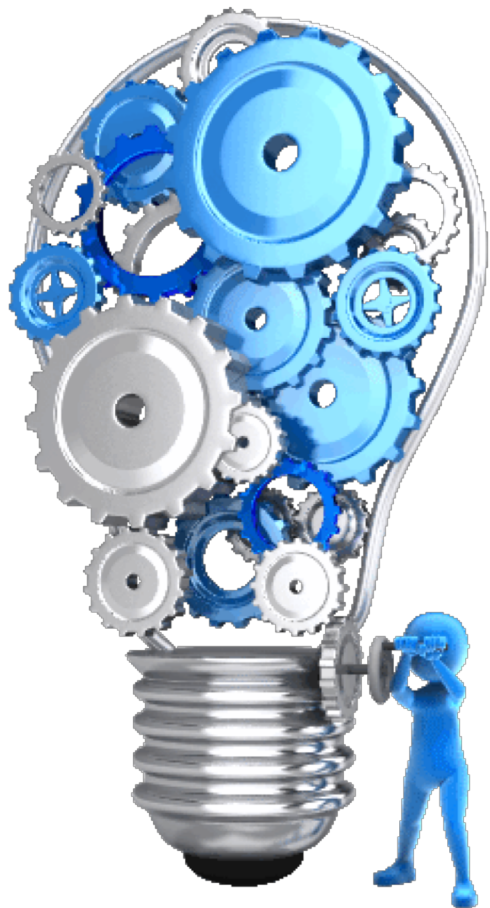




# How to manage changes to CDISC standards at Novo Nordisk

**PhUSE EU Connect 2018**

*Sune Dandanell and Mikkel Traun*

# How to manage changes to CDISC standards

## Challenge:

- Many CDISC SDTM CT changes during recent releases
- Operational systems and collection standards are used consistently over long time
- New SDTM versions and TAUGs
  - Data needs to be mapped to new domains and variables

## Requirement:

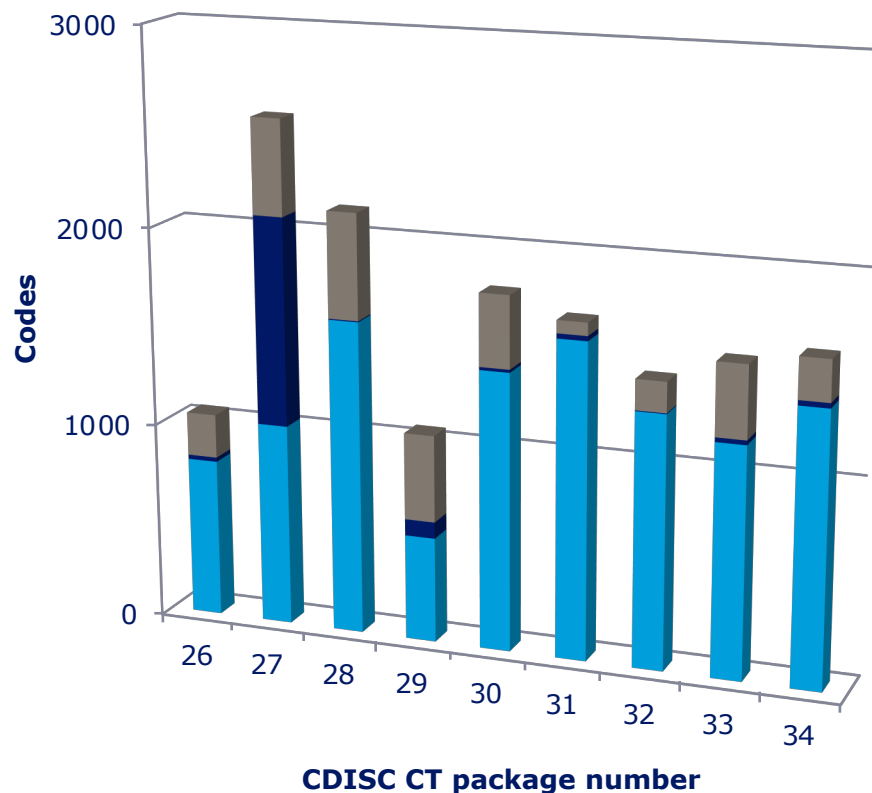
- Compliance to CDISC standards and CT must be managed

## Our solution:

- Topic Code Concept, CDISC CT and SDTM domain linkage
- Process for handling changes to CDISC CT

CT: Controlled Terminology; TAUG: Therapeutic Area User Guide

# Changes to CDISC CT from 2016-2018



- Update CDISC Synonym
- Update CDISC Definition
- Update NCI Preferred Term
- Update CDISC Submission Value
- Remove CDISC Code
- Remove CDISC Code List
- Add CDISC Code
- Add CDISC Code List

# The famous example by Johannes Ulander:

## The BUN mystery – whodunnit?



Code List Item Changes

Show 10 entries Search: urea nitro

| Identifier | Label                                               | Submission Value | 2015-03-27 | 2015-06-26 | 2015-09-25 | 2015-12-18 | 2016-03-25 | 2016-06-24 | 2016-09-30 | 2016-12-13 | 2017-03-31 | 2017-06-30 | 2017-09-29 | 2017-12-22 |
|------------|-----------------------------------------------------|------------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| C125949    | Urea Nitrogen Measurement                           | UREAN            |            |            |            |            | ✓          | -          | -          | -          | -          | -          | -          | -          |
| C125950    | Urea Nitrogen to Creatinine Ratio Measurement       | UREANCRT         |            |            |            |            | ✓          | -          | -          | -          | -          | -          | -          | -          |
| C61019     | Blood Urea Nitrogen Measurement                     | BUN              | -          | -          | -          | -          | ✗          |            |            |            |            |            |            |            |
| C74753     | Blood Urea Nitrogen To Creatinine Ratio Measurement | BUNCREAT         | -          | -          | -          | -          | ✗          |            |            |            |            |            |            |            |

2015-12-18

| Code    | CDISC Submission Value | CDISC Synonym(s)                      |
|---------|------------------------|---------------------------------------|
| C111142 | BUCEH                  | Acylcholine Acylhydrolase; Butyrylcho |
| C61019  | BUN                    | Blood Urea Nitrogen                   |
| C75352  | BUPREN                 | Buprenorphine                         |

SDTM

| LBTESTCD | LBTEST              | LBORRES | LBORRESU |
|----------|---------------------|---------|----------|
| BUN      | Blood Urea Nitrogen | 7,1     | mmol/L   |

