



SDTM and ADaM: Metadata Playing Together Nicely



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Octagon Research Solutions

- A development partnering organization that offers regulatory, clinical, process and IT solutions to the life sciences industry.

Octagon Experience on Topic

- 700+ studies converted to SDTM & ADaM (14,000+ domains) in support of over 54 regulatory submissions to the FDA
- CDISC SDTM Co-authors
- CDISC SDS Team Lead
- Current CDISC team membership: SDS, ADaM, CDASH, SEND, SHARE, and Controlled Terminology
- FDA awarded a contract to Octagon for Legacy Data Conversion Services

Acquired by Accenture

- Acquisition finalized late September 2012
- Incorporating Octagon's CDISC data and electronic submission expertise into the broader set of Accenture's specialized life science services

Integration

SDTM AE

ADaM ADAE

**Metadata
Model**

**Metadata in
the Process**

MDR

Sponsors Present State

SDTM Metadata: Data Management or Programming?

ADaM Metadata: Programming or Statistics?

Handoff points?

Integration

- Integration prevents the problems and inconsistencies often seen at “handoff points” in the clinical data lifecycle, such as:
 - Data meanings
 - Visit structures
 - Baseline derivations

SDTM AE Metadata

Variable Name	Variable Label	Type	Controlled Terminology	Length	Format	CDISC	IG Version	Concept Group	Concept ID
USUBJID	Unique Subject Identifier	Char		30	\$30	SDTM	3.1.2	Global	Unique Subject Identifier within Submission
AESEQ	Sequence Number	Num		8	3.0	SDTM	3.1.2	Global	Subject Sequence
AETERM	Reported Term for Adverse Event	Char		200	\$200	SDTM	3.1.2	Adverse Event	Verbatim Adverse Event
AEDECOD	Dictionary -Derived Term	Char		200	\$200	SDTM	3.1.2	Dictionary	Dictionary Preferred Term
AESEV	Severity / Intensity	Char	AESEV	20	\$20	SDTM	3.1.2	Adverse Event	Severity
AEREL	Causality	Char	REL	20	\$20	SDTM	3.1.2	Adverse Event	Causal Relationship
AESTDTC	Start Date/Time of Adverse Event	Char	ISO 8601	30	\$30	SDTM	3.1.2	Adverse Event	AE Onset

CDISC

SPONSOR

ADaM ADAE Metadata

Variable Name	Variable Label	Type	Length	Controlled Terminology	Format	Source	Derivation
USUBJID	Unique Subject Identifier	Char	30		\$30	AE.USUBJID	
AESEQ	Sequence Number	Num	8		3.0	AE.AESEQ	
AETERM	Reported Term for the Adverse Event	Char	200		\$200	AE.AETERM	
TRTEMFL	Treatment Emergent Analysis Flag	Char	1	Y	\$1	ADSL.TRTSDT, ASTDT, ADSL.TRTEDT	If ADSL.TRTSDT <= ASTDT <= (ADSL.TRTEDT +21) then TRTEMFL='Y'
AESTDTC	Start Date/ Time of Adverse Event	Char	30	ISO 8601	\$30	AE.STDTC	
ASTDT	Analysis Start Date	Num	8		yymmdd10.	AE.STDTC	Macro [DTCN,AE.AESTDTC]
AOCCPFL	1st Occurrence of Preferred Term Flag	Char	1	Y	\$1	TRTEMFL USUBJID AEDECOD ASTDT AESEQ	(TRTEMFL='Y') Sort Order (USUBJID), (AEDECOD), (ASTDT) If FIRST.AEDECOD, then (AOCCPFL ='Y')
AGEGR1	Pooled Age Group 1	Char	20	AGEG1	\$20	ADSL. AGEGR1	

- A well-thought out and appropriate metadata model plays an important role in the successful use of metadata.
- The following metadata topics need to be considered for evaluation in order to define the metadata model that will be fit-for-purpose for the sponsor.

Distinct levels of standards (global, project, etc.)

Taxonomy (directory structure)

Templates for import and export (MS Excel, XML, etc.)

