

CDISC SHARE

CDISC Shared Health and Research Electronic Library Requirements

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Table of Contents

1	INTRODUCTION	5
2	REFERENCES	6
3	ACRONYMS	7
4	CONVENTIONS	8
5	TERMS	9
6	ISSUES	10
7	REQUIREMENTS	11
7.1	METADATA MODEL	11
7.2	USERS	11
7.2.1	User Management	11
7.2.2	Password Management	12
7.2.3	User Profiles	12
7.2.4	User Dashboard	12
7.2.5	User Roles	13
7.3	WORK ITEMS	14
7.3.1	State Machine	14
7.3.2	Create a New Work Item	15
7.3.3	Assessment State	16
7.3.4	Waiting	19
7.3.5	Development	19
7.3.6	Review	20
7.3.7	Approved	20
7.3.8	In Appeal	21
7.3.9	Archived State	21
7.3.10	In all States	21
7.4	AUDIT	23
7.5	OBJECT MANAGEMENT	24
7.5.1	Create a Managed Object	25
7.5.2	Draft State	25
7.5.3	Team Review State	29
7.5.4	Review State	30
7.5.5	Pre-Production State	30
7.5.6	Production State	31

7.5.7 Frozen State	31
7.5.8 In All States	32
7.6 PRINTING	33
7.7 EXPORT	33
7.8 SEARCH& BROWSE	34
7.9 REPORTING & DISSEMINATION.....	36
7.9.1 Adhoc Notifications	36
7.9.2 Regular Notifications	36
7.10 METRICS	37
7.11 AVAILABILITY	38
7.12 FUTURE.....	39
8 REQUIREMENT PACKAGE 1.....	40

1 Introduction

CDISC has developed standards for use across the various points in the research study lifecycle. As adopters have realized the benefits of these standards, it has become apparent that there is a need for a foundational standard to support computable semantic interoperability (CSI) – the predictable exchange of meaning between two or more systems -- across multiple standards including, but not limited to, those developed by CDISC. In addition there is a pressing need to fill the gaps in the content of the existing standards, to efficiently manage, consistently maintain and easily access the standards, to bring those standards closer together while at the same time developing therapeutic area standards; and, adopters would like CDISC do all of this at an increased pace.

To address these challenges it is considered by many that an industry-wide shared semantic library would meet these needs and solve the issues CDISC and its stakeholders face. The value proposition for CDISC SHARE (CDISC Shared Health And Research Electronic Library – CSHARE) is the assumption that the creation of a library of shared semantics will enable CDISC stakeholders – global biopharmaceutical companies, academic institutions and clinical research organizations – to achieve multiple benefits including improved operational efficiency around the collection, processing, exchanging and reporting of data, evaluation of drug safety concerns across traditional organizational boundaries, and, in the end, enhanced scientific capabilities and resulting patient benefits and therapeutic efficacies.

This document details the requirements for such a system.

The rationale behind CDISC SHARE is documented in reference [1] while pilot work is described in reference [2].

2 References

Reference	Document
1	Scope & Vision
2	Pilot Report
3	Metadata model

3 Acronyms

Acronym	Detail
BRIDG	Biomedical Research Integrated Domain Group (BRIDG) Model
CDASH	Clinical Data Acquisition Standards Harmonization
CDISC	Clinical Data Interchange Standards Consortium
CSHARE	CDISC Shared Health and Clinical Research Electronic Library
SDTM	Study Data Tabulation Model
FDA	Food and Drug Administration
ICD	The International Classification of Diseases

4 Conventions

Certain conventions are used within the document:

1. Information text is shown in *italics*. This text does not form part of the formal requirements.
2. All requirements are referenced using a unique number. This number is allocated to the requirement and is never re-used.
3. If a requirement is deleted the requirement text is replaced by the words “Requirement Deleted”. The unique requirement number remains with the text indicating that the requirement has been deleted and ensuring the number cannot be re-used.
4. There is no significance implied by the ordering of requirements by requirement unique numbers.
5. Certain terms have specific meaning within the context of the requirements. The terms are defined within the requirements once and referenced from other requirements. A more descriptive explanation is provided in the Terms section.
6. The word **shall** is used within the requirement statements to indicate a mandatory requirement. The word **will** is used to indicate an optional requirement.

Reference is made to releases within the requirement tables. The release refer to

1. Release 1 – The very first release of the CSHARE system. The minimum that is needed to deliver content electronically to CDISC’s users
2. Release 2 – That functionality that CDISC would like to have as soon as possible after the first release; in other words mandatory requirements that can wait a little time.
3. Release 3+ – Functionality that can wait for a third or later release. All optional requirements would fall into this category.

