

CDISC Analysis Results Standard

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Background

ADaM currently provides basic ***standardized inputs*** to enable analysis

- Subject-Level Analysis Dataset (ADSL)
- Basic Data Structure (BDS)
 - Time to Event (TTE)
- Occurrence Data Structure (OCCDS)
 - Adverse Events (ADAE)
- Limited Controlled Terminology



Background

- Analysis Results Metadata (ARM) *extension to the Define-XML 2.0 model*
 - Provides traceability for a given analysis result to the specific ADaM data that were used as input to generating the analysis result
 - Provides standard metadata fields to represent analysis method used and the reason the analysis was performed

Table 4.2.2: HbA1c Longitudinal Repeated Measures Analysis Results Metadata

Metadata Field	Metadata
DISPLAY IDENTIFIER	Table 4.2.1/Figure 4.2.1
DISPLAY NAME	Mean Change from Baseline in HbA1c (Percent) Longitudinal Repeated Measures Analysis, 24-Week Short-term Double-blind Treatment Period, Intention-to-treat Population
RESULT IDENTIFIER	Treatment difference results (LSMean, confidence interval, p-value)
PARAM	HbA1c (%)
PARAMCD	HBA1C
ANALYSIS VARIABLE	CHG (Change from baseline)
ANALYSIS REASON	SPECIFIED IN SAP
ANALYSIS PURPOSE	PRIMARY OUTCOME MEASURE
ANALYSIS DATASET	ADHBA1C
SELECTION CRITERIA	ITTFL= "Y" and PARAMCD = "HBA1C" and CHG ne . and ANL01FL = "Y" and DTYPE = " "
DOCUMENTATION	See SAP Section XX for details. Program: t-hba1c-repmeas.sas LS means and 95% CIs are based on repeated measures model adjusting for planned treatment, baseline HbA1c value, avisit, avisit*baseline and avisit*treatment interaction.
PROGRAMMING STATEMENTS	[SAS version 9.2] <pre> PROC MIXED DATA = ADHBA1C; WHERE ITTFL = "Y" and PARAMCD = "HBA1C" and CHG ne . and ANL01FL = "Y" and DTYPE = " "; CLASS TRTP AVISIT; MODEL CHG = TRTP BASE AVISIT BASE*AVISIT AVISIT*TRTP / DDFM=KR; LSMEANS TRTP / CL DIFF; REPEATED usubjid / subject = USUBJID TYPE=UN; RUN ; </pre>



N: the number of subjects in the Intention-to-treat (ITT) Population.
 M: the number of subjects in the ITT population with non-missing baseline and non-missing Week 2 value.
 Repeated measures model: change = baseline treatment visit visit*treatment
 Program Name: %%%%%%%%%%%\source\trial\trial-regress.sas <date> <time>

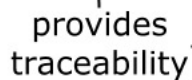


Table 4.2.2: HbA1c Longitudinal Repeated Measures Analysis Results Metadata

Enhancing ADaM standards



Add features that support automation of analysis results by extending Analysis Results Metadata (ARM) for Define-XML

