



# cdisc® 2026 Europe Interchange

THE FUTURE IS CONNECTED: STANDARDS AND AI POWERING DIGITAL TRANSFORMATION



MILAN, ITALY | MAIN CONFERENCE: 20-21 MAY | TRAININGS & WORKSHOPS: 18, 19, & 22 MAY

## **SDTM at FPFV+1 Day – How to Achieve It?**

Vicky Poulsen, Standards Development Director, Novo Nordisk A/S

Sofie Skourup Brodin, Associate Clinical Data Management Director, Novo Nordisk A/S

## Speakers



**Vicky Poulsen**  
Standards Development Director  
Novo Nordisk A/S



**Sofie Skourup Brodin**  
Associate Clinical Data Management Director  
Novo Nordisk A/S

# Agenda

1. Recap and Current Status
2. Business Operation Landscape and Impact
3. Innovations Supporting Ramp-up
4. Takeaways

# Recap and Current Status

# Process/Standard Re-engineering

- Golden opportunities presented by implementation of new EDC/CDMS systems



Item-level standardisation



EDC Design Principle



EDC to SDTM  
Automation



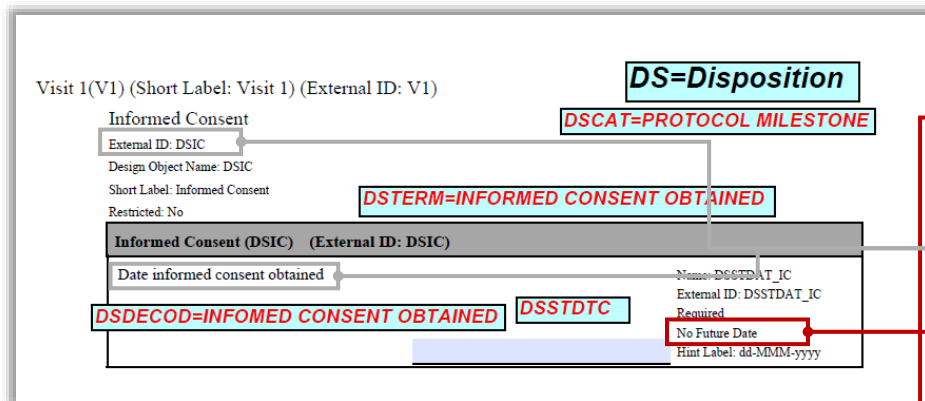
# Item-level Standardisation

## Item Definition

- A technical specification enabling automation of SDTM Generation – extending CDASH principles
  - Item Naming Convention
  - Biomedical Concepts
  - SDTM structure
  - Mapping properties
  - Form reference
- Embedded lineage bridging CRF design with EDC build and SDTM generation
- Reusable across forms to allow study-level adjustment
- Allow flexibility while maintaining **100% standardisation**



# Item Definition: A Simple Illustration



*Date informed consent obtained*

Item

- DSSTDAT\_IC

Biomedical  
Concept

- INFORMED\_CONSENT\_DATE

SDTM  
Structure

- DS domain: DSSTDTC
- 1 record per DSSTDAT\_IC

Mapping  
Properties

- DSTERM
- DSDECOD

Save X Cancel Copy link X

|                                         |                                 |                         |                       |
|-----------------------------------------|---------------------------------|-------------------------|-----------------------|
| <b>* name</b>                           | <b>Item</b>                     | <b>* primary_item</b>   | <b>SDTM Structure</b> |
| DSSTDAT_IC                              |                                 | DSSTDAT_IC              |                       |
| <b>item_label</b>                       |                                 | <b>* form</b>           | <b>Reference</b>      |
| Date informed consent obtained          |                                 | DSIC                    |                       |
| <b>* presdtm_table</b>                  |                                 | <b>* presdtm_column</b> | <b>SDTM Structure</b> |
| DS                                      |                                 | DSSTDTC                 |                       |
| <b>presdtm_assign</b>                   | <b>presdtm_column_dependent</b> |                         |                       |
| "INFORMED CONSENT OBTAINED":DSDECOD DS1 |                                 |                         |                       |
| <b>presdtm_concat</b>                   | <b>presdtm_eventdate</b>        |                         |                       |
| Find items                              | Find items                      |                         |                       |
| <b>presdtm_formseq</b>                  | <b>presdtm_format</b>           |                         |                       |
| Find items                              |                                 |                         |                       |
| <b>presdtm_partialdtc</b>               |                                 |                         |                       |
| Find items                              |                                 |                         |                       |
| <b>topiccd</b>                          | <b>Biomedical Concept</b>       |                         |                       |
| INFORMED_CONSENT_DATE                   |                                 |                         |                       |

