Turbocharging operational efficiency with 100% standardisation

Presented by Vicky Poulsen, Standards Director, Novo Nordisk A/S
Sinna Lisa Vange, Senior IT Solution Architect , Novo Nordisk A/S

Meet the Speakers

Vicky Poulsen

Title: Standards Director

Organization: Novo Nordisk A/S

Vicky Poulsen 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. In her present role as strategic expert, besides being responsible for the operational part of the SDTM strategy, Vicky also acts as business solution architect across systems involved in the clinical data flow and helps define the strategic direction of related initiatives.

Sinna Lisa Vange

Title: Senior IT Solution Architect

Organization: Novo Nordisk A/S

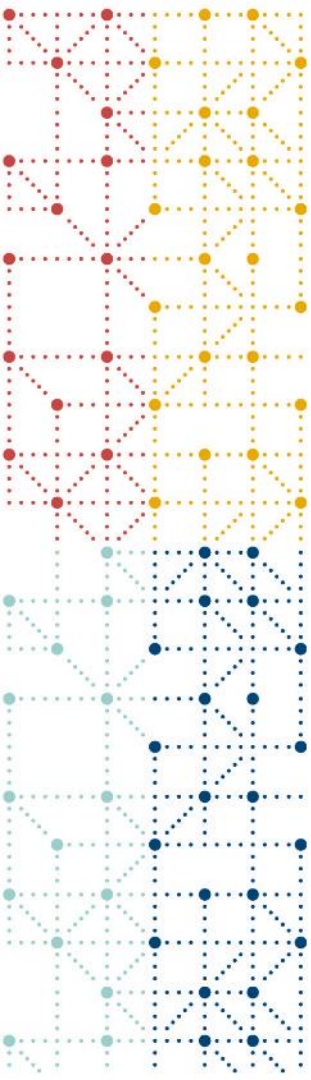
Sinna has +30 years of Novo Nordisk experience in positions from research to clinical development, including as medical writer and clinical submission team lead. In her present role, Sinna serves as information and data architect helping business users gain knowledge from clinical study data. The work includes analysing and conceptualising the problem/solution space, translating business needs to UI/UX designers and developers and developing clinical data dashboards.

