

PHUSE Europe 2021

Stream: Data Standards & Governance (DS)

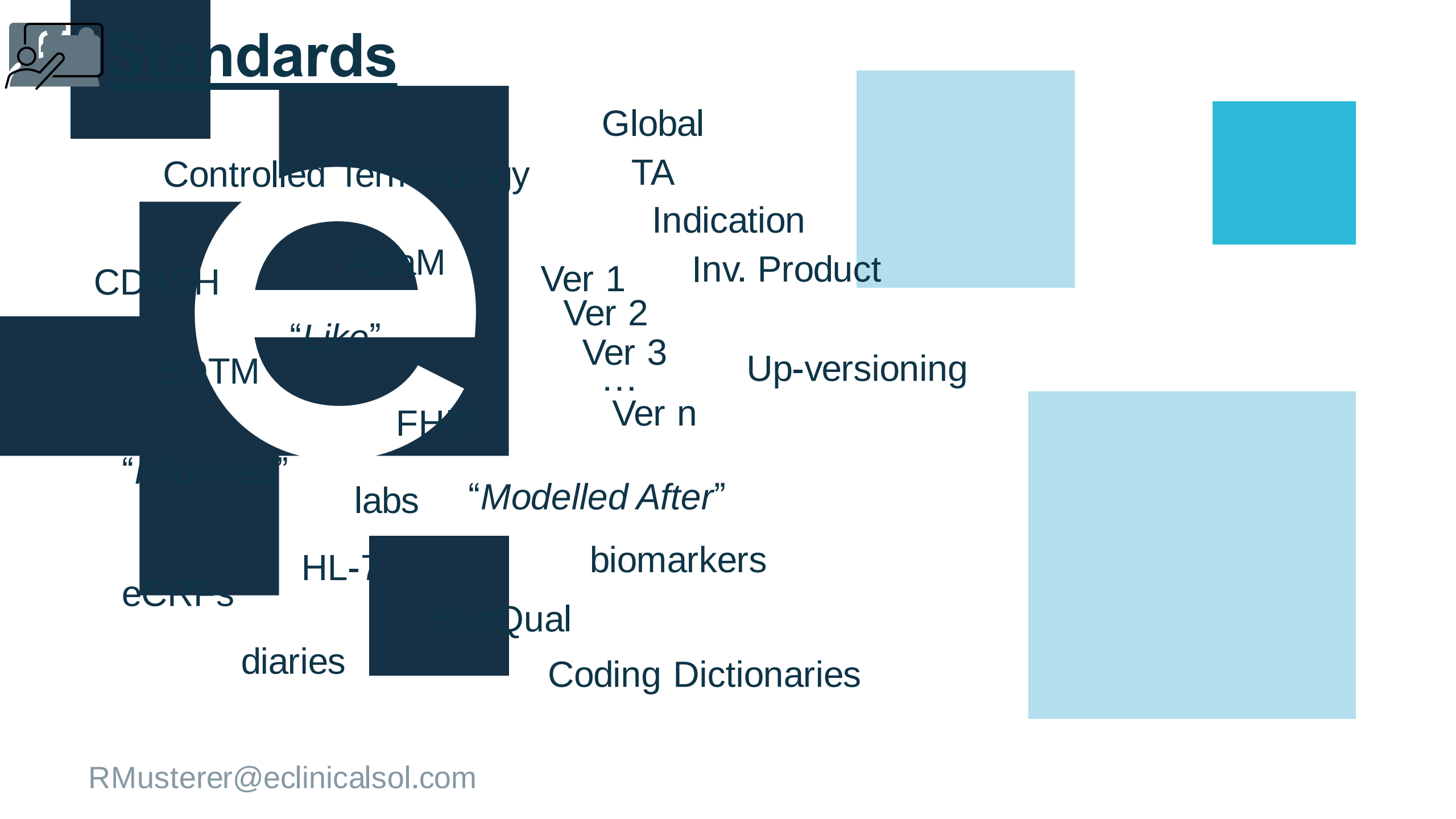
Presentation: DS01

Standards and Governed Data Clinical Data Pipeline

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Standards

Global

TA

Indication

Inv. Product

Ver 1

Ver 2

Ver 3

...
Ver n

Up-versioning

Controlled Terminology

CD

H

TM

FH

“Like”

