WITH STANDARDS – UNLOCK THE POWER OF DATA

cdisc

2022
US
INTERCHANGE
26-27 OCTOBER | AUSTIN

CDISC Perspective: Advancing Pre-Market Safety Analytics

Presented by Bess LeRoy, CDISC

Meet the Speakers

Bess LeRoy

Title: Head of Standards Innovation

Organization: CDISC

Bess has been a CDISC team member since 2011. She is a member of the CDISC Technical Leadership Team and leads the CDISC Global Governance Group. Bess has over 15 years' experience working in public health research and has held positions at the Framingham Heart Study, the Rotterdam Study, the Arizona Cancer Center, and the Critical Path Institute

Background

- Unnecessary variation in analysis results reporting
- Limited CDISC standards to support analysis results and associated metadata
- CDISC has been working towards creating standards to support, consistency, traceability, and reuse of results data
- Anticipate that the CDISC work will support sponsor submissions of analysis results in a standard format that aligns with the new FDA effort to standardize tables and figures

cdisc

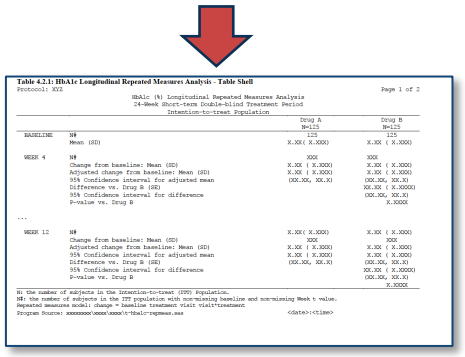
Analysis Results Current State

- May be hundred of tables in PDF format, often difficult to navigate
- Variability between sponsors
- Expensive to generate and only used once, no or limited reusability
- Limited traceability

Analysis Ready ADaM Dataset

Table 3.1.1: ADHYPO Analysis Dataset

Row	STUDYID	USUBJID	MIDS	CEDECOD	WASAEYN	ASTDTM
1	XYZ	000001	HYPO 1	Hypoglycemia	Y	07Sep2012 22:29:00
2	XYZ	000001	HYPO 2	Hypoglycemia	N	10Sep2012 09:12:00
3	XYZ	000001	HYPO 3	Hypoglycemia	N	10Sep2012 23:05:00
4	XYZ	000001	HYPO 4	Hypoglycemia	N	11Sep2012 15:24:00
5	XYZ	000001	HYPO 5	Hypoglycemia	N	18Sep2012 11:39:00
6	XYZ	000002	HYPO 1	Hypoglycemia	N	22Oct2012 13:28:00
7	XYZ	000002	HYPO 2	Hypoglycemia	N	25Oct2012 13:59:00
8	XYZ	000002	HYPO 3	Hypoglycemia	N	17Nov2012 05:01:00



Static Display

Analysis Results Current State

Table 3.1.1: ADHYPO Analysis Dataset

Row	STUDYID	USUBJID	MIDS	CEDECOD	WASAEYN	ASTDTM
1	XYZ	000001	HYPO 1	Hypoglycemia	Y	07Sep2012 22:29:00
2	XYZ	000001	HYPO 2	Hypoglycemia	N	10Sep2012 09:12:00
3	XYZ	000001	HYPO 3	Hypoglycemia	N	10Sep2012 23:05:00
4	XYZ	000001	HYPO 4	Hypoglycemia	N	11Sep2012 15:24:00
5	XYZ	000001	HYPO 5	Hypoglycemia	N	18Sep2012 11:39:00
6	XYZ	000002	HYPO 1	Hypoglycemia	N	22Oct2012 13:28:00
7	XYZ	000002	HYPO 2	Hypoglycemia	N	25Oct2012 13:59:00
8	XYZ	000002	HYPO 3	Hypoglycemia	N	17Nov2012 05:01:00

ADaM Dataset

Table 4.2.1: HbA1c Longitudinal Repeated Measures Analysis - Table Shell
Protocol: XYZ
Page 1 of 2

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

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

N: the number of subjects in the Intention-to-treat (ITT) Population.
N#: 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*treatment
Program Source: xxxxxxxx\xxxx\xxxx\t-hba1c-rptmeas.sas <date>:<time>

