

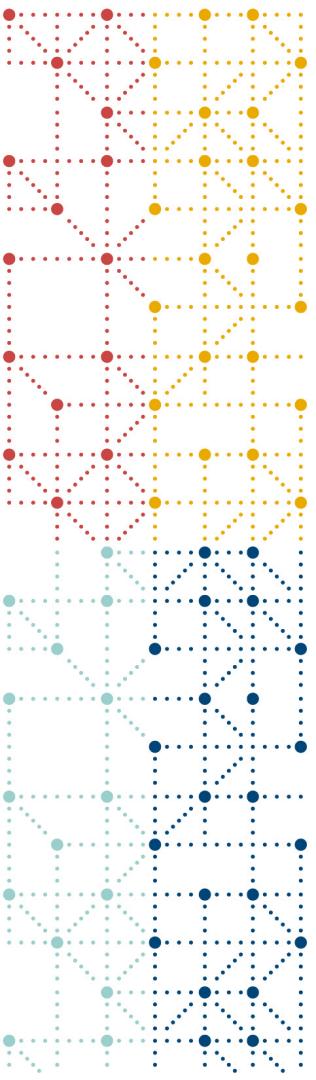
# What is CDISC 360: an enterprise architecture perspective

Sam Hume, DSc - VP, Data Science, CDISC

Tianna Umann – Cross Domain Solution Architect, Microsoft

28 April 2020



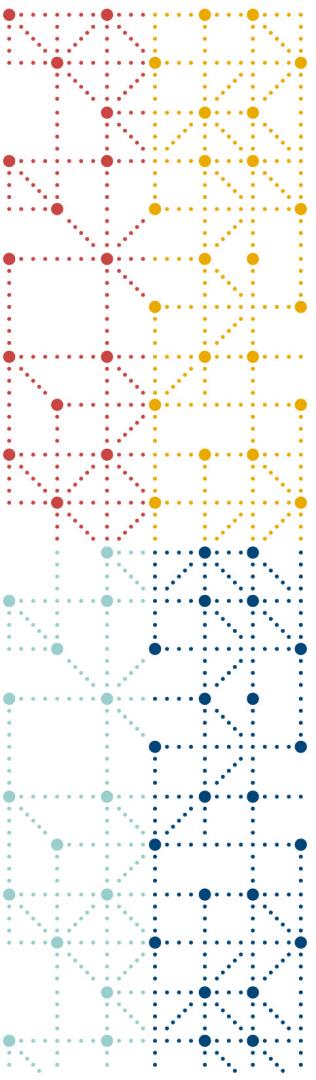


Business

Metadata

Application

Technology

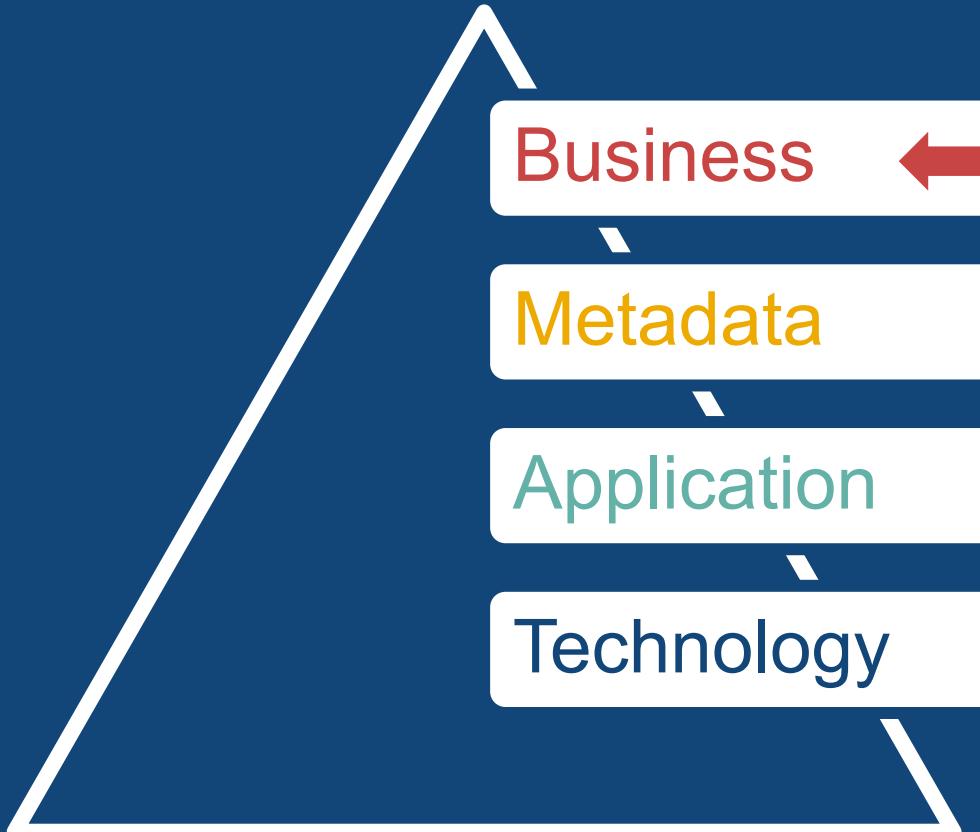


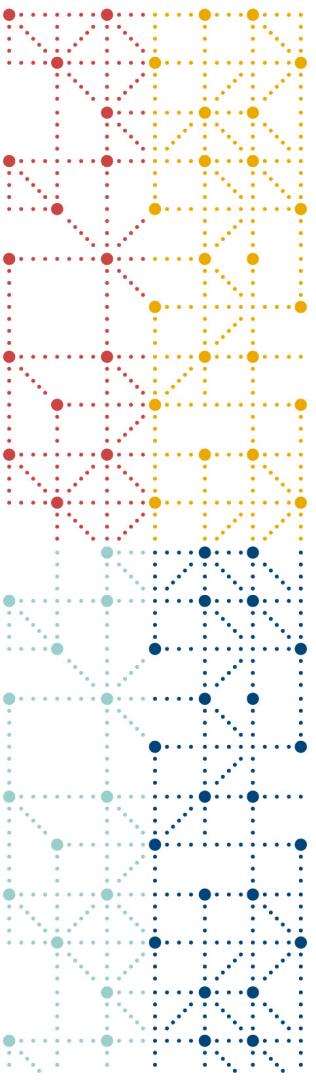
Business

Metadata

Application

Technology



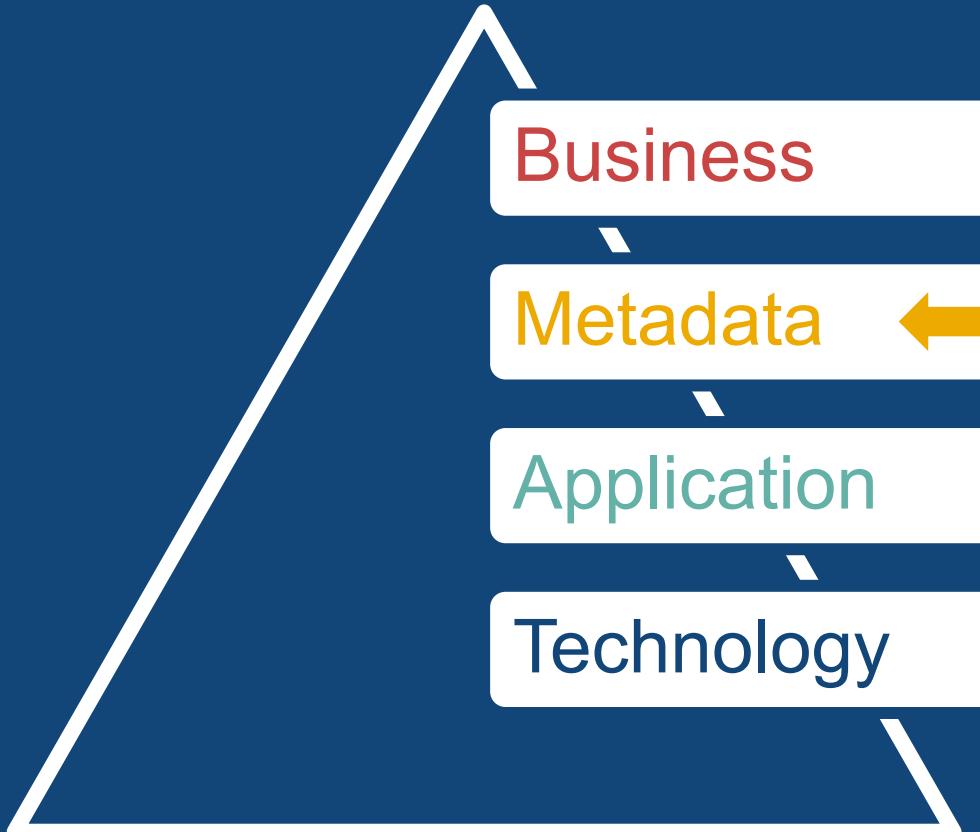


Business

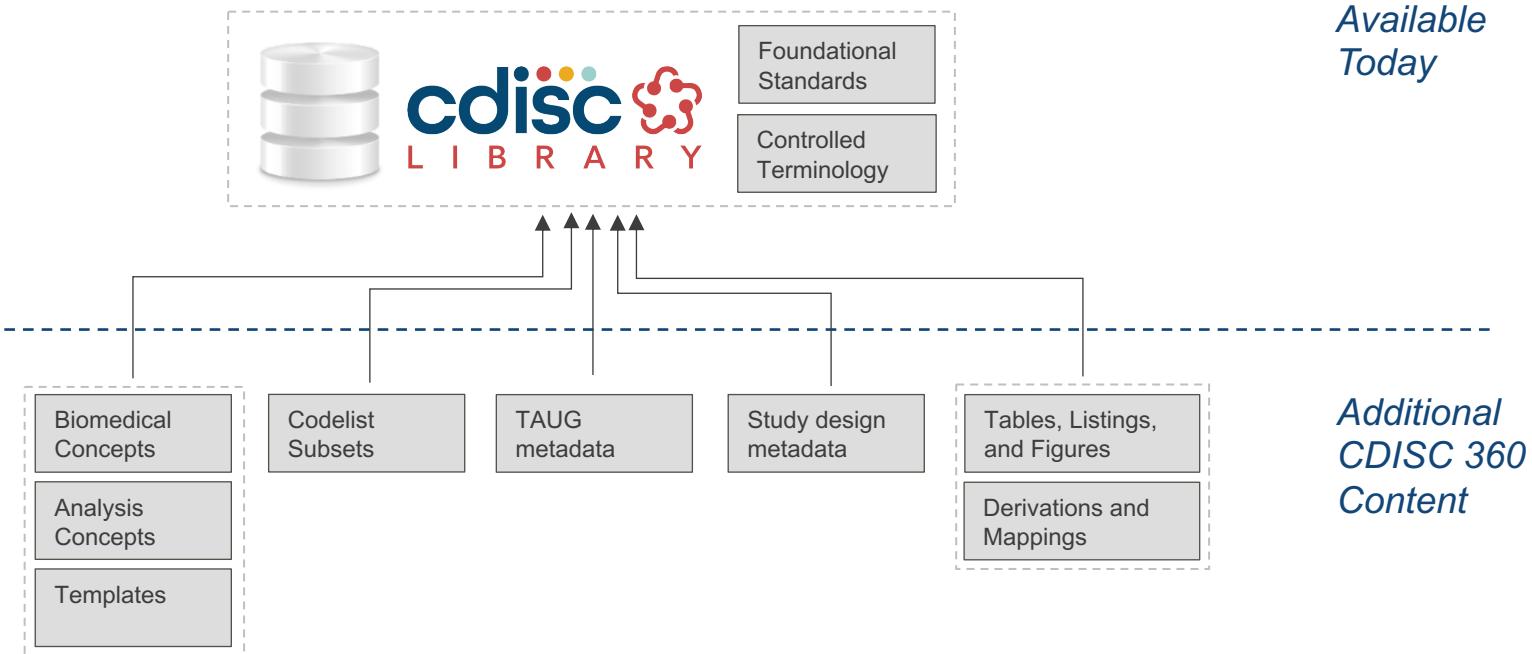
Metadata

Application

Technology



# CDISC 360 Metadata Inventory



# CDISC 360 Perspective 1: Metadata Flow within the Project



*Enhance  
Standards*

*Publish  
Standards*

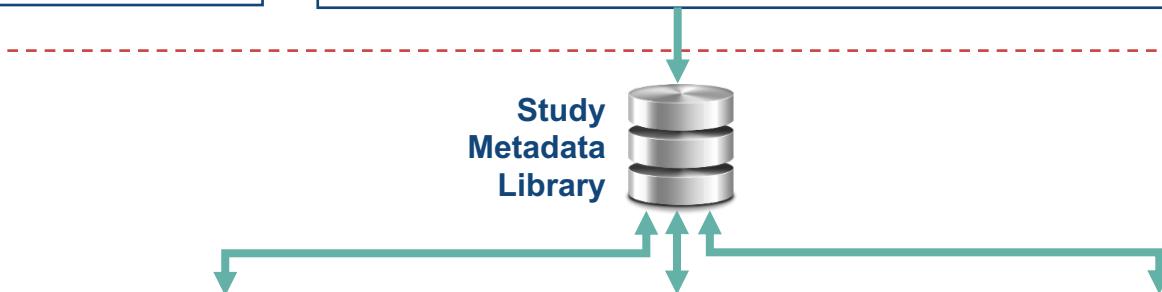
Study  
Metadata  
Library



*Define*

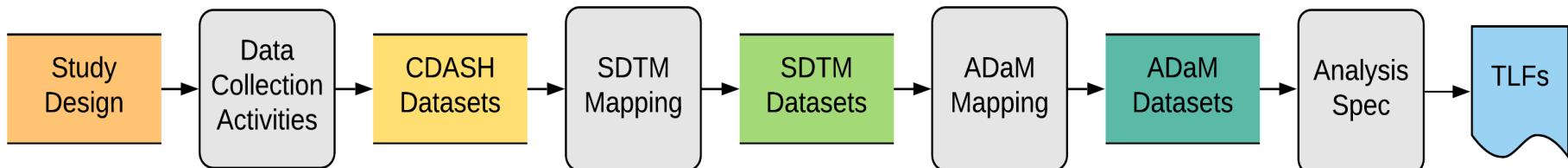
*Build*

*Execute*



# CDISC 360 Perspective 2: End-to-end Data Flow

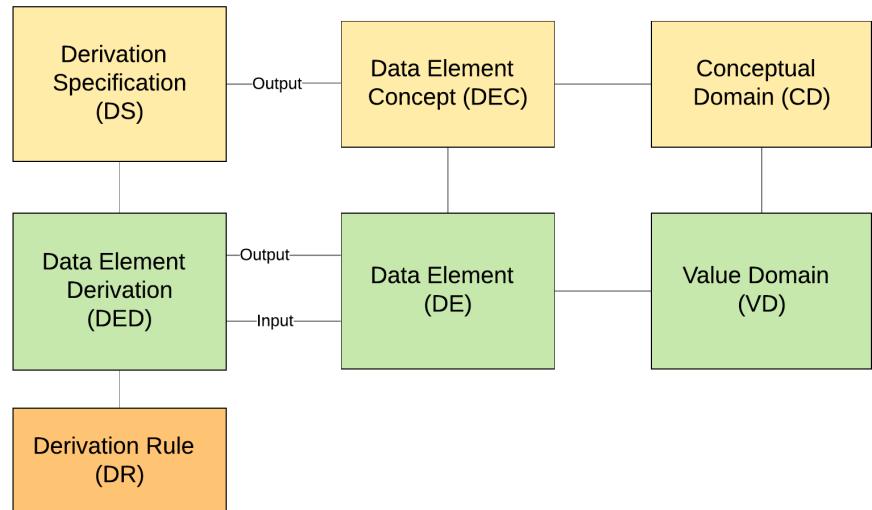
Data Flow Diagram: Data State and Data Flow



→ *Increased Automation & Reduced Variability*

# CDISC 360 Perspective 2: Code as Metadata

- Data flow metadata to capture logic needed to drive data **transformations** and **derivations**
- Capture Pseudocode descriptions
- Capture input and output variables
- Add multiple executable reference implementations (e.g. SAS, R, Python)
- Represented in ODM and Define-XML as a MethodDef