Note: The last used requirement number is: 2700

5 Terms

Term	Definition
Work Item	The main mechanism for managing work within the system. A Work Item may create or modify one or more Managed Objects.
Work Item State Machine	The states and state transitions that a Work Item may undertake
Work Item Allocator	The role that performs the very quick and initial assessment of a work item and allocates it to a Work Item Lead.
Work Item Submitter	The role of a user who initiates a Work Item.
Work Item Lead	The role for a user who is the lead (responsible) for the Work Item
Work Item Assessor(s)	The list of participants (along with the Work Item Team Lead) who are responsible for the Work Item.
Work Item Notification List	The list of users to be notified when the state of a Work Item changes. A separate list is maintained for each Work Item
Managed Object	An object that is managed within the system, such management to obey the Object State Machine and to which version management is applied. Could be a code list, a Scientific Concept etc.
Managed Object Definition	The definition of a Managed Object. Such a definition may consist of a set of definitions and attributes dependent upon the particular form of the object in question
Object State Machine	The states and state transitions that a Managed Object may undertake
Candidate Data Element	A data element (DE) that has been loaded into the system for the purposes of reconciliation and alignment with other such Candidate DEs such that a standard element can be created and combined with other such elements to form a new Scientific Concept. A Candidate Data Element will have a certain structure
Candidate Code List	A code list that has been loaded into the system for the purposes of reconciliation and alignment with other such code lists (and DEs that may use the code lists) such that a standard code list can be created and combined with other such elements to form a new Code List
Candidate Code List Item	An item within a Candidate Code List
External Controlled Content	Existing sources of authoritative definitions such as ICD 9, ICD 10, MEDRA, LOINC, NCI Metathesaurus, HL7 DCM, openEHR.
User Dashboard	A mechanism for displaying all information relevant to a given user such as Notifications, Work Items and other status information
System Function	A particular atomic function that can be performed by a user using the system.
System Notification	The mechanism by which a user is notified on some system event such as a change to content, a review being posted etc.

6 Issues

The following issues exist within this release of the document.

1. The R1 flags have yet to be set against the core requirements. See the R1 mind map for this information
2. There are questions within the requirements that need answers
3. Need to define the user roles (they are discussed/detailed within the requirements). We need a table of roles versus functions that users can use.

7 Requirements

7.1 Metadata Model

The metadata model is the core of the CSHARE system. The model will permit the range of content that CDISC has developed can be represented in a machine readable form. The metadata model mandates the use of BRIDG and ISO 21090.

Unique Req Id	Requirement	Release
0010	The system shall support the metadata model as defined within the MDM (Metadata Model) document [3].	R1
0020	The system shall constrain the creation of content to those objects defined by the metadata model.	R2
0021	The system shall ensure that all content is consistent with the metadata model.	R2
0030	The system shall provide for the maintenance of the objects defined within the Meta Data Model	R2

7.2 Users

CSHARE must support good security and appropriate roles to protect content.

7.2.1 User Management

Unique Req Id	Requirement	Release
0110	The system shall support multiple users.	R2
0120	The system shall allow each user to be allocated one or more User Roles	R2
0130	The system shall always maintain at least one user with administrative rights (the System Administrator role)	R2
0140	The system shall permit a new user to be created within the system by a user with the System Administrator role.	R2
0150	The system shall allow a user to self-register with the system.	R2
0160	When a user self-registers the system shall support mechanisms to prevent spam users being created.	R2
0170	The system shall allocate a Read-Only role to a self-registered user.	R2
0180	The system shall allow for a user to be deleted by a user with the System Administrator role.	R2
0190	The system shall permit a user with the System Administrative role to assign a role to a user.	R2
	<i>Note: This includes the System Administrative role.</i>	

7.2.2 Password Management

Unique Req Id	Requirement	Release
0200	The system shall require that all users login to use any system function.	R2
0210	The system shall require that a user login consist of a username and a password.	R2
0211	The system shall allow the user to select their username.	R2
0212	The system shall ensure usernames are unique.	R2
0220	The system shall allow a user with system administrative rights to reset a user's password.	R2
0230	The system shall allow a user to change their password.	R2

7.2.3 User Profiles

User profiles can contain information about each user. Not that there is no requirement for the information to be entered other than email address or that all information is entered. The information is there so as to allow other users to see who is working on particular items of work.

Unique Req Id	Requirement	Release
0300	Requirement Deleted	NA
0310	The system shall allow additional information to be associated with a user account (the User Profile) consisting of	R2
0320	a) Email address (required).	R2
0321	a) Contact details including Job title, phone numbers, company name, company address (optional)	R2
0330	b) Experience And Interests including biographical details and therapeutic areas interested in (optional)	R2
0340	c) Current Work Items assigned to (maintained by system)	R2
0350	d) Work Items previously worked on (maintained by system)	R2
0361	e) The mechanism to be used for System Notifications (via email, via the User's Dashboard, Both, others TBD)	R2
0360	f) Requirement deleted.	R2

7.2.4 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.

Unique Req Id	Requirement	Release
2800	When a user logs in to the system shall display the User Dashboard	R2
2810	The content of the User Dashboard shall be individually configurable by each user	R2
2820	A User Dashboard shall be capable of displaying:	R2
2830	a) All current notifications	R2
2840	b) All current Work Items to which the user is allocated	R2
2850	c) Recent updates to system content	R2
2860	d) Other information TBD	R2

7.2.5 User Roles

The user roles and the functions that each role can perform needs to be defined.