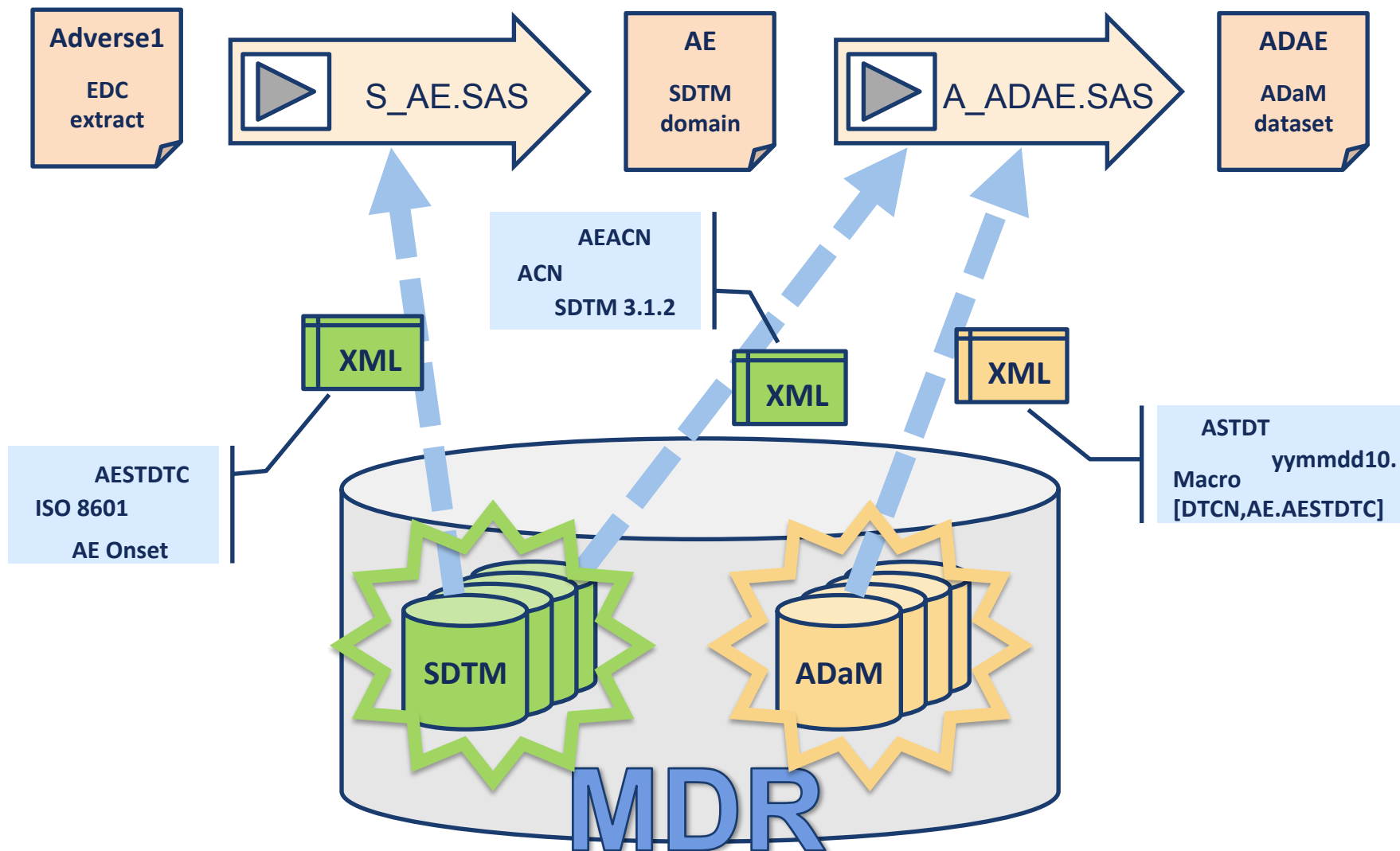
Impact analysis for changes to the standards

