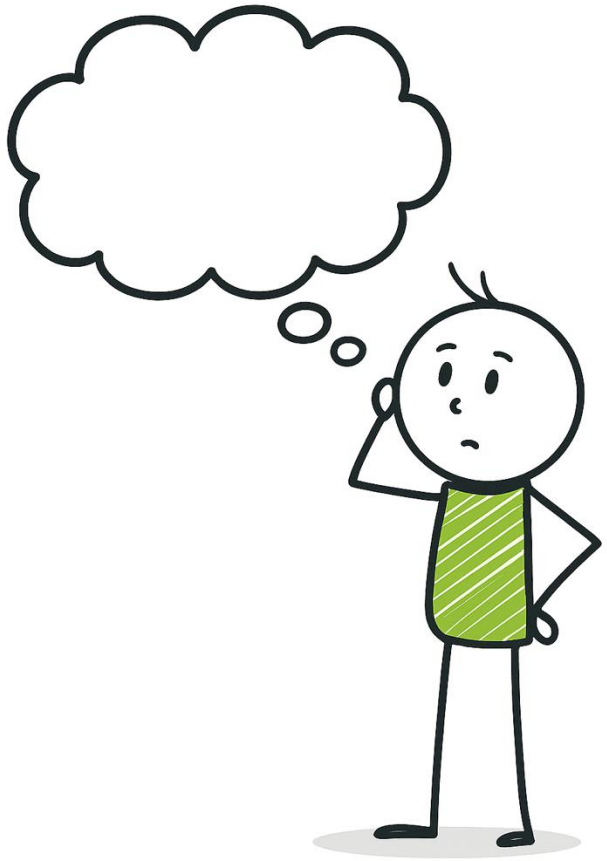
CDISC 360

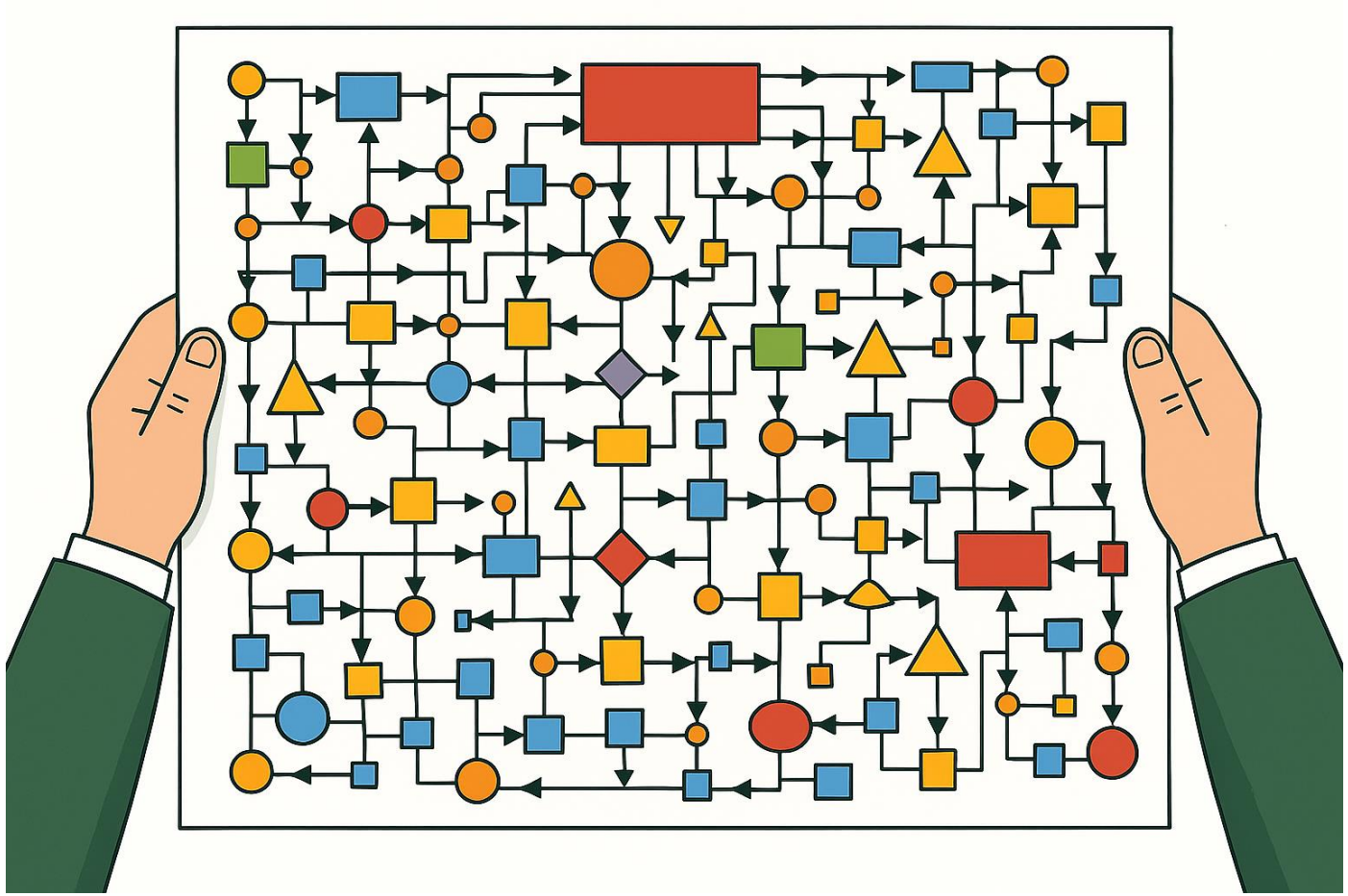
7 Nov 2025

Objective

- What is CDISC 360?
- What is currently available?
- What is the impact on statistical programming?

