Public Review – JIRA Issues

Dave Iberson-Hurst, 29th March 2022

Changes

- 9th March 2022 – Initial draft.
- 15th March 2022 – Updated with addition of DDF-228, DDF-219, DDF-197, DDF-196 and DDF-185
- 17th March 2022 – Updated with addition of DDF-224, DDF-198, DDF-186, DDF-185, DDF-133, DDF-102
- 21st March 2022 – Add in DDF-226 and DDF-227
- 23rd March 2022 – Add in DDF-106 and DDF-114. Restructure the Topic Areas section to facilitate what needs to be undertaken for public review and the questions that are to be posed to reviewers.
- 24th March 2022 – Add in DDF-103
- 28th March 2022 – Add in DDF-221 and DDF-225
- 29th March 2022 – Add in review questions and fix an incorrect reference.

Purpose

This note assembles all the DDF JIRA tickets that have not been processed prior to the first CDISC public review of the USDM. The note provides an overview of the tickets, groups the tickets into topic area and provides a detailed export for each of the tickets.

Those participating in the public review are requested to note the questions in **red text** in the **Topic Areas** section below.

Ticket Summary

The following table provides a list of all the tickets that have been deferred to public review.

Ticket	Title
DDF-228	Amendment Version
DDF-227	Procedure Type
DDF-226	Intervention Status
DDF-225	Study Identifier
DDF-224	Study Status
DDF-221	"To Do" found in the "Return type" under get /studydefinitionrepository/v1/{study}/studydesign/{studydesignid}
DDF-219	TCB Glossary
DDF-216	Section History
DDF-215	Estimands
DDF-210	Workflow

DDF-208	Study Data
DDF-207	Observational Studies versus Clinical Trials
DDF-204	Workflow Sequence
DDF-203	Arm relationship from Workflow Item
DDF-200	Link to External Controlled Terminologies
DDF-198	DDF CT v1.8 Study Design Cell (p.11) and Study Design Element (p.9) and Study Epoch (p.12)
DDF-197	DDF CT v1.8 Study Arm Origin Type
DDF-196	Add CPT Synonyms to CT document
DDF-193	Link from study_design to Epoch/element/arm/cell should be via arm
DDF-192	Link between class study and objectives, study design, indication eg is lost
DDF-187	Data Dictionary: Study Protocol Version and Study Protocol Version Identifier
DDF-186	Sprint 9, Protocol Status
DDF-185	OriginType vs Origin
DDF-152	In the Common - PatientReportedOutcome Class description is not complete.
DDF-133	Definition considerations for study design cell
DDF-121	API review
DDF-119	UML Diagram
DDF-114	PointinTime entity
DDF-106	Study Indication
DDF-103	InvestigationalIntervention
DDF-102	Protocol_Release date
DDF-95	Study Visits
DDF-93	Reference to CDISC CT
DDF-91	Introduce Syntax Templates as in CDISC 360 POC
DDF-90	General comment to API
DDF-66	Study Identifier Type is vague

Topic Areas

General

The following table places each of the JIRA tickets above into a topic area for ease of processing, provides a summary description, a suggested method of dealing with the issue, the public review questions, and any other relevant notes.

Methods

The methods suggested are:

1. Internal Team – The current CDISC team deal with the issue during the public review and ticket resolution period.
2. Product Owners – CDISC and TCB product owners plus selected SMEs as needed.
3. SMEs – The CDISC, TCB and SMEs meet to focus on each topic individually during the public review and ticket resolution period.
4. Public Review – A question to be issued as part of the public review to solicit a wide range of views.

The methods are presented in an order of "increasing visibility", e.g. anything in public review is open to the SMEs, Product Owners etc.

Detail

The suggested resolution is presented in the following table:

Area	Tickets	Description	Method	Notes
Controlled Terminologies	DDF-219, DDF-196	Alignment with the TransCelerate glossary and CPT document fields.	Internal Team	
Sections and Section History	DDF-216, DDF-192	The section mechanism and associated history.	Public Review	The current USDM contains the notion of sections and section history. Some reviewers have raised concerns that this is not a necessary feature and that such capability should not be part of an industry model that

				representments studies and their definition. Consequently, we would like to solicit the views of the community on this aspect of the USDM. It is noted that any changes to the USDM in this respect would have a similar impact on the API specification.
API	DDF-121, DDF- 90	The API is very specific to the current implementation and other implementations may have difficulty in being able to recreate it due to the sections in the model. Also, the API works at a very high-level providing bulk transfers and a more granular API might be wise.	Public Review	See above, combined question.
Model Design	DDF-225, DDF-215, DDF-201, DDF-119, DDF-114, DDF-106, DDF-95, DDF-66	There are several comments where adjustment or refinements have been suggested. These are collected under this heading to facilitate their processing.	Internal Team	One or two of the issues may require SME input.
Study Data	DDF-208, DDF-152	The whole Study Data area was simplified during development to reduce the scope and thus maintain the timeline. This needs to be revisited.	Public Review	The area where the STUDY_DATA class currently resides was simplified during USDM development. Any thoughts from the community of the approach, level of specificity or modelling of the

				precise study data needs would be appreciated.
Workflow	DDF-210, DDF-204, DDF-203	Workflow is a tricky area and needs a good review and check that the logic within the USDM is what is needed.	SMEs	
Study, Protocol and Amendments	DDF-228, DDF-224, DDF-187, DDF-102	The relationship between Study, Study Design, Protocol and amendments and version needs checking.	Public Review	Currently the USDM defines the STUDY, STUDY_PROTOCOL and AMENDMENT classes to hold the relationships and information to relate a study and the associated protocol. There is a need to improve this area, to better represent the needs of the community including the complexity of protocol amendments. We are therefore requesting reviewers pay attention to this area and consider their current practices of handling studies, protocols, and the associated amendments and what is needed in the USDM to support this. We would however also note that the current practices in a paper-based world may not make for the best practices in an electronic world and the community needs to strike the appropriate balance.

