

# Single Day Event

Unifying Metadata Design for End-to-End  
CDISC Automation while Ensuring Compliance

Nithiya Ananthakrishnan  
Algorics

- Burgers and automation
- Metadata design framework
- Maintaining metadata compliance
- Role of AI/ML in metadata mapping
- Regulatory agency expectations
- Unified metadata design
- Benefits and scale
- Questions



BURGER BUN



KETCHUP



ONIONS



LETTUCE



PICKLES



TOMATOES



AMERICAN C



BEEF PATTY



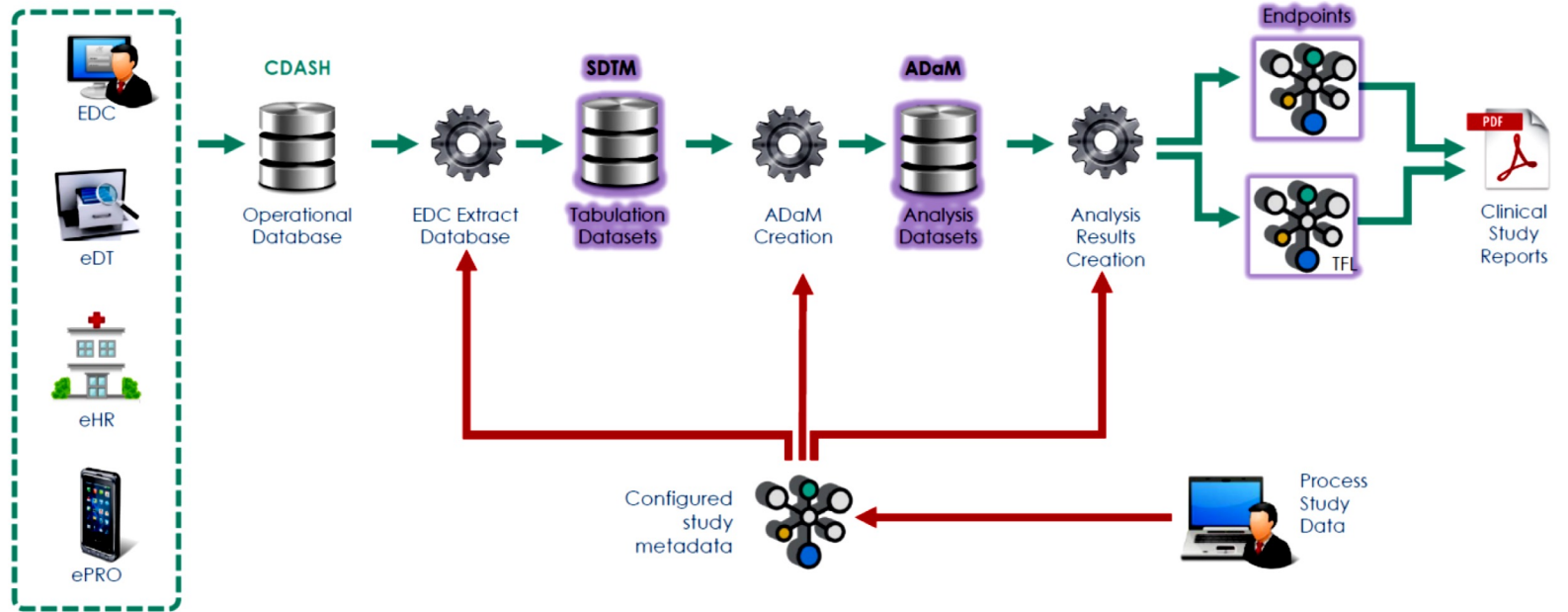
BURGER BUN

# Burgers



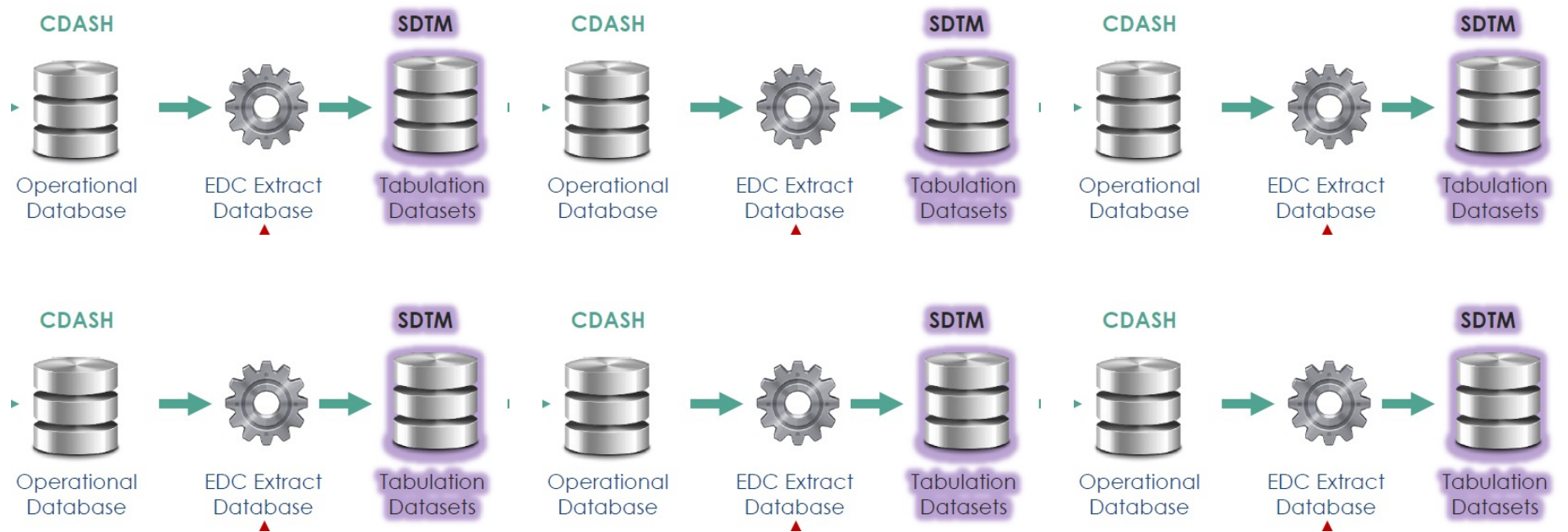
More demand – More volume

# Clinical Data flow: Source & Target

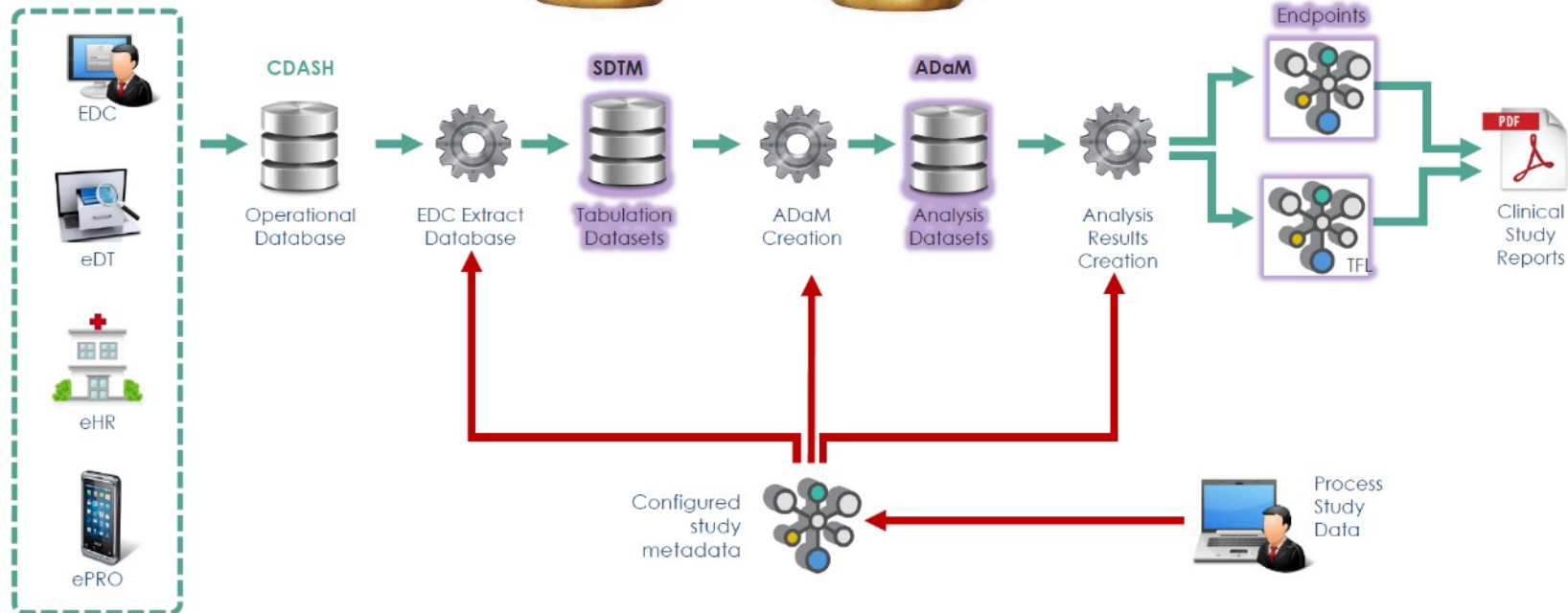


**Metadata for different data states should be scalable with consistent design and not bespoke**

# More demand – More volume



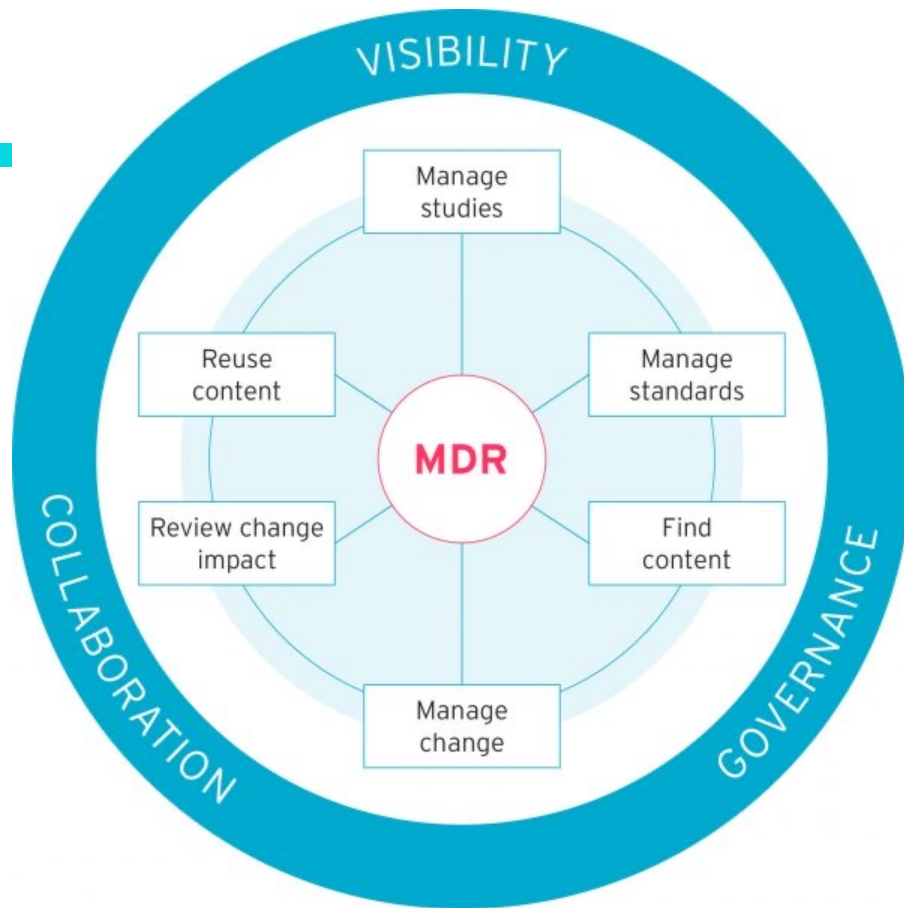