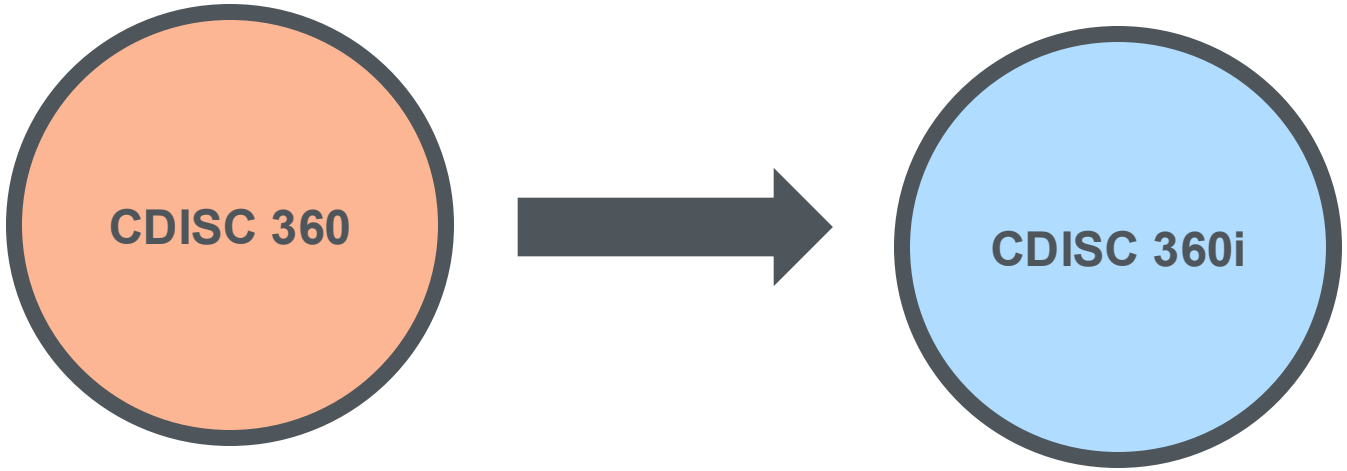


What is CDISC 360?



What is CDISC 360?

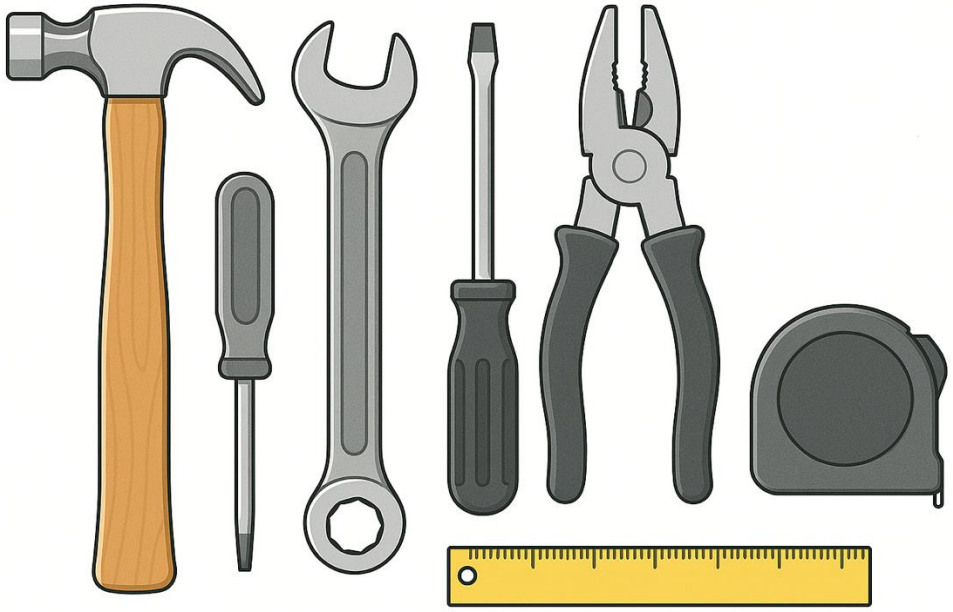
- **CDISC 360**: Development of end-to-end machine-readable CDISC standards that would allow for automated workflows that runs from study design through to data analysis and reporting.



https://www.cdisc.org/sites/default/files/2021-06/CDISC_360_Project_White_Paper.pdf

What is CDISC 360?

- **COSA** (CDISC Open-Source Alliance): Community driven open-source software projects related to CDISC standards.

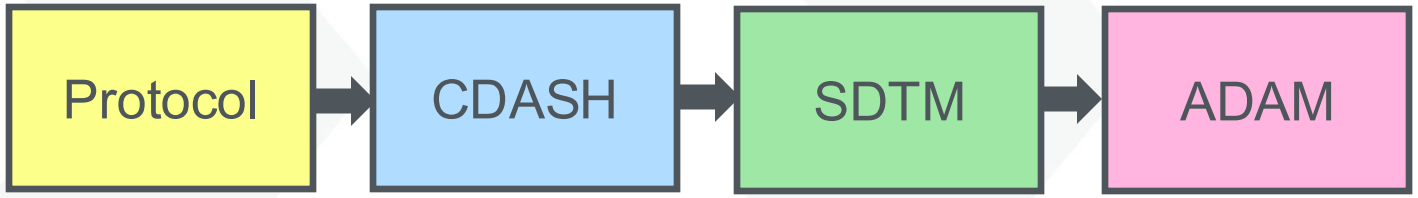


https://www.cdisc.org/sites/default/files/pdf/360i-Program-Kickoff20250218.pdf

CDISC 360 Standards

What is currently available?

What is currently available?



What is currently available?

What is currently available?

- **USDM** (Unified Study Data Model)

What is currently available?

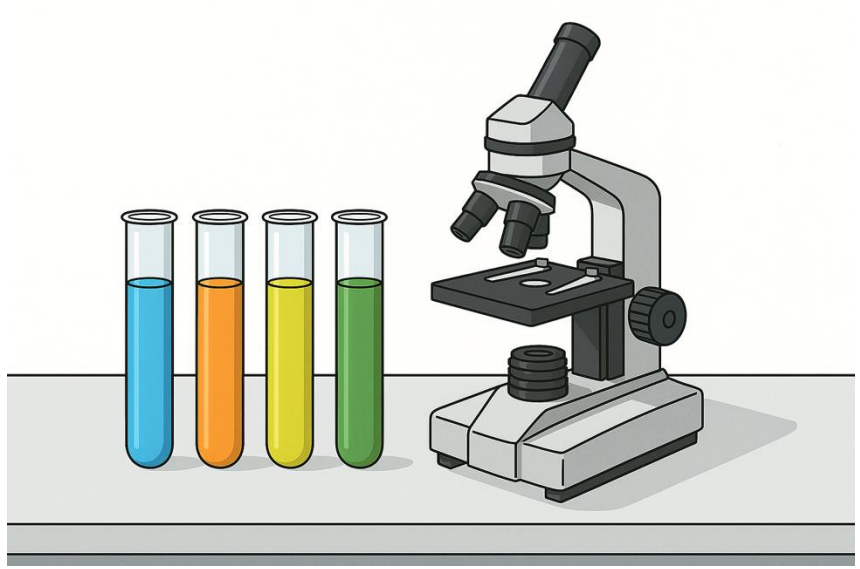
- **USDM** (Unified Study Data Model)
- **ARS** (Analysis Results Standard)

USDM

- **USDM** (Unified Study Data Model): A framework to capture protocol information in a structured digital format.