External CT	DDF-227, DDF-103, DDF-200, DDF-93	Tickets relating to the use of external CT and how CT is referenced. Once particular example is procedure types and using external CT.	Public Review	Within the USDM there are places where the CODE class can be used to refer to external (to the USDM) terminology. The project has already received comments about expanding the ability to refer to external terminology for such items as interventions and procedures. As part of this review, it would be useful to know what the CT the community is using for such items with their current protocols or what may be useful as the community moves from a paper paradigm to an electronic one.
Suggestions and Ideas	DDF-207, DDF-91	A few tickets suggesting new capabilities in the model.	Product Owners	
Origin and Origin Type	DDF-197, DDF-185	A new area and idea and there is some work needed to clarify the naming of fields and their use.	Public Review	We would like to ask the community to consider the classes STUDY_ARM_ORIGIN and the associated TYPE class and consider the values that the origin type should cover. We would also ask the community to note that this notion does not directly relate to the source data origin seen within the define.xml but that there is a link between the two ideas and comment on those aspects as well.

Study Cell, Element, Arm & Epoch	DDF-198, DDF-193, DDF-133	Get precise relationships between Study Arm, Epoch, Cell, and Element resolved. Some differences of opinion.	Product Owners	
Intervention Status	DDF-226	A field that does not appear to have a use case. Seems to have been requested by the implementation team.	Internal Team	

Tickets

This section provides an export in full of each JIRA ticket in the interests of transparency and providing a stand-alone document.

[DDF-228] Amendment Version **Created: 14/Mar/22 Updated: 14/Mar/22**	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	To be assigned
Reporter:	Dave Iberson-Hurst	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Issue Links:	**Relates**			
	relates to	DDF-187	Data Dictionary: Study Protocol Versi...	Under Team Review

Description

amendment_version (CLASS AMENDMENT): Logically this makes no sense: We see the concept of 'version' related to the study protocol. An amendment may yield a new version of the protocol but the amendment itself is not versioned, as far as our experience has shown.

Comments

Comment by Dave Iberson-Hurst [14/Mar/22]

Deal with this a part of the general Protocol / Amendment issues in public review. Handle under DDF-187

[DDF-227] Procedure Type **Created: 14/Mar/22 Updated: 21/Mar/22**	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	Minor
Reporter:	Dave Iberson-Hurst	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Description

Comments from DDF DD / CT review
procedure_type_desc (Class PROCEDURE_TYPE): what are the expected values for this? We aren't really sure what this means.

Comments

Comment by Christopher E Upkes [16/Mar/22]

Procedure is polypmorphic. Types are SpecimenCollection, SubstanceAdministration, PatientInterview, PatientReportedOutcome,MedicalProcedure

Comment by Dave Iberson-Hurst [17/Mar/22]

I think this one we will put to public review. How much do we want to use external Thesaurus versus put the types into the USDM.

[DDF-226] Intervention Status **Created: 14/Mar/22 Updated: 21/Mar/22**	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	Minor
Reporter:	Dave Iberson-Hurst	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Description

Comments from DDF DD / CT review
intervention_status (Class INVESTIGATIONAL_INTERVENTION): What is this and what are the expected values for this? Was the intention to control these responses with CDISC CT?

Comments

Comment by Christopher E Upkes [16/Mar/22]
Dunno. Should I know? It was likely in the mind-map. Who should know?
Comment by Dave Iberson-Hurst [21/Mar/22]
Let's delete the status field until someone comes up with a proper use case.
Comment by Dave Iberson-Hurst [21/Mar/22]
From Chris U: We need to ask the implementation team. It was their request. Move to public review

[DDF-225] Study Identifier **Created: 14/Mar/22 Updated: 28/Mar/22**	
Status:	In Progress
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	Minor
Reporter:	Dave Iberson-Hurst	**Assignee:**	Erin Muhlbradt
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Attachments:	Screenshot 2022-03-21 at 13.39.58.png
Review Period:	Public Review

Description

Comments from DDF DD / CT review
study_identifier_name (Class STUDY_IDENTIFIER): What is this and what are the expected values for this?

Comments

Comment by Christopher E Upkes [16/Mar/22]

This is the name of the identifying organization. One example I have is: name":"ClinicalTrials.gov. Based on that, there can be no pre-defined expected values list, but rather some common values.

Comment by Dave Iberson-Hurst [17/Mar/22]

The fields in this class could do with a review, not the best named, I noticed this when setting up the study data. Might want to push to public review?

Comment by Dave Iberson-Hurst [21/Mar/22]

Using my example DB based on Berber's data. I extracted this from a query. I had three identifiers for the study, two for CT.gov and one for the sponsor itself:


```
[
 {
  "study_identifier_name": "ClinicalTrials.gov",
  "study_identifier_type_id": "RegistryID",
  "org_code": "NCT04298021"
 },
```

```
 {
  "study_identifier_name": "ClinicalTrials.gov",
  "study_identifier_type_id": "RegistryID",
  "org_code": "NCT04298023"
 },
 {
  "study_identifier_name": "SponsorNo",
  "study_identifier_type_id": "SponsorID",
  "org_code": "AZ002020202"
 }
]
```


The name field is seen in the data example as the org who scopes the identifier, the type is the type of org and the org code is the actual identifier in the scope of the org.
I have attached the current CT entries for the two classes, STUDY_IDENTIFIER and STUDY_IDENTIFIER_TYPE.
Note the slight difference between the UML and the above. I put type_id in with the STUDY_IDENTIFIER class while the UML has it separate as the STUDY_IDENTIFIER_TYPE class, but logically the same (it is 1:1).
Erin Muhlbradt we have a little mismatch between the data sent by Berber and definitions in the CT spreadsheet. The name of the fields are not the most meaningful. Any thoughts?

Comment by Erin Muhlbradt [21/Mar/22]

To confirm: was 'study_identifier_name' meant to go with the org_code field in the UML? Is the one a **code** for the organziation that assigns the identifier (org_code) and the other is the **name** of the organization that assigns the identifer (study_identifier_name)? If this is true, then 'study_identifier_name' is not intuitive or descriptive enough (incidentally neither is org_code).
Chris' original explanation of 'org_code' (another attribute within that same entity) to us was 'It's the ID for the org that provided the identifier. For example, it would be "Colorado DMV" for my drivers license number.' The above explanation of what 'study_identifier_name' is makes 'org_code' and 'study_identifier_name' sound the same but I assume they are meant to be different, yes?
What about (for the CT file, because that is all I control):

STUDY_IDENTIFIER	STUDY_IDENTIFIER	Entity	C83082	Study Identifier		A sequence of characters used to identify, name, or characterize the study.
STUDY_IDENTIFIER	org_code	Attribute	CNEW	Study Identifier Assignee Organization Code		A coded value specifying the organization that creates and/or

						assigns the study identifier.
STUDY_IDENTIFIER	study_identifier_name	Attribute	CNEW	Study Identifier Assignee Organization Name		The literal identifier (i.e., distinctive designation) of the organization that creates and/or assigns the study identifier.