Static Display

ARM for Define-XML

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

ARM v1

cdisc

Analysis Results Future State

Table 3.1.1: ADHYPO Analysis Dataset

Row	STUDYID	USUBJID	MIDS	CEDECOD	WASAEYN	ASTDTM
1	XYZ	000001	HYPO 1	Hypoglycemia	Y	07Sep2012 22:29:00
2	XYZ	000001	HYPO 2	Hypoglycemia	N	10Sep2012 09:12:00
3	XYZ	000001	HYPO 3	Hypoglycemia	N	10Sep2012 23:05:00
4	XYZ	000001	HYPO 4	Hypoglycemia	N	11Sep2012 15:24:00
5	XYZ	000001	HYPO 5	Hypoglycemia	N	18Sep2012 11:39:00
6	XYZ	000002	HYPO 1	Hypoglycemia	N	22Oct2012 13:28:00
7	XYZ	000002	HYPO 2	Hypoglycemia	N	25Oct2012 13:59:00
8	XYZ	000002	HYPO 3	Hypoglycemia	N	17Nov2012 05:01:00

ADaM Dataset

Analysis Results Future State

Table 3.1.1: ADHYPO Analysis Dataset

Row	STUDYID	USUBJID	MIDS	CEDECOD	WASAEYN	ASTDTM
1	XYZ	000001	HYPO 1	Hypoglycemia	Y	07Sep2012 22:29:00
2	XYZ	000001	HYPO 2	Hypoglycemia	N	10Sep2012 09:12:00
3	XYZ	000001	HYPO 3	Hypoglycemia	N	10Sep2012 23:05:00
4	XYZ	000001	HYPO 4	Hypoglycemia	N	11Sep2012 15:24:00
5	XYZ	000001	HYPO 5	Hypoglycemia	N	18Sep2012 11:39:00
6	XYZ	000002	HYPO 1	Hypoglycemia	N	22Oct2012 13:28:00
7	XYZ	000002	HYPO 2	Hypoglycemia	N	25Oct2012 13:59:00
8	XYZ	000002	HYPO 3	Hypoglycemia	N	17Nov2012 05:01:00

ADaM Dataset

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 Ana 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

ARM v1

ARM Extension Technical Specification

Analysis Results Future State

Table 3.1.1: ADHYPO Analysis Dataset

Row	STUDYID	USUBJID	MIDS	CEDECOD	WASAEYN	ASTDTM
1	XYZ	000001	HYPO 1	Hypoglycemia	Y	07Sep2012 22:29:00
2	XYZ	000001	HYPO 2	Hypoglycemia	N	10Sep2012 09:12:00
3	XYZ	000001	HYPO 3	Hypoglycemia	N	10Sep2012 23:05:00
4	XYZ	000001	HYPO 4	Hypoglycemia	N	11Sep2012 15:24:00
5	XYZ	000001	HYPO 5	Hypoglycemia	N	18Sep2012 11:39:00
6	XYZ	000002	HYPO 1	Hypoglycemia	N	22Oct2012 13:28:00
7	XYZ	000002	HYPO 2	Hypoglycemia	N	25Oct2012 13:59:00
8	XYZ	000002	HYPO 3	Hypoglycemia	N	17Nov2012 05:01:00

ADaM Dataset

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 Ana 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

ARM v1

ARM Extension Technical Specification

Automation

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

Analysis Results Dataset

Reuse

Traceability

Table 4.2.1: HbA1c Longitudinal Repeated Measures Analysis - Table Shell

Protocol: XYZ

Page 1 of 2

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

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

N: the number of subjects in the Intention-to-treat (ITT) Population.
N#: 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*treatment
Program Source: xxxxxxxx\xxxx\xxxx\t-hba1c-repmeas.sas <date>:<time>