2016-03-25

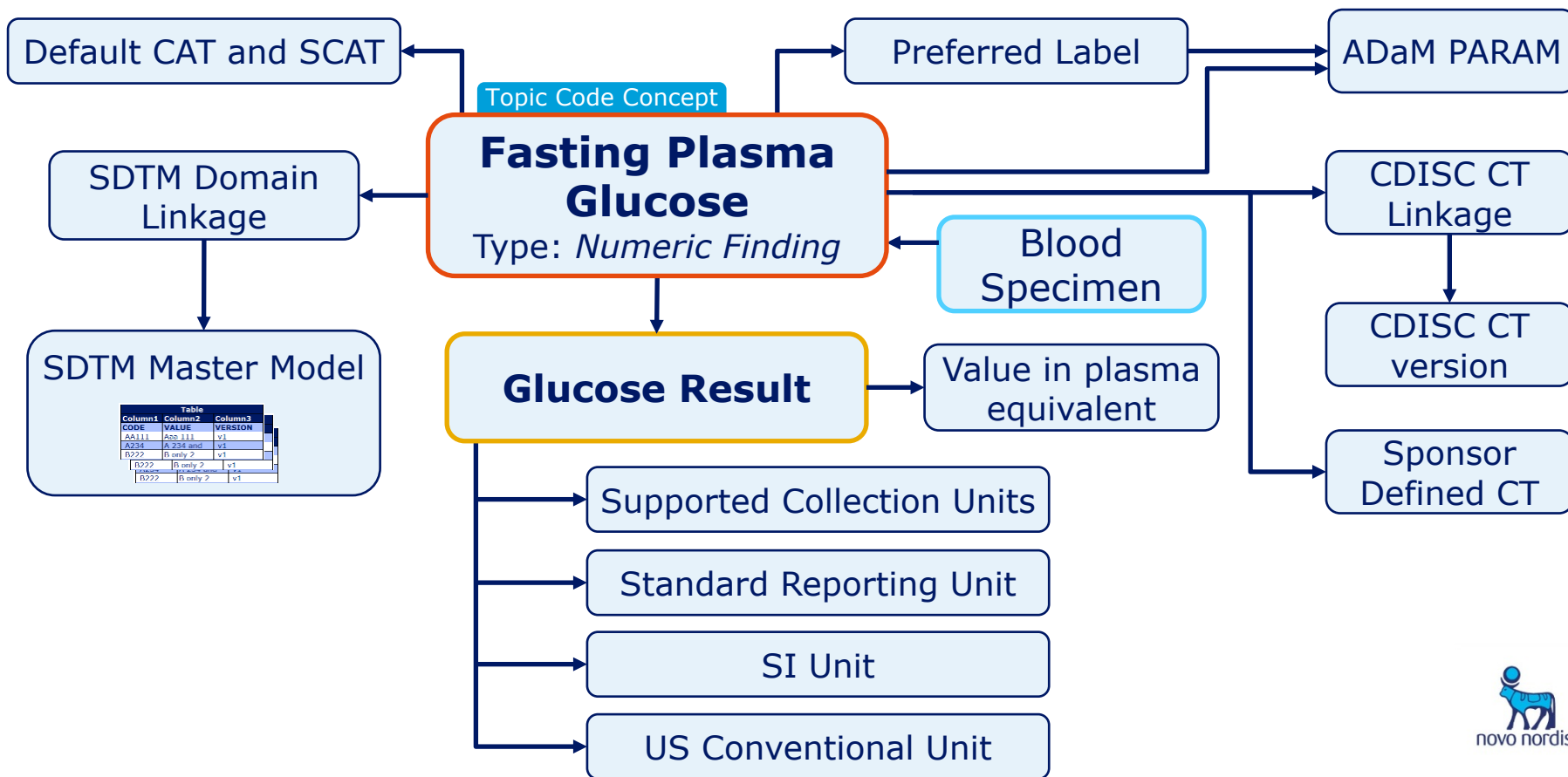
| Code              | CDISC Submission Value | CDISC Synonym(s)                         |
|-------------------|------------------------|------------------------------------------|
| C111142           | BUCEH                  | Acylcholine Acylhydrolase; Butyrylcholin |
| <del>C61019</del> | <del>BUN</del>         | <del>Blood Urea Nitrogen</del>           |
| C125949           | UREAN                  | Urea Nitrogen                            |
| C75352            | BUPREN                 | Buprenorphine                            |

SDTM

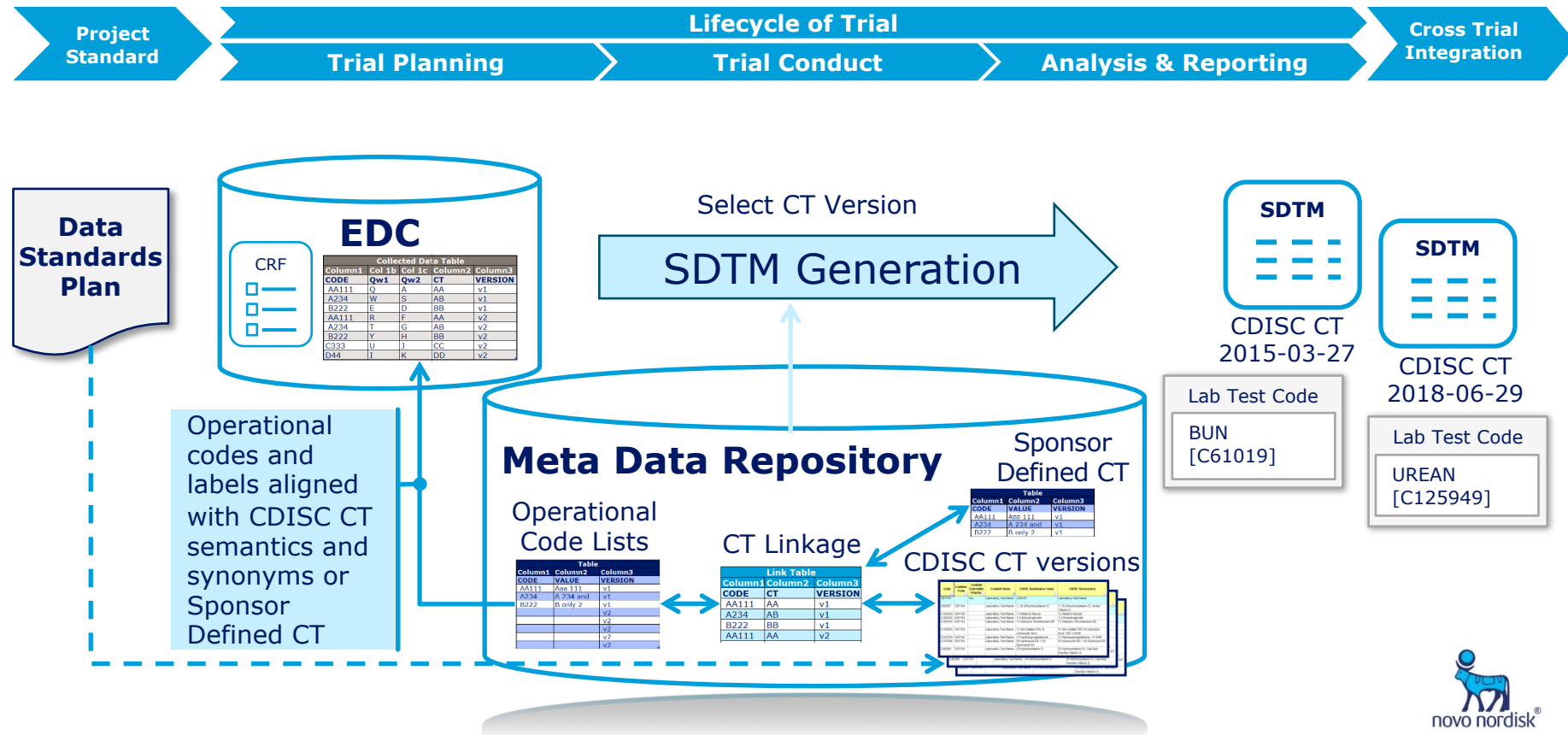
| LBTESTCD | LBTEST        | LBORRES | LBORRESU | LBSPEC |
|----------|---------------|---------|----------|--------|
| UREAN    | Urea Nitrogen | 7,1     | mmol/L   | BLOOD  |

