How to Build a Global, Reusable, Shareable Metadata Flow with a Customer-Centric Focus

Presented by Anja Lundgreen, Standards Director & Martin Gram, Principal Standards Specialist, Novo Nordisk

Meet the Speakers

Anja Lundgreen

Title: Standards Director

Organization: Novo Nordisk A/S

Anja Lundgreen is Standards Director at Novo Nordisk, bringing over a decade of expertise in clinical data standards and even more in project management. She is subject matter expert in the StudyBuilder project and defines features for protocol metadata and downstream use. With a focus on organizational change management, Anja drives standardization efforts for submission data and heads global projects. Anja has a combined clinical and IT background with experience as study coordinator and IT project manager.

Martin Gram

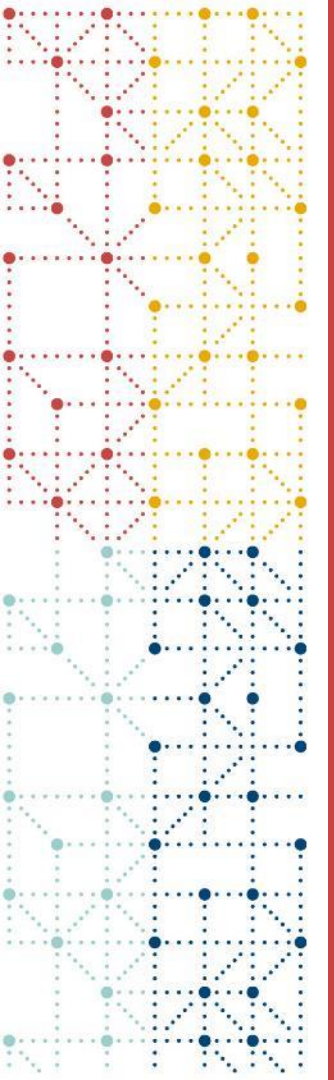
Title: Principal Standards Specialist

Organization: Novo Nordisk A/S

Martin Gram is a principal standards specialist within Novo Nordisk, where he is utilising his background as a clinical researcher in human physiology to help drive the field of standardisation and data specifications. In addition, Martin is also involved in several cutting-edge initiatives incl. the StudyBuilder project aiming at creating a seamless, reusable metadata flow.

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.*



Agenda

1. Introduction
2. Does automation always make us more efficient
3. How do we create a common language across skill types
4. Is one-source-of-truth always great
5. Do we benefit from 100% alignment
6. Considerations & aspirations end-to-end
7. Questions

Introduction

- At Novo Nordisk, we are building the OpenStudyBuilder in collaboration with COSA and CDISC DDF
- The goals are multiple, e.g.
  - Align to external standards
  - Automation
  - Use common language across skill areas
  - One-source-of-truth
  - Alignment and end-to-end metadata flow

- The most mature part in metadata is the **SDTM standards -** the experience within SDTM is used to push standardisation to other areas

How to align to external standards

"It all depends on the perspective…"

CDISC

- Controlled terminologies
- Standards toward authorities and submissions
- Standards for CRF
- Standards for data pooling
- Standards for data

"Clear data, clear impact"

Company

- Culture & values
- Traditions
- Data vs documents
- Standardisation versus creativity and science

Somewhere in between

TransCelerate

- Medical Science
- Protocol towards investigator and site staff
- Protocol towards authorities and ethical committees
- Standards for protocol

"Accelerating and simplifying the research and development of innovative new therapies"

Does automation always make us more efficient?

When the automation creates the challenges instead of being the solution

The good idea

Screening	Visit 1	-14 days	1	100	V1
Treatment	Visit 2	0 days	2	200	V2
Treatment	Visit 3	7 days	3	300	V3
Treatment	Visit 4	14 days	4	400	V4

#	Inclusion Criteria
1	Diagnosed with type 2 diabetes mellitus >= 1 years before screening.
2	Age 18 years or above at the time of signing the informed consent.
3	No participation in other clinical studies for the last 6 weeks

Protocol amendments without impacting data already collected

The solution

Provide more flexibility to bypass the automation – while maintaining the standardisation

Goal: to support all steps (and processes) in the end-to-end flow

How do we create a common language across skill types?

Use common language across skill types - When we think we are user-friendly, but get wiser

Protocol Schedule of Assessment

- Visit schedule
- Baseline

-7	-7
Day	Day
0	1
7	8
14	15

SDTM

- --BLFL
- Rule/assessment based

Use common language across skill types - When we think we are user-friendly, but get wiser

Protocol Schedule of Assessment

- Visit schedule
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SDTM

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Let's call it
"Global anchor visit"

Is one-source-of-truth always great?