# Clinical data flow



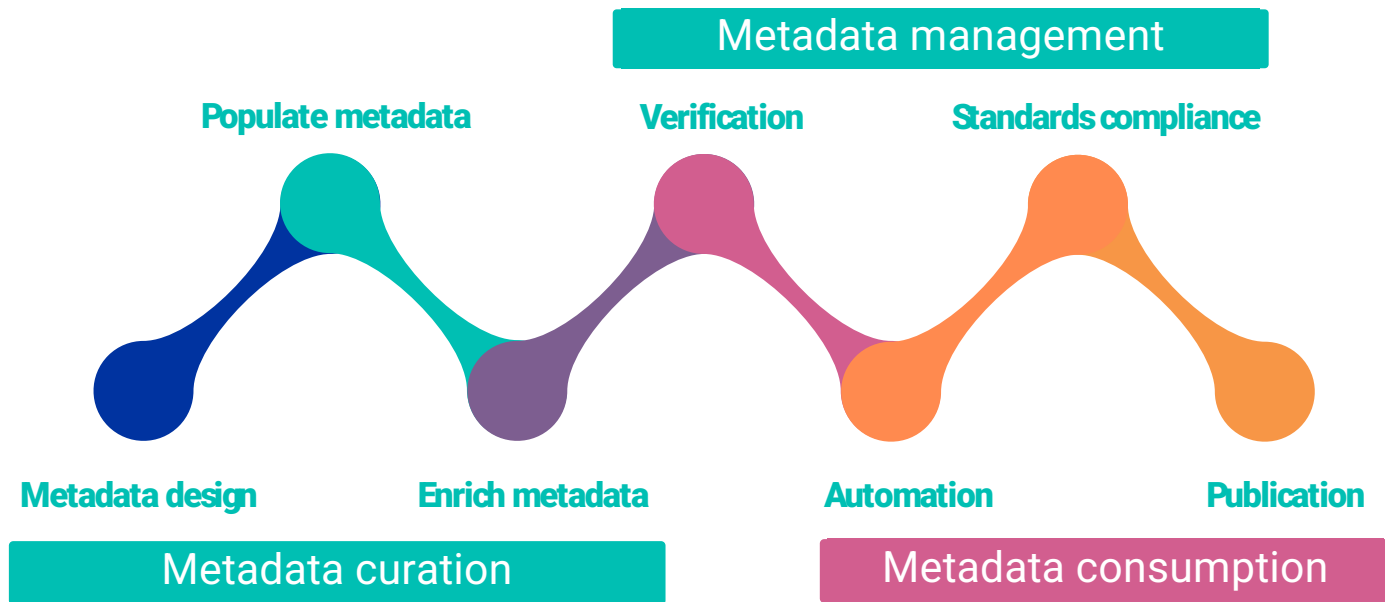


Standards Library

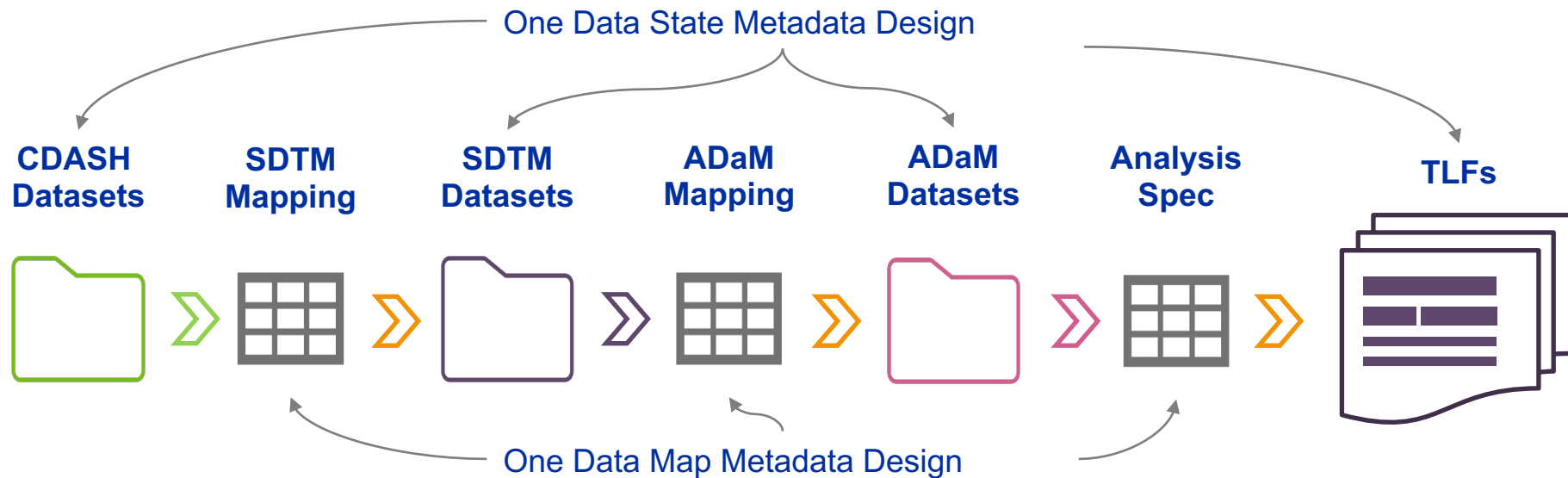
## Metadata design framework



# Metadata design framework



# Data flow in clinical trials





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# Metadata

- Source Metadata
- Target Metadata
- Map Metadata
- Coding snippets for derivation
- NCI code terminologies
- Auto mapping algorithms
- Data conformance rules



