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INTERCHANGE
COPENHAGEN | 26-27 APRIL

Standardisation in a fast-growing environment; MDR, EDC and other abbreviations.

Presented by Jasmine Kestemont and Louella Schoemacher

Meet the Speakers

Jasmine Kestemont

Title: Consultant Data Management

Organization: Innovion

Jasmine Kestemont is an entrepreneurial business leader with significant experience in both Sponsor and services organizations. After a few years of global work experience, she has returned to the area she is most passionate about, data and project management, with a special interest in data standardization and regulatory submissions.

Louella Schoemacher

Title: Data Standards Data Manager

Organization: OCS Life Sciences

Louella Schoemacher is an analyst/programmer working for OCS Life Sciences. She has a background in nutrition which triggered her interest in research. Within clinical research she is passionate about data visualization and standardizing processes.

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.*

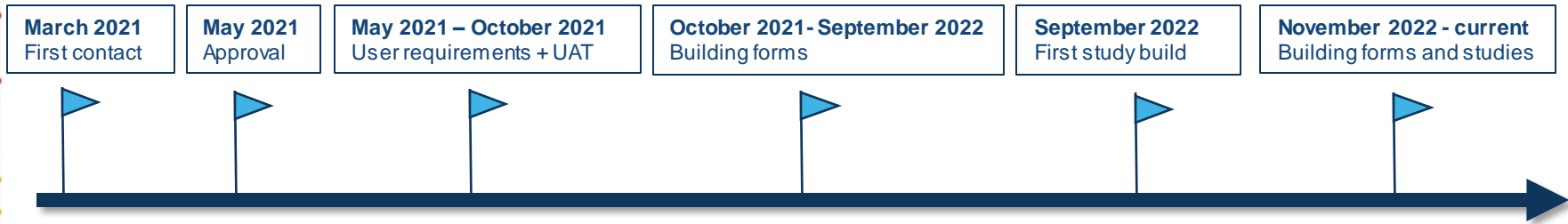- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

1. Re-cap of MDR Implementation
2. Current activities
3. Learnings
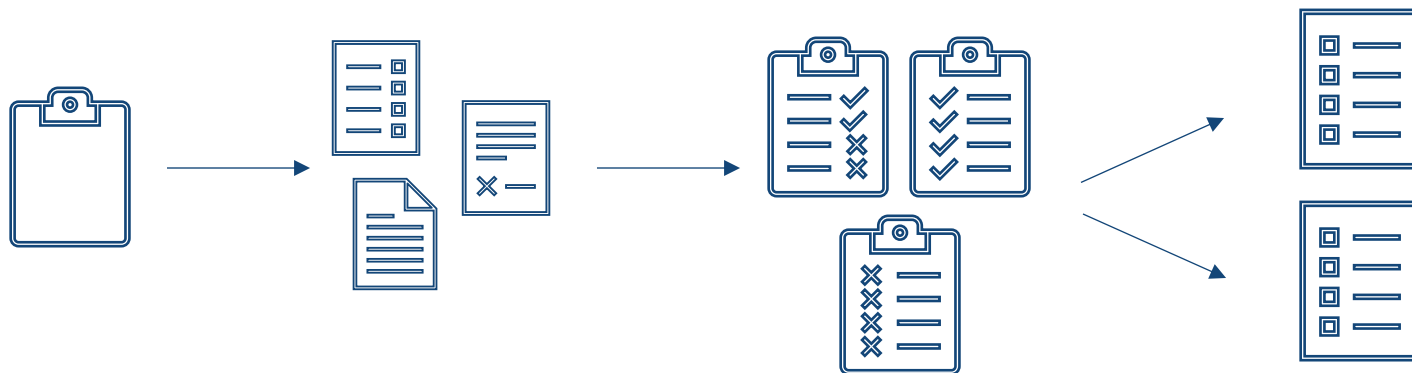4. Integration and standardization in other DM processes