Unique Req Id	Requirement	Release
1300	The system shall provide a map between a User Role and System Functions	R2
1301	The User Role to System Function map shall be configurable	R2
1302	The default values for the map shall be: <i>This is where we shall define the original map</i>	R2

7.3 Work Items

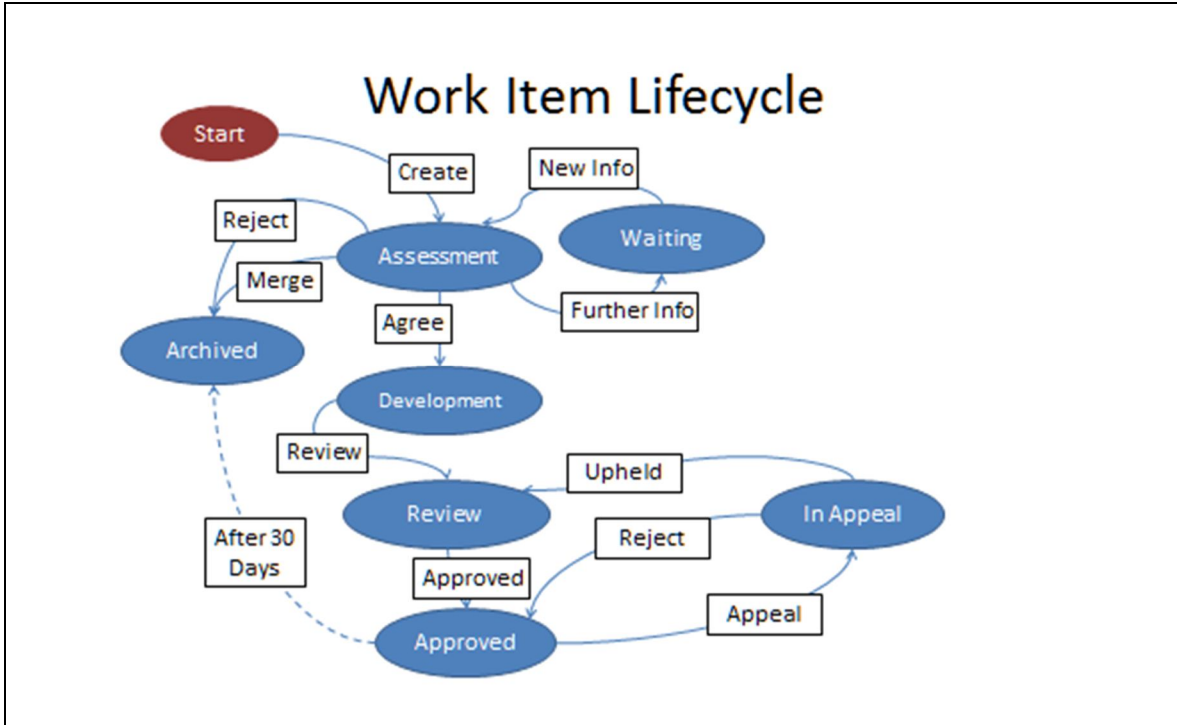
Work Items are the main work flow control mechanism within the CSHARE environment.

7.3.1 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 the purpose. Note the system makes no assumption about the techniques etc to be applied but will support 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*

Unique Req Id	Requirement	Release
0400	The system shall enforce the Work Item State Machine	R2



7.3.2 Create a New Work Item

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

Unique Req Id	Requirement	Release
0410	The system shall provide a user with the ability to create a new Work Item.	R2
0420	A Work Item shall consist of:	R2
0430	a) A description of the need.	R2
0440	b) Optional supporting documents.	R2
	<i>N: Should not be restricted. Needs to encompass PDF, Images, notes, scans, word documents, excel spreadsheets, example CRFs etc.</i>	
0450	c) An optional reference to a list of existing Managed Objects.	R2
0460	d) An optional set of Candidate Data Elements and Candidate Code Lists.	R2
	<i>N: These need to be structured to allow for manipulation. Note there could be many sources of Candidate Data Elements and Code Lists which might result in a single draft Scientific Concept (Many to One). Thus the candidate content is not even a draft at this point in the lifecycle.</i>	
0461	e) A "wiki style" notes section (Work Item Notes) to which any ad-hoc	R2

	information can be inserted.	
0470	The system shall allow partially created Work Items to be saved.	R2
0480	The system shall allow for the Work Item to be submitted for assessment.	R2
0490	Upon the Work Item being submitted the system shall:	R2
0500	a) Move the Work Item to the Assessment state	R2
0510	b) Notify all Work Allocators regarding the submitted Work Item	R2
0520	c) Add the submitting user to the Work Item Notification List (WINL)	R2

7.3.3 Assessment State

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).

7.3.3.1 Lead

We first need to assign a lead to the Work Item

Unique Req Id	Requirement	Release
0530	The system shall allow a Work Item Allocator to allocate a user to a Work Item as a Work Item Lead.	R2
0540	The system shall add the Work Item Lead to the WINL.	R2

7.3.3.2 Assessors

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

Unique Req Id	Requirement	Release
0550	The system shall allow the Work Item Allocator to assign users as Work Item Assessors to the Work Item	R2
0551	The system shall allow the Work Item Lead to assign users as Work Item Assessors to the Work Item	R2
0560	The system shall add Work Item Assessors to the WINL.	R2
0570	The system shall allow Work Item Assessors to add further information and comments to a Work Item.	R2

7.3.3.3 Impact Analysis

What is the impact of this change? Assessors and Leads will need support to work out the impact.

Unique Req Id	Requirement	Release
0580	See if Managed Object is part of another Work Item	R2
0581	Others TBD	R2

7.3.3.4 Further Information

There may be a need to gather further information from the submitter to help explain the need etc. This will be performed by the WI Lead or one of the Assessors.