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 and Novo Nordisk A/S.*

Agenda

1. The Data Utopia
2. Our Imperfect Present
3. 100% Standardisation for EDC to SDTM Automation
4. Operational Efficiency



The Data Utopia

The Data Utopia

A completely **friction-less** or **seamless flow** of study data/information

from early ideation through all study phases

planning and design

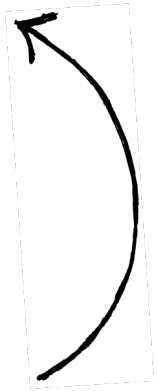
conduct and data collection

cleaning and monitoring

analysis and reporting

regulatory submission

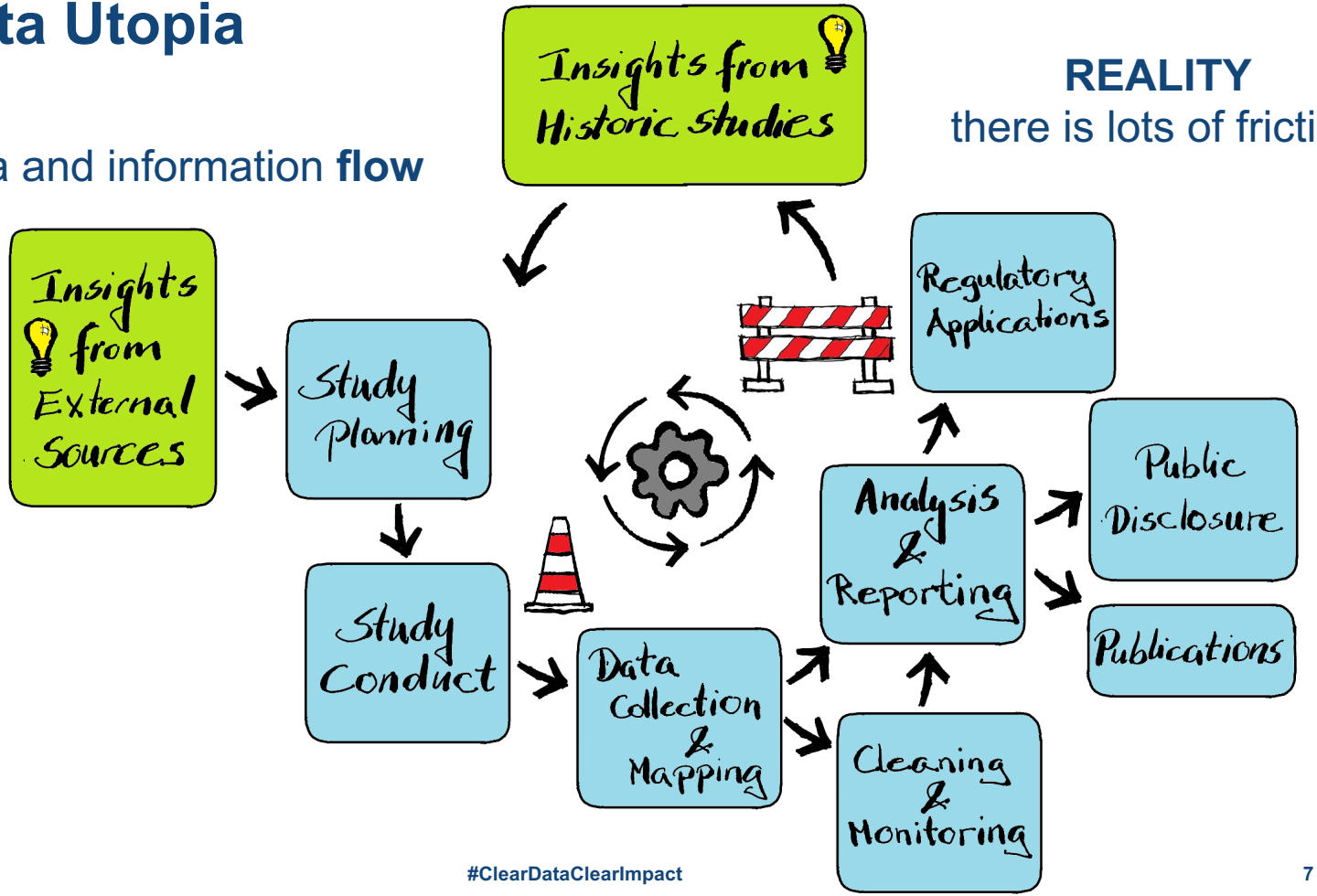
public disclosure and publications



with easy continuous access to cumulative insights / knowledge

The Data Utopia

Study data and information **flow**

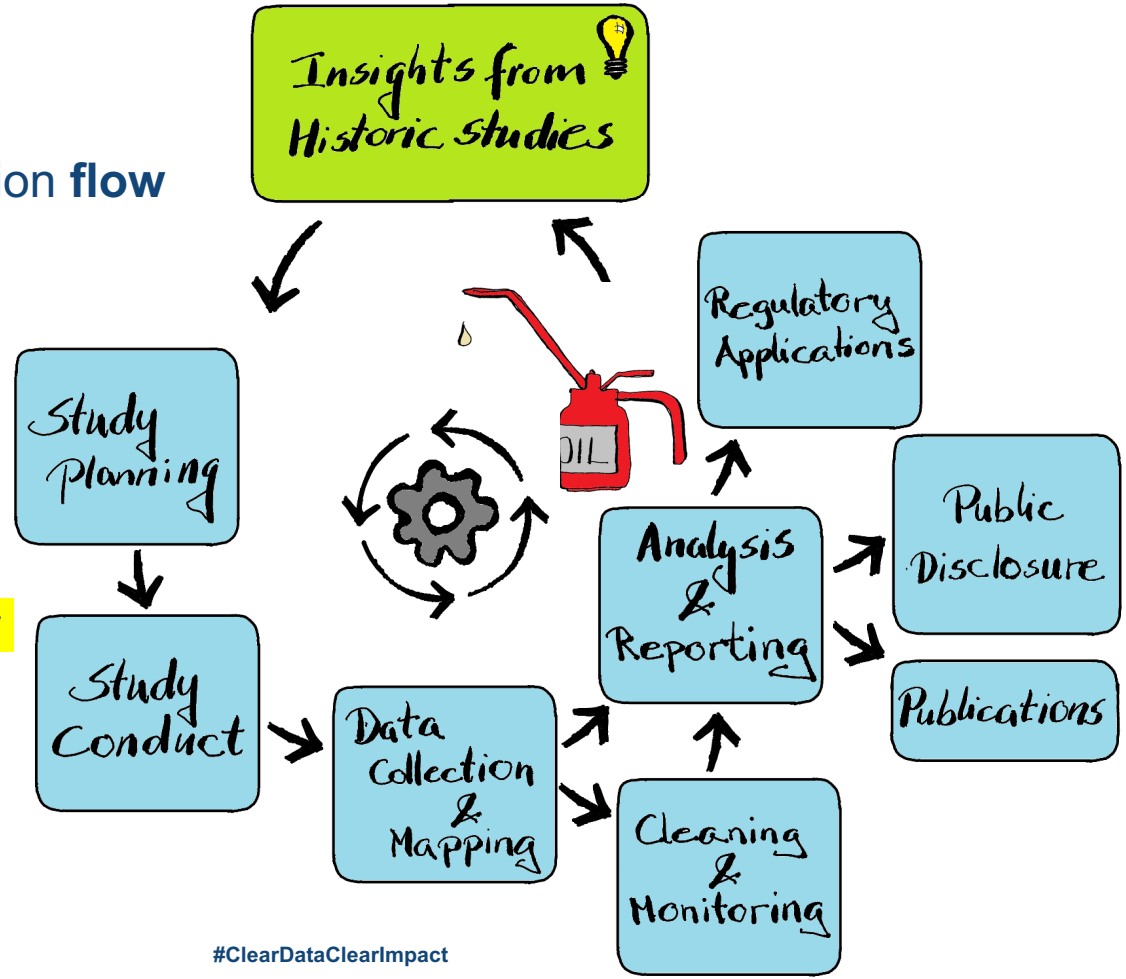


REALITY
there is lots of friction

The Data Utopia

Study data and information **flow**

HYPOTHESIS
we can reduce friction via extensive implementation of comprehensive modular **standards**



The Standards

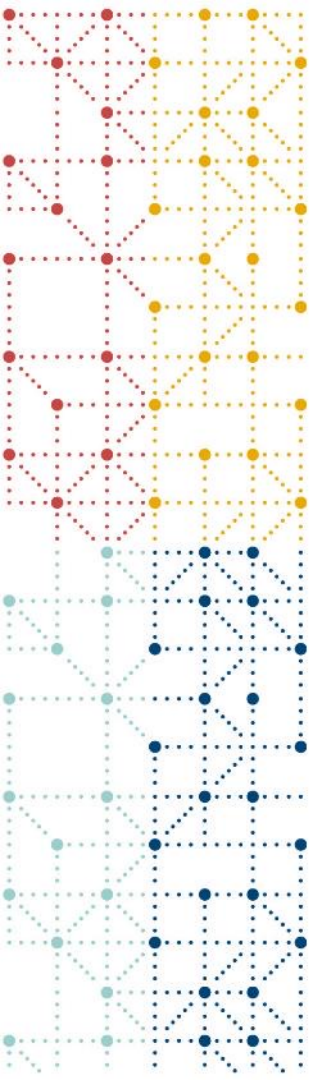
Standards

- Terminology
- Definitions
- Granularity
- Detailing
- Structure
- Syntax
- Conversions

