

Path to a Metadata-Driven Standards Environment – Collection to Submission

M. Binz *Novartis Pharmaceuticals Corporation, East Hanover, NJ 07936*

Objective: To demonstrate the process flow and applications used at Novartis to develop, utilize and govern clinical data and reporting/submission standards.

Birth of an Element

CRF Request

Metadata Proposal

Governance

Metadata in Production

Multi-System Implementation

How does metadata impact...

Clinical Data Management System

- Consistency and reusability of standard data elements, leading to efficiencies in database development

Data Warehouse

- Increases data mining capabilities based on metadata
- Single source of clinical data for cross-functional use (safety, modeling, PK)
- Effective integration of data to support timely decision-making (before, during and after submission)

Reporting

- Reporting system based on reusable metadata vs. study/project level
 - Streamlines downstream analysis and reporting processes

Governance Board (meets weekly)

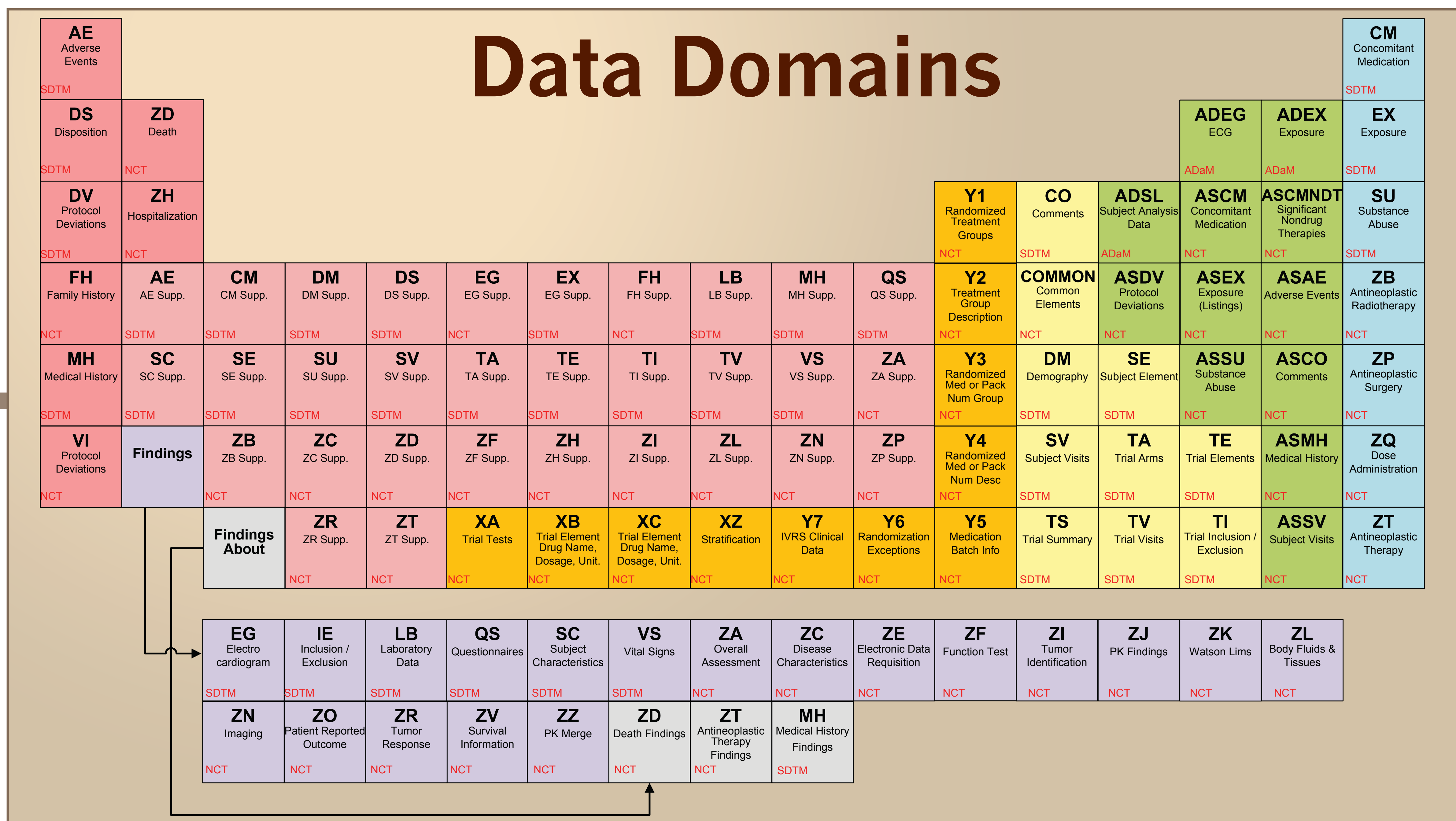
- Act as the expert team on all matters concerning data standards; provide consultancy to stakeholders as needed or requested
- Provide consistent oversight of data collection and reporting standards to ensure alignment with all applicable internal clinical trial policies and procedures, health authority requirements, industry, best practice, and industry data submission standards [e.g. Study Data Tabulation Model (SDTM)]
- Recommend and oversee implementation of business processes which will allow for the definition, adoption and enforcement of these standards
- Requests for standards approval managed via service requests in an incident management system