# CDISC 360 Perspective 3: CDISC Library

## M3: Meta-Meta-Model

- Production: W3C RDF
- Sandbox: JSON or XML Schema

## M2: Meta-Model

- ISO 11179

## M1: Model

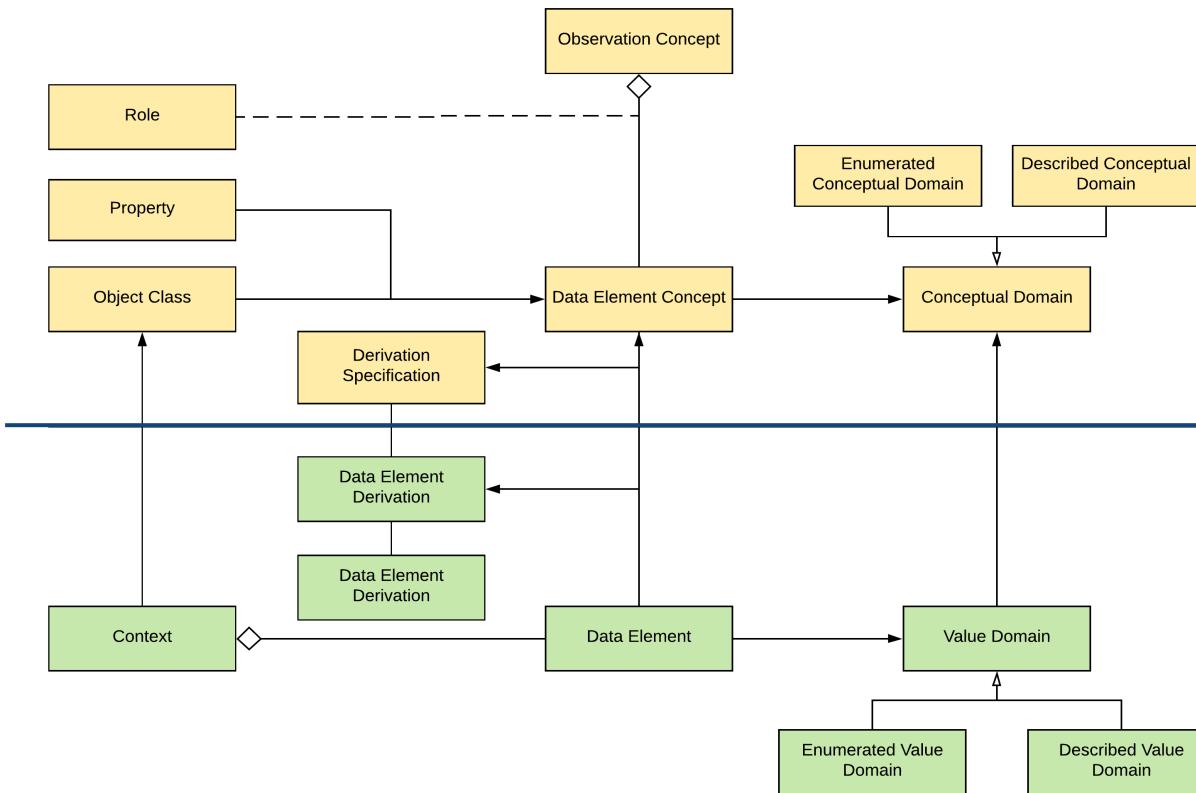
- CDISC Standards

## M0: Model Runtime

- Trial Metadata and Data

# CDISC 360 Perspective 3: CDISC Library

ISO 11179-based Model

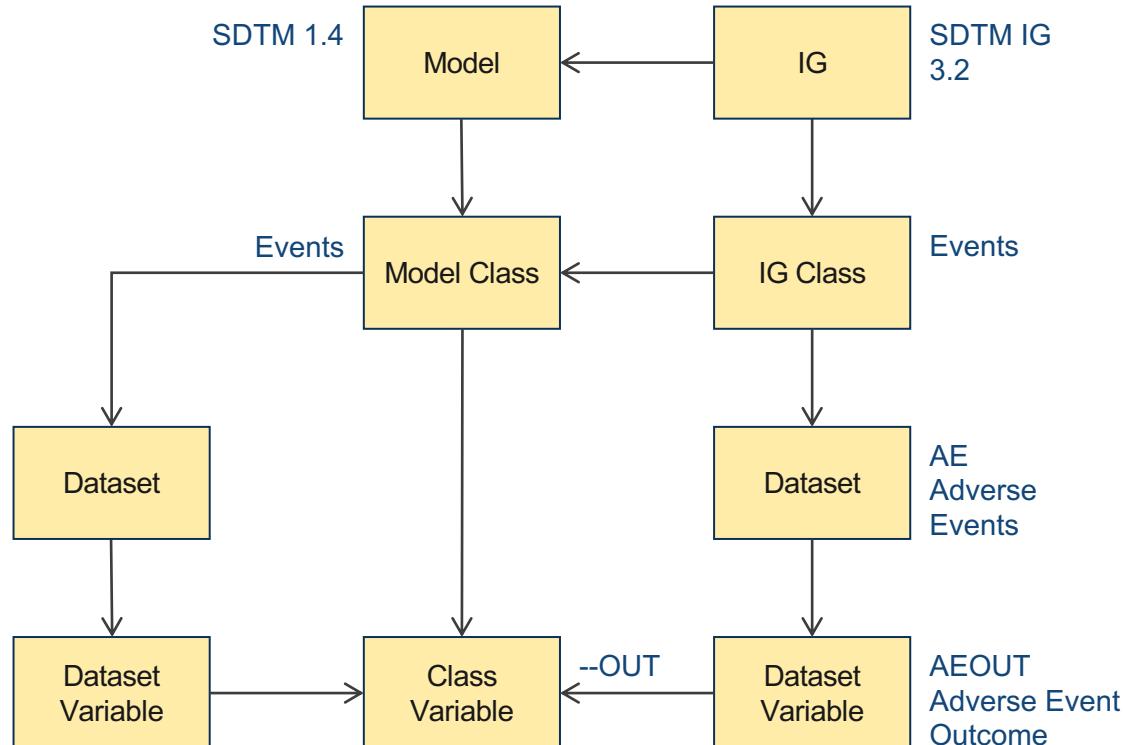


**CDISC 360  
Biomedical Concepts**

**CDISC IG  
Standards Metadata**

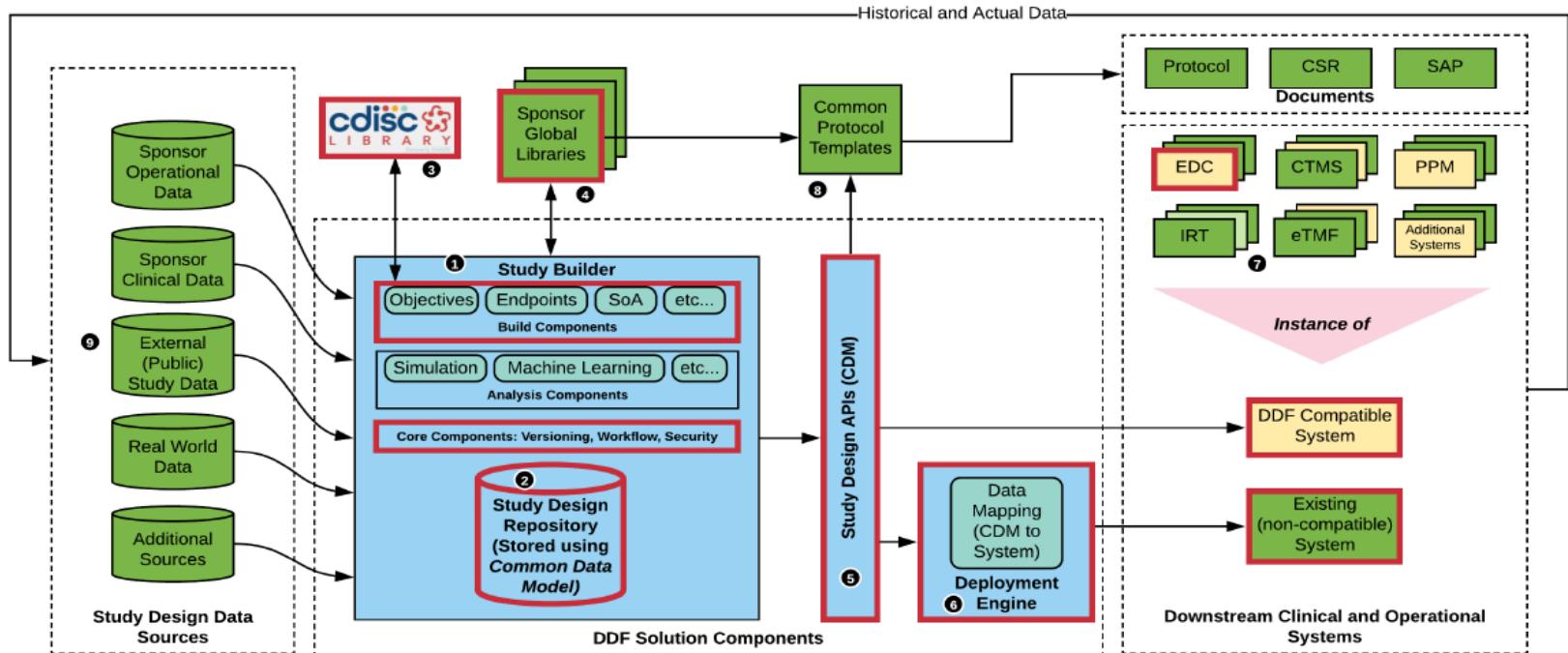
# CDISC 360 Perspective 3: CDISC Library