Unique Req Id	Requirement	Release
0590	The system shall allow for a Work Item Lead or an Assessor to request additional information from the Submitter for the Work Item	R2
0600	When additional information is requested the system shall:	R2
0610	a) Set the Work Item to the Waiting state	R2
0620	b) Send a System Notification to the submitter requesting the further info	R2

7.3.3.5 Agree

The work item may be agreed. Note that we are not using voting here but consensus amongst the Work Item Lead and the Assessors.

Unique Req Id	Requirement	Release
0629	The system shall allow for the Work Item Lead or an Assessor to remove an associated Managed Object from the Work Item	R2
0630	The system shall allow for the Work Item Lead to approve a Work Item	R2
0640	When the Work Item is approved the system shall:	R2
0641	a) Set the state to Development State	R2
0642	b) Associate any referenced Managed Objects with the Work Item.	R2
0643	c) Warn the user if any associated Managed Object is associated with another Work Item	R2
	<i>We have here two work items working on the same Managed Object (e.g. a code list). May not be desirable. May want to stop this</i>	

7.3.3.6 Reject

The request may be rejected.

Unique Req Id	Requirement	Release
0650	The system shall allow the Work Item Lead or an Assessor to reject the Work Item.	R2
0660	When a Work Item is rejected the system shall:	R2
0670	a) Set the Work Item state to Archived.	R2
0680	b) Send a System Notification to submitter containing the reasons for rejection.	R2
0681	c) Save the reason for rejection within the Work Item	R2

7.3.3.7 Merge

We 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).

Unique Req Id	Requirement	Release
0690	The system shall allow a Work Item (the Source) to be merged with another Work Item (the Destination)	R2
0700	When a Work Item is merged the system shall:	R2
0710	a) Set the state of the Source Work Item to Archived.	R2
0711	b) Note the reason for merging and a reference to the Destination Work item in the Source Work Item..	R2
0720	c) Send a System Notification to the submitter containing the reasons for merging the Work Items and a reference to the Destination Work Item	R2
0730	d) Set the Work Item Lead to the Lead of the Destination Work Item.	R2
0731	e) Combine the Work Item Assessors and the Notification List for both Work Items and place into the Destination Work Item.	R2

7.3.3.8 Split

This is where we might want to split a Work Item into two Work Items. The requirements below cover the split. The Work Items would then need adjusting (covered by other requirements) to make them unique/different.

Unique Req Id	Requirement	Release
0690	The system shall allow a Work Item (the Source) to be split into two Work Items.	R2
0700	When a Work Item is split the system shall:	R2

0710	a) Copy the entire Source Work Item into a second Copy Work Item	R2
0711	b) Note the reason for splitting and a reference to the other Work Item into each of the Source and Copy Work Items.	R2
0720	c) Send a System Notification to the submitter containing the reasons for splitting the Work Item and a reference to the Copy Work Item	R2
0730	d) Set the Work Item Lead to the Lead of the Destination Work Item.	R2
0731	e) Combine the Work Item Assessors and the Notification List for both Work Items and place into the Destination Work Item.	R2

7.3.4 Waiting

In this state the submitter is adding further information and then re-submitting

Unique Req Id	Requirement	Release
0740	The system shall permit the submitter to add further information to a Work Item	R2
0750	The system shall allow a user to re-submit the Work Item containing the additional information	R2
0760	When the Work Item is re-submitted the system shall set the state to the Assessment state	R2

7.3.5 Development

We are now in to working on the Work Item. 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.

****** IMPORTANT NOTE ******

This is the link between Managed Object (Code List, Scientific Concept etc) and the Work Item. A Work Item may include several Managed Objects. Each can be worked on separately. Only when all are stable can the Work Item be reviewed.

Unique Req Id	Requirement	Release
0770	The system shall allow for a Work Item Lead or a Work Item Assessor to allocate users (WI Members) to a Work Item	R2
0771	The system shall allow Managed Objects to be created by those users allocated to the Work Item	R2
0772	The system shall allow Managed Objects associated with the Work Item to be modified by those users allocated to the Work Item	R2
0780	The system shall allow a Work Item to be sent for review	R2
0790	When the Work Item is sent for review the system shall set the state to Review	R2

0791	The system shall allow an allocated user to attach a Managed Object to the Work Item	R2
0792	The system shall allow a allocated user to add further Candidate Data Elements and Code Lists to the Work Item	R2

7.3.6 Review

Now in the review state. The review is really 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. Note there is no actual voting on the Work Item as a whole, this is done on each of the Managed Objects.

Unique Req Id	Requirement	Release
0800	The system shall allow a Work Item Lead to place the Work Item in to the Development state.	R2
0810	The system shall allow a Work Item Lead to approve the Work Item.	R2
0820	When the Work Item is approved the system shall be moved to the Approved state.	R2
0830	The system shall 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.	R2

7.3.7 Approved

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

Unique Req Id	Requirement	Release
0838	On entering the Approved state an appeal timeout shall be initiated	R2
0839	The appeal timeout shall be configurable [default value 30 days]	R2
0840	The system shall allow for a user to lodge an appeal regarding the decision to approve a Work Item (Work Item Appeal).	R2
0850	When an appeal is raised:	R2
0851	a) the Work Item state shall be set to In Appeal.	R2
0860	b) Notify users involved in the work item	R2
0861	c) Cancel the appeal timeout	R2
0862	If the appeal timeout expires the Work item state shall be set to Archived	R2

7.3.8 In Appeal

7.3.8.1 Reject Appeal

The appeal against closing the Work Item can be rejected

Unique Req Id	Requirement	Release
0870	The system shall allow a Work Item Appeal to be rejected.	R2
0880	When the Work Item Appeal is rejected the system shall set the Work Item state to the Approved state	R2

7.3.8.2 Uphold Appeal

The appeal against closing the Work Item can be upheld. The Work Item is moved back to the Review state.

