



**2023**  
**EUROPE**  
**INTERCHANGE**  
**COPENHAGEN | 26-27 APRIL**



## **The joy (and pain) of implementing a higher SDTM and SDTMIG version - A sponsor story**

Presented by Kathleen Hectors, Data Collection Standards Expert, Janssen R&D



# Meet the Speaker

## Kathleen Hector

**Title:** Data Collection Standards Expert

**Organization:** Clinical Data Standards & Transparency (Janssen R&D)

*Role description: Developing data stream expertise and strategies, managing controlled terminology and biomedical concept dictionaries, supporting data managers and clinical programmers on collection and mapping of trial specific scientific data.*

*Volunteer in CDISC Microbiology & Immunogenicity Controlled Terminology team*

*13 years of experience in the pharmaceutical business; Joined Janssen in 2014 as Data Manager and Clinical Data Standards in 2017. Located in Beerse, Belgium*

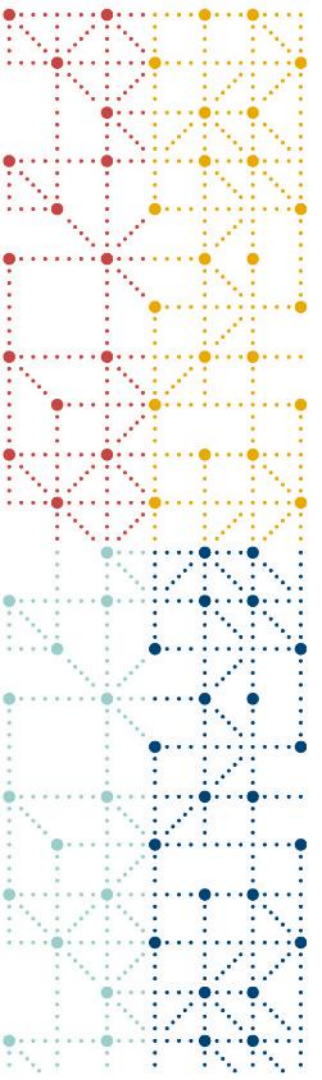
*Holding a PhD in Biology from the University of Antwerp, Belgium*



# Disclaimer and Disclosures

*The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC nor Janssen.*

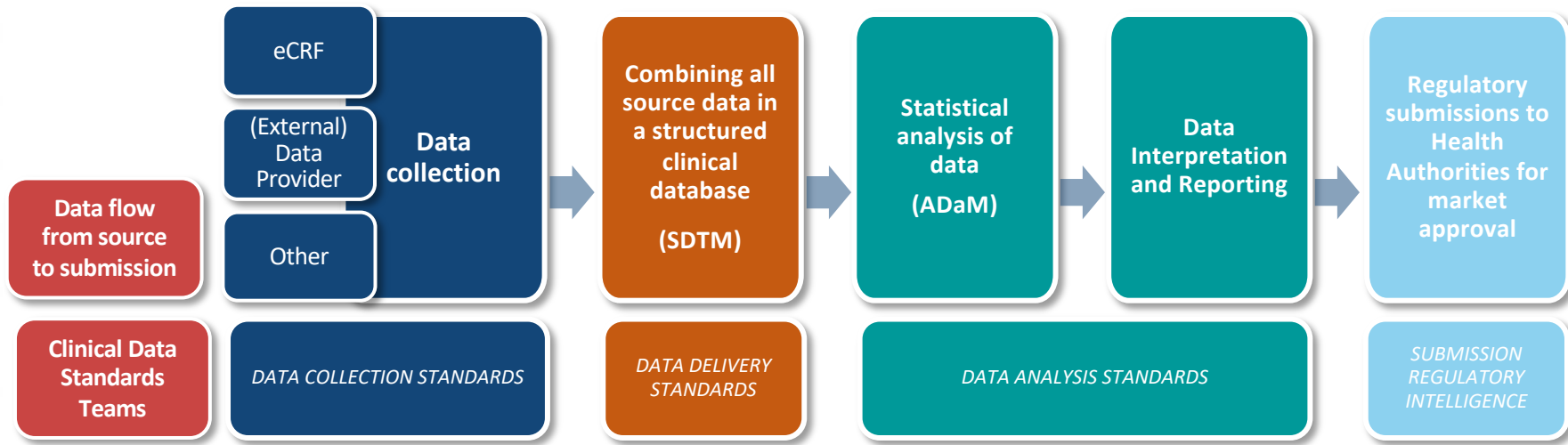
*The author(s) have no real or apparent conflicts of interest to report.*



# Setting the stage

How Clinical Data Standards are organized and managed at Janssen

# Organization of Janssen Clinical Data Standards



Standards components are available to support every step in this lifecycle.

