

How to manage changes to CDISC standards at Novo Nordisk

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1 ABSTRACT

At Novo Nordisk, we have worked on optimizing and standardizing the data collection and reporting in our operational data systems. When external data standard definitions are updated (e.g. CDISC standards), we face a number of challenges in managing these updates in our systems. In this paper/presentation we will share some of our methods and processes for adapting to changes in the following data standards:

- New version of CDISC Controlled Terminology (CT), e.g. addition of code lists and codes
- New version of SDTM Implementation Guides, e.g. addition of new domains

2 INTRODUCTION TO THE “TOPIC CODE CONCEPT”

Operationally we manage both CDISC and Sponsor Defined CT and SDTM domains by our Topic Code Concept within our Meta Data Repository (MDR).

The Topic Code Concept is defined by:

- A semantic definition of a collected assessment
 - Can be more specific than CDISC CT
- An operational code value and a preferred label, which is used in trial protocols, flowcharts and outputs
- A classification of the response type
 - Include definitions specific to response type, e.g. standard unit conversion
- Linkage to CDISC CT versions
- Linkage to Sponsor Defined CT, used when no appropriate match in CDISC CT version is available
- Linkage to SDTM Domain for specific internal SDTM versions
- Define ADaM PARAM and PARAMCD values

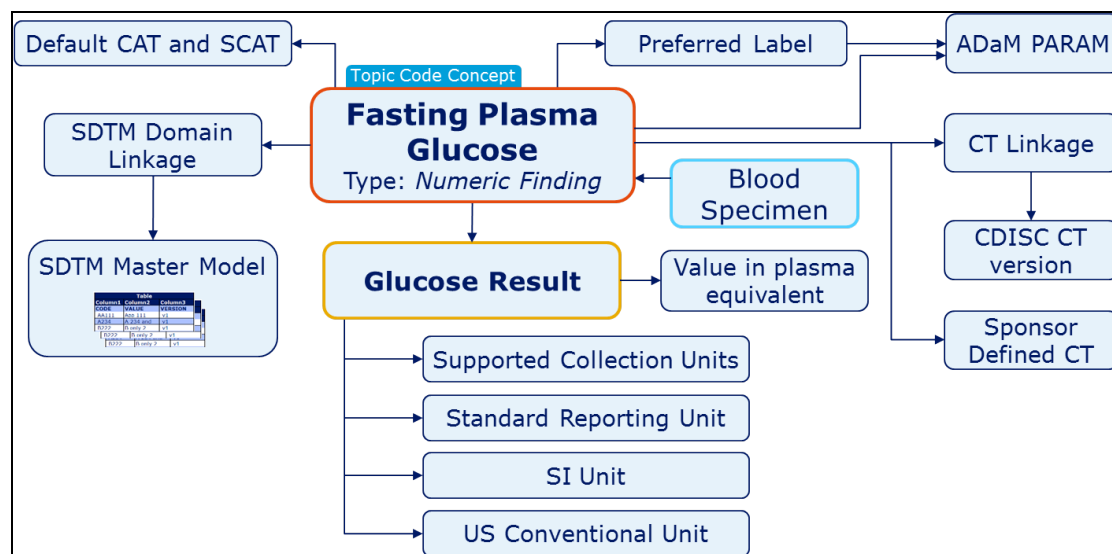


Figure 1: Overview of the Topic Code Concept

3 HOW TO MANAGE NEW VERSIONS OF CDISC CONTROLLED TERMINOLOGY

3.1 CHANGES TO CDISC CONTROLLED TERMINOLOGY

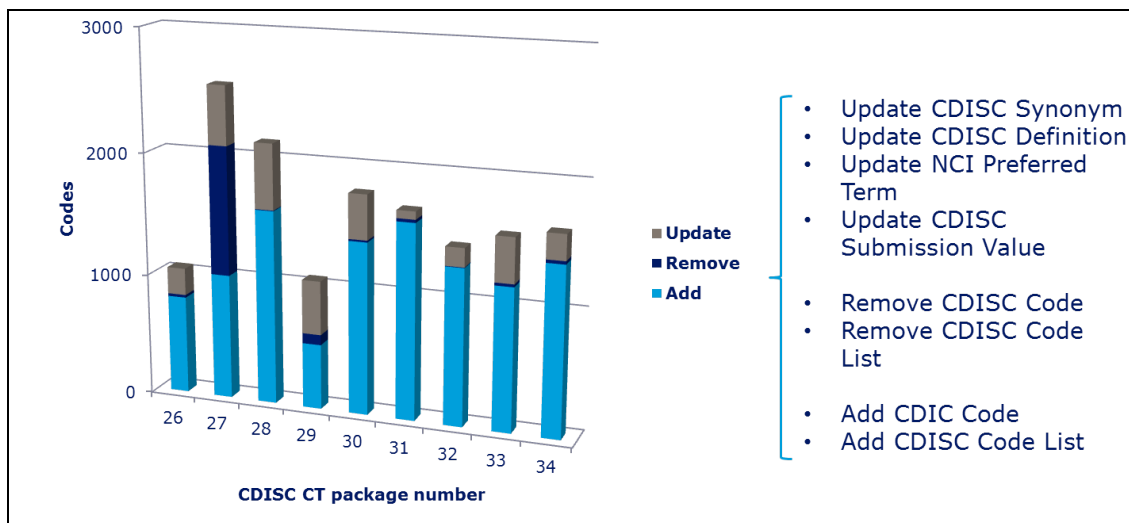


Figure 2: Number of changes to CDISC Code Lists and Codes per package over the last years