“Modelled After”

labs

biomarkers

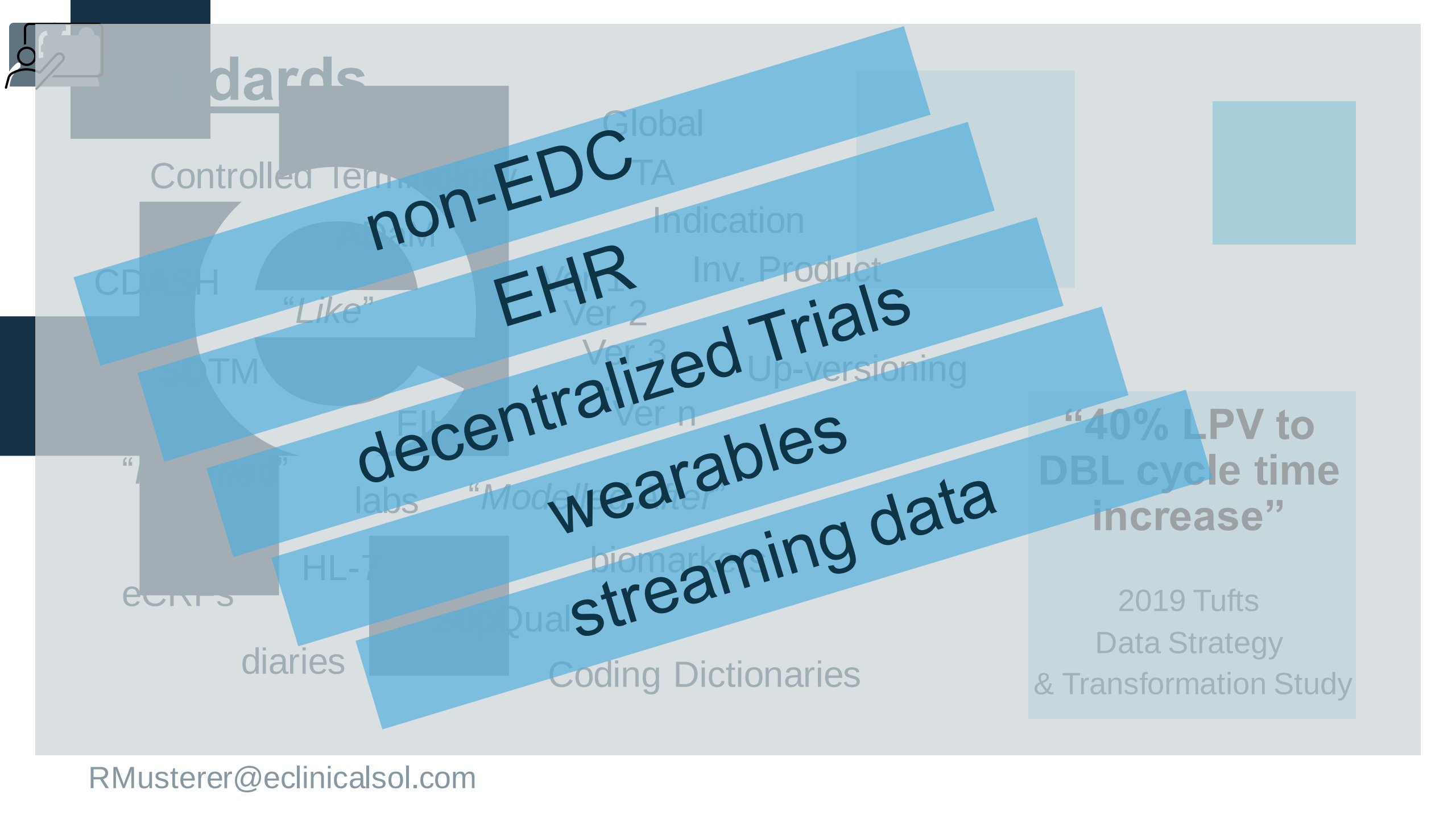
HL-7

Qual

Coding Dictionaries

diaries

eCRFs



non-EDC

EHR

decentralized Trials

wearables

streaming data

“40% LPV to
DBL cycle time
increase”

2019 Tufts
Data Strategy
& Transformation Study

Competing Forces on timelines

Data Collection Techniques
Data Processing Tools
Standards



Trial complexity
Increasing data sources
Increasing data volumes

**40% increase
in LPV to
DBL cycle time**

2019 Tufts
Data Strategy
& Transformation Study

a good process that starts at the beginning

“If you fail to plan, you’re planning to fail.”