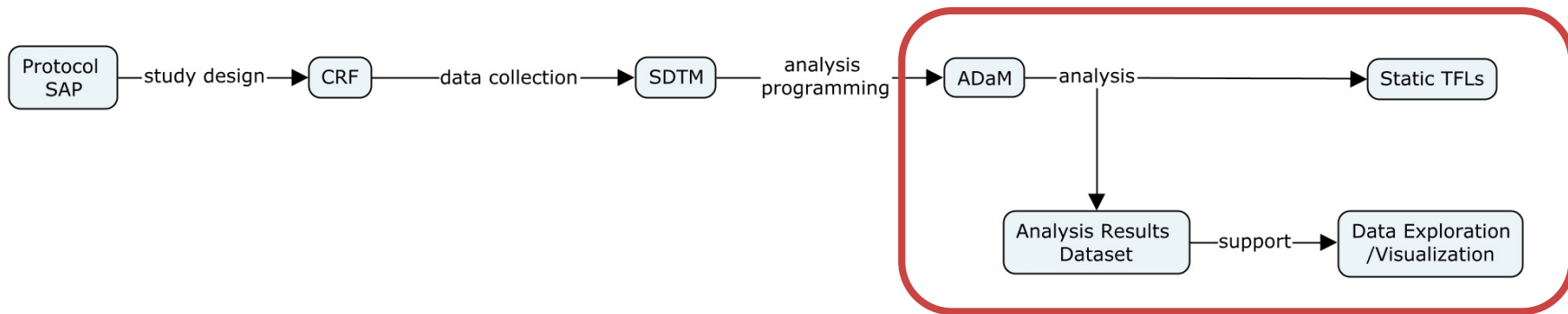


Create a standardized structure for analysis results to support reuse and dynamic data display generation

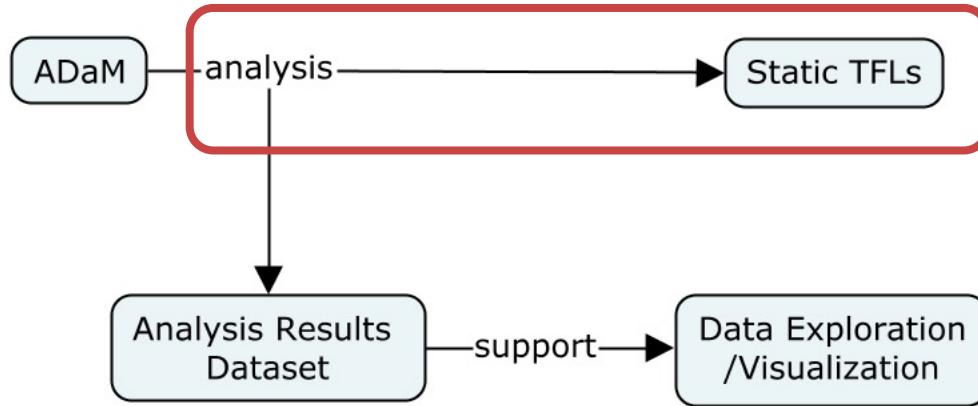


Decrease implementation variability by tightening the standardization of ADaM metadata for generally accepted analyses

Where Is Our Focus?



Goal 1: Extend ARM to Facilitate Automated TFL Generation



The ARM extension will be ***adding normative content*** to the existing ARM Define standard

Extend ARM Specification for Define.xml

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PROGRAMMING STATEMENTS	<pre>[SAS version 9.2] PROC MIXED DATA = ADHBA1C; WHERE ITTFL = "Y" and PARAMCD = "HBA1C" and CHG ne . and ANL01FL = "Y" and DTYPE = " "; CLASS TRTP AVISIT; MODEL CHG = TRTP BASE AVISIT BASE*AVISIT AVISIT*TRTP / DDFM=KR; LSMEANS TRTP / CL DIFF; REPEATED usubjid / subject = USUBJID TYPE=UN; RUN ;</pre>



**Analysis Results Metadata Specification
Version 1.0
for
Define-XML Version 2**

Need for standard analysis definition

The ARM specification standardizes the metadata structure for the define.xml

CDISC ARM v1 Metadata

Study - CDISC 360

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.
Datasets used - adsl
Executed by <Username> on DDMONYYYY:HH:MM

Result

ResultOID

Description

Reason

Purpose

Dataset

WhereClause

AnalysisVariable

Documentation

ProgrammingCode

Display

DisplayOID

Name

Title

Document

Reference: 'Automation of TFL Generation using CDISC 360 Enriched Metadata'; Bhavin Busa, Prasanna Murugesan, Stuart Malcom; CDISC US Interchange 2020

CDISC ARM v1 Metadata Extensions

Output (Study, Analysis, Group, Filename/Type, Style)

Result

Version
DisplayPattern
Grouping
- AnalysisVar
- ByVar
CodeReference

Study - CDISC 360

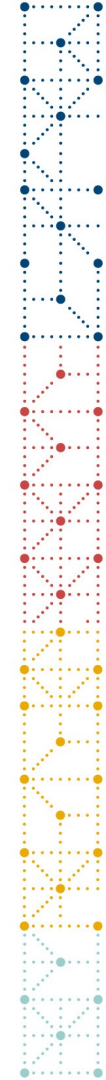
Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.
Datasets used - adsl
Executed by <Username> on DDMMYYYY:HH:MM