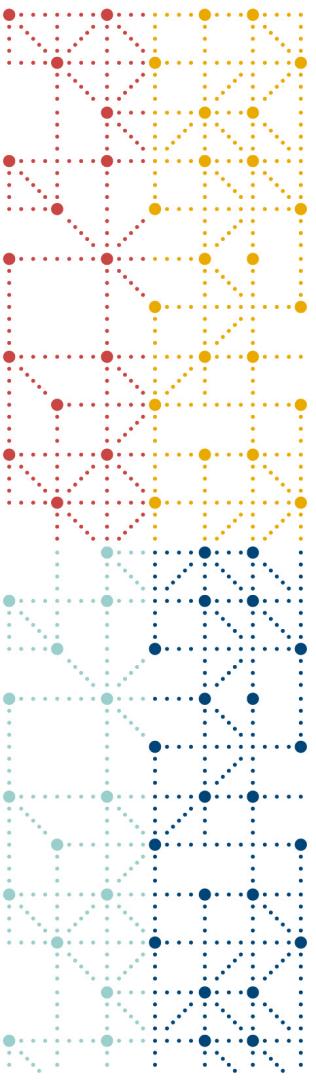
## CDISC Standards Model



# CDISC 360 Perspective 4: External Project Data Flow

## TransCelerate Digital Data Flow (DDF)





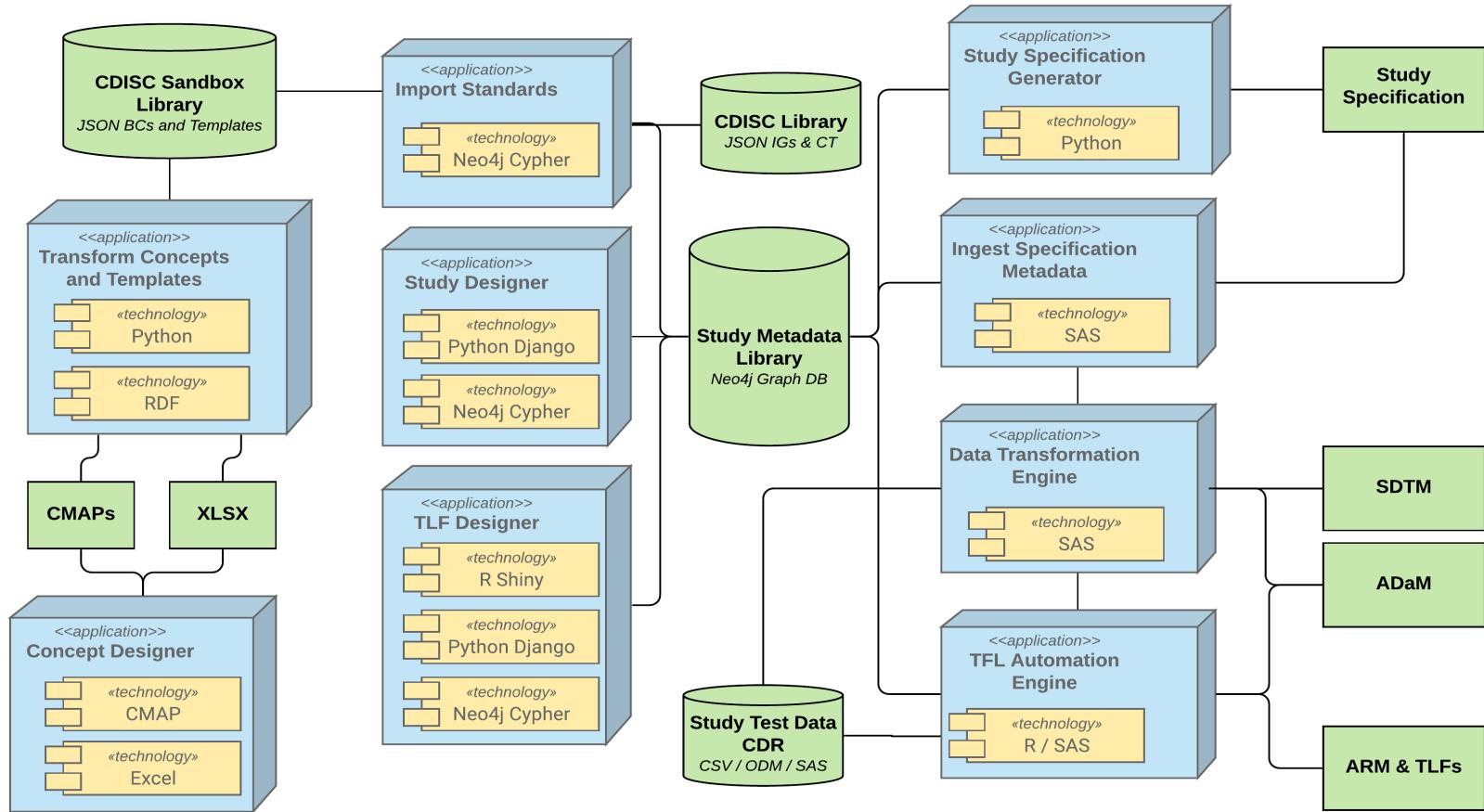
Business

Metadata

Application ←

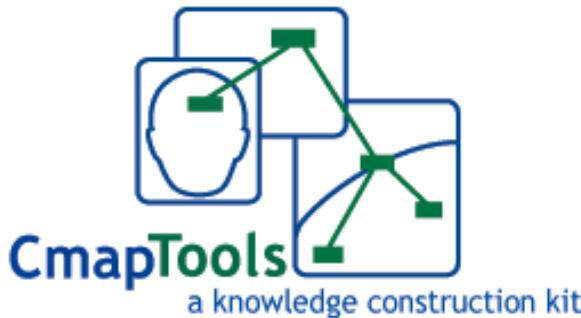
Technology

# CDISC 360 Applications Summary



# WS1 Enhance Standards: CMAP & Excel

Biomedical & Analysis  
Concepts



Templates, Codelist Subsets,  
& Methods



→ *Proof-of-Concept Metadata Creation*

# WS2 Publish Standards: CDISC Library

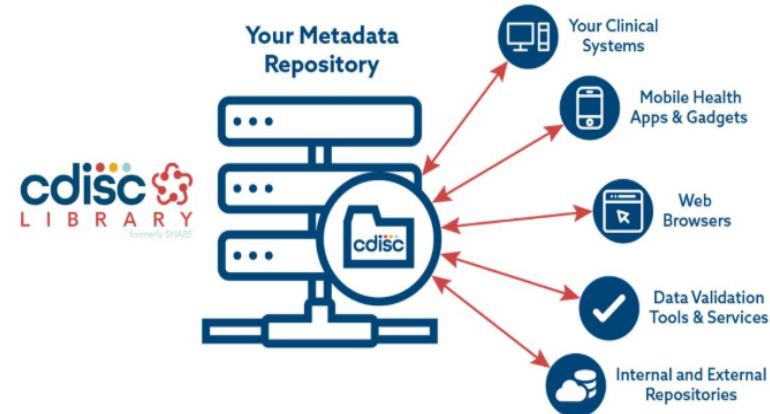
## CDISC 360 Created Metadata

- Bespoke code to generate metadata
  - Python
  - RDF



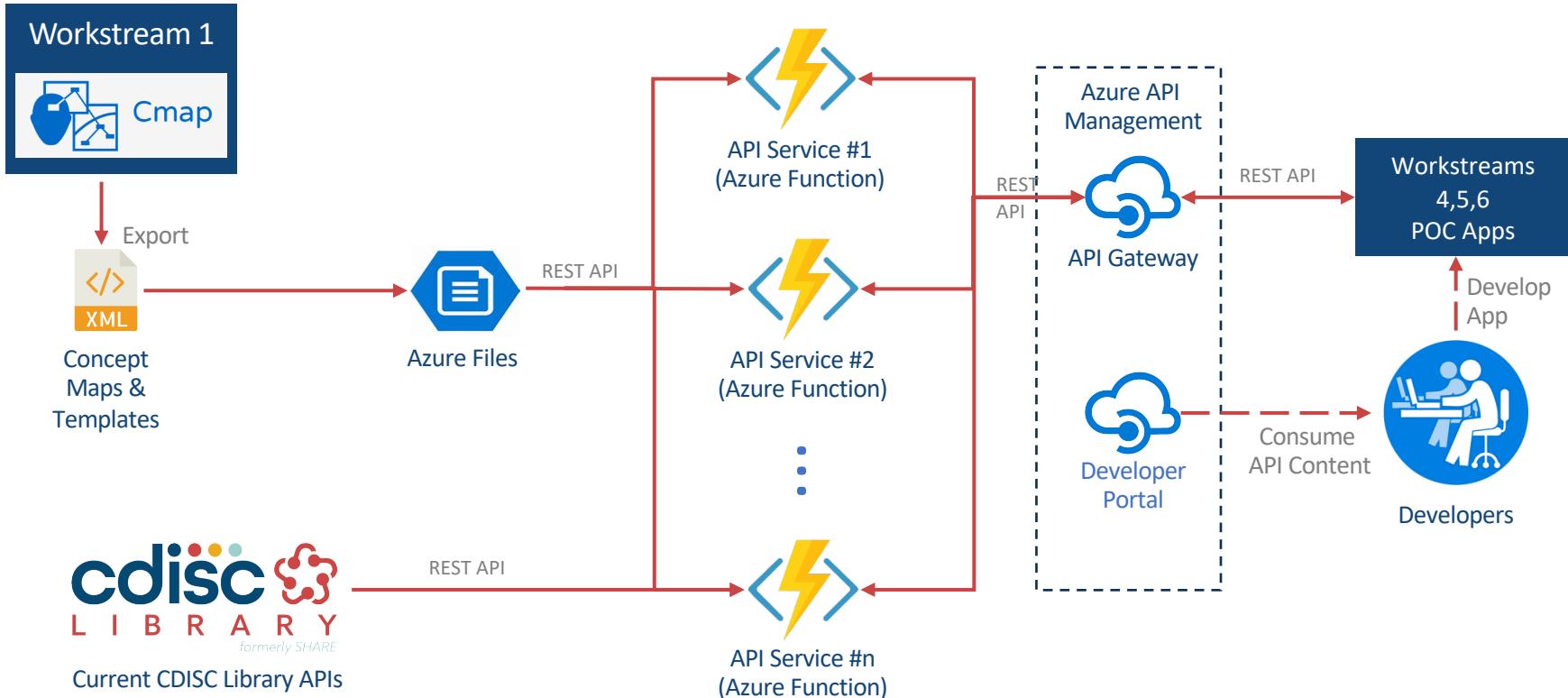
- Generate machine-readable metadata published to a CDISC Library Sandbox

## CDISC Foundational Standards & CT

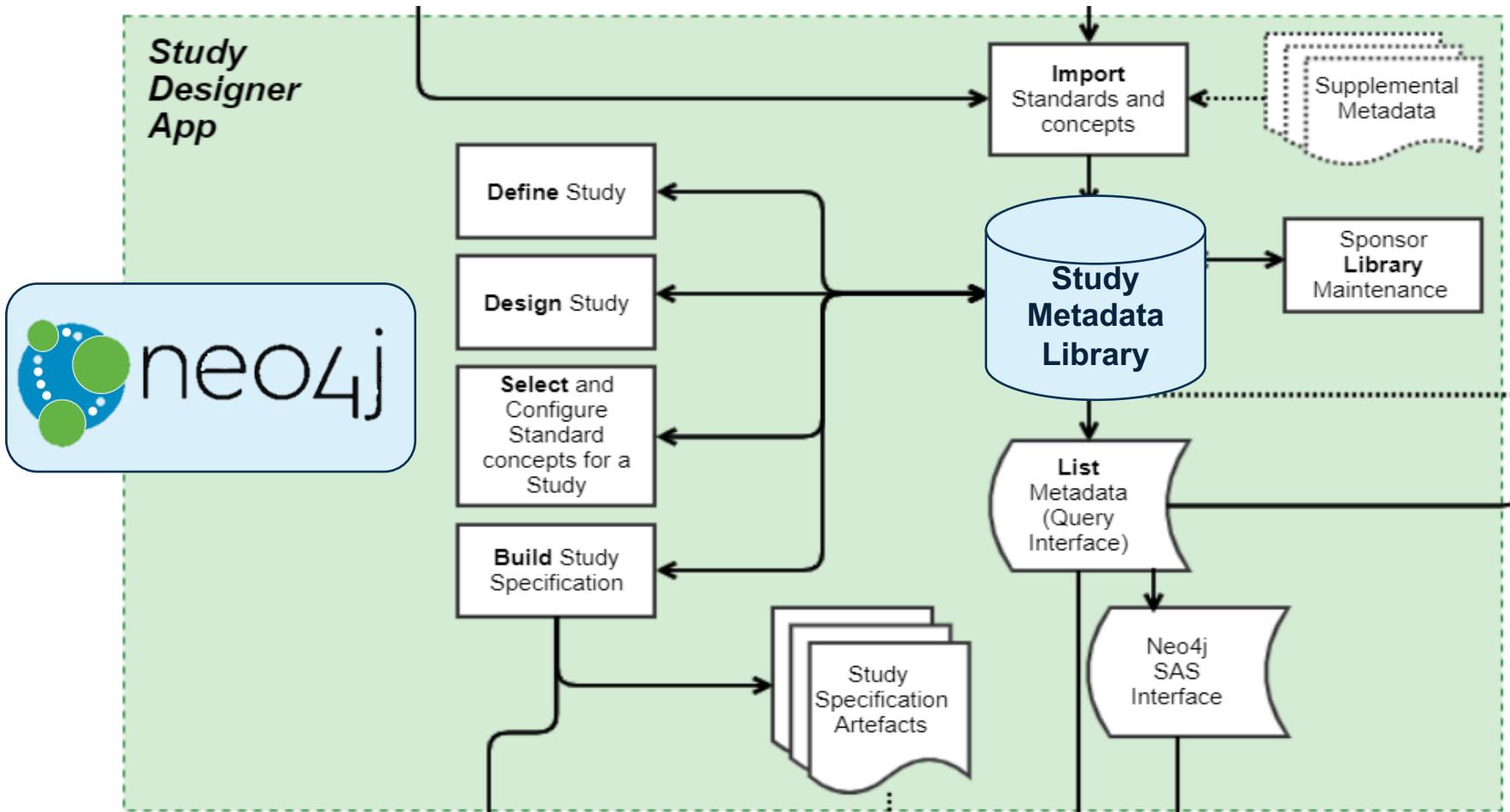


→ *Publish Standards Metadata via the CDISC Library or Sandbox Library*

# WS2 Publish Standards: Sandbox CDISC Library



# WS4 Define: Study Metadata Library



# WS5 – Build: Study Designer

The screenshot shows the cdisc360 Study Designer application. The top navigation bar includes links for Library, Studies, Define, Design, Select, Build, List, and Help, along with a user account icon and a 'CDISC360-2' dropdown.

The left sidebar menu is open, showing options like Summary, Study Data Standardization Plan, Common Protocol Template, ODM Tree, SDTM Tree & Define (which is selected), and ODM SDTM Mapping.