Unique Req Id	Requirement	Release
0890	The system shall allow a Work Item Appeal to be upheld.	R2
0900	When the Work Item Appeal is upheld the system shall set the Work Item state to the Review state	R2

Q: What about the Managed Objects

7.3.9 Archived State

In this state the Work Item has been archived and can no longer be modified. The only action permitted is viewing it.

Unique Req Id	Requirement	Release
0901	The system shall allow a Work Item to be viewed.	R2

7.3.10 In all States

What do we want to allow users to do while in any of the above states? Allow the Work Item to be viewed and?

Unique Req Id	Requirement	Release
0910	The system shall alert all users within the WINL when the Work Item changes state.	R2
0920	The system shall alert all users within the WINL when updates are made to a	R2

Work Item.		
0930	Requirement Deleted	R2
0940	The system shall allow for a user to remove themselves from a Work Item.	R2
0941	The system shall permit any user associated with the Work Item to amend the Work Item Notes	
0942	The system shall permit a Work Item Allocator to manage (Add, Delete, Replace) Work Item Leads and Work Item Assessors for Work Items	
0943	The system shall permit a Work Item Lead to manage Work Item Assessors and Work Item Members for Work Items	

7.4 Audit

When Release 1 is switched on the audit trail should, for each object, show the review that has taken place to ensure the content is correct.

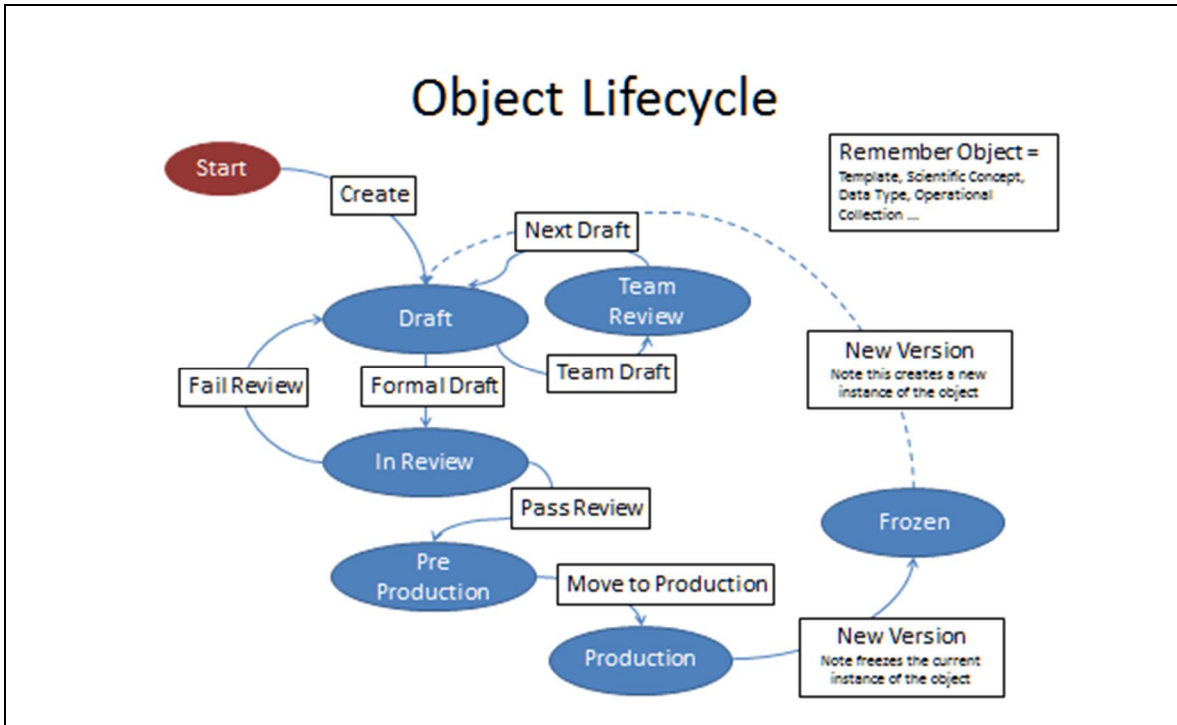
Unique Req Id	Requirement	Release
1000	An audit trail entry shall consist of:	R2
1010	a) Who performed the action	R2
1020	b) What action was performed	R2
1030	c) Why the action was performed	R2
1040	d) When the action was performed	R2
1050	An audit trail shall be maintained for the following system actions	R2
1060	a) When a user logs in to the system	R2
1070	b) When a user logs out from the system	R2
1080	c) When a user account is modified	R2
1090	d) When a user is added to a Work Item	R2
1100	e) When a user is removed from a Work Item	R2
1110	f) When a Work Item is created	R2
1120	g) Requirement Deleted	R2
1130	h) When the state of a Work Item changes	R2
1131	a) When new content is added to a Work Item	R2
1132	a) When content is modified within Work Item	R2
1140	b) When a Managed Object is created	R2
1141	b) When new content is added to a Managed Object	R2
1142	c) When content is modified within a Managed Object	R2
1150	The system shall allow for the audit trail to be viewed:	R2
1160	a) By user	R2
1170	b) By type of event	R2
1171	c) By date / time range	R2
1180	d) By Work Item	R2
1181	e) By Managed Object	R2
1190	f) Others TBD	R2