Mapping Properties

# Lineage Embedded in Item Definition

CRF

SDTM

| DOMAIN | VISITNUM | VSDTC      | TOPICCD     | VSORRES | UNITCOLL |
|--------|----------|------------|-------------|---------|----------|
| VS     | 200      | 2024-12-09 | HEIGHT      | 166     | cm       |
| VS     | 200      | 2024-12-07 | HEIGHT      | 164     | cm       |
| VS     | 200      | 2024-12-05 | HEIGHT      | 167     | cm       |
| VS     | 200      | 2024-12-06 | HEIGHT      | 149     | cm       |
| VS     | 200      | 2024-12-16 | BODY_WEIGHT | 117.3   | kg       |
| VS     | 200      | 2024-12-09 | BODY_WEIGHT | 85.5    | kg       |
| VS     | 200      | 2024-12-07 | BODY_WEIGHT | 75.7    | kg       |
| VS     | 200      | 2024-12-05 | BODY_WEIGHT | 128.1   | kg       |
| VS     | 200      | 2024-12-06 | BODY_WEIGHT | 62.3    | kg       |

Body Measurements 1 (BM1)

External ID: BM1

Design Object Name: BM1

Short Label: Body Measurements 1

Restricted: No

**VS=Vital Signs**

**VSCAT=BODY MEASUREMENT**

**VSDTC**

Body Measurements 1 (BM1) (External ID: BM1)

Height

cm

in

**VSORRES/VSORRESU when VSTESTCD=HEIGHT**

Body weight

(xxxxx.y)

kg

lb

**VSORRES/VSORRESU when VSTESTCD=WEIGHT**

BMI

**Note: BMI is derived to VSTESTCD=B**

VSORRES\_HEIGHT

VSORRES\_HEIGHT\_UOM

VSORRES\_WEIGHT

VSORRES\_WEIGHT\_UOM

EDC database

Item Definition

| presdtm_table | presdtm_column | topiccd     | form | primaryitem    | name               | itemlabel   |
|---------------|----------------|-------------|------|----------------|--------------------|-------------|
| VS            | VSORRES        | HEIGHT      | BM1  | VSORRES_HEIGHT | VSORRES_HEIGHT     | Height      |
| VS            | UNITCOLL       | HEIGHT      | BM1  | VSORRES_HEIGHT | VSORRES_HEIGHT_UOM | Height      |
| VS            | VSORRES        | BODY_WEIGHT | BM1  | VSORRES_WEIGHT | VSORRES_WEIGHT     | Body weight |
| VS            | UNITCOLL       | BODY_WEIGHT | BM1  | VSORRES_WEIGHT | VSORRES_WEIGHT_UOM | Body weight |