One-source-of-truth

The idea:

- StudyBuilder includes unit metadata to be used end-to-end
- Used as one-source-of-truth for multiple stakeholders
- All units are enriched with metadata to convert between units
- All units are linked to controlled dictionaries e.g. CDISC, UCUM and SPOR RMS
- Subsets specify where different units can be used

One-source-of-truth

Protocol units also represented

CDISC	NCI Preferred Term	UCUM	SPOR RMS	Protocol text
DAYS (AGEU, UNIT) Day (PKUNIT)	Day	d	day	Day; day; Days; days
LB	Pound	[lb_av]	pound	Pound; pound; Pounds; pounds
nm	Nanometer	nm	nanometre(s)	nm
kg/L (UNIT) g/mL (PKUNIT)	Kilogram per Liter	kg/L; g/mL; g/ml; kg/l	kilogram(s)/litre	kg/L

Endpoint units

Use case:

- Generate the objective and endpoint table in the protocol from metadata
- Include a unit column for increased transparency
- Data also to be used for disclosure (e.g. clinicaltrials.gov)

Objectives	Endpoints		
Primary	Title	Time frame	Unit
To demonstrate superiority of Drug A once-weekly versus placebo, both added to standard of care, in improving symptoms and physical function for participants with disease.	**Primary:**		
	Change in COA	From baseline (week 0) to end of treatment (week 52)	**Score** (score on scale; range; 0-100)
	Confirmatory secondary:		
	Change in COA B	From baseline (week 0) to end of treatment (week 52)	**Metres**
	Change in Body weight	From baseline (week 0) to end of treatment (week 52)	**%**
	Change in Biomarker	From baseline (week 0) to end of treatment (week 52)	**Ratio to baseline**
	Supportive secondary:		
	Hierarchical composite (assessed by the win ratio) of: - time to event - number of events requiring hospitalisation - time to first event requiring hospitalisation - difference of at least 20 in the COA - difference of at least 15 in the COA - difference of at least 10 in the COA - difference of at least 5 in the COA - difference at least 30 metres in COA B	Time-to-event: from baseline (week 0) to end of study (week 52)	**Total wins for each treatment group**

Do we benefit from 100% alignment?

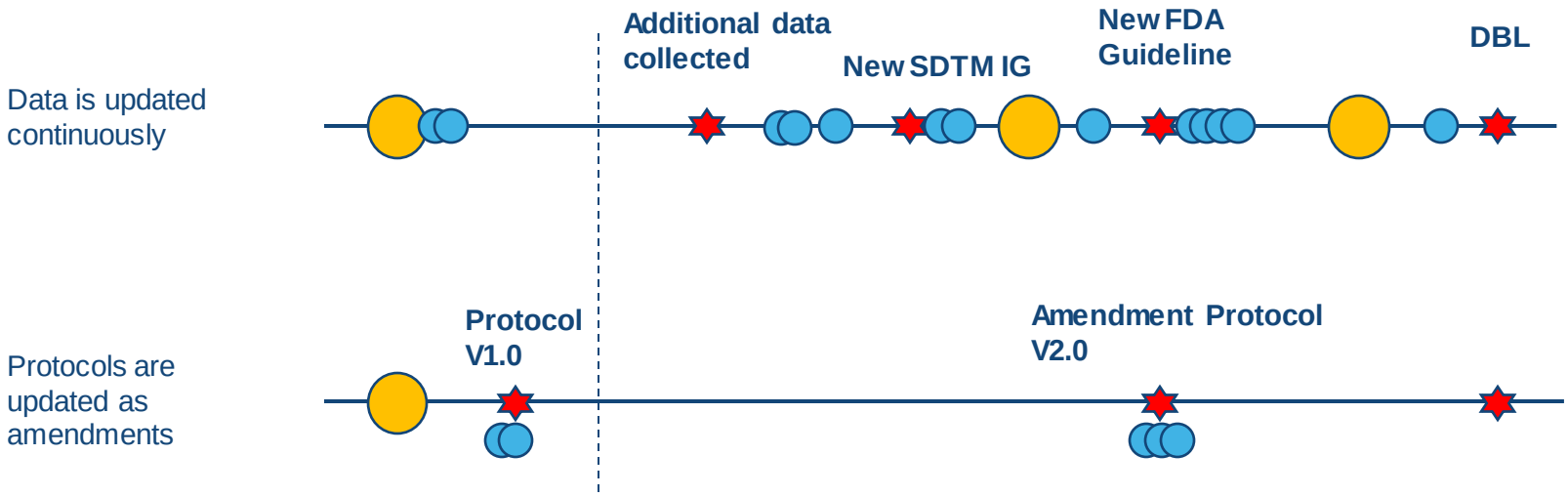
Alignment and end-to-end metadata flow

Milestone

Sponsor defined CT term update/creation (date)

CDISC CT package release (date)

Versioned metadata from StudyBuilder:



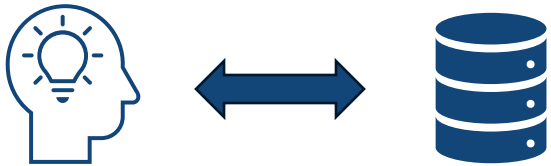
Considerations & aspirations end-to-end

How to enable different skill types use the same metadata - introducing layers:

- It should be possible to work in a layer without impacting or limiting the impact on other layers
- Work together using the same metadata but being able to assess the impact of rejecting or accepting an update from another layer
- Have separate governance structures for each logical part of metadata use – can be controlled by access groups
- Have one-source-of-truth but make it possible for a layer (a project, study or document) to use an old version of one-source-of-truth

Considerations & aspirations end-to-end

- Accept that our worlds are different and take it as a main task to understand each other better
- Standard Governance to be extended to include new areas, while still anchored within relevant part of Line of Business
  - A standard is much more than a CRF form or an SDTM IG – it is a culture change and adoption that cannot wait
  - Reuse of metadata is creating a dependency between skill types – for good and for bad - understanding this dependency is crucial
  - Reuse of metadata forces skill areas not familiar with metadata to adopt this approach – whether they see the value or not



Questions?

Thank You!

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