

Managing ADaM Metadata

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 - ADaM metadata spec builder
 - ADaM metadata manager
- Toolkit interaction (how all components work together)
- Conclusion / Summary
- Questions

What's ADaM Metadata?



Recap

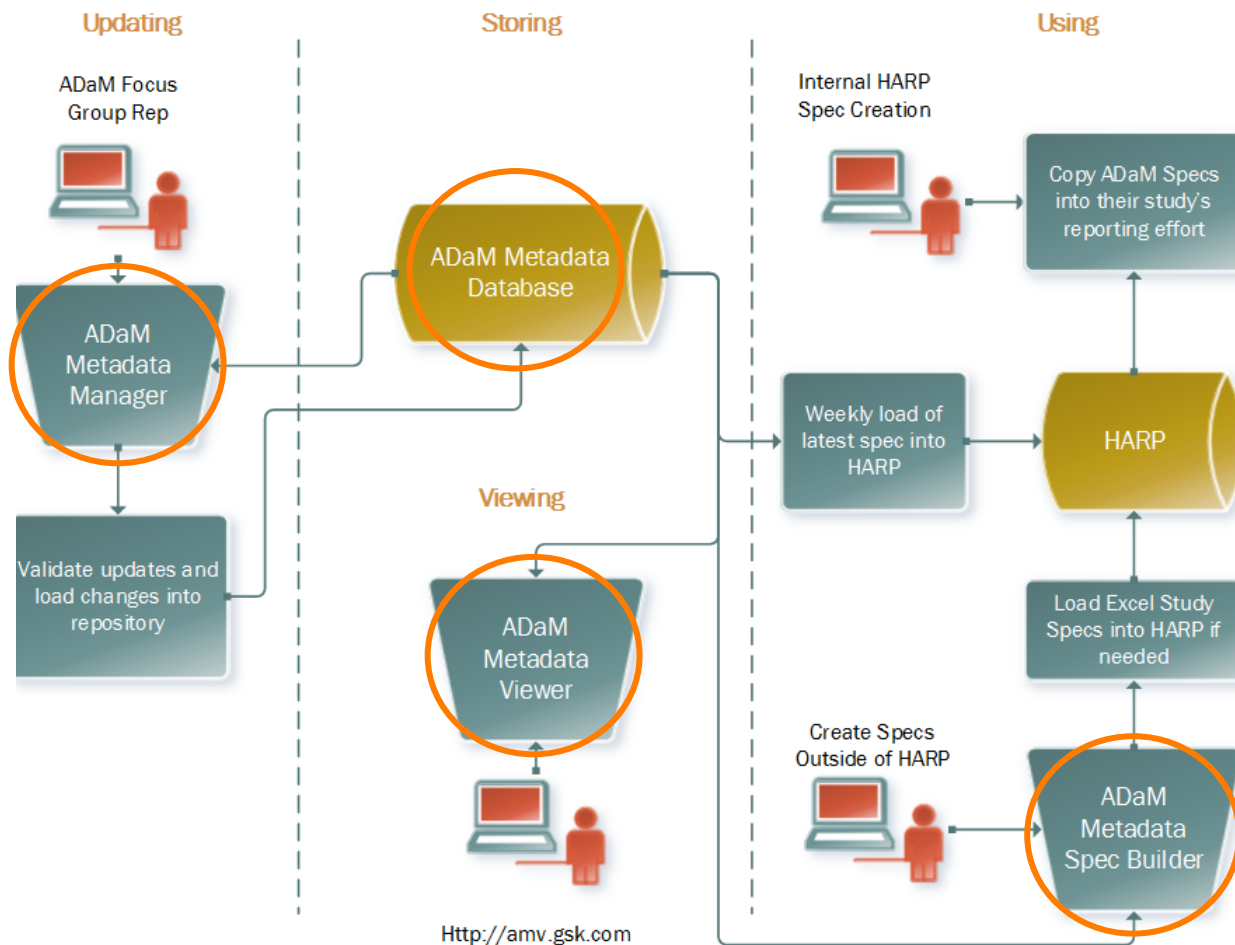
- Metadata is central to the whole process of a CDISC-compliant submission
- It provides a framework for the data;
 - some metadata (e.g. variable type, maximum length etc) is fixed in the standards
 - the metadata can be used as a data specification, e.g. for sharing with suppliers
- and traceability;
 - A key concept in CDISC is a fully-traceable analysis,
Analytical Results → Analysis Dataset → Collected Data → Source
- at every level of the data;
 - Metadata for datasets, variables, values of variables
 - Additionally, displayed data can optionally have metadata