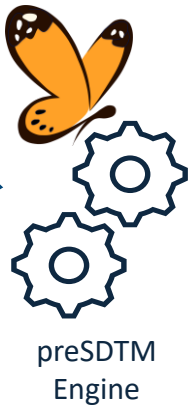


# EDC to SDTM Automation

Item Definition

| name       | primaryitem                                                       | item_label                                                                                                            | form                    | logbook                                                 | presdtm_table | presdtm_column | presdtm_group | presdtm_assign                                    |
|------------|-------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------|-------------------------|---------------------------------------------------------|---------------|----------------|---------------|---------------------------------------------------|
| ECSTORRES  | ECSTORRES and ECSTORRES and ECSTORRES eq "Y" and ECSTORRES eq "Y" | Start Date and time of administration                                                                                 | ADMIN_MFPE              | FIRST_TRIAL_PROD...                                     | DS            | DISSTORRES     |               | "FIRST DATE ON TRIAL PRODUCT"DISSTORRESDISSTORRES |
| DISSTORRES | DISSTORRES                                                        | Date consent obtained - Did the subject consent to allow biosamples to be used for future research?                   | CONSENT_FUTURE_RESEARCH | FUTURE RESEARCH BIOSAMPLE CONSENT OBTAINED              | DS            | DISSTORRES     |               | TOPICCD=DISSTORRESDISSTORRES                      |
| DISSTORRES | DISSTORRES                                                        | Did subject consent to collection of biosamples for Future Research?                                                  | CONSENT_FUTURE_RESEARCH | FUTURE RESEARCH BIOSAMPLE CONSENT OBTAINED              | DS            | DISSTORRES     |               | TOPICCD=DISSTORRESDISSTORRES                      |
| DISSTORRES | DISSTORRES                                                        | Did subject consent to Genomic Analysis on the biosamples collected for Future Research?                              | CONSENT_FUTURE_RESEARCH | FUTURE RESEARCH GENOMIC ANALYSIS CONSENT OBTAINED       | DS            | DISSTORRES     |               | TOPICCD=DISSTORRESDISSTORRES                      |
| DISSTORRES | DISSTORRES                                                        | Did subject consent for converting residual samples into biosamples for Future Research?                              | CONSENT_FUTURE_RESEARCH | FUTURE RESEARCH USING RESIDUAL SAMPLES CONSENT OBTAINED | DS            | DISSTORRES     |               | TOPICCD=DISSTORRESDISSTORRES                      |
| DISSTORRES | DISSTORRES                                                        | Date consent obtained - Did the subject consent to allow genomic analysis on the samples donated for future research? | CONSENT_FUTURE_RESEARCH | FUTURE RESEARCH GENOMIC ANALYSIS CONSENT OBTAINED       | DS            | DISSTORRES     |               | TOPICCD=DISSTORRESDISSTORRES                      |
| DISSTORRES | DISSTORRES                                                        | Date consent obtained - Did the subject consent to allow genomic analysis on the samples donated for future research? | CONSENT_FUTURE_RESEARCH | FUTURE RESEARCH GENOMIC ANALYSIS CONSENT OBTAINED       | DS            | DISSTORRES     |               | TOPICCD=DISSTORRESDISSTORRES                      |

The preSDTM engine identifies the Item Definitions that are applicable to a study (manifest.json) and creates study-level mapping and preSDTM generation codes



EDC\_MAPPING x

Lineage Metadata

|    | presdtm_table | presdtm_column | presdtm_qnam | name               | primaryitem    | topiccd     | item_label          | form |
|----|---------------|----------------|--------------|--------------------|----------------|-------------|---------------------|------|
| 47 | VS            | VSORRES        |              | VSORRES_HEIGHT     | VSORRES_HEIGHT | HEIGHT      | Height              | BMS  |
| 48 | VS            |                | UNITCOLL     | VSORRES_HEIGHT_UOM | VSORRES_HEIGHT | HEIGHT      | Body Weight         | BMS  |
| 49 | VS            | VSDTC          |              | VSDAT              | VSORRES_HEIGHT | HEIGHT      | Date of examination | BMS  |
| 50 | VS            | VSORRES        |              | VSORRES_WEIGHT     | VSORRES_WEIGHT | BODY_WEIGHT | Body weight         | BMS  |
| 51 | VS            |                | UNITCOLL     | VSORRES_WEIGHT_UOM | VSORRES_WEIGHT | BODY_WEIGHT | Body Weight         | BMS  |
| 52 | VS            | VSDTC          |              | VSDAT              | VSORRES_WEIGHT | BODY_WEIGHT | Date of examination | BMS  |