Membership

Senior representatives with a background in Clinical Science, Biostatistics, Statistical Reporting and/or Data Management; Representatives from the Global Library team, Reporting Operations and Data Warehouse Operations; Extended team representation - Imaging, Pharmacokinetics, Biomarkers, Drug Safety and Epidemiology, and Clinical Quality Assurance

Lessons Learned

- Designing quality checks is an evolving process – and it's best that this is incorporated into system entry as much as possible
- Proactively manage expectations around defining fields in the MDR
 - Avoid creating a lot of metadata fields that are not used
 - Accept that you will want/need to add more metadata fields as your strategy evolves
- The definition of fields in the MDR is critical – make sure everyone has the same understanding
- Need to allow time for people to get used to reading and interpreting metadata
- Create a versioning strategy and methodology for each type of metadata stored upfront
 - Consider business requirements vs. theoretical when defining this strategy
- Maintaining an MDR that is not fully integrated with the systems that consume the metadata leads to sizeable efforts in keeping them consistent
- Have a technical solution for holding, defining, editing, searching the metadata



Metadata Repository

System Metadata Fields

Data Domain	CRF Domain	Domain Type	Data Element	Generic Type	Display Type	Length
AE	AE	EVENTS	AETERM	text	Char	70
AE	AE	EVENTS	AETERMFM	text	Char	200

Definitional Metadata Fields

Data Domain	SDTM domain	Dataset Label	Domain Type	Owner	Owner Version	DW Required