**Mission of Clinical Data Standards:  
Support End-to-End from data sources to regulatory submissions**

End-to-End

Protocol templates



Pre-configured libraries,  
Completion & user guidelines

eCRFs libraries



Statistical Analysis  
Plan templates



Tables, Listings,  
Figures specifications



End-to-End Standards  
Collection ↔ Analysis



DNA



External Data

Standardized transfer  
metadata for main volume  
vendors



SDTM Metadata

Controlled Terminology,  
Concepts & Dictionaries  
Define.xml specifications

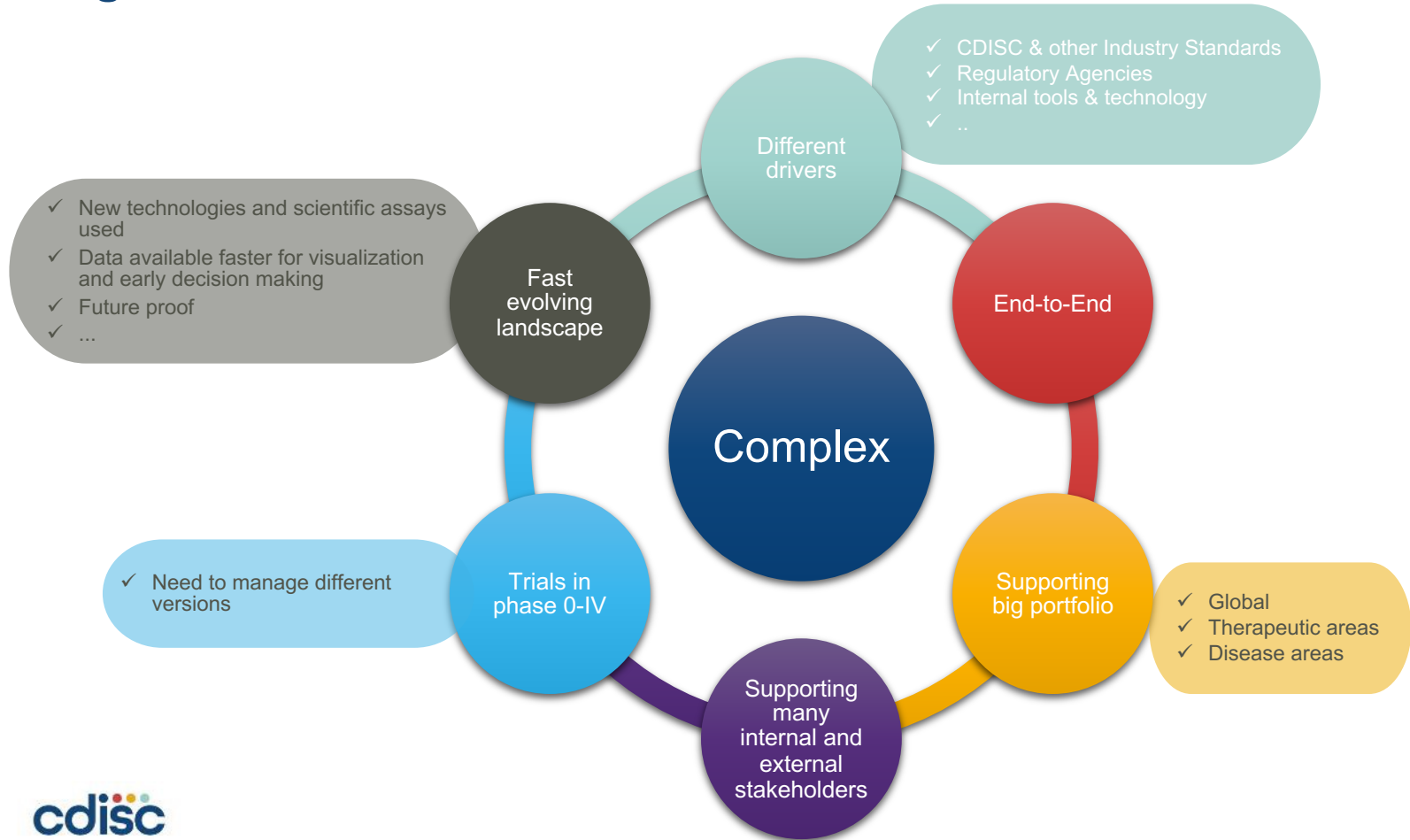


ADaM Metadata

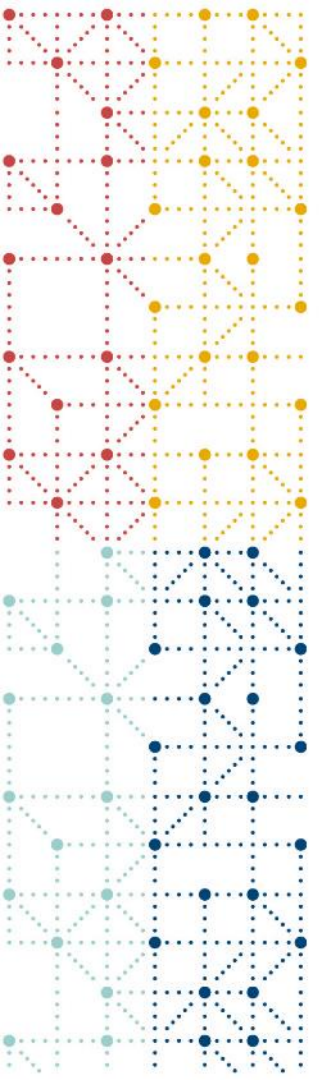


Programming code

# Organization of Janssen Clinical Data Standards







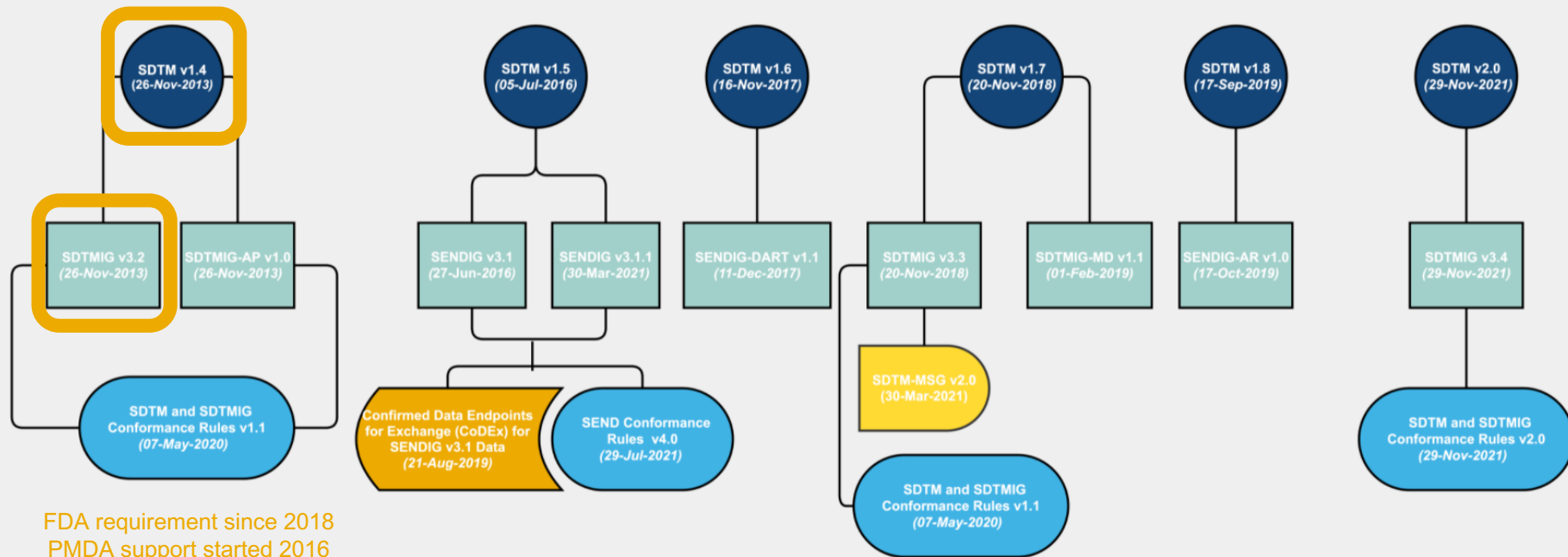
# Versioning

Clinical Data Standards versioning

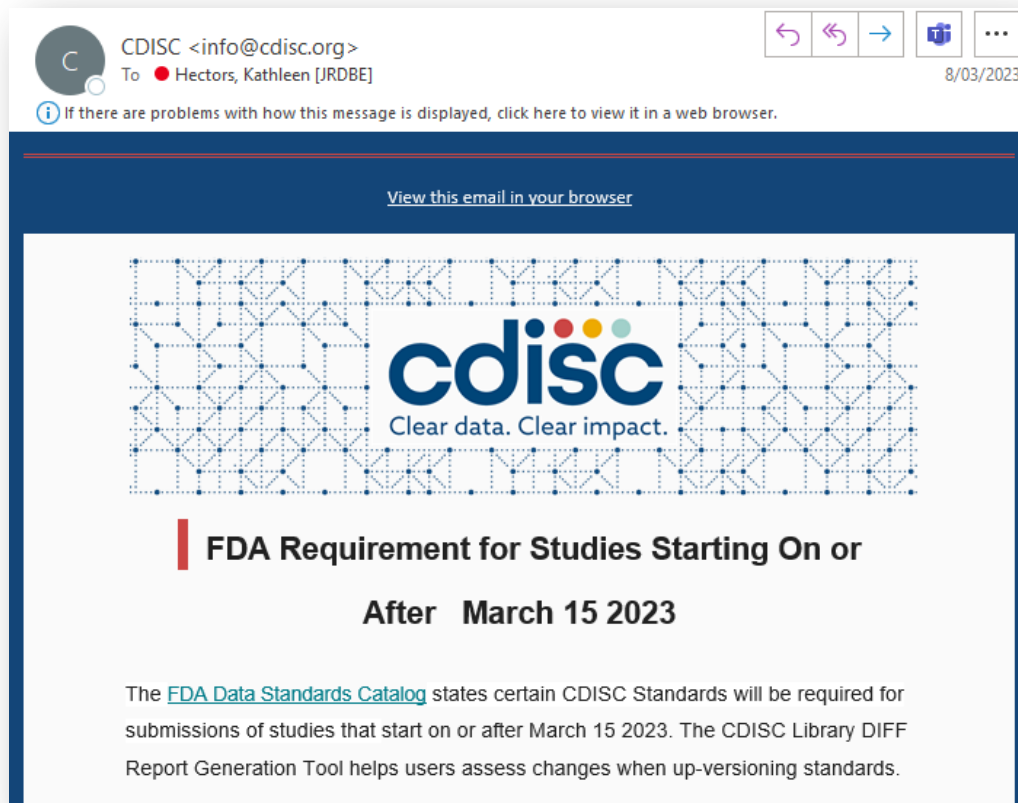