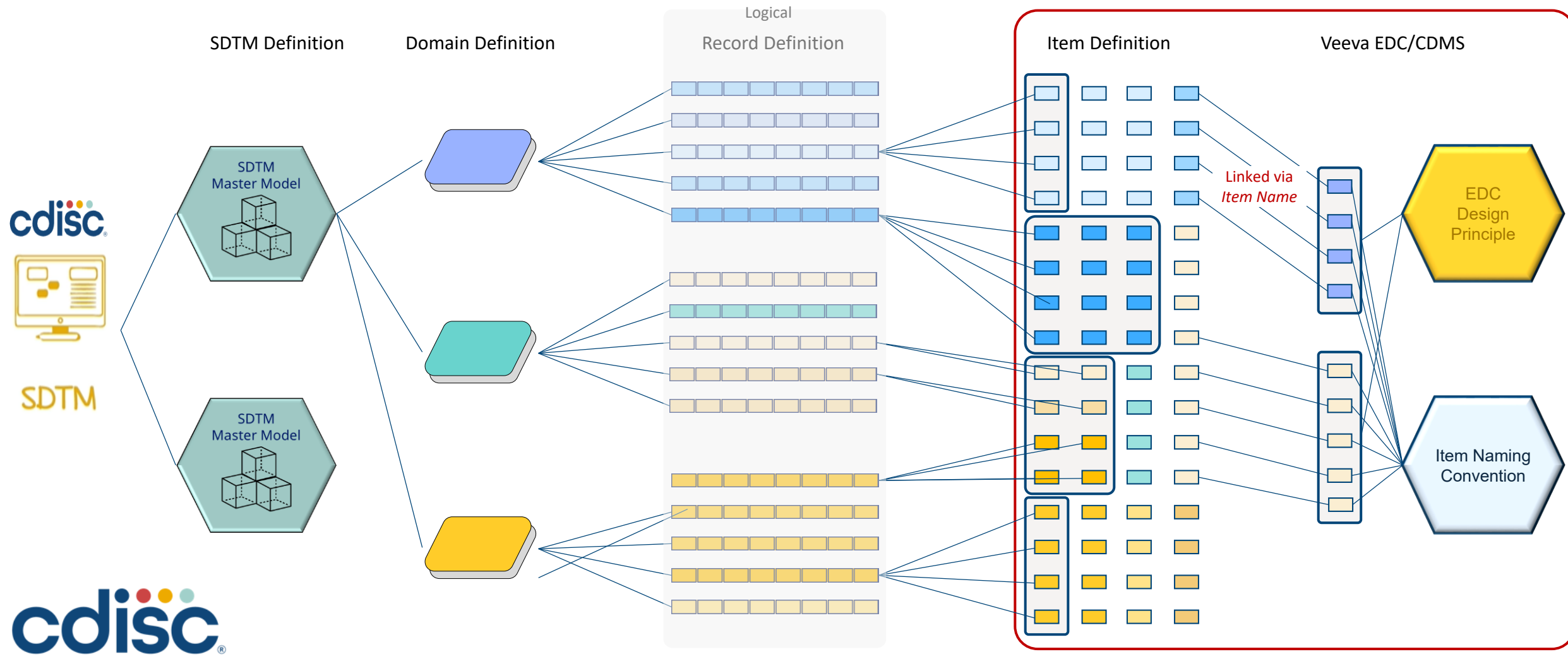


VS x

preSDTM

|   | EDCTABLE           | SPKEY                                                            | VSORRES | UNITCOLL | VISITNUM | VSDTC      | TOPICCD               |
|---|--------------------|------------------------------------------------------------------|---------|----------|----------|------------|-----------------------|
| 1 | BODY_MEASUREMENT_1 | 0da636d0751df60948758fa62f01bdd97695cdb661d906211098b5a97aee8c1  | 35.267  | kg/m^2   | 100      | 2025-11-05 | BMI_SYSTEM_CALCULATED |
| 2 | BODY_MEASUREMENT_1 | 0da636d0751df60948758fa62f01bdd97695cdb661d906211098b5a97aee8c1  | 179     | cm       | 100      | 2025-11-05 | HEIGHT                |
| 3 | BODY_MEASUREMENT_1 | 0da636d0751df60948758fa62f01bdd97695cdb661d906211098b5a97aee8c1  | 113     | kg       | 100      | 2025-11-05 | BODY_WEIGHT           |
| 4 | BODY_MEASUREMENT_3 | e68e4530a84df631f33f7e5c59d44bc6eb754216d64eb2cab6f50db8e54cd875 | 34.955  | kg/m^2   | 200      | 2025-11-26 | BMI_SYSTEM_CALCULATED |
| 5 | BODY_MEASUREMENT_3 | e68e4530a84df631f33f7e5c59d44bc6eb754216d64eb2cab6f50db8e54cd875 | 112     | kg       | 200      | 2025-11-26 | BODY_WEIGHT           |
| 6 | BODY_MEASUREMENT_3 | e68e4530a84df631f33f7e5c59d44bc6eb754216d64eb2cab6f50db8e54cd875 | 118     | cm       | 200      | 2025-11-26 | WAIST_CIRCUMFERENCE   |
| 7 | VITAL_MAX          | bcd2d793d2242af9f36712c6b4967c6e9c9a0a2621c861d68f4974cd4b056f9c | 64      | mmHg     | 100      | 2025-11-05 | BP_DIASTOLIC          |
| 8 | VITAL_MAX          | d77fab5b4a73d09a4fc64fec0c125c11ab207b26029ca6d9c4a10dfcc2b38658 | 65      | mmHg     | 200      | 2025-11-26 | BP_DIASTOLIC          |