Process Metadata Fields

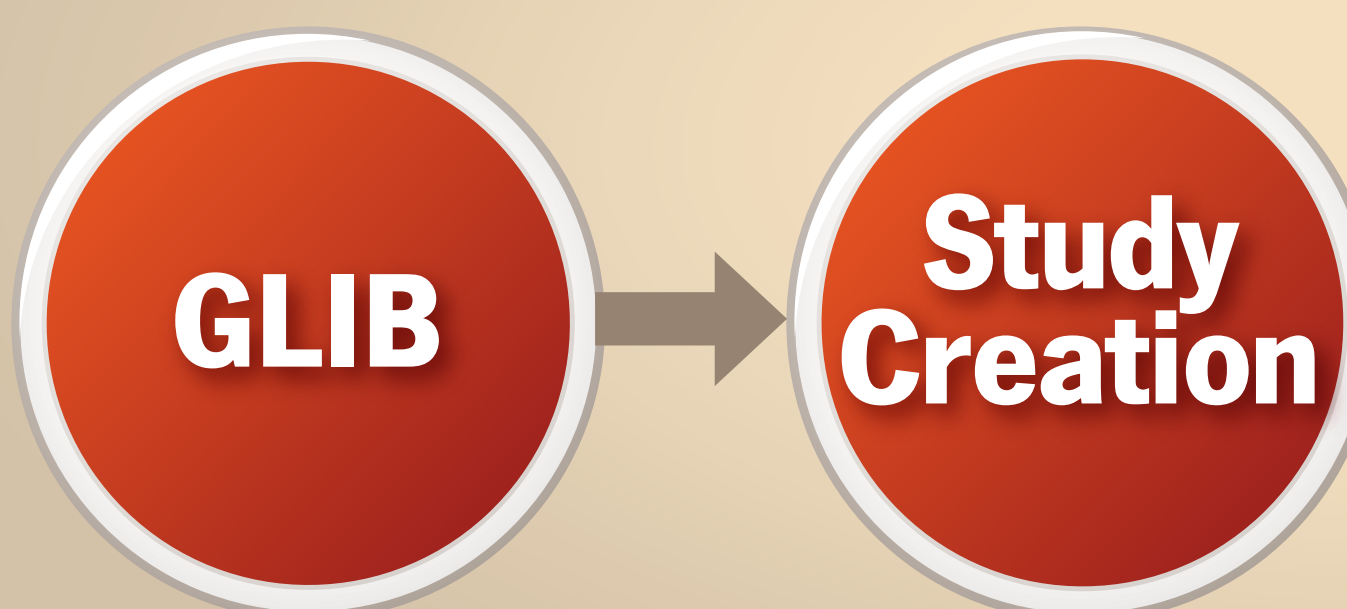
Data Domain	Derivation/Imputation Name	Execution Area
AE	D_AETERM_G01	CDMS
AE	D_AETERM_G01	CDMS
AE	TMS	CDMS
AE	TMS	CDMS

Transformational Metadata Fields

	Logical Name	Derivation/Inputation Name	Execution area	Final Data Elements	Fully qualified data element name	Keep Final Element	Contributing Data Elements
VS	STUDY_DAY_MERGE	MERGE_ELEMENT	SCR	RFSTDTN	DR VS RFSTDTN	No	DR VS PRTPART DR VS PATENT DR DM PRTPART DR DM PATENT DR DM PRSTDTN
VS	STUDY_DAY_MERGE	STUDY_DAY	SCR	VS DY	DR VS VS DY	Yes	DR VS VSOTDR VS RFSTDTN

Data Collection Metadata (i.e. CDASH standards)

Clinical Data Management System



Question Name	Question Domain	Occ Seq#	Disp Seq#	Data Type
AESQ	STANDARD	0	1	CHAR
SAERPDIT	STANDARD	0	2	DATE
AESTDAT	STANDARD	0	3	DATE
AESTTIM	STANDARD	0	4	TIME
AENDAT	STANDARD	0	5	DATE
AESTTIM	STANDARD	0	6	TIME
AESTXGR	STANDARD	0	7	CHAR
SAEID	STANDARD	0	8	CHAR
AFCAT	STANDARD	0	9	CHAR