Display

Parent
Version
Grouping:
- Dataset
- WhereClause
- AnalysisVar
- ByVar
Template
Title 1..N
RowLabelHeader
Header 1..N
Footer 1..N



CDISC 360 Enriched TFL Metadata

- Based on CDISC ARM v1
- Added OUTPUT & STYLE
- Extended DISPLAY and RESULT
 - Parent
 - Version
 - Grouping and ByVar
 - CodeReference
- Use-cases for production TFL automation

Reference: 'Automation of TFL Generation using CDISC 360 Enriched Metadata' ; Bhavin Busa, Prasanna Murugesan, Stuart Malcom; CDISC US Interchange 2020

Extended Analysis Results Metadata Example

Study - CDISC 360

Table 14.1.1.1
Demographic characteristics (Safety Population)

Characteristics	METFORMIN (N=XX)	HUMAN INSULIN (N=XX)
Age (years)		
n	XX	XX
Mean	XX.X	XX.X
SD	XX.XX	XX.XX
Min	XX	XX
Q25	XX.X	XX.X
Median	XX.X	XX.X
Q75	XX.X	XX.X
Max	XX	XX
Age Group - n (%)		
15 - <30 years	XX (XX.X)	XX (XX.X)
30 - <45 years	XX (XX.X)	XX (XX.X)
>=45 years	XX (XX.X)	XX (XX.X)
Gender - n (%)		
Male	XX (XX.X)	XX (XX.X)
Female	XX (XX.X)	XX (XX.X)

Max = Maximum. Min = Minimum. N = Number of subjects in treatment group. n = Number of subjects included in analysis. SD = Standard deviation.
Datasets used - adsl
Executed by <Username> on DDMMYYYY:HH:MM

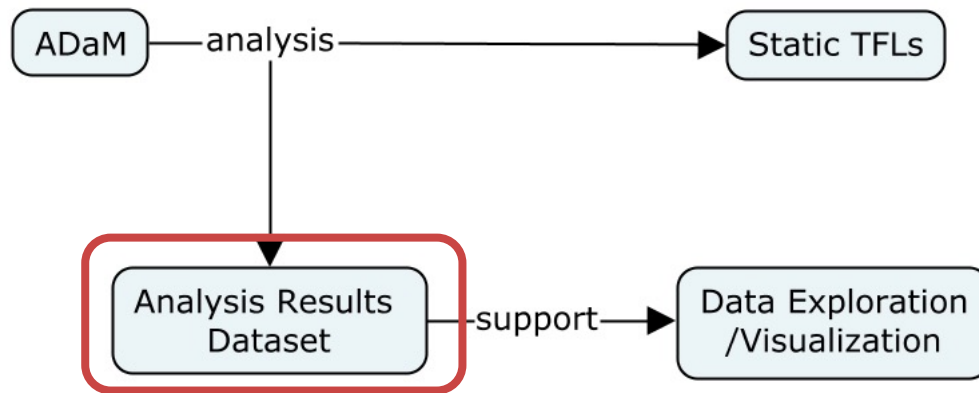
Study	Analysis	Group	Order	DisplayID	DisplayVersion	Filename	Type	StyleID
CDISC	CDISC 360	Safety	1	T14111_SAF_DEMOG	1	tdemog_saf	rtf	table_rtf
CDISC	CDISC 360	Safety	2	T14131_SAF_AE2TIER	1	tae_soc_pt_saf	rtf	table_rtf
CDISC	CDISC 360	Efficacy	3	T1421_EFF	1	tmace_edpt_fas	rtf	table_rtf

DisplayID	DisplayName	DisplayTitle	Title1	Title2	Title3
T14111_SAF_DEMOG	Table 14.1.1.1	Demographic characteristics (SAF)	Study - CDISC 360	Table 14.1.1.1	Demographic characteristics (Safety Population)