Comment by Dave Iberson-Hurst [22/Mar/22]

Berber's test data looks like this. She is using name as the name of the org, the type as the type of the org and code as the actual identifier used by the org. We want those three pieces I think, the name of the org, the org type and the identifier allocated by that org for this study. What we name them is the issue I think. Thoughts?


```
[
 {
  "study_identifier_name": "ClinicalTrials.gov",
  "study_identifier_type_id": "RegistryID",
  "org_code": "NCT04298021"
 },
 {
  "study_identifier_name": "ClinicalTrials.gov",
  "study_identifier_type_id": "RegistryID",
  "org_code": "NCT04298023"
 },
 {
  "study_identifier_name": "SponsorNo",
  "study_identifier_type_id": "SponsorID",
  "org_code": "AZ002020202"
 }
]
```


Comment by Dave Iberson-Hurst [22/Mar/22]

And I seem to have repeated myself, apologies, with the data. But, three fields like:
org_name "ClinicalTrials.gov"
org_type "Registry"
org_identifier "NCT12345..."

Comment by Erin Muhlbradt [22/Mar/22]

Dave Iberson-Hurst I agree with these 3 fields, logically they make sense. The CT would then look something like:
Study Identifier Assignee Organization Name
Study Identifier Assignee Organization Type
Study Identifier Assignee Organization Identifier (this one I'm not sure about; it could simply be 'Study Identifier' with relationships to the other two concepts)

Comment by Christopher E Upkes [24/Mar/22]

Easy to change, however, do we care if this impacts MS/Accenture?

[DDF-224] Study Status **Created: 14/Mar/22 Updated: 16/Mar/22**	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	Minor
Reporter:	Dave Iberson-Hurst	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Description

Comments from DDF DD / CT review
study_status (Class STUDY): Did they actually mean/want 'Study Protocol Status' here? We did develop CT for that one. If they truly wanted, 'study status' what are the expected response values? Was the intention to control these responses with CDISC CT? We aren't really sure how to define this as the language used is too broad.

[DDF-221] "To Do" found in the "Return type" under get /studydefinitionrepository/v1/{study}/studydesign/{studydesignid} **Created: 11/Mar/22 Updated: 28/Mar/22**	
Status:	In Progress
Project:	Digital Data Flow
Component/s:	API Specification
Affects Version/s:	None
Fix Version/s:	None

Type:	Improvement	**Priority:**	Minor
Reporter:	Rebecca Baker	**Assignee:**	Christopher E Upkes
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Review Period:	GGG for Public Review

Description

In the API Firefox HTML:
under:
get /studydefinitionrepository/v1/
{study}
/studydesign/
{studydesignid}
There is a "TODO" under "Return type"

Comments

Comment by Christopher E Upkes [16/Mar/22]

Can I get a screenshot of this? There is nothing wrong with the API spec in SwaggerHub that I can see.

Comment by Christopher E Upkes [16/Mar/22]

Ahhh. Ok. Nobody created an actual mock for the StudyDesignSections stub call. Got it. I'm working on this.

Comment by Christopher E Upkes [24/Mar/22]

This won't be done prior to public review.

[DDF-219] TCB Glossary **Created: 08/Mar/22 Updated: 14/Mar/22**	
Status:	In Progress
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Improvement	**Priority:**	Minor
Reporter:	Dave Iberson-Hurst	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	DDF-CPT-Glossary		

Attachments:	DDF Glossary_Terms and Definitions_Draft Nov 2021.xlsx

Description

How to include the draft TransCelerate Glossary into the DDF public review

[DDF-216] Section History Created: 28/Feb/22 Updated: 28/Feb/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Dave Iberson-Hurst	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Issue Links:	Relates
	relates to DDF-199 Set of comments from TCB SMEs Under Team Review

Description

Section_history: No direct link between study and other elements any more due to sectioning. Although this might be helpful for the SDR. This is, as we discussed at the internal TransCelerate meeting not logical and insightful for the vendors and other users. The structure of the table section_history implies that there might be a direct link between 1 objective and 1 population for example which is not the case. In addition, errors in filling this table correctly to reflect a usable structure are very likely. If sectioning is necessary for the SDR it should be an add-on. Not part of the main model.

Comments

Comment by Dave Iberson-Hurst [28/Feb/22]
This is where the implementation has crept into the model. Will not be changed for the immediate future but something to be discussed with TCB as part of the wide vision.

[DDF-215] Estimands Created: 28/Feb/22 Updated: 02/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Dave Iberson-Hurst	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Issue Links:	Relates
	relates to DDF-199 Set of comments from TCB SMEs Under Team Review

Description

Estimands should also be linked to endpoints

Comments

Comment by Dave Iberson-Hurst [28/Feb/22]
Moved to public review so as to be discussed with TCB

[DDF-210] Workflow Created: 28/Feb/22 Updated: 03/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Major
Reporter:	Dave Iberson-Hurst	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Issue Links:	Relates
	relates to DDF-199 Set of comments from TCB SMEs Under Team Review

Description

Workflow: Workflow is related to epochs. (But not in this model.) It is now also confusing with workflow_items which refers to a specific sequence of activities within an encounter. I would store the epoch sequence instead and try to add items that account for additional requirements for workflow.
Workflow_items: It is now only accounting for 1 potential workflow in a study – in case of more than 1 design or different wokflows for different arms for example.
The most straightforward method would be to add optional arm and study_design id to this table
Workflow_item_sequence: How would the NOT NULL requirement work for prev_workflow_item_id if you are the first item in the workflow and there is no previous workflow item?
I also don't see why you have to solve the ordering/sequencing in such a complex way while a ordernumber in the workflow_items table would be sufficient.

Comments

Comment by Dave Iberson-Hurst [02/Mar/22]
This is a significant issue and will be moved to public review

[DDF-208] Study Data Created: 24/Feb/22 Updated: 02/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Major
Reporter:	Dave Iberson-Hurst	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Issue Links:	Relates			
	relates to	DDF-168	In the UML diagram, shouldn't StudyDa...	Under Team Review
	relates to	DDF-199	Set of comments from TCB SMEs	Under Team Review

Description

During the development of the USDM the area around STUDY_DATA was simplified so as to reduce scope and maintain the timeline. However, this is an important area and this ticket has been added have a single placeholder for that work.