# Practical delivery challenges

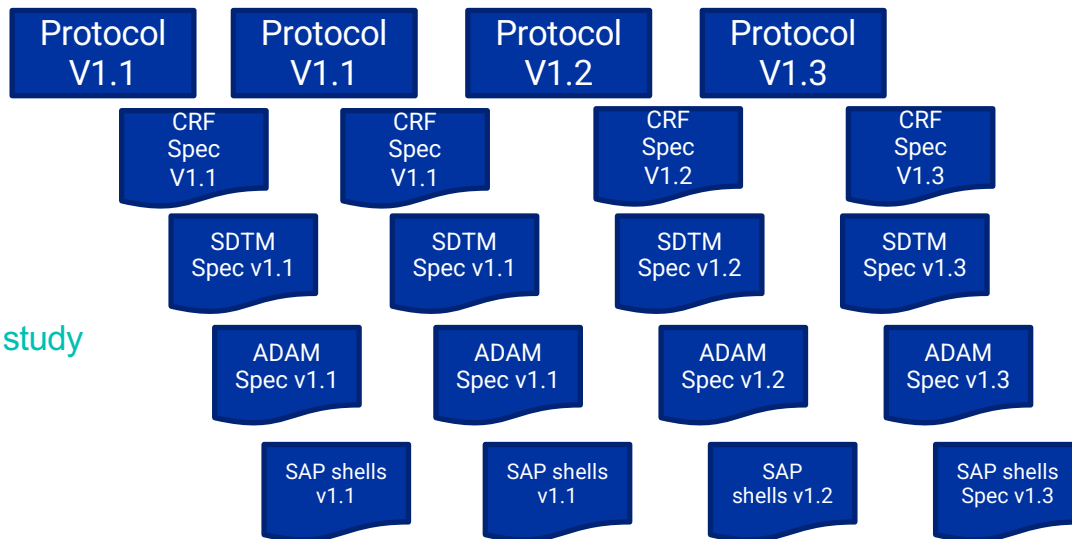
1. Protocol amendments

2. Data level issues

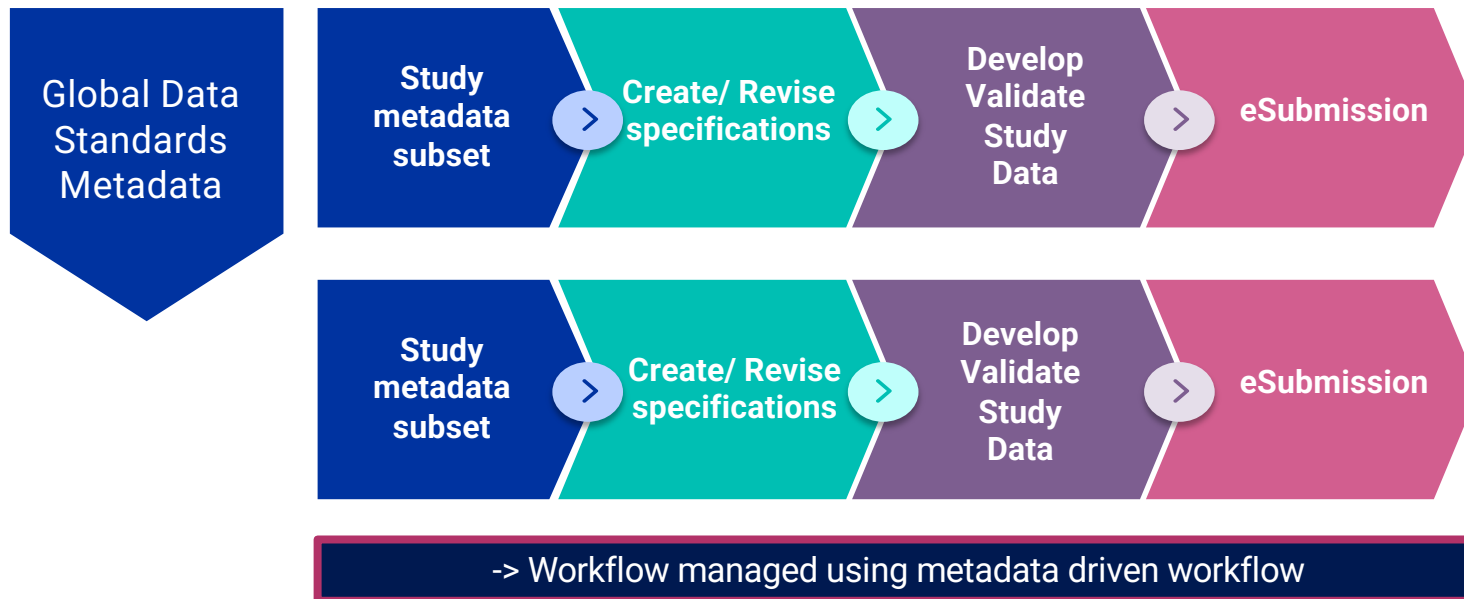
3. Resource attrition

4. Copy paste code from previous study

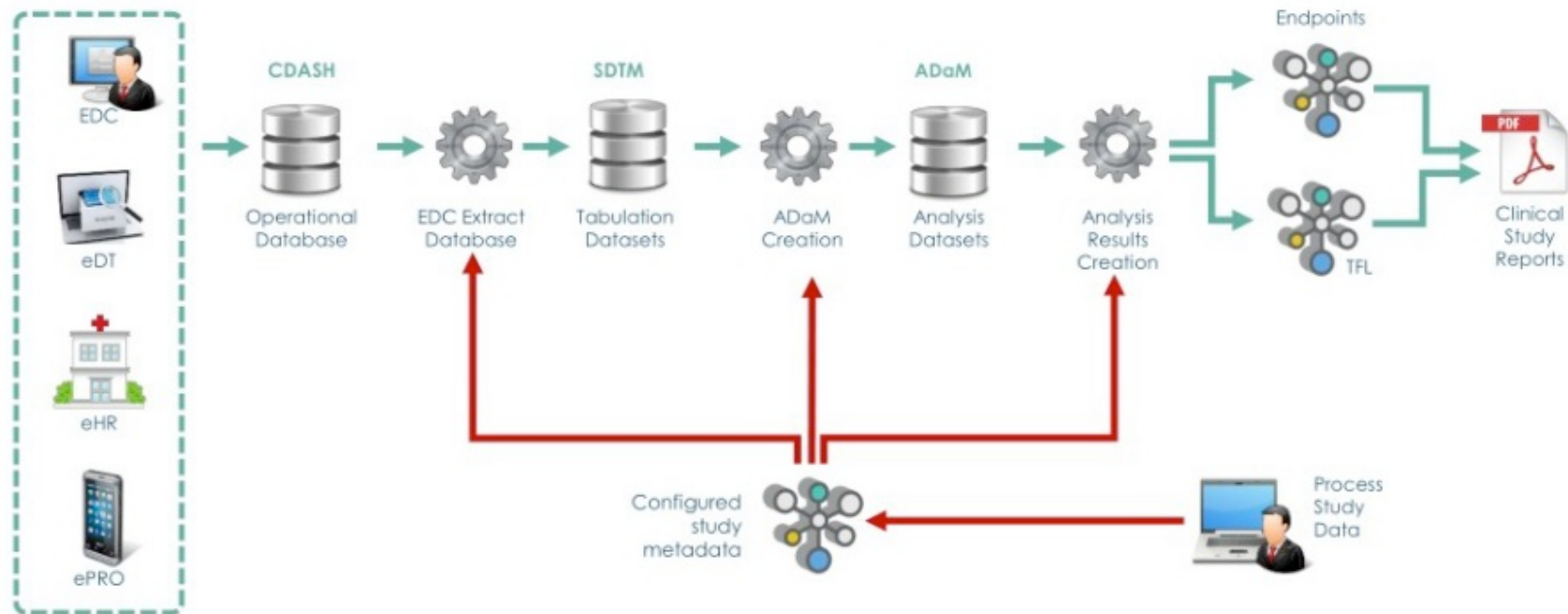
5. P21 errors with define.xml