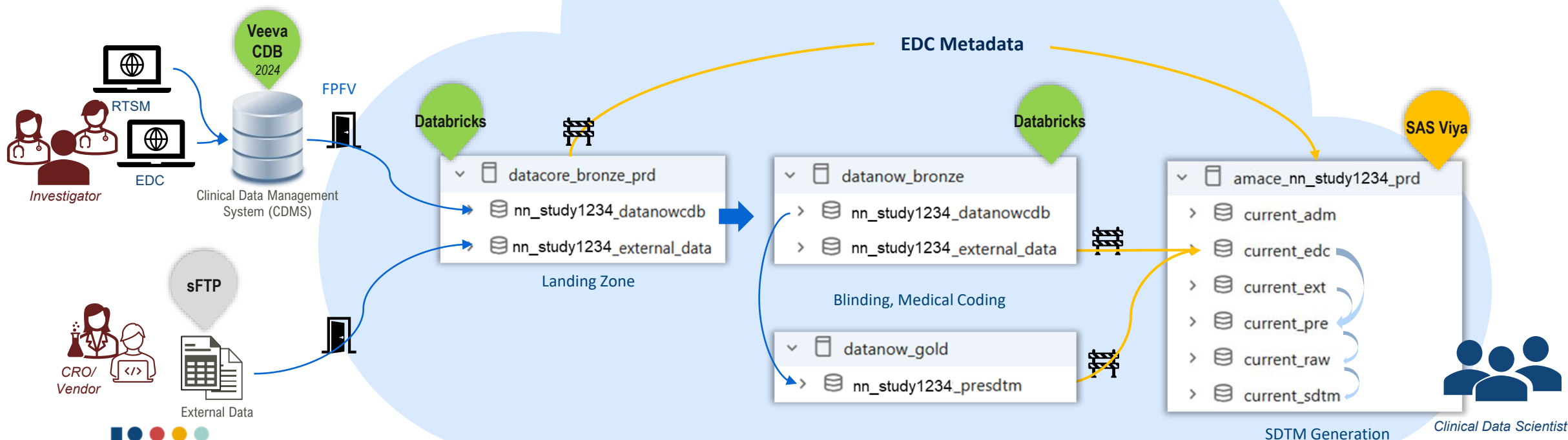
# End-to-end Standards



# Seamless, Automated End-to-end Data Flow



From EDC extract to SDTM  
**FPFV+1D**  
Turnaround time ~2H



# Business Operation Landscape and Impact

# Standard Governance

## GST process

Global Standard Team  
Governs overall STDM  
implementation

## PST process

Project Standard Team  
Governs study specific form  
implementation

# Roles and Responsibilities

## Clinical Data Manager

- Collects requirements for study specific forms
- Conduct meetings in the DM team
- Ensure PST approval of form design

## Clinical Data Scientist

- Provide input to data collection requirements
- Provide SDTM annotations
- Ensure data can be used in analysis

## Clinical Data Programmer

- Build the form in EDC
- Create Item Definition and secure required GST approval