USDM

- **USDM** (Unified Study Data Model): A framework to capture protocol information in a structured digital format.
  - **Biomedical Concepts**: Standardized, unambiguous descriptions of clinical trial observations, measurements, and interventions.

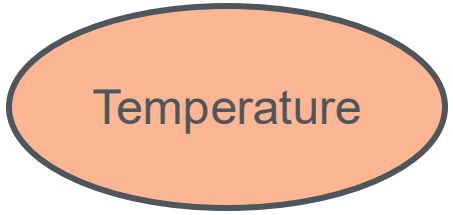


Biomedical Concepts

- **Conceptual / Abstract Layer**
  - Provides the semantic definition for each BC.
- **Implementation Layer (Dataset Specializations)**
  - Maps the abstract concepts to specific CDISC foundational standards (CDASH/SDTM).

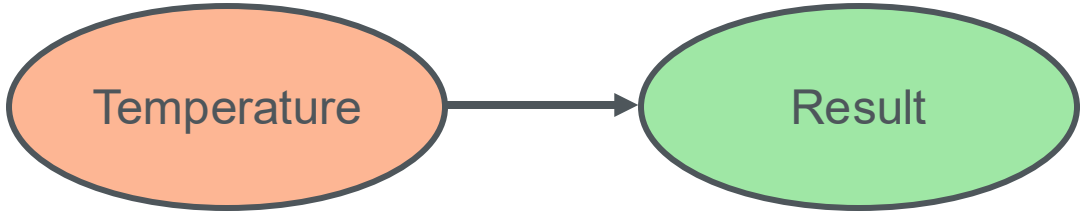
Biomedical Concepts

- Conceptual layer



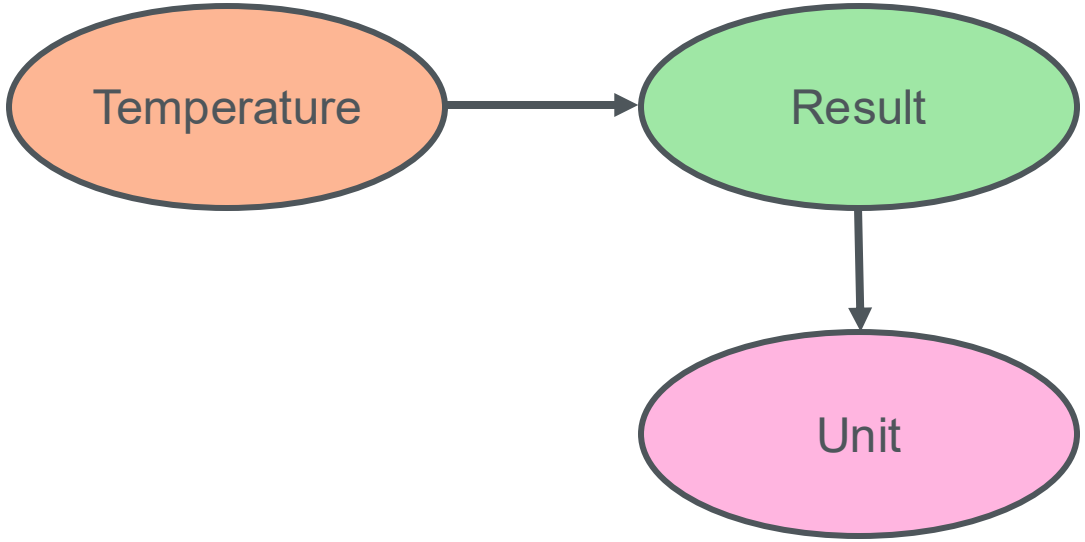
Biomedical Concepts

- Conceptual layer



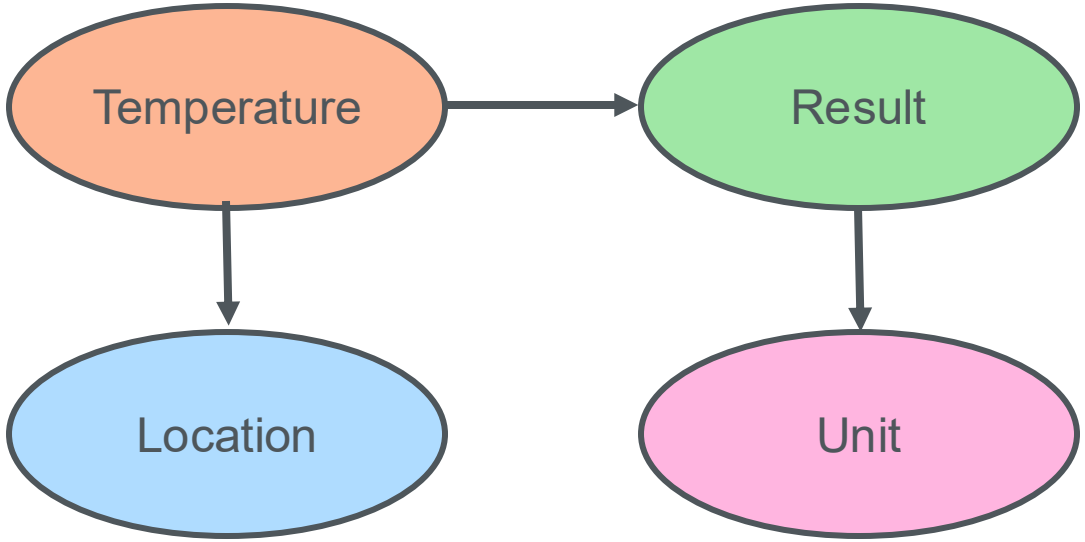
Biomedical Concepts

- Conceptual layer



Biomedical Concepts

- Conceptual layer



Biomedical Concepts

- Implementation layer

VSTEST	VSTESTCD	VSORRES	VSUNIT	VSLOC
Temperature	TEMP	37	C	ORAL

Biomedical Concepts

- CDISC website
  - Latest CDISC Biomedical Concepts (Excel spreadsheet)
  - Latest SDTM Dataset Specializations (Excel spreadsheet)

Biomedical Concepts

Biomedical Concepts

short_name	bc_id	bc_categories	synonyms	definition	dec_id	dec_label
Body Temperature	C174446	Vital Signs	Temperature	A measurement of the temperature of the body.	C70856	Observation Result
Body Temperature	C174446	Vital Signs	Temperature	A measurement of the temperature of the body.	C44276	Unit of Temperature
Body Temperature	C174446	Vital Signs	Temperature	A measurement of the temperature of the body.	C13717	Anatomic Site
Body Temperature	C174446	Vital Signs	Temperature	A measurement of the temperature of the body.	C82515	Collection Date Time

