



Development Process and Governance of Implementing ADaM

d-Wise Technologies

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Agenda

- ADaM Development Methodology
- Follow the Rules
- Standards Governance
- Lessons Learned

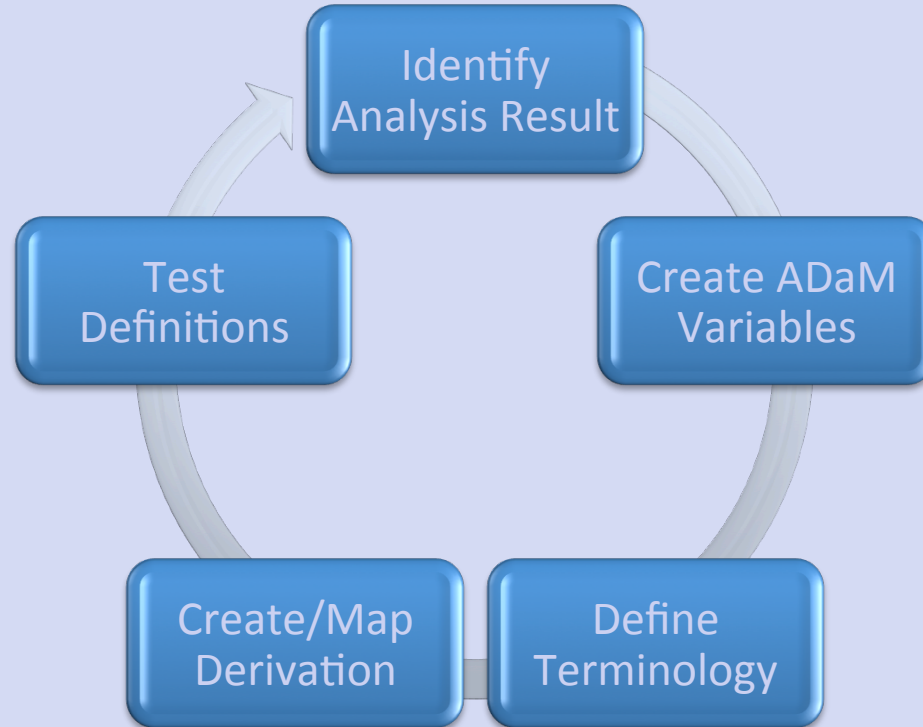
The Old Way

	Drug A (N=)	Drug B (N=)	All (N=)
Sex	$\bar{n}$ (%)	$\bar{n}$ (%)	$\bar{n}$ (%)
Male	xx (x.x)	xx (x.x)	xx (x.x)
Female	xx (x.x)	xx (x.x)	xx (x.x)
Race	$\bar{n}$ (%)	$\bar{n}$ (%)	$\bar{n}$ (%)
Caucasian	xx (x.x)	xx (x.x)	xx (x.x)
Hispanic	xx (x.x)	xx (x.x)	xx (x.x)
Asian	xx (x.x)	xx (x.x)	xx (x.x)
African	xx (x.x)	xx (x.x)	xx (x.x)
Age			
N			
Mean			
Standard Deviation			
Median			
Minimum			
Maximum			

Analysis Result Drives Data

	Drug A (N=)	Drug B (N=)	All (N=)
Sex	n (%)	n (%)	n (%)
Male	xx (x.x)	xx (x.x)	xx (x.x)
Female	xx (x.x)	xx (x.x)	xx (x.x)
Race	n (%)	n (%)	n (%)
Caucasian	xx (x.x)	xx (x.x)	xx (x.x)
Hispanic	xx (x.x)	xx (x.x)	xx (x.x)
Asian	xx (x.x)	xx (x.x)	xx (x.x)
African	xx (x.x)	xx (x.x)	xx (x.x)
Age			
N			
Mean			
Standard Deviation			
Median			
Minimum			
Maximum			

Analysis Result Methodology



Identify Analysis Result

- A Table does not define an Analysis
- Analysis Result is the most granular analysis component
- Define Analysis Result attributes:
 - Unique Identifier
 - Result Label
 - Reporting Requirements (i.e. Type, Stats)
 - Data Requirements (i.e. Analysis Value, Treatment, Population), Time, Parameter

Analysis Result Example

Analysis Result Identifier	Analysis Result Label	Reporting Requirements		Data Requirements					
		Type	Stats	Analysis Value	Treatment	Population	Parameter	Time	Covariate 1
AR4	Comparison of Treatments for Weekly Mean Pain Score	PVALUE	T-TEST	Dose	Planned Treatment	Per Protocol	Weekly Mean Dose	Week	Pain at Baseline
AR5	Weekly Mean Dose	CONT	N, Mean, etc.	Dose	Planned Treatment	Per Protocol	Weekly Mean Dose	Week	

Create ADaM Variables

- Define ADaM variables based on Analysis Result definition

AR Identifier	Element Type	ADaM Structure	ADaM Variable	Variable attribute 1	Variable attribute 2	Terminology	Algorithm
AR5	Analysis Value	ADPN	AVAL	Float	8.		Description
AR5	Treatment	ADSL	TRT01P	Text		TRT01P	Description
AR5	Population	ADSL	PPROTFL	Text	\$1	YN	Description
AR5	Time	ADPN	AVISIT	Text	\$10	AVISIT	Description
AR5	Parameter	ADPN	PARAMCD	Text	\$8	WKPNSCR	Description

