



How to find the best MDR solution for your organization

Kevin Lee, Director of Data Science

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The Agenda

- MDR Selection Process
 - Defining business objectives
 - PoC
 - Evaluation
- MDR Implementation Process
 - SDLC
 - Integration with other systems
 - Change Management
- Final Thoughts



Buying a new CAR



MDR

Selection Process



Defining
Business
Objectives



PoC



Evaluation

Business Objectives of MDR

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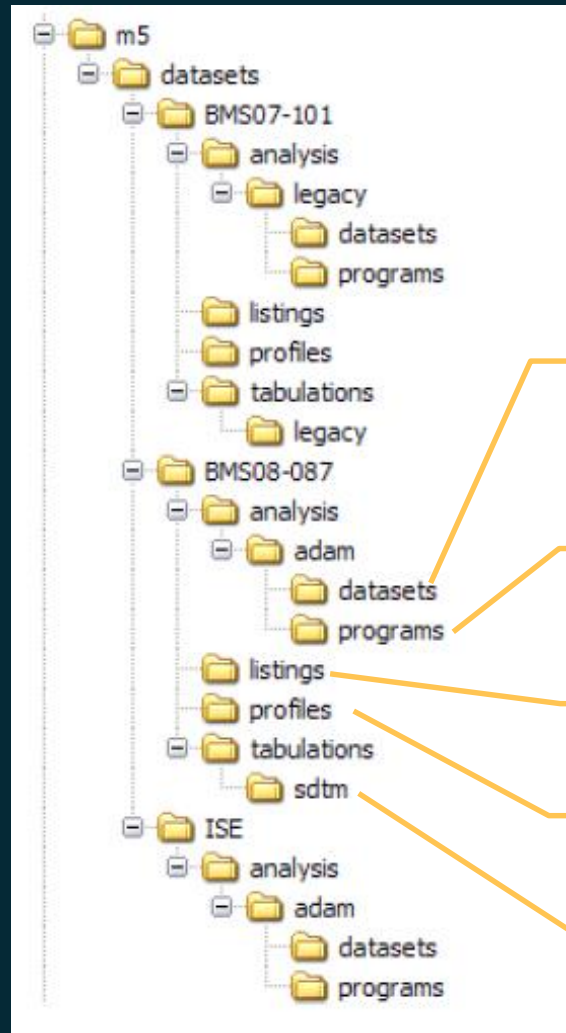


Why MDR?

Business Objectives of MDR:

Regulatory Compliance

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ADaM xpt datasets, Define.xml, ADRG