Re-cap of MDR Implementation

MDR Implementation from start until now

March 2021	May 2021	May 2021 – October 2021	October 2021 - September 2022	September 2022	November 2022 - current
First contact	Approval	User requirements + UAT	Building forms	First study build	Building forms and studies

Standardisation process

DS (Disposition)

DM (Demographics)

Question identifier	Question	
--DAT		
DM_AGE	Age at info...	eater than 18 years.
DM_AGE	Age at info...	ter than 20 years.
DM_BIRTHYY	Birth year	
DM_BIRTHYY	Birth year	it time of ICF
DM_RACE	Race (tick...	d:
DM_RACE	Race (tick...	a pre-defined
DS_IC_DSSTDAT	Date infor...	
DS_IC_DSSTDAT	Date infor...	date.
DS_IC_DSSTDAT	Date infor...	
XD_INITSCRN	Previous p...	

Site Number

Participant Number

Demographic Data and Informed Consent Recording

1 Informed Consent
DSTERM/DSDECOD (CL.PROTMLST) = INFORMED CONSENT OBTAINED

Please do not forget to complete the Additional/Updated ICF form

1.1	Date of protocol version (DD-MMM-YYYY)	D D M M M Y Y Y Y
		PROTDTC in SUPPDS
1.2	Date informed consent obtained (DD-MMM-YYYY)	D D M M M Y Y Y Y
		DSSTDTC
1.3	Date of informed consent form version (DD-MMM-YYYY)	D D M M M Y Y Y Y
		ICFDTC in SUPPDS

