



**2023**  
**EUROPE**  
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## **SDTM and define.xml automation made easy**

Vicky Poulsen, Principal Standards Specialist, Novo Nordisk A/S  
Hanne van Kints, Principal Standards Specialist, Novo Nordisk A/S

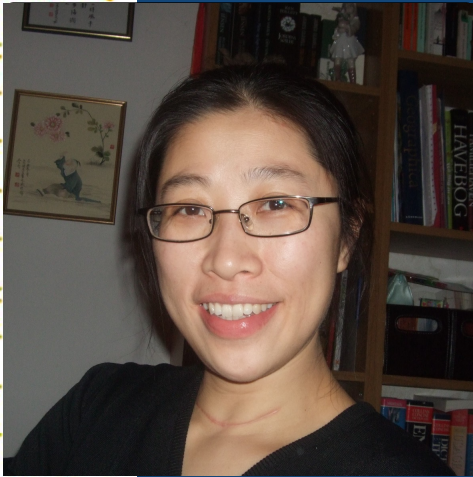
# Meet the Speakers

## Vicky Poulsen

**Title:** Principal Standards Specialist

**Organization:** Novo Nordisk A/S

Joined Novo Nordisk A/S in 2015 after being a SAS consultant for a decade in the public health sector specialising in End-to-End BI solutions. She participated in the CDISC Implementation Project shortly after. In her present position, Vicky leads the standard programming strategy and development efforts that drive the SDTM Generation Framework for SDTM and define.xml automation.



## Hanne van Kints

**Title:** Principal Standards Specialist

**Organization:** Novo Nordisk A/S

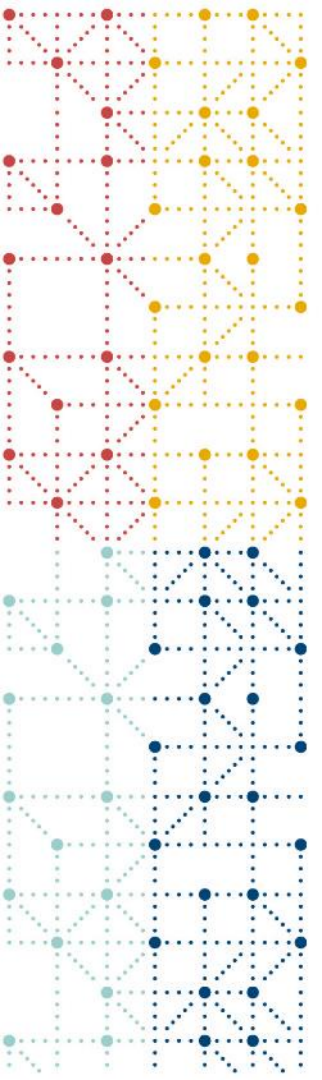
Hanne van Kints has more than 30 years' experience within the pharmaceutical industry and data management. She has worked across all areas within data management and has participated in several IT and business improvement projects. She is supporting end-to-end standardisation, CDISC SDTM implementation, use of DMW and other CDMS systems.





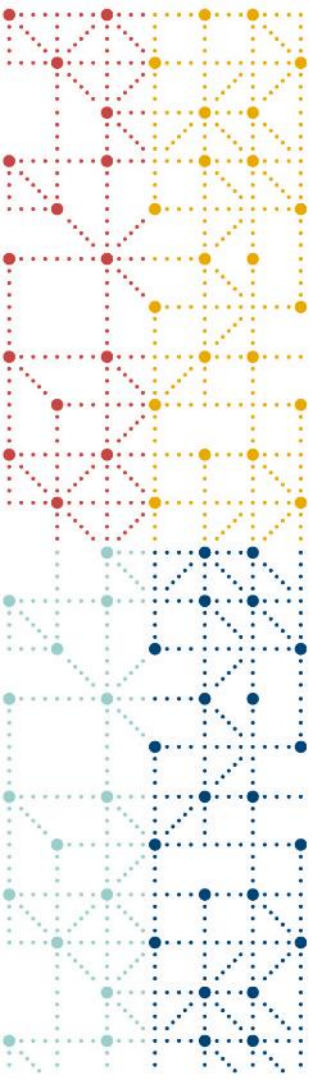
# Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the authors' and do not necessarily reflect the official policy or position of CDISC/Novo Nordisk A/S.*



