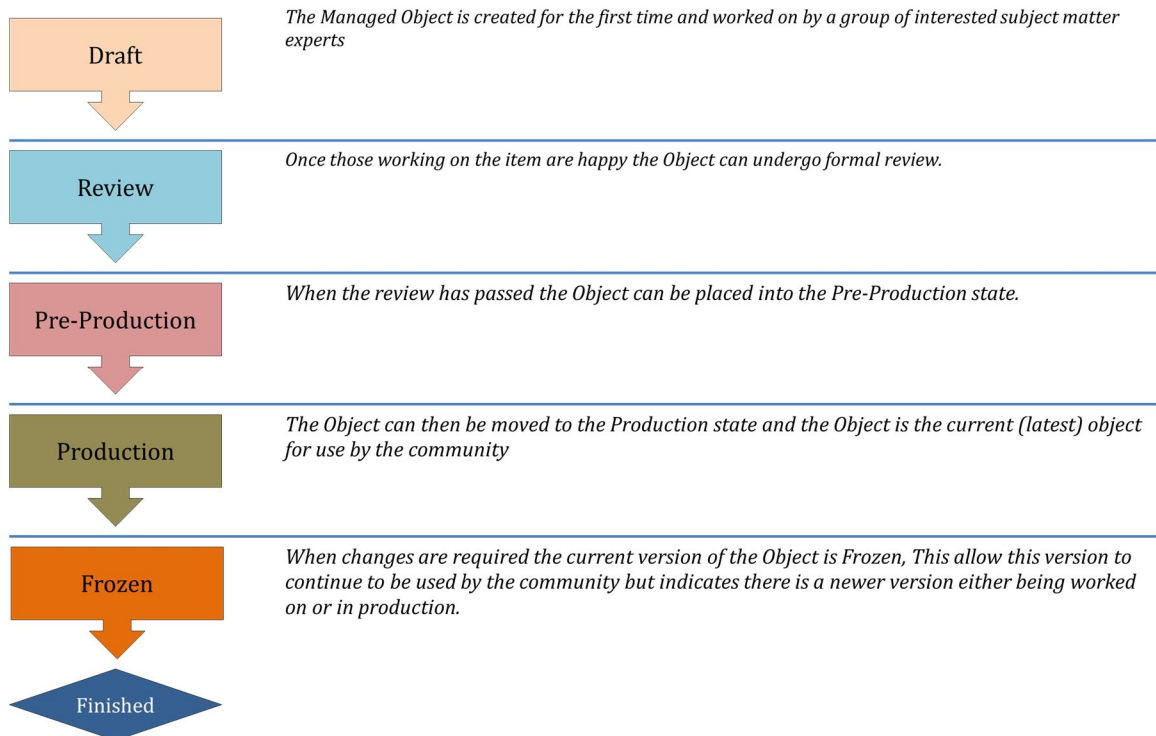
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Operational Collection, Standard. A Managed Object will consist of content defined by the metadata model and wiki-style notes section in which ad-hoc information can be included. The system will enforce version management for each managed object in accordance with the Object life cycle.

## 6.1 Diagram Object Lifecycle



### Managed Object State Descriptions



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## 6.2 Create a Managed Object

A Managed Object is created within the system. To enable this the system will permit the creation of a Managed Object and the constituent parts defined. Upon creation the Managed Object will be placed into Draft state, version 1. The system will ensure that duplicates are prevented. When CDISC Research Concepts are created the system will ensure that the structure of the CDISC Research Concept is based on one of the Content Templates present in the system. When constructing a CDISC Research Concept the system will provide assistance to a user based upon the CDISC Research Concept Template selected. This assistance will take the form of a wizard, which provides guidance through a set of steps.

## 6.3 Draft State

In the Draft State the definition of the Managed Object may be partially defined and discussed by those contributing to the Work Item to which the Managed Object is a part. We may be amending an existing Managed Object; we may be creating one from several Candidate Data Elements.

One thing to note is that impact assessment is dealt with in the section on operations that are available in all states. It will be desirable to assess the impact of any change at any stage of content manipulation.

The requirement is that while in the Draft state the Managed Object may only be modified by those on the Work Item team.

## 6.4 Candidate Content Manipulation

The system should include the capability to present multiple Candidate Code Lists side by side to permit comparison and matching of Code Lists. The system will provide facilities to harmonize multiple Candidate Code Lists and allow users to browse and search while on Candidate Code Lists. The system will also allow code lists to be combined in a CDISC Research Concept using the Content template as the basis.

The system should allow the presentation of CDISC Research Concepts and Candidate Data Elements side by side to permit comparison and permit a Candidate Code List to be used as the basis for a Code List Object. Where External Controlled Content is used within an Object, the system shall reference the content and shall not copy the content.

## 6.5 ISO 21090 Data Type Definition

The use of ISO 21090 data types is an important aspect of the model so the system must permit the creation, amending and deletion of data type attributes.

## 6.6 Code Lists

Functionality required around code lists includes the ability to insert a new item into or delete an item from a code list.

## 6.7 Code List Subsets

The system needs to support the ability to insert a new item into or delete an item from a code list subset. All items within a Code List Subset must belong to a single parent Code List.

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## 6.8 CDISC Research Concept Template

The system will allow a BRIDG class to be inserted into or deleted from a CDISC Research Concept Template. The system shall permit a BRIDG class or attribute to be inserted into or deleted from a CDISC Research Concept Template.

## 6.9 CDISC Research Concept

The system is envisioned to permit a BRIDG class to be deleted from a CDISC Research Concept. The system shall permit a BRIDG class or attribute to be inserted into or deleted from a Scientific Concept.