Credits: Johannes Ulander, S-Cubed

# Our 'Topic Code' concept and domain linkage



# CT Versions over the lifecycle of a Trial



# Solution for the BUN mystery

## CDW Operations

### Metadata Management

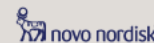
Metadata

▼ Trial

▼ Manage

▼ Logout

development/V3R1C5/MT



## Finding Definition Overview

Add, edit and delete Finding Definitions

Filter Finding Topic Codes

Type:  Category:

Code or label contains:  Sub Category:

Derived: ☐ All ☐ Yes ☒ No Status: ☒ All ☐ Draft ☐ Active ☐ Retired

CDISC CT Package name:  Package status: Active

| Topic Code | Topic Code Label          | Type            | Derived | Default Flowchart Group | Category     | Sub Category | Status | Domain | CDISC Code | CDISC Submission value   | NCI Preferred Term              | Sponsor Defined Code | Sponsor Defined Label |
|------------|---------------------------|-----------------|---------|-------------------------|--------------|--------------|--------|--------|------------|--------------------------|---------------------------------|----------------------|-----------------------|
| BUN_SERUM  | Blood Urea Nitrogen serum | Numeric Finding | No      | Safety                  | Biochemistry |              | Active | LB(*)  | C61019     | BUN, Blood Urea Nitrogen | Blood Urea Nitrogen Measurement |                      |                       |

Delete

Add

Edit

CDISC CT Package name:  Package status: Active

| Topic Code | Topic Code Label          | Type            | Derived | Default Flowchart Group | Category     | Sub Category | Status | Domain | CDISC Code | CDISC Submission value | NCI Preferred Term        | Sponsor Defined Code | Sponsor Defined Label |
|------------|---------------------------|-----------------|---------|-------------------------|--------------|--------------|--------|--------|------------|------------------------|---------------------------|----------------------|-----------------------|
| BUN_SERUM  | Blood Urea Nitrogen serum | Numeric Finding | No      | Safety                  | Biochemistry |              | Active | LB(*)  | C125949    | UREAN, Urea Nitrogen   | Urea Nitrogen Measurement |                      |                       |

Edit

Topic Code concept

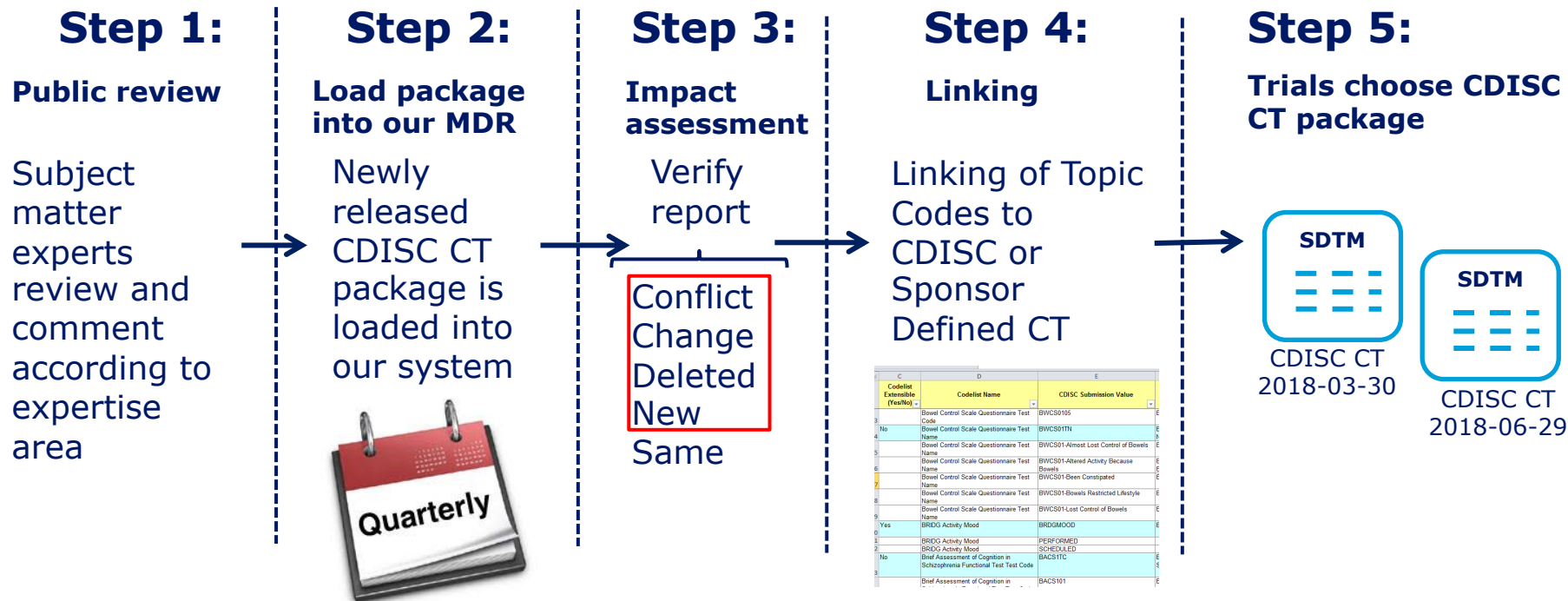
ADaM PARAM

SDTM Domain

Linked CDISC CT

Sponsor Defined CT

# Process for handling changes to CDISC CT



## Step 2: Load of package into our MDR

**CDW Operations** Metadata Management

Metadata ▼ Trial ▼ Manage ▼ Logout Production/V3R1C3/SDNE

Import CDISC Controlled Terminology

*Import CDISC CT from external file and add to new or existing package*

Import File: H:\STANDARDS SHARE\CDISC CT version compare\SDTM\_2018-06-2 Browse...

☒ Create new package from file with package scope: SDTM ▼

☐ Add to existing package: ▼

Import Cancel

Load from local folder

# Step 2: Load of package into our MDR

Edit/View CDISC CT package

Edit or view CDISC CT package

Package attributes

Package Name:

Status:

Content: SDTM 2018-06-29

Verified against:

Comment:

Filter codelist

Code/Value/Name contains:  Verification result:  Status:

| CDISC CT Scope | Codelist Code | CDISC Subm. Value | Codelist Name                                                  | Verification result | Status | No. of codes | Verification result |      |        |     |      | Status |        |        |
|----------------|---------------|-------------------|----------------------------------------------------------------|---------------------|--------|--------------|---------------------|------|--------|-----|------|--------|--------|--------|
|                |               |                   |                                                                |                     |        |              | Same                | Chg. | Confl. | New | Del. | Draft  | Active | Retire |
| SDTM           | C103458       | ACGC01TN          | Change Questionnaire Test Code                                 |                     | Draft  | 1            | -                   | -    | -      | -   | -    | 1      | -      | -      |
| SDTM           | C66767        | ACN               | Action Taken with Study Treatment                              |                     | Draft  | 8            | -                   | -    | -      | -   | -    | 8      | -      | -      |
| SDTM           | C101865       | ACSPCAT           | Acute Coronary Syndrome Presentation Category                  |                     | Draft  | 5            | -                   | -    | -      | -   | -    | 5      | -      | -      |
| SDTM           | C100132       | ADCTC             | Alzheimer's Disease Assessment Scale - Cognitive CDISC Version |                     | Draft  | 110          | -                   | -    | -      | -   | -    | 110    | -      | -      |
|                |               |                   | Alzheimer's Disease Assessment Scale - Cognitive CDISC Version |                     |        |              |                     |      |        |     |      |        |        |        |

CDISC CT version loaded

All codelists and codes loaded in draft

# Step 3: Impact assessment

Edit/View CDISC CT package

Edit or view CDISC CT package

Package attributes

Package Name:   
 Status:   
 Content: SDTM 2018-06-29  
 Verified against:  
 Comment:

Filter codelist

Code/Value/Name contains:

You are about to start the verification procedure...