The main content area has tabs for 'SDTM Tree View' (selected) and 'SDTM Define in Html'. Below these tabs, there are two buttons: 'Domain' (blue) and 'Variable' (orange).

The 'Domain' section displays a tree view of domains under 'CDISC360-2':

- DM [Demographics] (checked)
- SE [Subject Elements] (checked)
- DS [Disposition] (checked)
- TA [Trial Arms] (checked)
- TE [Trial Elements] (checked)
- TV [Trial Visits] (checked)
- TD [Trial Disease Assessments] (checked)
- TI [Trial Inclusion/Exclusion Criteria] (checked)
- TS [Trial Summary] (checked)
- AE [Adverse Events] (checked)
- MH [Medical History] (checked)
- LB [Labs] (checked)
- VS [Vital Signs] (checked)

The right side of the screen shows the 'SDTM Domain Level' configuration for the 'DM' domain:

Domain Name*	Domain Label*	Domain Class*
DM	Demographics	Special-Purpose Database

Domain Description\*: A special-purpose domain that includes a set of essential standard variables that describe each subject in a clinical study. It is the parent domain for all other observations for human clinical subjects. (Source: CDISC Controlled

Domain Structure*	Domain Key(s)*
One record per subject	STUDYID USUBJID

Domain Ordinal*	Reference Data*	Repeating ?*
2	No	No

At the bottom of the main content area, a copyright notice reads: © cdisc360 - WS#4 2019-2020

# WS5 Build: Study Builder UI/UX Demo

The screenshot shows a web-based application interface for the CDISC Study Builder. The top navigation bar includes the CDISC 360 logo, Microsoft branding, a search bar, and user profile icons.