# CDISC versions used in Janssen Standards

Janssen Standards state  
until March 2023




# Health Authority Requirements



CDISC <info@cdisc.org>  
To: Hectors, Kathleen [JRDBE] 8/03/2023

If there are problems with how this message is displayed, click here to view it in a web browser.

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**FDA Requirement for Studies Starting On or After March 15 2023**

The [FDA Data Standards Catalog](#) states certain CDISC Standards will be required for submissions of studies that start on or after March 15 2023. The CDISC Library DIFF Report Generation Tool helps users assess changes when up-versioning standards.

SDTM v1.7 & SDTMIG v3.3  
to be used for  
FDA submissions  
for trials with FPI on or after  
15 March 2023

**Dilemma**  
*Upgrading... To what version?*

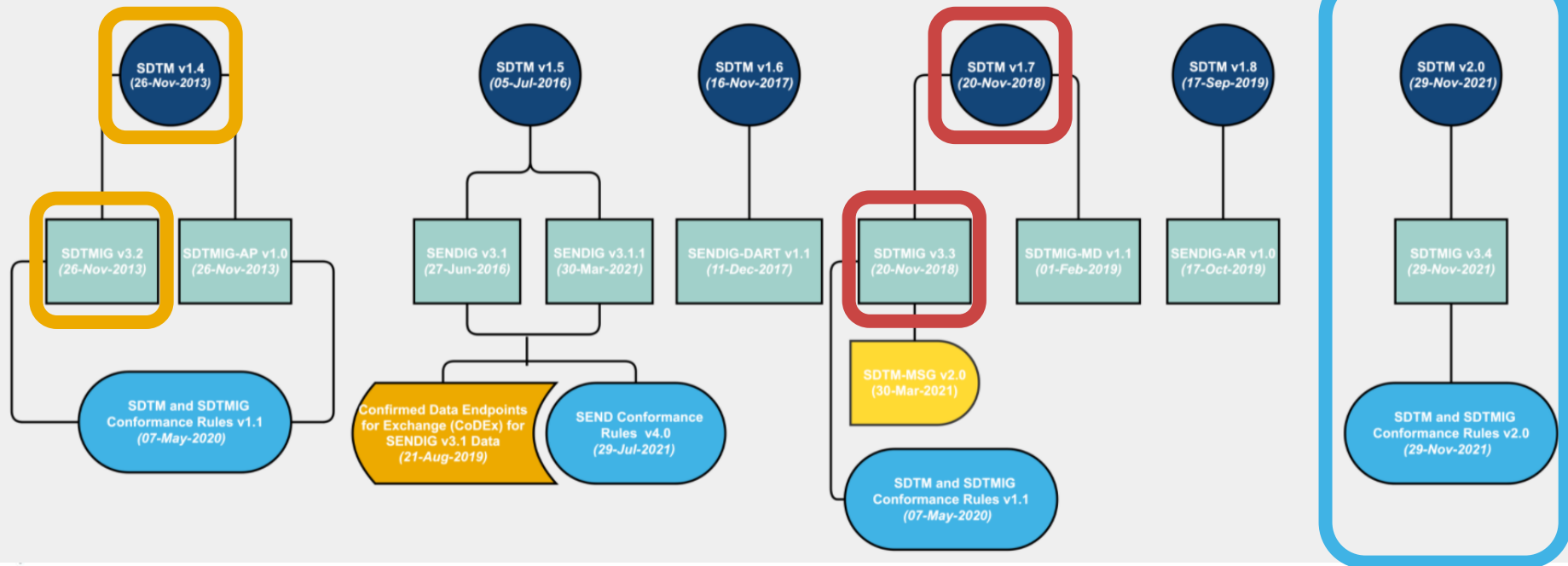
# CDISC versions used in Janssen Standards