Package SDTM\_2018-06-29 with content:  
 - SDTM 2018-06-29

will be verified against:

Package SDTM\_2018-03-30 with content:  
 - SDTM 2018-03-30

Continue

Cancel

Save

Cancel

Status:

Filter

Verify

Change status

Edit

Return

| CDISC CT Scope | Codelist Code | CDISC Subm. Value | Codelist Name                                                                                      | Verification result | Status | No. of codes | Verification result |      |        |     |      | Status |        |        |
|----------------|---------------|-------------------|----------------------------------------------------------------------------------------------------|---------------------|--------|--------------|---------------------|------|--------|-----|------|--------|--------|--------|
|                |               |                   |                                                                                                    |                     |        |              | Same                | Chg. | Confl. | New | Del. | Draft  | Active | Retire |
|                |               |                   | Change Questionnaire Test Code                                                                     |                     |        |              |                     |      |        |     |      |        |        |        |
| SDTM           | C103458       | ACGC01TN          | Alzheimer's Disease Cooperative Study-Clinical Global Impression of Change Questionnaire Test Name |                     | Draft  | 1            | -                   | -    | -      | -   | -    | 1      | -      | -      |
| SDTM           | C667 67       | ACN               | Action Taken with Study Treatment                                                                  |                     | Draft  | 8            | -                   | -    | -      | -   | -    | 8      | -      | -      |
| SDTM           | C101865       | ACSPCAT           | Acute Coronary Syndrome Presentation Category                                                      |                     | Draft  | 5            | -                   | -    | -      | -   | -    | 5      | -      | -      |
|                |               |                   | Alzheimer's Disease Assessment Scale - Cognitive CDISC Version                                     |                     |        |              |                     |      |        |     |      |        |        |        |

Verification report  
against previous  
version of CDISC  
CT

# Step 3: Impact assessment

**CDW Operations** Metadata Management

Metadata Trial Manage Logout Production/V3R1C3/SDNE

**Edit/View CDISC CT package**

*Edit or view CDISC CT package*

Package attributes

Package Name: SDTM\_2018-06-29

Status: Loaded

Content: SDTM 2018-06-29

Verified against: SDTM\_2018-03-30

Comment:

Save Cancel

Filter codelist

Code/Value/Name contains: Verification result: Conflict Status: Filter

Verify Change status Edit Return

| CDISC CT Scope | Codelist Code | CDISC Subm.Value | Codelist Name                  | Verification result | Status | No. of codes | Verification result |      |        |     |      | Status |        |        |
|----------------|---------------|------------------|--------------------------------|---------------------|--------|--------------|---------------------|------|--------|-----|------|--------|--------|--------|
|                |               |                  |                                |                     |        |              | Same                | Chg. | Conflc | New | Del. | Draft  | Active | Retire |
| SDTM           | C74558        | DSCAT            | Category for Disposition Event | Same                | Active | 3            | 2                   | -    | 1      | -   | -    | 1      | 2      | -      |
| SDTM           | C78735        | EVAL             | Evaluator                      | Same                | Active | 22           | 21                  | -    | 1      | -   | -    | 1      | 21     | -      |
| SDTM           | C67154        | LBTEST           | Laboratory Test Name           | Same                | Active | 1859         | 1831                | 3    | 10     | 15  | -    | 10     | 1849   | -      |
| SDTM           | C65047        | LBTESTCD         | Laboratory Test Code           | Same                | Active | 1859         | 1831                | 3    | 10     | 15  | -    | 10     | 1849   | -      |
| SDTM           | C100129       | QSCAT            | Category of Questionnaire      | Same                | Active | 228          | 216                 | -    | 2      | 10  | 1    | 2      | 226    | 1      |
| SDTM           | C100130       | RELSUB           | Relationship to Subject        | Same                | Active | 75           | 68                  | -    | 1      | 6   | -    | 1      | 74     | -      |

## Verification report result:

- Same
- Change
- Conflict
- New
- Delete

Change + Conflict + Delete => Lost link of Topic Code to CDISC CT!!

# Step 3: Impact assessment

CDISC Scope: SDTM  
CDISC Version: 2018-06-29

**CDISC attributes**

Codelist Code: C67154  
Codelist Code value: LBTEST  
Codelist Name: Laboratory Test Name  
Codelist Extensible: Y  
Codelist Description: Terminology used for laboratory test names of the CDISC Study Data Tabulation Model.

**CDW attributes**

Verification result: Same  
Status: Active  
Comment:

**Filter code values**

Code/Value contains:  Verification result: Conflict Status:  Filter

Change status Edit Return

| Code    | Code value                | Verification result | Status |
|---------|---------------------------|---------------------|--------|
| C150814 | Albumin Excretion Rate    | Conflict            | Draft  |
| C150815 | Calcium Excretion Rate    | Conflict            | Draft  |
| C150816 | Chloride Excretion Rate   | Conflict            | Draft  |
| C150817 | Creatinine Excretion Rate | Conflict            | Draft  |
| C150818 | Glucose Excretion Rate    | Conflict            | Draft  |
| C150819 | Iron Excretion Rate       | Conflict            | Draft  |
| C150821 | Phosphorus Excretion Rate | Conflict            | Draft  |

Change status Edit Return

Filters can be applied for "conflicts", "change", "delete", which are the lost links we need to resolve

Manual process to evaluate all lost links

# Step 3: Impact assessment

- 1) SDTM terminology change log available at <https://www.cancer.gov/research/resources/terminology/cdisc>

2)

| CDISC CT Version Overview |                      |            |            |            |            |            |            |            |            |            |          |  |
|---------------------------|----------------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|----------|--|
|                           |                      | CT VER     |            |            |            |            |            |            |            |            |          |  |
|                           |                      | 2013-04-12 | 2013-12-20 | 2014-03-28 | 2015-03-27 | 2016-03-25 | 2017-03-31 | 2017-06-30 | 2018-03-30 | 2018-06-29 |          |  |
| RELSUB                    | CHILD                | -          | -          | -          | -          | -          | -          | -          | -          | -          | New      |  |
|                           | CHILD, BIOLOGICAL    | New        | Same       | Same       | Same       | Same       | Same       | Same       | Same       | Same       | Conflict |  |
|                           | DAUGHTER, BIOLOGICAL | -          | -          | -          | -          | -          | -          | -          | -          | -          | New      |  |
|                           | PARENT               | -          | -          | -          | -          | -          | -          | -          | -          | -          | New      |  |
|                           | SIBLING              | -          | -          | -          | -          | -          | -          | -          | -          | -          | New      |  |
|                           | SON, BIOLOGICAL      | -          | -          | -          | -          | -          | -          | -          | -          | -          | New      |  |
|                           | WIFE                 | -          | -          | -          | -          | -          | -          | -          | -          | -          | New      |  |

Conflict in "CHILD, BIOLOGICAL"