SDTM Dataset Specializations

bc_id	domain	vlm_group_id	short_name	sdtm_variable	dec_id
C174446	VS	TEMP	Temperature	VSORRES	C70856
C174446	VS	TEMP	Temperature	VSSTRESC	C70856
C174446	VS	TEMP	Temperature	VSSTRESN	C70856

USDM

- USDM will not replace the CSP (not human readable)
- USDM makes important information contained in the protocol available in a digital format
- USDM can be used to help create CSP
- Benefits
  - Content Reuse
  - Enhanced Interoperability
  - Automation

ARS

- **ARS** (Analysis Results Standard)**:** Framework to standardize the output of statistical analyses (TLFs)

ARS

- **ARS** (Analysis Results Standard)**:** Framework to standardize the output of statistical analyses (TLFs)
  - **ARM-TS** (Analysis Results Metadata Technical Specification): A technical specification that describes all the characteristics of the analysis, including the statistical methods, variables, populations, and display attributes.
  - **ARD** (Analysis Results Data): A data structure that formally defines the statistical results themselves.

ARM-TS

Deaths

Safety Population

Deaths	Xanomeline Low Dose (N=XX) n (%)	Xanomeline High Dose (N=XX) n (%)	Placebo (N=XX) n (%)
Total deaths	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cause of death	XX (XX.X)	XX (XX.X)	XX (XX.X)
Treatment-emergent deaths [1]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cause of death	XX (XX.X)	XX (XX.X)	XX (XX.X)
Non treatment-emergent deaths [2]	XX (XX.X)	XX (XX.X)	XX (XX.X)
Cause of death	XX (XX.X)	XX (XX.X)	XX (XX.X)

Source: ADSL; Program name: fda-ae-t07.sas;

Abbreviations: N, number of subjects in treatment arm; n, number of subjects with adverse event

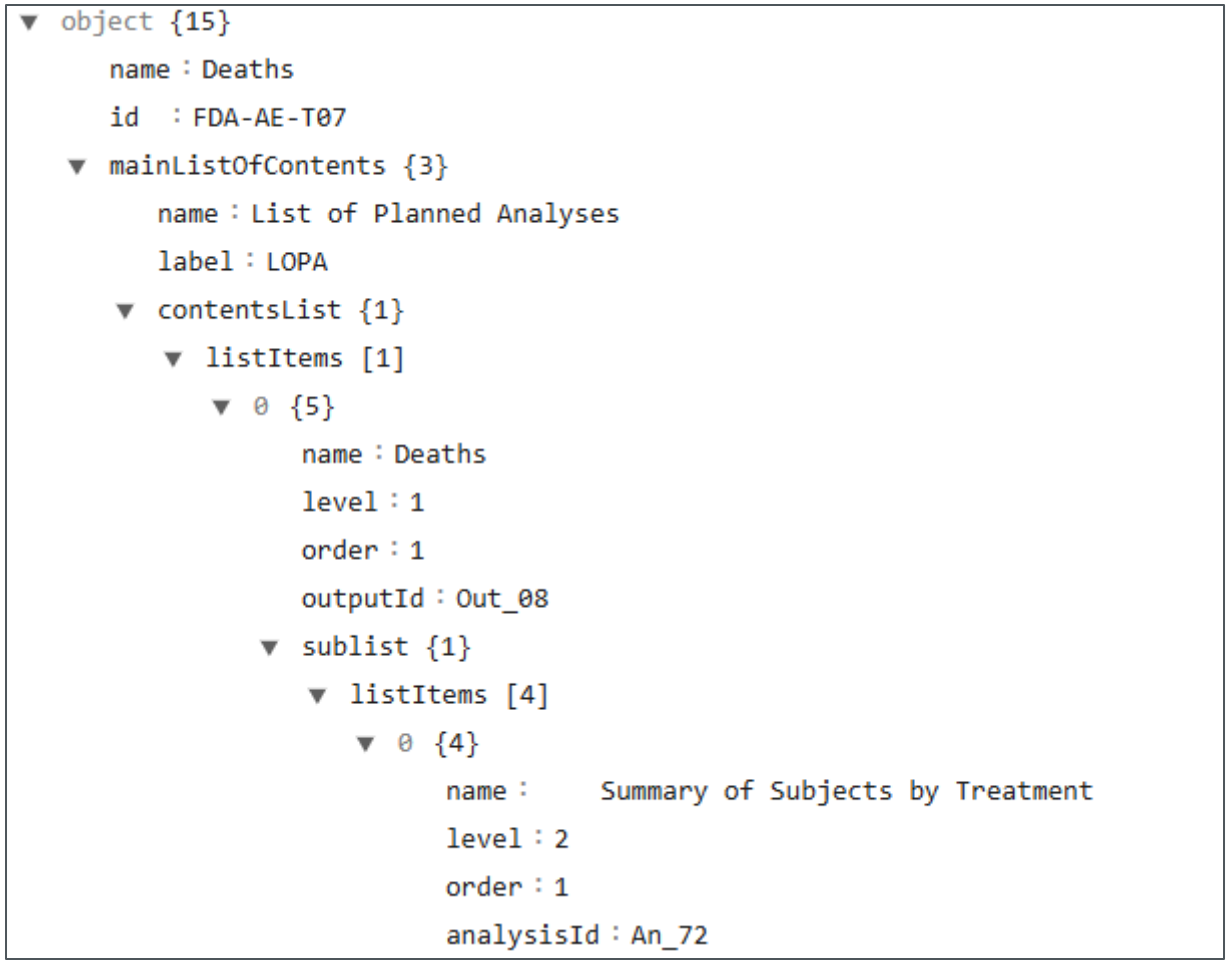
[1] Treatment-emergent death is defined as death with onset after the first dose of study drug.

[2] Non treatment-emergent death is defined as death that occurred beyond the protocol-defined treatment-emergent adverse event period.