ADaM SAS programs, TFL SAS programs

Any xpt datasets

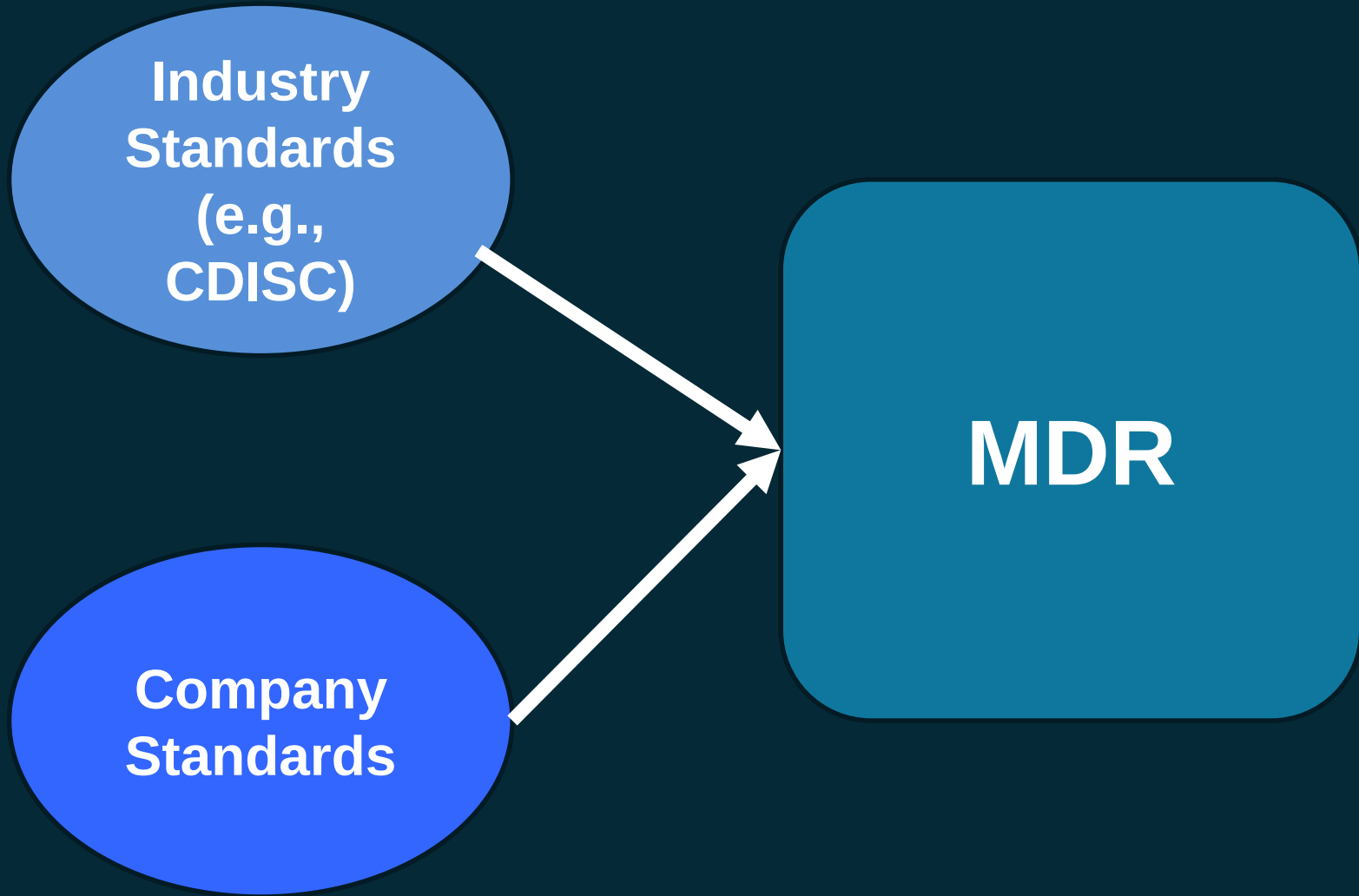
Patient profile

SDTM xpt datasets, Define.xml, SDTM annotated blank CRF, SDRG

FDA study data specification document

Business Objectives of MDR:

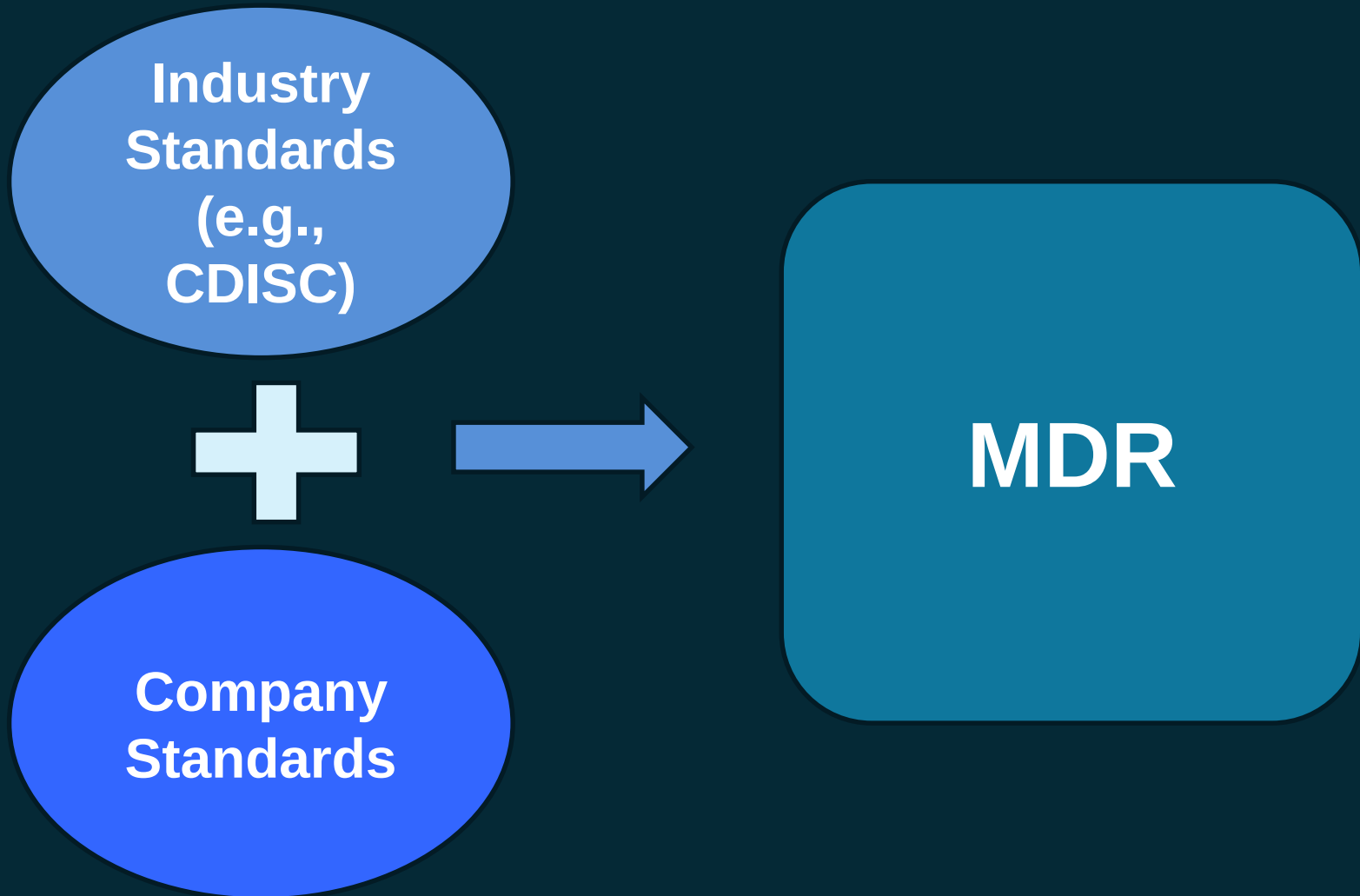
Industry or Company Standards



Business Objectives of MDR:

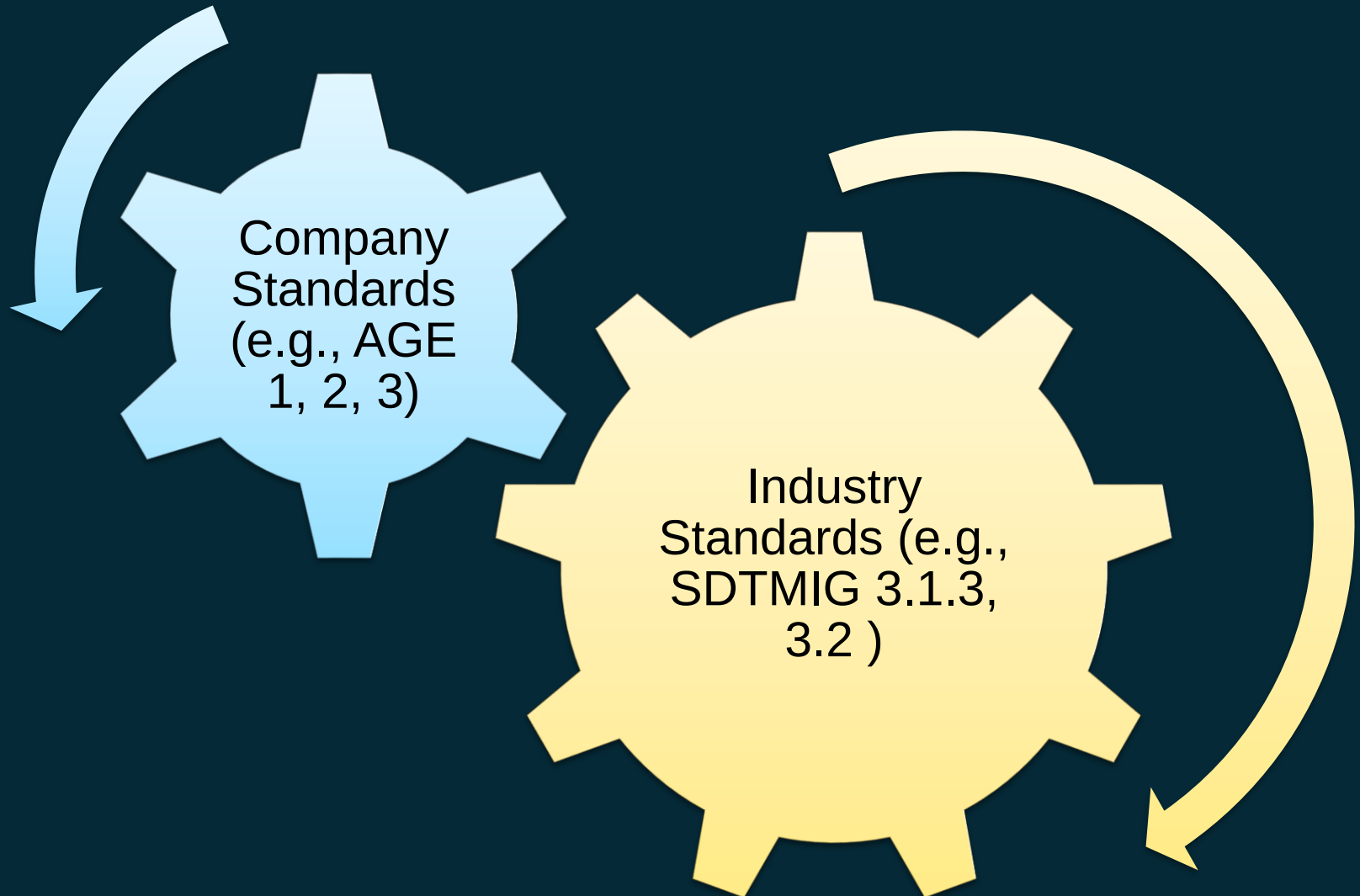
Industry and Company Standards

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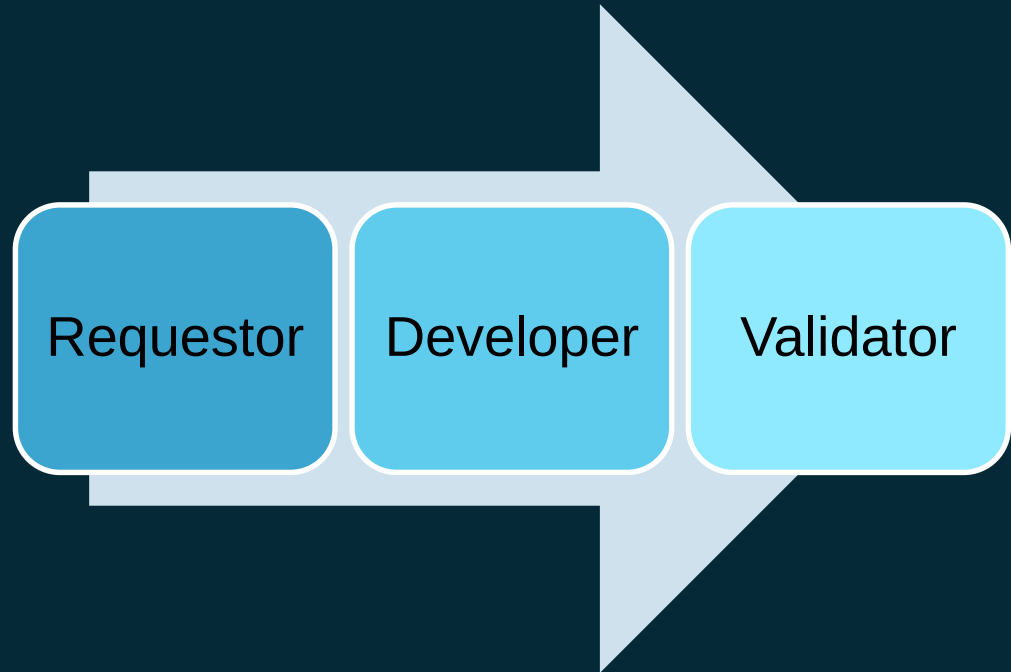
Business Objectives of MDR:

Version Control

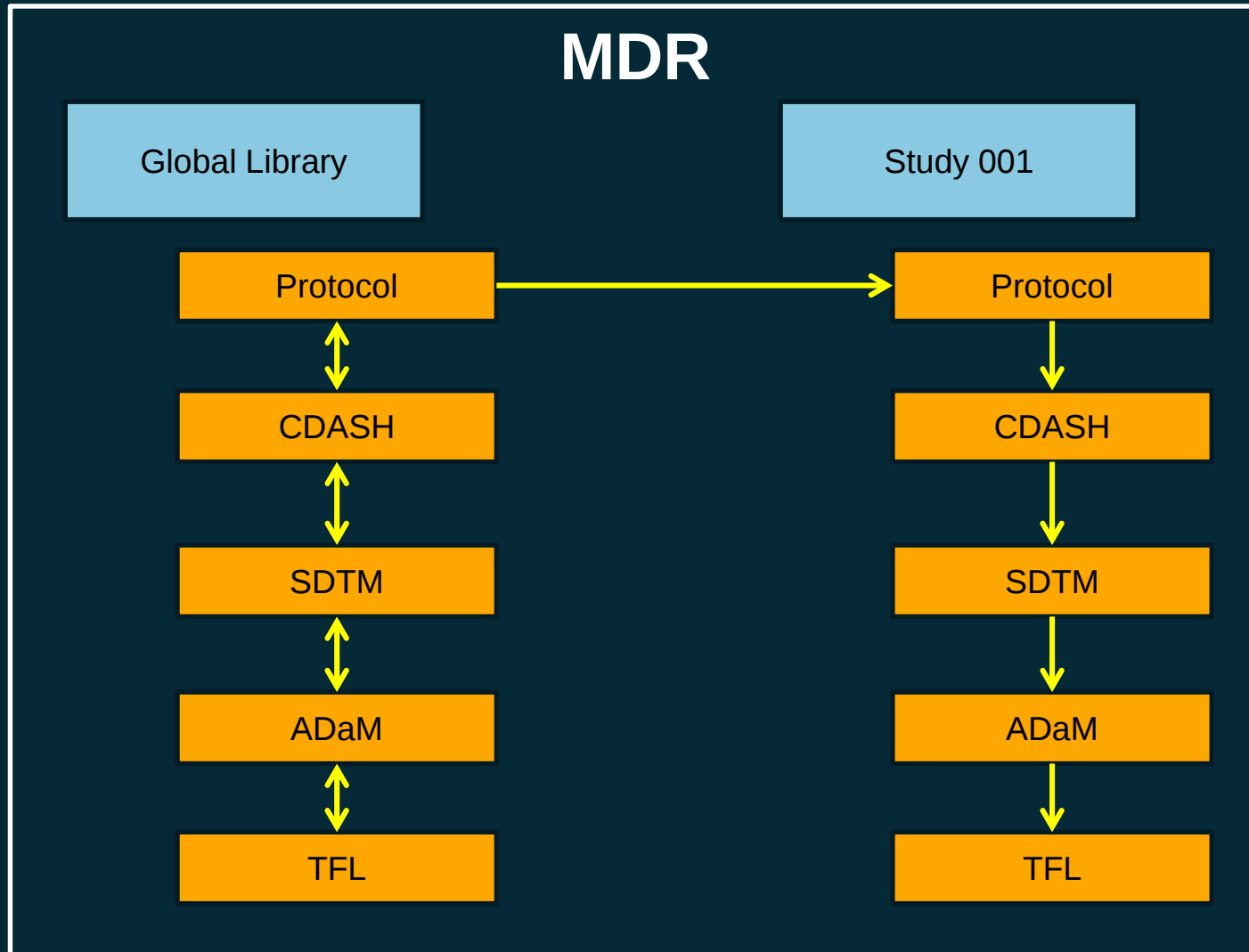


Business Objectives of MDR: 10

Standard Governance



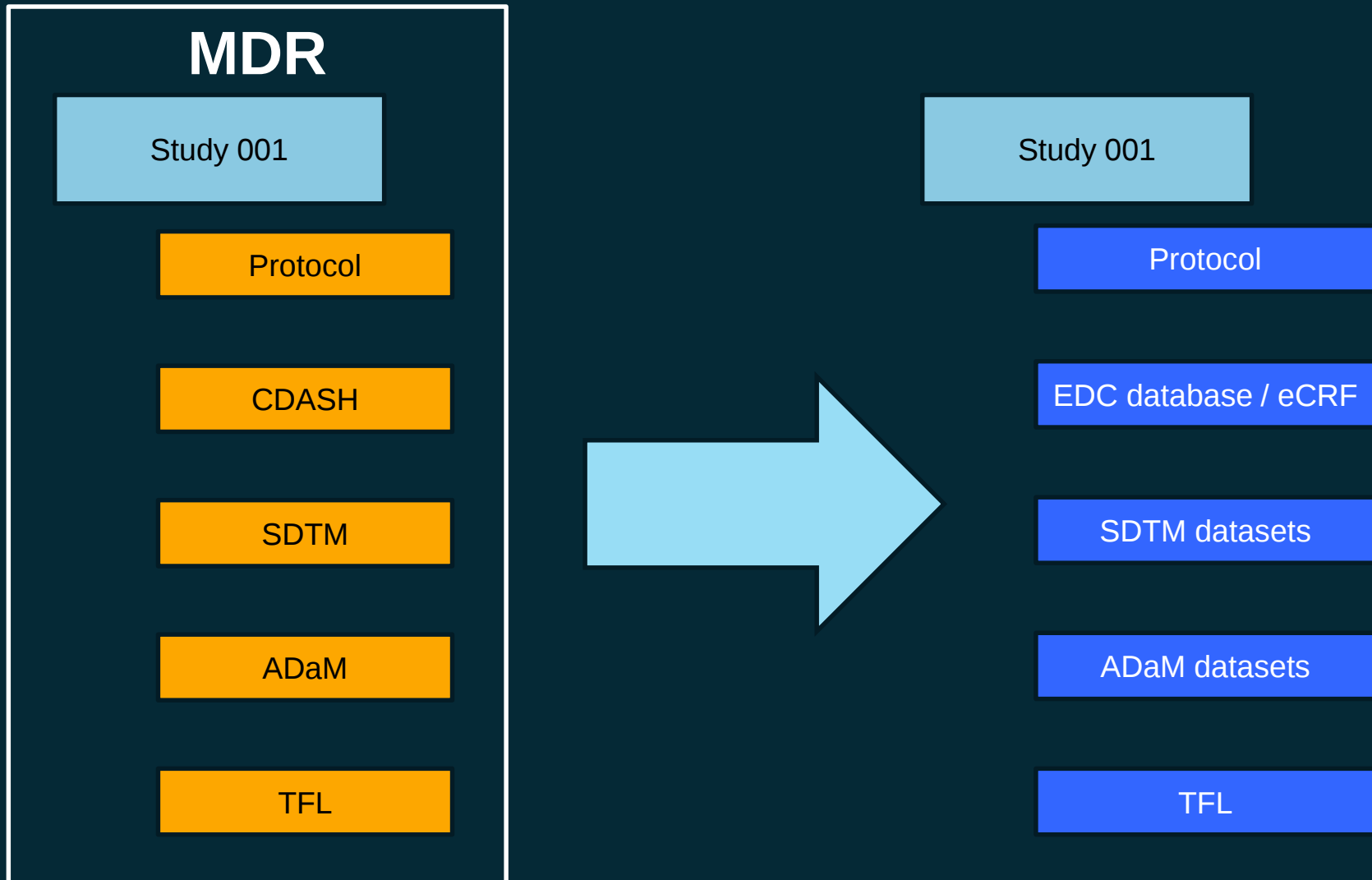
Business Objectives of MDR: Study Level Metadata