Janssen Standards state until March 2023

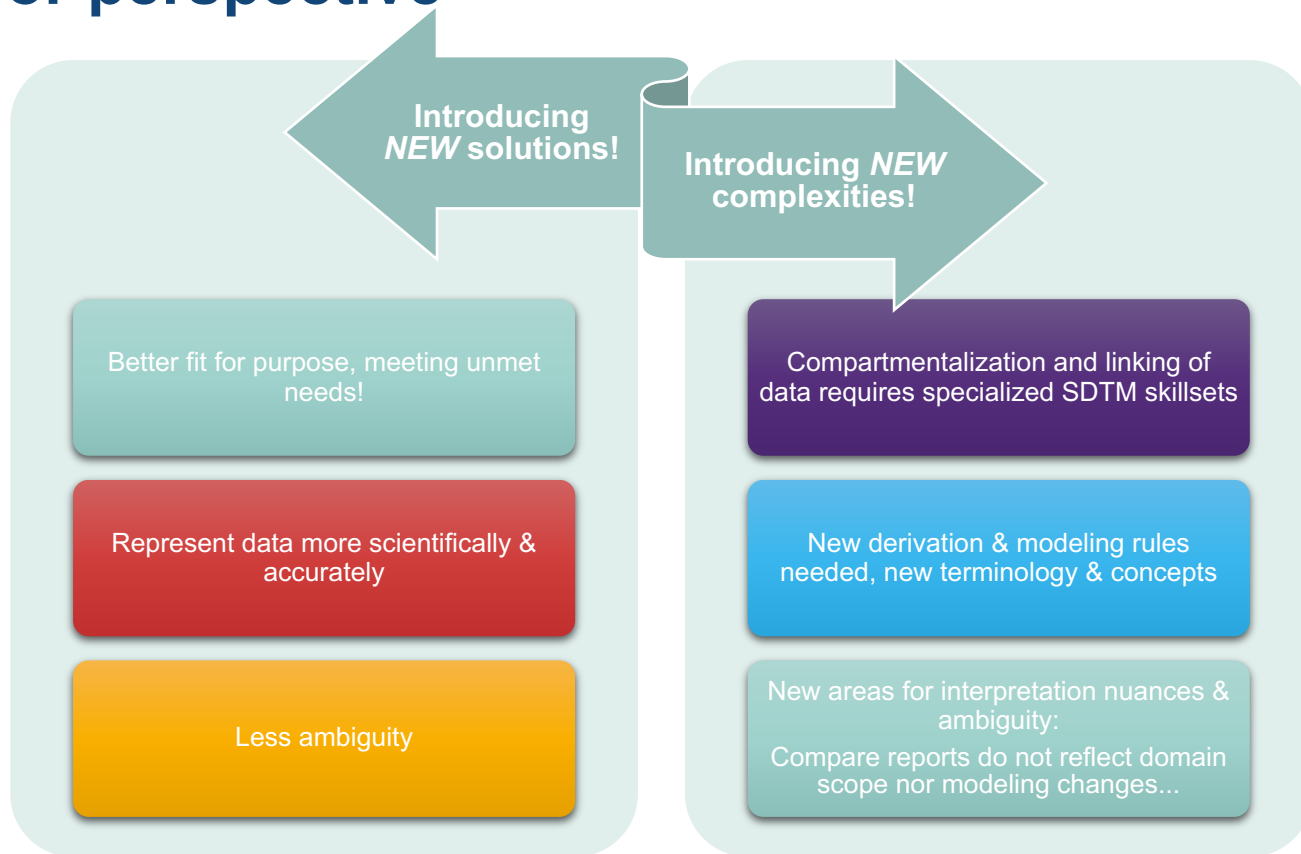
Janssen Standards state as of March 2023

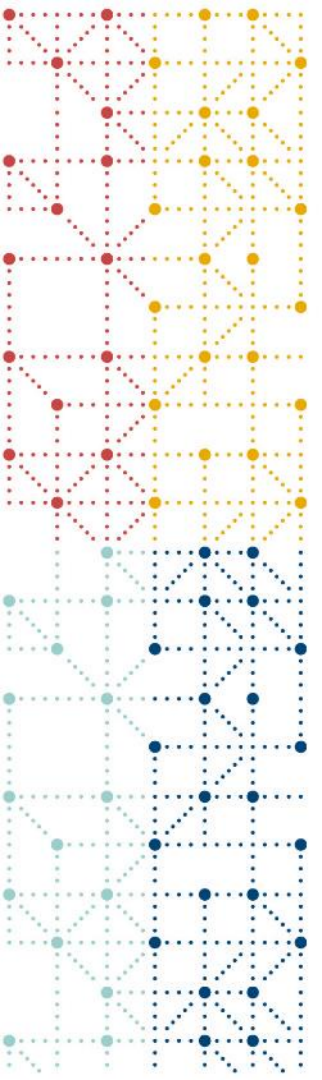
Long term future state as of ????

Not approved for use yet by FDA or PMDA



# Sponsor perspective





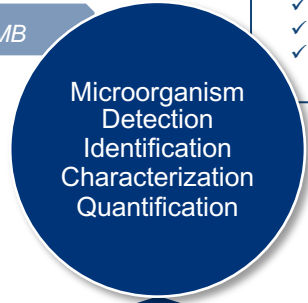
## Use Case

Changed scope of LB, MB and IS domains over different SDTM(IG) versions

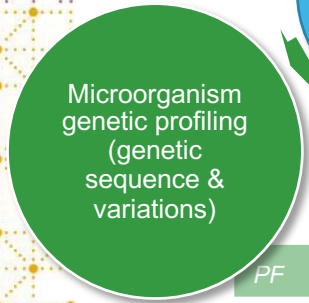
# Janssen Standards v3.2



LB or MB



- Assessments via e.g.
- ✓ Antigen tests
  - ✓ Antibody tests
  - ✓ Genetic based tests
  - ✓ Cultures/growth tests
  - ✓ Other



PF



MS



# Changed scope of LB and MB domains in SDTMIG 3.3

CDSIC SDTMIG 3.2 (Nov 2013)

## Microbiology Specimen (MB)

### MB - Description/Overview for Microbiology Specimen Domain Model

Microbiology specimen findings, including gram stain results, and organisms found.

Boundaries of LB vs MB were not clear for end-users and have been causing a lot of confusion.

## Laboratory Test Results (LB)

### LB - Description/Overview for Laboratory Test Results Domain Model

Laboratory test findings including, but is not limited to hematology, clinical chemistry and urinalysis data. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.