ResultDisplayOID	AnalysisResultOID	Version	ResultDescription	DisplayPattern
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	n	xxx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Mean	xx.x
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	SD	xx.xx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Min	xx
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Q25	xx.x
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Median	xx.x
T14111_SAF_DEMOG	T14111_01_SAF_DEMOG	1	Q75	xx.x

WhereClauseOID	Dataset	Variable	Comparator	Value
T14111_02_SAF_DEMOG_01	ADSL	AGEGR1	EQ	15 <= to <30 years
T14111_02_SAF_DEMOG_02	ADSL	AGEGR1	EQ	30 <= to <45 years
T14111_02_SAF_DEMOG_03	ADSL	AGEGR1	EQ	>=45 years
T14111_03_SAF_DEMOG_01	ADSL	SEX	EQ	M
T14111_03_SAF_DEMOG_02	ADSL	SEX	EQ	F

Goal 2: Create Standardized Structure for Analysis Results to Support Dynamic Data Display Generation and Reuse



The Analysis Results Dataset will be considered a ***new CDISC foundational standard***

Analysis Results Dataset

qb:Observation	qb:Table	dim.population	dim.treatment	dim.parameter	dim.sex	dim.agecat	dim.statistic	analysisResult
1001 dm.summary	enrolled	Treatment.A	param.subjects	sex.ALL	agecat.ALL	stat.freq	100	
1002 dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.freq	60	
1003 dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.percent	60	
1004 dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.freq	40	
1005 dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.percent	40	
1006 dm.summary	enrolled	Treatment.B	param.subjects	sex.ALL	agecat.ALL	stat.freq	50	
1007 dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.freq	30	
1008 dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.percent	60	
1009 dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.freq	20	
1010 dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.percent	40	
1011 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.ALL	agecat.ALL	stat.freq	150	
1012 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.freq	90	
1013 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.percent	60	
1014 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.freq	60	
1015 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.percent	40	
1016 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.freq	100	
1017 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.mean	40.7	
1018 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.stdev	10.7	
1019 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.median	37.0	
1020 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.min	21.0	
1021 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.max	66.0	
1022 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.freq	50	
1023 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.mean	41.2	
1024 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.stdev	10.3	
1025 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.median	36.0	
1026 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.min	23.0	
1027 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.max	67.0	
1028 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.freq	150	
1029 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.mean	40.9	
1030 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.stdev	10.4	
1031 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.median	37.0	
1032 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.min	21.0	
1033 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.max	67.0	

Reference: 'Analysis Results that Save Trees - #KillTFLs', Chris Decker, DH12 PHUSE US Connect 2019

Standardized Analysis Results Support Dynamic Data Display Generation and Reuse

qb:Observation	qb:Table	dim.population	dim.treatment	dim.parameter	dim.sex	dim.agecat	dim.statistic	analysisResult
1001 dm.summary	enrolled	Treatment.A	param.subjects	sex.ALL	agecat.ALL	stat.freq	100	
1002 dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.freq	60	
1003 dm.summary	enrolled	Treatment.A	param.subjects	sex.F	agecat.ALL	stat.percent	60	
1004 dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.freq	40	
1005 dm.summary	enrolled	Treatment.A	param.subjects	sex.M	agecat.ALL	stat.percent	40	
1006 dm.summary	enrolled	Treatment.B	param.subjects	sex.ALL	agecat.ALL	stat.freq	50	
1007 dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.freq	30	
1008 dm.summary	enrolled	Treatment.B	param.subjects	sex.F	agecat.ALL	stat.percent	60	
1009 dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.freq	20	
1010 dm.summary	enrolled	Treatment.B	param.subjects	sex.M	agecat.ALL	stat.percent	40	
1011 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.ALL	agecat.ALL	stat.freq	150	
1012 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.freq	90	
1013 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.F	agecat.ALL	stat.percent	60	
1014 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.freq	60	
1015 dm.summary	enrolled	Treatment.ALL	param.subjects	sex.M	agecat.ALL	stat.percent	40	
1016 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.freq	100	
1017 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.mean	40.7	
1018 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.stdev	10.7	
1019 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.median	37.0	
1020 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.min	21.0	
1021 dm.summary	itt	Treatment.A	param.age	sex.ALL	agecat.ALL	stat.max	66.0	
1022 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.freq	50	
1023 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.mean	41.2	
1024 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.stdev	10.3	
1025 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.median	36.0	
1026 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.min	23.0	
1027 dm.summary	itt	Treatment.B	param.age	sex.ALL	agecat.ALL	stat.max	67.0	
1028 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.freq	150	
1029 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.mean	40.9	
1030 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.stdev	10.4	
1031 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.median	37.0	
1032 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.min	21.0	
1033 dm.summary	itt	Treatment.ALL	param.age	sex.ALL	agecat.ALL	stat.max	67.0	