ARM-TS


```
{
  "name": "Deaths",
  "id": "FDA-AE-T07",
  "mainListOfContents": {
    "name": "List of Planned Analyses",
    "label": "LOPA",
    "contentsList": {
      "listItems": [
        {
          "name": "Deaths",
          "level": 1,
          "order": 1,
          "outputId": "Out_08",
          "sublist": {
            "listItems": [
              {
                "name": "    Summary of Subjects by Treatment",
                "level": 2,
                "order": 1,
                "analysisId": "An_72"
              },
              {
                "name": "    Total Deaths",
                "level": 2,
                "order": 2,
                "sublist": {
                  "listItems": [
                    {
                      "name": "        Summary of Total Deaths by Treatment ",
                      "level": 3,
                      "order": 1,
                      "analysisId": "An_73"
                    },
```

ARM-TS



ARM-TS

name	listItem_name	listItem_analysisId
List of Planned Analyses	Deaths	
List of Planned Analyses	Summary of Subjects by Treatment	An_72
List of Planned Analyses	Total Deaths	
List of Planned Analyses	Summary of Total Deaths by Treatment	An_73
List of Planned Analyses	Cause of death {alphabetical order}	
List of Planned Analyses	Summary of Total Deaths by Treatment and Cause of death	An_74
List of Planned Analyses	Treatment-emergent deaths [1]	
List of Planned Analyses	Summary of Treatment-emergent deaths by Treatment	An_75
List of Planned Analyses	Cause of death {alphabetical order}	
List of Planned Analyses	Summary of Treatment-emergent deaths by Treatment and Cause of death	An_76
List of Planned Analyses	Non treatment-emergent deaths [2]	
List of Planned Analyses	Summary of Non treatment-emergent deaths by Treatment	An_77
List of Planned Analyses	Cause of death {alphabetical order}	
List of Planned Analyses	Summary of Non treatment-emergent deaths by Treatment and Cause of death	An_78

ARM-TS

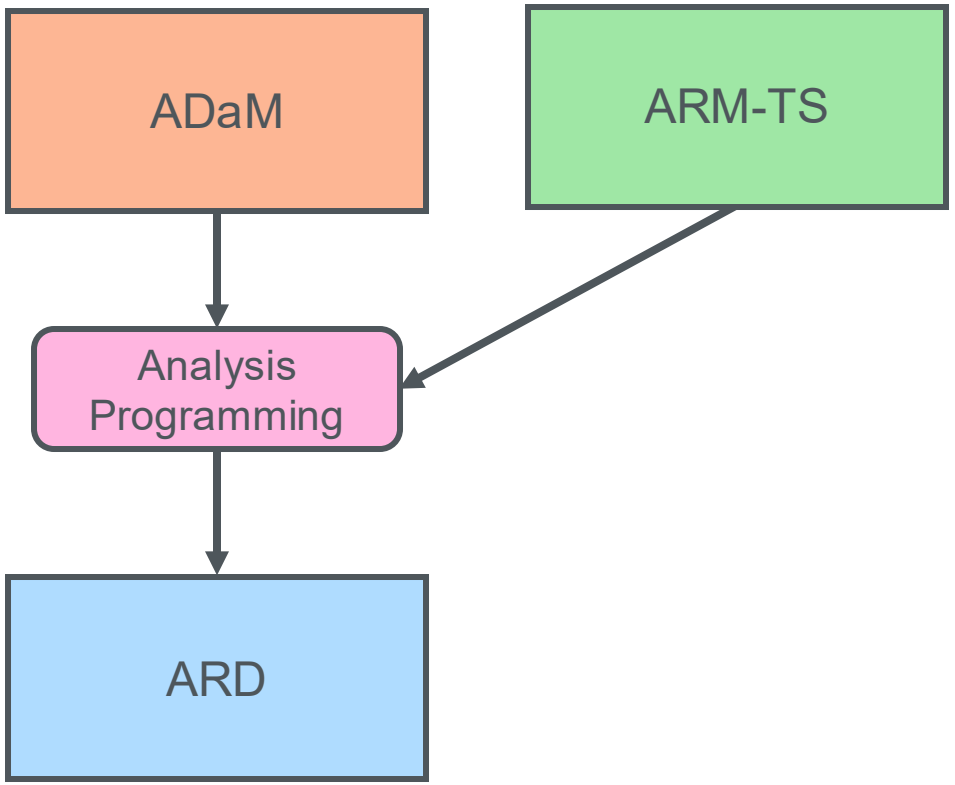
id	name	dataset	variable	method_id
An_72	Summary of Subjects by Treatment	ADSL	USUBJID	Mth_00_1
An_73	Summary of Total Deaths by Treatment	ADSL	USUBJID	Mth_03
An_74	Summary of Total Deaths by Treatment and Cause of death	ADSL	USUBJID	Mth_03
An_75	Summary of Treatment-emergent deaths by Treatment	ADSL	USUBJID	Mth_03
An_76	Summary of Treatment-emergent deaths by Treatment and Cause of death	ADSL	USUBJID	Mth_03
An_77	Summary of Non treatment-emergent deaths by Treatment	ADSL	USUBJID	Mth_03
An_78	Summary of Non treatment-emergent deaths by Treatment and Cause of death	ADSL	USUBJID	Mth_03

id	name	operation_id	operation_name	opera	operation_	operation_	operation_refe	operation_ref
Mth_00_1	bigN	Mth_00_1_01_n	n	(N=XX)				
Mth_03	Summary by group of a categorical variable	Mth_03_01_n	n	XX				
Mth_03	Summary by group of a categorical variable	Mth_03_02_%	%	(XX.X)	NUMERATOR	Mth_03_01_n	DENOMINATOR	Mth_00_1_01_n

ARM-TS

displaySection_sectionType	displaySection_subSection_i	displaySection_subSection_text
Header	GlobalDisp_Header_01	
Header	GlobalDisp_Header_02	
Header	GlobalDisp_Header_03	
Title	Disp_08_Title_01	FDA-AE-T07
Title	Disp_08_Title_02	Deaths
Title	Disp_08_Title_03	Safety Population
Footnote	Disp_08_Footnote_01	Source: ADSL; Program name: fda-ae-t07.sas;
Footnote	Disp_08_Footnote_02	Abbreviations: N, number of subjects in treatment arm; n, number of subjects with adverse event
Footnote	Disp_08_Footnote_03	[1] Treatment-emergent death is defined as death with onset after the first dose of study drug.
Footnote	Disp_08_Footnote_04	[2] Non treatment-emergent death is defined as death that occurred beyond the protocol-defined treatment-emergent adverse event period.
Rowlabel Header	Disp_08_RowlabelHeader_01	Characteristics