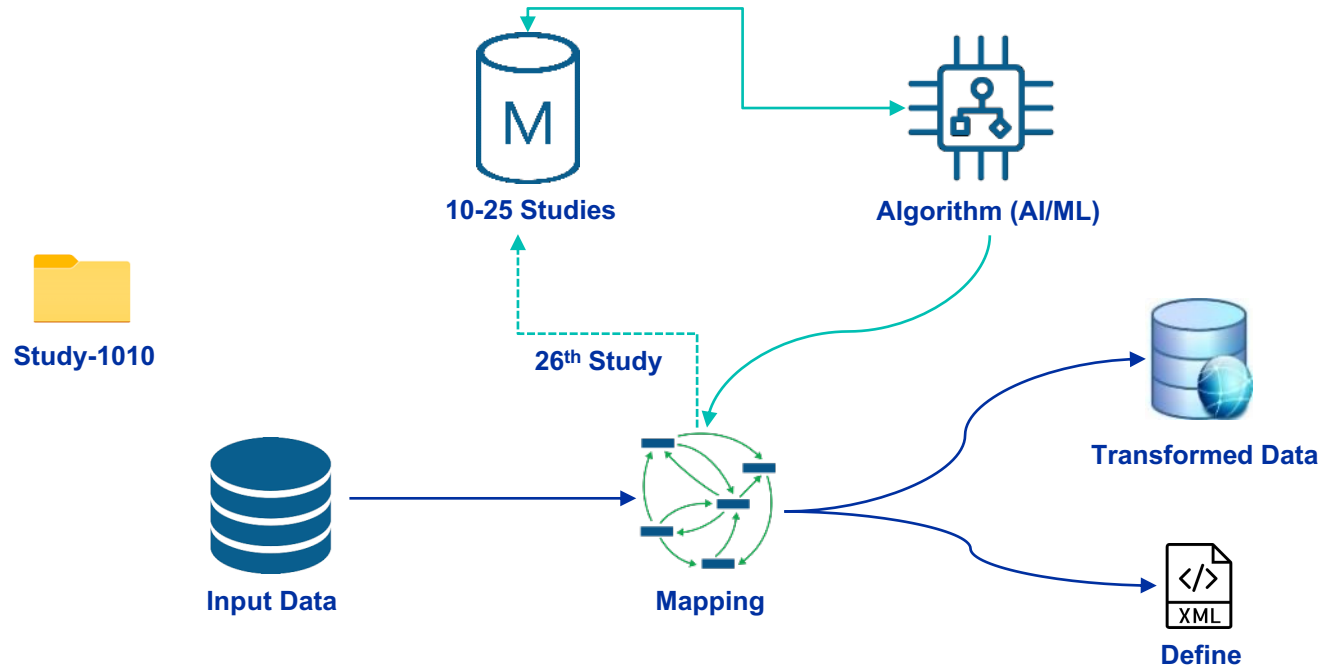
# Maintaining Metadata Compliance



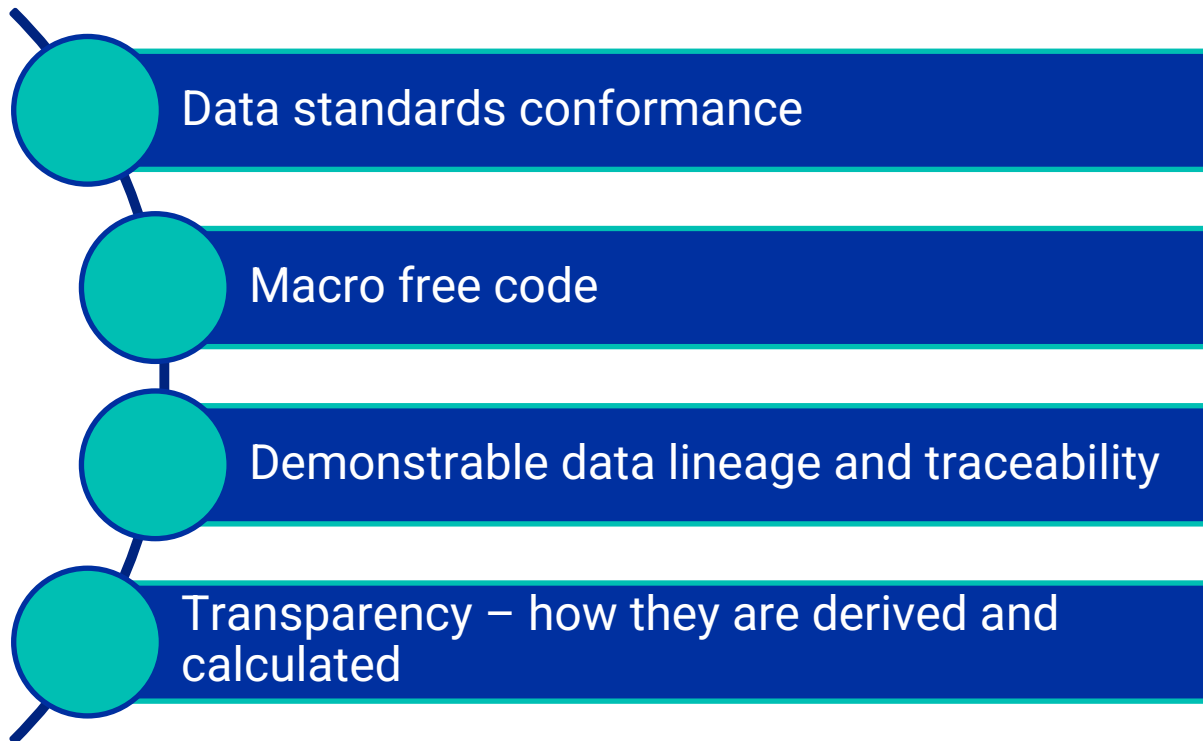
# Top-down approach for compliance



# Role of AI/ML in data standards mapping



# Regulatory expectations



# Regulatory requirements for automation

- aCRF – annotation
- Datasets compliant with CDISC standards