The left sidebar contains a vertical list of steps:

- ① Disease Category  
✓ Endocrine
- ② Disease Area  
✓ Diabetes - Type 2
- ③ Study Focus  
✓ Safety
- ④ Domains  
✓ Vital Signs
- ⑤ Concepts
- ⑥ Data Collection
- ⑦ Confirmation

The main content area displays a message: "Please select vital signs concepts". Below this, there is a grid of nine cards, each representing a concept:

<b>Height</b> The vertical measurement or distance from the base to the top of an object; the vertical dimension of extension.	<b>Weight</b> The vertical force exerted by a mass as a result of gravity.	<b>Heart rate</b> The number of heartbeats per unit of time, usually expressed as beats per minute.
<b>Temperature</b> The property of a body or region of space that determines whether or not there will be a net flow of heat into it or out of it from a neighboring body or region and...	<b>Blood Pressure</b> The pressure of the circulating blood against the walls of the blood vessels.	<b>Respiratory Rate</b> The rate of breathing (inhalation and exhalation) measured within in a unit time, usually expressed as breaths per minute.
<b>Oxygen Saturation</b> A measurement of the oxygen-hemoglobin saturation of a volume of blood.	<b>Hip Circumference</b> The distance around an individual's pelvic area or hips.	<b>Body Fat Measurement</b> A measurement of the total fat mass within the subject's body.
<b>Body Frame Size</b> The categorization of a person's body frame into small, medium and large based on the measurement of wrist circumference or the breadth of the elbow.		

At the bottom of the page are two buttons: "Back" and "Continue".

# WS5 Build: Metadata Artifacts

- Bespoke code to generate:
  - ODM CRFs / aCRFs
  - Define-XML
- ODM and Define-XML visualizations
  - Stylesheets
  - Formedix On
- End-to-end with ODM and Define-XML
  - Test driving automation with ODM and Define-XML metadata

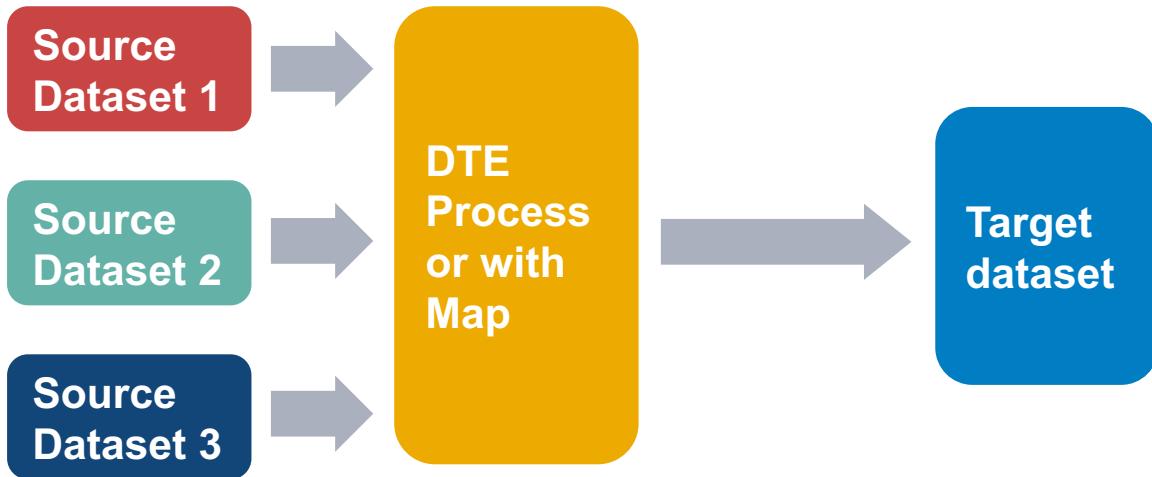
Formedix CRF / aCRF Visualization

 Protocol CDISC 360	Site Number	Subject Number
---	-------------	----------------

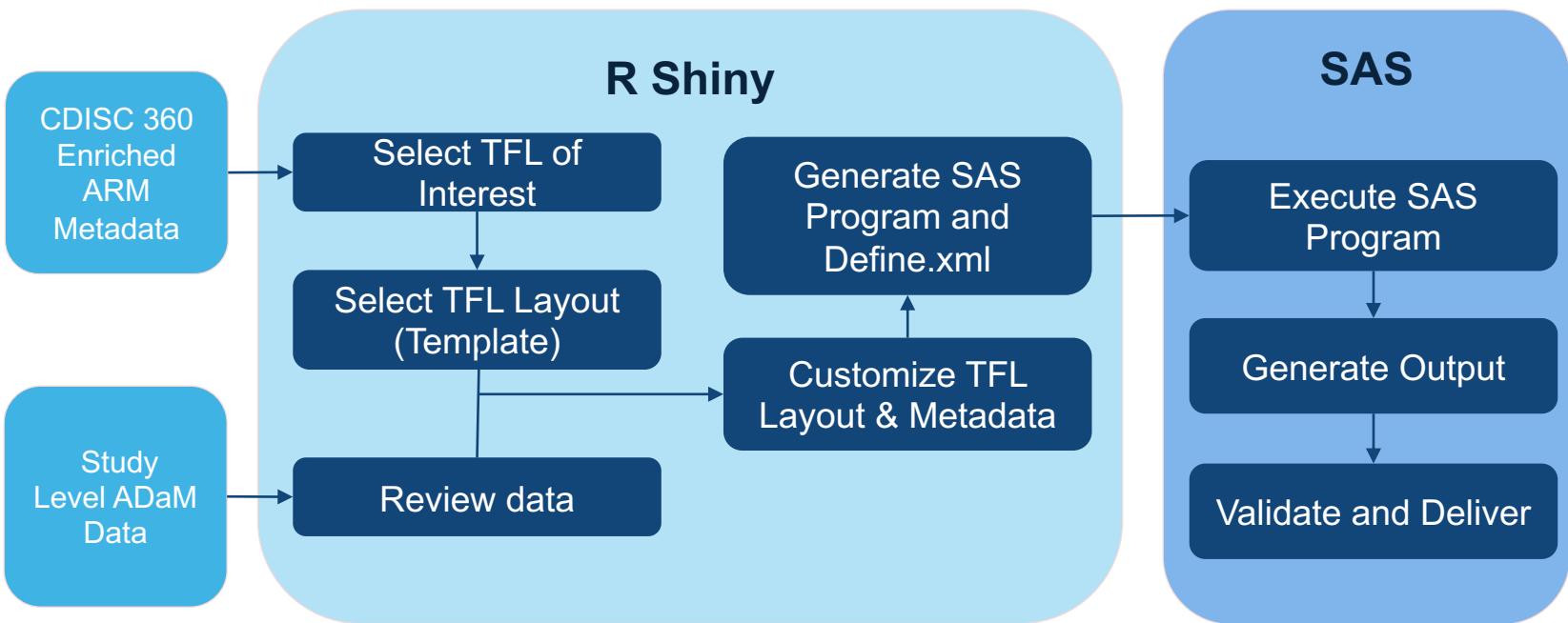
Vital Signs (Timepoint)	
What was the date of the vital signs measurement? (DD-MMM-YYYY)	<input type="text"/>
What was the time of the vital signs measurement? (24 hour clock)	<input type="text"/>
Were vital signs performed?	<input checked="" type="radio"/> Yes <input type="radio"/> No Reason Not Performed <input type="text"/>
What was the result of the weight measurement?	<input type="text"/> kg <input type="radio"/> LB
What was the result of the height measurement?	<input type="text"/> cm <input type="radio"/> in
What was the result of the temperature measurement?	<input type="text"/> C <input type="radio"/> F

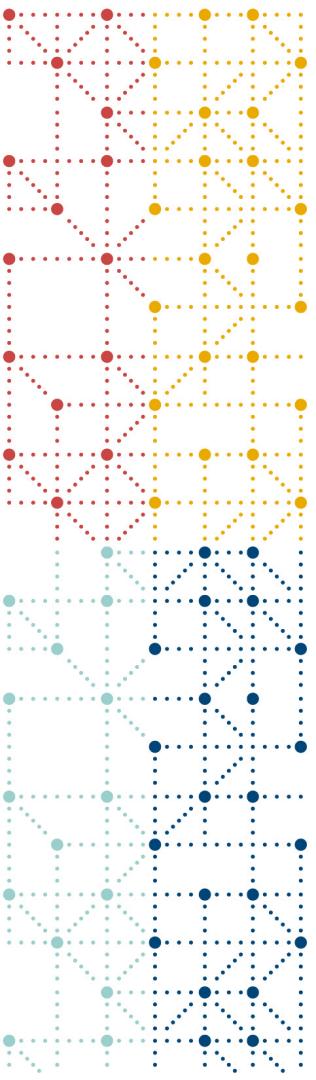
What is the planned time point for this vital signs measurement?	What was the position of the subject during the measurement?	What was the result of the systolic blood pressure measurement?	What was the result of the diastolic blood pressure measurement?	What was the result of the heart rate measurement?
5 min pre-dose	<input type="radio"/> Sitting <input type="radio"/> Standing <input type="radio"/> Supine	<input type="text"/> mmHg <input type="radio"/> inHg	<input type="text"/> mmHg <input type="radio"/> inHg	<input type="text"/> beats/min
30 min post-dose	<input type="radio"/> Sitting <input type="radio"/> Standing <input type="radio"/> Supine	<input type="text"/> mmHg <input type="radio"/> inHg	<input type="text"/> mmHg <input type="radio"/> inHg	<input type="text"/> beats/min

# WS6 Execute: Data Transformation Engine & SAS



# WS6 Execute: TLF Automation Engine





Business

Metadata

Application

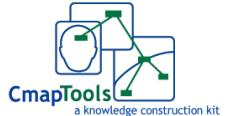
Technology ←

# Technology: Code Development and Execution

## Code Development & Execution



Cypher Query  
Language



Azure Jupyter  
Notebooks



# CDISC 360: Cloud-based Computing

CDISC 360 Azure Cloud



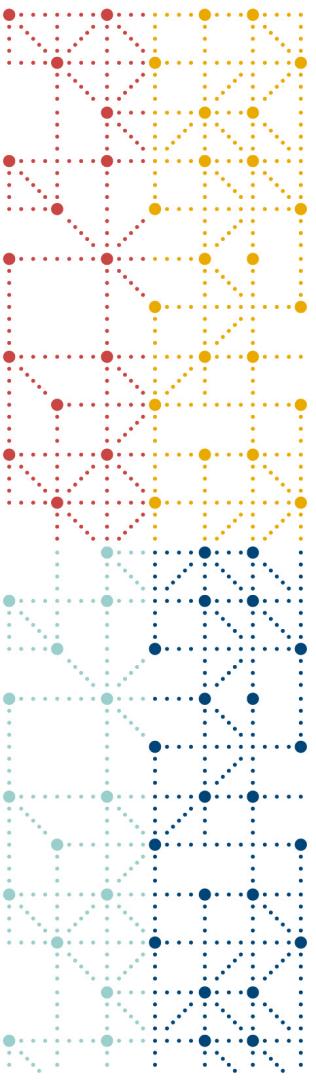
CDISC  
Library



CDISC  
collaboration  
tools



CMAP



# Future State

How does research change once we implement  
the learnings from CDISC 360?