ARS

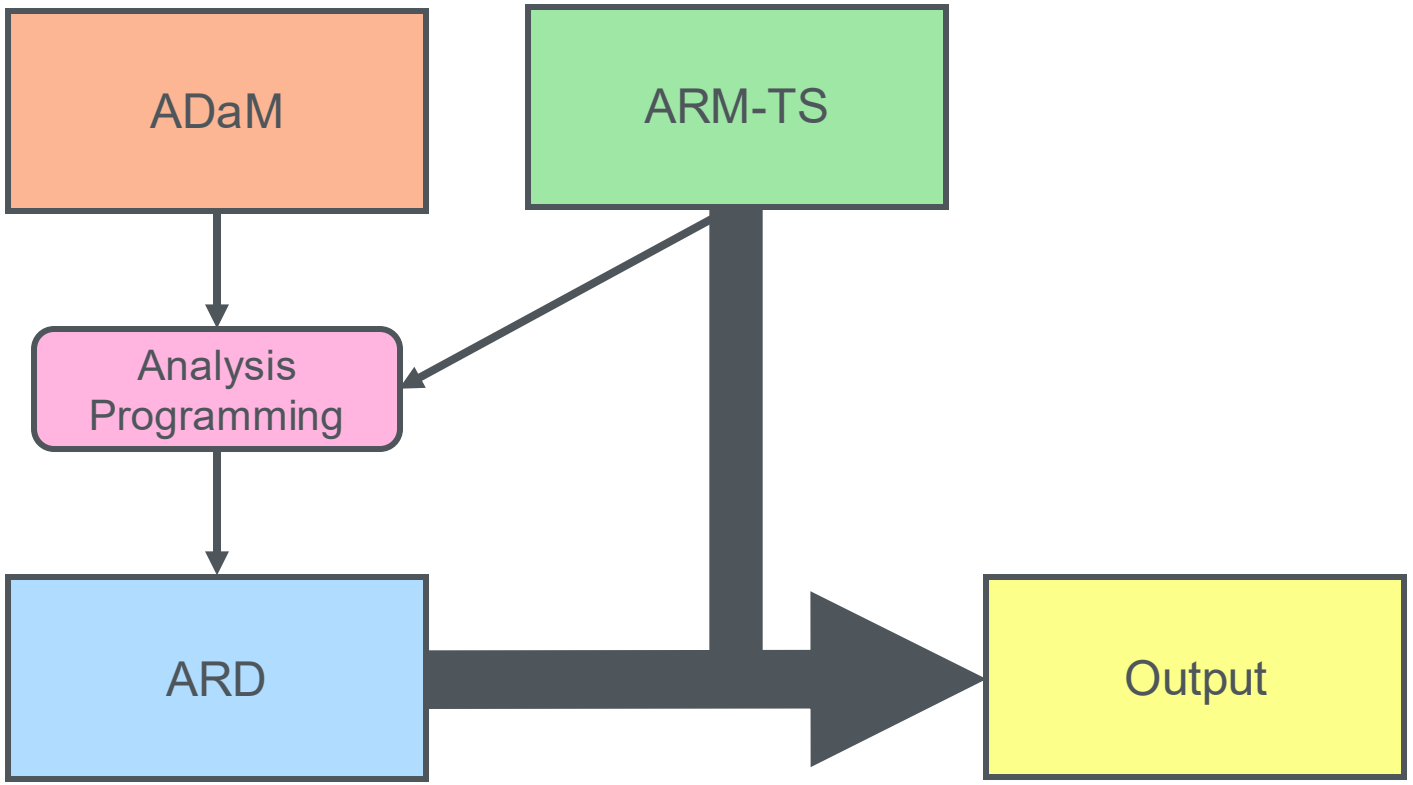


https://phuse.s3.eu-central-1.amazonaws.com/Archive/2022/Connect/EU/Belfast/PAP_DS09.pdf

ARD

outputId	analysisId	analysis_name	methodId	operationId	operation_label	pattern	Group1	res	disp
Out_08	An_72	Summary of Subjects by Treatment	Mth_00_1	Mth_00_1_01_n	n	(N=XX)	Xanomeline Low Dose (N=XX) n (%)	84	(N=84)
Out_08	An_72	Summary of Subjects by Treatment	Mth_00_1	Mth_00_1_01_n	n	(N=XX)	Xanomeline High Dose (N=XX) n (%)	84	(N=84)
Out_08	An_72	Summary of Subjects by Treatment	Mth_00_1	Mth_00_1_01_n	n	(N=XX)	Placebo (N=XX) n (%)	86	(N=86)
Out_08	An_73	Summary of Total Deaths by Treatment	Mth_03	Mth_03_01_n	n	XX	Xanomeline Low Dose (N=XX) n (%)	1	1
Out_08	An_73	Summary of Total Deaths by Treatment	Mth_03	Mth_03_01_n	n	XX	Xanomeline High Dose (N=XX) n (%)	0	0
Out_08	An_73	Summary of Total Deaths by Treatment	Mth_03	Mth_03_01_n	n	XX	Placebo (N=XX) n (%)	2	2
Out_08	An_73	Summary of Total Deaths by Treatment	Mth_03	Mth_03_02_%	%	(XX.X)	Xanomeline Low Dose (N=XX) n (%)	1.190476191	-1.2
Out_08	An_73	Summary of Total Deaths by Treatment	Mth_03	Mth_03_02_%	%	(XX.X)	Xanomeline High Dose (N=XX) n (%)	0	0
Out_08	An_73	Summary of Total Deaths by Treatment	Mth_03	Mth_03_02_%	%	(XX.X)	Placebo (N=XX) n (%)	2.325581395	-2.3

ARS



https://phuse.s3.eu-central-1.amazonaws.com/Archive/2022/Connect/EU/Belfast/PAP_DS09.pdf

COSA Tools

OpenStudyBuilder

- **OpenStudyBuilder**: Open-source tool designed to create digital protocols for clinical trials.

OpenStudyBuilder


```
{
 "study":{
  "id":"e2382120-9999-4c70-87d6-e534ae57cf33",
  "name":"T000-000",
  "description":"Characterization of Atrial Fibrillation Type, Symptoms, and Ablation
History",
  "label":"Characterization of Atrial Fibrillation Type",
  "versions":[
   {
    "id":"StudyVersion_1",
    "extensionAttributes":[],
    "versionIdentifier":"None",
    "rationale":"",
    "documentVersionIds":[],
    "dateValues":[],
    "amendments":[],
    "businessTherapeuticAreas":[],
    "studyIdentifiers":[],
    "referenceIdentifiers":[],
    "studyDesigns":[
     {
      "id":"StudyDesign_1",
      "extensionAttributes":[],
      "name":"Study Design 1",
      "label":null,
      "description":"The main design for the study",
```

OpenStudyBuilder

ICH M11 Template

1 PROTOCOL SUMMARY

No text is intended here (header only).

1.1 Protocol Synopsis

The protocol synopsis is a short summary of the key points of the trial.

No text is intended here (header only).

Primary and Secondary Objectives and Endpoints

Include a copy of the Objectives/Endpoints Table including primary and secondary endpoints only from Section 3 of the protocol and follow all the same instructions. Not all trials will have a complete estimand. Do not include exploratory endpoints in the synopsis.