2 Demographics

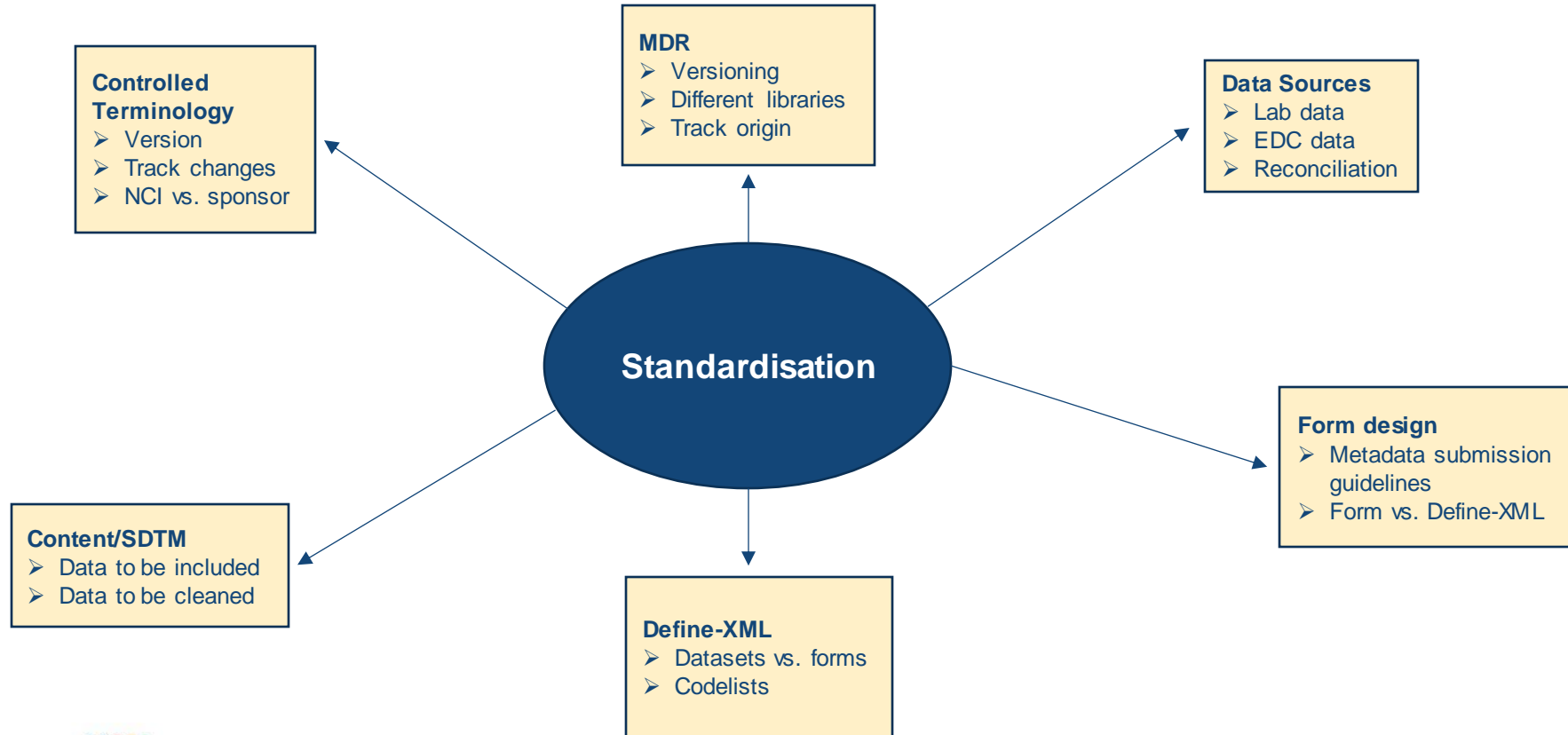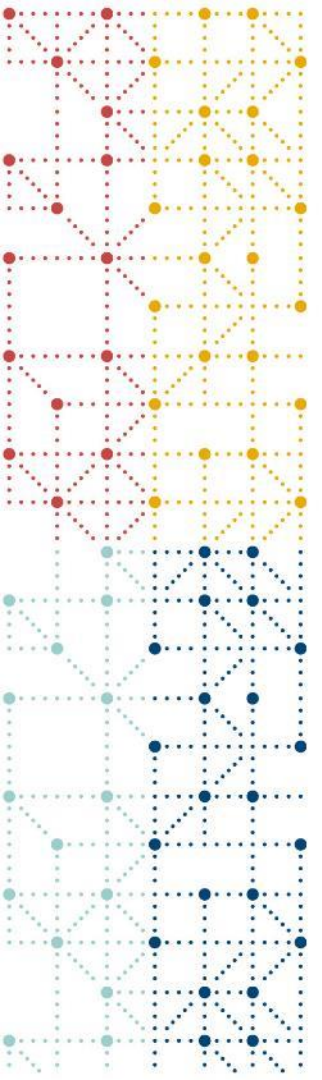| 2.1 | Birth year (YYYY) (DD-MMM-YYYY) | N A N A P Y Y Y Y |
		BRTHDTC
2.2	Age at informed consent	Years — AGE/AGEU (CL.AGEU)
2.3	Sex at study start	○ Female ○ Male ○ Intersex ○ Unknown — SEX (CL.SEX)
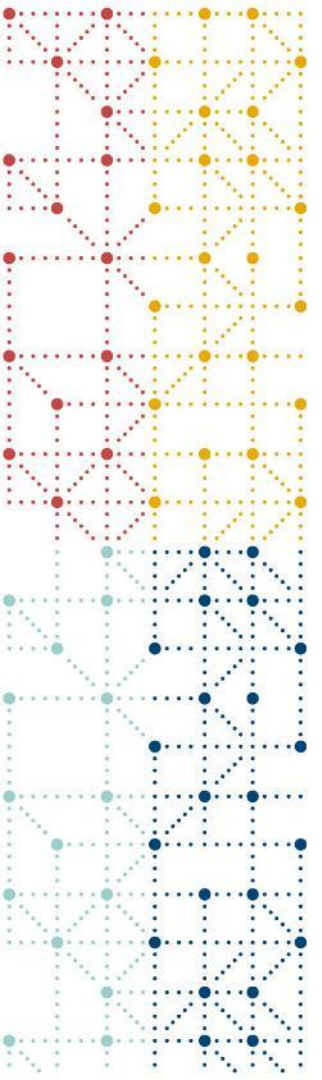
Current activities