Every quarter when a new package of CDISC CT is released, a substantial amount of changes are introduced. From 2016-2018 the average amount of changes per package was 1654, which is the result of either: 1) Updates, 2) Removal or 3) Addition of CDISC Code Lists and Codes to the existing Code Lists and Codes.

3.2 THE PROCESS FOR MANAGING CHANGES TO CDISC CT AT NOVO NORDISK

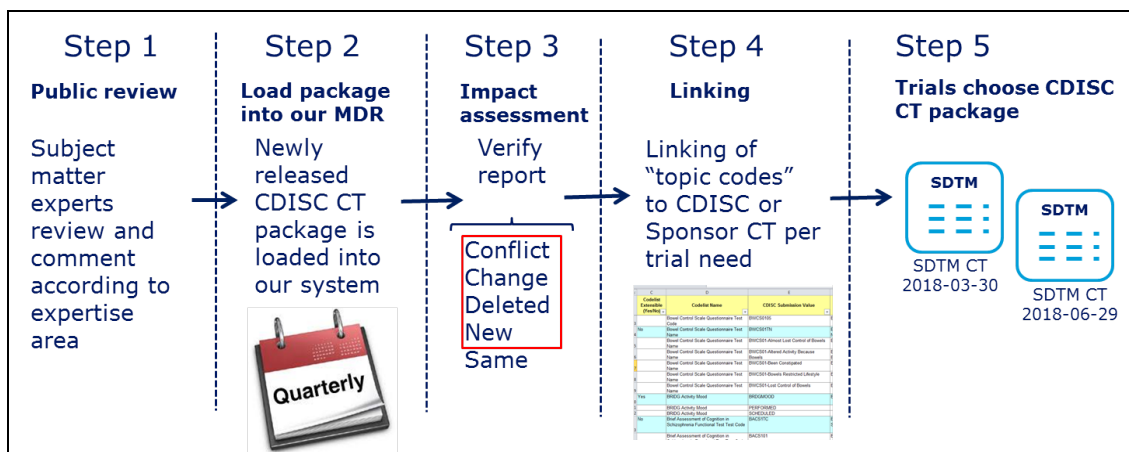


Figure 3: The process for managing changes to CDISC CT at Novo Nordisk consists of 5 overall steps. The individual steps and definitions/terms are described in detail below.

To accommodate the many changes per new CDISC CT version, we have established a 5-step process consisting of the following elements:

- 1) Public review:** In order to give input to proposed changes and to monitor trends, we actively take part in the public review process, where we have named subject matter experts to evaluate each of the sub-packages (e.g. general, lab, etc.).
- 2) Load of CDISC CT into MDR:** This is an automated process, where we upload the newly released CDISC CT version.

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- 3) **Impact assessment:** First step of the impact assessment is to run a verify report, where the new version is compared against the previous version. The verify report results in one of the below listed options for each CDISC Code List and Code, which have to be evaluated.
- Conflict:** C-Code or Submission Value is changed
 - Change:** Definition or NCI Preferred Term is updated
 - Deleted:** Code List or Code is deleted
 - New:** New Code List or Code is added
 - Same:** No change to Code List or Code

In addition to the verify report generated within the MDR system, we use the following tools to evaluate the impact of the change:

- The SDTM change log published at www.cancer.gov to identify the reason for the change
- A report to get an historical overview of when the Code List or Code was created, and if it has changed over time
- A report to identify the exact change, i.e. whether the change is to Submission Value, C-Code, Definition etc.