→

- Automate
- Reuse
- Aggregate
- Leverage AI

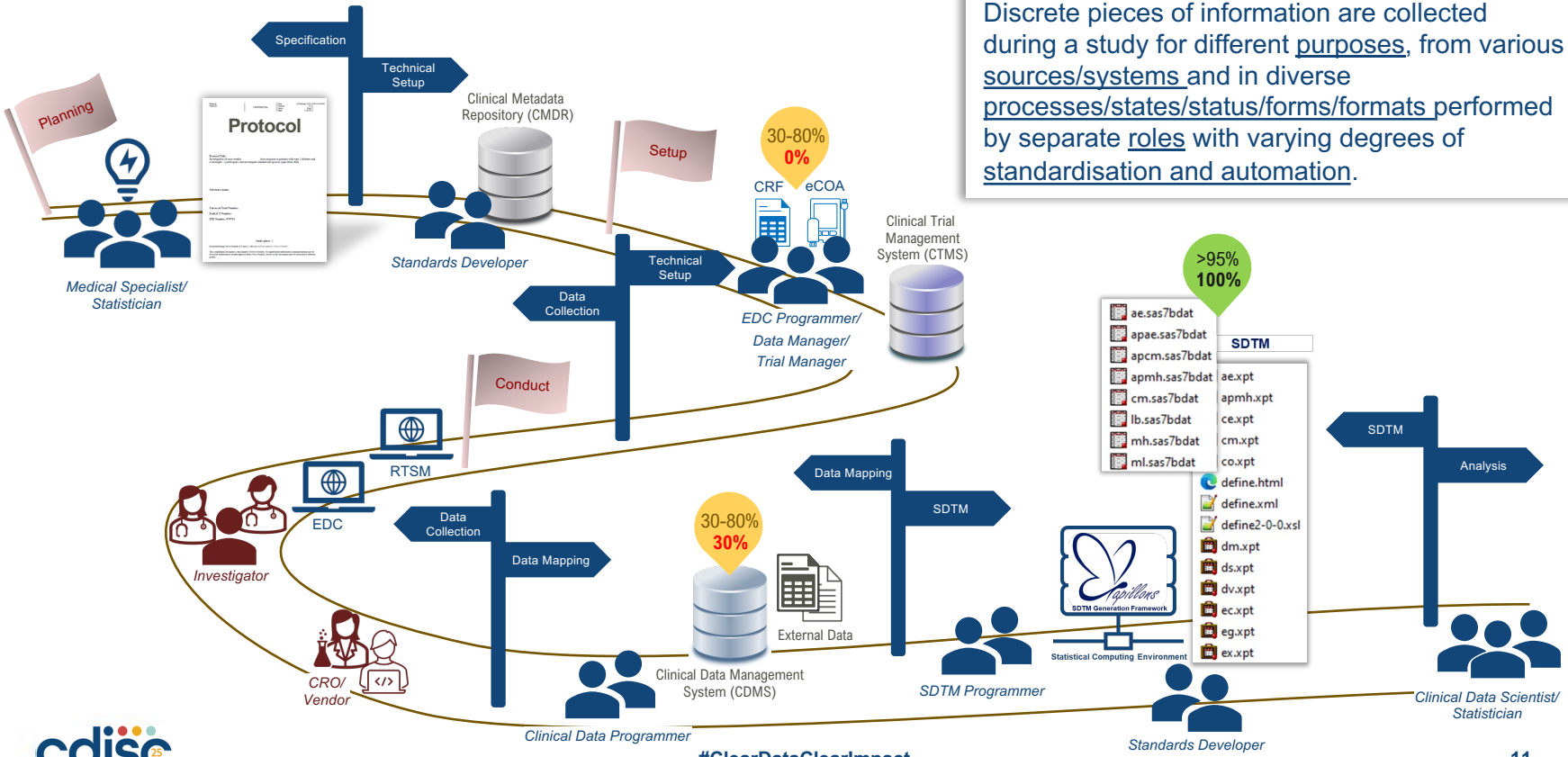
comprehensive modular standards ensure flexibility, translation, connection, contextualisation



Our Imperfect Present

The Long and Winding Road to SDTM

Discrete pieces of information are collected during a study for different purposes, from various sources/systems and in diverse processes/states/status/forms/formats performed by separate roles with varying degrees of standardisation and automation.

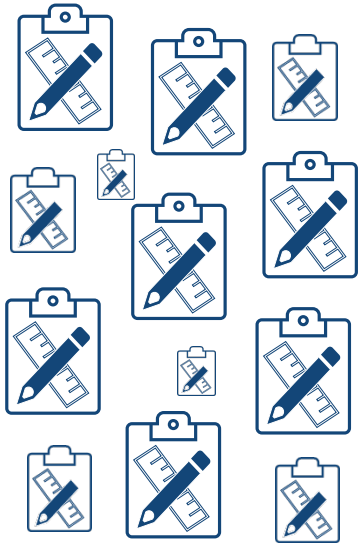


Study-specific Implementation

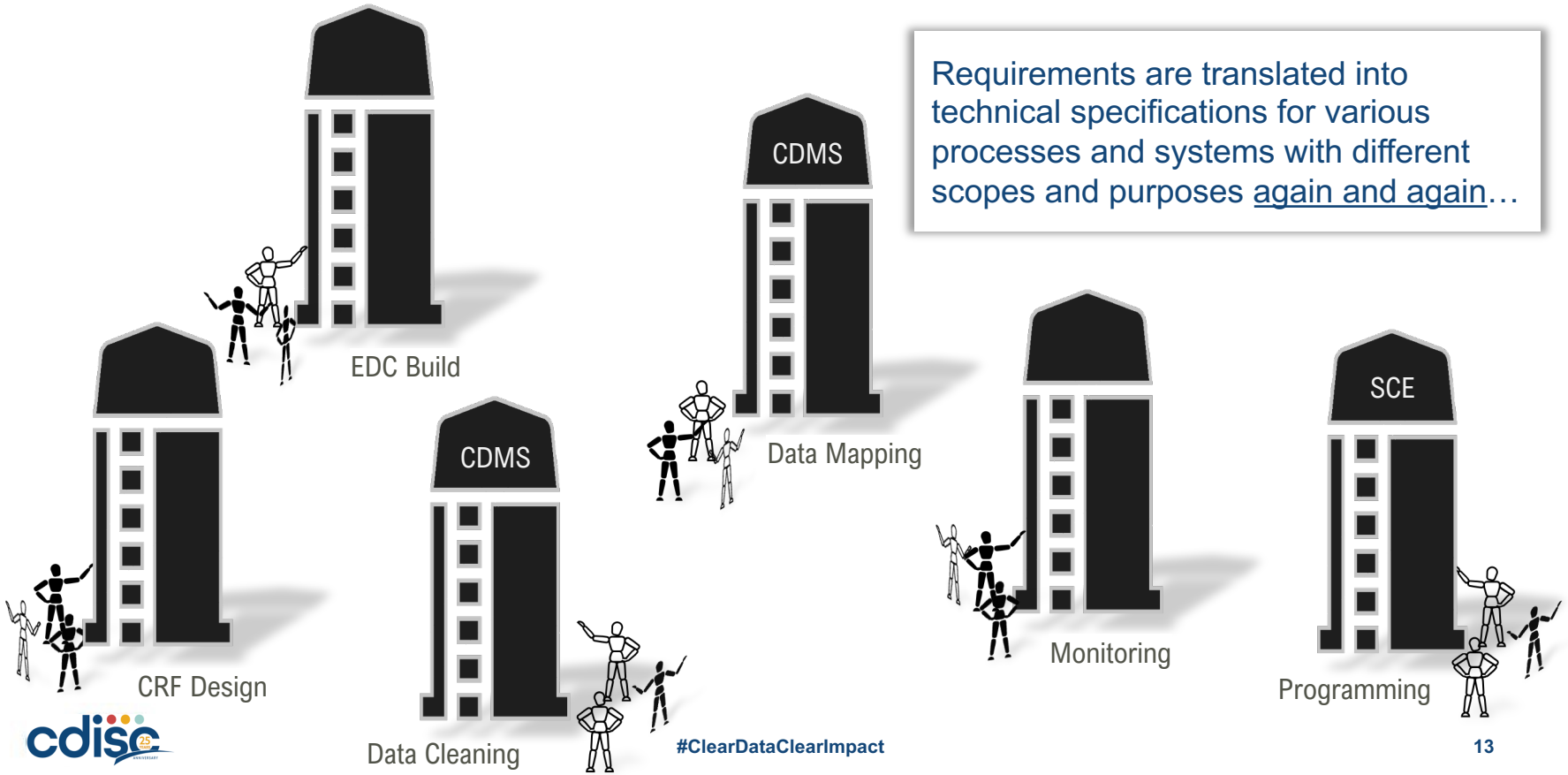
Growing number of study-specific adaptations/implementations