Code	Codelist Code	Codelist Extensible (Yes/No)	Codelist Name	CDISC Submission Value	CDISC Synonym(s)	CDISC Definition
C103403	C67154		Laboratory Test Name	Helicobacter pylori IgG Antibody	Helicobacter pylori IgG Antibody	A measurement of the Helicobacter pylori IgG antibody in a biological specimen.
C92534	C67154		Laboratory Test Name	Hepatitis A Virus Antibody	Hepatitis A Virus Antibody	A measurement of the hepatitis A virus antibody in a biological specimen.
C92271	C67154		Laboratory Test Name	Hepatitis A Virus IgM Antibody	Hepatitis A Virus IgM Antibody	A measurement of hepatitis A virus IgM antibody in a biological specimen.
C125944	C67154		Laboratory Test Name	Hepatitis B Virus Antibody	Hepatitis B Virus Antibody	A measurement of an unspecified hepatitis B antibody in a biological specimen.
C96660	C67154		Laboratory Test Name	Hepatitis B Virus Core Antibody	Hepatitis B Virus Core Antibody	A measurement of the hepatitis B virus core antibody in a biological specimen.
C119280	C67154		Laboratory Test Name	Hepatitis B Virus Core IgG Antibody	Hepatitis B Virus Core IgG Antibody	A measurement of the hepatitis B virus core IgG antibody in a biological specimen.
C96661	C67154		Laboratory Test Name	Hepatitis B Virus Core IgM Antibody	Hepatitis B Virus Core IgM Antibody	A measurement of the hepatitis B virus core IgM antibody in a biological specimen.
C96662	C67154		Laboratory Test Name	Hepatitis B Virus e Antibody	Hepatitis B Virus e Antibody	A measurement of the hepatitis B e antibody in a biological specimen.
C74711	C67154		Laboratory Test Name	Hepatitis B Virus Surface Antibody	Anti-HBs; HBsAb; Hepatitis B Virus Surface Antibody	A measurement of the hepatitis B virus surface antibody in a biological specimen.
C92535	C67154		Laboratory Test Name	Hepatitis C Virus Antibody	Hepatitis C Virus Antibody	A measurement of the hepatitis C virus antibody in a biological specimen.



# Changed scope of LB and MB domains in SDTMIG 3.3

## CDSIC SDTMIG 3.2

### Microbiology Specimen (MB)

#### MB - Description/Overview for Microbiology Specimen Domain Model

Microbiology specimen findings, including gram stain results, and organisms found.

### Laboratory Test Results (LB)

#### LB - Description/Overview for Laboratory Test Results Domain Model

Laboratory test findings including, but is not limited to hematology, clinical chemistry and urinalysis data. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.

## CDISC SDTMIG 3.3 (+ SDTMIG 3.4)

### 6.3.7 Microbiology Domains

The microbiology domains consist of Microbiology Specimen (MB) and Microbiology Susceptibility (MS). The MB domain is used for the detection, identification, quantification, and other characterizations of microorganisms in subject samples, except for drug susceptibility testing. MS is used for representing data from drug susceptibility testing on the organisms identified in MB. All non-host infectious organisms, including bacteria, viruses, fungi, and parasites are appropriate for the microbiology domains.

### 6.3.6 Laboratory Test Results

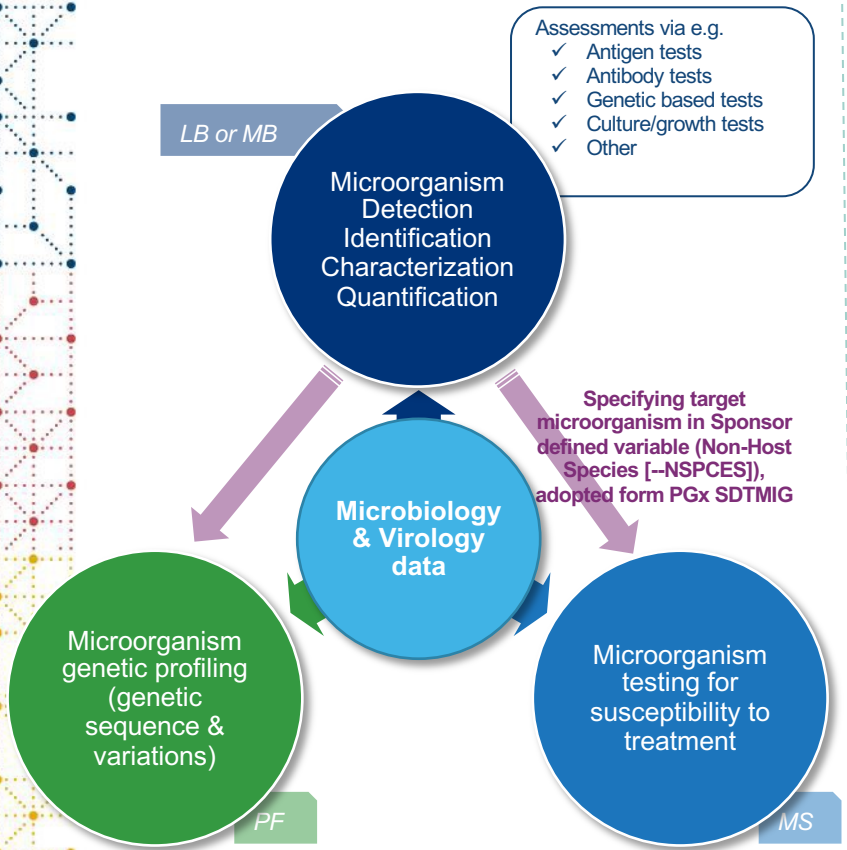
#### LB – Description/Overview

A findings domain that contains laboratory test data such as hematology, clinical chemistry and urinalysis. This domain does not include microbiology or pharmacokinetic data, which are stored in separate domains.

Scope of domains finetuned in SDTMIG v3.3 (Nov 2018).