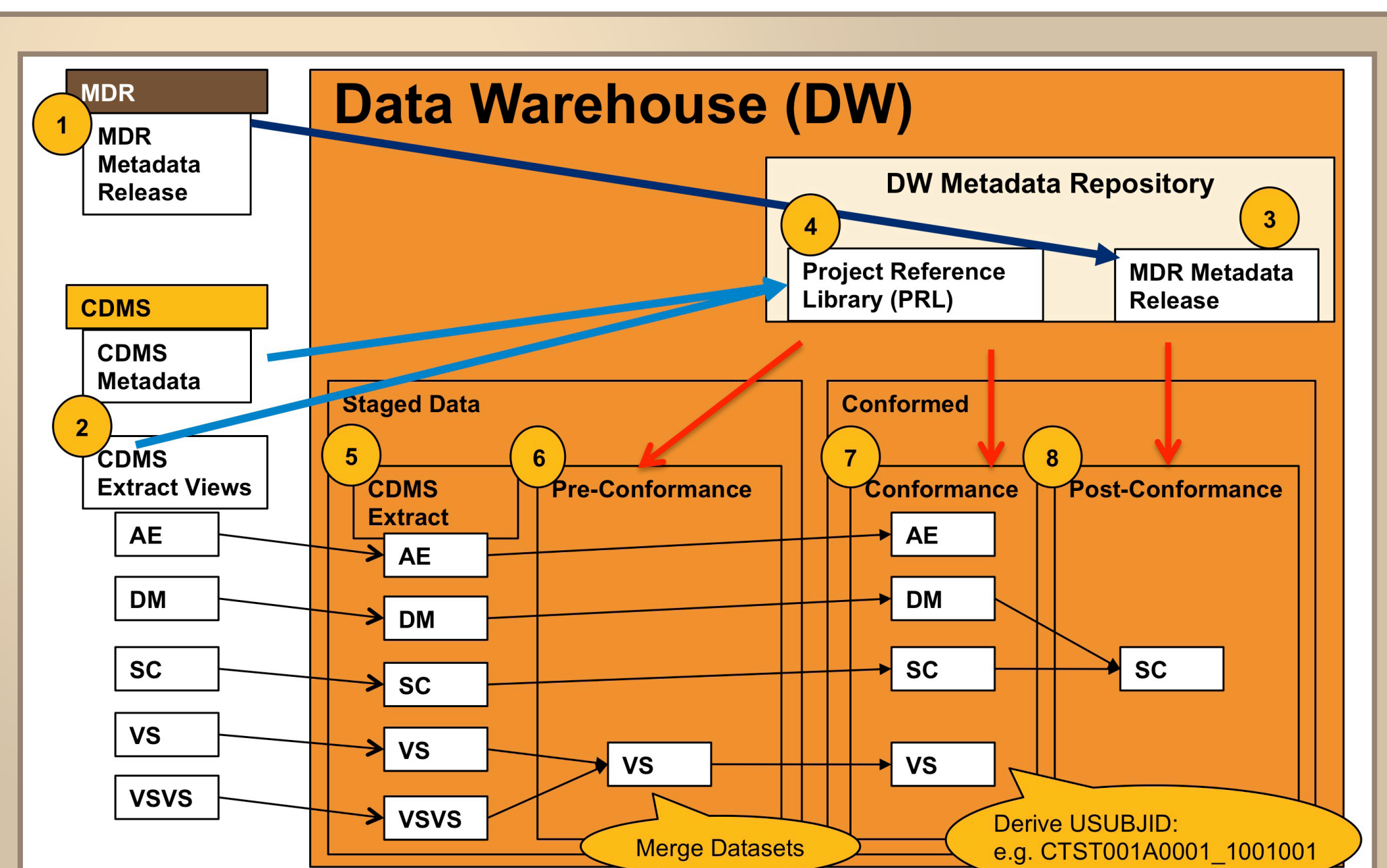
[illegible]

AEADJ_DLY	AEADJ	AEADJ_DLY	AEADJ_FUL	SAFETY
1 NONE	None	NONE		2010
2 DOSE ADJUSTED	Dose adjusted	DOSE ADJUSTED		2010
1 NONE	None	NONE		
1 NONE	None	NONE		
4 PERMANENTLY DISCONTINUED	Permanently discontinued	PERMANENTLY DISCONTINUED		
3 TEMPORARILY INTERRUPTED	Temporarily interrupted	TEMPORARILY INTERRUPTED		2010
1 NONE	None	NONE		
2 DOSE ADJUSTED	Dose adjusted	DOSE ADJUSTED		2010
1 NONE	None	NONE		

3rd Party Data

Quality Checks

Data Warehouse (DW)

[illegible]

Reporting



Clinical Study Report

[illegible]