



Goodbye Excel My Old Friend: A Collaboration

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Abstract

Those working in clinical trials love Excel. It is flexible and can be deployed in a whole host of ways. How many times do we hear, "I'll put it into Excel"? But it comes with limitations: multiple users, ensuring consistent use, audit trails are just some of the issues that teams face when using our old friend.

In 2019 Sanofi, with the team from S-cubed, embarked on upgrading their process for managing terminology standards: moving from Excel to a cloud-based solution. This removed the limitations of Excel and brought new capabilities such as traceability and impact analysis while also improving the user experience.

This presentation will detail:

- The processes using excel and issues encountered
- Process of upgrading
- The cloud solution
- Identified added-value
- Lessons Learnt

The presentation will end with conclusions from the work and the next steps.

Excel

An Old Friend

- Even with old friends sometimes the truth is necessary
- Includes relationships, some can be hidden
- Flexible but that can be abused
- Overloaded columns – using columns for multiple purposes
- Mistakes – unless code is behind the worksheets then limited ability to check data
- Consistency of content as size increases
- Size limitations
- Single user access

			CDISC Submission Value	CDISC Synonym(s)	
		4 Stair Ascend Functional Test Test Code	A4STR1TC	4 Stair Ascend Functional Test Test Code	4 Stair Ascend test code.
		4 Stair Ascend Functional Test Test Code	A4STR101	A4STR1-Time to Ascend 4 Stairs	4 Stair Ascend - Time taken to ascend 4 stairs.
		4 Stair Ascend Functional Test Test Code	A4STR102	A4STR1-Test Grade	4 Stair Ascend - Test grade.
		4 Stair Ascend Functional Test Test Code	A4STR103	A4STR1-Wear Orthoses	4 Stair Ascend - Did subject wear orthoses?
		4 Stair Ascend Functional Test Test Name	A4STR1TN	4 Stair Ascend Functional Test Test Name	4 Stair Ascend test name.
		4 Stair Ascend Functional Test Test Name	A4STR1-Test Grade	A4STR1-Test Grade	4 Stair Ascend - Test grade.
		4 Stair Ascend Functional Test Test Name	A4STR1-Time to Ascend 4 Stairs	A4STR1-Time to Ascend 4 Stairs	4 Stair Ascend - Time taken to ascend 4 stairs.
		4 Stair Ascend Functional Test Test Name	A4STR1-Wear Orthoses	A4STR1-Wear Orthoses	4 Stair Ascend - Did subject wear orthoses?
	No	6 Minute Walk Functional Test Test Code	SIXMW1TC	6 Minute Walk Functional Test Test Code	6 Minute Walk Test test code.
		6 Minute Walk Functional Test Test Code	SIXMW101	SIXMW1-Distance at 1 Minute	6 Minute Walk Test - Distance at 1 minute.
		6 Minute Walk Functional Test Test Code	SIXMW102	SIXMW1-Distance at 2 Minutes	6 Minute Walk Test - Distance at 2 minutes.
		6 Minute Walk Functional Test Test Code	SIXMW103	SIXMW1-Distance at 3 Minutes	6 Minute Walk Test - Distance at 3 minutes.
		6 Minute Walk Functional Test Test Code	SIXMW104	SIXMW1-Distance at 4 Minutes	6 Minute Walk Test - Distance at 4 minutes.
		6 Minute Walk Functional Test Test Code	SIXMW105	SIXMW1-Distance at 5 Minutes	6 Minute Walk Test - Distance at 5 minutes.
		6 Minute Walk Functional Test Test Code	SIXMW106	SIXMW1-Distance at 6 Minutes	6 Minute Walk Test - Distance at 6 minutes.
	No	6 Minute Walk Functional Test Test Name	SIXMW1TN	6 Minute Walk Functional Test Test Name	6 Minute Walk test name.
		6 Minute Walk Functional Test Test Name	SIXMW1-Distance at 1 Minute	SIXMW1-Distance at 1 Minute	6 Minute Walk Test - Distance at 1 minute.
		6 Minute Walk Functional Test Test Name	SIXMW1-Distance at 2 Minutes	SIXMW1-Distance at 2 Minutes	6 Minute Walk Test - Distance at 2 minutes.
		6 Minute Walk Functional Test Test Name	SIXMW1-Distance at 3 Minutes	SIXMW1-Distance at 3 Minutes	6 Minute Walk Test - Distance at 3 minutes.
		6 Minute Walk Functional Test Test Name	SIXMW1-Distance at 4 Minutes	SIXMW1-Distance at 4 Minutes	6 Minute Walk Test - Distance at 4 minutes.
		6 Minute Walk Functional Test Test Name	SIXMW1-Distance at 5 Minutes	SIXMW1-Distance at 5 Minutes	6 Minute Walk Test - Distance at 5 minutes.
		6 Minute Walk Functional Test Test Name	SIXMW1-Distance at 6 Minutes	SIXMW1-Distance at 6 Minutes	6 Minute Walk Test - Distance at 6 minutes.
	No	ADNI Auditory Verbal Learning Functional Test Test Code	AVL01TC	ADNI Auditory Verbal Learning Functional Test Test Code	ADNI AVL test code.
		ADNI Auditory Verbal Learning Functional Test Test Code	AVL01001	AVL01-List A Recall 1 Word 1	Auditory Verbal Learning Test Version A - List A, Recall 1, Word 1.
		ADNI Auditory Verbal Learning Functional Test Test Code	AVL01002	AVL01-List A Recall 1 Word 2	Auditory Verbal Learning Test Version A - List A, Recall 1, Word 2.
		ADNI Auditory Verbal Learning Functional Test Test Code	AVL01003	AVL01-List A Recall 1 Word 3	Auditory Verbal Learning Test Version A - List A, Recall 1, Word 3.
		ADNI Auditory Verbal Learning Functional Test Test Code	AVL01004	AVL01-List A Recall 1 Word 4	Auditory Verbal Learning Test Version A - List A, Recall 1, Word 4.
		ADNI Auditory Verbal Learning Functional Test Test Code	AVL01005	AVL01-List A Recall 1 Word 5	Auditory Verbal Learning Test Version A - List A, Recall 1, Word 5.
		ADNI Auditory Verbal Learning Functional Test Test Code	AVL01006	AVL01-List A Recall 1 Word 6	Auditory Verbal Learning Test Version A - List A, Recall 1, Word 6.