Display

Analysis Results Standards Goals

Model that describes analysis results and associated metadata

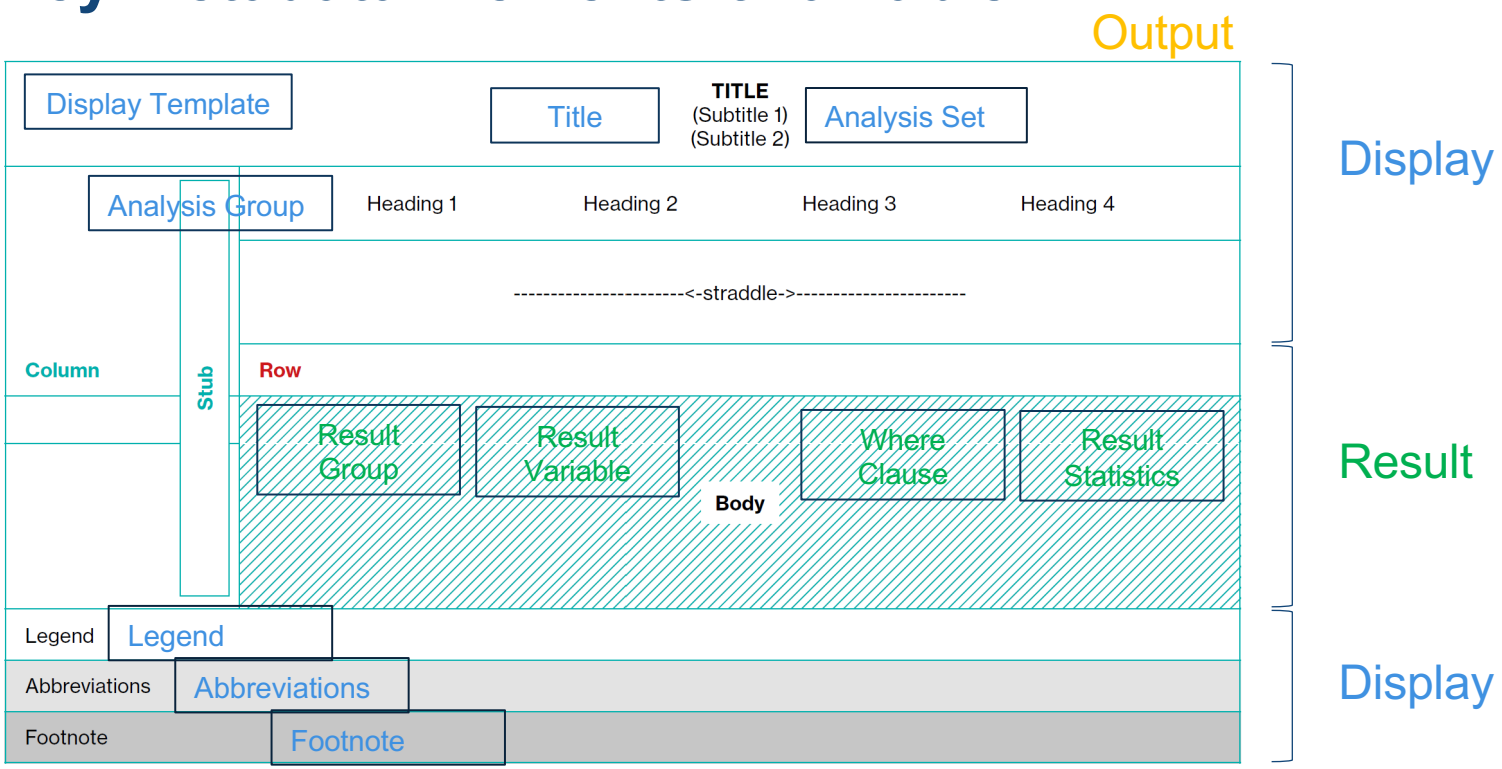
Analysis Results Metadata Technical Specification (ARM-TS), to support automation, traceability, and creation of data displays

Define an Analysis Results Data (ARD) structure, to support reuse and reproducibility of results data

Illustrate and exercise ARD and ARM-TS with a set of machine-readable common safety displays

cdisc

Key Metadata Elements of a Table



Reference: PHUSE White Paper "*General Output Tips and Considerations*", Doc ID: WP-034, Version 1.0, Aug 2020

Demographics Analysis Results and Metadata

Display Template | Title | Analysis Set

Table 2. Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses (or Trial X)