[DDF-207] Observational Studies versus Clinical Trials Created: 17/Feb/22 Updated: 22/Feb/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Question	Priority:	Minor
Reporter:	Herve Louis Fouche	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Issue Links:	Relates		
	relates to	DDF-92 Use 'Study' consistently	Under Team Review

Description

It might be worth retaining some distinction (in the nomenclature) between the pocket of observational studies and the pocket of clinical trials, if such distinction helps to process the items across the "value chain" from operating protocol-driven CDISC/CDASH data acquisition steps down to miscellaneous reporting requirements (i.e. CSR, SDTM and/or ADaM datasets) imposed by Health Authorities in context.

Comments

Comment by Dave Iberson-Hurst [17/Feb/22]
Split from DDF-92. Important point that should not be forgotten.
Comment by Dave Iberson-Hurst [22/Feb/22]
Going to move this to public review as this point wont be addressed until then.

[DDF-204] Workflow Sequence Created: 16/Feb/22 Updated: 02/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Critical
Reporter:	Dave Iberson-Hurst	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Attachments:	UML_Sprint10FeedbackBerber2.jpg

Description

Consider the changes for Workflow Items and Workflow Item Sequence as noted in the attached and see if the change makes sense

Comments

Comment by Dave Iberson-Hurst [02/Mar/22]
Consider as part of public review

[DDF-203] Arm relationship from Workflow Item Created: 16/Feb/22 Updated: 02/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Major
Reporter:	Dave Iberson-Hurst	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Attachments:	UML_Sprint10FeedbackBerber2.jpg

Description

Consider adding a relationship between Arm and Workflow Item as per the comments in the attached

Comments

Comment by Dave Iberson-Hurst [02/Mar/22]
Consider as part of public review

[DDF-200] Link to External Controlled Terminologies Created: 14/Feb/22 Updated: 02/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Improvement	Priority:	Minor
Reporter:	Michael Morozewicz	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Description

After working with the TransCelerate Procedure Library team, we had defined a goal of better linking activities and assessments defined within the SOA to external controlled terminologies. Would it be possible to add attributes to store the name of the external controlled terminology being used to define the activity/assessment along with the activity/assessment term from the external CT, and an identifier for the term from the external controlled terminology? I think this might fit best under the Biomedical Concept attributes under sprint 6 or the Study Activity attributes from sprint 3.

Comments

Comment by Dave Iberson-Hurst [21/Feb/22]

Mike
I think this sounds sensible etc but time will not allow this to be acted upon. Therefore I am labelling it as "Moved to Public Review" to that it can be preserved and treated as a public review comment and then a decision on "when" can be made.
Dave IH

[DDF-197] DDF CT v1.8 Study Arm Origin Type **Created: 12/Feb/22 Updated: 14/Mar/22**	
Status:	In Progress
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Improvement	**Priority:**	Minor
Reporter:	Rebecca Baker	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Issue Links:	**Relates**			
	relates to	DDF-185	OriginType vs Origin	Under Team Review
Review Period:	Internal Review			

Description

Study Arm Origin Type in CT v1.8 is defined as:
"A characterization or classification of the study arm with respect to where the study arm data originates."
consider
"A characterization or classification of the subject data with respect to where the study arm data originates."
Not sure if this is correct given the possible examples include: historical data, real world data, synthetic data. If this is the case, would it be better to call it "Study Arm Data Origin Type"?
The suggestion is for data that is collected and the subject changes to a different arm. For example, the subject enrolls in a RCT double blind study. Treatment is stopped, however, the subject continues to be followed. When unblinding occurs, the subject data originally was in Arm A (study drug) but once study drug was stopped the subject was in Arm B (placebo).
As I type this, it seems the subject data would not be part of the digital data flow study protocol development and study design.

Comments

Comment by Dave Iberson-Hurst [14/Mar/22]

Manage under DDF-185 and push to public review

[DDF-198] DDF CT v1.8 Study Design Cell (p.11) and Study Design Element (p.9) and Study Epoch (p.12) **Created: 12/Feb/22 Updated: 17/Mar/22**

Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Improvement	**Priority:**	Minor
Reporter:	Rebecca Baker	**Assignee:**	Erin Muhlbradt
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Issue Links:	**Relates**
	relates to DDF-133 Definition considerations for study d... In Progress
Review Period:	Public Review

Description

The Study Design Cell is defined as: A partitioning of a study arm into individual pieces, which are associated with an epoch and represent an implementation of the purpose of its associated epoch. (SDTMIGv3.3, section 7.1.2)
The Study Design Element is defined as: A basic building block for time within a clinical study comprising the following characteristics: a description of what happens to the subject during the element; a definition of the start of the element; a rule for ending the element.
The Study Epoch is defined as: A named time period defined in the protocol, wherein a study activity is specified and unchanging throughout the interval, to support a study-specific purpose.
SDTMIG v3.3 7.1.2 describes the interplay between these concepts. Consider pointing out the differences in the definition.
"Many, perhaps most, clinical trials involve a single, simple administration of a planned intervention within a Study Cell, but for some trials, the treatment strategy associated with a Study Cell may involve a complex series of administrations of treatment. It may be important to track the component steps in a treatment strategy both operationally and because secondary objectives and safety analyses require that data be grouped by the treatment step during which it was collected. The steps within a treatment strategy may involve different doses of drug, different drugs, or different kinds of care, as in pre-operative, operative, and post-operative periods surrounding surgery. When the treatment strategy for a Study Cell is simple, the Study Cell will contain a single Element, and for many purposes there is little value in distinguishing between the Study Cell and the Element. However, when the treatment strategy for a Study Cell consists of a complex series of treatments, a Study Cell can contain multiple Elements. There may be a fixed sequence of Elements, or a repeating cycle of Elements, or some other complex pattern. In these cases, the distinction between a Study Cell and an Element is very useful."

Comments

Comment by Erin Muhlbradt [16/Mar/22]
Will resolve during public review, along with DDF-133.

[DDF-196] Add CPT Synonyms to CT document **Created: 11/Feb/22 Updated: 08/Mar/22**	
Status:	In Progress
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Improvement	**Priority:**	Major
Reporter:	Belinda Griffin	**Assignee:**	Erin Muhlbradt
Resolution:	Unresolved	**Votes:**	0
Labels:	DDF-CPT-Glossary		

Attachments:	DDF Mapping_MO.xlsx

Description

For the each of the data elements in the USDM that have been identified as corresponding to CPT fields (TCB can provide a list) can we add the corresponding CPT field name in the synonyms section of the CT. This will aid in future mapping activities between USDM and eCPT.