Excel

Example: SDTM Implementation Guide

Version	Seq. For Order	Observation Class	Domain Prefix	Variable Name (minus domain prefix)	Variable Name	Variable Label	Type	Controlled Terms or Format	Role	CDISC Notes (for domains) Description (for General Classes)	Core
SDTMIG 3.3	10	Special-Purpose	CO	EVAL	COEVAL	Evaluator	Char		Record Qualifier	Used to describe the originator of the comment. Examples: CENTRAL, REVIEWER, ADJUDICATION COMMITTEE, PRINCIPAL INVESTIGATOR.	Perm
SDTMIG 3.3	11	Special-Purpose	CO	EVALID	COEVALID	Evaluator Identifier	Char	(MEDEVAL)	Record Qualifier	Used to distinguish multiple evaluators with the same role recorded in --EVAL. Examples: RADIOLOGIST, RADIOLOGIST1, RADIOLOGIST2.	Perm
SDTMIG 3.3	12	Special-Purpose	CO	DTC	CODTC	Date/Time of Comment	Char	ISO 8601	Timing	Date/time of comment on dedicated comment form. Should be null if this is a child record of another domain	Perm
SDTMIG 3.3	13	Special-Purpose	CO	DY	CODY	Study Day of Comment	Num		Timing		Perm
SDTMIG 3.3	1	Special-Purpose	DM	STUDYID	STUDYID	Study Identifier	Char		Identifier		Req
SDTMIG 3.3	2	Special-Purpose	DM	DOMAIN	DOMAIN	Domain Abbreviation	Char	DM	Identifier		Req

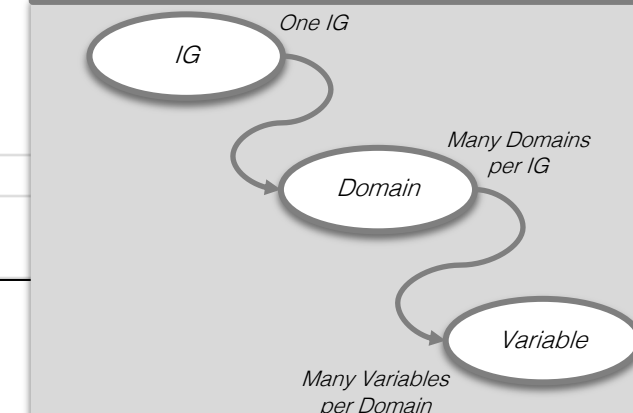
Overloaded

Overloaded column, three purposes, Code list reference (MEDEVAL), a format ISO 8601 and a fixed value DM

Relationships

Repeating rows indicating relationships. They are there but are not defined. We need to be told what they are in another specification.

Relationships



Excel

Example: CDISC Terminology

Relationships

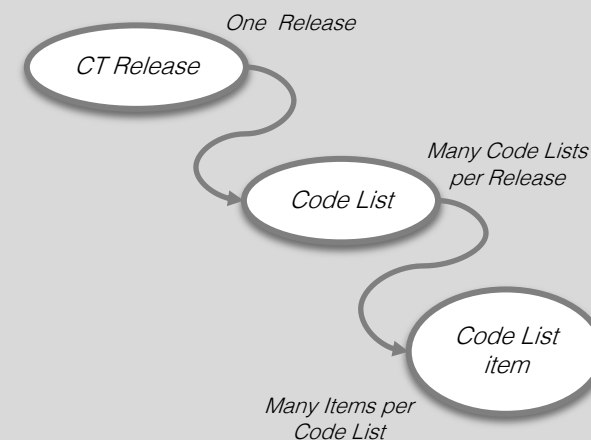
Again, repeating rows indicating relationships.

