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Single Day Event

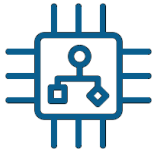
Automating with ‘MetaFication’

Syed Yusuff Hussain & Kaja Najumudeen MS,
Algorics

Metadata experience

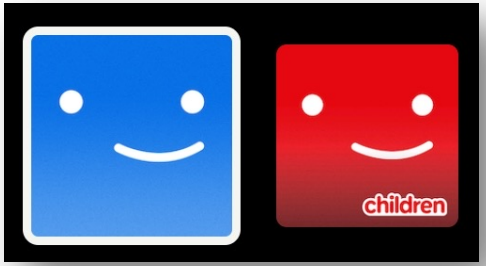
Data

Metadata



Algorithm (AI/ML)

Metadata experience



Profiles

Card Catalog

Library

Metadata evolution in clinical trial

Non-Standard

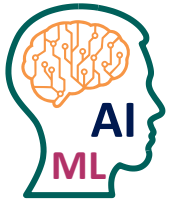
- ✓ Data pooling unrealistic
- ✓ Data clarity is deficit
- ✓ Collection, transformation
- ✓ No transparency

Corporate

- ✓ Database Metadata
- ✓ Standardized database structure
- ✓ Corporate unique
- ✓ No adequate standards