Auto-propagation of changes between standards levels

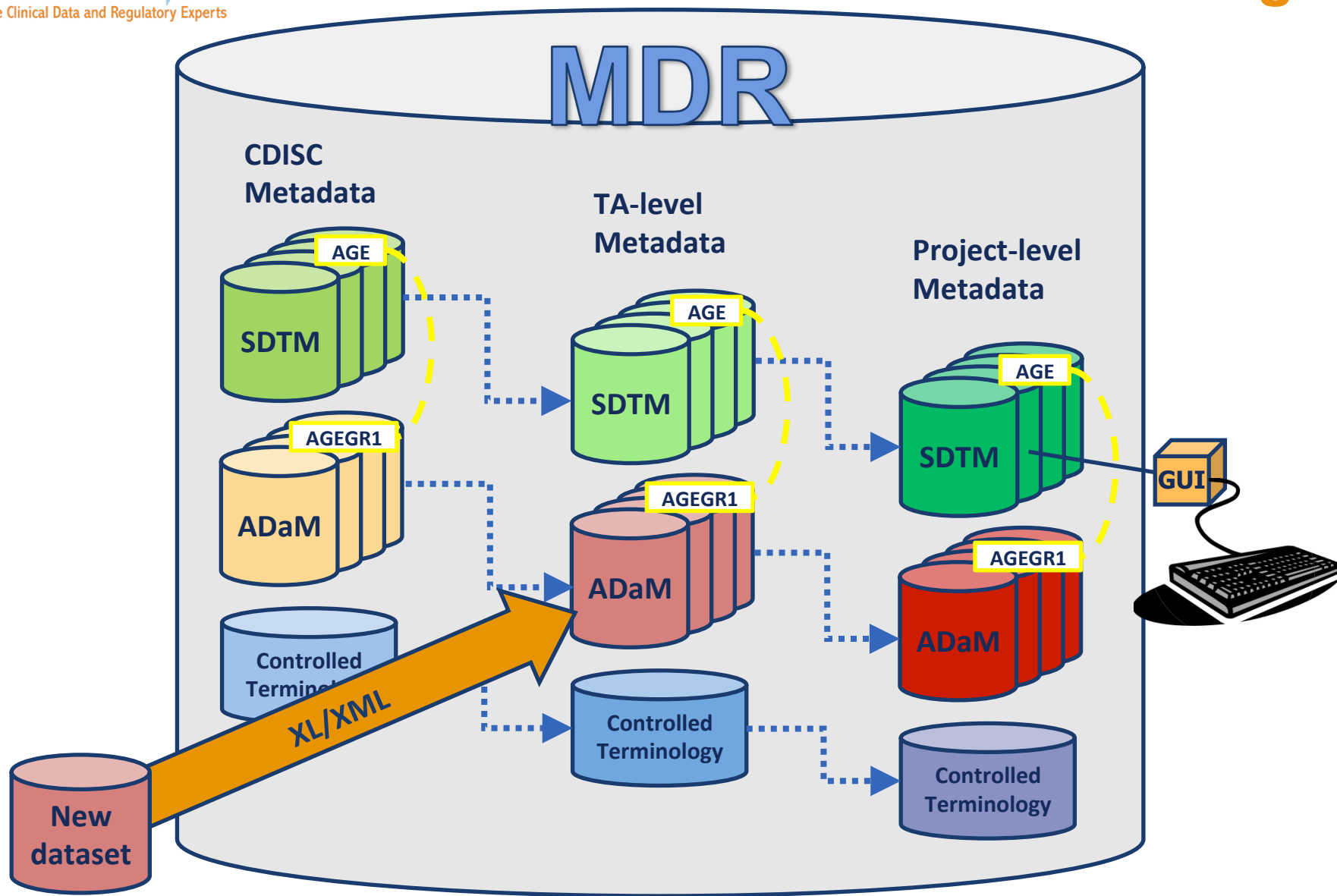
Sponsor-specific attributes beyond the CDISC attributes

Groupings of attributes for specific purposes (versioning, EDC, access, etc.)

Metadata Working Together



Metadata Storage





Optimizing the production of regulatory compliant deliverables?

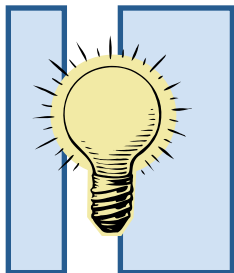
- Integrated development and maintenance of SDTM and ADaM
- Flexibility of metadata model to accommodate multiple standards domain models
- MDR functionality to support metadata maintenance and metadata export
- Systems and processes of the clinical data lifecycle consumption of centrally-managed metadata

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***Feel free to visit the Octagon booth for
more information on Octagon's solutions***

Questions