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition	NCI Preferred Term
C141663		No	4 Stair Ascend Functional Test Test Code	A4STR1TC	4 Stair Ascend Functional Test Test Code	4 Stair Ascend test code.	CDISC Functional Test 4 Stair Ascend Test Code Terminology
C141706	C141663		4 Stair Ascend Functional Test Test Code	A4STR101	A4STR1-Time to Ascend 4 Stairs	4 Stair Ascend - Time taken to ascend 4 stairs.	4 Stair Ascend - Time to Ascend 4 Stairs
C141707	C141663		4 Stair Ascend Functional Test Test Code	A4STR102	A4STR1-Test Grade	4 Stair Ascend - Test grade.	4 Stair Ascend - Test Grade
C147590	C141663		4 Stair Ascend Functional Test Test Code	A4STR103	A4STR1-Wear Orthoses	4 Stair Ascend - Did subject wear orthoses?	4 Stair Ascend - Wear Orthoses
C141662		No	4 Stair Ascend Functional Test Test Name	A4STR1TN	4 Stair Ascend Functional Test Test Name	4 Stair Ascend test name.	CDISC Functional Test 4 Stair Ascend Test Name Terminology
C141707	C141662		4 Stair Ascend Functional Test Test Name	A4STR1-Test Grade	A4STR1-Test Grade	4 Stair Ascend - Test grade.	4 Stair Ascend - Test Grade
C141706	C141662		4 Stair Ascend Functional Test Test Name	A4STR1-Time to Ascend 4 Stairs	A4STR1-Time to Ascend 4 Stairs	4 Stair Ascend - Time taken to ascend 4 stairs.	4 Stair Ascend - Time to Ascend 4 Stairs
C147590	C141662		4 Stair Ascend Functional Test Test Name	A4STR1-Wear Orthoses	A4STR1-Wear Orthoses	4 Stair Ascend - Did subject wear orthoses?	4 Stair Ascend - Wear Orthoses
C115388		No	6 Minute Walk Functional Test Test Code	SIXMW1TC	6 Minute Walk Functional Test Test Code	6 Minute Walk test code.	CDISC Functional Test 6 Minute Walk Test Code Terminology
C115800	C115388		6 Minute Walk Functional Test Test Code	SIXMW101	SIXMW1-Distance at 1 Minute	6 Minute Walk - Distance at 1 Minute	6 Minute Walk - Distance at 1 Minute
C115801	C115388		6 Minute Walk Functional Test Test Code	SIXMW102	SIXMW1-Distance at 2 Minutes	6 Minute Walk - Distance at 2 Minutes	6 Minute Walk - Distance at 2 Minutes
C115802	C115388		6 Minute Walk Functional Test Test Code	SIXMW103	SIXMW1-Distance at 3 Minutes	6 Minute Walk - Distance at 3 Minutes	6 Minute Walk - Distance at 3 Minutes
C115803	C115388		6 Minute Walk Functional Test Test Code	SIXMW104	SIXMW1-Distance at 4 Minutes	6 Minute Walk - Distance at 4 Minutes	6 Minute Walk - Distance at 4 Minutes
C115804	C115388		6 Minute Walk Functional Test Test Code	SIXMW105	SIXMW1-Distance at 5 Minutes	6 Minute Walk - Distance at 5 Minutes	6 Minute Walk - Distance at 5 Minutes
C115805	C115388		6 Minute Walk Functional Test Test Code	SIXMW106	SIXMW1-Distance at 6 Minutes	6 Minute Walk - Distance at 6 Minutes	6 Minute Walk - Distance at 6 Minutes

Types of Definition

Different row formats indicating different types of definition. Again, we need a secondary specification to tell us what these rows are

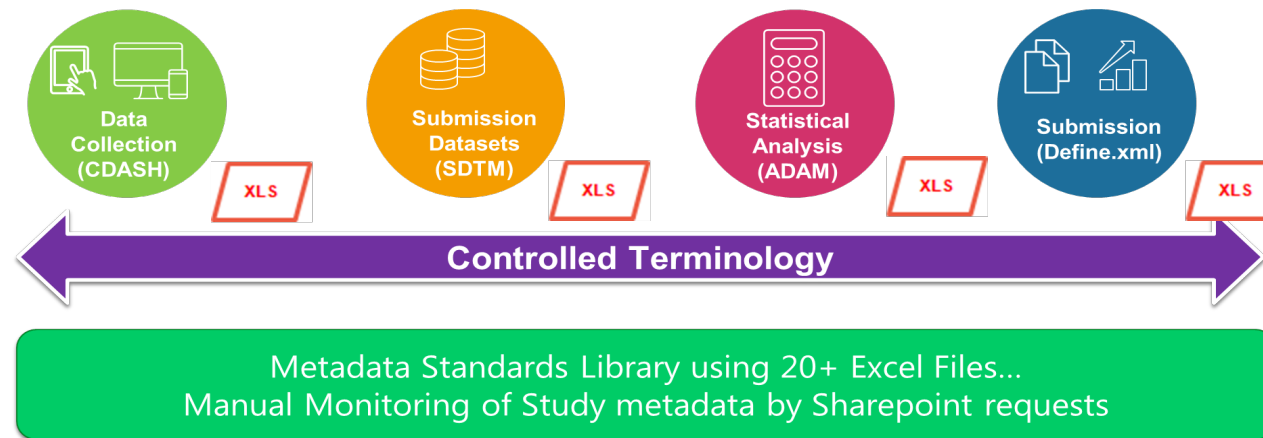
Relationships



Sanofi Clinical Metadata Landscape

Inherited Process

- Metadata maintained in numerous Excel files
 - Technical limitation
 - no concurrent access
 - no versioning, no data traceability, no impact analysis, no data lineage, no audit trail
 - Custom changes for every study, no reusability
- Process limitation
 - Numerous copies in different locations
 - Manual procedural controls required to maintain integrity
 - Cumbersome to administer & maintain with increased risks due to lack of automation
 - Difficult to define & access information transversally



Sanofi Project

Why do we Collaborate?