Requirements

- A central repository to store key ADaM metadata
 - version control
 - Easily updatable
- Easily incorporate to MS tools
- Web based solution
- Consuming of data

Introduction to the Toolkit

Metadata EcoSystem



Components of the Toolkit : Storage



ADaM Metadata Database

- Oracle Database storing a series of tables containing the Metadata.
- Key tables within the AMD include:
 - The Domains table
 - The specifications table
- Version Control
 - controlled terms list that has no version control
 - Specs and Variables tables have Implementation Guide version and date version control
 - **“From IG Version”** is populated when a spec is entered into the database
 - **“To IG Version”** (initially missing). When a specification changes as per the IG, the old spec has the “To IG Guide” populated with the old version and a new spec is created for the new IG.

DomName	TA	Ind	FromIGVer	ToIGVer
ADSL	CORE	CORE	1.0	2.0
ADSL	CORE	CORE	2.0	

Components of the Toolkit : Storage



ADaM Metadata Database

Each piece of metadata in the database has “From Date” and “To Date” attributes associated with it.

- This allows updates and new versions to be stored in the same way as the IG version.

The database has been set up so that the **specifications are additive**. We hold Core, Therapeutic Area (TA), and Indication level specifications.

- Core is the lowest level and all the core variables are available in the TA and Indication level specifications.
- The TA and Indication specific variables and metadata are then added to the core specification.
- This inter-dependence means that any changes made to the core specifications get cascaded down to the TA and Indication levels.

Components of the Toolkit : Storage



ADaM Metadata Database

- There are 2 tables relevant to Controlled Terms within the database.
- The first is The controlled Terms List that stores the domain and type that are associated with the controlled term. This table has no version control.
- The second is the Controlled Term table that stores the code/decode pairs this has internal control only.
- Computational Methods table stores default computational methods. If a default CM is updated then it automatically applies to all new studies, no version control is applied.

Components of the Toolkit : Viewing

ADaM Metadata Viewer



ADaM Metadata Viewer

ADaM Domains	ADaM Specs	Master Variable List	Value Level Metadata	Computational Methods	Controlled Terminology List
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Filters:

Domain Name: Class: [Filter Table](#)

Tools:

[Reset All Filters](#)[Export to Excel](#)

Click on column headers to sort table

Domain Name	Label	Repeating	Class	Source	Data Structure	Key Variables	Description	Documentation
ADAE	Adverse Events Analysis	Y	ADAE	AE	One record per subject per each adverse event recorded in SDTM AE domain	STUDYID, USUBJID, ASTDT, AEDECOD	Contains the adverse event analysis	
ADCM	Concomitant Medications Analysis	Y	OTHER	CM	One record per subject per medication/ingredient	USUBJID, ADECOD, CMSTDTC, CMENDTC	Contains Concomitant Medications	The GSK drug version should be same as the one used for SDTM.
ADCOMP	Compliance Analysis	Y	BDS	DA	One record per usubject per avisit per dascat per paramcd	STUDYID, USUBJID, APERIOD, AVISITN, DACAT, DASCAT, PARAMN	Contains the compliance analysis	
ADDS	Disposition Analysis	Y	BDS	DS	One record per subject per datetime per parameter per result	STUDYID, USUBJID, ADT, ATM, PARCAT1, PARAMCD, AVALORD	Contains Disposition analysis	
ADDEV	Deviation and Pop Exclusion Analysis	Y	ODS	DV, POPEXC	One record per study, per subject, per term, per start time, per reporting timepoint	STUDYID, USUBJID, ATERM, ASTDT, ARETPT	Contains protocol deviation and analysis population exclusion details	
ADEG	ECG Analysis	Y	BDS	EG, ADSL	One record per subject per parameter per analysis visit per timepoint	STUDYID, USUBJID, PARAM, AVISIT, ADT, ATM, ASTDT	Contains ECG analysis	

Components of the Toolkit : Viewing

ADaM Metadata Viewer



ADaM Metadata Viewer

ADaM Domains	ADaM Specs	Master Variable List	Value Level Metadata	Computational Methods	Controlled Terminology List
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Filters:

Domain Name: Therapeutic Area: Indication: Variable Name: [Filter Table](#)

Tools:

[Reset All Filters](#)
[Export to Excel](#)