Current activities

- Consistency check

- Creation of sponsor CT library

- Governance meeting format

- Up versioning

Standardisation.. beyond aCRF design

MDR
- ➤ Versioning
- ➤ Different libraries
- ➤ Track origin

Controlled Terminology
- ➤ Version
- ➤ Track changes
- ➤ NCI vs. sponsor

Data Sources
- ➤ Lab data
- ➤ EDC data
- ➤ Reconciliation

Standardisation

Form design
- ➤ Metadata submission guidelines
- ➤ Form vs. Define-XML

Content/SDTM
- ➤ Data to be included
- ➤ Data to be cleaned

Define-XML
- ➤ Datasets vs. forms
- ➤ Codelists

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Learnings

Learnings

➤ Finding a balance
  ➤ Variants
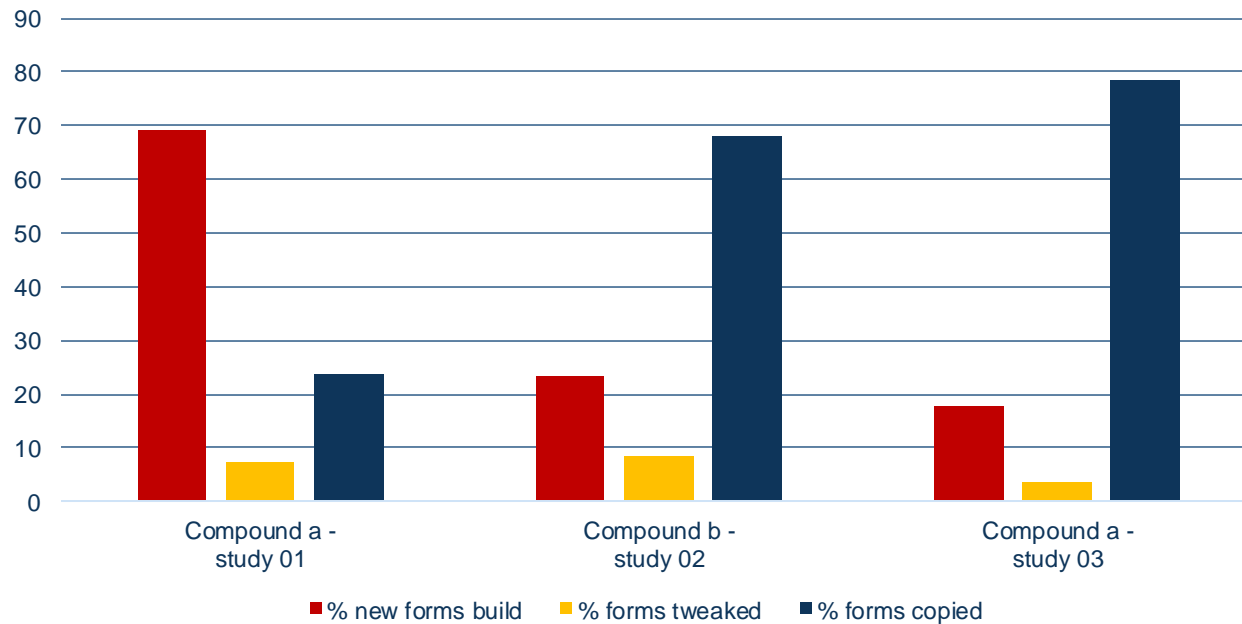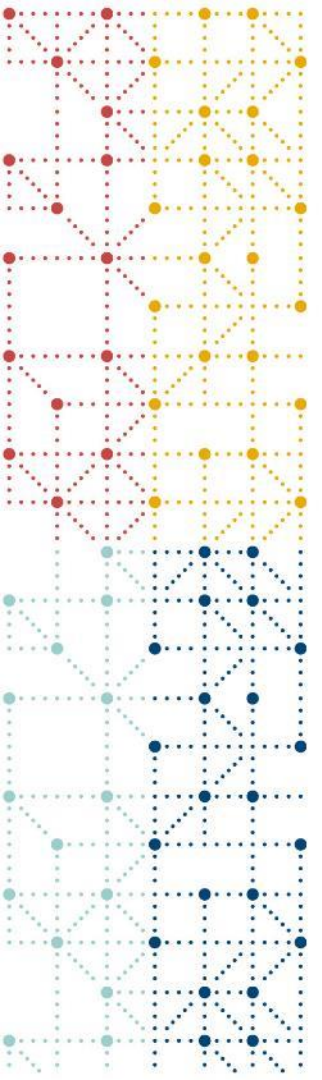 ➤ What can we know up front