# Operational Landscape – Old Process

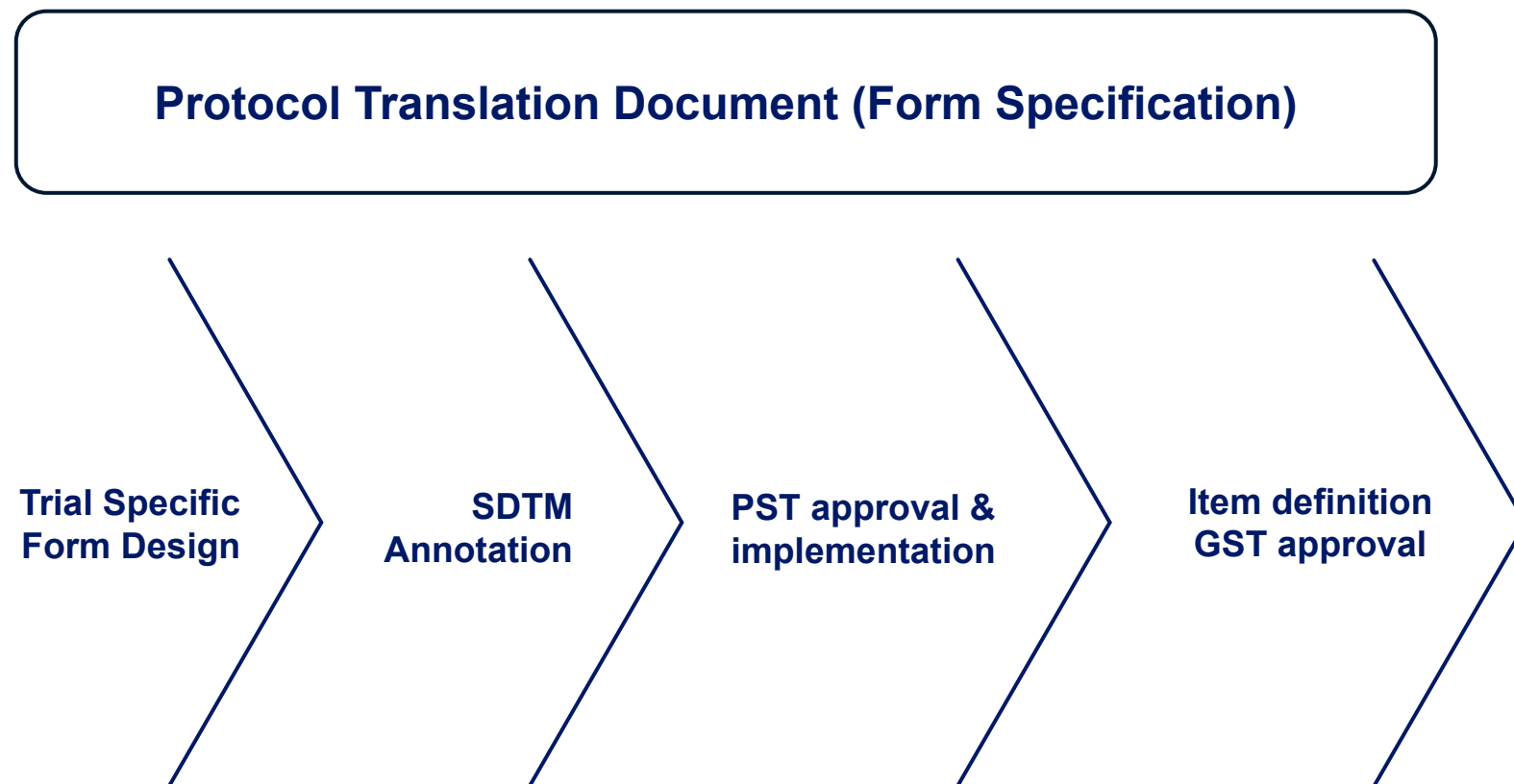
**Trial Specific  
Form Design**

**SDTM  
Annotation**

**PST approval &  
implementation**



# Operational Landscape – New Process





# Operational Impact – Benefits

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SDTM data available for data review and monitoring from day 1

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Well defined process and training before implementation

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Hypercare for early adopter trials

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Improved form design

“World class dataflow, congrats to all involved!!!!”

*Quote from Novo Nordisk VP of Clinical Operations*

# Operational Impact – Challenges

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Re-work required: Item Definition approval last in the workflow