Business Objectives of MDR:

Study Level Metadata-driven process

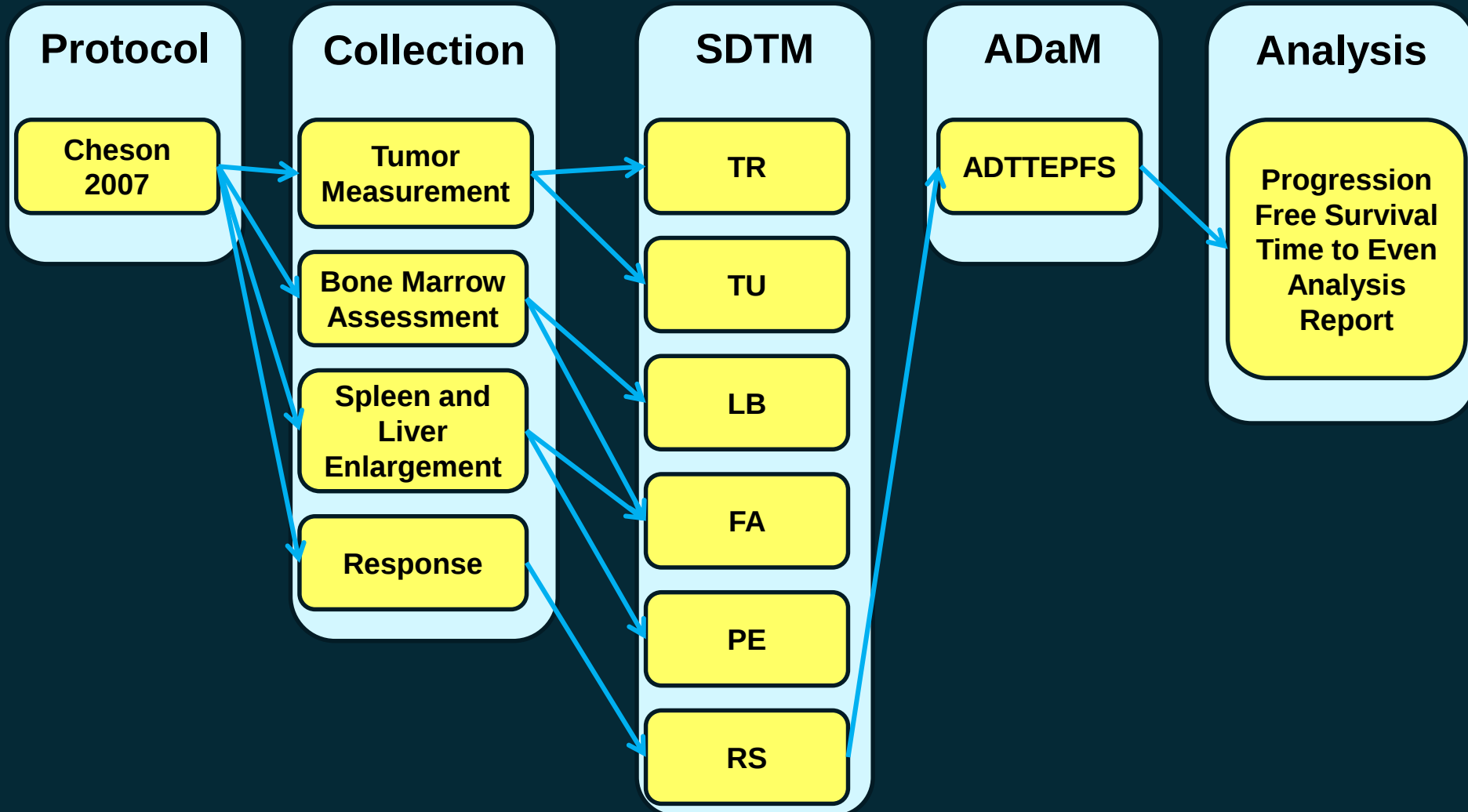
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Business Objectives of MDR