[Primary and Secondary Objectives and Endpoints]

Overall Design

Several key aspects of the trial design are summarised below.

Intervention Model:	[intervention model]	**Population Type:**	[population type]
Control:	[control]	**Population Diagnosis or Condition:**	[diagnosis or condition]
Active Comparator:	[comparator]	**Population Age:**	Minimum: [minimum age] – Maximum: [maximum age]
Trial Intervention Assignment Method:	[intervention assignment method]	**Site Distribution:**	[geographic scope]

{sdtm.oak}

- **sdtm.oak**: Open-source R project to streamline the creation of SDTM datasets.

{sdtm.oak}

Algorithm Name	Description	Example
assign_no_ct	One to One mapping with no controlled terms.	AE.AETERM
assign_ct	One to One mapping with controlled terms.	VS.VSPOS
assign_datetime	One-to-one mapping of a date, time, or datetime component. Also handles unknown dates and converts them to ISO8601 format.	MH.MHSTDTC
hardcode_ct	Hard code the target based on the source with controlled terms.	VS.VSORRESU = ‘mmHg’
hardcode_no_ct	Hard code the target based on the source without controlled terminology.	FA.FASCAT = ‘COVID-19 PROBABLE CASE’
condition_add	Algorithm that is used to filter source and/or target based on a condition. Used in conjunction with assign_ct, assign_no_ct, hardcode_ct, hardcode_no_ct, assign_datetime.	If MDPRIOR == 1 then CM.CMSTRTPT = ‘BEFORE’.

{sdtm.oak}

```
cm <- cm %>%
  # Map qualifier CMDOSU
  assign_ct(
    raw_dat = cm_raw,
    raw_var = "DOSU",
    tgt_var = "CMDOSU",
    ct_spec = study_ct,
    ct_clst = "C71620",
    id_vars = oak_id_vars()
  )
```

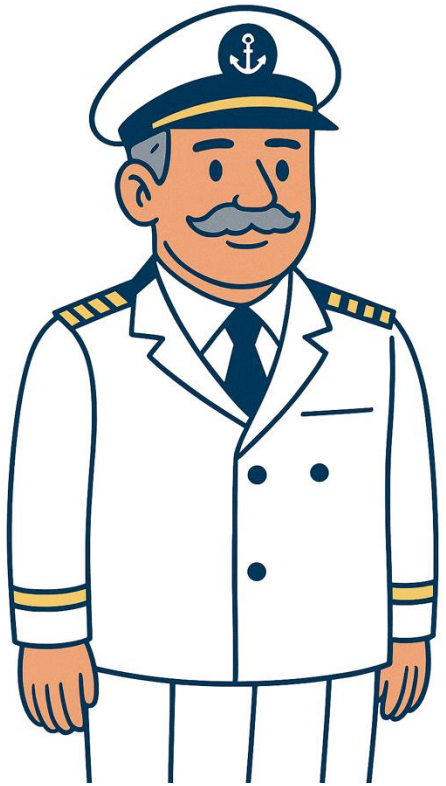
```
cm <- cm %>%
  # Map CMSTDTC. This function calls create_iso8601
  assign_datetime(
    raw_dat = cm_raw,
    raw_var = c("MDBDR", "MDBTM"),
    tgt_var = "CMSTDTC",
    raw_fmt = c(list(c("d-m-y", "dd mmm yyyy")), "H:M"),
    raw_unk = c("UN", "UNK"),
    id_vars = oak_id_vars()
  )
```

{sdtm.oak}

- Modular and reusable
- Reduced production time
- V2.0 does NOT currently cover Trial Design Domains, SV, SE, RELREC, or the EPOCH variable
- Future release
  - More algorithms
  - Automated workflow using custom specifications

{admiral}

- **admiral:** Open source toolbox with which to create ADaM datasets in R.



{admiral}

```
advs <- derive_basetype_records(
  dataset = advs,
  basetypes = exprs(
    "LAST: AFTER LYING DOWN FOR 5 MINUTES" = ATPTN == 815,
    "LAST: AFTER STANDING FOR 1 MINUTE" = ATPTN == 816,
    "LAST: AFTER STANDING FOR 3 MINUTES" = ATPTN == 817,
    "LAST" = is.na(ATPTN)
  )
)
```

```
advs <- derive_var_base(
  advs,
  by_vars = exprs(STUDYID, USUBJID, PARAMCD, BASETYPE),
  source_var = AVAL,
  new_var = BASE
)
```

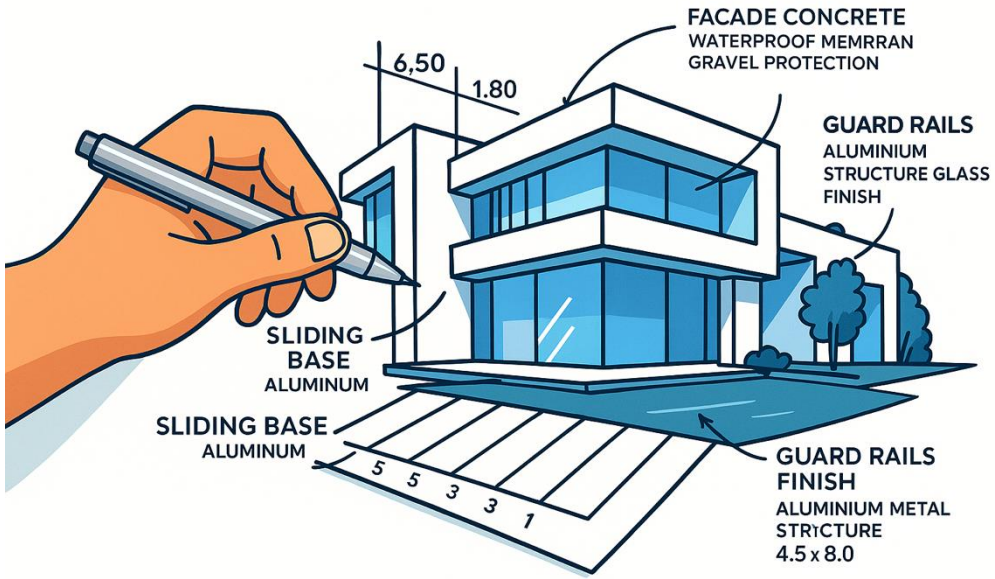
```
advs <- derive_var_chg(advs)

advs <- derive_var_pchg(advs)
```

{admiral}

- Currently handles ADSL, BDS and OCCDS datasets
- TA (Therapeutic Area) package extensions available (e.g. admiralonco)
- 12 ADaM templates available (ADSL, ADEX, ADPC…)
- No plans for automation

TFL Designer

- **TLF Designer**: Software tool for creating TFL shells. It also generates machine-readable metadata (ARM-TS) which downstream applications can use to produce TLFs.