Architecture  
Patterns



Evolution of  
Cloud platforms



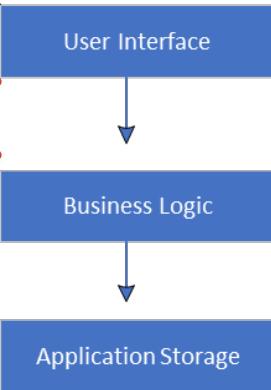
Automation



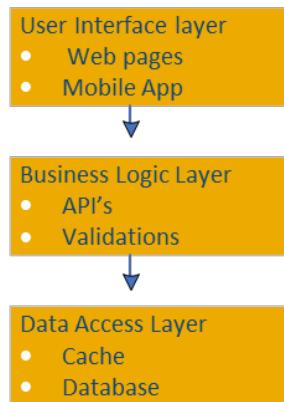
Multi Data  
Source ELT

# Proof of Concept to Production

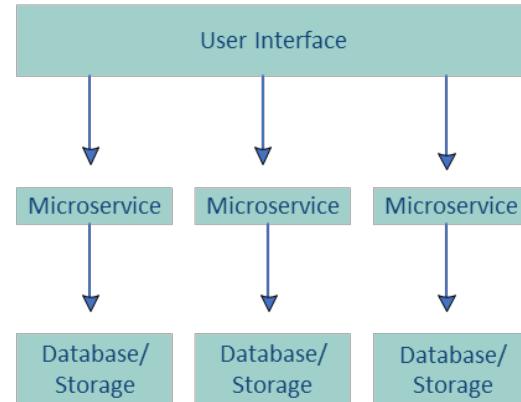
## Monolithic



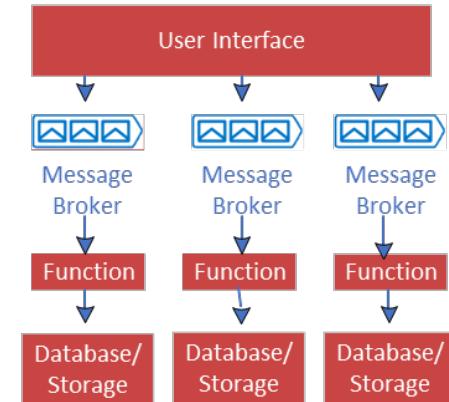
## N-Tier



## Microservices

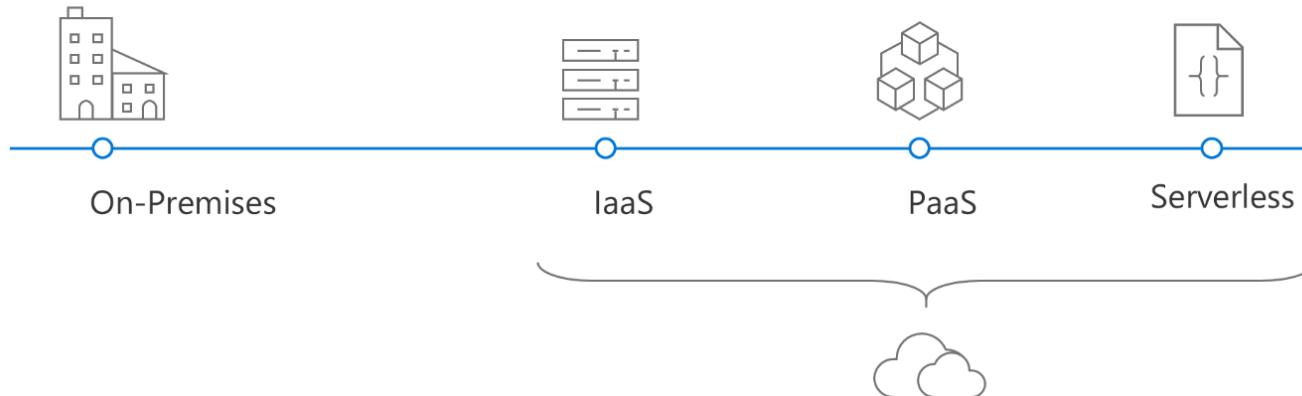


## Serverless

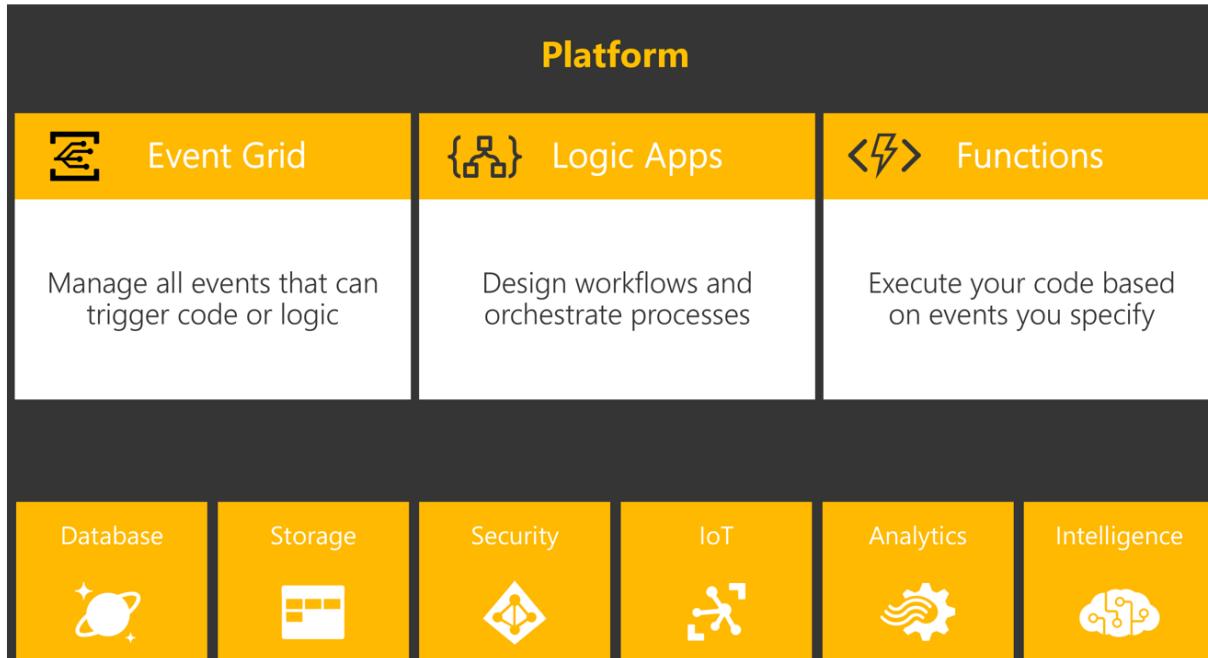


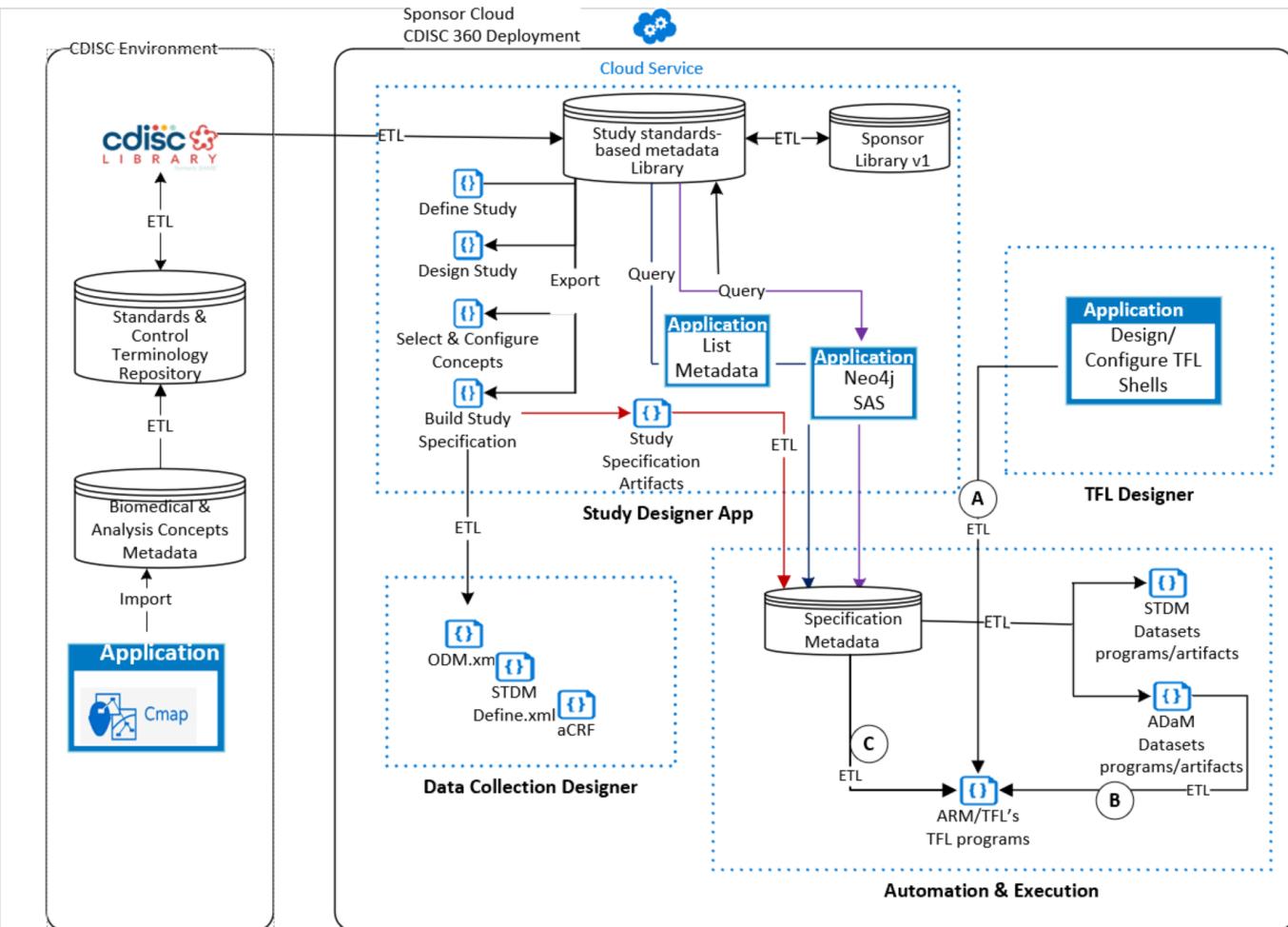
# Evolution of Cloud Platforms

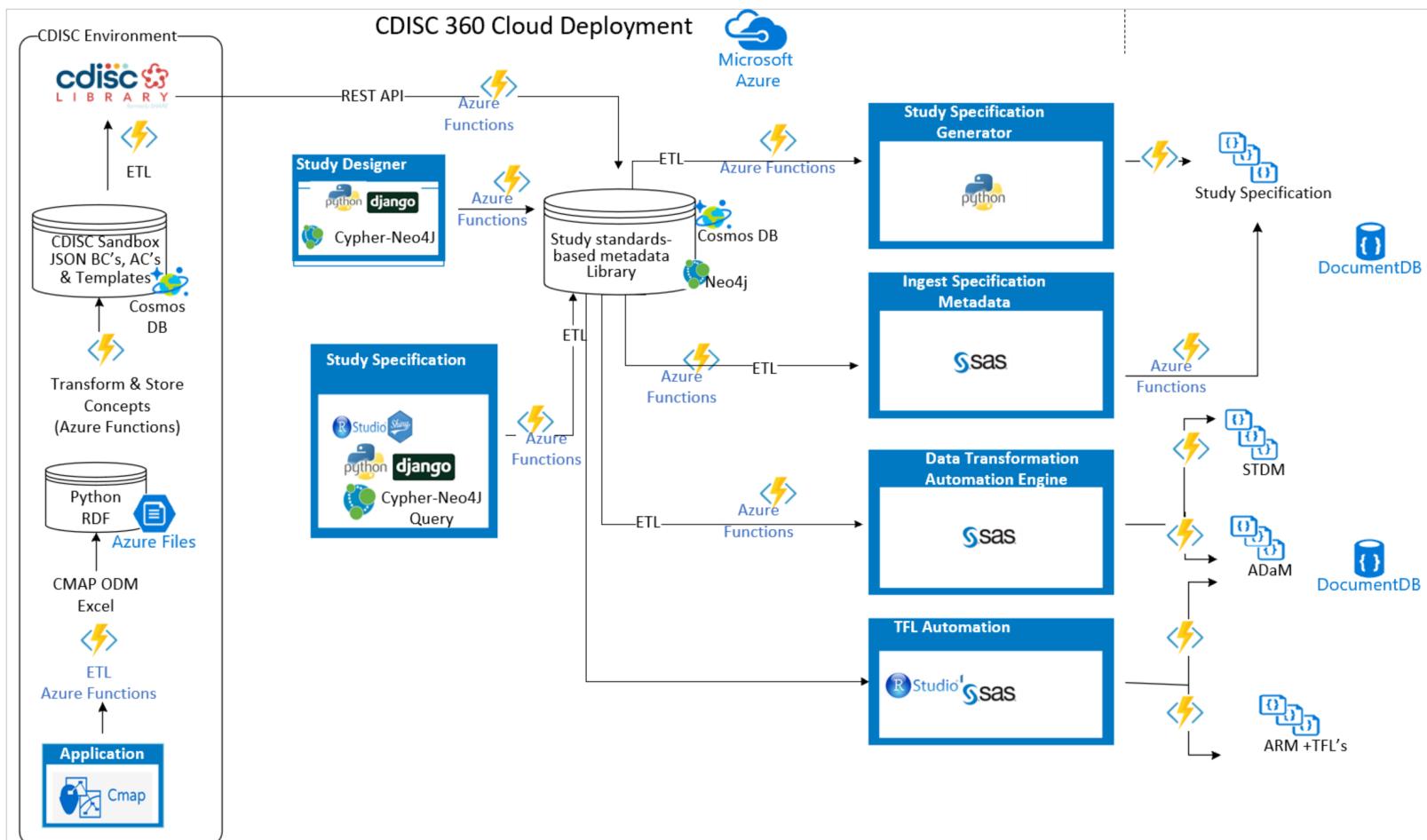