- Macro free SAS code
- Log file with no errors or warnings
- Define.xml generation
- Define.xml validation
- Data reviewers guide



**U.S. FOOD & DRUG**  
ADMINISTRATION



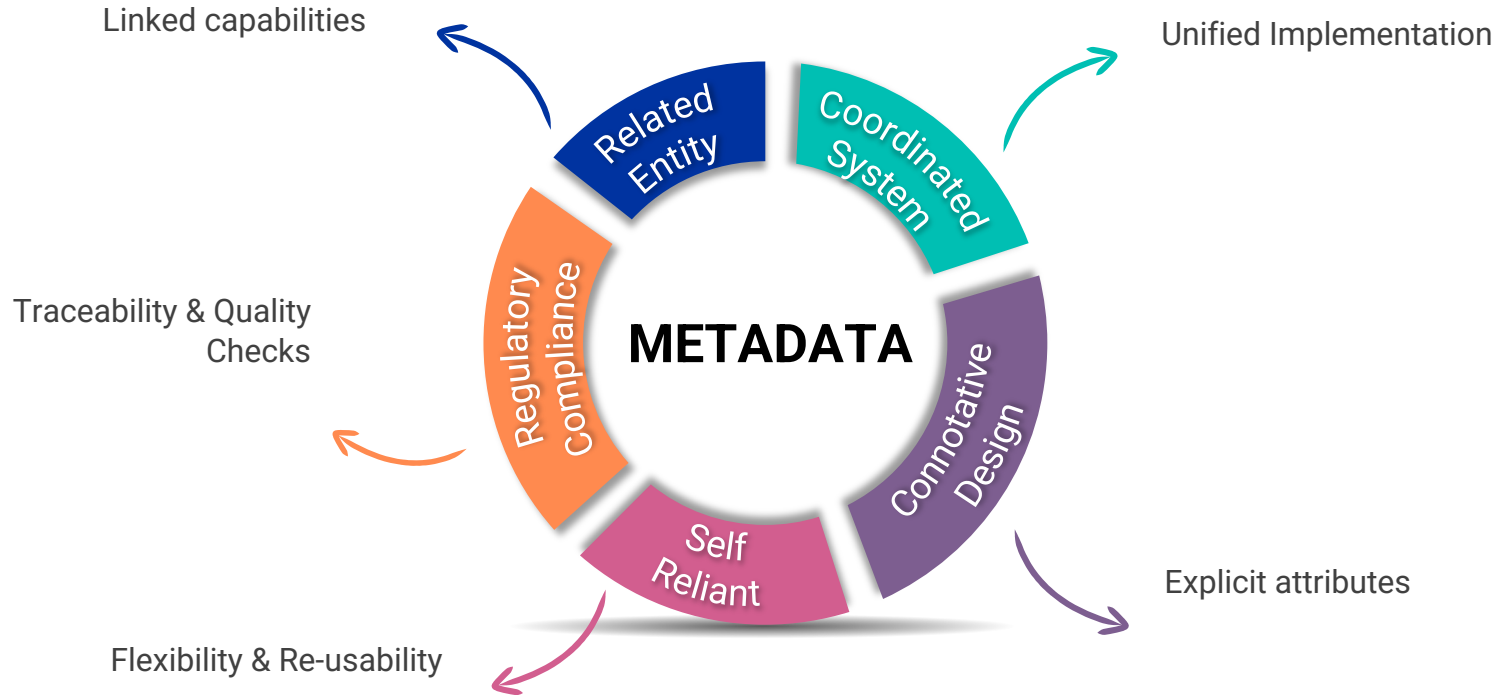
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独立行政法人 医薬品医療機器総合機構  
Pharmaceuticals and Medical Devices Agency



# Metadata Design Principles





# Customer requirements

## Combo

- Burger
- Coke
- French fries



# Unified design model



Ujn f !ò!Sf qf bubcrf!n pef r!psu f sl  
epn bjot

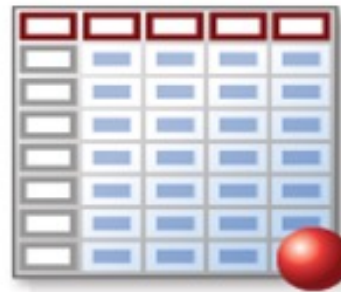


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rht t !sf t pvsdf t !!