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Study Level Linked E2E Process



Business Objectives of MDR:

Other objectives

Define-xml
generation

API (e.g.,
REST, SOAP)

Output
format(e.g.,
pdf, xml, excel)

System
stability

Interactive UI

Reports



Proof of Concept (PoC)



Business
Objectives



MDR
Features



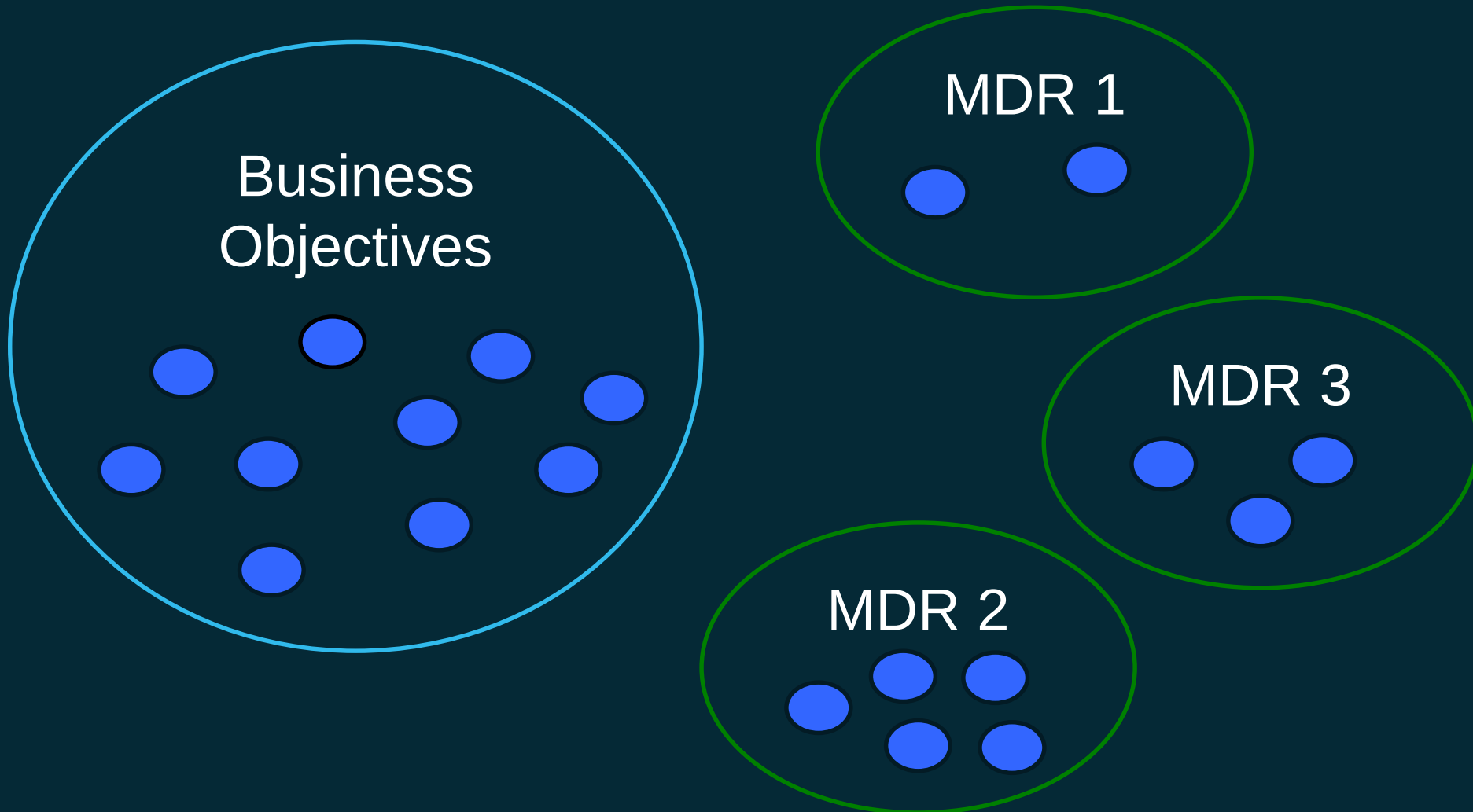
Sense on
MDR

Evaluation of MDR



Evaluation of MDR:

Business Objectives vs. MDR Functionalities



Evaluation of MDR: Expertise

Business
Domain
Knowledge
(e.g.CDISC)

System
Integration

MDR
Technology

Service

Evaluation of MDR:

Cost vs. Value

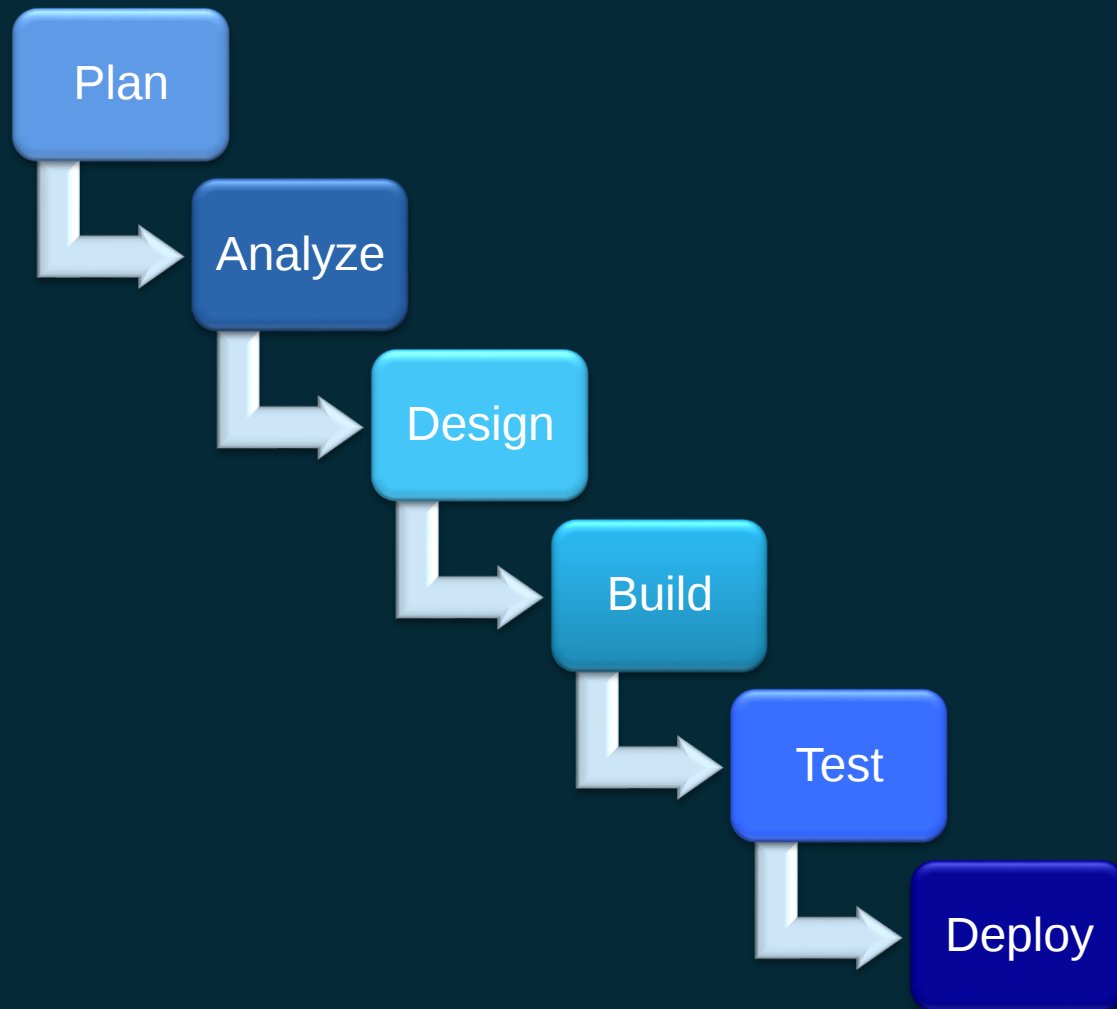


MDR Implementation Process

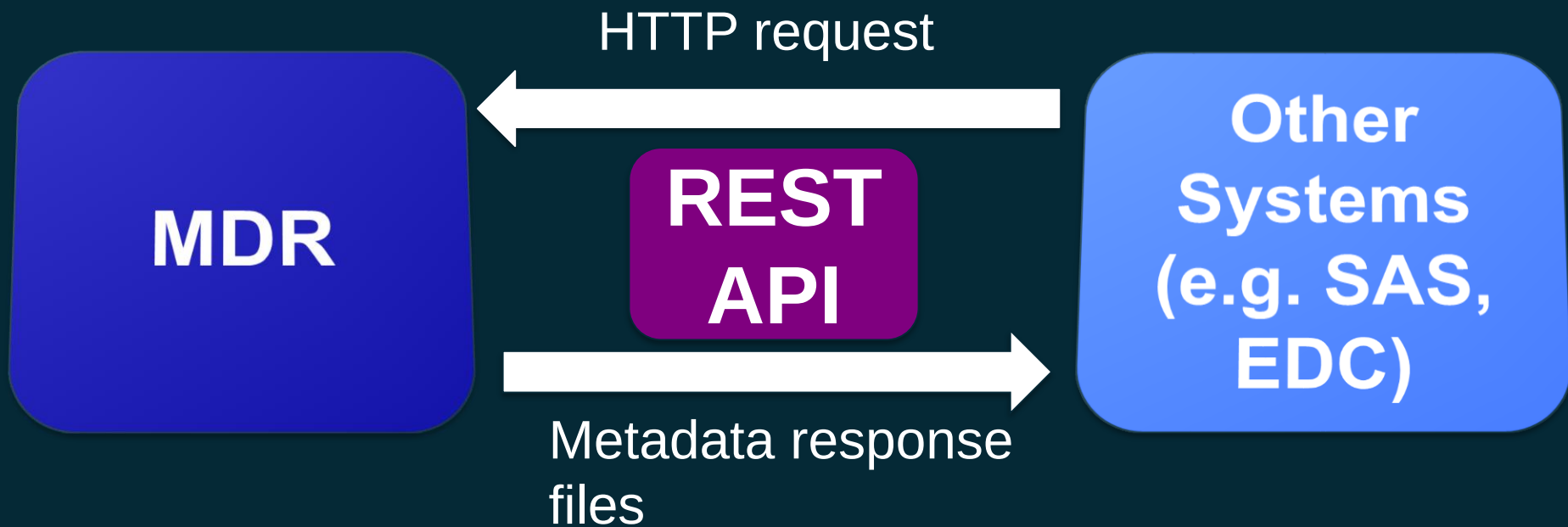
- SDLC
- Integration with Other Systems
- Change Management