7.5 Object Management

This section is about the state model for the objects that CSHARE will manage. What goes on in each state is described in the following sections not this one. An item (Code List Item) within a Code List or Code List Subset is NOT a managed object.

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

Unique Req Id	Requirement	Release
1200	The system shall manage objects (the Managed Objects) of the following types:	R2
1210	a) ISO 21090 Data Type Definition (Data Type)	R2
1220	b) Code List	R2
1230	c) Code List Subset	R2
1240	d) Scientific Concept Template	R2
1250	e) Scientific Concept	R2
1260	f) Operational Collection	R2
1270	g) Standard	R2
1280	The system shall enforce the Object State Machine for Managed Objects	R2
1281	A Managed Object shall consist of:	R2
1282	a) The content as defined for the object within the Metadata Model.	R2
1283	b) A "wiki style" notes section (Managed Object Notes) in to which any ad-hoc information can be inserted.	R2
1290	The system shall enforce version management for each Managed Object in accordance with the Object State Machine	R2



7.5.1 Create a Managed Object

This is the point where a Managed Object is created within the system for the first time.

Unique Req Id	Requirement	Release
1310	The System shall permit a Managed Object to be created and the constituent parts defined	R2
1320	Upon creation, a Managed Object shall be placed into Draft State	R2
1330	Upon creation, a Managed Object version shall be set to 1	R2
1340	The system shall provide mechanisms to assist in the prevention of duplicate object definitions.	R2
	<i>Need more here as to how we achieve this</i>	
1341	When Scientific Concepts are created the system shall ensure that the structure of the Scientific Concept is based on one of the Scientific Concept Templates present in the system	R2
1342	When constructing a Scientific Concept the system shall provide assistance to a user based upon the Scientific Concept Template selected (a wizard)	R2

7.5.2 Draft State

In the Draft State the definition of the Managed Object may be partially defined and being 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 on any change at any stage of content manipulation.

7.5.2.1 General

Unique Req Id	Requirement	Release
1350	While in the Draft state the Managed Object may only be modified by those on the Work Item team	R2

7.5.2.2 Candidate Content Manipulation

Unique Req Id	Requirement	Release
1360	The system shall be capable of presenting multiple Candidate Code Lists side by side to permit comparison.	R2
1370	The system shall provide facilities to harmonize multiple Candidate Code Lists	R2
1380	The system shall allow for the matching (comparing) of terms within submitted Candidate Code Lists.	R2
1390	The system shall be capable of presenting multiple Candidate Data Elements side by side to permit comparison	R2
1400	The system shall provide facilities to harmonize multiple Candidate Data Elements	R2
1410	The system shall allow internal content to be browsed and searched while on Candidate Data Elements and Code Lists	R2
1420	The system shall allow External Controlled Content to be browsed and searched while working on Candidate Data Elements and Code Lists	R2
1430	The system shall permit Candidate Data Elements to be combined into a Scientific Concept Object using a Scientific Concept Template as the basis of Scientific Concept.	R2
1431	The system shall be capable of presenting Scientific Objects and Candidate Data Elements side by side to permit comparison	R2
1440	The system shall permit a Candidate Code List to be used as the basis for a Code List Object	R2
1450	Where External Controlled Content is used within an Object, the system shall reference the content and shall not copy the content	R2

7.5.2.3 ISO 21090 Data Type Definition

Unique Req Id	Requirement	Release
1460	The system shall permit a Data Type attribute to be created	R2
1470	The system shall permit a Data Type attribute to be amended <i>N: The use of the attribute has changed</i> <i>N: What is the impact here</i>	R2
1480	The system shall permit a Data Type attribute to be deleted	R2

7.5.2.4 Code Lists

Unique Req Id	Requirement	Release
1490	The system shall permit a new item to be inserted into a Code List	R2
1500	The system shall permit an item to be deleted from a Code List	R2

7.5.2.5 Code List Subsets

Unique Req Id	Requirement	Release
1510	The system shall permit a new item to be inserted into a Code List Subset	R2
1520	The system shall permit an item to be deleted from a Code List Subset	R2
1530	All items within a Code List Subset must belong to a single parent Code List	R2

7.5.2.6 Scientific Concept Template

Unique Req Id	Requirement	Release
0000	The system shall permit a BRIDG class to be inserted into a Scientific Concept Template	R2
1540	The system shall permit a BRIDG class to be deleted from a Scientific Concept Template	R2
1550	The system shall permit a BRIDG class attribute to be inserted into a Scientific Concept Template the attribute being associated with a BRIDG class	R2
1560	The system shall permit a BRIDG class attribute to be deleted from a Scientific Concept Template	R2

7.5.2.7 *Scientific Concept*

Unique Req Id	Requirement	Release
1570	The system shall permit a BRIDG class to be deleted from a Scientific Concept.	R2
1580	The system shall permit a BRIDG class attribute to be inserted into a Scientific Concept, the attribute being associated with a BRIDG class	R2
1590	The system shall permit a BRIDG class attribute to be deleted from a Scientific Concept	R2
1600	Others TBD	R2

7.5.2.8 *Operational Collection*

An operational collection is a collection of Scientific Concepts. There may be additional rules between objects within the collection. An operational collection is analogous with a SDTM Domain, a CRF or a similar level of operational structure.