➤ Training component

➤ End to end impact
  • Log forms at site
  • Vendor libraries

Learnings

Study build over time

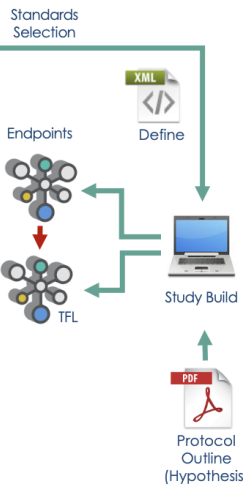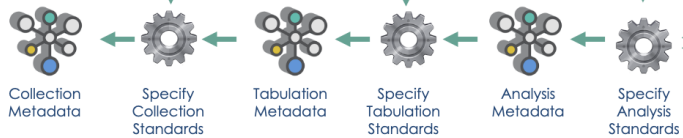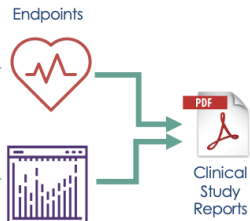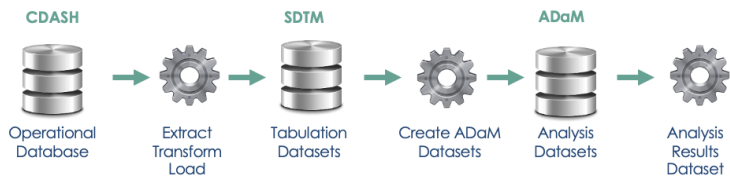# Integration and standardization in other DM processes

Image: Courtesy CDISC
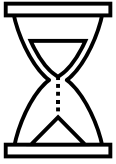
Traditional Set-Up Path Prior to MDR Implementation

- **EDC Go-Live on Critical**

Go-live

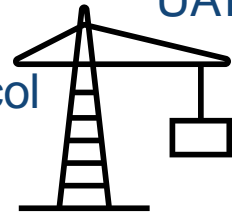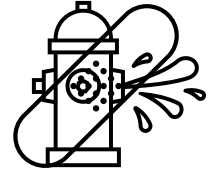Set-up phase | Conduct phase
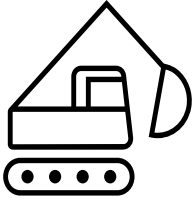
Draft protocol
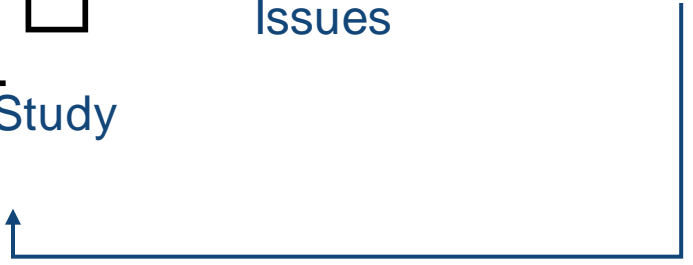
Draft Study Build