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Change resistance

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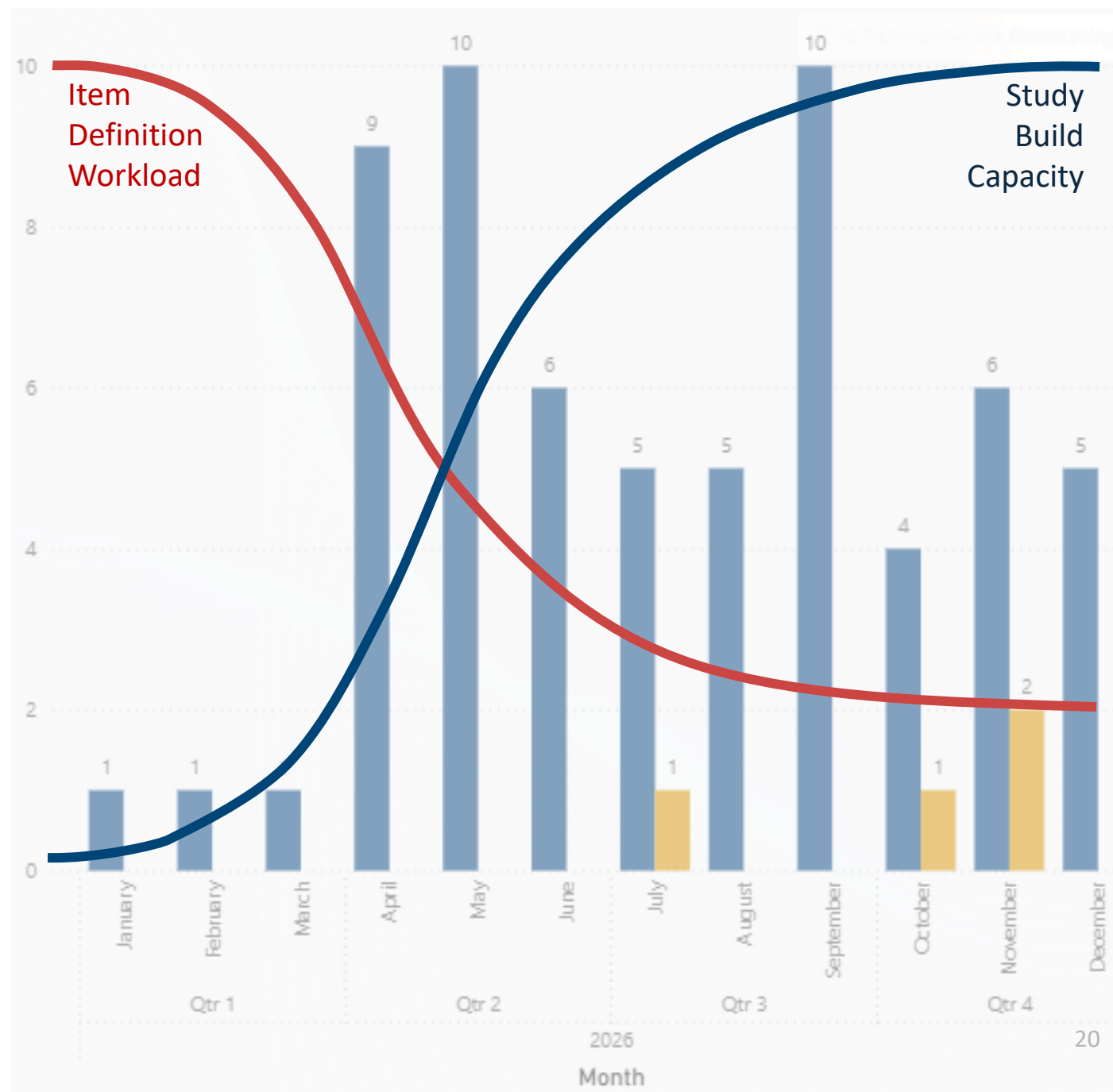
Requires competency development



# Innovations Supporting Ramp-up

# Ramp-up in 2026

- 75% of all new studies in the new setup
- Action Plan to ensure study execution comply with the planned timeline with focus on build process
  - Form Libraries
  - Cross-study/role coordination
  - Role-based activities
    - Competence build
    - Process improvement
    - Focus Area decided on monthly basis
  - Hyper-care Team



# Item Definitions Enabling Innovations

## Chrysalis

An AI-assisted CRF Sketcher

Suggest CRF design by  
reusing existing standards:  
form, Item Definition,  
Biomedical Concepts and  
Controlled Terminologies

Improve efficient and promote  
standardisation

Chrysalis Steps

User input ✓

Draft CRF

Update CRF

Annotate CRF

Edit annotations

Complete

Download Current CRF

HTMLPDF

Start Over

Guidance Slides

Queries / Feedback

Chrysalis

Trial Specific CRF Sketcher

BETA

Help

Please keep in mind that the app is a Work in progress. If you encounter errors, press "Start Over" to refresh, or submit a query on "Queries/Feedback".

body measurement with system calculated BMI

Body Measurement

|                         |                               |
|-------------------------|-------------------------------|
| Study ID: NNXXXX-XXXX   |                               |
| * Height                | xxxxxx .  = cm = m = in       |
| * Body weight           | xxxxxx .  = kg = lb           |
| * Body Mass Index (BMI) | xxxxxx .  (System calculated) |

How would you like to update the draft CRF?