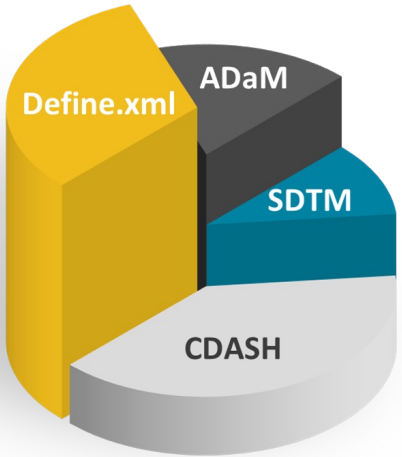
Industry

- ✓ Database Metadata standards (CDISC)
- ✓ Define.xml
- ✓ Description of data



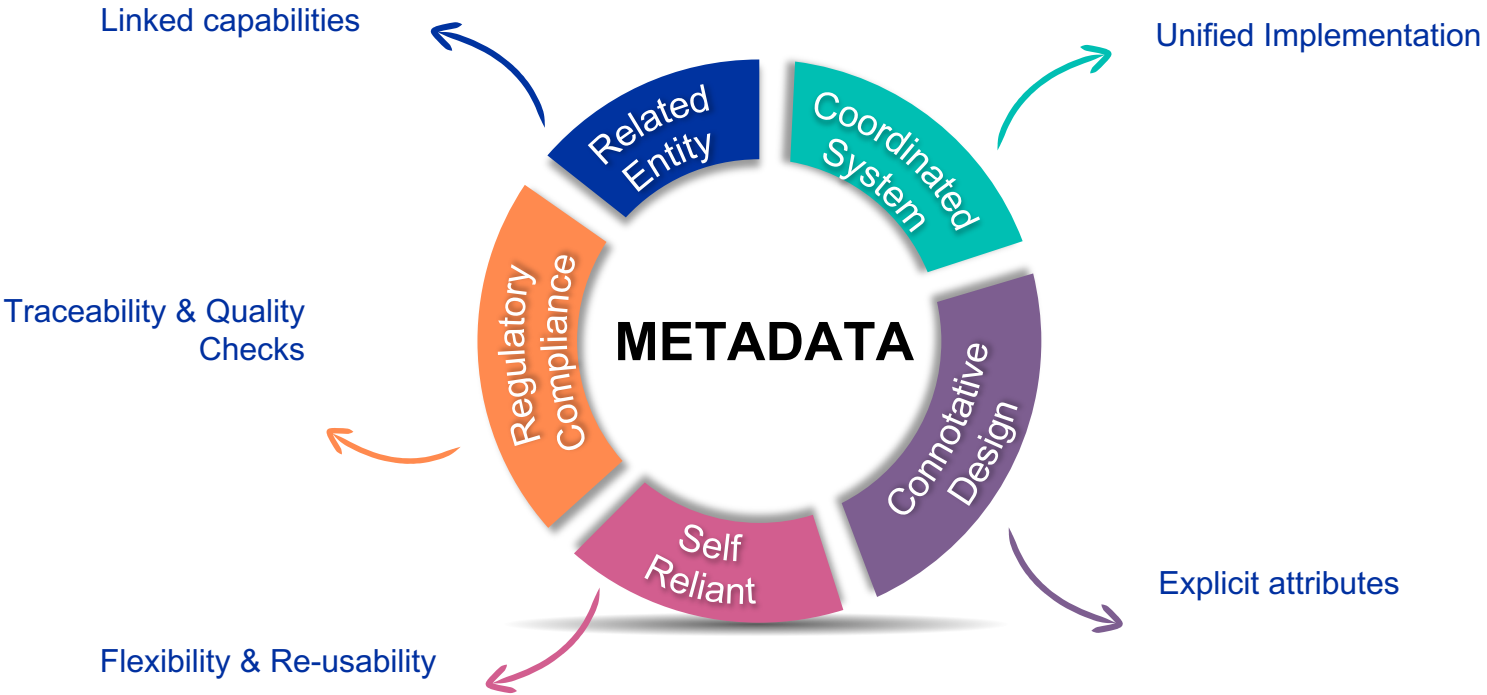
Purpose

Standard Agnostic Transformation (any standard to any standard)



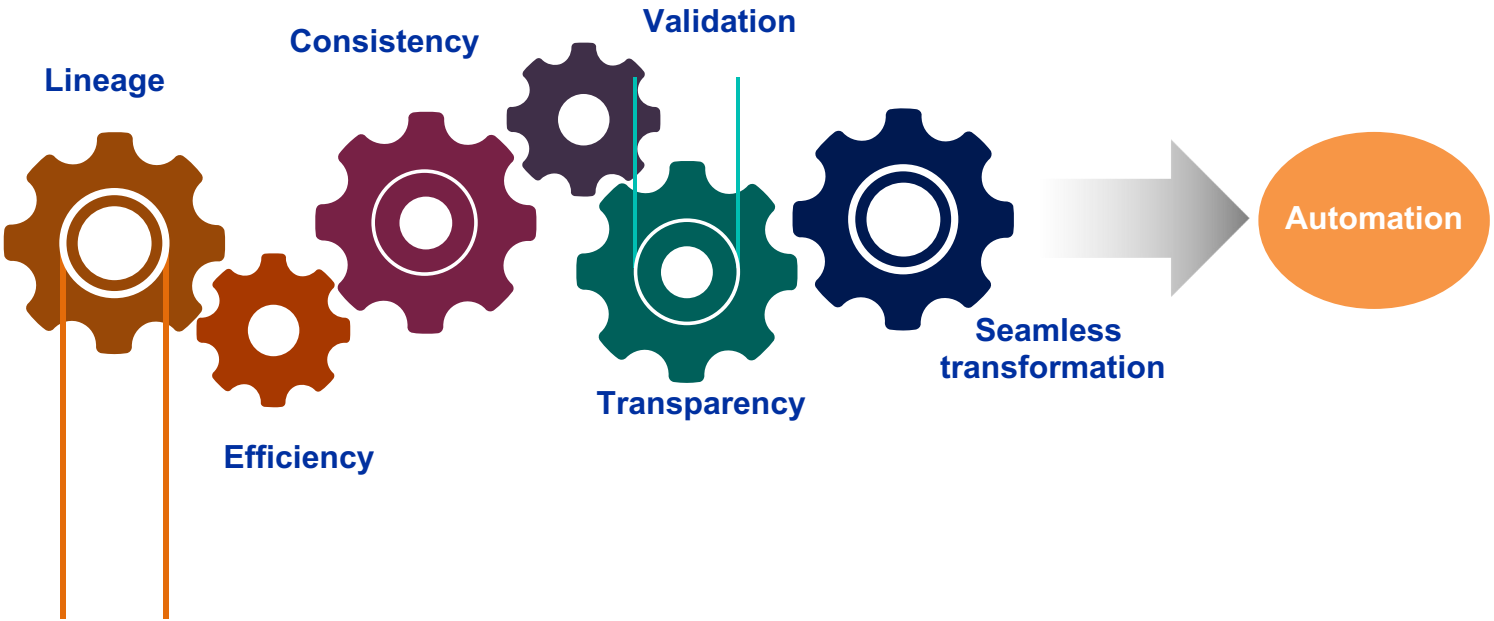
Source	Target
RAW	CDASH
RAW	SDTM
CDASH	SDTM
SDTM	ADAM
ADAM	ARM
3rd Party Data	Corporate Standards
Legacy Data	Corporate Standards