Click on column headers to sort table

Domain Name	Therapeutic Area	Indication	Variable Name	Label	Type	Max Length	Significant Digits	Variable Order	Value Level Metadata	Controlled Term or Formats	Computational Method	Mandatory	Sort Order	Definition / Comments	Additional Information	Required
ADPFT	RESPIRATORY	RESPIRATORY: CORE	STUDYID	Study Identifier	Text	9		10				Y	1	RE.STUDYID		Req
ADPFT	RESPIRATORY	RESPIRATORY: CORE	USUBJID	Unique Subject Identifier	Text	30		20				Y	2	RE.USUBJID		Req
ADPFT	RESPIRATORY	RESPIRATORY: CORE	SITEID	Study Site Identifier	Text	10		30				Y		ADSL.SITEID		Perm
ADPFT	RESPIRATORY	RESPIRATORY: CORE	AGE	Age	Integer	8		40						ADSL.AGE		Perm
ADPFT	RESPIRATORY	RESPIRATORY: CORE	SEX	Sex	Text	1		50		SEX		Y		ADSL.SEX		Perm
ADPFT	RESPIRATORY	RESPIRATORY: CORE	RACE	Race	Text	100		60		RACE		Y		ADSL.RACE		Perm
ADPFT	RESPIRATORY	RESPIRATORY: CORE	ACOUNTRY	Analysis Country	Text	100		70				Y		ADSL.ACOUNTRY		Perm
ADPFT	RESPIRATORY	RESPIRATORY: CORE	COMPLFL	Completers Population	Text	1		80		NY				ADSL.COMPFL		Perm

Components of the Toolkit : Using

ADaM Metadata Spec Builder



The screenshot displays the ADaM Metadata Spec Builder application. A 'Create New Study Spec' dialog box is open, featuring the following fields and controls:

- Select ADaM IG Version:** A dropdown menu with '1.0' selected.
- Select Therapeutic Area:** A dropdown menu with 'CORE' selected.
- Select Indication:** A dropdown menu with 'CORE' selected.
- Select GSK Version Date:** A date field showing '13/Aug/2015' and a calendar icon.
- Buttons:** 'OK' and 'Cancel' buttons at the bottom.

An orange arrow points to the 'OK' button. The background interface includes a 'Start: Initialize Spec' button, a 'Reset Workbook' button, and a 'Server' button. The application window has a menu bar with 'Setup', 'VLMs', 'Controlled Terms', 'Computational Methods', and 'ADSL'.

Components of the Toolkit : Updating

ADaM Metadata Manager



GSK ADaM Metadata Manager v0.4.01

Instructions:
To start, click the "Start: Load Domain" button.
Choose the dataset to be modified from the list or choose