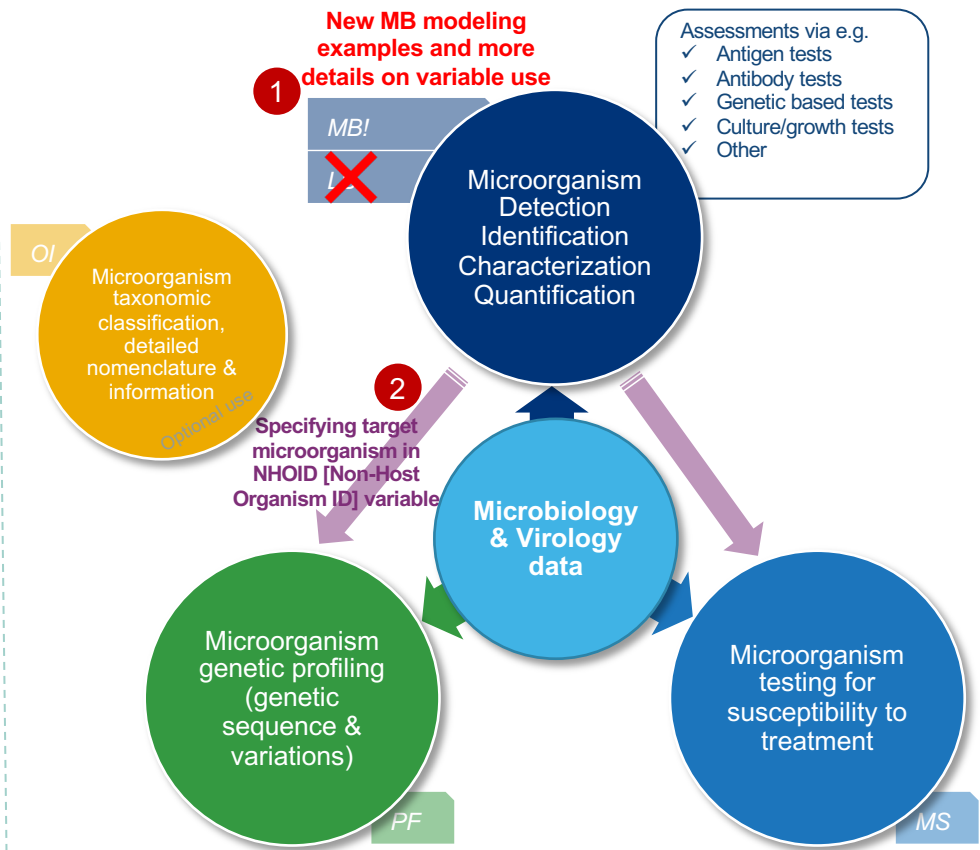
Implementation in Controlled Terminology occurred in September 2019.

# Janssen Standards v3.2



Assay specifications (commercial kit names) in Sponsor defined variables

# Janssen Standards v3.3



Assay specifications (commercial kit names) in DI [Device Identifiers] domain and SPDEVID [Sponsor Device Identifier] variable

# New changes as of SDTMIG v3.4

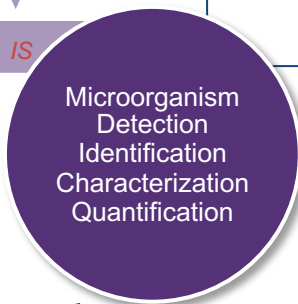
“Direct” assessments via e.g.

- ✓ Antigen tests
- ✗ Antibody tests
- ✓ Genetic based tests
- ✓ Culture/growth tests
- ✓ Other

MB



IS



Microbial antibody tests are considered as host/subject humoral immune responses.

“Indirect assessments”

- e.g.
- Hepatitis B Virus Surface Antibody (HBSAB)
  - Hepatitis C Virus Antibody (HCAB)
  - HIV-1/2 Antibody (HIV12AB)
  - SARS-CoV-2 Antibody (SAR2AB)

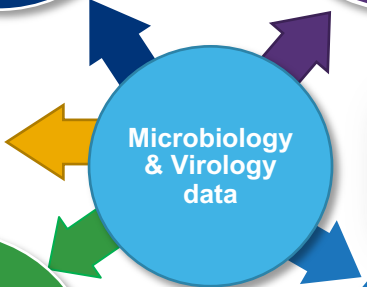
CDISC SDTMIG 3.3

**6.3.5 Immunogenicity Specimen Assessments**  
IS – Description/Overview  
A findings domain for assessments that determine whether a therapy induced an immune response.

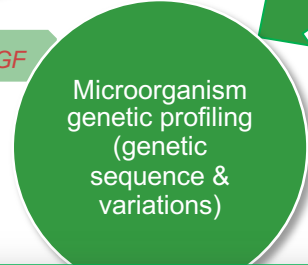
CDISC SDTMIG 3.4

**6.3.5.5 Immunogenicity Specimen Assessments (IS)**  
IS – Description/Overview  
A findings domain for assessments of antigen induced humoral or cell-mediated immune response in the subject.

OI



GF

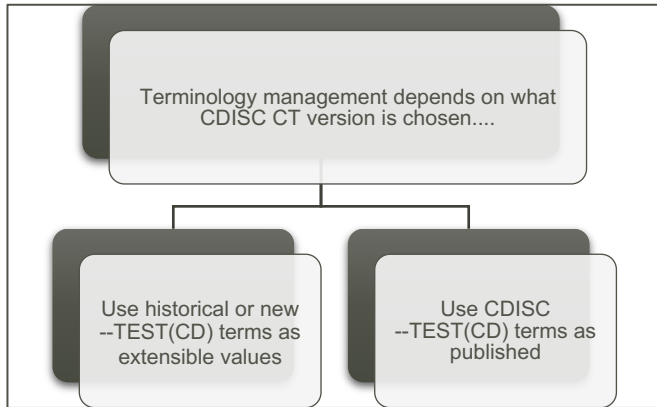
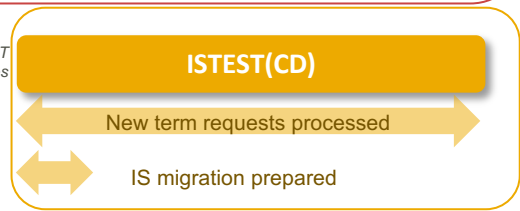
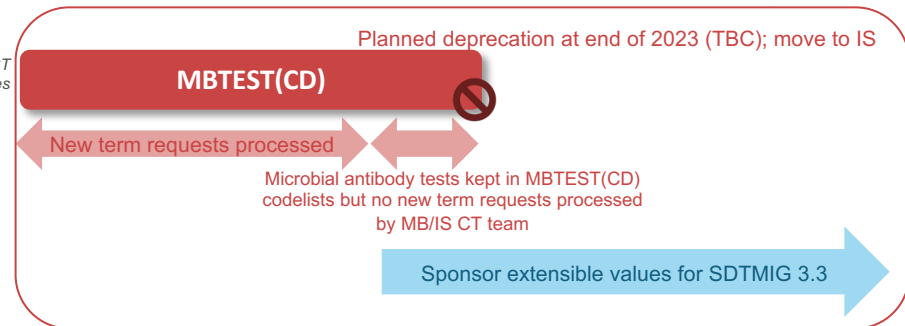


MS



**6.3.5.4 Genomics Findings (GF)**  
GF - Description/Overview  
A findings domain that contains data related to the structure, function, evolution, mapping, and editing of subject and non-host organism genomic material of interest. This domain includes but is not limited to assessments and results for genetic variation and transcription, and summary measures derived from these assessments. The GF domain is used for findings from characteristics assessed from nucleic acids and may include subsequent inferences and/or predictions about related proteins/amino acids.