Unique Req Id	Requirement	Release
1700	The system shall permit a Scientific Concept to be deleted from an Operational Collection	R2
1710	The system shall permit a Scientific Concept to be added to an Operational Collection	R2
1720	The system shall permit a rule to be deleted from an Operational Collection	R2
1730	The system shall permit a rule to be added to an Operational Collection	R2
1740	The system shall permit an existing Operational Collection rule to be modified	R2

7.5.2.9 *Standard*

A standard is a collection of operational collections.

Unique Req Id	Requirement	Release
1750	The system shall permit an Operational Collection to be deleted from an Standard	R2
1760	The system shall permit an Operational Collection to be added from a Standard	R2
1770	The system shall permit a rule to be deleted from a Standard	R2

1780	The system shall permit a rule to be added to a Standard	R2
1790	The system shall permit an existing Standard rule to be modified	R2

7.5.2.10 Additional Tools and Techniques

As we learn e will understand better ways to view and manipulate content (techniques) and take donated content (the Candidate Data Elements and Code Lists) and fashions 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 plugins; we wish to build a technique toolset so as to provide users with multiple ways to manipulate and view content.

Unique Req Id	Requirement	Release
1791	The system shall allow for other methods of content manipulation to be easily accommodated within future releases of the system	R2

7.5.2.11 Review

Unique Req Id	Requirement	Release
1800	The system shall allow an object to be issued for review within the Work Item team	R2
1810	When a Managed Object is issued for review it shall be moved to the Team Review state	R2
1820	The system shall permit the Managed Object to be issued for public review	R2
1830	When a Managed Object is issued for public review it shall move to the In Review state	R2

7.5.3 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. Is the team happy.

Unique Req Id	Requirement	Release
1850	The system shall prevent changes to the Managed Object	R2
1860	The system shall allow Work Item team members to vote on the Managed Object	R2
1870	If the vote passes then the system shall permit a Managed Object to be opened for public review	R2

1871	Passing shall be configurable TBD	R2
1880	Requirement Deleted	R2
1890	If the vote fails system shall permit a Managed Object to be further updated by the Work Item team	R2
1900	When further updates are required the system shall place the Work Item into Draft state	R2

7.5.4 Review State

Once the team is happy the Managed Object can undergo a public review.

Unique Req Id	Requirement	Release
1900	The system shall permit a review of a Managed Object to be notified to all users (System Notification).	R2
1910	The system shall permit users to register as reviewers for the Work Item review to which the Managed Object belongs.	R2
1920	The system shall allow Work Item reviewers to vote on the Managed Object	R2
1930	If the vote fails the system shall permit the Managed Object to be worked upon further by the Work Item team	R2
1940	When further work is required the system shall place the Managed Object into the Draft state	R2
1950	If the vote passes the system shall permit a Managed Object to be approved for draft use	R2
1951	Passing shall be configurable TBD	
1960	When the Managed Object is approved for draft use the system shall	R2
1961	a) set the Managed Object state to Pre-Production.	R2
1962	b) set the previous version of the Managed Object that is in the Pre-Production or Production state to the Frozen State	R2

7.5.5 Pre-Production State

A pre-production state.

Unique Req Id	Requirement	Release
2000	The system shall prevent any changes to the Managed Object	R2
2010	The system shall permit the Managed Object to be approved for production use	R2
2020	When approved for production use the system shall set the Managed	R2

 Object state to Production

7.5.6 Production State

The final production state in which the current version of the Managed Object 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.

It should be noted that for a single Managed Object, say a Scientific Concept of Height, there could be three versions in the Frozen State, one in Production State and one version in Draft State

Unique Req Id	Requirement	Release
2030	The system shall prevent any changes to the [current version] Managed Object	R2
2040	The system shall permit a new version of the Managed Object to be created.	R2
2050	When a new version is created the system shall	R2
2060	a) Requirement Deleted.	R2
2070	b) Create a new copy of the Managed Object	R2
2080	c) Take the version of the existing managed object, increment it and apply it as the version of the new copy of the Managed Object	R2
2090	d) Set the state of the new Copy of the Managed Object to Draft state	R2

7.5.7 Frozen State

Can never move out of this state once in.

Unique Req Id	Requirement	Release
2100	The system shall prevent any changes to the Managed Object	R2

7.5.8 In All States

One thing that is required in all states is to see the impact of a change. Impact is assessed by noting where a Managed Object is used.

Unique Req Id	Requirement	Release
2110	While in any state the system shall provide the means by which the use of a Managed Object by other Managed Objects can be viewed by a user <i>What else here</i>	R2
2111	The system shall permit any user allocated to a Work Item to which a Managed Object is linked to amend the Managed Object Notes	R2

7.6 Printing

Users will need to be able to print whatever they see on the screen.