3)

| A                                                             | B                   | C                 | D  | E       | F       | G  | H                | I                | J  | K                                                                | L                                                                | M  | N             | O                | P  | Q           | R                   | S        | T         | U   | V    |
|---------------------------------------------------------------|---------------------|-------------------|----|---------|---------|----|------------------|------------------|----|------------------------------------------------------------------|------------------------------------------------------------------|----|---------------|------------------|----|-------------|---------------------|----------|-----------|-----|------|
| CDISC CT Changes - Version: SDTM_2018-06-29 - SDTM_2018-03-30 |                     |                   |    |         |         |    |                  |                  |    |                                                                  |                                                                  |    |               |                  |    |             |                     |          |           |     |      |
| CDISC CT                                                      | CT Submission Value |                   |    | CT Code |         |    | Synonyms         |                  |    | Definition                                                       |                                                                  |    | NCI Pref Term |                  |    | CDW Comment | Verification Result |          | NN Status |     |      |
| Code List                                                     | New                 | Prev              | Ch | New     | Prev    | Ch | New              | Prev             | Ch | New                                                              | Prev                                                             | Ch | New           | Prev             | Ch | New         | Prev                | New      | Prev      | New | Prev |
| RELSUB                                                        | CHILD, BIOLOGICAL   | CHILD, BIOLOGICAL |    | C42708  | C100807 | Y  | Biological Child | Biological Child |    | A son or daughter with genetic makeup inherited from the parent. | A son or daughter with genetic makeup inherited from the parent. |    | Offspring     | Biological Child | Y  |             |                     | CONFLICT | SAME      | A   | A    |

# Recent example: "CHILD/CHILD, BIOLOGICAL"

| A            | B            | C           | D        | E               | F                           | G                          | H                                  | I                 | J                    | K                                                                                                     |
|--------------|--------------|-------------|----------|-----------------|-----------------------------|----------------------------|------------------------------------|-------------------|----------------------|-------------------------------------------------------------------------------------------------------|
| Release Date | Request Code | Change Type | NCI Code | CDISC Term Type | CDISC Codelist (Short Name) | CDISC Codelist (Long Name) | Change Summary                     | Original          | New                  | Change Implementation Instructions                                                                    |
| 2018-06-29   | CDISC-3353   | Add         | C25204   | Term            | RELSUB                      | Relationship to Subject    | Add new term to existing codelist  | ---               | SIBLING              |                                                                                                       |
| 2018-06-29   | CDISC-3353   | Add         | C42708   | Term            | RELSUB                      | Relationship to Subject    | Add new term to existing codelist  | ---               | CHILD, BIOLOGICAL    | C100807 is removed from codelist and being replaced with C42708, which is being added to the codelist |
| 2018-06-29   | CDISC-3106   | Add         | C42709   | Term            | RELSUB                      | Relationship to Subject    | Add new term to existing codelist  | ---               | PARENT               |                                                                                                       |
| 2018-06-29   | CDISC-3106   | Add         | C71587   | Term            | RELSUB                      | Relationship to Subject    | Add new term to existing codelist  | ---               | WIFE                 |                                                                                                       |
| 2018-06-29   | CDISC-3106   | Remove      | C100807  | Term            | RELSUB                      | Relationship to Subject    | Remove term entirely from codelist | CHILD, BIOLOGICAL | ---                  | C100807 is removed from codelist and being replaced with C42708, which is being added to the codelist |
| 2018-06-29   | CDISC-3106   | Add         | C150886  | Term            | RELSUB                      | Relationship to Subject    | Add new term to existing codelist  | ---               | CHILD                |                                                                                                       |
| 2018-06-29   | CDISC-3106   | Add         | C150887  | Term            | RELSUB                      | Relationship to Subject    | Add new term to existing codelist  | ---               | DAUGHTER, BIOLOGICAL |                                                                                                       |
| 2018-06-29   | CDISC-3106   | Add         | C150888  | Term            | RELSUB                      | Relationship to Subject    | Add new term to existing codelist  | ---               | SON, BIOLOGICAL      |                                                                                                       |

ADD/  
REMOVE  
of  
"CHILD,  
BIOLOGICAL"

New  
CDISC  
Code for  
"CHILD"  
in  
RELSUB  
Codelist

| NCI/EVS Request Number | Therapeutic Area Request | Codelist Short Name | TESTCD, PARMCD or Submission Value | TEST or PARM | Synonym(s) | CDISC Definition                                                                                                                                                                                              |
|------------------------|--------------------------|---------------------|------------------------------------|--------------|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| CDISC-3106             |                          | RELSUB              | CHILD                              |              |            | A biological or non-biological first generation offspring, including but not limited to biological children (including those born outside of marriage), adopted children, step children, and foster children. |

- What is the impact of new CDISC-code for existing code?
- What is the impact addition of a more unspecific code?

# Step 4: Linking

## Codelist Value Definitions Overview

Add, edit and delete Codelist Value Definitions

Codelist ID: ASSOC\_PERSON\_RELAT

CDISC CT Package name:

Package status: Active

Delete Add Edit Return

| Code Value              | Code Value Label       | Status | CDISC Code | CDISC Submission Value  | NCI Preferred Term     | Sponsor Defined Code | Sponsor Defined Label |
|-------------------------|------------------------|--------|------------|-------------------------|------------------------|----------------------|-----------------------|
| BROTHER, BIOLOGICAL     | Biological Brother     | Active | C96570     | BROTHER, BIOLOGICAL     | Biological Brother     |                      |                       |
| CHILD, BIOLOGICAL       | Biological Child       | Active | C100807    | CHILD, BIOLOGICAL       | Biological Child       |                      |                       |
| DAUGHTER, BIOLOGICAL    | Biological Daughter    | Active |            |                         |                        |                      |                       |
| FATHER, BIOLOGICAL      | Biological Father      | Active | C96572     | FATHER, BIOLOGICAL      | Biological Father      |                      |                       |
| GRANDCHILD, BIOLOGICAL  | Biological Grandchild  | Active | C100805    | GRANDCHILD, BIOLOGICAL  | Biological Grandchild  |                      |                       |
| GRANDFATHER, BIOLOGICAL | Biological Grandfather | Active | C96573     | GRANDFATHER, BIOLOGICAL | Biological Grandfather |                      |                       |
| GRANDMOTHER, BIOLOGICAL | Biological Grandmother | Active | C96574     | GRANDMOTHER, BIOLOGICAL | Biological Grandmother |                      |                       |
| GRANDPARENT, BIOLOGICAL | Biological Grandparent | Active | C100806    | GRANDPARENT, BIOLOGICAL | Biological Grandparent |                      |                       |
| MOTHER, BIOLOGICAL      | Biological Mother      | Active | C96580     | MOTHER, BIOLOGICAL      | Biological Mother      |                      |                       |
| SIBLING, BIOLOGICAL     | Biological Sibling     | Active | C100809    | SIBLING, BIOLOGICAL     | Biological Sibling     |                      |                       |
| SON, BIOLOGICAL         | Biological Son         | Active |            |                         |                        |                      |                       |
| CHILD                   | Child                  | Active | C100807    | CHILD, BIOLOGICAL       | Biological Child       |                      |                       |
| CLINICIAN               | Clinician              | Active | C85499     | CLINICIAN               | Clinician              |                      |                       |

Different CDISC-Code in different versions of CDISC CT

Linking of "CHILD" is changed with new CDISC CT

Codelist ID: ASSOC\_PERSON\_RELAT

CDISC CT Package name:

Package status: Active

Delete Add Edit Return

| Code Value              | Code Value Label       | Status | CDISC Code | CDISC Submission Value  | NCI Preferred Term     | Sponsor Defined Code | Sponsor Defined Label |
|-------------------------|------------------------|--------|------------|-------------------------|------------------------|----------------------|-----------------------|
| BROTHER, BIOLOGICAL     | Biological Brother     | Active | C96570     | BROTHER, BIOLOGICAL     | Biological Brother     |                      |                       |
| CHILD, BIOLOGICAL       | Biological Child       | Active | C42708     | CHILD, BIOLOGICAL       | Offspring              |                      |                       |
| DAUGHTER, BIOLOGICAL    | Biological Daughter    | Active | C150887    | DAUGHTER, BIOLOGICAL    | Biological Daughter    |                      |                       |
| FATHER, BIOLOGICAL      | Biological Father      | Active | C96572     | FATHER, BIOLOGICAL      | Biological Father      |                      |                       |
| GRANDCHILD, BIOLOGICAL  | Biological Grandchild  | Active | C100805    | GRANDCHILD, BIOLOGICAL  | Biological Grandchild  |                      |                       |
| GRANDFATHER, BIOLOGICAL | Biological Grandfather | Active | C96573     | GRANDFATHER, BIOLOGICAL | Biological Grandfather |                      |                       |
| GRANDMOTHER, BIOLOGICAL | Biological Grandmother | Active | C96574     | GRANDMOTHER, BIOLOGICAL | Biological Grandmother |                      |                       |
| GRANDPARENT, BIOLOGICAL | Biological Grandparent | Active | C100806    | GRANDPARENT, BIOLOGICAL | Biological Grandparent |                      |                       |
| MOTHER, BIOLOGICAL      | Biological Mother      | Active | C96580     | MOTHER, BIOLOGICAL      | Biological Mother      |                      |                       |
| SIBLING, BIOLOGICAL     | Biological Sibling     | Active | C100809    | SIBLING, BIOLOGICAL     | Biological Sibling     |                      |                       |
| SON, BIOLOGICAL         | Biological Son         | Active | C150888    | SON, BIOLOGICAL         | Biological Son         |                      |                       |
| CHILD                   | Child                  | Active | C150886    | CHILD                   | Child Relation         |                      |                       |
| CLINICIAN               | Clinician              | Active | C85499     | CLINICIAN               | Clinician              |                      |                       |

## Step 5: Trials select CDISC CT version

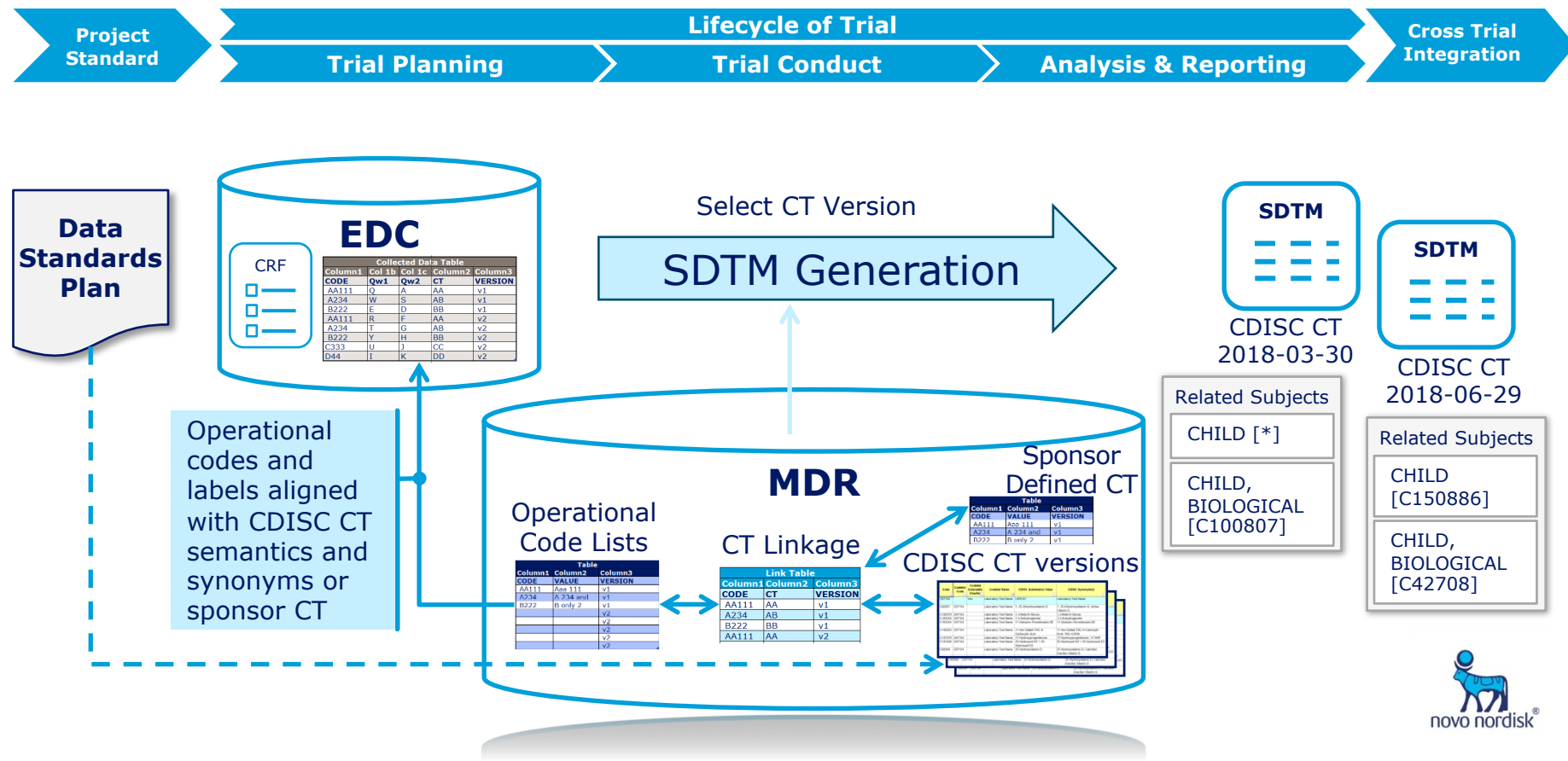
|                                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>7.* Did any of the subject's first degree relatives ever have overweight or obesity?<br/>[Obesity in first degree relatives?]</p> | <p>[WGTHX_OBESITY_YN]<br/>[A:2] <input type="radio"/> No<br/>[A:1] <input type="radio"/> [grpWGTHX_OBESITY] <input type="checkbox"/><br/>Yes<br/>[WGTHX_OBESITY]<br/>If yes, whom:<br/>[WGTHX_OBESYES]<br/><br/>[A:8] <input type="checkbox"/> Mother<br/>[A:9] <input type="checkbox"/> Father<br/><br/>[WGTHX_OBESYES2]<br/>[A:2] <input type="checkbox"/> [WGTHX_OBESITY_NUM1]<br/>Any sibling(s)<br/>If yes, please specify number<br/>N2<br/><br/>[WGTHX_OBESYES3]<br/>[A:3] <input type="checkbox"/> [WGTHX_OBESITY_NUM2]<br/>Any children<br/>If yes, please specify number<br/>N2</p> |
|--------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