# Anti-Microbial Antibody Test terminology



## Other examples

Allergen tests/autoantibodies  
(immune diseases)

Immunophenotyping tests

Questionnaires, Ratings, and  
Scales (QRS)

### SDTMIG 3.2

LB

LB

*Sponsor defined terminology*

QS

### SDTMIG 3.3

LB

LB

*Sponsor defined terminology*

Questionnaires (QS)  
*Respondent answers*

Functional Tests (FT)  
*Respondent rated to a set of  
tasks*

Clinical Classifications (RS)  
*Structured evaluations by a  
clinician*

*Domain scope expanded  
(clinical classifications +  
oncology disease response)*

### SDTMIG 3.4

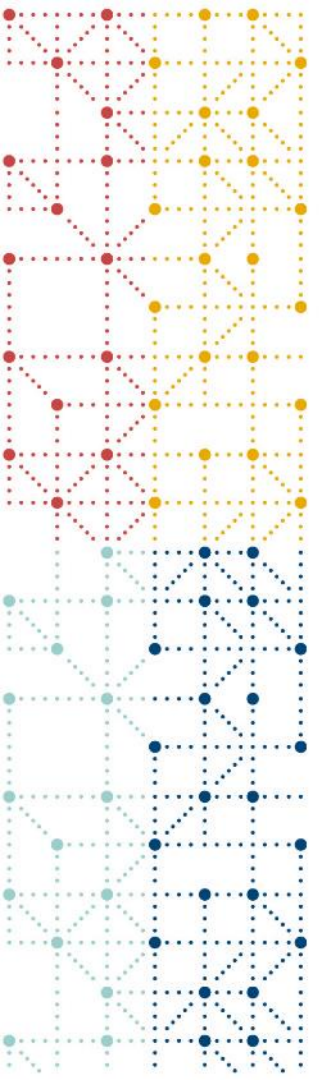
Immunogenicity Specimen  
Assessments (IS)

Cell Phenotype Findings  
(CP)

Questionnaires (QS)

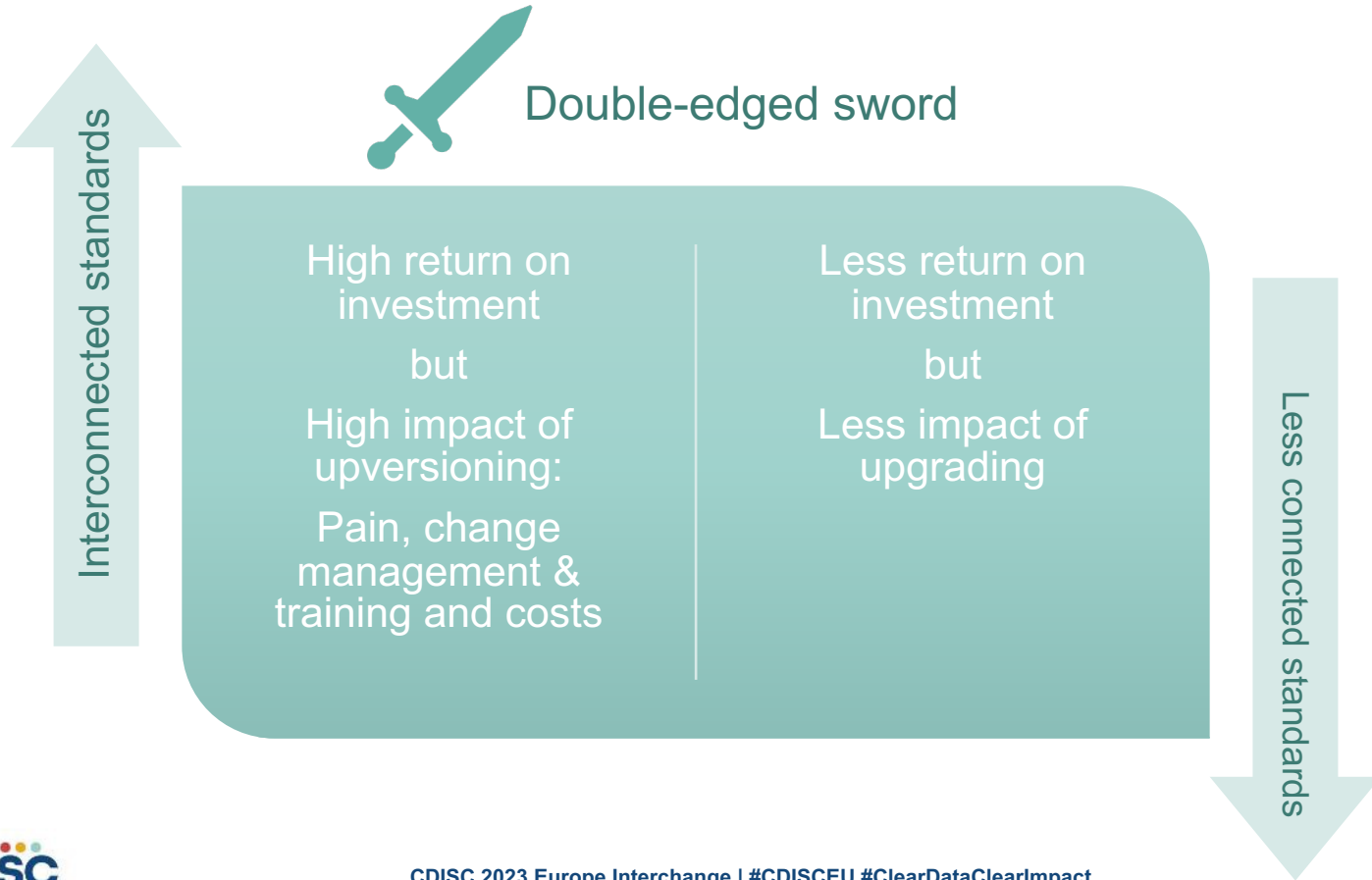
Functional Tests (FT)

Clinical Classifications (RS)