During the actual impact assessment we consider consequences for data collection, e.g. what is the impact for our standard CRF's? Change of Submission Value might require a changed annotation, whereas removal of a Code might result in linkage to a different CDISC Code or a need for a Sponsor Defined Code. As impact assessment is a time-consuming process, we focus on the Codes, which the verify report has listed as "**Conflict**", "**Removed**" or "**Changed**". These are particularly critical since they might lead to errors in the SDTM datasets.

- Linking:** Trials make a request to our Global Standards Team, when a Topic Code in our MDR needs to be linked. Linking is the process, where we associate an assessment with a specific CDISC code. The Global Standards Team evaluate whether an appropriate Code exists in CDISC CT or a Sponsor Defined Code must be created.
- Trials select CDISC CT package:** As our Topic Codes are linked in all versions of CDISC CT, we can submit data in different versions CDISC CT for different trials.

4 HOW TO MANAGE NEW VERSIONS OF SDTM IMPLEMENTATION GUIDE?

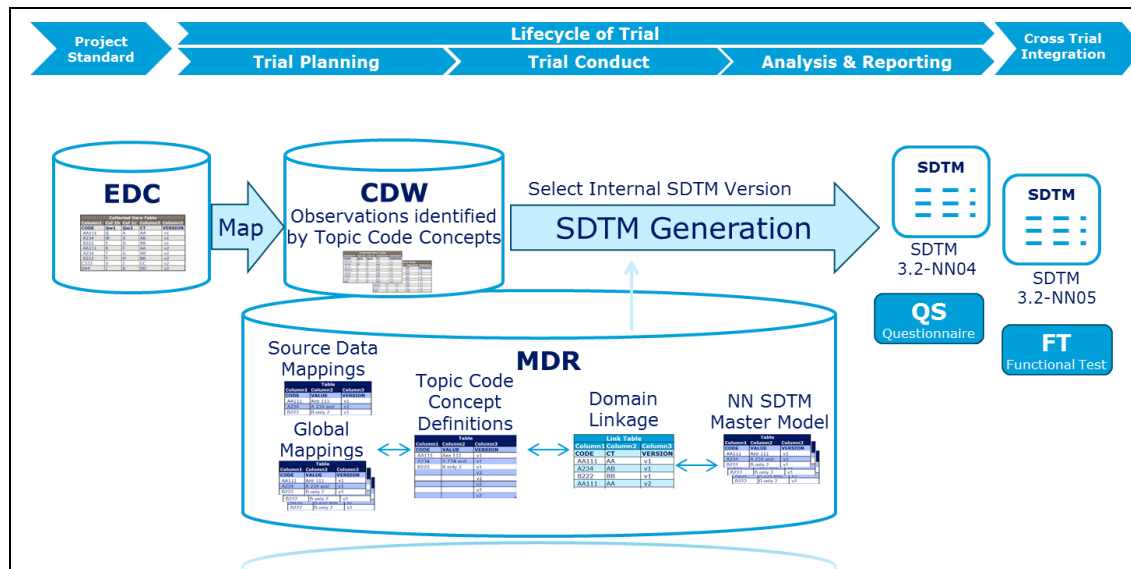


Figure 4: The process of mapping source data to SDTM versions via the CDW

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We have implemented a two-phased mapping process. First we map the collected data from EDC/CDMS¹ into a generalised SDTM model in our Clinical Data Warehouse (CDW), where records for specific assessments are identified by our Topic Code Concept. The Topic Code Concept is associated with a specific SDTM domain for each internal SDTM version. The internal SDTM versions reflect sponsor defined additions that can be based on TAUGs, draft SDTM versions or pure sponsor defined domains.

For example we have previously mapped the Walk Tests into the QS domain, but in our new internal SDTM model definition, we have included the draft Functional Tests (FT) domain as a sponsor defined domain (based on SDTM-IG 3.3). When a new internal SDTM version is selected for a trial, data will be mapped into the new FT domain during the SDTM generation. This is supported from the MDR given that the domains are within the same general domain class.

CONCLUSION

Within the MDR we manage our Topic Code Concept, which enables us to support different versions of CDISC CT and SDTM models per trial. However, before implementation of a new standard in our systems, it is important that all potential issues have been identified, impact assessed and handled.

CONTACT INFORMATION

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¹ EDC: Electronic Data Capture system; CDMS: Clinical Data Management System