SDLC (System Development Life Cycle)

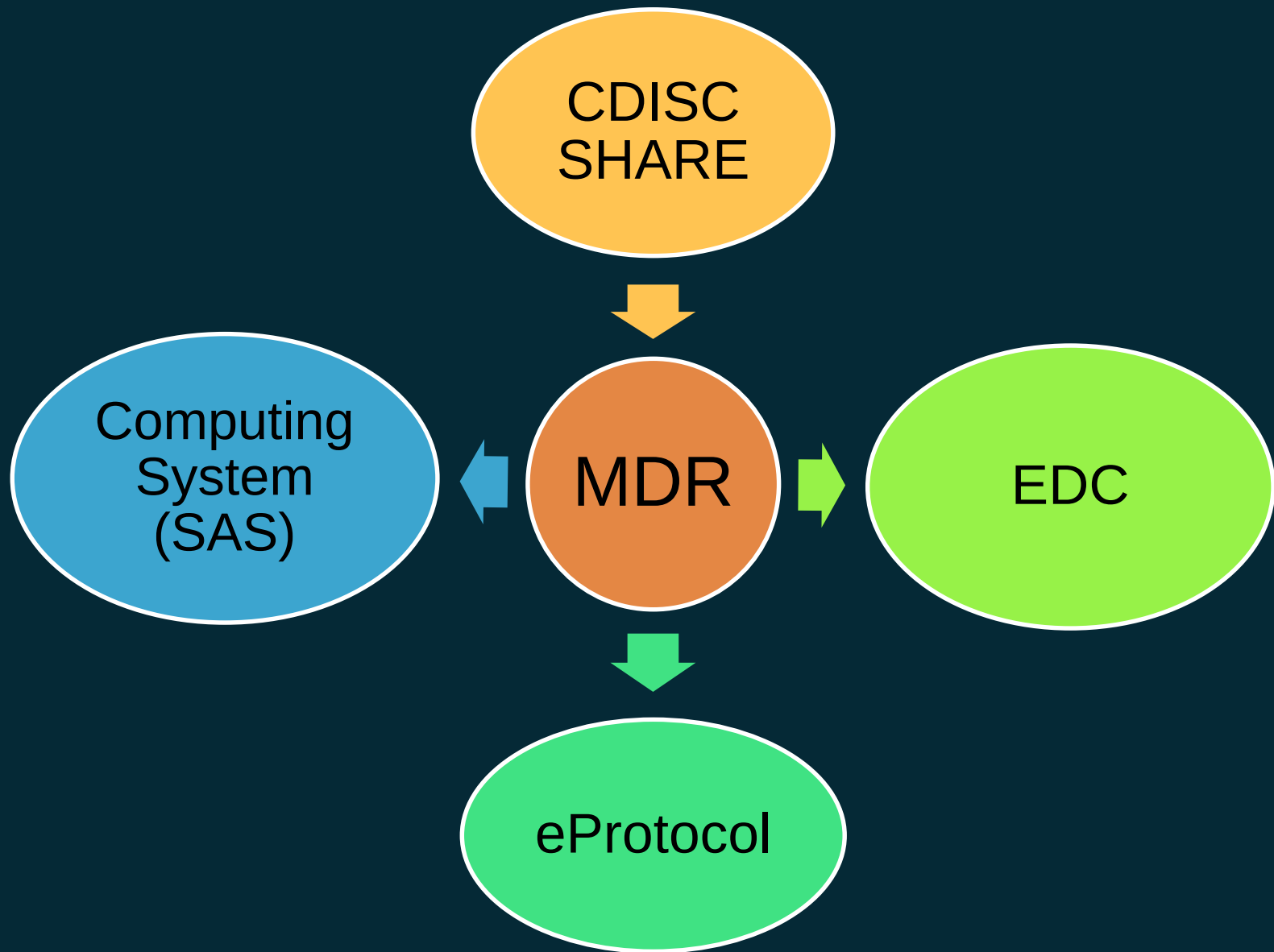


Integration with Other Systems



MDR Integration Architecture

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Change Management: Reality



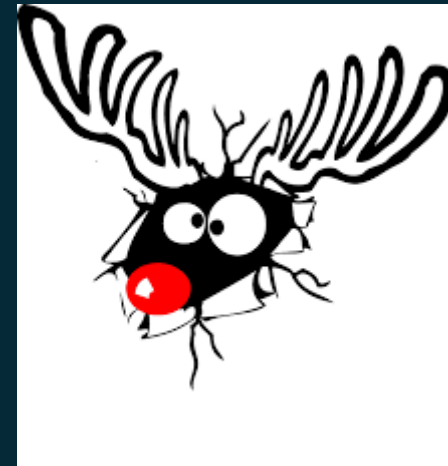
Change Management: Process



Our Selection



Final Thoughts



Rudolph the Red-Nosed Reindeer on every Christmas

Can MDR at your organization be Rudolph?

Contact Us!

Contact Clindata Insight to learn more about **MDR**:

Email us at  consulting@clindatainsight.com

klee@clindatainsight.com

WWW.LINKEDIN.COM/IN/HELLOKEVINLEE

Twitter [@clindatainsight](https://twitter.com/clindatainsight),
[@HelloKevinLee](https://twitter.com/HelloKevinLee)



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