Metadata design principles



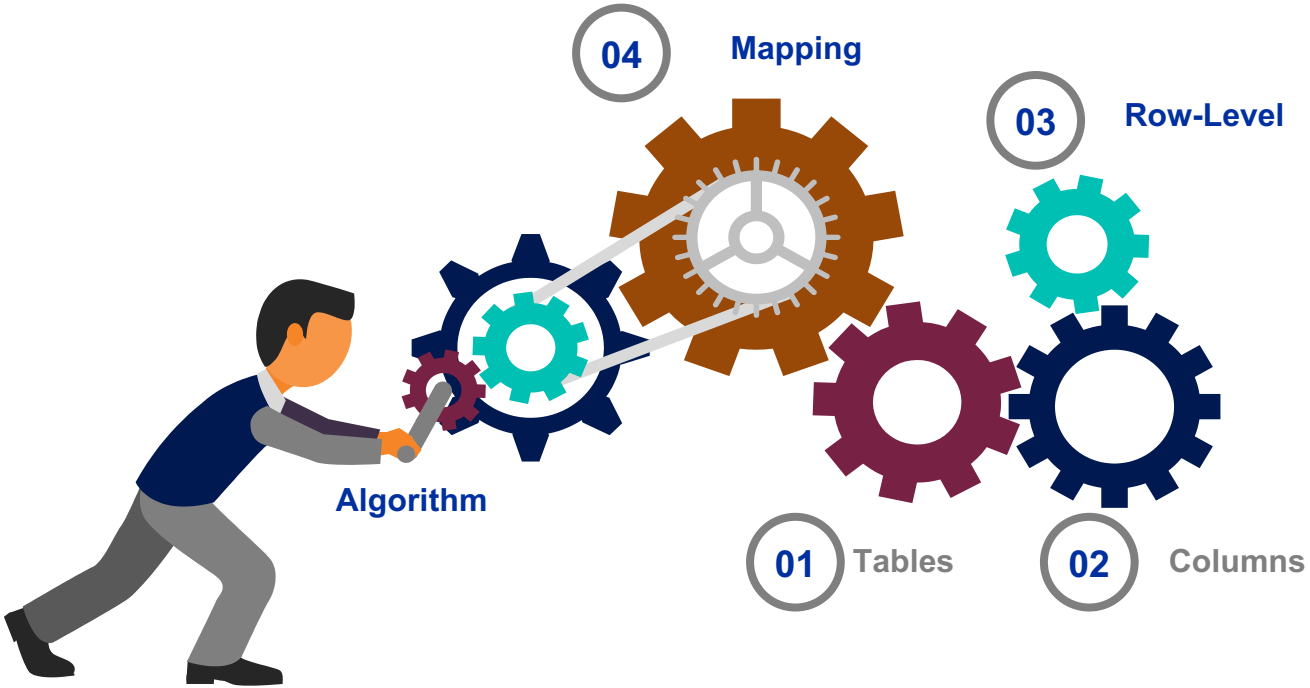
Benefits

Metadata guarantees that data are FAIR: findable, accessible, interoperable, and reusable