Unique Req Id	Requirement	Release
2700	The system shall permit a user to print any information presented to them at any time while using the system.	R2

7.7 Export

SHARE needs to be able to export the content from the system in useful formats and be able to filter what is exported.

Unique Req Id	Requirement	Release
2200	The system shall permit the Managed Object content held to be exported:	R2
2210	a) For inclusion into SDTM/CDASH human readable specifications in a Microsoft Word format.	R2
2220	b) In an Excel spread sheet format	R2
2230	c) In ODM XML Format	R2
2240	The system shall permit an export to contain:	R2
2250	a) All of the defined content	R2
2260	b) A defined subset of the content	R2
2270	c) Others TBD	R2

7.8 Search& Browse

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.

Unique Req Id	Requirement	Release
2300	The system shall allow system content to be searched and viewed:	R2
2310	a) For Managed Objects	R2
2320	a. By State	R2
2330	b. By Version	R2
2340	c. Changes Since	R2
2400	d. By a SDTM or CDASH variable name being associated with it	R2
2410	e. By a Code List being associated with it	R2
2420	f. By content being present within a Managed Object	R2
2421	g. By a combination of the above	R2
2350	b) For Work Items	R2
2360	a. By State	R2
2370	b. By Version	R2
2380	c. Changes since	R2
2390	d. By a User being associated with it	R2
2390	e. By a combination of the above	R2
2430	c) For the Audit Trail	R2
2440	a. By the attributes within the audit trail	R2
2441	b. By the contents held within the audit trail	R2
2441	a. By a combination of the above	R2
2450	d) For Users	R2
2460	a. By the attributes held on each user	R2
2470	b. By Work Item the user is associated with	R2
2471	c. Inactive in a given time period or since a given time	R2
2471	d. By a combination of the above	R2
2480	e) For External Controlled Content	R2
2710	f) When searching the system shall, where applicable	R2
2720	a. Recognizing hierarchical relationships	R2
2730	b. Recognize synonyms	R2
2740	c. Ignore differences between American and British spelling	R2
2750	d. Ignore certain word endings (e.g., plural vs. singular).	R2

2760	g) The results of any search should be made available by the system for subsequent use by the user in another system function	R2
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7.9 Reporting & Dissemination

7.9.1 Adhoc Notifications

Unique Req Id	Requirement	Release
2500	The system shall permit a user to request notification, using a System Notification, about any changes to a Managed Object	R2
2510	The system shall permit a user to receive a System Notification whenever the state of a Managed Object changes	R2

7.9.2 Regular Notifications

Unique Req Id	Requirement	Release
2520	The system shall allow users to sign up to a listserv	R2
2530	The listserv shall, at regular periods, send out information about updates and changes to system content	R2
2540	When a user logs on to the system, the system shall display:	R2
2550	a) a list of changes relevant to the user	R2
2560	b) Changes in work items the user is assigned to	R2
2570	c) New work items started since the user last logged on	R2

7.10 Metrics

CSHARE should have some mechanisms to work out how successful the system is being.

Unique Req Id	Requirement	Release
2580	The system shall provide metrics on:	R2
2590	a) The number of times an object definition is viewed	R2
2600	b) The number of times an object definition is included within an export	R2

7.11 Availability

CSHARE needs to have very high system availability and reliability. Sizing is problematic but CDISC is looking to support 100 concurrent users from a community of 500 global users. The system is assumed to be web based accessed via standard desktop browsers

Unique Req Id	Requirement	Release
2610	The system shall be accessible to the global user community.	R2
2611	The system shall be accessible via the internet using standard desk-top browsers (Microsoft Internet Explorer, Firefox, Google Chrome, Apple Safari).	R2
2620	The system shall be available 24 hours a day, 7 days a week	R2
2630	The system shall make all information available in real-time	R2
2631	The system shall be capable of supporting all of CDISC's standards development activities	R2

7.12 Future

What else might we want in the next steps

- Semantic Web
- ADaM
- Derived data and machine executable derivations

8 Requirement Package 1

Some items from the package 1 requirements that need some thought

4.1.2 NCI to Define Upload Template

In order for contributed data to be uploaded efficiently, NCI to inform CDISC regarding the specification (i.e. structure, etc.) for loading agreed metadata into the repository staging area. Agreed instructions to be written and displayed (“How to use template to upload data”).

4.1.1 CDISC to Define Required Metadata

After the repository objects have been defined, CDISC to inform NCI what metadata CDISC’s user community will be loading into the repository.

6 FDA Clinical Data Warehouse Structure Interoperability

The system must ensure semantic interoperability with FDA’s JANUS warehouse structure.

2.7 Globalization

2.7.1 Support Global Biomedical Research and Healthcare

The repository will contain information pertinent to biomedical research and healthcare globally. The repository should provide the appropriate references and/or attributes to enable use of all objects internationally. Note: This statement will be expanded into more positive, concrete requirements in package 2.

2.8 Traceability

2.8.1 Tracking of Contribution Source

The repository and associated tools should provide a mechanism for preserving and viewing contributing sources of an object (tracing the origins), and/or contributing organization(s). Detailed tracking from an object to the which contributed to its development is not required.