- Unmet needs fueled by adaptive trial design and technological innovations in health science
- Lack of awareness
- Insufficient governance
- Short-sighted silo mentality
- Rigid standards

Domino effect on all downstream processes

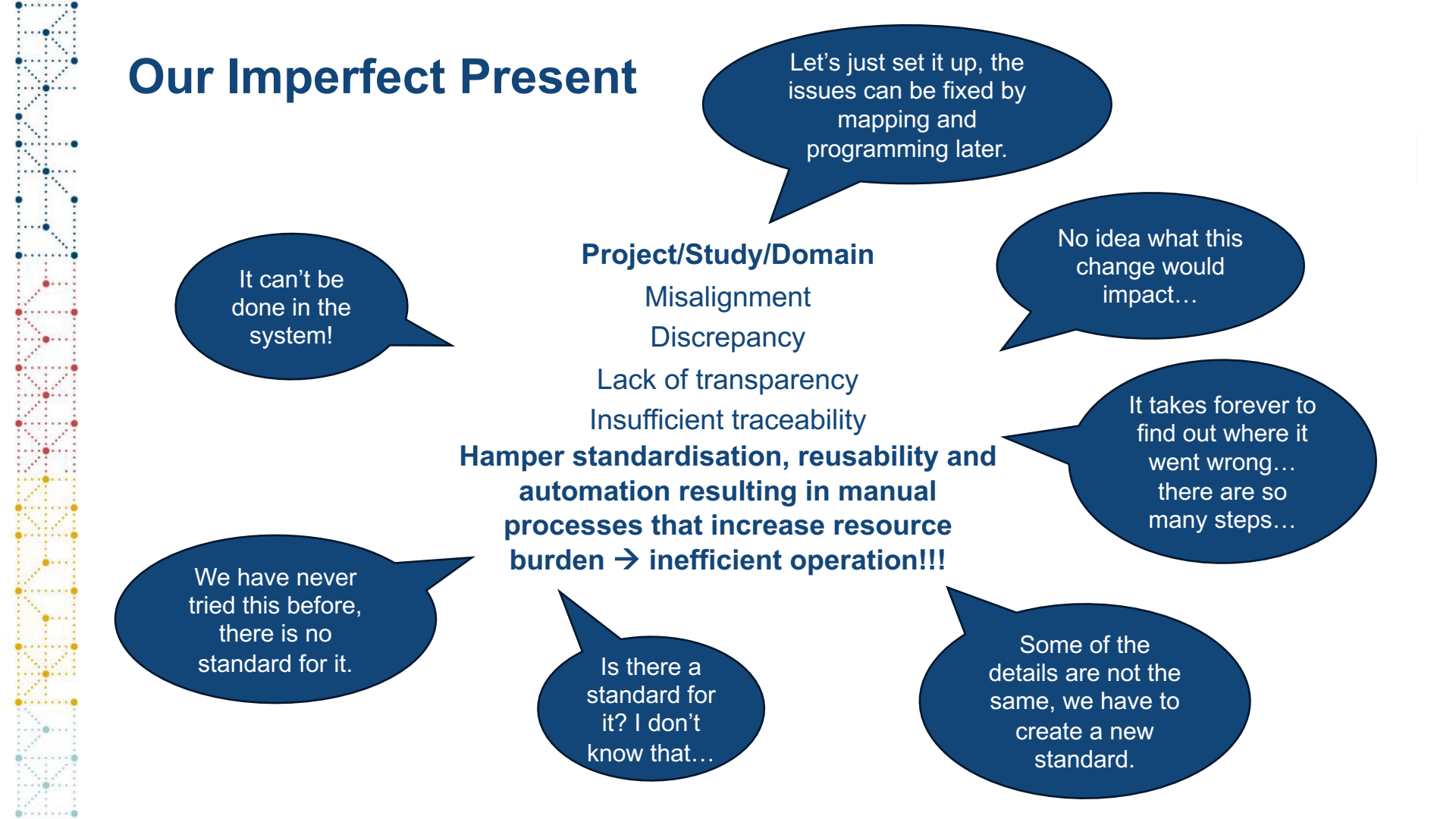


Fragmented Workflows and Silos



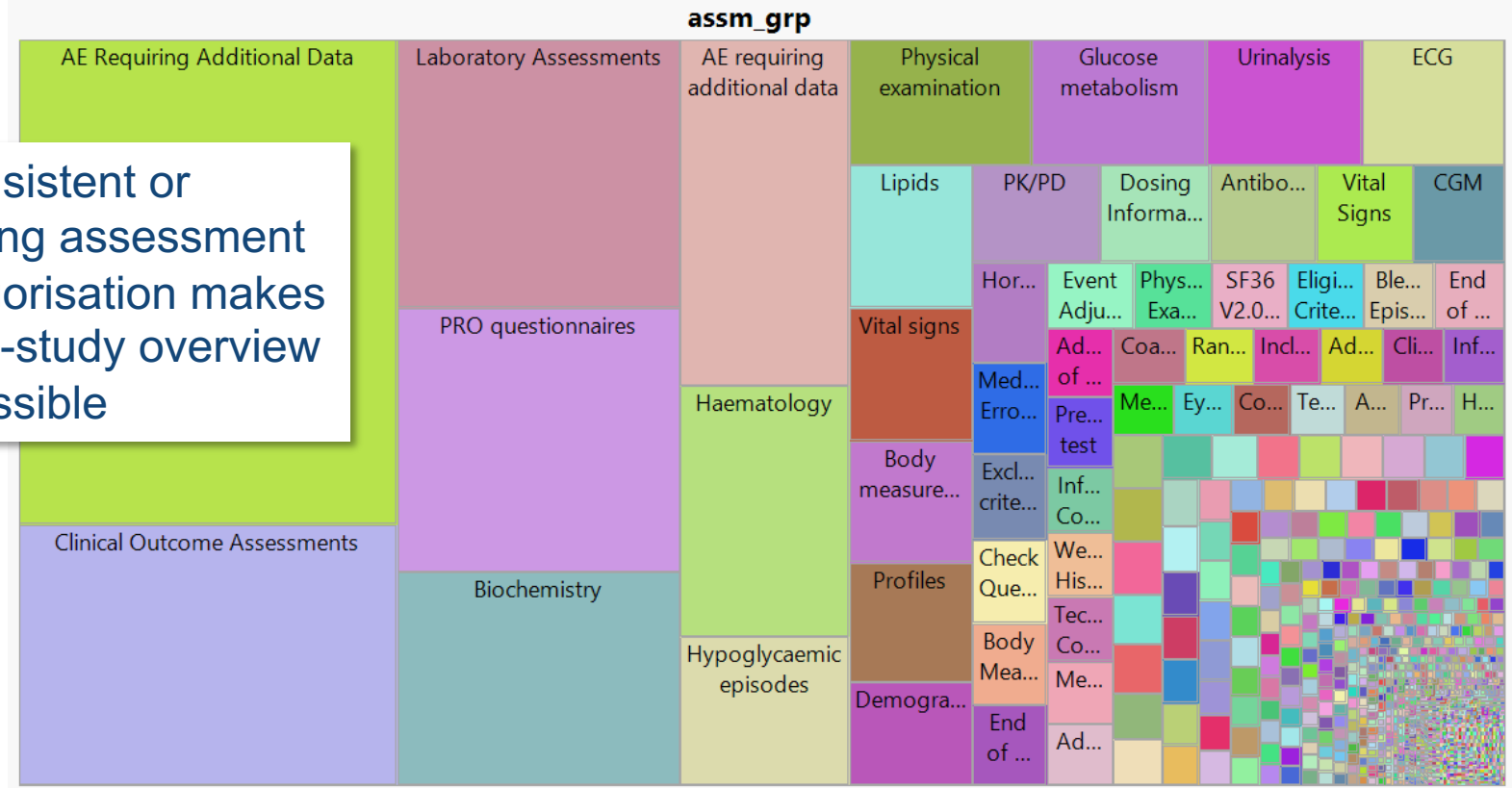
Requirements are translated into technical specifications for various processes and systems with different scopes and purposes again and again…

Our Imperfect Present



Our Imperfect Present

Inconsistent or missing assessment categorisation makes cross-study overview impossible



100% Standardisation for EDC to SDTM Automation

An achievable goal?

Process/Standard Re-engineering

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

Data Specification → CRF Design → Item Definition → EDC Build → SDTM