No  
specification  
of  
"BIOLOGICAL"  
or "NON-  
BIOLOGICAL"  
relationship  
on this CRF

Solution: Link to "CHILD", use previous version of CDISC CT or  
Sponsor Define

Future trials should have the term "BIOLOGICAL" on CRF if that is what  
we intend to collect

# CT Versions over the lifecycle of a Trial



# Linking to CDISC or Sponsor Defined CT

**Finding Definition Overview**  
Add, edit and delete Finding Definitions

Filter Finding Topic Codes:

Type:    
 Code or label contains:    
 Derived: ☐ All ☐ Yes ☒ No

Sub Category:    
 Status: ☒ All ☐ Draft ☐ Active ☐ Retired

CDISC CT Package name: **SDTM\_2014-03-28** Package status: Active

| Topic Code                      | Topic Code Label                 | Type            | Derived | Default Flowchart Group | Category     | Sub Category | Status | Domain | CDISC Code | CDISC Submission value | NCI Preferred Term | Sponsor Defined Code | Sponsor Defined Label     |
|---------------------------------|----------------------------------|-----------------|---------|-------------------------|--------------|--------------|--------|--------|------------|------------------------|--------------------|----------------------|---------------------------|
| CALCIUM_ALBUMIN_CORRECTED_SERUM | Calcium Albumin corrected, serum | Numeric Finding | No      | Safety                  | Biochemistry |              | Active | LB(*)  |            |                        |                    | CACR                 | Calcium Albumin Corrected |

CDISC CT Package name: **SDTM\_2015-03-27** Package status: Active

| Topic Code                      | Topic Code Label                 | Type            | Derived | Default Flowchart Group | Category     | Sub Category | Status | Domain | CDISC Code | CDISC Submission value  | NCI Preferred Term            | Sponsor Defined Code | Sponsor Defined Label     |
|---------------------------------|----------------------------------|-----------------|---------|-------------------------|--------------|--------------|--------|--------|------------|-------------------------|-------------------------------|----------------------|---------------------------|
| CALCIUM_ALBUMIN_CORRECTED_SERUM | Calcium Albumin corrected, serum | Numeric Finding | No      | Safety                  | Biochemistry |              | Active | LB(*)  | C119272    | CACR, Calcium Corrected | Calcium Corrected Measurement | CACR                 | Calcium Albumin Corrected |

# Linking to CDISC or Sponsor Defined CT

## Laboratory Test Code [CL.LBTESTCD, C65047]

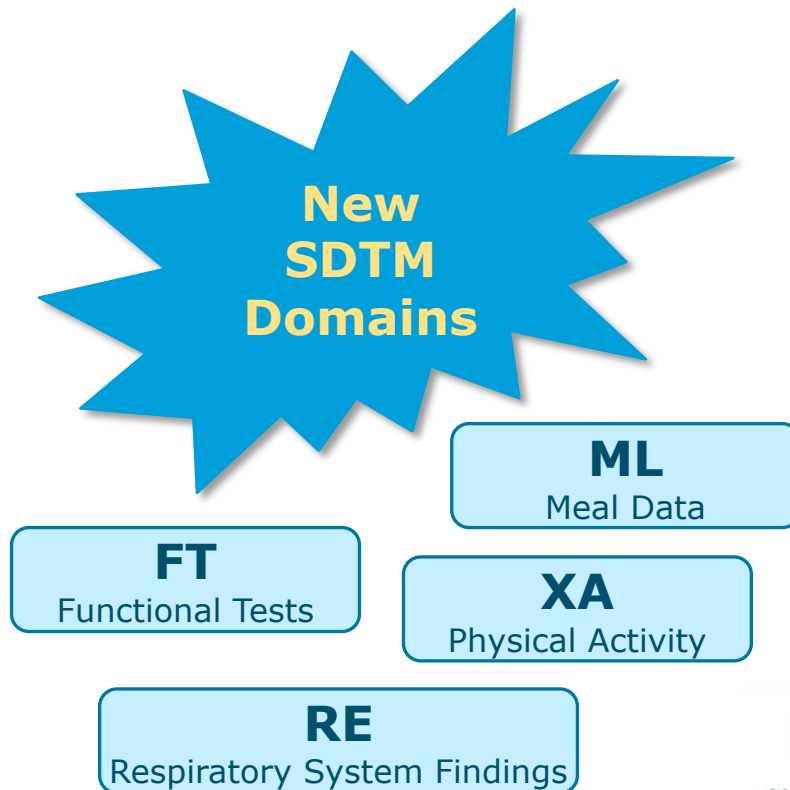
Terminology used for laboratory test codes of the CDISC Study Data Tabulation Model.

| Permitted Value (Code) | Display Value (Decode)        |                                                                           |
|------------------------|-------------------------------|---------------------------------------------------------------------------|
| CACR [*]               | Calcium Albumin Corrected     | CT in Define.xml for version <b>2014-03-28</b><br>CACR is Sponsor Defined |
| CACR [C119272]         | Calcium Corrected Measurement | CT in Define.xml for version <b>2015-03-27</b><br>CACR is CDISC CT        |

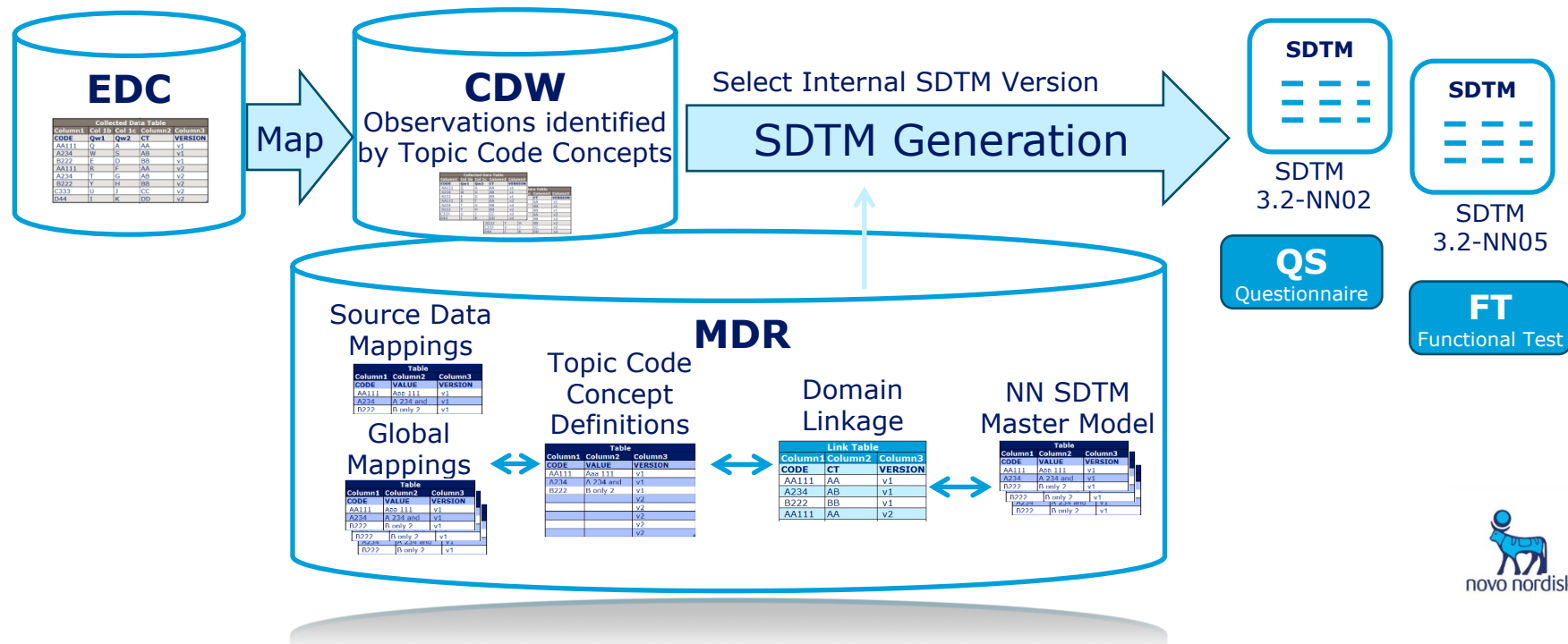
| Code    | Codelist Code | Codelist Extensible (Yes/No) | Codelist Name        | CDISC Submission Value | CDISC Synonym(s)  | CDISC Definition                                                                          | NCI Preferred Term            |
|---------|---------------|------------------------------|----------------------|------------------------|-------------------|-------------------------------------------------------------------------------------------|-------------------------------|
| C119272 | C65047        |                              | Laboratory Test Code | CACR                   | Calcium Corrected | A measurement of calcium, which has been corrected for albumin, in a biological specimen. | Calcium Corrected Measurement |