A Data Strategy is the 1st Step in Improving:

EFFICIENCY

**ABILITY TO USE DATA TO
DRIVE DECISIONS**

OVERSIGHT

Which yields Improved:

**ABILITY GET NEW THERAPIES
TO PATIENTS SOONER**

BUSINESS BOTTOM LINE

**EASE OF MEETING
REGULATORY EXPECTATIONS**

of Plans

Integrated Data
Review Plan

Monitoring
Plan

Statistical
Analysis
Plan

Data
Management
Plan

Risk
Assessment
Categorization
Tool

Safety
Review Plan

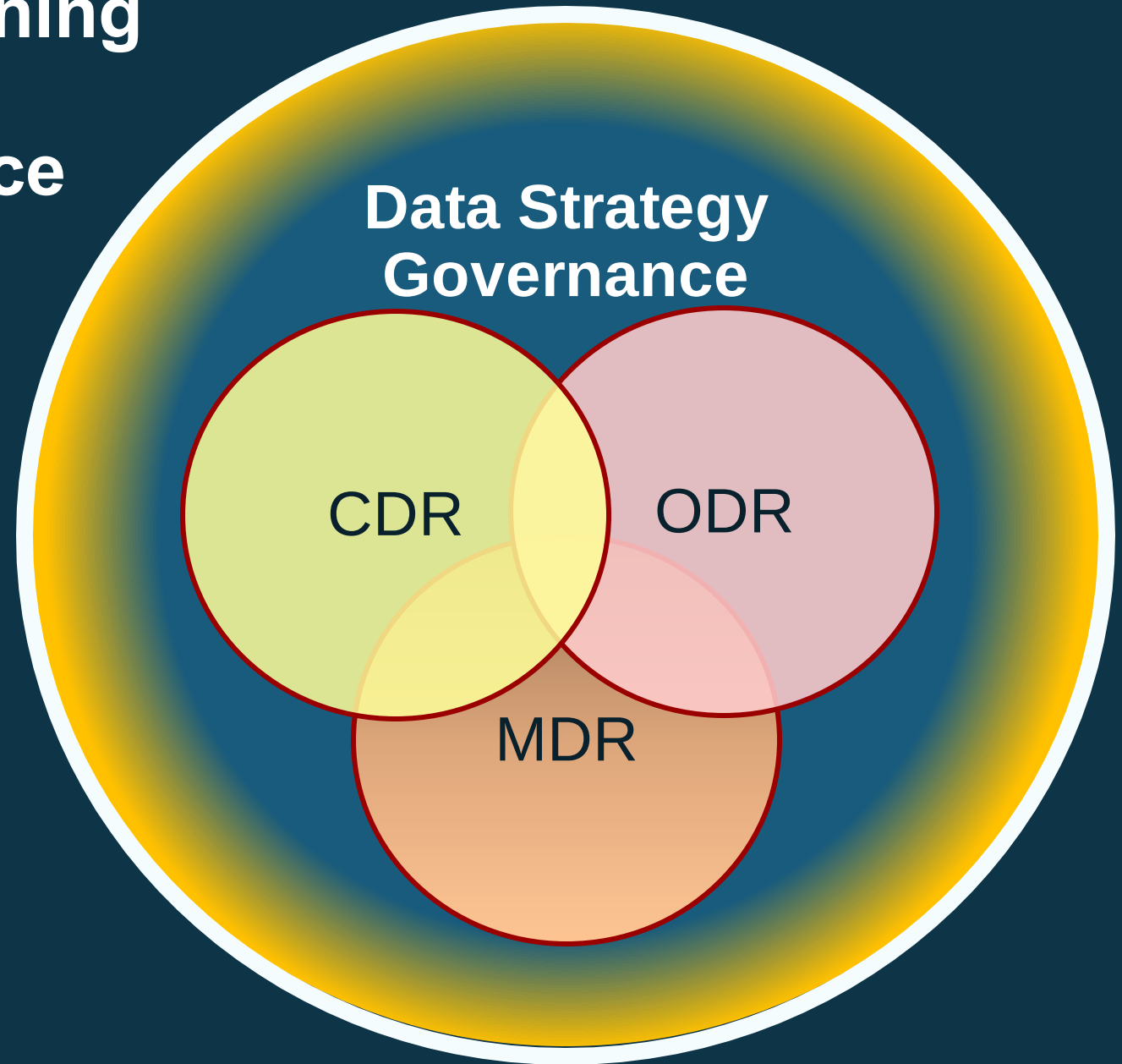
Risk Based
Monitoring
Plan

Quality
Tolerance
Limits

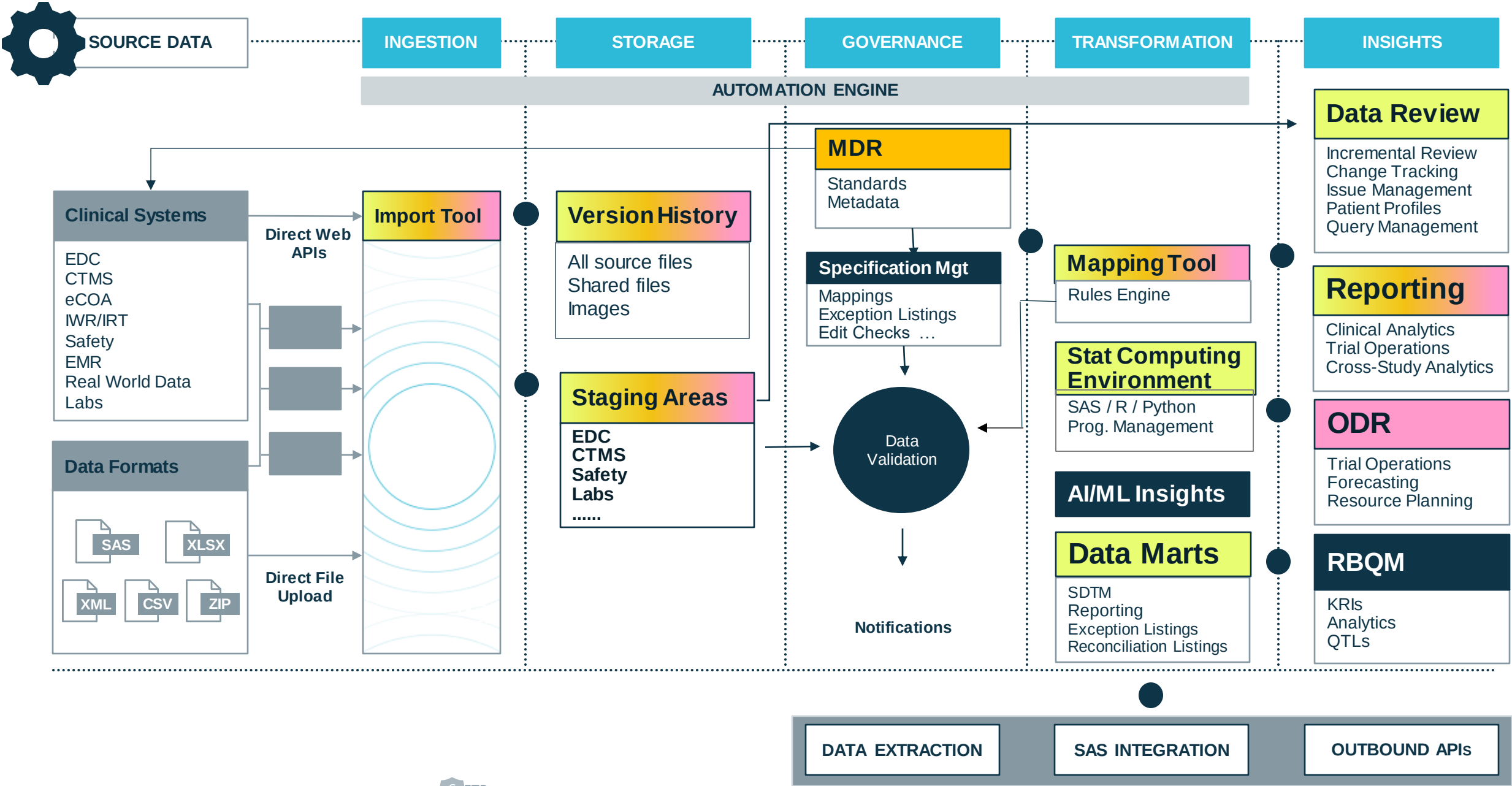
Integrated Quality
Risk Management
Plan

View of platform combining CDR, ODR, MDR Data Strategy Governance