Final Protocol

UAT

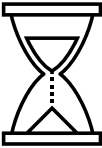Final Study Build

Issues

amended Protocol

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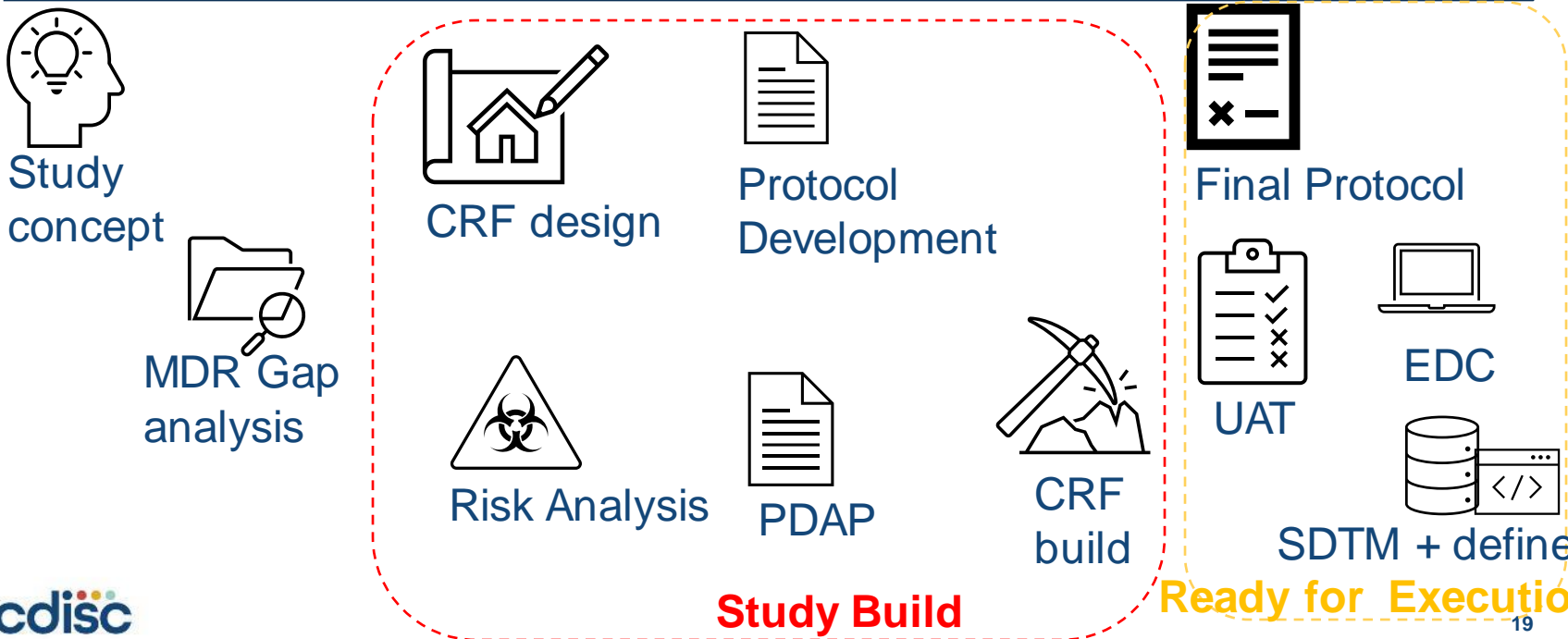# Traditional Set-Up Path Prior to MDR Implementation

• Conduct phase

❑ Third-Party Vendor Set-up (eDT)
❑ SDTM Database Design
❑ Defining Protocol Deviations

