GSKs journey towards an MDR

Presented by Igor Klaver, Principal Project Lead, Data Standards, GSK

Meet the Speaker

Igor Klaver

Title: Principal Project Lead, Data Standards

Organization: GSK

Igor Klaver is a Principal Project Lead, Data Standards at GSK.

In this role, Igor supports study teams in SDTM related questions and supports maintenance of standards and is working in improvement projects for data standards.

Igor holds an MSc in Biology and joined GSK in 2006, where he held several positions in data management from data management, to clinical systems and standards with affinity for lab data and data flows.

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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*

- *The author(s) have no real or apparent conflicts of interest to report.*

Agenda

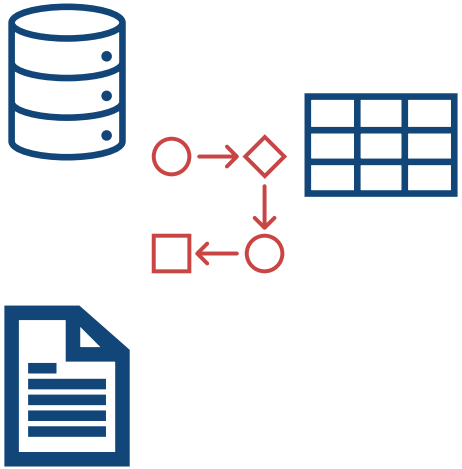
1. Previous explorations MDR
2. Where are we now
3. Vision on MDR
4. Next steps

Previous explorations MDR

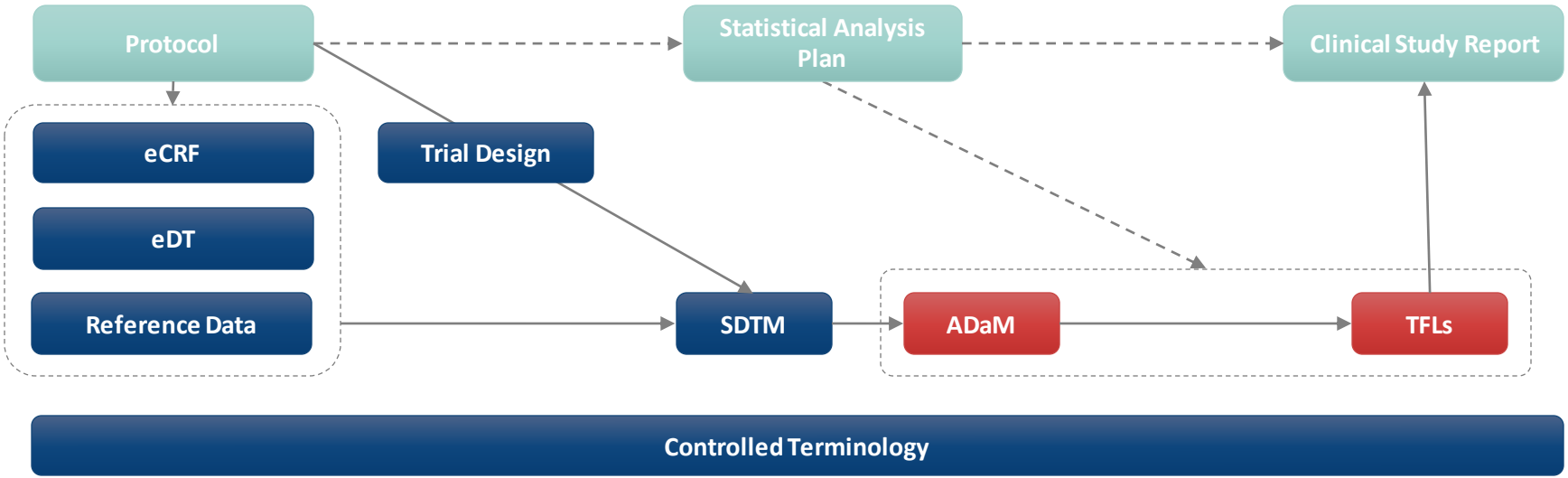
Previous explorations MDR

How did we see standards?