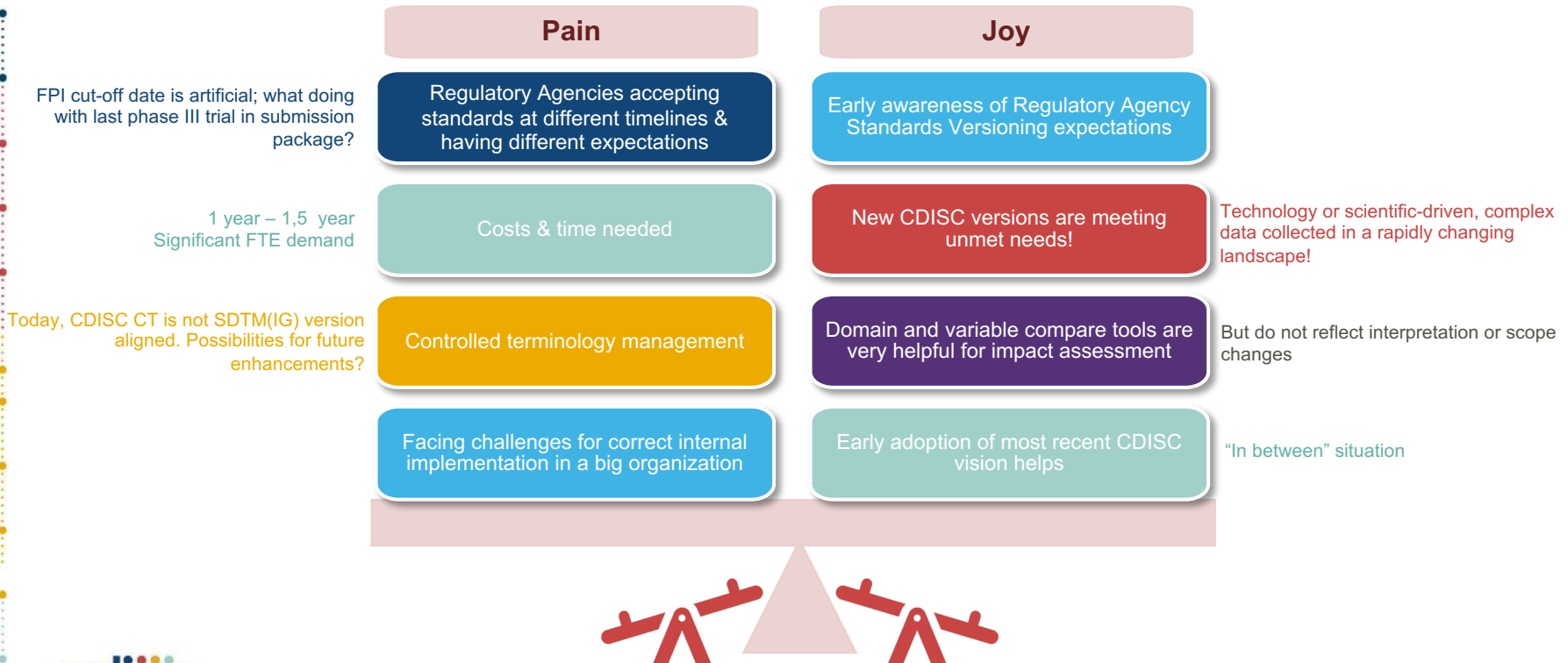
# Conclusions

# Strategy of managing Standards determines impact of upgrading





# Impact & consequences of SDTM(IG) version upgrade for a Sponsor





**Thank You!**

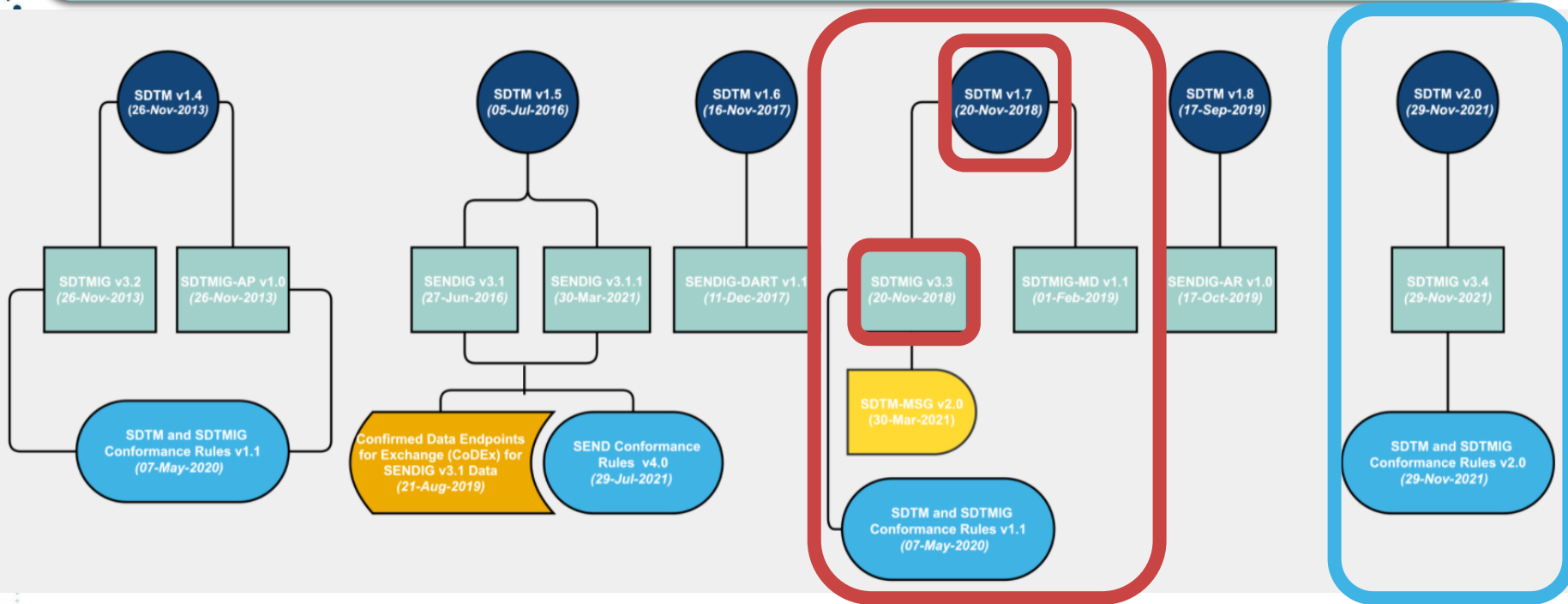
**cdisc**

# Poll 1. If you were a sponsor, to what version would you upgrade?

A: SDTM v1.7 & SDTMIG v3.3

B: SDTM v2.0 & SDTMIG v3.4

C: No preference/do not know



FDA requirement to use for trials with FPI as of March 2023;  
 PMDA accepting as of 01 April 2023



## Strategic dilemma

*Upgrading... What CDISC Controlled Terminology (CT) version to use?*

**Poll 2. If you were a sponsor, what CDISC CT version would you use?**

A: Stick with one single version

B: Continuously upgrade to latest version available (< 1 year)

C: No preference/do not know