## 6.10 Operational Collection

An operational collection is a collection of Research Concepts. There may be additional rules between objects within the collection. An operational collection is analogous with an SDTM Domain, a CRF or a similar level of operational structure. The system should allow a concept to be added to or deleted from an operational collection.

## 6.11 Standard

A standard is a collection of Operational Collections. To support this the system will allow Operational Collections to be added to or deleted from a Standard.

## 6.12 Additional Tools and Techniques

As we learn more and we identify better ways to view and manipulate content (i.e., develop techniques) and take donated content (the Candidate Data Elements and Code Lists) and fashion these into Scientific Concepts and the higher-level collections, the system should enable additional functionality to support these techniques to be easily added to the system in the same way as browsers allow for third-party plug-ins; we wish to build a technique toolset so as to provide users with multiple ways to manipulate and view content.

## 6.13 Review

The system will allow an object to be issued for review within the Work Item team. When a Managed Object is issued for review it moves to the Team Review state. The system will then allow the Managed Object to be issued for public review and move to the In Review state.

## 6.14 Team Review State

We need for the new Managed Object(s) to be reviewed by the team creating them prior to exposing to a public review stage. The system will then prevent changes to the Managed Object and allow Work Item team members to vote on the Managed Object. If the vote passed, the system will permit the Managed Object to be open for public review. The passing vote will be configurable. If the vote fails, the system will permit the Managed Object to be further updated by the Work Item team.

## 6.15 Review State

Once approved by the team the Managed Object can undergo public review. The system will permit a review of a Managed Object to be notified to all users (System Notification) and permit users to register as reviewers for the Work Item review to which the Managed Object belongs. The system will allow Work Item reviewers to vote on the Managed Object. If the vote fails, the system will allow the Managed Object to be worked upon further by the Work Item team. When further work is required the system will place the Managed Object into the Draft state. When the vote passes, the system will permit a Managed Object to be approved for draft use.

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When the Managed Object is approved for draft use the system will set the status of the Managed Object to Pre-Production and set the status of the previous version of the Managed Object to the Frozen State.

## 6.16 Pre-Production State

Once the pre-production state is entered, the system will prevent further changes to the Managed Object. The Managed Object is then approved for production use and the system sets the status to production.

## 6.17 Production State

The final production state in which the current version of the Managed Object will be is frozen. We can then create a new version by copying the current version and starting the whole life cycle over again, but the old version remains unchanged. The system will prevent any changes to the current version of a Managed Object and permit a new version to be created.

For a single Managed Object, for example a clinical concept of height, there could be three versions at the same time:

1. Frozen State
2. Production State
3. Draft State

## 6.18 Frozen State

In the frozen state the system will prevent any changes to the Managed Object. Once a Managed Object is frozen it cannot be changed.

## 6.19 In all States

In all states it is required that users be able to see the impact of a change. The impact is assessed by the work team reviewing where a Managed Object is used. To facilitate this the system will provide the means by which the use of a Managed Object by other Managed Objects can be viewed by users. Along with this the system will allow a user allocated to a work item to which a Managed Object is linked to amend the Managed Object notes.

## 7.0 Printing, Exporting

The system will allow users to print anything presented to them on screen while in the system.

The system will allow the export of content in useful formats and be able to filter what is exported.

## 8.0 Search & Browse

CDISC SHARE must have robust search capabilities, (i.e. “wild card” functionality, synonym searches, and the exclusion of some results). These capabilities must include being able to view hierarchies, where available. To facilitate this the system will allow content to be searched and viewed for managed object by state, version, changes since, by SDTM or CDASH variable name, by code list, by content within a managed object, by any combination of the above.

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## 8.1 Work Items

The system will allow content to be searched by state, version, changes since, by User associated to the Object, by any combination of the above.

## 8.2 Audit Trail

For the audit trail, the system will allow content to be searched by attributes within the audit trail, by contents held within the audit trail, or by any combination of the above.

## 8.3 Users

For Users, the system will allow content to be searched by attributes on each user, by the work item associated with the user, by interactive time period or since a given time, or by any combination of the above.

## 8.4 External Users

For external users, when searching the system the system will recognize hierarchical relationships and synonyms and be able to ignore differences between American and British spelling and certain word endings (e.g. plural vs. singular).

## 9.0 Reporting & Dissemination

The system will allow for ad hoc notification that permits users to request notification about any changes to a managed object whenever they occur.

### 9.1 Regular Notifications

The system will allow users to sign up to a listserv. This listserv will send out information periodically about updates and changes to system content. It is envisioned that when a user logs on the system will display a list of relevant changes, changes in work items the user is assigned to and new work items started since the last user log in.

## 10.0 Metrics

CDISC SHARE will have some mechanisms in place to determine how successful the system is by tracking the number of times an object definition is viewed and the number of times an object definition is included in an export.

## 11.0 Availability

CDISC SHARE must have high system availability and reliability. CDISC anticipates that the system should support 100 concurrent users from a community of 500 global users initially. The system is assumed to be web-based and accessed via standard desktop browsers. To accommodate the global community the system will be accessible via the internet using standard desk-top browsers (Microsoft Internet Explorer, Firefox, Google Chrome, Apple Safari), 24 hours a day/7 days a week and will make information available in real-time. The system must be capable of supporting all of CDISC's standards development activities.

## 12.0 Future

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CDISC SHARE is envisioned to include ADaM, derived data and machine executable derivations as well as emerging therapeutic area standards. Another area is the semantic web or Linking Clinical Data Standards. For more information see <http://www.webcentralstation.ca/2011/02/08/an-intro-to-the-semantic-web>.

It is expected that the requirements document will be updated with requirements identified as a result of the work of other CDISC Share sub-teams, i.e. the Governance and User Interface, Model/Technology, Lab, Study Construction Concepts and Content teams.

Additional requirements will also be identified once software tools have been identified and testing commenced.

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