Item-level standardisation

Form-level standardisation

EDC Design Automation

EDC to SDTM Automation

Item-level Standardisation

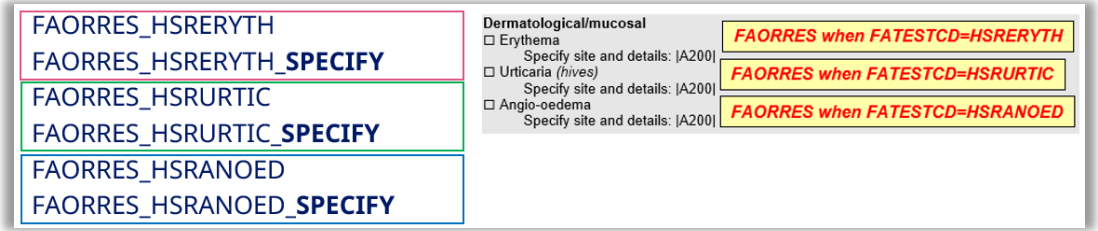
Item Definition

- 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 Naming Convention

- Multiple items may collect data for the same SDTM target on the same form and stored in a denormalised structure in EDC database

<SDTM Target>_<Topic>_<Other details>



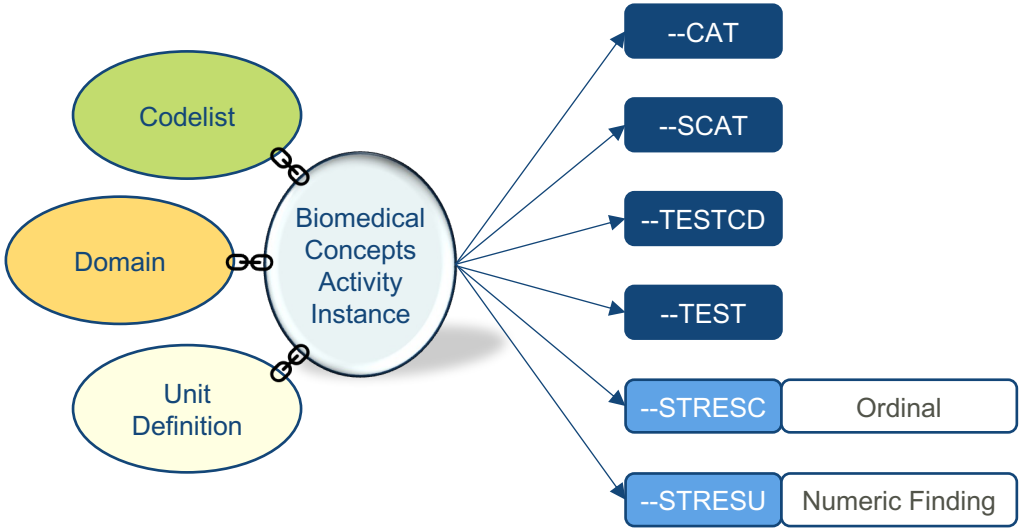
- Adopting CDASH principle:

Denormalized	The organization of data such that multiple observations (results) are presented in a single row of data. For example, the result values for PULSE, HEIGHT, WEIGHT would be presented in the same row of data with PULSE, HEIGHT, and WEIGHT as column headers. This is also called a *horizontal data structure*.