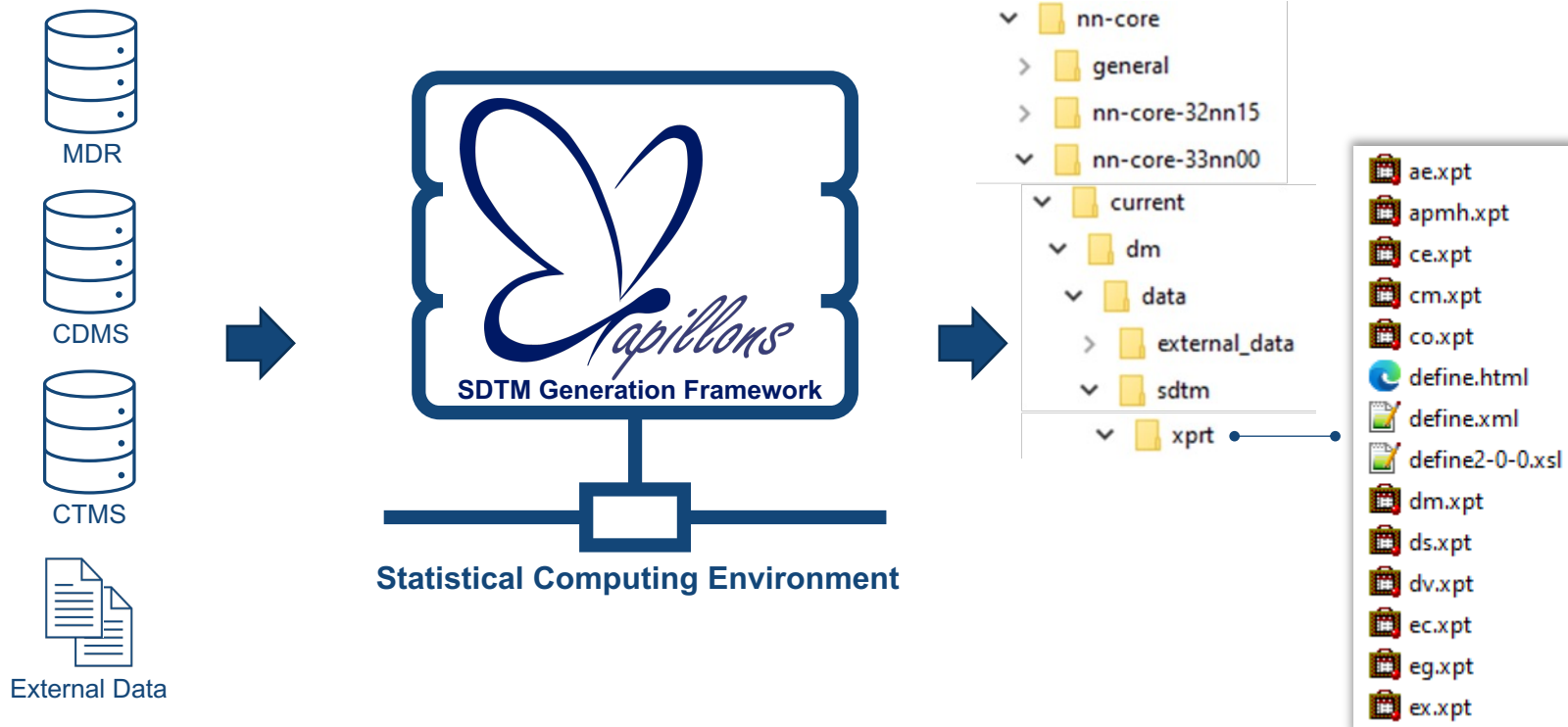
# Agenda

1. Introduction
2. Metadata/Data-driven Approach
3. SDTM Generation Framework
4. Standards Governance
5. Conclusion and Outlook