Rvb!nz!ò!Qsf ejdubcrf!dpot jt uf odz!cz!  
n f ubeblt vct dsjqjpo!

- Source Metadata
- Target Metadata
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| Source | Target |
|--------|--------|
| RAW    | CDASH  |
| RAW    | SDTM   |
| CDASH  | SDTM   |
| SDTM   | ADAM   |
| ADAM   | ARM    |

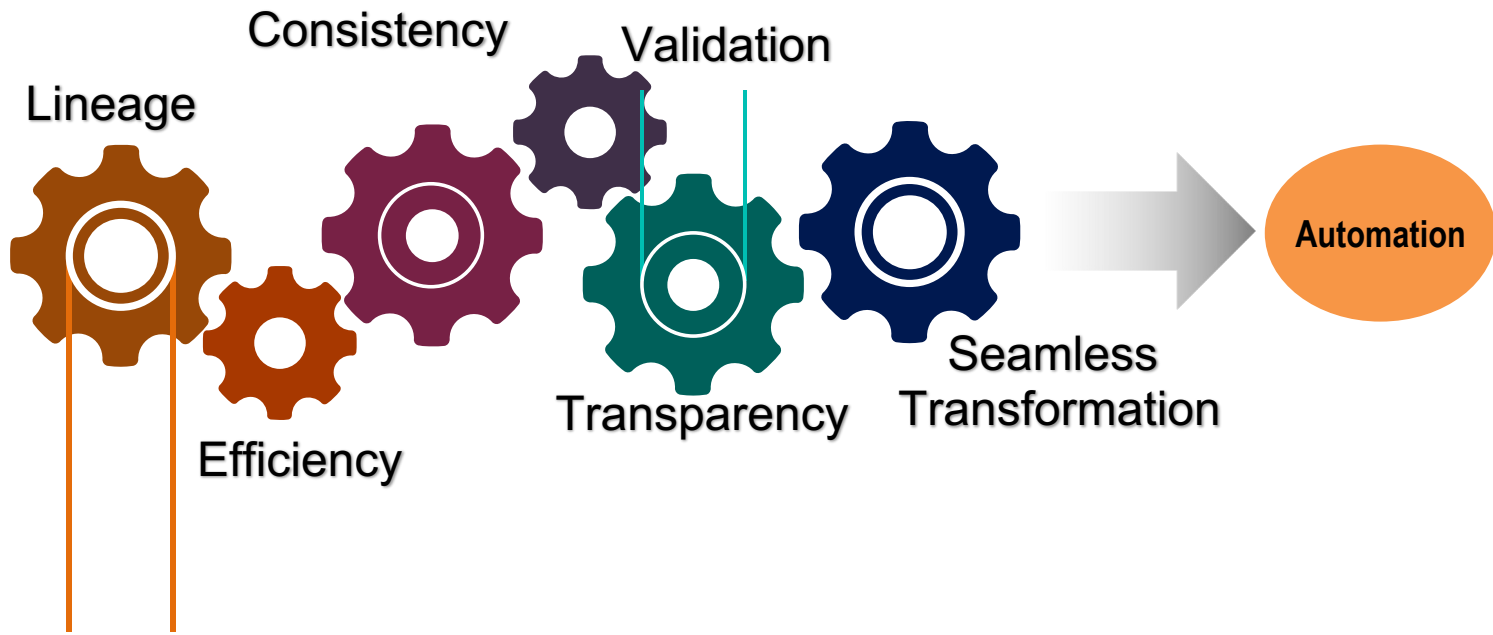
# Scalability - Flavors and Variations



| Source                     | Target                   |
|----------------------------|--------------------------|
| 3 <sup>rd</sup> Party Data | Corporate Standards/SDTM |
| Legacy Data                | Corporate Standards/SDTM |



# Benefits of unified design model







# Burgers and Metadata

**Question: Can you apply the analogy of a burger and metadata elements?**

Response: Certainly! Here's the food analogy with a burger and metadata:

Metadata is like the toppings and condiments on a burger. While the patty and bun are the main components of a burger, the toppings and condiments enhance the taste, texture, and overall experience. In the same way, metadata complements and enriches the data.

Imagine a juicy burger with a perfectly grilled patty and a soft bun as the data itself. It's satisfying on its own, but when you start adding slices of cheese, lettuce, tomato, onions, pickles, and your favorite sauces, the burger becomes even more flavorful and personalized. These toppings and condiments provide additional information about the burger, just as metadata provides additional information about data.

Metadata can include attributes such as the file format, file size, date created, author, keywords, and descriptive tags associated with a document or file. Similar to how the toppings and condiments add layers of taste, texture, and visual appeal to a burger, metadata adds layers of information and context to the data, making it easier to search, categorize, and understand.

Whether it's organizing a file system, improving search functionality, or ensuring data integrity, metadata acts as the "toppings" that enhance the data's value and usability. Just as you can customize your burger with different condiments to suit your preferences, metadata allows you to customize and optimize data management according to specific needs and requirements.

# Thank you

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