- Control
- Re-use
- Prevent copying mistakes
- A registry
  - Standards
  - Project
  - Study
- A repository
  - Mapping
  - Programming specifications
- Isolated objects



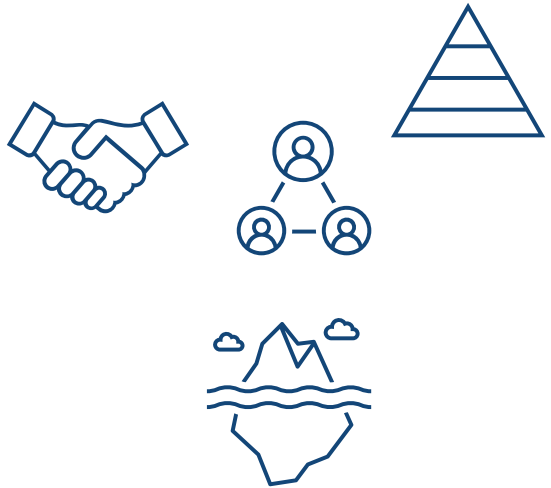
Previous explorations MDR



Previous explorations MDR

What environment are we in?

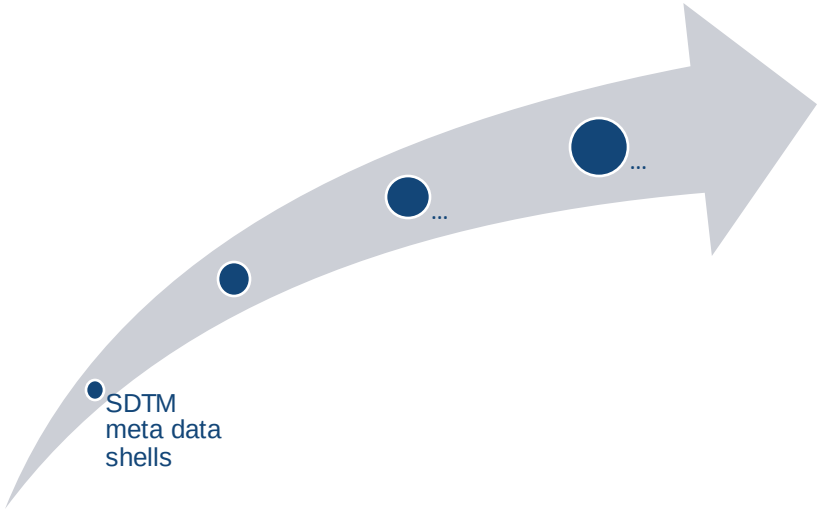
- Mergers, divestments, acquisitions and reorganizations
- Smaller flexible organizations
- Larger companies managing large variety of assets
- Siloed organizations
- Deeply rooted practices
- Customized system landscapes



Previous explorations MDR

First example

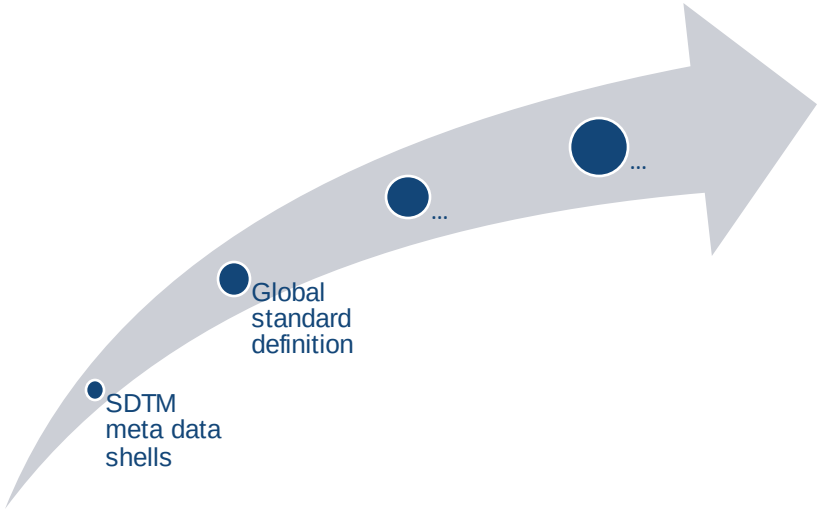
- Defining SDTM meta data as shells
  - Global standards
  - Add project and study specific metadata
  - Controlling standards allowing study flexibility
  - Separate CDASH to SDTM mapping from source to target but output controlled by shells
  - Allow flexibility on controlled terminology