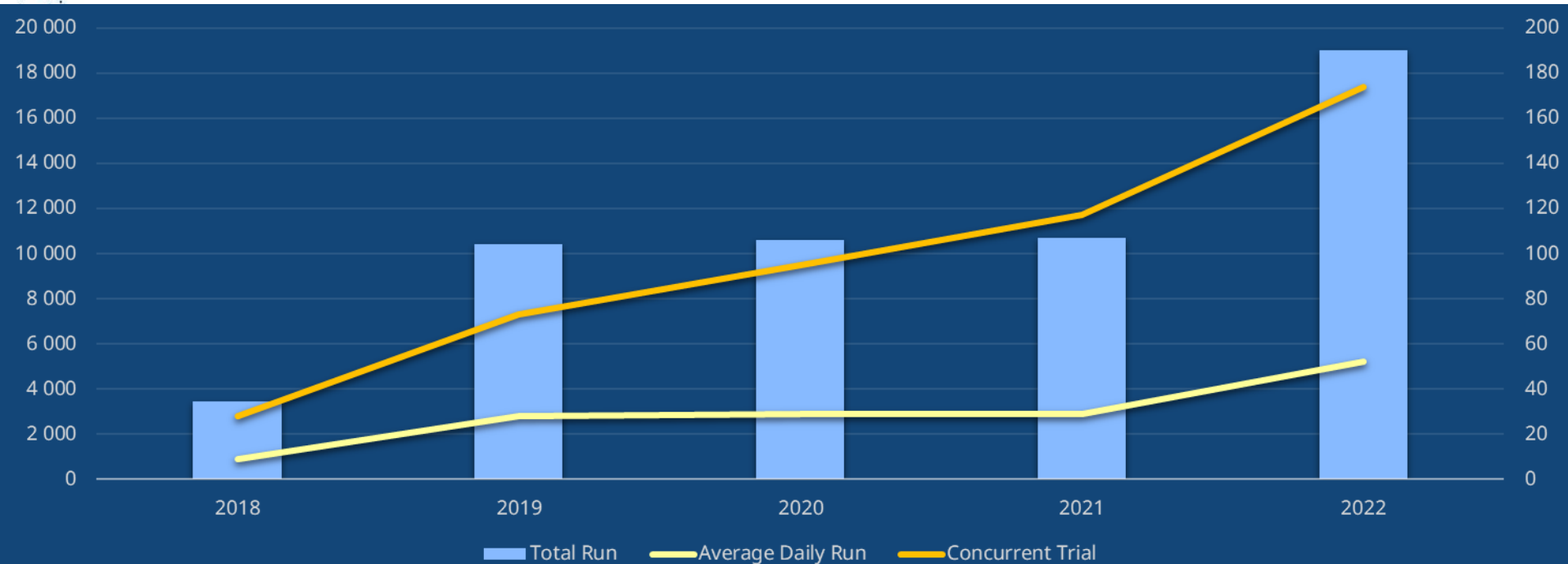


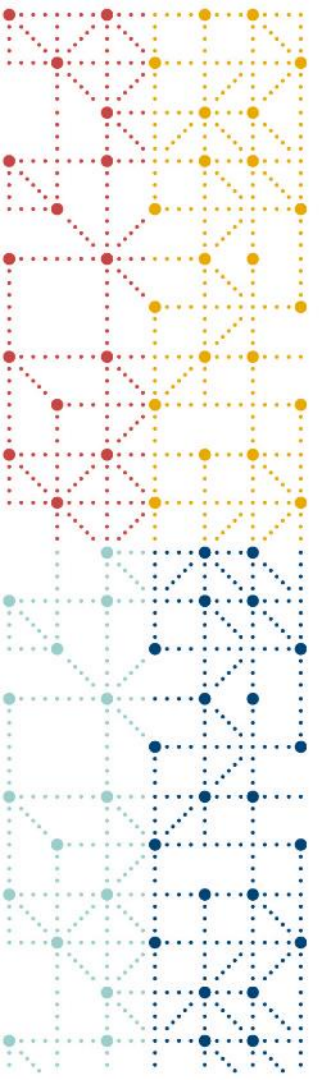
# Introduction

# Automated SDTM and define.xml Generation



# Implementation Timeline

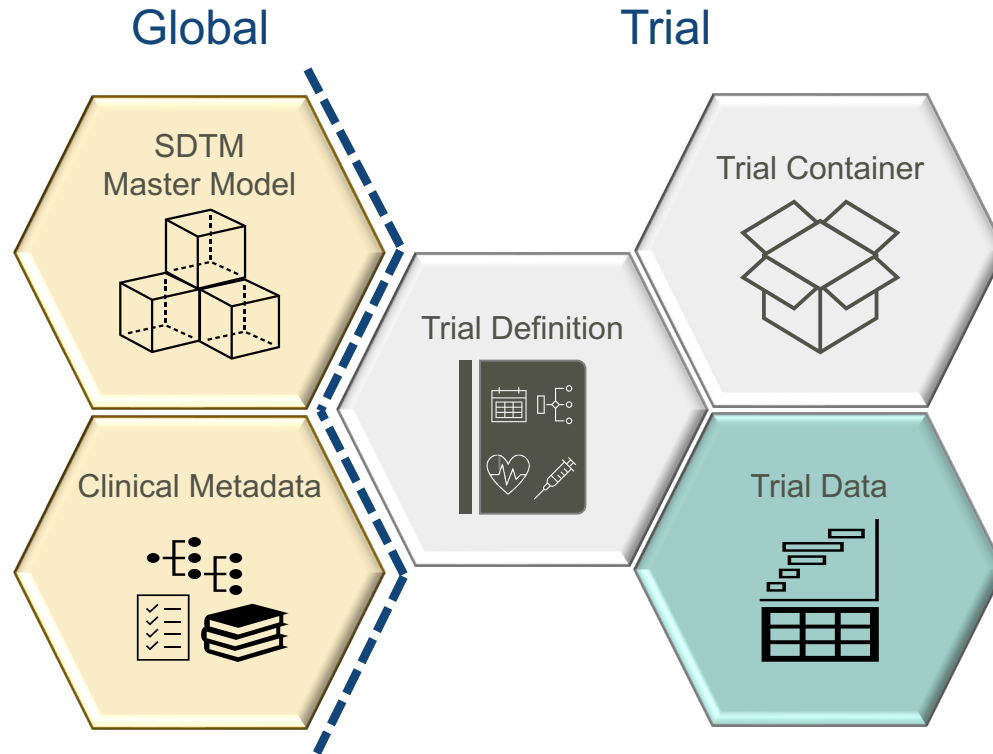




# Metadata/Data-driven Approach

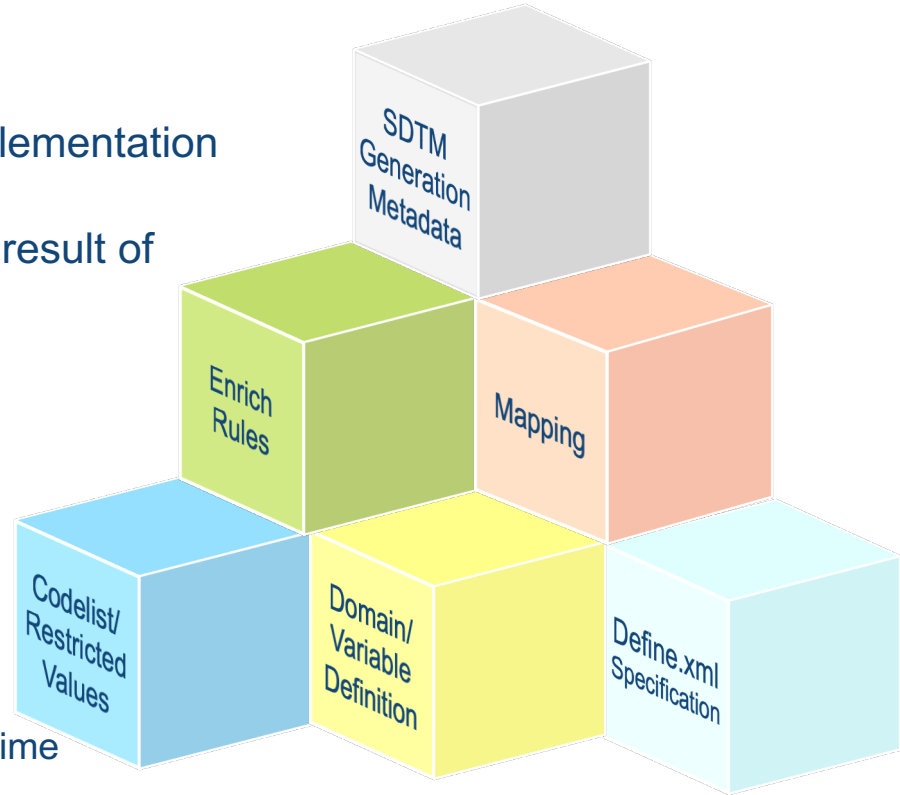


# Metadata/Data-driven Approach



# SDTM Master Model

- NN's approach to standardise SDTM implementation per SDTMIG version
- Contain maximum allowed contents as a result of thorough end-to-end assessment
  - CDISC compliance
  - NN specific implementation
    - Custom domains
    - Non-Standard Variables (NSV)
  - Authorities' requirements
  - Traceability
  - Operationality
- Version-controlled
  - Changes in requirements and usage over time
  - Reproducibility



# SDTM Master Model: Domain Definition

Fixed      SDTMIG      Custom

basic_st	Table	Label	Keys	SortKeys	map_domain_flg	suppl_qual_flg	include_in_raw	gen_raw_seqno_flg	extended_doma	enrich_build_orde
Y	DS	Disposition	STUDYID USUBJID DSSTDTC DSDECOD DSTERM	STUDYID USUBJID DSSTDTC DSDTC DSDECOD DSTERM	Y	Y	Y	Y		120
Y	LB	Laboratory Test Results	STUDYID USUBJID LBTESTCD LBSPEC VISITNUM LBTPPTNUM LBPTREF		Y	Y	Y	Y	XL	250
Y	SE	Subject Elements	STUDYID USUBJID SESTDTC SEENDTC ETC							50
	ZA	Event Adjudication Results	STUDYID USUBJID ZATESTCD ZAOBJ VISITNUM ZATPTNUM ZATPTREF		Y	Y	Y	Y		460

- Keys
- SortKeys
- Enable CDMS mapping
- Include in RAW SDTM generation
- Supplemental Qualifiers dataset
- Extended domain
- Build order in Enriched SDTM Generation

# SDTM Master Model: Variable Definition

Fixed
SDTMIG
Custom

basic_s	table	column	order	xmlcodelist	xmlcodelist_multi	origin	term	algorithm	map_var_flag	fixed_mapping	include_in_raw	nn_intern
	APDM	SEX	190	SEX		Assigned	(SEX)		Y		Y	
	APDM	RACE	200	RACE			(RACE)		Y		Y	
	APDM	ETHNIC	210	ETHNIC		CRF	(ETHNIC)		Y		Y	
	APDM	COUNTRY	220	COUNTRY		Assigned	ISO 3166					
	DM	OM_GRP	10							src.src_random_grp	Y	Y
Y	DM	STUDYID	20			Assigned			*	src.tri_id	Y	
Y	DM	DOMAIN	30			Assigned	DM		*		Y	