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New Process with MDR

- CRF for Visual Confirmation of the protocol

Set-up phase

Study concept

MDR Gap analysis

CRF design

Protocol Development

Risk Analysis

PDAP

CRF build

Final Protocol

UAT

EDC

SDTM + define

Study Build

Ready for Execution

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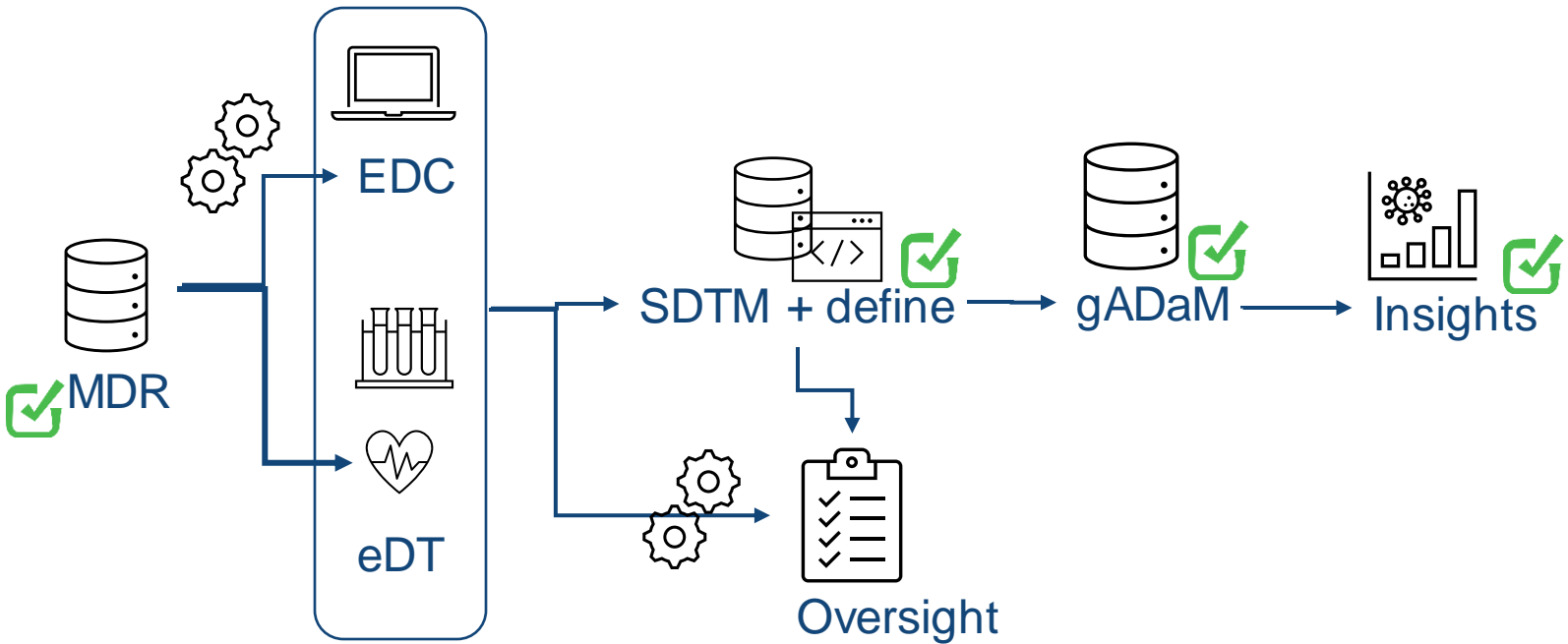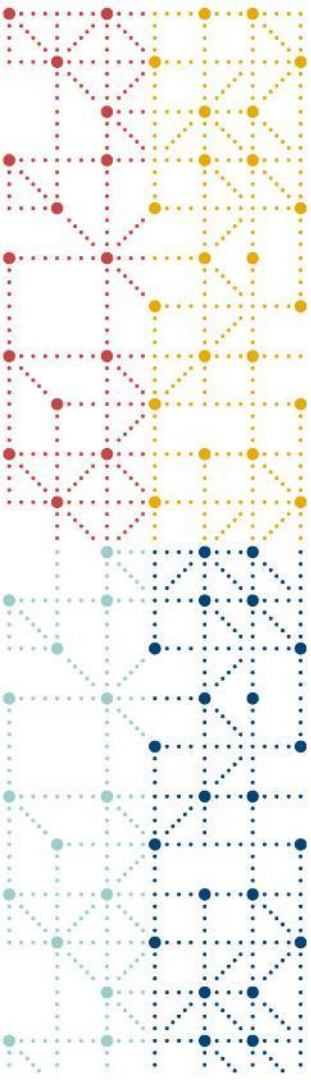# What hasn't changed yet

<div style="text-align:center">• Conduct phase</div>

❑ Third-Party Vendor Set-up (eDT)

Next steps in our roadmap

MDR

EDC

eDT

SDTM + define

gADaM

Insights

Oversight

Image: Freepik

Thank You!