Implement a tool to develop and maintain controlled terminology from Collection to Reporting

Key attributes



CUSTOMIZABLE



CHANGE REQUEST MANAGEMENT



OBJECT INHERITANCE



IMPACT ANALYSIS



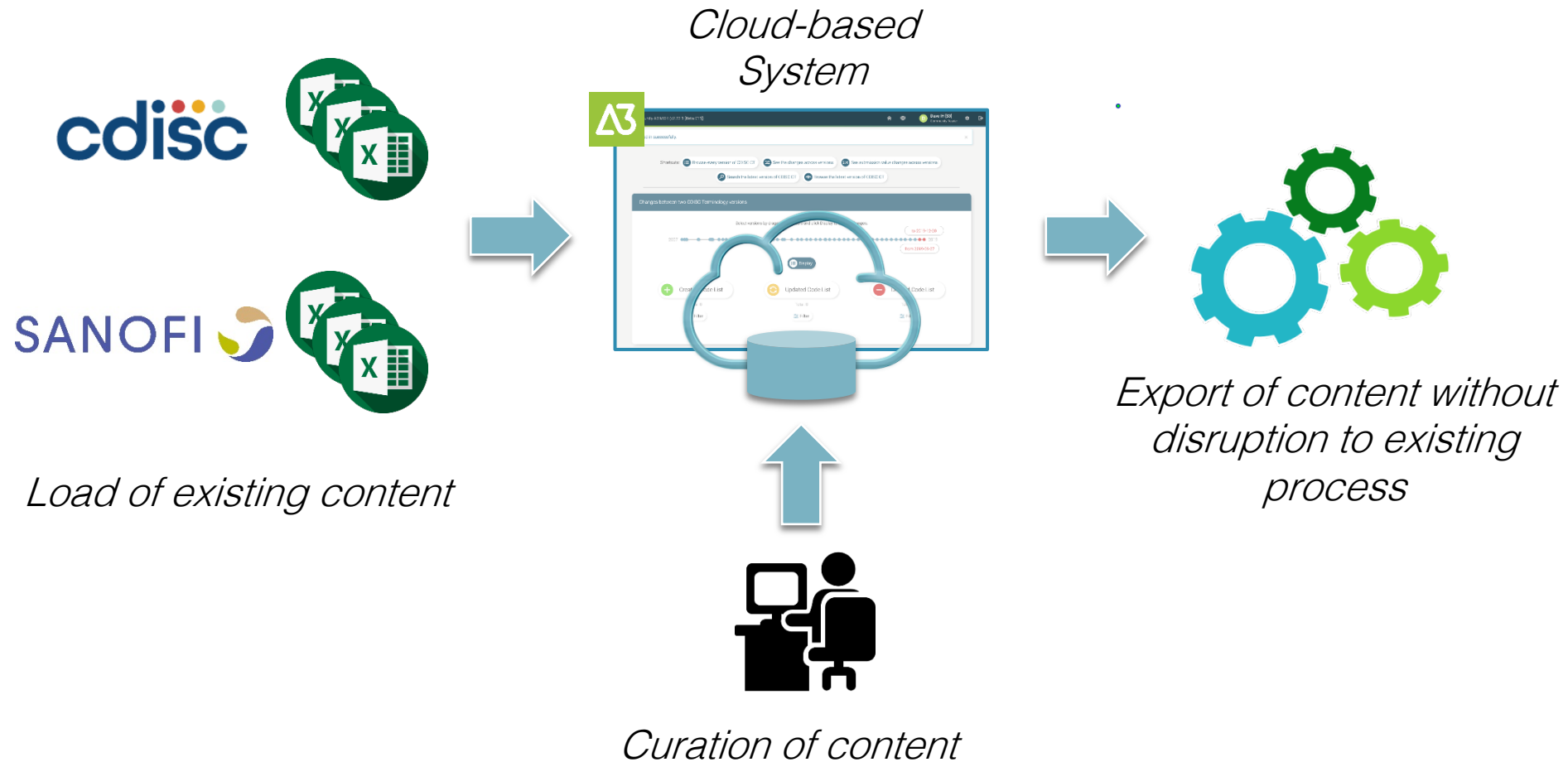
VERSIONING STANDARDS



INTEGRATION TO SANOFI CLINICAL TRIALS TOOLS
(API ACCESS)