Start: Load Domain **Reset Work**

Admin Only: **Prepare** **Server**

Select Domain to Modify

Select Domain: ADLB

Select Therapeutic Area: CORE

Select Indication: CORE

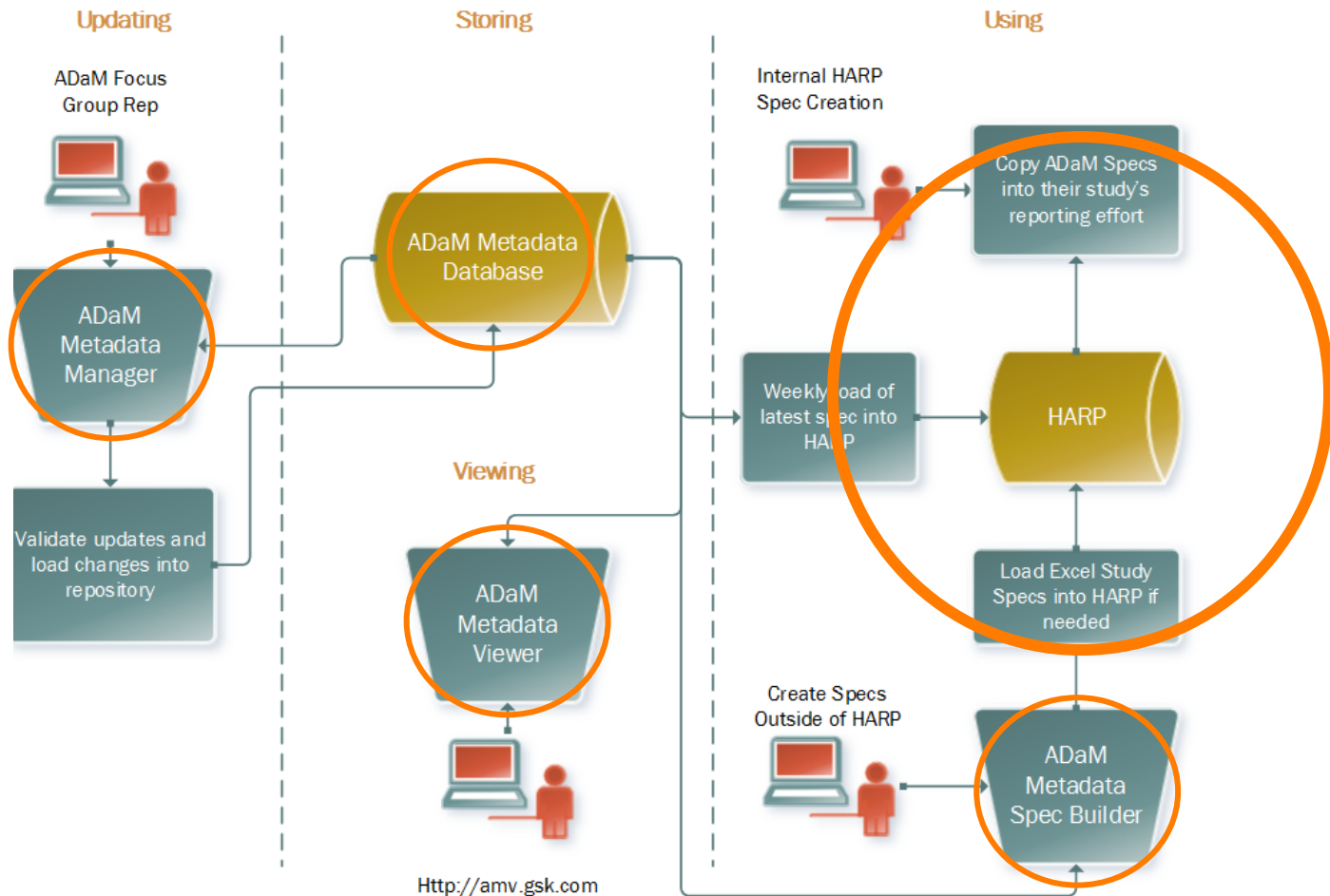
OK **Cancel**

Components of the Toolkit : Updating ADaM Metadata Manager



	A	B	C	D	E	F	G	H	I	J	K	L
1	Add New Variable to Spec		Remove Variable(s)		Attach VLM to Variable		Attach Controlled Terminology to Variable		Attach Computational Method to Variable			
2	Dataset Name:	ADSL	Label:	Subject-Level Analysis						Documentation:		
3	Class:	ADSL	Data structure:	One record per subject								
4	Repeating:	N	Key Variables:	USUBJID								
5	Source data:	DM, DS, EX, VS	Description:									
6	Therapeutic Area	Indication	Variable Name	ADaM IG From Version	ADaM IG To Version	Variable Order	Mandatory	Significant Digits	Sort Order	Required	Controlled Term or Formats	Value Level Metadata
102	CONSUMER HEALTHCARE	CONSUMER HEALTHCARE: CORE	TRTEDTM	1.0		960				Cond Exp		
103	CORE	CORE	TRTEDTF	1.0		970				Cond Exp	DATEFL	
104	CORE	CORE	TRTETMF	1.0		980				Cond Exp	TIMEFL	
105	CONSUMER HEALTHCARE	CONSUMER HEALTHCARE: CORE	DTHDT	1.0		990				Exp		
106	CONSUMER HEALTHCARE	CONSUMER HEALTHCARE: CORE	SCRDT	1.0		1000				Perm		
107	CONSUMER HEALTHCARE	CONSUMER HEALTHCARE: CORE	FSTCTDT	1.0		1010				Perm		
108	CONSUMER HEALTHCARE	CONSUMER HEALTHCARE: CORE	LSTCTDT	1.0		1020				Perm		
109	CONSUMER HEALTHCARE	CONSUMER HEALTHCARE: CORE	BRTHDT	1.0		1030				Perm		
110	CORE	CORE	HEIGHTBL	1.0		1040				Perm		
111	CORE	CORE	WEIGHTBL	1.0		1050				Perm		
112	CORE	CORE	BMIBL	1.0		1060				Perm		

Toolkit interaction (how all components work together)



- The ADaM Metadata Toolkit is the current method that enables the management, storage and viewing of the metadata that has thus far been developed. The toolkit is user friendly enabling the metadata to be viewed by version and/or date and allows updates to the metadata by administrators.
- Uploading of updated metadata is loaded into the database via a SAS® script. The creation of a define.xml from AMSB is also via a SAS script. These SAS scripts complete the requirements of the toolkit.
- The toolkit provides a complete system to manage GSK's ADaM Metadata and the initial user feedback (for the pilot) has been very positive on every aspect.



Thank-you