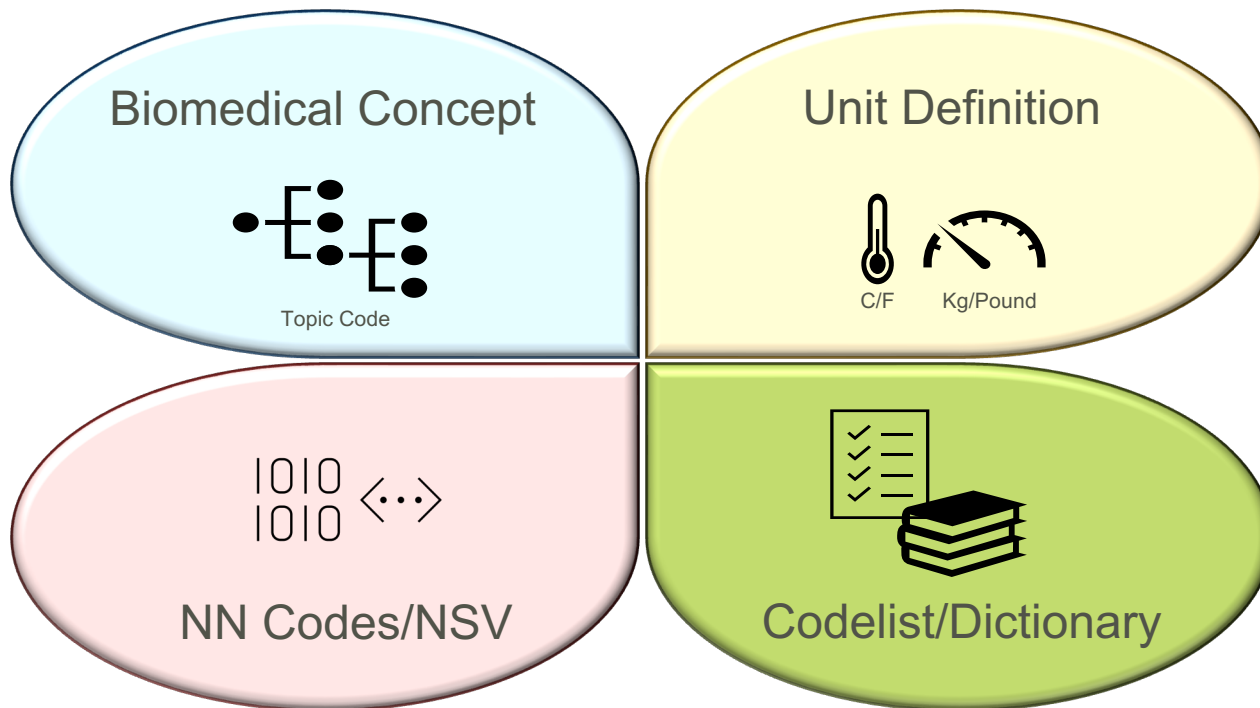
basic_s	table	column	value_lv_where_col	value_lv_label_col	value_lv_collect_ct_val	value_lv_ct_cdlist_id_col	enrich_build_order	enrich_rule	xmlcodelistvalue
Y	DM	RFXENDTC					10	sdme_dm_rfats_v\$\$	
Y	DM	RFICDTC					10	sdme_dm_rfats_v\$\$	
Y	DM	RFPENDTC					10	sdme_dm_rfats_v\$\$	
Y	DM	DTHDTC					40	sdme_dm_dth_v\$\$	
Y	DM	DTHFL					40	sdme_dm_dth_v\$\$	Y
Y	DM	SITEID							
Y	DM	INVD							

SDTM Standard Program

- Order
- Codelist/restricted values
- Origin
- Algorithm
- Comment

- Enable CDMS mapping
- Include in RAW SDTM generation
- Value-level Metadata
- Enrich Rule

# Global Clinical Metadata



# Trial Definition

A Collection of Trial Metadata

- Flowchart
- Trial Attributes
- Trial Population
- Trial Design
  - Arm
  - Element
  - Epoch
- Trial Summary Parameters
- Intervention: Compound
- Visit structure

- Version control: Trial Metadata Version

CDW Operations Metadata Management

Metadata Trial Manage Logout Production/V3R2C11/MICP novo nordisk

Select Trial Definition

Select Trial Definition to work with

Project:

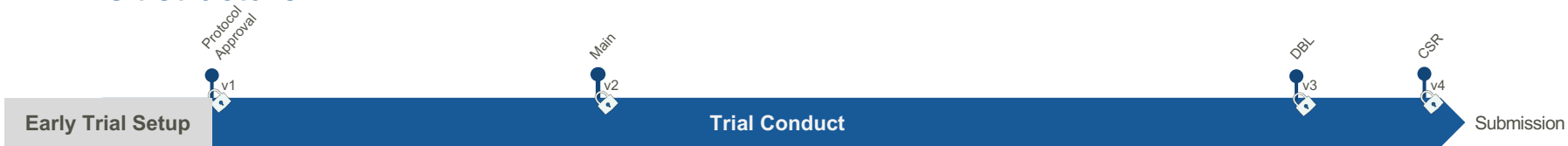
Trial ID contains:

Trial Def. ID contains:

Filter

Project	Trial ID	Trial Definition ID	Trial Metadata Version	Status
Trial Metadata Version	NN-CORE-LIBRARY	Library	1	Locked
	NN-CORE-LIBRARY	Library	2	Locked
	NN-CORE-LIBRARY	Library	3	Locked
	NN-CORE-LIBRARY	Library	4	Locked
	NN-CORE-LIBRARY	Library	5	Released

- Lock Trial Metadata Version at key milestones for traceability e.g. Protocol Approval, DBL



# Trial Container

- Trial Container holds **trial-level operational metadata** required for **transfer of clinical data/trial metadata from CDMS/MDR to SCE** for automated SDTM and define.xml generation

CDW Operations

Metadata Management

Production/V3R2C11/HAVK

Schedule Trial Container

Define Trial Container

Schedule all Trial Definitions in a Trial Container

Trial Container: NN-CORE-33NN01

Transfer Frequency:

Enable Transfer:

Transfer Time Zone:

Transfer Day Number:

**Scheduling 1**

Trial Container:

Trial Container Name:

Trial Container Short Name:

CDW Project Folder:

Reporting MedDRA Version:

Reporting WHODRUG Version:

SDTM CT Version:

ADaM CT Version:

Assign UNIX SCE folders

Project Folder contains:

Trial Folder contains:

Project Folder:

Trial Folder:

**2 Trial Folder**

**Controlled Terminology/ Dictionary Version 5**

**Trial Definition/ Trial Metadata Version 3**

Project	Trial ID	Trial Definition ID	Trial Metadata Version	Status	Use latest version
NN-CORE-LIBRARY		33NN00	2	Released	Yes

**Blinding Status 4**

Blinding:

Trial Cut Off Date:

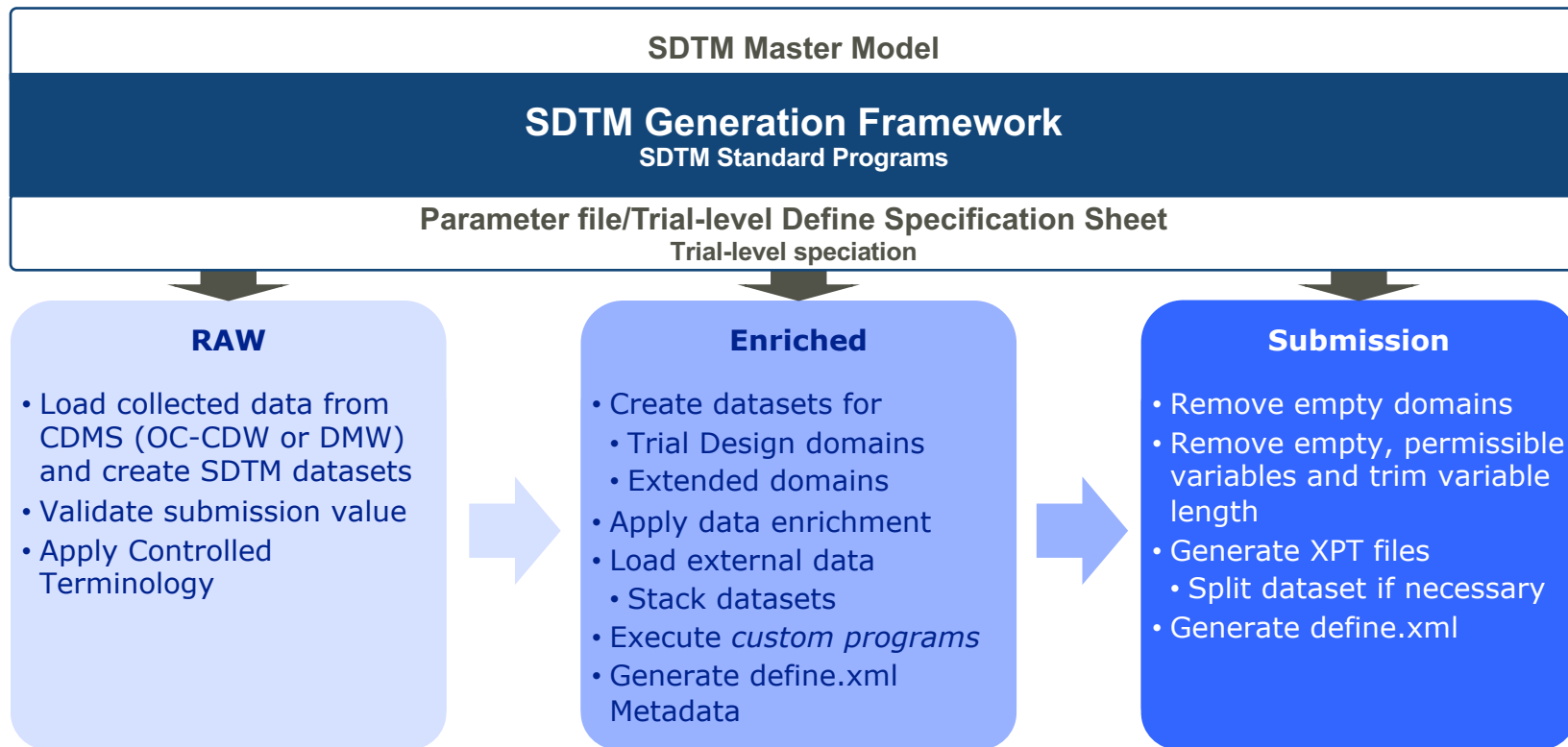
Use latest Version:

# SDTM Generation Framework



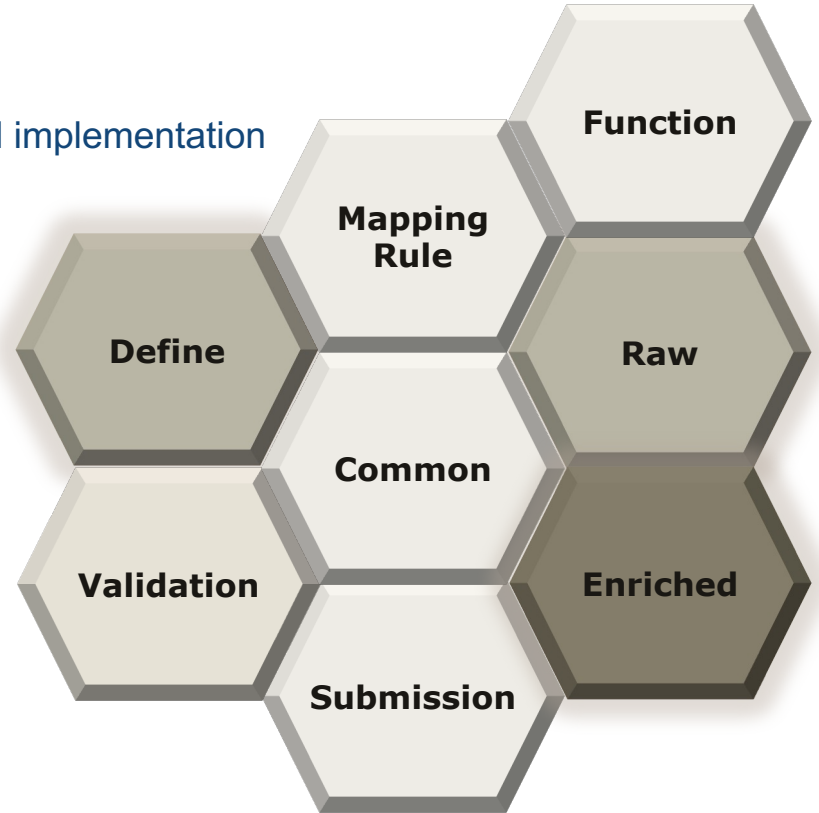


# SDTM Generation Stages

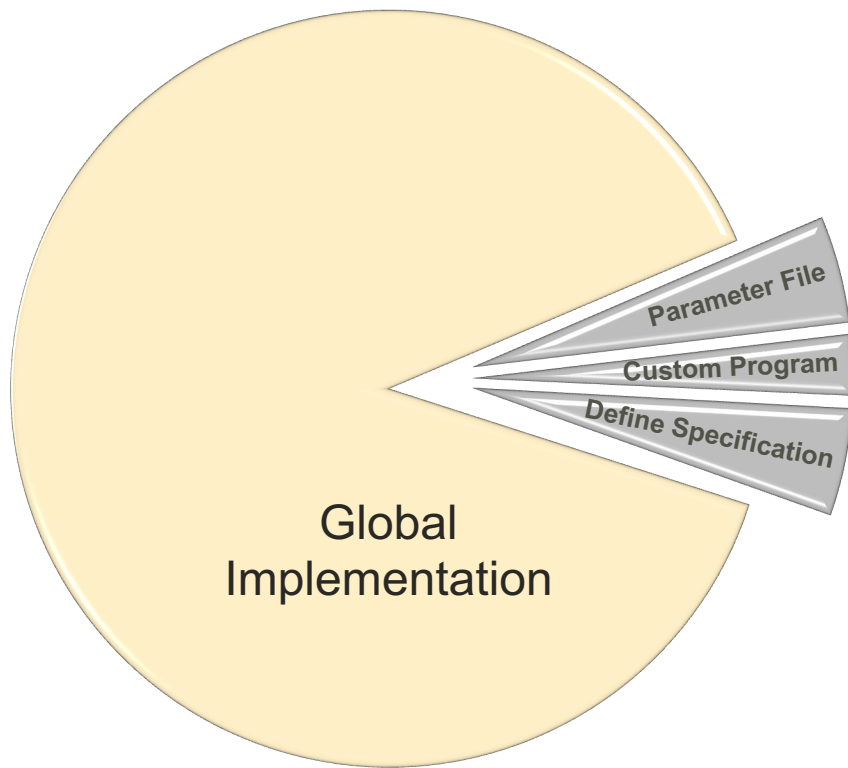


# SDTM Standard Programs

- Component-based Design
  - Governed and maintained centrally for global implementation
- Metadata/Data-driven code automation
  - **SDTM Master Model**
  - Global Clinical Metadata
  - Parameter file
  - Trial-level Define Specification
- Plus:
  - Robust
  - Maximise reusability and flexibility
  - Minimise maintenance
  - Versioning
- Minus:
  - Dependency between components
  - Increased complexity



# Trial-level Leverage



## Parameter File Controls SDTM Generation

```
# Staged
sav      = Y      |stape
version  = Y      |stape
submit   = N      |stape
copy     = N      |stape
#
# General parameters, for gmd_version and edimous_date (DBI date) the value must be in yyyyMMdd format
gmd_version =      |iparam
edimous_date =      |iparam
optional_report = N |iparam
#
# Specify columns to be excluded from DSW data extract (remove # when specifying value), use ! as separator
dsw_exclusions =      |iparam
#
# Trial Parameters
#
# -> topiccode_gspan default to topiccd, do not change/delete
# -> iparm_topictl: one per LDRM to Topic Code mapping; ! as separator
# -> actitem_end_vis: treatment emergent end visits, (space) as separator
# -> mstrang: dummy lower reference range
# -> maxrang: dummy upper reference range
# -> rlan_maxstatl: one per EXTRACT to EXTRACT mapping; ! as separator
#
topiccode_gspan = topiccd |iparam
iparm_topictl   =         |iparam
actitem_end_vis =         |iparam
mstrang         =         |iparam
maxrang         =         |iparam
rlan_maxstatl  =         |iparam
#
# OCY Parameters
#
# Reference to OCY program version
<!-->ocypreference = p11a |iparam
#
# End of parameter file.
```

## Custom Program

Covers trial-specific requirements, such as special trial design

## Define Specification

Table-/column-/value-level adjustments as supplement to SDTM Master Model

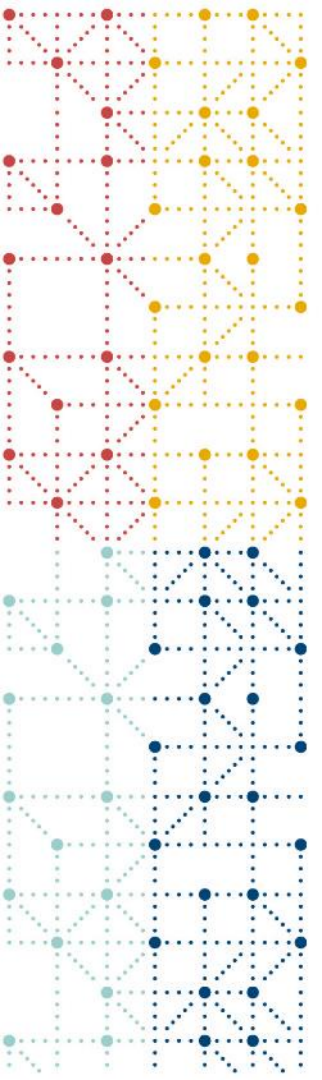
#	A	B	C	D	E
1	Table	Structure	Keys	SortKeys	comment
2	AE	STUDYID USUBJID LBTESTCD LBSPFC VISTNUM LBPTNUM LBOTC LBELTM			limited to hematology, clinical chemistry and urinalysis data. This domain does not include microbiology or pharmacokinetic data, which are
3	XL	LBSCAT LBSCAT LBORRES			
4	CM	STUDYID USUBJID AEDICCD AESTOTC			
5	CM	STUDYID USUBJID CMTRT CMBDSTOT			

#	A	B	C	D	E	F	G	H	I	J	K	L
1	table	column	displayformat	unitcd	algorithm	comment	value_ML_where_vals	value_ML_where_val	value_ML_where_val	value_ML_where_val	value_ML_where_val	value_ML_where_val
2	AE	LBORRES			Denial	Denial according to lab status metadata						
3	AE	LBORRES					LBTESTCD LBSCAT LBSPFC	LBTEST				CATSD_C1
4	AE	LBORRES					LBTESTCD LBSCAT LBSPFC	LBTEST				CATSD_C1
5	AE	LBORRES	33									

VLM definition

#	A	B	C	D	E	F	G	H
1	table	column	whereclause	label	xmccodelist	origin	algorithm	comment
2	LB	LBORRES	LBSCAT EQ 'GLUCOSE METABOLISM' and (LBSPFC EQ 'BLOO') and (LBTESTCD EQ 'HBA1C')	Testing				
3	XV	VSORRES	VSTESTCD EQ 'SYSBP'					