Previous explorations MDR

Second example

- Have global level standard definition
- Include value level definition
  - All is standard
- All in one solution
  - Including study level specification
  - High automation
  - Resource intensive
- Attempt to link data via VLD
  - Tabular
  - Reaching technical limitations
  - Not machine readable
  - Immature solution

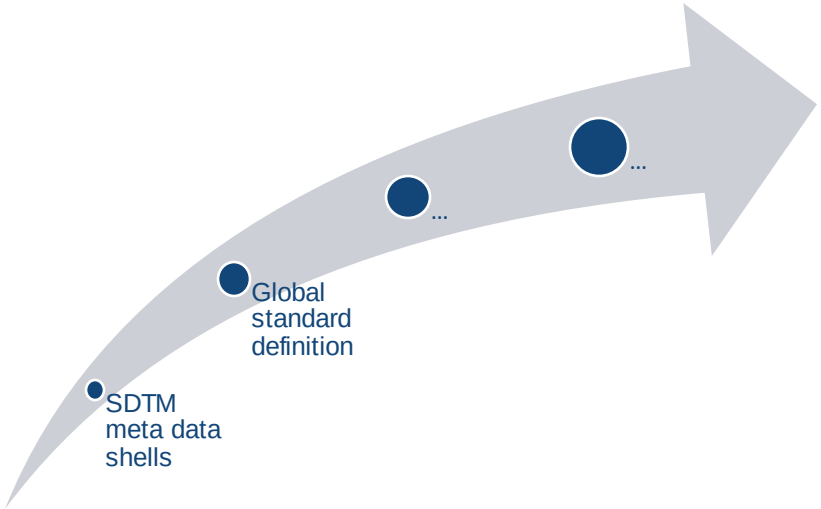


Where we are now

Where we are now

Third example

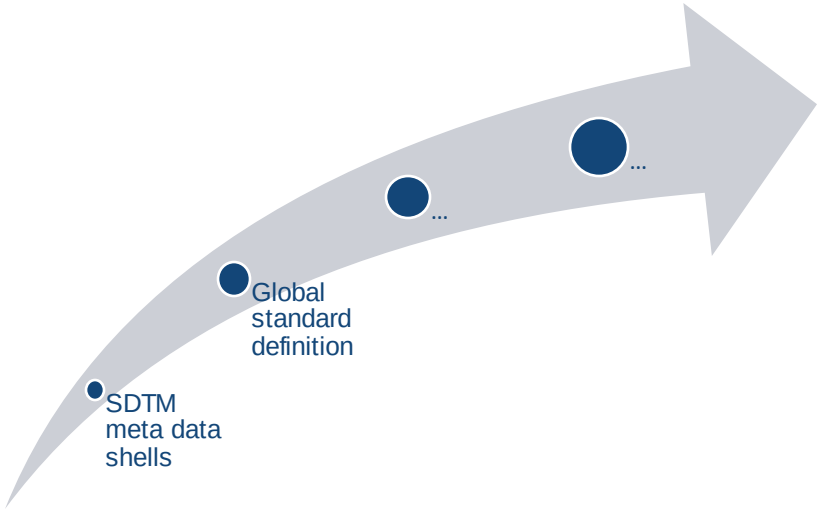
- Based on second example
- Include value level definition (VLD)
  - All is standard
  - Include programming instructions
- Abandon all in one solution
- Use VLD to derive values
  - Tabular
  - Supporting vendor specifications
  - Not machine readable, needing interpretation from programmer