Create Terminology

- Different from data values
- Different types of metadata
 - Analysis result identifiers
 - ADaM structures
 - ADaM variable names and attributes
 - Variable value (typical terminology)
 - Value level terminology
 - Derivation terminology where possible

Create Value Level Metadata

- Defining attributes of one variable based on a value of another variable
- Linking PARAM to the related variable
- Soon to be supported in define 2.0

Parameter Identifier	Parameter Name	Parameter Value	Parameter Code	Linked Variable	Linked Format	Linked Derivation	OTHER LINKED METADATA
PVK1	PARAMCD	Systolic Blood Pressure (mmHg)	ASYSTBP	AVAL	4.	LDERV1	Contains other metadata describing AVAL

Create Derivations

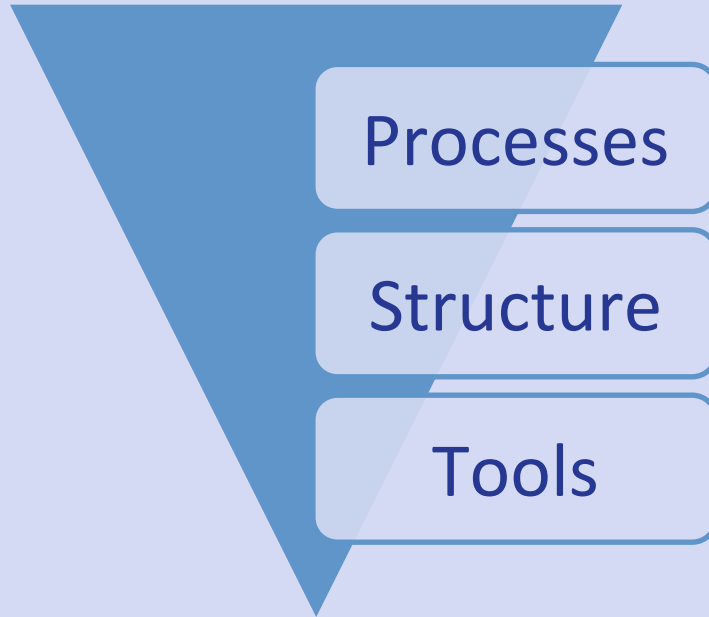
- Can we standard a derivation language?
- No...But maybe we can take small steps

Derivation Identifier	Derivation Name	Category	Description	Executable Code	Derivation Link 1
DV1	RACE	COPY	Copy from SDTM	DM.RACE	Link to source information
DV2	AGEGR1	DIRECT	Age Grouping <65, >=65	If AD.SL.AGE<65 then AGEGR1='AGE<65' Else if AD.SL.AGE>=65 then AGEGR1='AGE>=65'	Link to source information
DV3	WEEKMN DOSE	INTERNAL	Weekly Mean Dose calculated over 7 days	%WEEKLYMNDOSE(var1=, var2=, var3=,...)	Link to source information
DV4	TIMETO EVENT	EXTERNAL		%TIMETOEVENT()	Link to source information

‘Regulating’ the Process

- Significant flexibility within analysis data: Blessing and a curse
- Need to define rules and follow them
 - Data Flow
 - Source of ADaM
 - Derive or Not to Derive
 - Large or Small
 - Source of Analysis
 - Integration

Governance Structure



Process Definition

ADaM Development

- Develop process for defining ADaM elements
- Review and approval process

Standards Hierarchy

- Define levels of standards (e.g. Global vs. Therapeutic)
- Define scope of all ADaM elements

Implementation

- How will people use the ADaM elements
- How do they add, change, access ADaM library

Maintenance

- Ongoing control of the library
- Individual study control and maintenance

People – Who and Why

Global

Standards
Board

Therapeutic

Therapeutic
Team

Therapeutic
Team

Submission

SMEs

SMEs

SMEs

SMEs

Lessons Learned

- Control, Control, Control
 - Need tight control over development and use of standards
- Crawl Before you Walk
 - Cannot do it all at once, but yet we still try
- Metadata Gone Wild
 - Start small and build in parallel to tools

Metadata Infrastructure



Metadata Infrastructure



So I called this meeting today because the developers say they need our marketing data for their software. Unfortunately, all the data is stuck in an Access database, and I don't know how to use Access, so we have to figure something out. Any ideas?



Access?! If they wanted a database, then why didn't they just use Word?



You idiot! Word is a spreadsheet program. Obviously, we need to somehow get this data into Excel.



I know! I know! We could cut and paste! I know how to cut and paste. We could do that!



No! No cutting! Remember what happened last time? Look at my stump!



Ooooooh! I know! We could print out the data, scan it in, and then paste the image into Excel!



Lessons Learned

- Stop Coding
 - Mentality of heads down coding
 - Need design, processes, and structure
- Avoiding “It Depends”
 - Analyses are not really that unique
 - Don’ t void the hard decisions

Summary

- Let the Analysis Results drive the definition of ADaM
- Spend time to build robust ADaM metadata
- Governance is more important than the actual standards
- Plan, process, and iteration

“In preparing for battle I have always found that plans are useless, but planning is indispensable.”, Dwight D. Eisenhower