# Standards Governance

# SDTM Master Model Version

**CDW Operations** Metadata Management

Metadata Trial Manage Logout Production/V3R2C11/HAVK

### Manage SDTM Versions

Import and Manage SDTM Versions

SDTM Version	Status	Import date
3.3-NN01	Active	26okt.2022:01:52:40
3.2-NN15	Active	20apr.2022:08:36:08
3.2-NN14	Active	22mar.2021:08:15:37
3.2-NN13	Retired	04sep.2020:08:29:19
3.2-NN12	Retired	15maj2020:08:00:40
3.2-NN11	Retired	23okt.2019:08:20:10
3.2-NN10	Retired	25apr.2019:07:20:10
3.2-NN09	Retired	14mar.2019:05:10:10
3.2-NN08	Retired	14jan.2019:10:10:10
3.2-NN07	Retired	14nov.2018:08:10:10
3.2-NN06	Retired	07nov.2018:01:10:10
3.2-NN05	Retired	16aug.2018:09:10:10
3.2-NN04	Retired	13jun.2018:08:10:10
3.2-NN03	Retired	08feb.2018:06:10:10
3.2-NN02	Retired	26jan.2018:12:10:10
3.2-NN01	Retired	26sep.2017:10:10:10

Import Activate

**CDW Operations** Source Data Mapping

Trial Definitions Sites&Investigators Mappings Logout

### Edit Trial Definition

Supply Trial Definition Attributes

Trial Def. Type: Library

Trial Def. ID: 33NN00

Trial ID: NN-CORE-LIBRARY

Locked:

SDTM Version: 3.3-NN01  
3.2-NN15  
3.2-NN14

Trial Def. Purpose:

# CDISC Controlled Terminology Version

CDW Operations Metadata Management

Metadata Trial Manage Logout Production/V3R2C11/HAVK

## CDISC Controlled Terminology Overview

Import and manage CDISC CT packages

Filter packages

Package Scope:  Package Name contains:  Filter

Import Edit Deploy Lost Links Activate Retire Delete

Created Date	Package Scope	Package Name	Status	CDISC CT Scope	CDISC CT Version
2016-09-26	SDTM	SDTM_2013-04-12	Active	QS	2013-04-12
				SDTM	2013-04-12
2017-06-23	SDTM	SDTM_2013-12-20	Active	SDTM	2013-12-20
				QS	2013-12-20
2017-07-28	SDTM	SDTM_2014-03-28	Active	SDTM	2014-03-28
				QS	2014-03-28
2017-07-28	SDTM	SDTM_2015-03-27	Active	COA	2015-03-27
				SDTM	2015-03-27
2017-07-28	SDTM	SDTM_2016-03-25	Active	SDTM	2016-03-25
2017-07-31	SDTM	SDTM_2017-03-31	Active	SDTM	2017-03-31
2017-07-31	SDTM	SDTM_2017-06-30	Active	SDTM	2017-06-30
2018-06-11	SDTM	SDTM_2018-03-30	Active	SDTM	2018-03-30
2018-09-05	SDTM	SDTM_2018-06-29	Active	SDTM	2018-06-29
2018-10-24	SDTM	SDTM_2018-09-28	Active	SDTM	2018-09-28
2019-05-02	SDTM	SDTM_2018-12-21	Active	SDTM	2018-12-21
2019-11-05	SDTM	SDTM_2019-03-29	Active	SDTM	2019-03-29
2019-11-05	SDTM	SDTM_2019-06-28	Active	SDTM	2019-06-28
2019-11-05	SDTM	SDTM_2019-09-27	Active	SDTM	2019-09-27
2020-01-21	SDTM	SDTM_2019-12-20	Active	SDTM	2019-12-20
2020-07-16	SDTM	SDTM_2020-03-27	Active	SDTM	2020-03-27
2020-08-27	SDTM	SDTM_2020-06-26	Active	SDTM	2020-06-26
2021-01-21	SDTM	SDTM_2020-12-18	Active	SDTM	2020-12-18
2021-05-10	SDTM	SDTM_2021-03-26	Active	SDTM	2021-03-26
2021-11-22	SDTM	SDTM_2021-06-25	Active	SDTM	2021-06-25
2022-02-18	SDTM	SDTM_2021-09-24	Active	SDTM	2021-09-24
2022-08-26	SDTM	SDTM_2021-12-17	Active	SDTM	2021-12-17
2022-10-13	SDTM	SDTM_2022-03-25	Active	SDTM	2022-03-25
2023-01-17	SDTM	SDTM_2022-06-24	Active	SDTM	2022-06-24
2023-01-31	SDTM	SDTM_2022-09-30	Active	SDTM	2022-09-30
2023-02-13	SDTM	SDTM_2022-12-16	Active	SDTM	2022-12-16

Import Edit Deploy Lost Links Activate Retire Delete

## Define Trial Container

Trial Container: \*

Trial Container Name: \*

Trial Container Short Name: \*

CDW Project Folder: \*

Reporting MedDRA Version:

Reporting WHODRUG Version:

SDTM CT Version:

ADaM CT Version:

SDTM\_2013-04-12

SDTM\_2013-12-20

SDTM\_2014-03-28

SDTM\_2015-03-27

SDTM\_2016-03-25

SDTM\_2017-03-31

SDTM\_2017-06-30

SDTM\_2018-03-30

SDTM\_2018-06-29

SDTM\_2018-09-28

SDTM\_2018-12-21

SDTM\_2019-03-29

SDTM\_2019-06-28

SDTM\_2019-09-27

SDTM\_2019-12-20

SDTM\_2020-03-27

SDTM\_2020-06-26

SDTM\_2020-12-18

SDTM\_2021-03-26

SDTM\_2021-06-25

SDTM\_2021-09-24

SDTM\_2021-12-17

SDTM\_2022-03-25

SDTM\_2022-06-24

SDTM\_2022-09-30

**SDTM\_2022-12-16**

ADAM\_2022-06-24

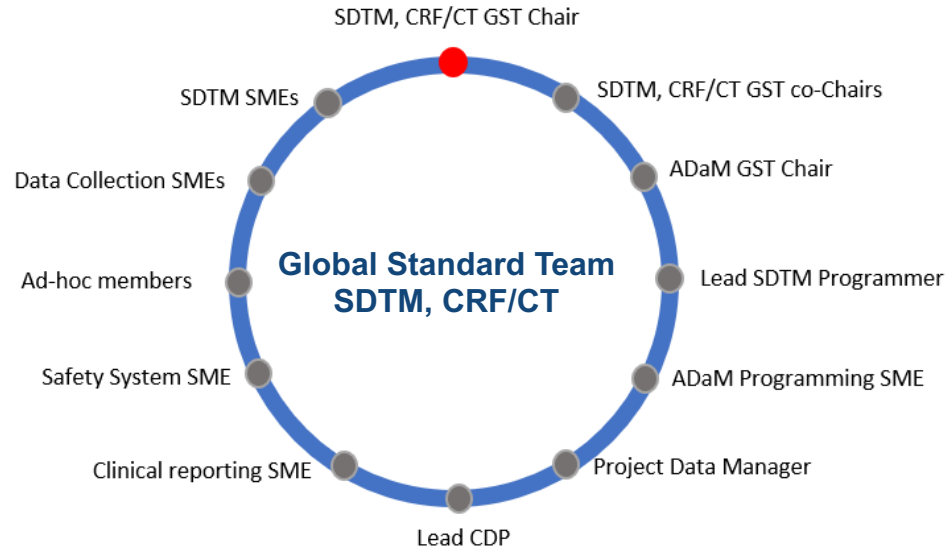
# Centralised Governance

QRS

Global  
Template

Data Collection  
Standards

Controlled  
Terminology



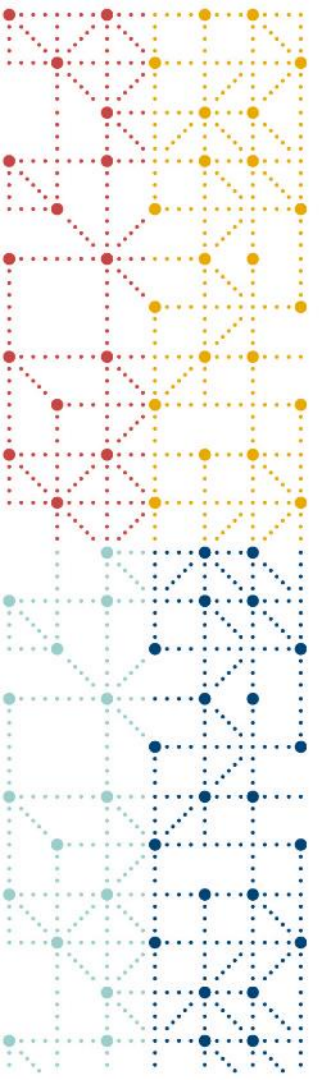
QNAM/CAT

Master Model

Device/New Data  
Sources and Types

Validation

Programming



## Conclusion and Outlook



# SDTM and define.xml automation made easy

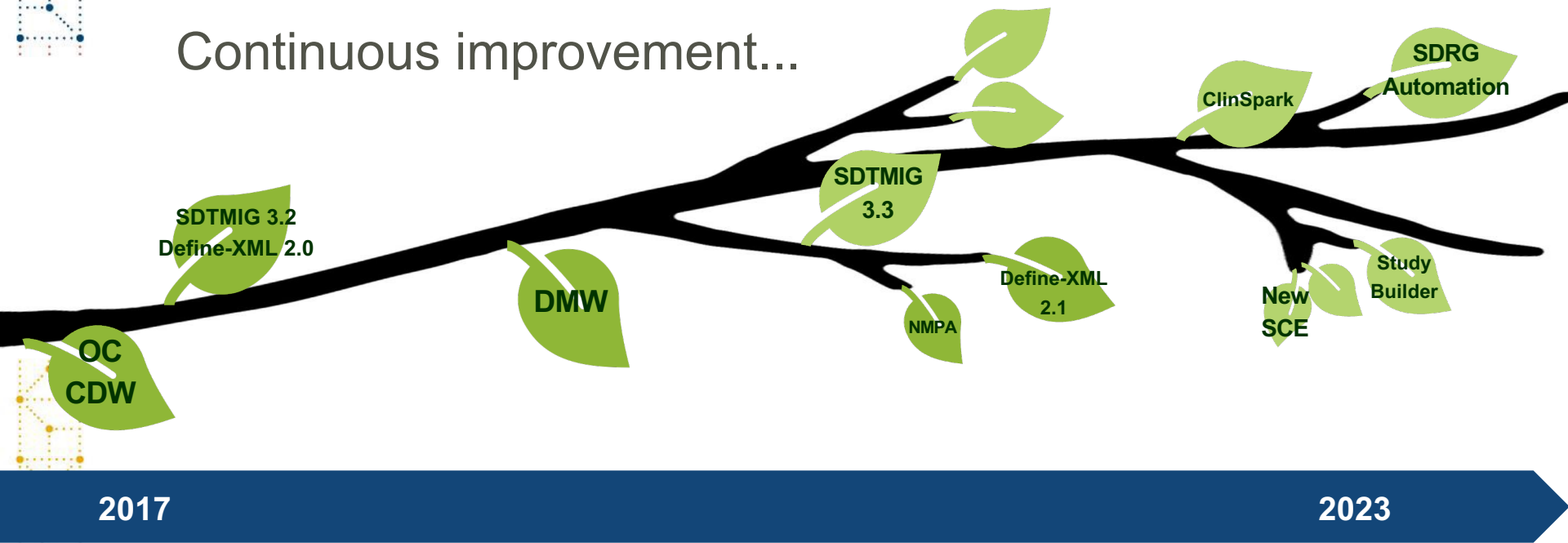
- Mature Metadata Repository
- Centralised governance
- High level of standardisation
  - Data collection
  - EDC-CDMS Mapping
  - Trial Metadata Setup
  - SDTM Generation Framework
- End-to-end mindset
- Focus on global implementation while allowing for trial-specific adjustments in a controlled manner
- Strive for continuous improvement



# Outlook

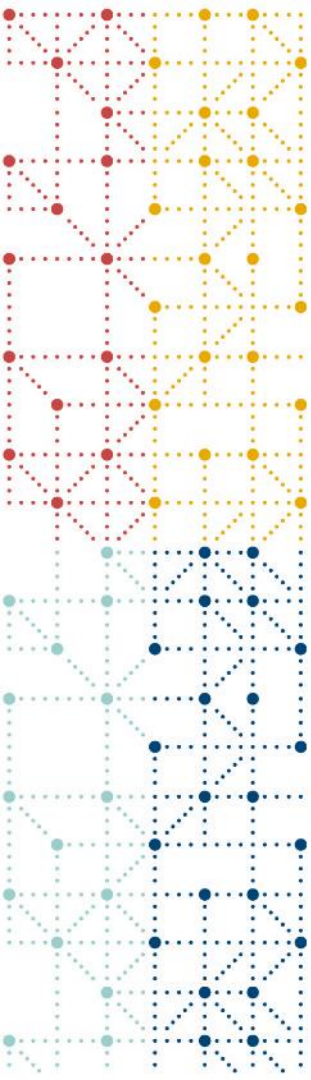
...embrace changes

Continuous improvement...



2017

2023



# Thank You!

Vicky Poulsen

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Hanne van Kints

[havk@novonordisk.com](mailto:havk@novonordisk.com)

The logo for cdisc, featuring the word "cdisc" in a dark blue, lowercase, sans-serif font. Above the "i" and "s" are three small colored dots: a red dot above the "i", a yellow dot above the "d", and a light green dot above the "s".