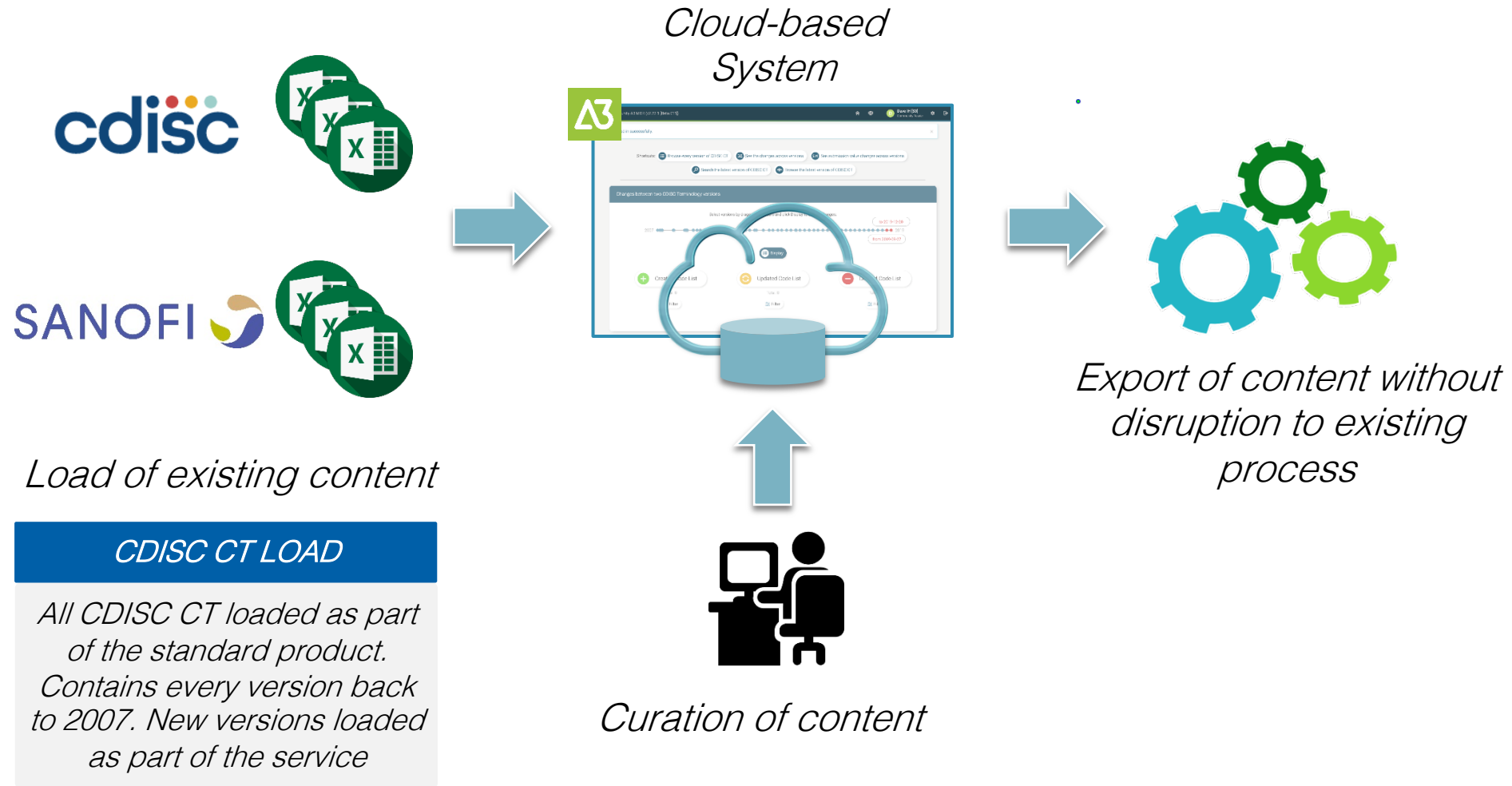
Process of Upgrading

Overview



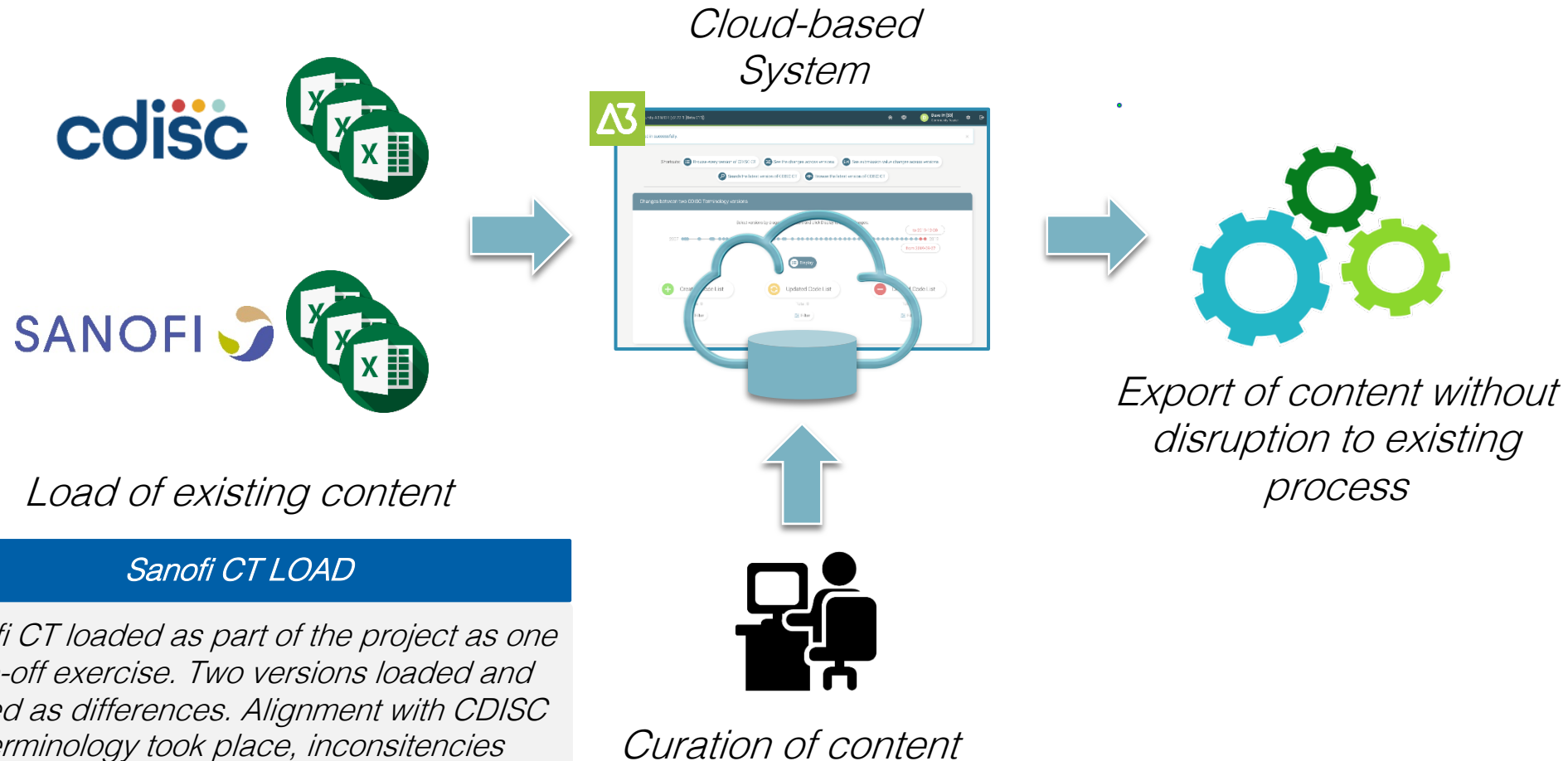
Process of Upgrading

Base Content - CDISC



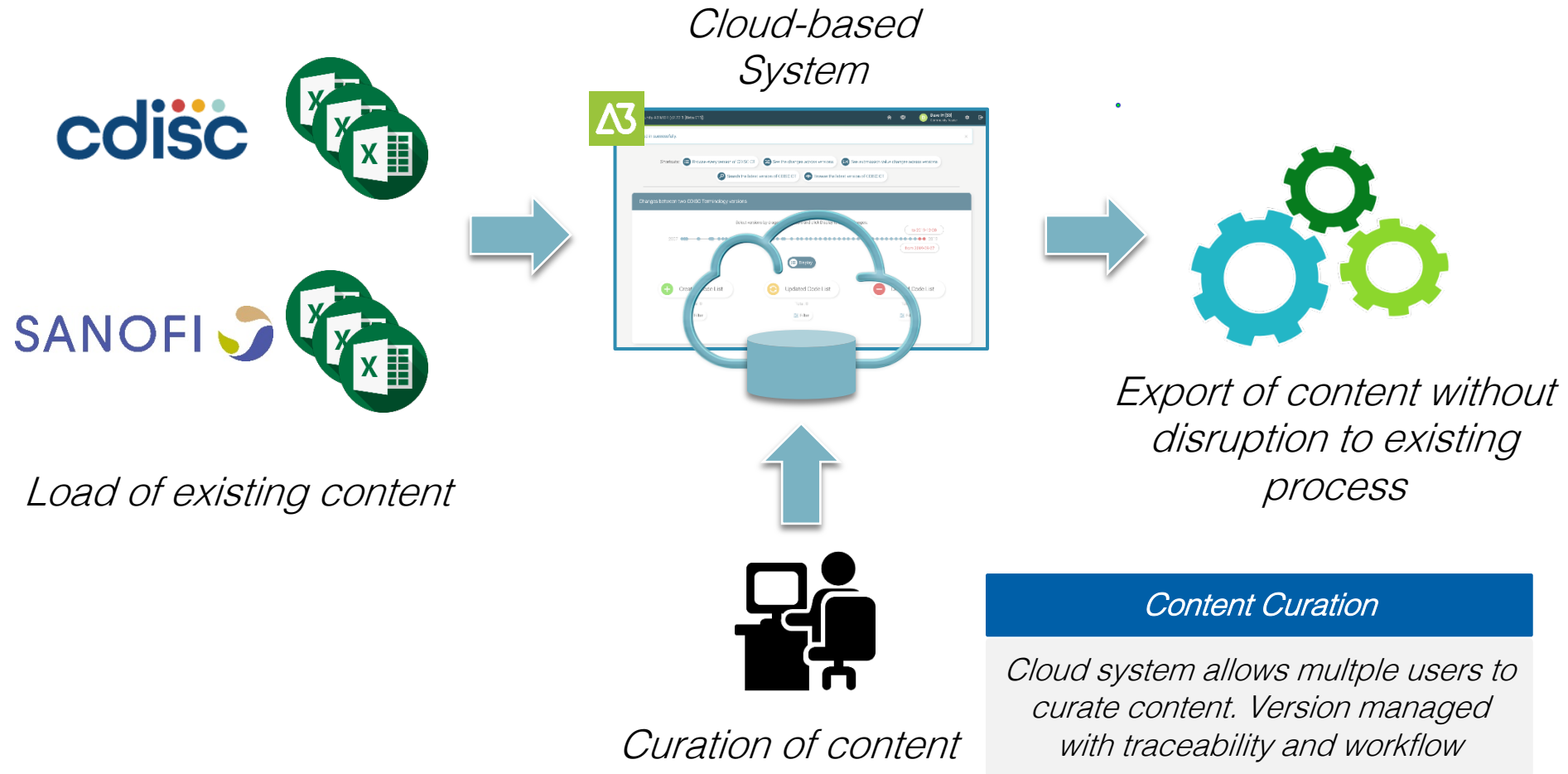
Process of Upgrading

Base Content - Sanofi



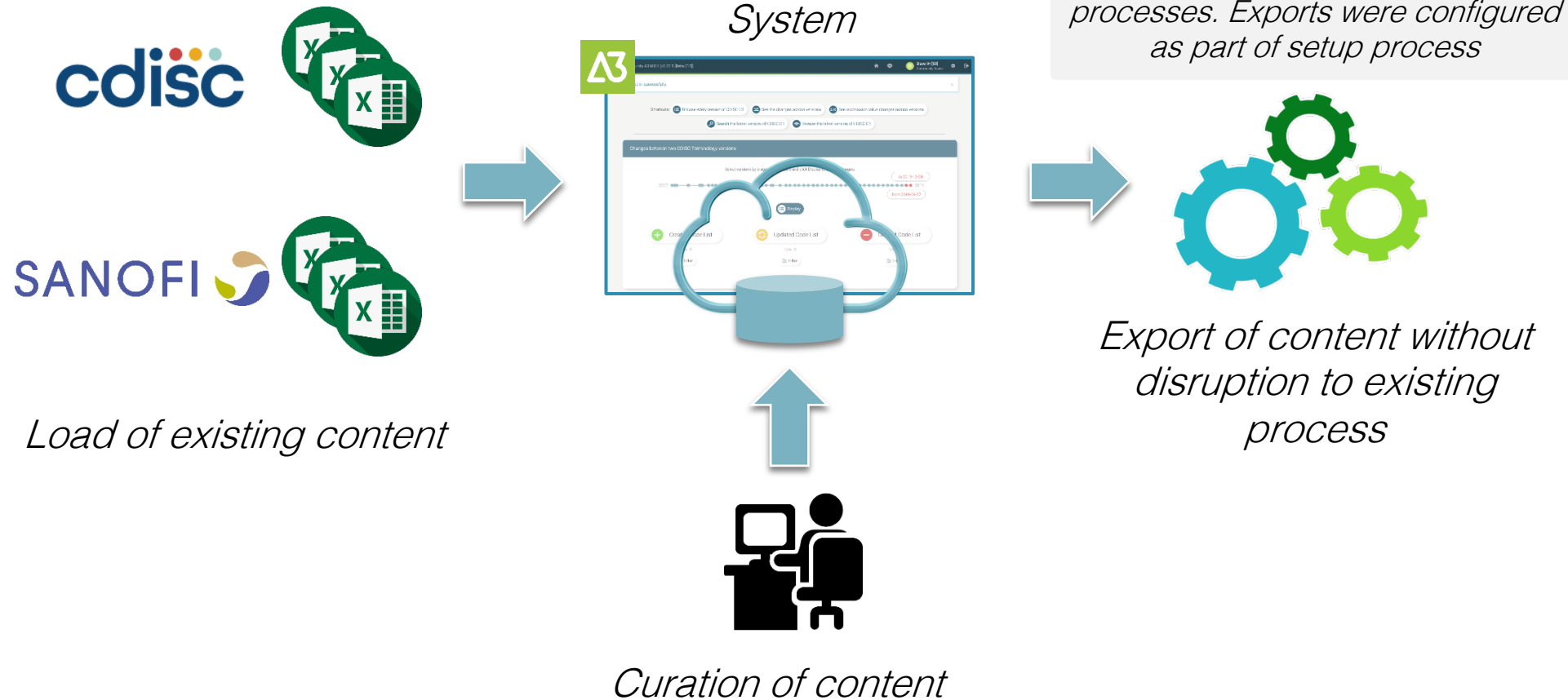
Process of Upgrading

Curation of Content



Process of Upgrading

Integration with Existing Processes



Project Approach

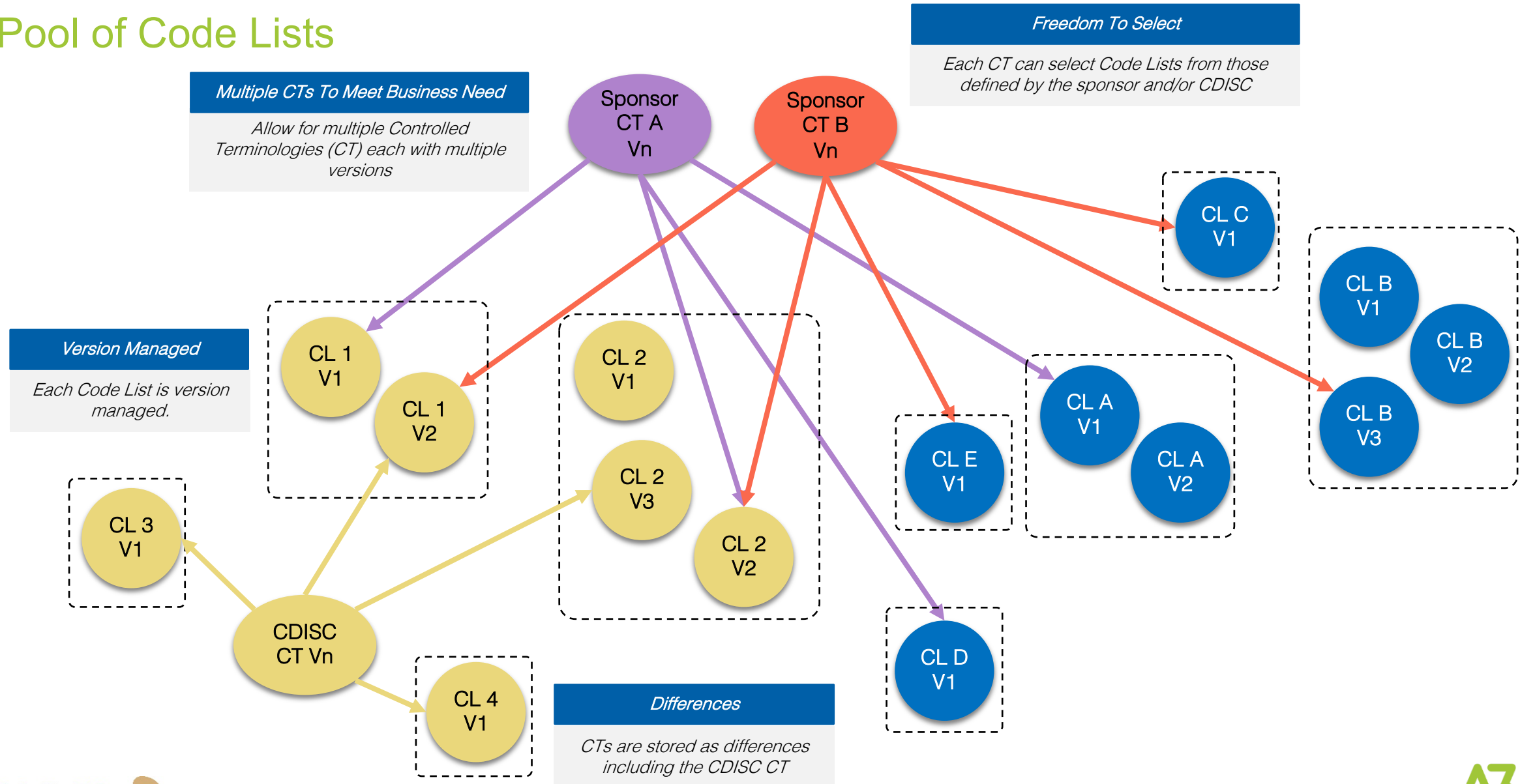
Agile

- We use the Agile methodology internally for the actual software development
- We applied similar principles to the delivery project
- Delivered several versions based on discussions with Sanofi
- Feedback guided subsequent development of new features and improvements
- Requests were always evaluated against generic industry needs. We build a single version for all customers.
- There are no customer specials other than configuration or using reports that can be loaded into the system



CT Releases and Code Lists

Pool of Code Lists



Features

Range of CT Management Capability

CDISC Code Lists

Provide access to all CDISC CT Content:

- Browse content
- View changes
- View differences

Extensions

Allow for CDISC Code Lists to be extended with new terms