MetaFication mindset

Reimagine the metadata structure in four-dimensional way



1D-Tables

Class	Table	Label	Structure
Trial Design	TA	Trial Arms	One record per planned Element per Arm
Trial Design	TE	Trial Elements	One record per planned Element
Trial Design	TI	Trial Inclusion/Exclusion Criteria	One record per I/E crierion
Trial Design	TS	Trial Summary Information	One record per trial summary parameter value
Trial Design	TV	Trial Visits	One record per planned Visit per Arm
Special-Purpose	DM	Demographics	One record per subject
Special-Purpose	SE	Subject Elements	One record per planned Element per subject

2D-Columns

Table	Column	Label	Type	Length	Origin	Order	Primary Key	Values Name
DM								
DM	STUDYID	Study Identifier	C	200		1	1	
DM	DOMAIN	Domain Abbreviation	C	200		2		DOMAIN
DM	USUBJID	Unique Subject Identifier	C	200		3	2	
DM	SUBJID	Subject Identifier for the Study	C	200		4		
DM	RFSTDTC	Subject Reference Start Date/Time	C	200		5		ISO 8601
DM	RFENDTC	Subject Reference End Date/Time	C	200		6		ISO 8601
DM	RFXSTDTC	Date/Time of First Study Treatment	C	200		7		ISO 8601
DM	RFXENDTC	Date/Time of Last Study Treatment	C	200		8		ISO 8601
DM	RFICDTC	Date/Time of Informed Consent	C	200		9		ISO 8601
DM	RFPENDTC	Date/Tim rticipation	C	200		10		ISO 8601

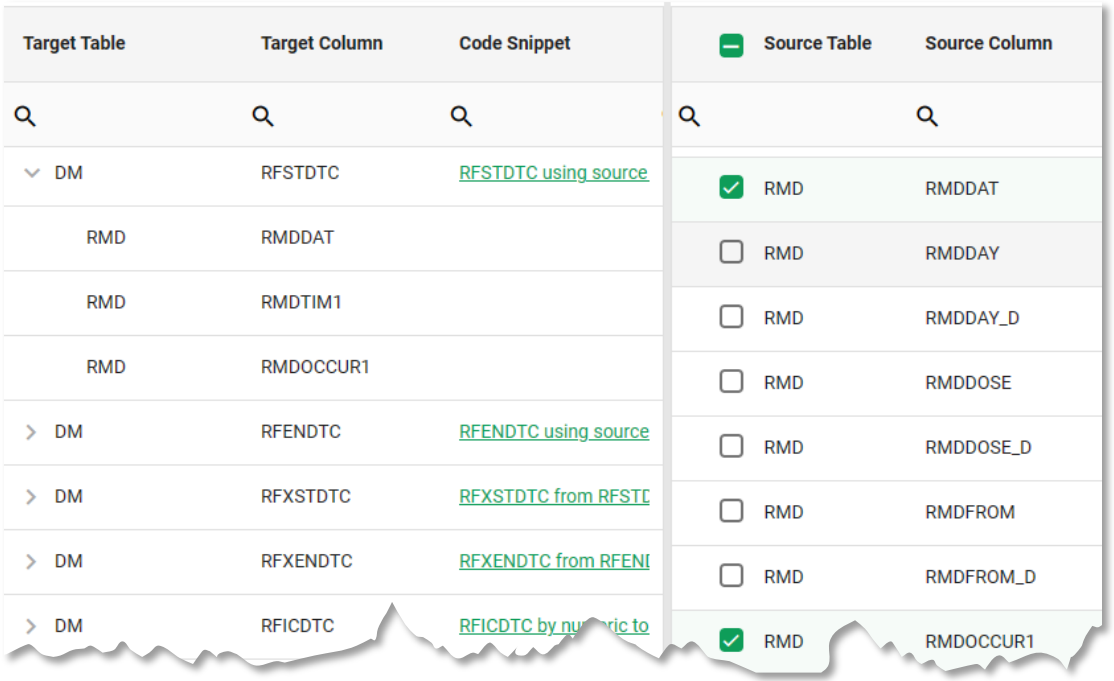
3D – Values Level / Row Level

VSTESTCD	Type	Length	Related Variable
BMI	C	200	VSORRES
BMI	C	200	VSORRESU
BMI	C	200	VSSTRESC
BMI	N	8	VSSTRESN
BMI	C	200	VSSTRESU
BMI	C	200	VS[illegible]