Describe what should be updated...

Update

Download CRF as HTML

Approve draft CRF and continue

Edit draft CRF

Similar Standard CRFs

Similar standard CRF: Body Measurements (BODY\_MEASUREMENT\_1)

Similarity: 50.00%

Use this CRF instead

21



## Tracking CRF Data End-to-end BETA

Filter SDTM domain

All

Filter VEEVA library

All

Select CRF

Body Measurements Measurement 1

?

### CRF

View FALCON CRF

#### Body Measurements

Date of examination

[entry field]

[VSDAT]

Date and time of examination

[entry field]

[VSDTC] ★

Was the subject fasting when the body measurement was done?

☐ Yes  
☐ No

[QNAM\_FASTING] ★

Height

[entry field]

[VSORRES\_HEIGHT]

Body weight

[entry field]

[VSORRES\_WEIGHT]

Waist circumference

[entry field]

[VSORRES\_WSTCIR]

Hip circumference

[entry field]

[VSORRES\_HIPCIR]

[VEEVA EDC item name]

★ This item is auto-mapped

\* This item is auto-mapped when presdtm\_qnam\_automap = Y

### Item Definition

View Full Table

| name               | primaryitem    | form                | topiccd | presdtm_table | presdtm_column | presdtm_qnam | presdtm_qnam_auto |
|--------------------|----------------|---------------------|---------|---------------|----------------|--------------|-------------------|
| VSORRES_HEIGHT     | VSORRES_HEIGHT | BODY_MEASUREMENT_\$ | HEIGHT  | VS            | VSORRES        |              | Y                 |
| VSORRES_HEIGHT_UOM | VSORRES_HEIGHT | BODY_MEASUREMENT_\$ | HEIGHT  | VS            |                | UNITCOLL     |                   |
| VSDAT              | VSORRES_HEIGHT | BODY_MEASUREMENT_\$ | HEIGHT  | VS            | VSDTC          |              |                   |

### SDTM Test Data

View Full Table

| DOMAIN | USUBJID  | VSORRES | VISITNUM | VSDTC               | TOPICCD | UNITCOLL | FASTING * |
|--------|----------|---------|----------|---------------------|---------|----------|-----------|
| VS     | SCR-0006 | 176.00  | 10       | 2025-08-01T11:11:00 | HEIGHT  | cm       | Y         |
| VS     | SCR-0009 | 45.00   | 10       | 2025-09-04T11:11:00 | HEIGHT  | in       | N         |
| VS     | SCR-0008 | 121.00  | 10       | 2025-09-04          | HEIGHT  | cm       |           |
| VS     | SCR-0010 | 34.00   | 10       | 2025-09-03T00:00:00 | HEIGHT  | cm       | Y         |
| VS     | SCR-0011 | 176.00  | 10       | 2025-09-01          | HEIGHT  | cm       | Y         |
| VS     | SCR-0012 | 1.23    | 10       | 2025-09-02T12:32:00 | HEIGHT  | m        | N         |
| VS     | SCR-0013 | 5.34    | 10       | 2025-07-30          | HEIGHT  | in       | N         |
| VS     | SCR-0001 | 165.0   |          | 2026-03-04          | HEIGHT  | cm       |           |
| VS     | SCR-0001 | 62.9    | 10       | 2026-03-11          | HEIGHT  | in       | N         |

## TRACE

A data lineage tool that visualises the end-to-end data flow from CRF to preSDTM  
Promote end-to-end understanding and data literacy

# What's next?

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Re-engineer business processes to remove redundant steps

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Centralise the development of study specific forms

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Establish custom library in EDC to ensure efficient re-use



# Key Takeaways

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Standards and solid data foundation accelerate innovation

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Build in flexibility to ensure standards can be operationalised

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Secure stakeholders buy-in

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Instate standard governance

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Upskill across the organisation





# Thank You!

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## Credits

Anja Jazbec  
Clara Giménez Arteaga  
Jannick Reymann Ravnborg

## Reference

CDISC Europe Interchange 2025: [Turbocharging operational efficiency with 100% standardization](#)

CDISC Europe Interchange 2026: Visualising the end-to-end data lineage of standards