Subsets

Allow for subsets of CDISC and Sponsor Code Lists to be managed

Sponsor Code Lists

Support Sponsor Code Lists:

- Sponsor definitions
- Reference CDISC CT terms as needed
- Browse content
- View changes
- View differences
- Perform impact analysis
- Upgrade
- Import from Excel

Rank and Ordering

Ability to set a rank and order code lists

CT Release Management

Support creation and maintenance of CT releases:

- Browse
- Create
- Edit
- Perform impact Analysis
- Upgrade
- Compare & differences

Owner: Sanofi | Identifier: 2020 R2

2020 Release 2

Incomplete 0.1.0

Show more

Find & Select Code Lists

CDISC CLs Sponsor CLs Sponsor Subsets Sponsor Extensions 2020 Release 2

CDISC version used: 2017-09-29

Select CDISC Terminology version by dragging the slider (must be a later version):

2007 2020

ver. 2017-09-29

Submit selected version

Hide CDISC version selector

Show 25 entries

Identifier	Submission Value	Preferred Term	Synonym(s)	Definition	Tags
C99079	EPOCH	CDISC SDTM Epoch Terminology	Epoch	The name of the EPOCH.	SDTM
✓ C99078	INTTYPE	CDISC SDTM Intervention Type Terminology	Intervention Type Response	A terminology codelist relevant to the kind of product or procedure studied in a trial.	SDTM