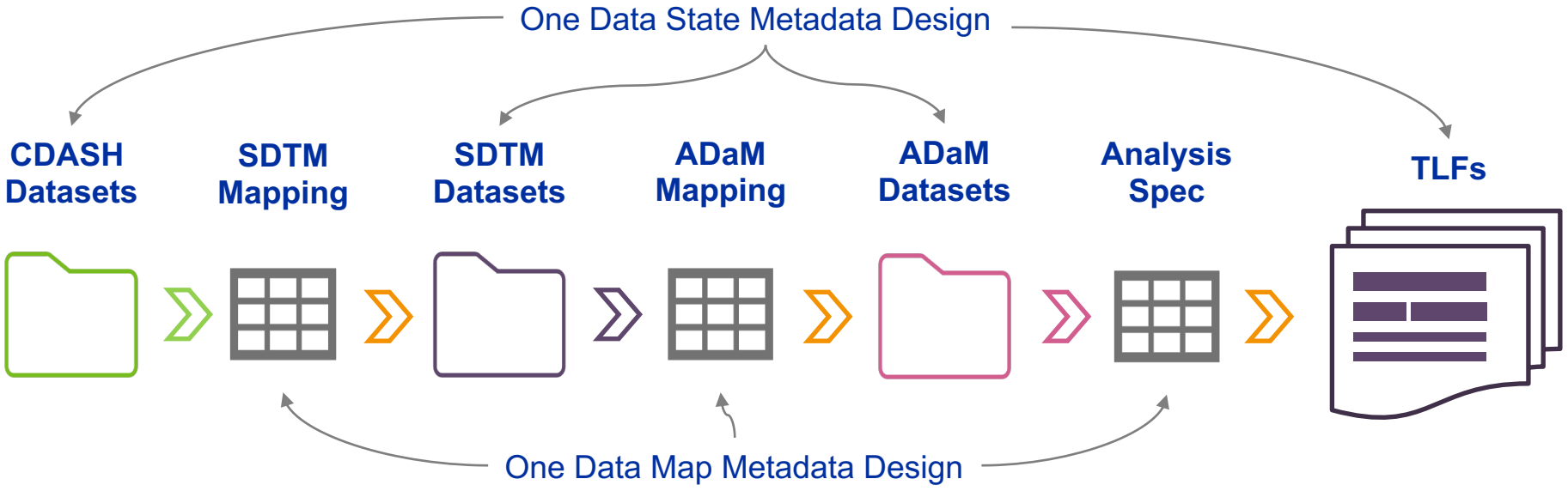
Display Selected Records

Start	Label
kg/m2	Kilogram per Square Meter

4D – Map


Target Table
Target Column
Code Snippet
Source Table
Source Column
DM
RFSTDTC
RFSTDTC using source
RMD
RMDDAT
RMD
RMDTIM1
RMD
RMDOCCUR1
DM
RFENDTC
RFENDTC using source
DM
RFXSTDTC
RFXSTDTC from RFSTD
DM
RFXENDTC
RFXENDTC from RFEND
DM
RFICDTC
RFICDTC by numeric to
RMD
RMDDAT
RMD
RMDDAY
RMD
RMDDAY_D
RMD
RMDDOSE
RMD
RMDDOSE_D
RMD
RMDFROM
RMD
RMDFROM_D
RMD
RMDOCCUR1