- Serverless is the culmination of several iterations of cloud platforms. The evolution began with physical metal in the data center and progressed through infrastructure as a Service (IaaS) and Platform as a Service (PaaS)

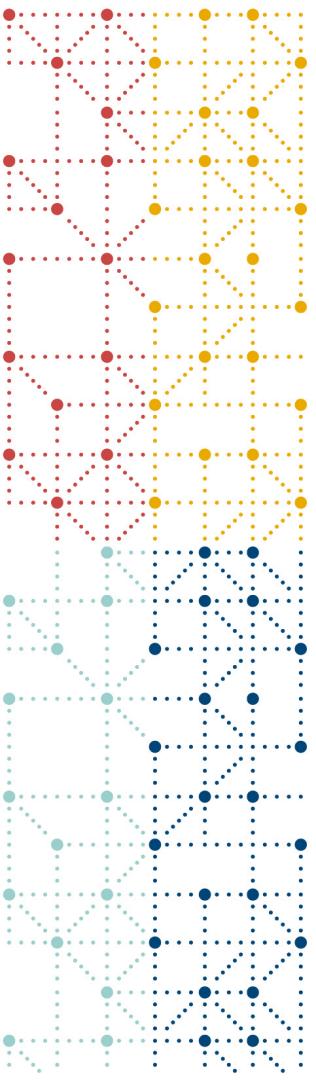


# Serverless Event Grid, Logic Apps, Functions









# Thank You!



# Monoliths



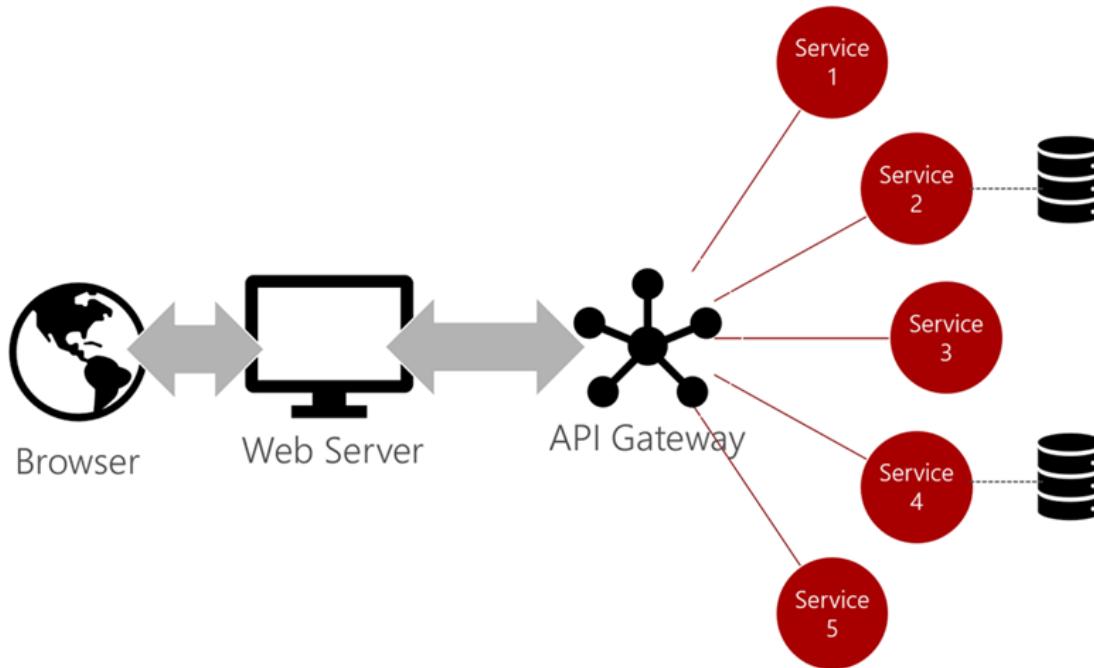
## Advantages

- Easy to re-create an environment with multiple components and applications

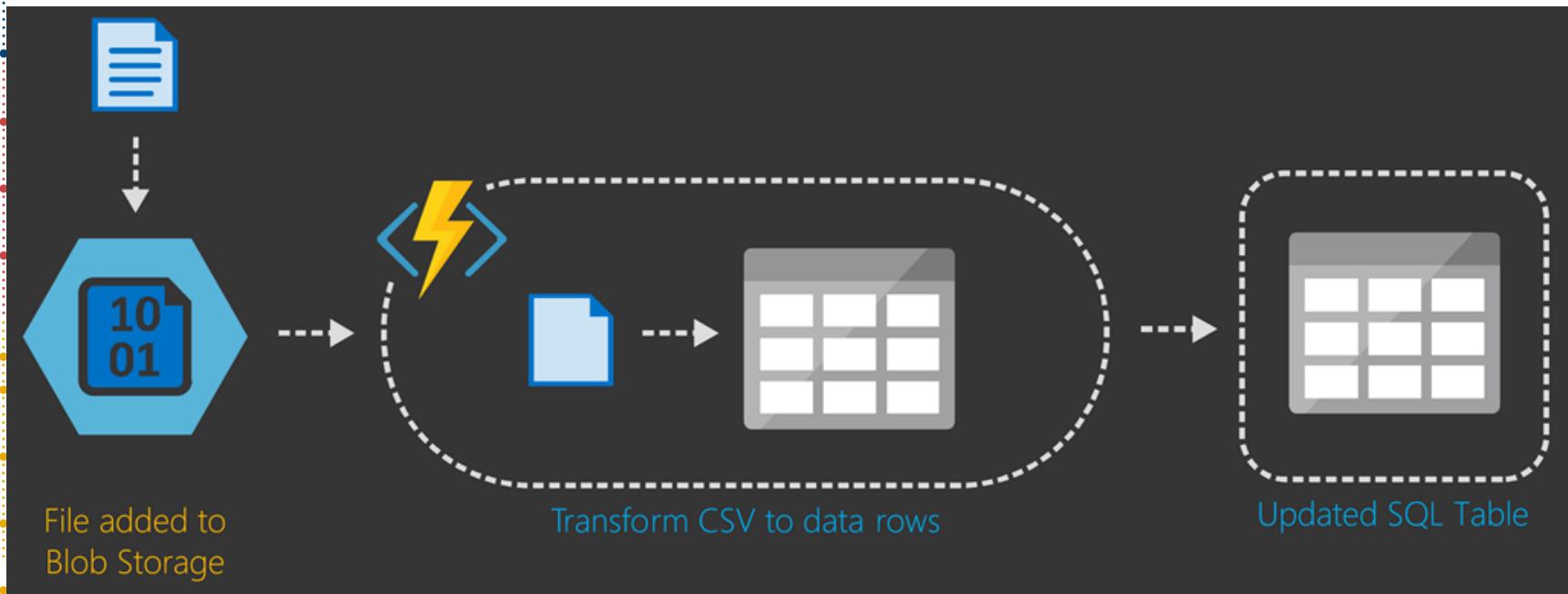
## Disadvantages

- Tends to break down at scale
- Difficult to work in parallel on code
- Any change requires deploying new version of the application