When implementing CDASH in a denormalized structure, denormalized CDASH variable names are created by the sponsor, when needed. Denormalized CDASH variable names generally use the following the naming convention:

<Topic Variable values > _<*Qualifier(s)*>_<SDTMIG Target>. **Sponsors may define their own conventions for creating denormalized CDASH variable names.**

Biomedical Concepts



Schedule of Activity

V1	V2	V3	Topic Code
x		x	BODY_WEIGHT
x		x	HEIGHT
x		x	BMI

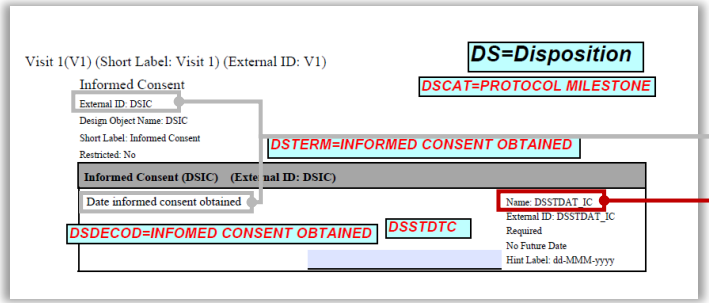
Unit Definition

SI Unit	US conventional unit
kg	LB

SDTM

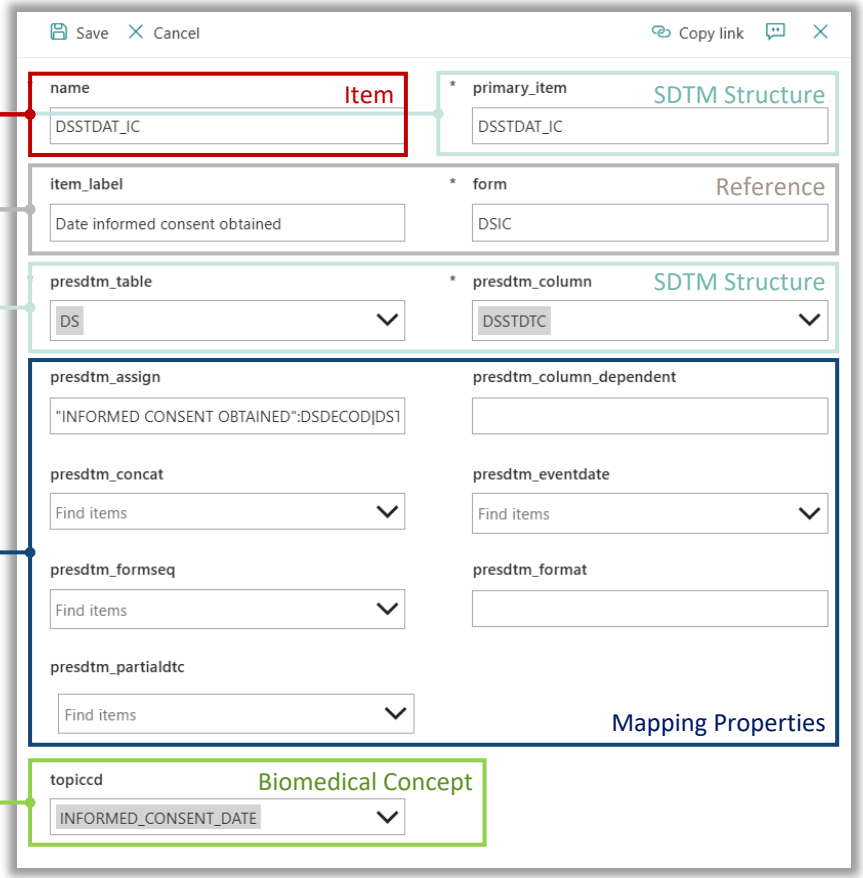
Domain	--CAT	--SCAT	--TESTCD	--TEST
VS	BODY MEASUREMENT		WEIGHT	Body Weight

Item Definition: A Simple Illustration



Date informed consent obtained

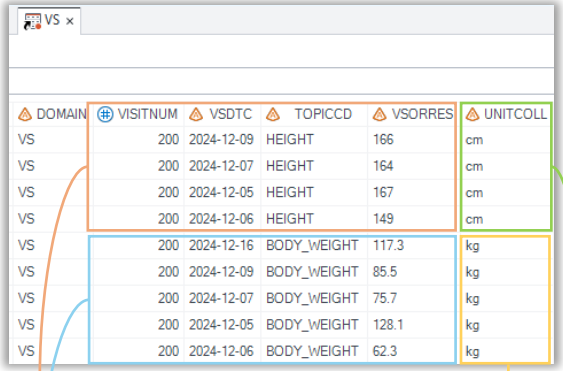
- **Item** • DSSTDAT_IC
- **Biomedical Concept** • INFORMED_CONSENT_DATE
- **SDTM Structure** • DS domain: DSSTDTC • 1 record per DSSTDAT_IC
- **Mapping Properties** • DSTERM • DSDECOD