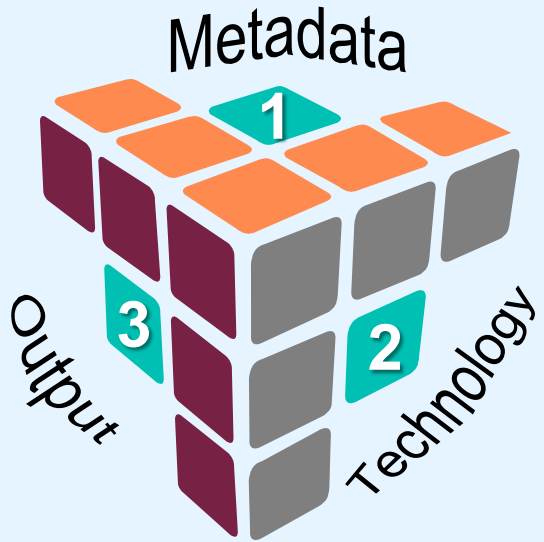
Data flow in clinical trials



Automation in clinical trials

Prescriptive

Context in metadata



Transparent

Regulatory Compliance

Flexibility

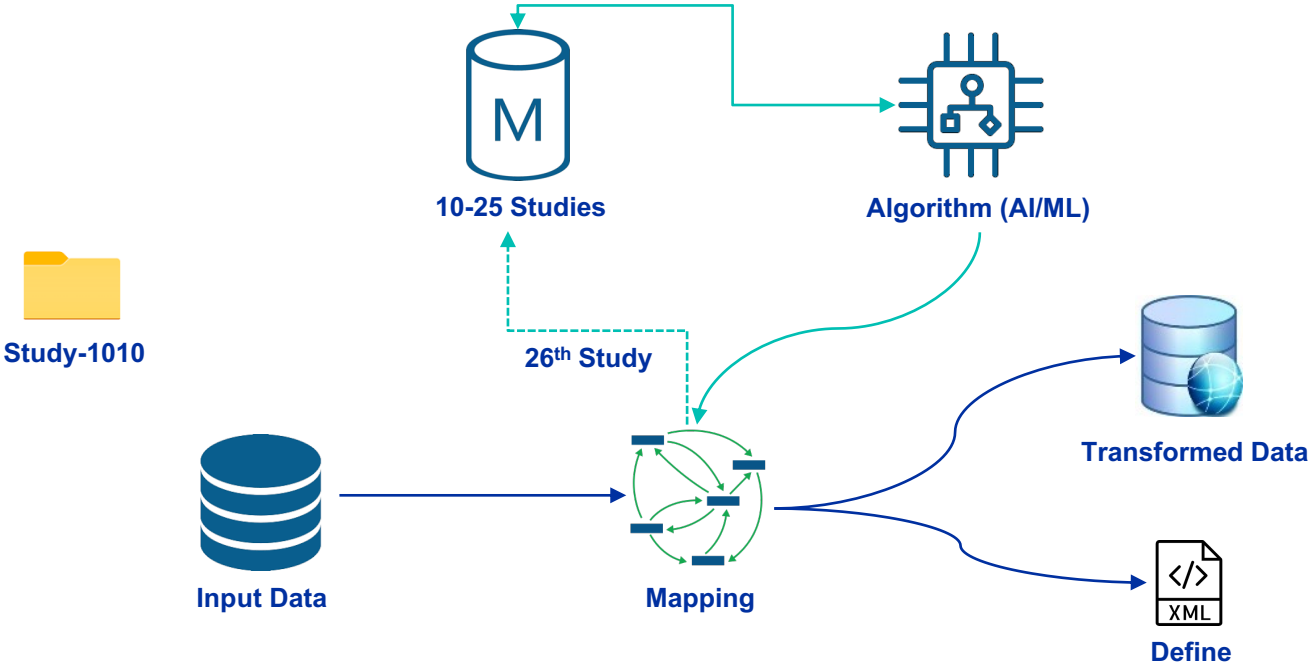
Scalability

Promulgation

Source	Target
RAW	CDASH
RAW	SDTM
CDASH	SDTM
SDTM	ADAM
ADAM	ARM
3rd Party Data	Corporate Standards
Legacy Data	Corporate Standards

Source	Target
X	Y
A	B
Any	Any

Role of AI in data standards



Thank you

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The Global Healthcare
Data Science Community

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