Where we are now

Third example expanded

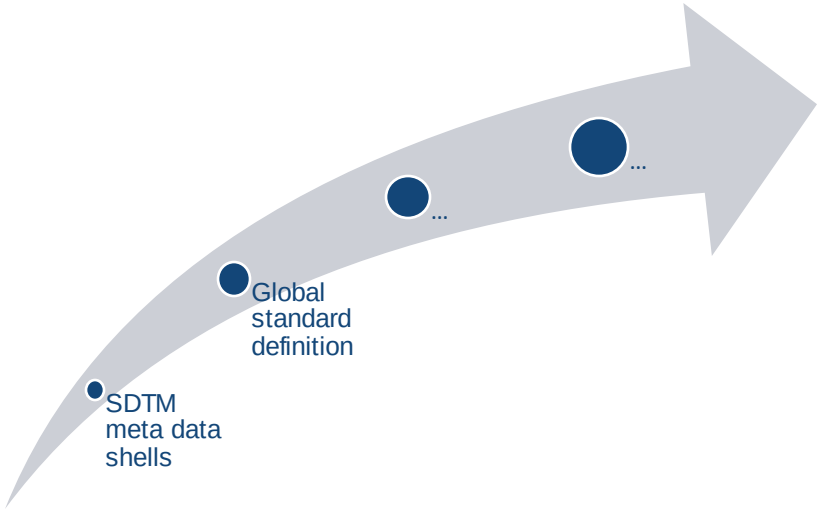
- Output for define.xml standards
  - Create where clauses based on VLD
  - Metadata conformance validation against standards
  - Use for define creation
- Separate standard programming specifications but controlled by standard shells
- Harmonized with end-to-end in mind and upgraded to IG 3.3 with parts from 3.4



Where we are now

Platform agnostic:

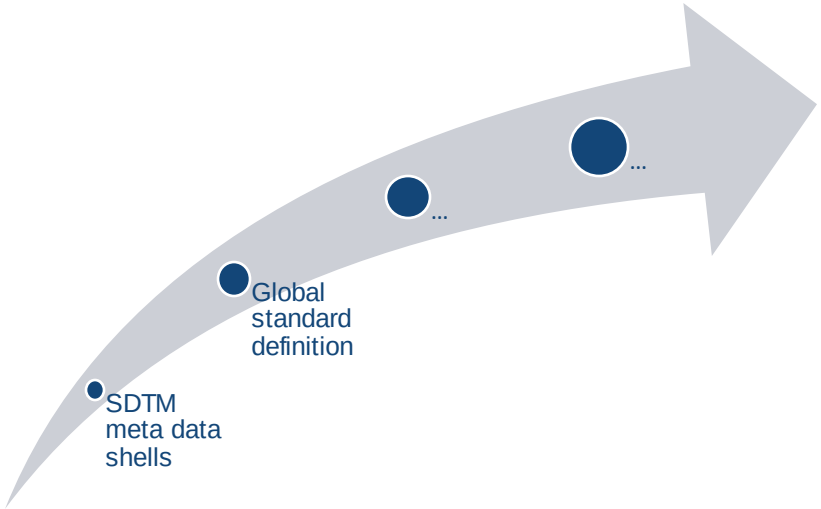
- Structured data
  - Excel based for storage
    - Datasets
    - Variables
    - Value Level Definitions
    - Code lists
  - VBA scripts to support updates
- Basic versioning
- Request process to govern updates
- Supporting SDTM IG 3.2 and 3.3
- Fixed CT version with sponsor specific codes
- Supports SDTM and Vendor specs



Where we are now

Metadata flow:

- Distribution in different formats above study level
  - Define.xml creation and validation
  - Programming specifications
  - Sharing with external partners

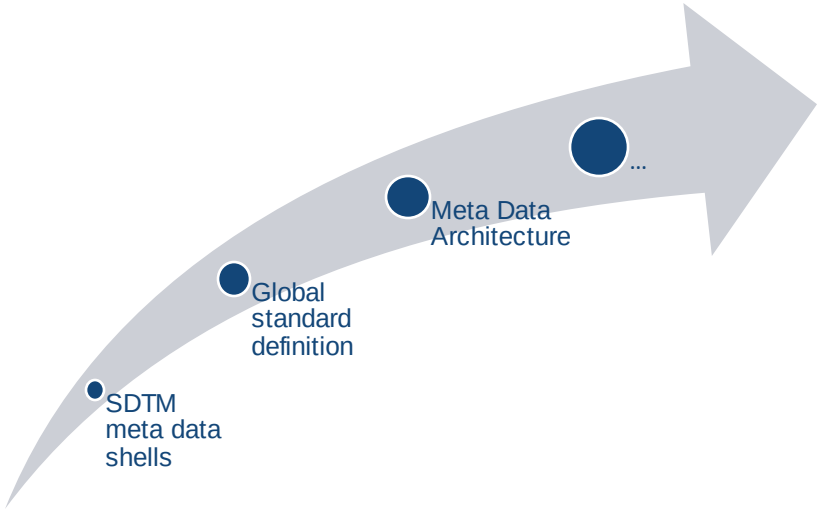


Vision on MDR

Vision on strategic MDR

Where we want to be:

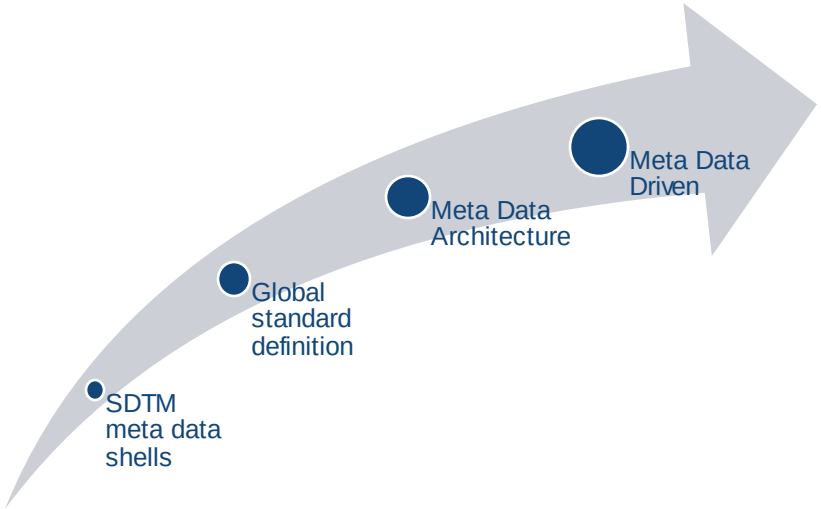
- Move away from traditional MDR and move towards a Metadata Architecture (MDA)
- Harmonized and simplified
- Commitment to standards



Vision on strategic MDR

Where we want to be:

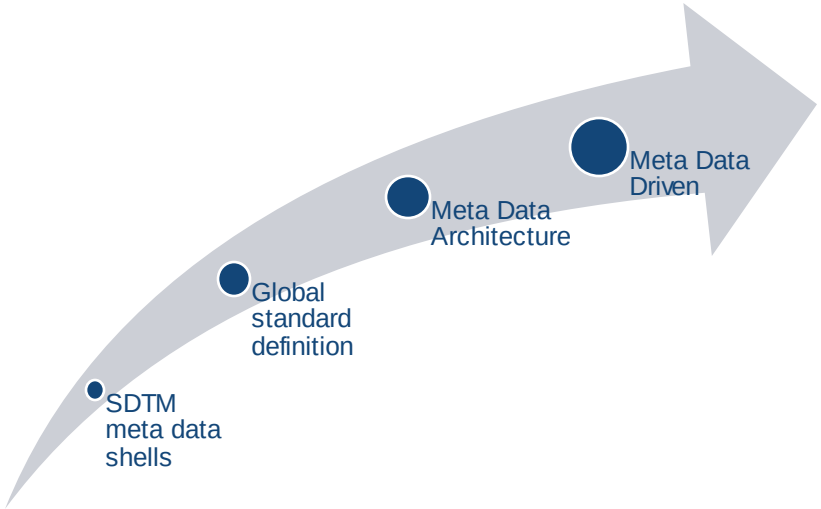
- Move away from traditional MDR and move towards a Metadata Architecture (MDA)
- Harmonized and simplified
- Commitment to standards
- Metadata driven automation



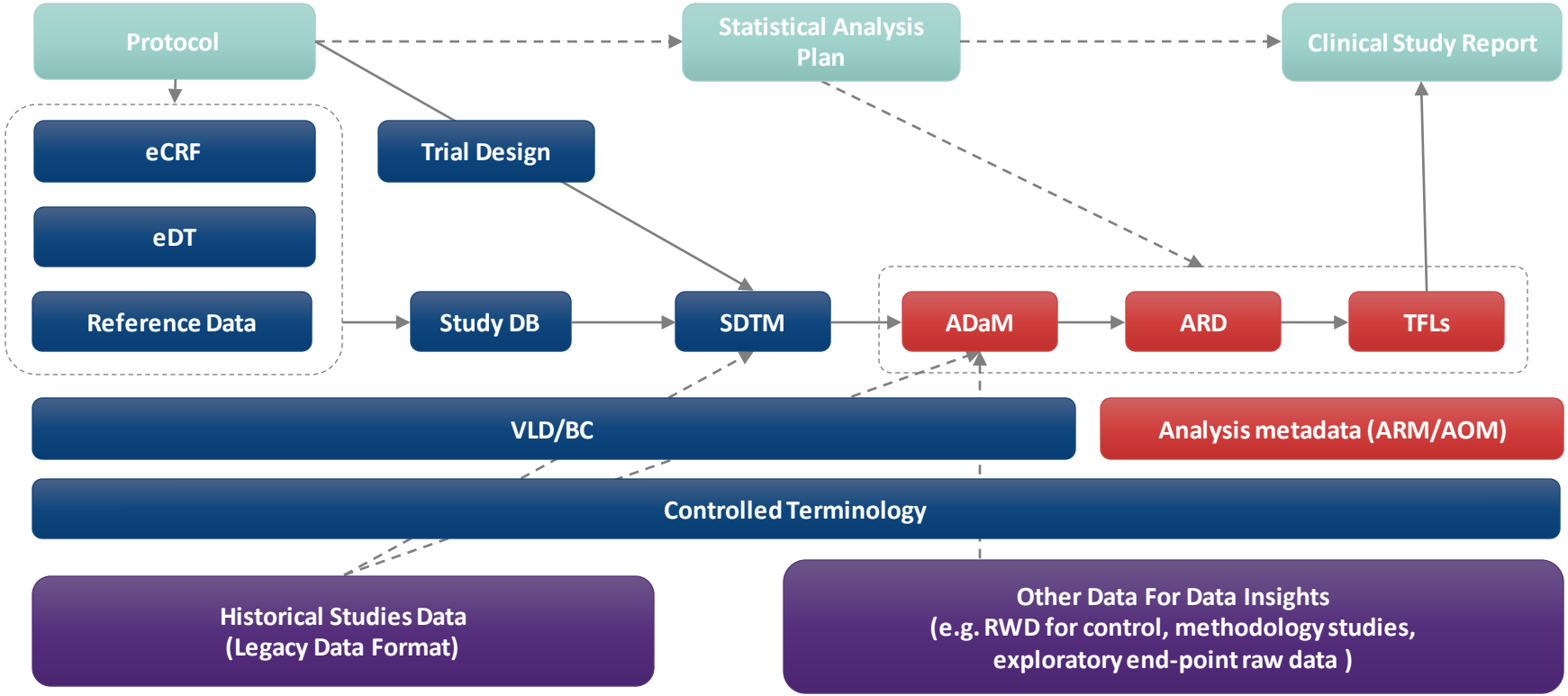
Vision on strategic MDR

How:

- Use Biomedical Concepts
- Uplift our VLD to be able to integrate with Biomedical concepts
- Clinical linked data
- Include Data Standards browser supporting different users



Vision on MDR

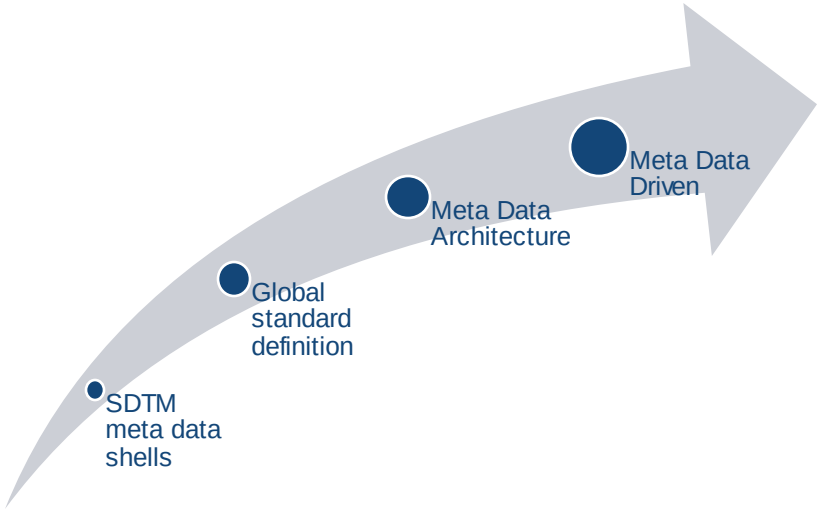


Next steps

Next steps

How:

- Define what we see as MVP
- Start experiments with linked data in knowledge graphs
- Experiment with Meta Data Driven Automation
- Build Data Standards Browser based on existing content, which is flexible to evolve and provides an immediate user experience



Next steps

Uplift Value Level definitions to Biomedical Concepts:

- Build linked data model
- Build data standards browser user experience
- Uplift our VLD to be able to integrate with Biomedical concepts

VLDsource	WhereVar	CODELIST	COMPARATOR	Value	TARGET	Data_Type	Origin	Length	Mandatory
VS VSTESTCD	VSORRES			<define at study level>	True	text	CRF	200	No
VS VSTESTCD	VSPOS	POSITION_VS		<define at study level>					
VS VSTESTCD	VSSTRESC			<define at study level>					
VS VSTESTCD	VSSTRESN			<define at study level>					
VS VSTESTCD	VSTESTCD	VSTESTCD	EQ	DIABP					
VS VSTESTCD	VSTEST	VSTEST		Diastolic Blood Pressure					
VS VSTESTCD	VSORRESU	VSRESU		mmHg					
VS VSTESTCD	VSSTRESU	VSRESU		mmHg					

define.xml

Dataset	Variable	Where Clause	Data Type	Length	Mandatory	Assigned Value	Codelist	Decoded Variable	Origin
VS	VSORRES	VSTESTCD EQ DIABP	text	200	No				CRF

```
packageDate: "2022-10-26"
packageType: bc
conceptId: C25299
categories:
  - Vital Signs
shortName: Diastolic Blood Pressure
```

Next steps

Where do we see risks:

- What do we see as MVP and will it be scalable
- How will we embrace an immature solution
- How can we integrate existing off-the-shelf products while keeping control and staying flexible

Thank You!