Comments

Comment by John Owen [17/Feb/22]

Email from Belinda 17 Feb 2022
Hi Dave:
As just discussed, please find attached the analysis that Mary Ost from J&J has done that is referenced in Jira ticket 196. She has also indicated that she would be available to walk someone from CDISC through it if that is helpful. If you'd like to go that route just let me know and I can make the connection.
Thank you,

Belinda Griffin

Comment by Dave Iberson-Hurst [21/Feb/22]

Erin, Can you have a think about this one please, Dave

[DDF-193] Link from study design to Epoch/element/arm/cell should be via arm Created: 10/Feb/22 Updated: 07/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Major
Reporter:	Berber Snoeijer	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Issue Links:	Duplicate			
	is duplicated by	DDF-52	Sprint 4 - Arms / Epochs UML	Under Team Review
	Relates			
	relates to	DDF-195	study_cell to study_element relationship	Under Team Review
	relates to	DDF-199	Set of comments from TCB SMEs	Under Team Review

Description

Although mentioned several times the link from study design to the epoch/element/arm/cell concept is still via cell instead of via arm.
The logical build of a study would be to first define epochs, elements and arms and then the cell based on that. This model implies does that but there is no direct link between the arms, epochs an delements and studydesign.
So for example, when you design a study you first want to name your arms. Or if yo are getting info from clintrials.gov you only have information of arms. Then you want to be able to directly link that to the study design without the requirement of having to define a cell first.

Comments

Comment by Dave Iberson-Hurst [21/Feb/22]

Chris
A quick discussion on this one might be wise
Dave

Comment by Dave Iberson-Hurst [02/Mar/22]

This is the main ticker for the Study / Cell / Arm / Epoch discussion and will be handled as part of the public review.

[DDF-192] Link between class study and objectives, study design, indication eg is lost Created: 10/Feb/22 Updated: 03/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Critical
Reporter:	Berber Snoeijer	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Description

In the UML diagram - the attributes for interventions, objectives, indications are no longer present in the class Study. The link between Study and studyDesign classes is also removed.
In the UML diagram - the link is now via Section class.
In the SQL the link is via section_history table (which is not available in the UML) where for each row you have a section_class and options for IDs of objectives, Interventions, Study Design etc. This is very confusing as it does not show the true relation between the different classes and implies that there is a direct relation between particular interventions, objectives, study designs etc. But only one can be filled at a time like this:

Section_id	study_id	objective_id	indication_id	study_design_id	study_cell_id
SS01	ST01	OB01			
SS02	ST01	OB02			
SS03	ST01		IN01		
SS04	ST01		IN02		
SS05	ST01			SD01	
SS06	ST01			SD01	SC01
SS07	ST01			SD01	SC02

It also does also not account for the requirement that a study_cell does need a study_design_id to be correct. Let alone that study_cell is not the right option but rather the link should be via study_arm (see next ticket).
I understand why the sectioning is handy but can't we model it in another way as an extra feature instead of a link between study relevant information classes. In the previous sprints this was the case and now it is removed.
That would keep it logical for the users and then you differentiate between the actual model to capture the data and the technical added features to make it usable for versioning etc?

Comments

Comment by Dave Iberson-Hurst [02/Mar/22]

This is really about the sectioning approach. I would agree with Berber that sections "hide" the proper relationships and is confusing. This is not something we can change in the immediate future but we should consider carefully as part of the public review.

Comment by Christopher E Upkes [03/Mar/22]

Sections are an artifice of implementation, requested by the Microsoft team. The change in section design should first be brought up with the Microsoft team.

[DDF-187] Data Dictionary: Study Protocol Version and Study Protocol Version Identifier Created: 21/Jan/22 Updated: 07/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Linda Lander	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Description

The entity, Study Protocol, in the Data Dictionary includes id and version among other attributes. The CT for Sprint 9 defines 'Study Protocol Version' as an entity and Study Protocol Version Identifier' as an attribute of Study Protocol Version. Should the Data Dictionary include another entity for Study Protocol Version separate from Study Protocol?

Comments

Comment by Christopher E Upkes [03/Mar/22]
Excellent observation. So, the StudyProtocol object in the model is actually always a StudyProtocol version, however the identifier is not particular to that version. What you've pointed out is nuanced and DIFFERENT than what we have. I think the team has to discuss this. Dave IH, Erin, Craig?
Comment by Dave Iberson-Hurst [04/Mar/22]
Moving this to the public review bucket.

[DDF-186] Sprint 9: Protocol Status **Created: 21/Jan/22 Updated: 17/Mar/22**	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	Minor
Reporter:	Linda Lander	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Review Period:	Public Review

Description

Protocol Status is marked as 'NEW'. I was curious about the connection (if any) between the NCI Thesaurus concept and the new Protocol Status for DDF: NCI has Document Version Workflow Status and Document Version Workflow Status Code (C93822). The valid terms are different (On-hold, Accepted, Rejected, Abstracted, Abstraction Verified, Abstraction not verified).

Comments

Comment by Christopher E Upkes [03/Mar/22]

Ok. Erin, Team, should ProtocolStatus be an enum with values : On-hold, Accepted, Rejected, Abstracted, Abstraction Verified, Abstraction not verified ? Looks reasonable to me?

Comment by Erin Muhlbradt [16/Mar/22]

The Protocol Status valid values that we developed for this project are:

Draft
Pending Review
Approved
Final
Obsolete

These values were given to us by the Transcelerate scoping team. The cited valid values from this commenter are from BRIDG. We have not discussed with the SMEs which list is more valid and/or whether the lists could potentially be merged. We need feedback from the SMEs.

Comment by Dave Iberson-Hurst [17/Mar/22]

Lets add this to the Protocol pot for public review

[DDF-185] OriginType vs Origin **Created: 21/Dec/21 Updated: 14/Mar/22**	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	API Specification, Controlled Terminology, USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Content Error	**Priority:**	Minor
Reporter:	Berber Snoeijer	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Issue Links:	**Relates**			
	relates to	DDF-197	DDF CT v1.8 Study Arm Origin Type	In Progress
	relates to	DDF-115	Study Arm	Under Team Review

Description

The described content of OriginType is now in the API in the field Origin. So there is a mismatch. Origin is then superfluous unless we want to have the option to exactly describe where the data originates from. Like
OriginType=Real World Data ; origin = Electronic Health Records / Hospital records.
OriginType=Synthetic data ; origin = synthetic data company xxx ?
I would also add an OriginType for the conventional experimental design in the CT.