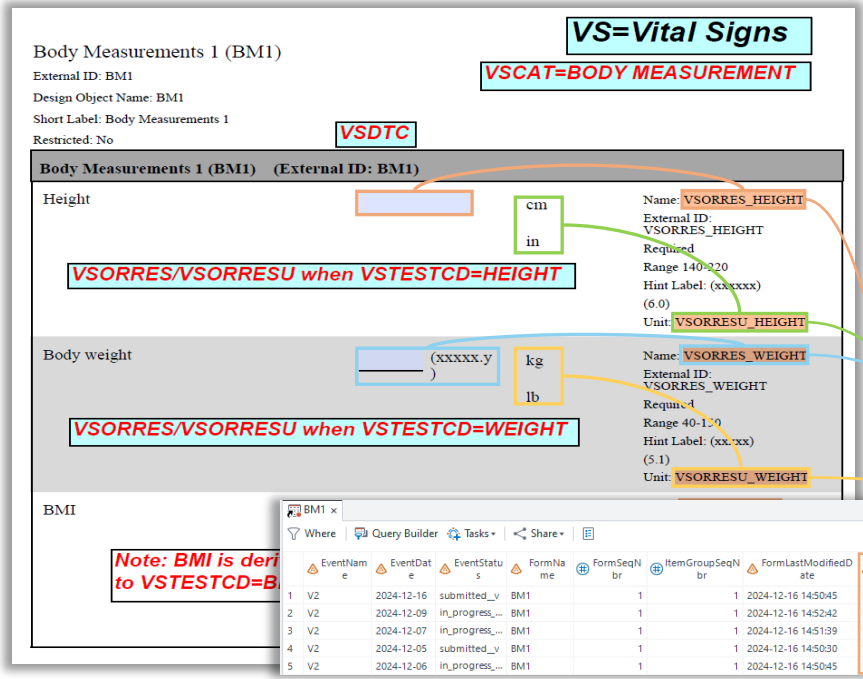


Lineage Embedded in Item Definition

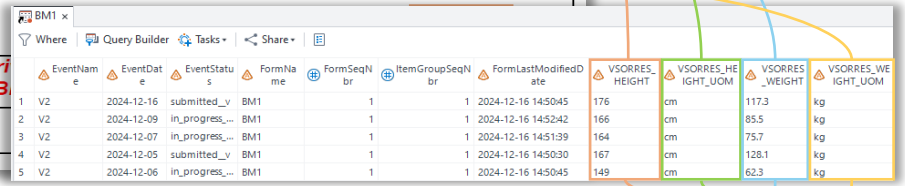
CRF

SDTM





EDC database

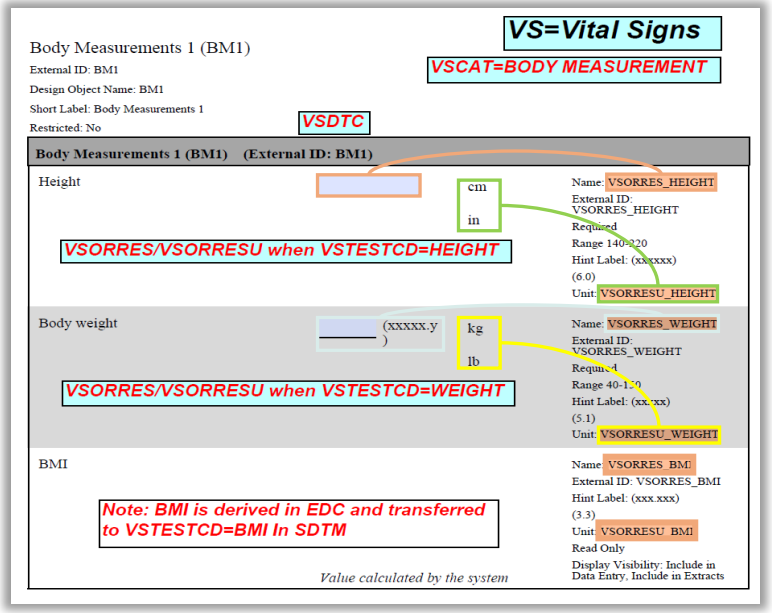


Item Definition

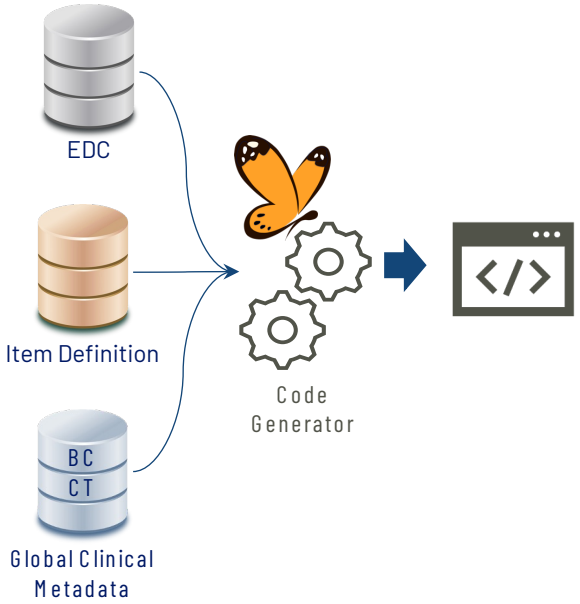
presdtm_table	presdtm_column	topiccd	form	primaryitem	name	itemlabel
VS	VSORRES	HEIGHT	BM1	VSORRES_HEIGHT	VSORRES_HEIGHT	Height
VS	UNITCOLL	HEIGHT	BM1	VSORRES_HEIGHT	VSORRES_HEIGHT_UOM	Height
VS	VSORRES	BODY_WEIGHT	BM1	VSORRES_WEIGHT	VSORRES_WEIGHT	Body weight
VS	UNITCOLL	BODY_WEIGHT	BM1	VSORRES_WEIGHT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

EDC Design Principle

- A set of rules that governs the technical implementation of forms in EDC system
  - Structure
  - Data type
  - Item naming convention
- A global approach to EDC Build:
  - Enable fast implementation and UAT cycle
  - Lower resource load
  - Ensure alignment with Item Definition
  - Consistent implementation across studies enabling standardisation and automation of downstream processes



EDC to SDTM Automation



Lineage Metadata

EDC_MAPPING

	presdtm_table	presdtm_column	topiccd	primaryitem	edcform	name	itemlabel	form	table	column
1	VS	VSORRES	BMI ON CRF	VSORRES_BMI	BM1	VSORRES_BMI	BMI	BM$	BM1	VSORRES_BMI
2	VS	UNITCOLL	BMI ON CRF	VSORRES_BMI	BM1	VSORRES_BMI_UOM	BMI	BM$	BM1	VSORRES_BMI_UOM
3	VS	VSORRES	HEIGHT	VSORRES_HEIGHT	BM1	VSORRES_HEIGHT	Height	BM$	BM1	VSORRES_HEIGHT
4	VS	UNITCOLL	HEIGHT	VSORRES_HEIGHT	BM1	VSORRES_HEIGHT_UOM	Height	BM$	BM1	VSORRES_HEIGHT_UOM
5	VS	VSORRES	BODY_WEIGHT	VSORRES_WEIGHT	BM1	VSORRES_WEIGHT	Body weight	BM$	BM1	VSORRES_WEIGHT
6	VS	UNITCOLL	BODY_WEIGHT	VSORRES_WEIGHT	BM1	VSORRES_WEIGHT_UOM	Body weight	BM$	BM1	VSORRES_WEIGHT_UOM
7	VS	VSORRES	BMI ON CRF	VSORRES_BMI	BM2	VSORRES_BMI	BMI	BM$	BM2	VSORRES_BMI
8	VS	UNITCOLL	BMI ON CRF	VSORRES_BMI	BM2	VSORRES_BMI_UOM	BMI	BM$	BM2	VSORRES_BMI_UOM