# Case on how new SDTM domains are to be used

- New SDTM domains in new SDTM versions
- New SDTM domains in TAUGs (may be Sponsor Defined)
- New Sponsor Defined domains for improved SDTM



# Internal SDTM versions over the lifecycle of a trial



# Linking Topic Code Concepts to SDTM Domains

CDW Operations

Metadata Management

Metadata

Trial

Manage

Logout

Internal SDTM Version

Linked SDTM Domain

SDTM Domain Links to Topic Codes

Maintain SDTM Domain linkage to Topic Codes per SDTM Version

SDTM Version

SDTM Version: 3.2-NN02

Import

SDTM Domain

Domain Class: FINDINGS

Domain: QS (Questionnaires)

Linked Topic Codes:

| Topic Code                               | Topic Code Label                       | Topic Code Type | Derived | Category        | Sub Category | Status | CDISC Code | CDISC Submission Value                 | NCI Preferred Term           |
|------------------------------------------|----------------------------------------|-----------------|---------|-----------------|--------------|--------|------------|----------------------------------------|------------------------------|
| 6_MINUTE_WALK_TEST_DISTANCE_AT_1_MINUTE  | 6 Minute Walk Test - Distance at 1 min | Numeric Finding | No      | Six Minute Walk |              | Active | C115800    | SIXMW1-Distance at 1 Minute, SIXMW101  | 6MWT - Distance at 1 Minute  |
| 6_MINUTE_WALK_TEST_DISTANCE_AT_2_MINUTES | 6 Minute Walk Test - Distance at 2 min | Numeric Finding | No      | Six Minute Walk |              | Active | C115801    | SIXMW1-Distance at 2 Minutes, SIXMW102 | 6MWT - Distance at 2 Minutes |
| 6_MINUTE_WALK_TEST_DISTANCE_AT_3_MINUTES | 6 Minute Walk Test - Distance at 3 min | Numeric Finding | No      | Six Minute Walk |              | Active | C115802    | SIXMW1-Distance at 3 Minutes, SIXMW103 | 6MWT - Distance at 3 Minutes |
| 6_MINUTE_WALK_TEST_DISTANCE_AT_4_MINUTES | 6 Minute Walk Test - Distance at 4 min | Numeric Finding | No      | Six Minute Walk |              | Active | C115803    | SIXMW1-Distance at 4 Minutes, SIXMW104 | 6MWT - Distance at 4 Minutes |

SDTM Domain Links to Topic Codes

Maintain SDTM Domain linkage to Topic Codes per SDTM Version

SDTM Version

SDTM Version: 3.2-NN05

Import

SDTM Domain

Domain Class: FINDINGS

Domain: FT (Functional Tests)

Linked Topic Codes:

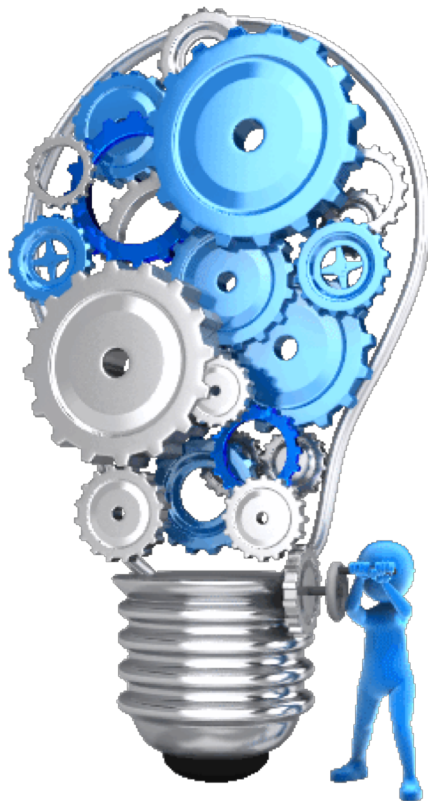
| Topic Code                               | Topic Code Label                       | Topic Code Type | Derived | Category        | Sub Category | Status | CDISC Code | CDISC Submission Value                 | NCI Preferred Term           |
|------------------------------------------|----------------------------------------|-----------------|---------|-----------------|--------------|--------|------------|----------------------------------------|------------------------------|
| 6_MINUTE_WALK_TEST_DISTANCE_AT_1_MINUTE  | 6 Minute Walk Test - Distance at 1 min | Numeric Finding | No      | Six Minute Walk |              | Active | C115800    | SIXMW1-Distance at 1 Minute, SIXMW101  | 6MWT - Distance at 1 Minute  |
| 6_MINUTE_WALK_TEST_DISTANCE_AT_2_MINUTES | 6 Minute Walk Test - Distance at 2 min | Numeric Finding | No      | Six Minute Walk |              | Active | C115801    | SIXMW1-Distance at 2 Minutes, SIXMW102 | 6MWT - Distance at 2 Minutes |
| 6_MINUTE_WALK_TEST_DISTANCE_AT_3_MINUTES | 6 Minute Walk Test - Distance at 3 min | Numeric Finding | No      | Six Minute Walk |              | Active | C115802    | SIXMW1-Distance at 3 Minutes, SIXMW103 | 6MWT - Distance at 3 Minutes |
| 6_MINUTE_WALK_TEST_DISTANCE_AT_4_MINUTES | 6 Minute Walk Test - Distance at 4 min | Numeric Finding | No      | Six Minute Walk |              | Active | C115803    | SIXMW1-Distance at 4 Minutes, SIXMW104 | 6MWT - Distance at 4 Minutes |


  
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# Conclusion

- **Within our MDR we manage our Topic Code Concept:**
  - Semantic definition
  - Link to CDISC CT by versions or Sponsor Defined CT
  - Link to SDTM domains by internal SDTM versions
  - Link to ADaM PARAM/PARAMCD definitions
  - Define our preferred labels, operational codes, unit conversions, etc.
- **This enable us to support:**
  - Impact assessment changes to CT and SDTM mappings and usage
  - Apply new versions of CT and SDTM on trials during execution
  - Up or down version SDTM deliverables when preparing data integrations

# Thank you

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