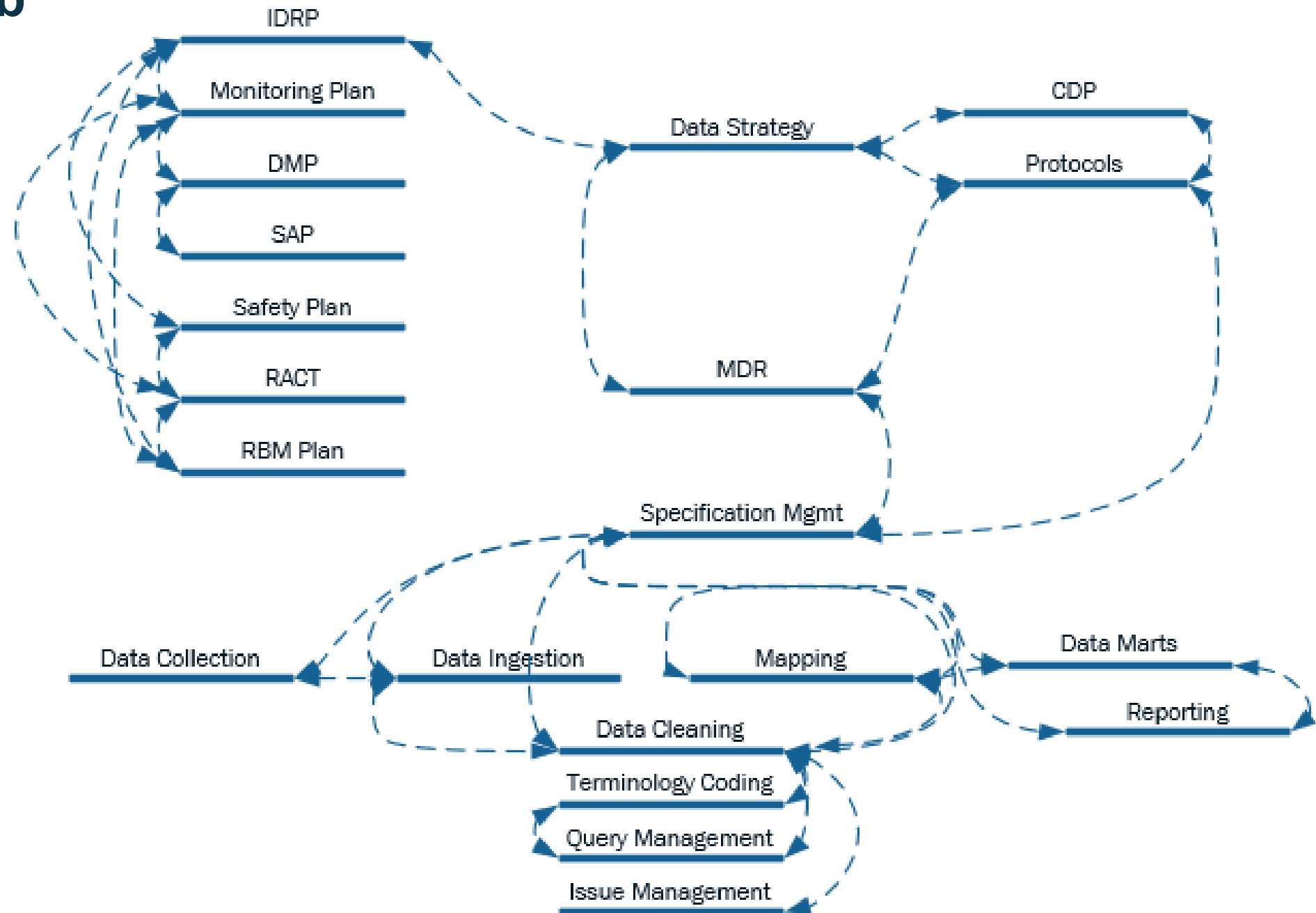
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CDR = Clinical Data Repository
ODR = Operational Data Repository
MDR = Metadata Repository



Ecosystem Web



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Thank you

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