Table 42.1: HbA1c Longitudinal Repeated Measures Analysis - Table Shell

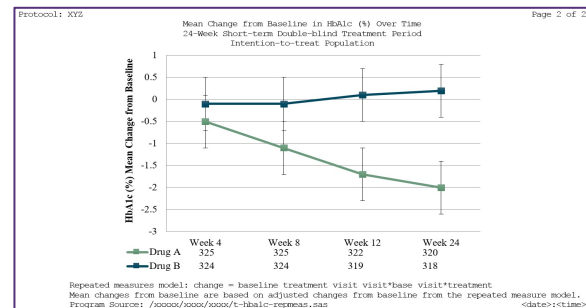
Protocol: XYZ

HbA1c (%) Longitudinal Repeated Measures Analysis
24-Week Short-term Double-blind Treatment Period
Intention-to-treat Population

Page 1 of 2

		Drug A N=125	Drug B N=125
BASELINE	SB	115	115
	Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
WEEK 4	SB	XXX	XXX
	Change from baseline: Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
	Adjusted change from baseline: Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
	95% Confidence Interval for adjusted mean difference vs. Drug B (SE)	(XX.XX, XX.X)	(XX.XX, XX.X)
	95% Confidence Interval for difference	XX.XX (X.XXXX)	XX.XX (X.XXXX)
	P-value vs. Drug B	X.XXXX	X.XXXX
...			
WEEK 12	SB	X.XX (X.XXXX)	X.XX (X.XXXX)
	Change from baseline: Mean (SD)	XXX	XXX
	Adjusted change from baseline: Mean (SD)	X.XX (X.XXXX)	X.XX (X.XXXX)
	95% Confidence Interval for adjusted mean difference vs. Drug B (SE)	(XX.XX, XX.X)	(XX.XX, XX.X)
	95% Confidence Interval for difference	XX.XX (X.XXXX)	XX.XX (X.XXXX)
	P-value vs. Drug B	(XX.XX, XX.X)	X.XXXX

N: the number of subjects in the treatment-to-treat (ITT) Population.
 SB: the number of subjects in the ITT population with non-missing baseline and non-missing Week t value.
 Repeated measures model: change = baseline treatment visit visit*base visit*treatment
 Program Source: /ssooo/sooo/sooo/t-hb1c-repmes.sas



How do the Analysis Results Metadata (ARM) and Analysis Results Data (ARD) relate?

- ARM is the general set of metadata related to analysis results. It contains metadata related to the analyses, analysis results, and the computation and visualization of the results. It is only about metadata.
- ARD represents the analysis results data set (ARDS) and the metadata describing the analysis results set (ARDM). ARD contains both a data part (ARDS) and its associated metadata (ARDM).
- There is an intersection between the two standards: the analysis results data metadata (ARDM) that describes the organization and semantic of the analysis results. It is both a part of the more general ARM and the meta-data part of the ARD.

ARM				
analysis	computation	Usage/visualization	Results description (ARDM)	Results Sets (ARDS)
			ARD	

Analysis Dataset Structure Including Relevant Controlled Terminology

- Provide ADaM dataset structure examples that are used to produce TFLs
- Challenges with variation in ADaM dataset that are generated for submission
 - Provide feedback to relevant ADaM teams to work towards a more consistent implementation for biomedical concepts