✓ C99077	STYPE	CDISC SDTM Study Type Terminology	Study Type Response	A terminology codelist relevant to the role the study plays in determining the interventions a subject receives.	SDTM
✓ C99076	INTMODEL	CDISC SDTM Intervention Model Terminology	Intervention Model Response	A terminology codelist relevant to the trial design developed to compare treatment groups.	SDTM
✓ C99075	PORTOT	CDISC SDTM Portion/Totality Terminology	Portion/Totality	Qualifier for anatomical location or specimen further detailing the portion or totality, which means arrangement of, or apportioning of an entity.	SDTM SEND
✓ C99074	DIR	CDISC SDTM Directionality Terminology	Directionality	CDISC terminology for anatomical location or specimen further detailing directionality.	SDTM SEND

Features

Impact Analysis and Upgrade

Impact Analysis

See when a newer version of item's dependencies exists and see the impact of those newer versions

Auto Upgrade

Easily update an item's dependencies to a latter version when those dependencies have been updated

**Impact Analysis R2x6 v0.1.0**
CDISC CT update from: 2015-03-27 Release - to: 2017-09-29 Release.

[CSV Report](#) [Return](#)

Changed CDISC Terms

Show entries

Search:

Type	Details
	Intervention Type INTTYPE (C99078)
	Method METHOD (C85492)
	Treatment Failure Reason REASTRTF (C102585)

Showing 1 to 3 of 3 entries

[Previous](#) [1](#) [Next](#)

Impact of C85492

[Affected Items](#) [Change Details](#) [Impact Graph](#)

Items affected by the CDISC Code List change

The list's scope is limited to items included in this Terminology.

Show entries

Search:

Type	Item
	Release 2.6 (Terminology) (R2x6)
	Method Subset 01 (Subset) METHOD SUBSET 01 (NP000506P)
	Method (Extension) METHOD (C85492E)

Showing 1 to 3 of 3 entries

[Previous](#) [1](#) [Next](#)

Added Value

Sanofi Feedback



Lessons Learnt

- We love Excel ... but we can let go
- Collaboration and the agile approach has been beneficial. It has allowed both sides to learn:
 - Sanofi about structure of the definitions
 - S-cubed about business needs and constraints
- Code List versions and the single pool are an important part of the solution
 - Provides for finer level of control
 - Use only what is needed
- Can be integrated into existing processes without disruption
- And, as always, there is more work to do

Contact Details

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Please feel free to ask questions