Characteristic	Drug Name Dosage X N = XXX	Drug Name Dosage Y N = XXX	Placebo N = XXX	Active Control N = XXX	Total Population N = XXX
	n (%)	n (%)	n (%)	n (%)	n (%)
Sex, n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
Male	n (%)	n (%)	n (%)	n (%)	n (%)
Female	n (%)	n (%)	n (%)	n (%)	n (%)
Age, years	**X.X (Y.Y)**	**X.X (Y.Y)**	**X.X (Y.Y)**	**X.X (Y.Y)**	**X.X (Y.Y)**
Mean (SD)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)	X.X (Y.Y)
Median (min, max)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)	X.X (Y.Y, Z.Z)
Age groups (years), n (%)					**n (%)**
≥17 to <65					n (%)
≥65					n (%)
≥65 to <75					n (%)
≥75	n (%)	n (%)	n (%)	n (%)	n (%)
Race, n (%)	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
American Indian or Alaska Native Asian	n (%)	n (%)	n (%)	n (%)	n (%)
Black or African American	n (%)	n (%)	n (%)	n (%)	n (%)
Native Hawaiian or Other Pacific Islander	n (%)	n (%)	n (%)	n (%)	n (%)
White	n (%)	n (%)	n (%)	n (%)	n (%)
Other	n (%)	n (%)	n (%)	n (%)	n (%)

Analysis Group

Result Group | Result Variable | Where Clause | Result Statistics

Source: [include Applicant source, datasets and/or software tools used].
[1] Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).
Abbreviations: N, number of patients in treatment arm; n, number of patients with given characteristic; SD, standard deviation

Footnote | Abbreviations | Legend

Analysis Results Dataset Example: Demographics

Identifiers		Analysis Group			Result Variable			Results Statistic		
Name	Title	Dataset	Variable	Value	Variable	Value	Label	Value	Name	Label
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	53	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	M	Male	61.6	Percent	%
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	33	Count	n
Table 2	Baseline Demographics and Clinical Characteristics, Safety Population	ADSL	TR01X	Drug Name Dosage X	SEX	F	Female	38.4	Percent	%

Traceability to the underlying ADaM dataset

cdisc

Machine Readable TFL Shells

```
<?xml version="1.0" encoding="UTF-8"?>
<TableShell>
    <ID>TEAE.01</ID>
    <Ordinal>1</Ordinal>
    <Type>Table</Type>
    <Name>TEAE-Overall</Name>
    <Title>Overall Summary of Treatment Emergent Adverse Events</Title>
    <Population>Safety Population</Population>
    <ColDefs>
        <TreatmentVar Name="TRT01" Num="4" StatOID="ST.01"/>
        <ComputeCols>
            <ComputeCol Name="Overall" StatOID="ST.01"/>
        </ComputeCols>
    </ColDefs>
    <ResultGroupDef OID="EAE.01.GRP.01" OrderNumber="1"> [3 lines]
    <ResultGroupDef OID="TEAE.01.GRP.02" OrderNumber="2"> [2 lines]
    <ResultDef OID="TEAE.01.GRP.01.RES.01"> [4 lines]
    <ResultDef OID="TEAE.01.GRP.01.RES.02">
        <Label>Subjects with a related AE</Label>
        <StatRef StatOID="ST.01"/>
        <StatRef StatOID="ST.02"/>
    </ResultDef>
    <ResultDef OID="TEAE.01.GRP.02.RES.01">
        <Label>Number of AEs</Label>
        <StatRef StatOID="ST.01"/>
    </ResultDef>
    <StatDef OID="ST.01" Name="N">
        <Label>Number of Subjects</Label>
        <Format>XX</Format>
    </StatDef>
    <StatDef OID="ST.02" Name="PCT">
        <Label>Percentage of Subjects</Label>
        <Format>(XX.X%)</Format>
    </StatDef>
</TableShell>
```

Adverse Events

Table 35. Patients With Adverse Events[1] by System Organ Class, Safety Population, Pooled Analysis (or Trial X)[2]

System Organ Class	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI)[3,4]
Blood and lymphatic system	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cardiac disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Ear and labyrinth disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Endocrine disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Eye disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Gastrointestinal disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Hepatobiliary disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Immune system disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Infections and infestations	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Injury, poisoning and procedural complications	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