See also ticket 115

Comments

Comment by Dave Iberson-Hurst [03/Mar/22]

Something for before or during public review. This is a tricky area. See also overlap in DDF-197

Comment by Christopher E Upkes [03/Mar/22]

This resolution is above my pay grade. I just implemented what was in the mind-map. It seems as if this is going to need refactoring. I'll implement as soon as I get a design direction.

Comment by Dave Iberson-Hurst [03/Mar/22]

Chris
This one is allocated to me. Will consider as part of public revew

Dave

[DDF-152] In the Common - PatientReportedOutcome Class description is not complete. Created: 10/Dec/21 Updated: 08/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Error/Typo	Priority:	Minor
Reporter:	Rebecca Baker	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Review Period:	Internal Review

Description

In Sprint 7 - UML-Class-Diagram 2021-12-09,
In the Common - PatientReportedOutcome Class description is not complete.
In the CT Patient Reported Outcome is:
A type of clinical outcome assessment. A measurement based
on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a
clinician or anyone else.
This is an Activity.
It is Study Data.
There are a number of intersections that are not easily seen in the current UML diagram.

Comments

Comment by Christopher E Upkes [03/Mar/22]
You raise an interesting point. We need to better figure out how we provide context to study data. Let's save this for after public review.
Comment by Dave Iberson-Hurst [04/Mar/22]
Adding this one to the public review pot.

[DDF-133] Definition considerations for study design cell **Created: 07/Dec/21 Updated: 17/Mar/22**	
Status:	In Progress
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Improvement	**Priority:**	Minor
Reporter:	Rebecca Baker	**Assignee:**	Erin Muhlbradt
Resolution:	Unresolved	**Votes:**	0
Labels:	None		

Issue Links:	**Relates**			
	relates to	DDF-198	DDF CT v1.8 Study Design Cell (p.11)...	Under Team Review
Review Period:	Public Review			

Description

In CT v1.4 2021-11-23, Study Design Cell is defined as: "A partitioning of a study arm into individual pieces, which are associated with an epoch and represent an implementation of the purpose of its associated epoch. (SDTMIGv3.3, section 7.1.2)"
In the SDM XML v1.0, page 8 the study cell is defined as:
"The part of study design that describes what happens in a particular epoch for a particular arm. The cell describes how the purpose of its epoch is fulfilled for each arm."
The later is clearer, however, maybe a better iteration could be:
"A partitioning of a study arm into individual pieces associated with a particular epoch for a particular arm that describes what happens. The cell describes how the purpose of its epoch is fulfilled for each arm."

Comments

Comment by Erin Muhlbradt [19/Jan/22]

We need DianeW and FredW on this one. We **think** that a design cell is a unique combination of Arm, Epoch, and Element(s). However the SDTMIG and SDM-XML documentation only describe a study cell with respect to the Arm and Epoch. It is unclear how Elements fit in. We think that neither definition from SDTMIG or SDM-XML is truly adequate in defining what a study cell is.
We think rather that the Study Cell is a unique combination of an Arm, Epoch, and Element(s) but need confirmation on this point.

[DDF-121] API review Created: 29/Nov/21 Updated: 08/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	API Specification
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Christopher Allan	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Description

I may be confused but I was expecting to see as part of the API specifications a description of the file format or formats that the data is provided – the only reference I see is to JSON. Is it correct that the data available from the API is in one or more specific file formats?

Comments

Comment by Jozef Aerts [07/Dec/21]
The idea was JSON coming first, adding XML, RDF-Turtle, maybe YAML coming later. I think it is more an implementation issue, the software developers needing to write software for each data format. I see them already protesting if I add "XML" to the API ...
Comment by Christopher Allan [08/Dec/21]
So the API is agnostic to the actual format - software developers are able to use the API for whatever data format is needed?
Comment by Jozef Aerts [08/Dec/21]
Essentially: yes. If someone wants to program the system using Fortran ... It's just that having "JSON" in the spec, makes it a bit easier for developers to automatically generate things when the exchange format is JSON. It does not exclude other formats though.
Comment by Dave Iberson-Hurst [08/Feb/22]
This will not happen in the current phase or work. The API is a JSON interface.

[DDF-119] UML Diagram Created: 29/Nov/21 Updated: 08/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Christopher Allan	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Description

Point in time type – this reflects study status during the phase when there are patients – is there consideration to track the study start-up and close-out phases – pre and post recruitment?
Is Study Indication the same as Therapeutic Area, if not can TA be indicated?
Is there a way of indicating that an Endpoint data is for safety, and in addition can data be categorised which is not Endpoint data but still critical?
There is sometimes confusion between subject visit and monitoring visit during general discussions about study execution – this is subject visit and therefore monitoring visit is not reflected? This is a key activity for many studies as is aspects such as source data verification – is this accounted for somewhere?
For subject visits certain visits are home where the subject competes the assessment increasingly we are seeing home nursing – can this be categorised?
How are assessments completed which are not associated with a visit reflected? I would expect to see assessments associated with a visit as well as assessments not associated with a visit?
I would expect to see associated data to the environment such as people, roles, addresses, etc – Sites details and Countries are key data for the execution of a study but are not currently reflected/
Devices are a key element which need to be considered in the execution of visits and assessments but not reflected in this UML?

Comments

Comment by Jozef Aerts [08/Dec/21]

Regarding "therapeutic area", no I do not consider it as the same as "indication". I think the indication might be a "specialization" or "further narrowing" of "therapeutic area".
Do protocol writers add "therapeutic area" to the protocol? Or is "therapeutic area" usually just an annotation about which TAUG to apply for SDTM and ADaM?

Comment by Christopher Allan [08/Dec/21]

From a data use perspective we are often asked to group data by Therapeutic areas and Indication, therefore any storage of data needs to be able to identify for example that the data is associated to Respiratory and Asthma.