Study-level lineage metadata and persistent key provide full traceability between EDC and SDTM data

preSDTM

VS

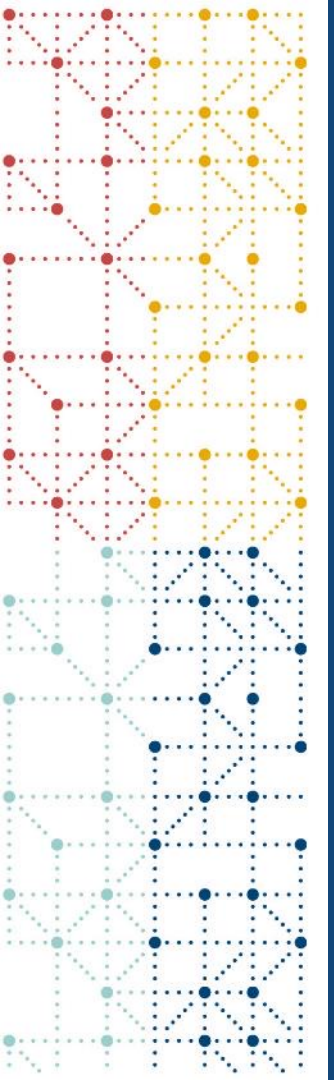
	primarykey	spid	STUDYID	DOMAIN	USUBJID	TOPICCD	VSORRES	UNITCOLL	VISITNUM	VSDTC
1	V2/BM1/1/2024-12-16 03:17:16	B9882D077EA2F54109083B3DF99718DB	41	VS	4001	BMI ON CRF	37.868	kg/m^2	200	2024-12-16
2	V2/BM1/1/2024-12-16 03:17:16	B9882D077EA2F54109083B3DF99718DB	41	VS	4001	HEIGHT	176	cm	200	2024-12-16
3	V2/BM1/1/2024-12-16 03:17:16	B9882D077EA2F54109083B3DF99718DB	41	VS	4001	BODY_WEIGHT	117.3	kg	200	2024-12-16
4	V3/BM2/1/2024-12-30 07:12:27	D124F06FACE6E43D7A2B800ADF8C735C	41	VS	4001	BMI ON CRF	37.126	kg/m^2	300	2024-12-30
5	V2/VS/1/2024-12-16 03:17:16	C108D1337FA85F841A1C782977B77FF9	41	VS	4001	DIABP_MEAN_CRF	106	mmHg	200	2024-12-16T10:11:00
6	V3/VS/1/2024-12-30 07:12:27	DAC1DB41FEEB2494DD2F3EDA2AA093F5	41	VS	4001	DIABP_MEAN_CRF	91	mmHg	300	2024-12-30T10:40:00
7	V2/VS/1/2024-12-16 03:17:16	C108D1337FA85F841A1C782977B77FF9	41	VS	4001	BP_DIASTOLIC	102	mmHg	200	2024-12-16T10:11:00
8	V3/VS/1/2024-12-30 07:12:27	DAC1DB41FEEB2494DD2F3EDA2AA093F5	41	VS	4001	BP_DIASTOLIC	91	mmHg	300	2024-12-30T10:40:00

Persistent key linking SDTM records to source data

EDC

BM1

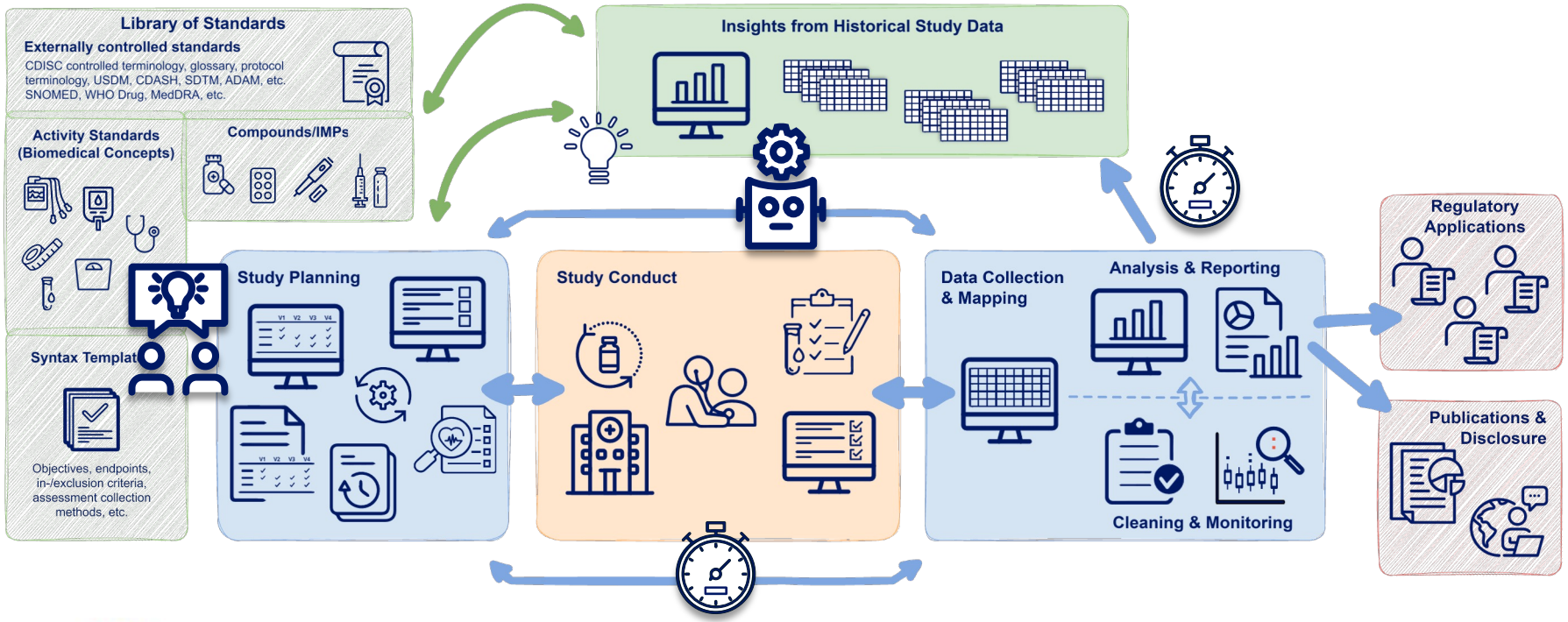
	EventName	EventDate	EventStatus	FormName	FormSeqNbr	ItemGroupSeqNbr	FormLastModifiedDate	VSORRES_HEIGHT	VSORRES_HEIGHT_UOM	VSORRES_WEIGHT	VSORRES_WEIGHT_UOM
1	V2	2024-12-16	submitted_v	BM1	1	1	2024-12-16 14:50:45	176	cm	117.3	kg
2	V2	2024-12-09	in_progress_...	BM1	1	1	2024-12-16 14:52:42	166	cm	85.5	kg
3	V2	2024-12-07	in_progress_...	BM1	1	1	2024-12-16 14:51:39	164	cm	75.7	kg



Operational Efficiency

How does good look like?

Operational Efficiency Across Areas



Key Takeaways

Shift Left **when benefits outweigh the overall costs**

- Standardise as early in the process flow as possible to lessen resource load

Think small **while focusing on the big picture**

- Breakdown the standard elements to increase flexibility

Be bold **with both feet on the ground**

- Remove restraints from existing practice to streamline processes

Think End to End **collectively with stakeholders to ensure buy-in**

- Eliminate silos to obtain seamless flow and optimise operational efficiency

Thank You!

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