Source: [include Applicant source, datasets and/or software tools used].
[1] Treatment-emergent adverse event defined as [definition].
[2] Duration = [e.g., X week double-blind treatment period or median and a range indicating pooled trial durations].
[3] Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).
[4] Table display is ordered by the risk difference.
Abbreviations: CI, confidence interval; N, number of patients in treatment arm; n, number of patients with at least one event

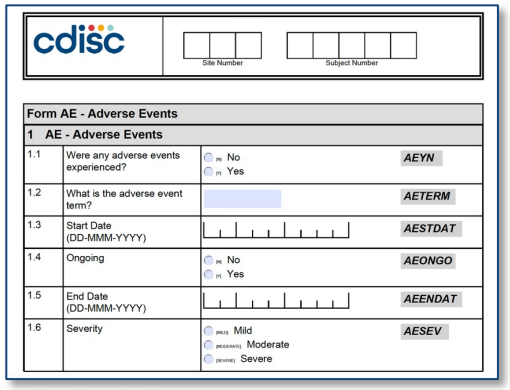
Develop schema/model for machine readable TFL shells

cdisc

End Goal: Reducing Unnecessary Variability

Standardized Metadata

CDASH (Collection) ← SDTM (Tabulation) ← ADaM (Analysis) ← Analysis Results ← TFL



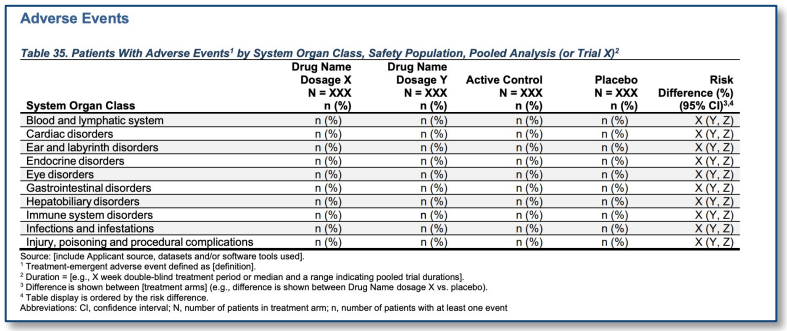
cdisc

Site Number | Subject Number

Form AE - Adverse Events

1 AE - Adverse Events

1.1	Were any adverse events experienced?	No / Yes	AEYN
1.2	What is the adverse event term?		AETERM
1.3	Start Date (DD-MMM-YYYY)		AESTDAT
1.4	Ongoing	No / Yes	AEONGO
1.5	End Date (DD-MMM-YYYY)		AEENDAT
1.6	Severity	Mild / Moderate / Severe	AESEV



Adverse Events

Table 35. Patients With Adverse Events[1] by System Organ Class, Safety Population, Pooled Analysis (or Trial X)[2]

System Organ Class	Drug Name Dosage X N = XXX n (%)	Drug Name Dosage Y N = XXX n (%)	Active Control N = XXX n (%)	Placebo N = XXX n (%)	Risk Difference (%) (95% CI)[3,4]
Blood and lymphatic system	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Cardiac disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Ear and labyrinth disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Endocrine disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Eye disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Gastrointestinal disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Hepatobiliary disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Immune system disorders	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Infections and infestations	n (%)	n (%)	n (%)	n (%)	X (Y, Z)
Injury, poisoning and procedural complications	n (%)	n (%)	n (%)	n (%)	X (Y, Z)

Source: [include Applicant source, datasets and/or software tools used].
[1] Treatment-emergent adverse event defined as [definition].
[2] Duration = [e.g., X week double-blind treatment period or median and a range indicating pooled trial durations].
[3] Difference is shown between [treatment arms] (e.g., difference is shown between Drug Name dosage X vs. placebo).
[4] Table display is ordered by the risk difference.
Abbreviations: CI, confidence interval; N, number of patients in treatment arm; n, number of patients with at least one event

Support for FDA Standard Safety Tables and Figures

- Model that describes analysis results metadata
- For a selection of FDA tables and figures, create packages containing
  - Machine readable displays
  - Associated analysis results metadata
  - Analysis results dataset examples
  - Underlying ADaM datasets
- Make packages freely available on the CDISC website