Comment by Christopher E Upkes [03/Mar/22]

Q. Is Study Indication the same as Therapeutic Area, if not can TA be indicated?
A. If it needs to be indicated with the Indication, I can add.
Q. Is there a way of indicating that an Endpoint data is for safety, and in addition can data be categorised which is not Endpoint data but still critical?
A. Yes, it's in the model as EndpointPurpose.
Q. There is sometimes confusion between subject visit and monitoring visit during general discussions about study execution – this is subject visit and therefore monitoring visit is not reflected? This is a key activity for many studies as is aspects such as source data verification – is this accounted for somewhere?
A. No, where should it exist?
Q. For subject visits certain visits are home where the subject competes the assessment increasingly we are seeing home nursing – can this be categorised?
A. Solved with EnvrionmentalSetting attribute.

Assessments are deprecated at this point. Can't answer those questions.
Only outstanding issue here is Theraperutic Area and questions related to monitoring visits.

Comment by Dave Iberson-Hurst [08/Mar/22]

Was in the concept map, we have CT available. Looks like it would be a sensible notion for the model to have TAs noted against designs. Move to public review.

[DDF-114] PointinTime entity Created: 27/Nov/21 Updated: 23/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	Minor
Reporter:	Linda Lander	**Assignee:**	Dave Iberson-Hurst
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Description

PointinTime entity is not aligned with the name in the CT file which calls this 'Study Period' and 'Study Period Name'. The latter has a valid value list which should align with PointinTime 'type' in the data dictionary. Field name 'type' in PointinTime has constraints/standard values which do not fully align with CT as defined in Sprint 4. It appears the decision was made by scoping team to make Point in Time (aka Study Period) a synonym of Epoch and use the CT for Epoch which has 12 valid values defined. PointinTime has a field name, subjectStatusGrouping' which should include constraints/standard values based on agreed CT. Refer to CT under Sprint 4.

Comments

Comment by Christopher E Upkes [03/Mar/22]

If what you say is true and a point in time is actually an Epoch, this is a flaw and should have been prioritized. Why would we have both. Dave IH?

Comment by Dave Iberson-Hurst [21/Mar/22]

I think the terminology for point_in_time_type_desc in POINT_IN_TIME_TYPE looks wrong. I think a POINT_IN_TIME is providing timing for a workflow item and not an epoch, so this is the timing associated with an activity at a single visit.

Comment by Erin Muhlbradt [21/Mar/22]

Please see the notes on the DDF CT work from sprint 4: https://wiki.cdisc.org/display/TEAMDDF/Sprint+4+CMAP+CT+Work+Area+-+Study+Assessments+and+Planned+Workflow+Part+1 (search 'point in time' on that page and you'll find it about 1/3 of the way down the attributes table)
'Point in time' came originally from the CMAP and we (Craig and I) had no idea what was meant by that concept either so we attended a scoping team meeting with the SMEs on

Oct 26th and the SMEs confirmed that what they meant by 'point in time' on the CMAP was an analogous concept to Epoch, which is why the CT reflects that.

[DDF-106] StudyIndication **Created: 21/Nov/21 Updated: 23/Mar/22**	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	Minor
Reporter:	Arjun Sridharan	**Assignee:**	Erin Muhlbradt
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Review Period:	Public Review

Description

Can this be called "Trial Disease/Condition Indication"? This language is as per the protocol terminology template.
What is this id? What do we plan to collect as part of the study indication ID

Comments

Comment by Jozef Aerts [08/Dec/21]

"Id"s are there to be used in references. They are created by the system upon creation of the object.

Comment by Arjun Sridharan [16/Jan/22]

Thank you Jozef Aerts. How about my first comment "Can this be called "Trial Disease/Condition Indication"? This language is as per the protocol terminology template."?

Comment by Jozef Aerts [16/Jan/22]

We were ordered to have it named "Study Indication" - but things can of course change (again). I don't take that decisiion ...

Comment by Christopher E Upkes [09/Feb/22]

This is a question for the CT team.

Comment by Christopher E Upkes [15/Feb/22]

This is not a question for me to decide. We don't use trial in the model, FYI.

Comment by Erin Muhlbradt [16/Mar/22]

In the CT product we have chosen to call this Trial Disease/Condition Indication to align it with the Trial Summary Parameter of the same name. CT team mapped that concept to

INDICATION in the model. CT team does not control what the model developers name the class entities and attributes. That is for the model team to action.
Comment by Dave Iberson-Hurst [23/Mar/22]
Will set to public Review and ask the implementation team

[DDF-103] InvestigationalIntervention **Created: 21/Nov/21 Updated: 23/Mar/22**	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	**Priority:**	Minor
Reporter:	Arjun Sridharan	**Assignee:**	Erin Muhlbradt
Resolution:	Unresolved	**Votes:**	0
Labels:	Move_To_Public_Review		

Review Period:	Public Review

Description

a) Can we use the "Intervention Attribute Terminology" code-list from the protocol terminology instead of calling it Investigational intervention?
The protocol terminology has the following values.
Intervention Name
Intervention Type
Intervention Description
b) What is this id all about? What do we plan to collect as an "id"?

Comments

Comment by Jozef Aerts [08/Dec/21]

For meaning of "Id", please see DDF-106.

Comment by Erin Muhlbradt [08/Feb/22]

a) Intervention Description is in the model and defined in the CT product. The other two potential values could be considered for inclusion within the model but that is up to the model development team to add them. All three of these items are defined in the CDISC Protocol Terminology.
b) Our understanding is that this is a system ID assigned by the system.

Comment by Dave Iberson-Hurst [23/Mar/22]

Ok, now I am on the same page. Put to Public Review since it is rather late in the day. Also, I am thinking should we be referring to external CT rather than having these fields? Just a thought. We will discuss.

[DDF-102] Protocol Release date Created: 21/Nov/21 Updated: 17/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Arjun Sridharan	Assignee:	Erin Muhlbradt
Resolution:	Unresolved	Votes:	1
Labels:	Move_To_Public_Review		

Issue Links:	Relates			
	relates to	DDF-182	Protocol version vs amendments and se...	Under Team Review
Review Period:	Public Review			

Description

How about having a protocol release date? This information would help especially when we have protocol amendments.

Comments

Comment by Alison Luckman [29/Nov/21]

Arjun Sridharan - protocol release date, or protocol version date I think would be more universally recognised and something captured (same applies for amendment version date/amendment release date)

Comment by Christine Connolly [03/Dec/21]

Erin Muhlbradt Assigning to CT first as this would need to be defined.

Comment by Christopher E Upkes [03/Mar/22]

Christine was going to assign I guess. Never did?