# Microservices



# Parse a CSV file and insert into a database



# N-Layer applications



## UI Layer

- Web Pages
- Mobile App



## Business Logic Layer

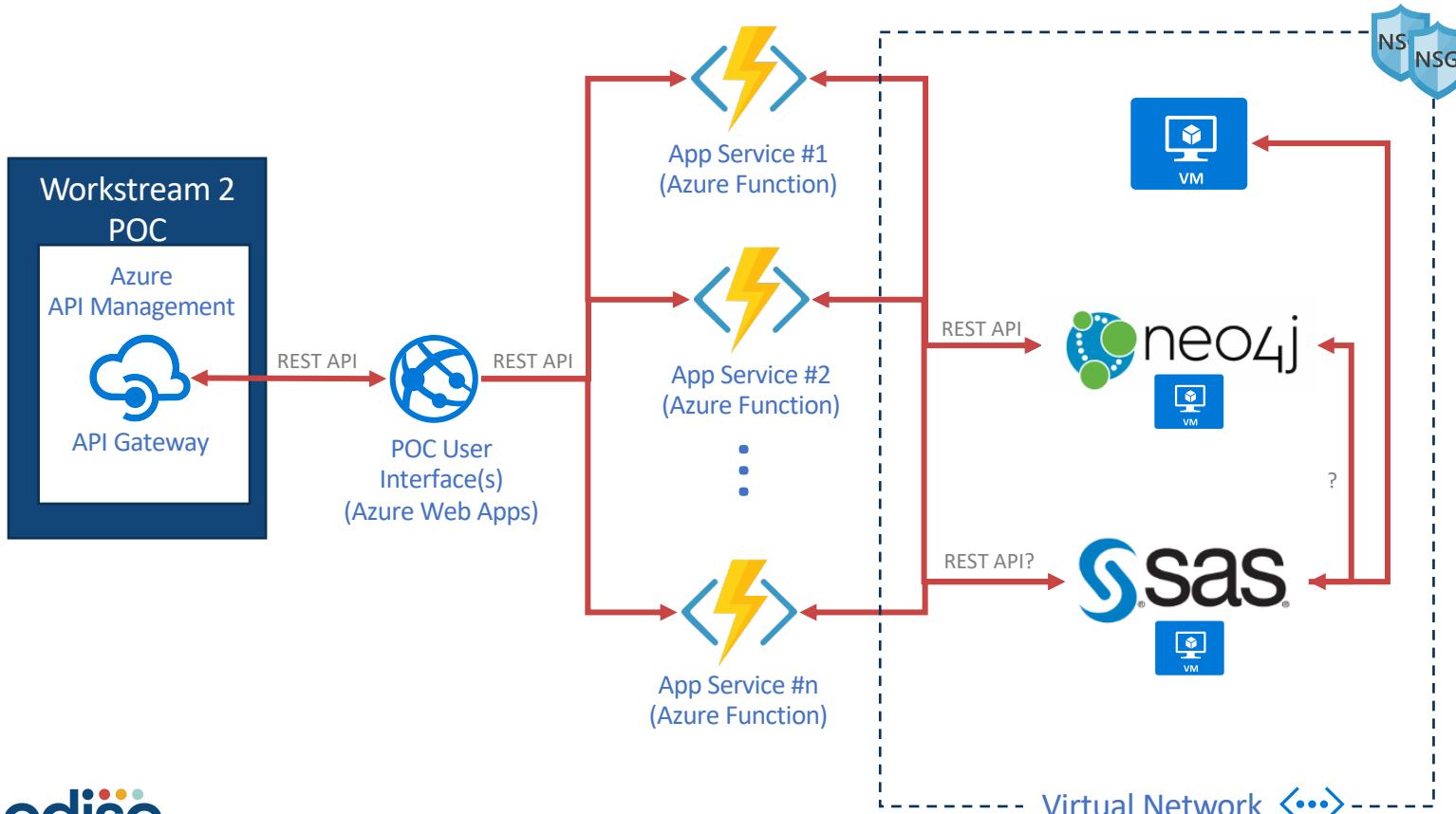
- APIs
- Validations



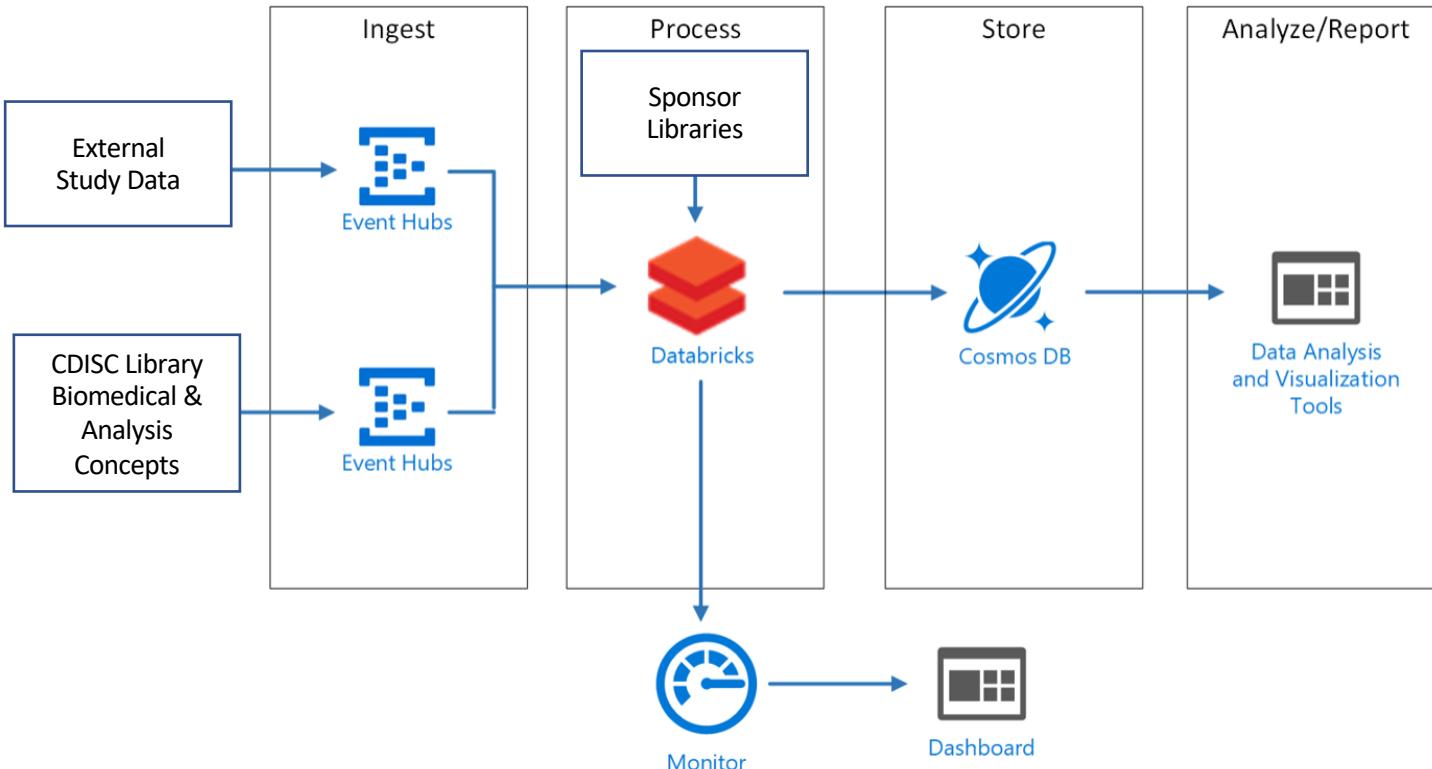
## Data Access Layer

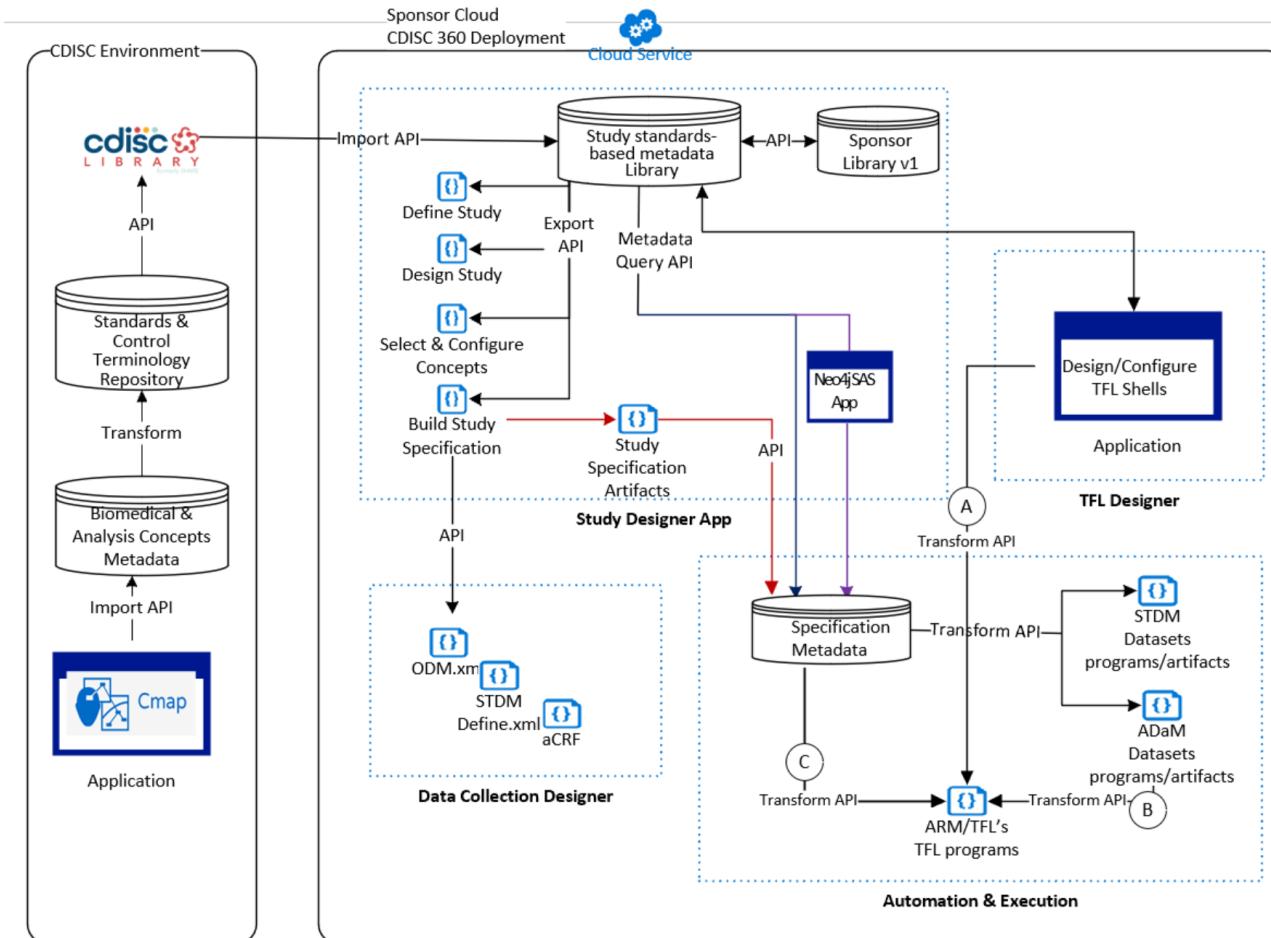
- Cache
- Database access

# Workstreams 4-6 POC Target Architecture - Draft



# Azure Databricks





# Data pipeline