CDISC 360: The Art of the Possible

 Powered by  Microsoft

Search the CDISC Library



1 Disease Area
✓ Endocrine

2 Therapeutic Area
✓ Diabetes - Type 2

3 Standards Focus
✓ Study Endpoint

4 Study Endpoint
✓ Analysis of Glycated Hemoglobin

5 Standard Analyses
✓ Mean Change from Baseline in HbA1c (%) Over Time

6 Selection Summary
Endocrine
Diabetes - Type 2
Study Endpoint
Analysis of Glycated Hemoglobin
Mean Change from Baseline in HbA1c (%) Over Time

Selection Summary

Study Endpoint

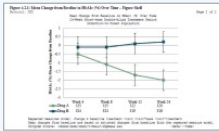
Analysis of Glycated Hemoglobin

Analysis of the continuous clinical endpoint of HbA1c. Example: a Phase III, parallel-group study designed to determine efficacy of Drug A for patients with Type II diabetes. The primary endpoint defined as the change in HbA1c from baseline.

View details

Analysis

Mean Change from Baseline in HbA1c (%) Over Time



Provides a visual display of the information in the "HbA1c Longitudinal Repeated Measures Analysis" table. Includes additional weeks beyond those in that table. The mean changes shown are based on adjusted changes from baseline from the repeated measures model.

View details
View analysis results metadata

Analysis Datasets

ADSL

Analysis Data Subject Level

View analysis dataset metadata
View sample analysis data
View analysis dataset structure

ADHBA1C

DB5 - Structured Dataset

View analysis dataset metadata
View sample analysis data
View analysis dataset structure

< Back

Save Selection

What Content Will Be the Focus?

- Most common safety analyses
- TAUGs with analysis components
- TAUGs without analysis components
- Community generated content
- Will not focus on TFL layout
 - Example options for layouts for illustration purposes

What Existing Work Are We Leveraging?



What Common Safety Analyses Do We Start With?

Summary of Subject Disposition

Summary of Reason for Subject Discontinuation

Summary of Protocol Deviations

Summary of Study Analysis Sets

Summary of Demographics and Other Baseline Characteristics

Summary of Medical History

Summary of Prior and Concomitant Medications

Summary of Study Drug Exposure

Summary of Subject Incidence of Adverse Events

Summary of Treatment Emergent Adverse Events by SOC and PT

Summary of TEAE SOC and PT by Maximum Severity

Summary of Laboratory Tests by Visit

Shifts from Baseline for Laboratory Tests

Summary of Abnormalities for Laboratory Tests

Summary of ECG Findings by Visit

Summary of Change in Vital Signs by Visit

Summary of Post Baseline Vital Sign Abnormalities

Example TFLs with Standardized Metadata

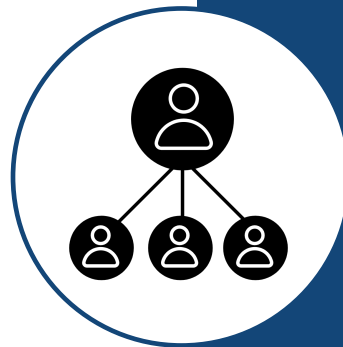


General Output Tips and Considerations

TITLE (Subtitle 1) (Subtitle 2)						
Column	Stub	Heading 1	Heading 2	Heading 3	Heading 4	
		-----<-straddle->-----				
		Row				
		Body				
Legend						
Abbreviations						
Footnote						

Logistics

- Small sub-teams working to develop initial examples. Examples will be presented and reviewed by the larger team for feedback.
 - Selecting TFL examples
 - Extending ARM
 - Analysis Results Dataset
- When stable examples have been created, we will formally develop structures and further analysis concepts that will go through the CDISC development process



Team Members

Bhavin Busa	Nate Freimark	Dante Di Tommaso
Cedric Davister	Kang Xie	Brian Harris
Hansjörg Frenzel	Sally Cassells	Greg Anglin
Kent Letourneau	Alana St. Clair	Karl Wallendszus
Jeffrey Abolafia	Amy Palmer	Prafulla Girase
Bess LeRoy	Jon Neville	Wenwen Fan
Nancy Brucken	Dmitry Kolosov	Chenoa Conley
Wenwen Fan	Lex Jansen	Mary Nilsson
Claudia Niemeyer	Hong Qi	Sumit Pradhan



Thank you!