Comment by Nicolas DE SAINT JORRE [08/Mar/22]

As mentioned by Alison Luckman a version control solution is required to handle protocol release strategy. In order to achieve that we need a global strategy on version management, not only at the protocol level.
We need a way to have a protocol in a draft status (because it was newly created) in version 0.1 with a defined set of elements (a set of specific metadata). At this stage, we should be able to add / modify / delete any elements to obtain a second draft in version 0.2. We can now 'accept' this protocol: the validation should move the status to final and the version to 1.0.
This can be used for production.

As we have to change one secondary objective by adding a better description, this should create a new draft document (copy of the Final one) and set the version to 1.1. Inside the protocol, the secondary objective is now using the newly created definition via a cascading update process. This small change need to be tracked in an audit trail system.
As soon as we have updated everything in our new version, a governance process should allow the protocol to get to a new final status with version 2.0 (this is here the amendment of the initial version). At every stage we need to store a start and a end date time to track when to apply each version.
Of course this version management should also work for CRF management. If we change an assessment at the protocol level, then the ODM-XML eCRF definition should also have a version - status management system aligned with the metadata expected by the protocol. Just an end-to-end process.

Comment by Dave Iberson-Hurst [17/Mar/22]

Public review pot

[DDF-95] Study Visits Created: 18/Nov/21 Updated: 08/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	Controlled Terminology, USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Mikkel Traun	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Issue Links:	Relates			
	relates to	DDF-86	Attributes of Visit	In Progress
CDISC Disposition:	Persuasive			
CDISC Disposition Description:	These requested properties seem valid.			

Description

'Virtual Visit' should not be an attribute of Visit, it should be on of the values for Visit Contact Mode (like on-site visit, virtual visit, phone contact)
Add 'Visit windows' and 'Time reference', 'Visit start rule' and 'Visit end rule'

Comments

Comment by Christopher E Upkes [15/Feb/22]
I think that I'm going to move that property to the Encounter super class. I think all Encounters should have some contact mode. Does this make sense?
Comment by Dave Iberson-Hurst [17/Feb/22]
Just so to minimise change I would not act on this yet though I agree with the change. Treat as a public review comment or pre public review change.

[DDF-93] Reference to CDISC CT Created: 18/Nov/21 Updated: 08/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	API Specification, Controlled Terminology, USDM UML Diagram
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Mikkel Traun	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Description

Each time we use a ConceptID code, it would make sense to provide both the CodeList and the Term, no?
But generally we suggest the Enumerations are not included in the UML Class Diagrams nor API spec - only reference to the codelist name and codelist 'C code'
'Study Endpoint' is also in the Protocol CT (see C25212) not published in the Glossary CT
'Study'Objective should have a relationship to ObjectiveLevel - it seems the relationship is made from Study

Comments

Comment by Herve Louis Fouche [29/Nov/21]

It might be that the strategy about documenting Enumerations "terms" versus hooking some CT Codelist has been already decided / implemented in UML Class Diagrams, but in such a case, how would you address smoothly the evolution of extensible NCI:CDISC CodeLists? As example, EnvironmentalSetting holds 15 enumerated terms (Sprint 6 UML) as the CDISC CT127262 offers 18 distinct codes - meaning a quantitative difference of 3 terms. Does it mean that the overall UML Diagram will be subject to revision for the (relevant) Enumerated terms every time an (applicable) valid source CDISC CT will be "modified" / expanded / truncated? Or?

Comment by Christine Connolly [10/Dec/21]

Erin Muhlbradt and Craig M. Zwickl - Will cover "* 'Study Endpoint' is also in the Protocol CT (see C25212) not published in the Glossary CT". See Sprint 1 table for C25212; add published in protocol terminology to the Publication Status column.

Comment by Dave Iberson-Hurst [17/Feb/22]

Added a "move to public review" tag to the ticker. This part "Each time we use a ConceptID code, it would make sense to provide both the CodeList and the Term, no?" is something that needs thinking about. See the references in the FHIR style in the Code class

"

[DDF-91] Introduce Syntax Templates as in CDISC 360 POC Created: 18/Nov/21 Updated: 08/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	API Specification
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Mikkel Traun	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Description

Our concept is generally to use a design with Syntax Templates, having Template Parameters - when these are Instantiated they will carry links/relationship from e.g. an StudyObjective to e.g. Compound Interventions, Indications, Assessments etc. - beside the specific relationship to Study Endpoints. And the Study Endpoints will similary be based on instantiations of syntax templates carrying relationships to e.g. Assessments. In this way we capture relationshipd between related objects.
The use of Syntax Templates is an important way to support standardisation of protocol sections readable for humans, linked to a structured linked graph representation readable for computers

Comments

Comment by Dave Iberson-Hurst [07/Feb/22]

Leave this comment to include within the public review comments
Dave

[DDF-90] General comment to API Created: 18/Nov/21 Updated: 08/Mar/22	
Status:	Under Team Review
Project:	Digital Data Flow
Component/s:	API Specification
Affects Version/s:	None
Fix Version/s:	None

Type:	Review Comments	Priority:	Minor
Reporter:	Mikkel Traun	Assignee:	Dave Iberson-Hurst
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

CDISC Disposition Description:	

Description

The API design seem to be to very granular, we will general recommend a more composite level (sections, clusters by topics)...
E.g. Study Type, Study Population, Study Design, Schedule of Activities, etc.

Comments

Comment by Dave Iberson-Hurst [07/Feb/22]
This should be moved to a public review comment. API is currently implemented as that desired by the implementers.

[DDF-66] Study Identifier Type is vague Created: 12/Nov/21 Updated: 08/Mar/22	
Status:	In Progress
Project:	Digital Data Flow
Component/s:	Controlled Terminology
Affects Version/s:	None
Fix Version/s:	None

Type:	Improvement	Priority:	Minor
Reporter:	Diane Wold	Assignee:	Erin Muhlbradt
Resolution:	Unresolved	Votes:	0
Labels:	Move_To_Public_Review		

Description

It would be better if the word "type" were replaced by something more specific, and the definition mentioned the basis on which study identifiers were to be categorized.

Comments

Comment by Dave Iberson-Hurst [17/Feb/22]
Have some sympathy with the comment but not a major issue at the moment but we will keep this open so we don't forget it.
Comment by Dave Iberson-Hurst [28/Feb/22]
Add this to public review. Not gojng to change it in the immediate future