TFL Designer

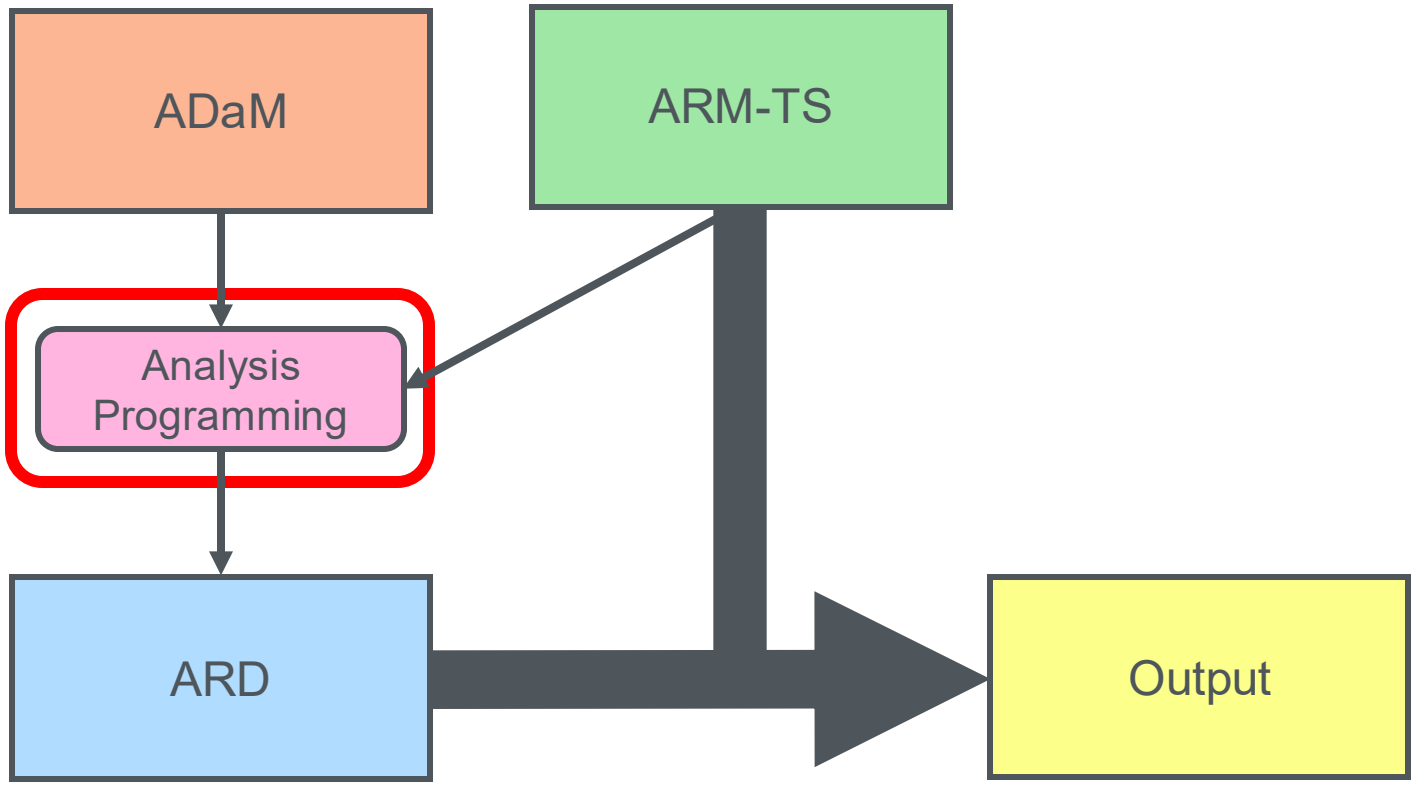
- TFL Designer available as both a community and enterprise version
- Enterprise version has some additional functionality (version control, user collaboration, review and approval…)

{siera}

- **siera**: Open-source R package that uses ARS metadata to produce R scripts that generate ARDs.

https://phuse.s3.eu-central-1.amazonaws.com/Archive/2022/Connect/EU/Belfast/PAP_DS09.pdf

{siera}



https://phuse.s3.eu-central-1.amazonaws.com/Archive/2022/Connect/EU/Belfast/PAP_DS09.pdf

{siera}

```
# ARS file path:
ARS_path <- ARS_file("arm_ts_temp.xlsx")

# Output folder:
output_folder <- temp()

# ADaM folder:
ADaM_folder <- temp()

# run the readARS to creates R scripts
readARS(ARS_path, output_folder, ADaM_folder)
```

{siera}

```
# Programme:    Generate code to produce ARD for Out14-1-1
# Output:       Summary of Demographics
# Date created: 2025-10-21 12:07:53



# load libraries ----
library(dplyr)
library(readxl)
library(readr)
library(cards)
library(cardx)
library(broom)
library(parameters)
library(tidyr)
library(magrittr)

# Load ADaM -------
ADSL <- readr::read_csv('C:\Users\VanderDi\AppData\Local\Temp\RtmpSASliA/ADSL.csv',
                                  show_col_types = FALSE,
                                  progress = FALSE) |>
  dplyr::mutate(dplyr::across(dplyr::where(is.character), ~ tidyr::replace_na(.x, '')))


# Analysis An01_05_SAF_Summ_ByTrt----
#Summary of Subjects by Treatment
# Apply Analysis Set ---
df_pop <- dplyr::filter(ADSL,
            SAFFL == 'Y')

df_poptot <- df_pop



#Apply Data Subset ---
df2_An01_05_SAF_Summ_ByTrt <- df_poptot

#Apply Method ---

# Method ID:              Mth01_CatVar_Count_ByGrp
# Method name:            Count by group for a categorical variable
# Method description:     Count across groups for a categorical variable, based on subject occurrence

if(nrow(df2_An01_05_SAF_Summ_ByTrt) != 0) {
                              in_data = df2_An01_05_SAF_Summ_ByTrt |>
    dplyr::select(USUBJID, TRT01A) |>
    unique()
df3_An01_05_SAF_Summ_ByTrt <-
  cards::ard_categorical(
    data = in_data
    , variables = 'TRT01A'
  ) |>
dplyr::filter(stat_name == 'n') |>
 dplyr::mutate(operationid = 'Mth01_CatVar_Count_ByGrp_1_n')}
if(nrow(df2_An01_05_SAF_Summ_ByTrt) != 0){
df3_An01_05_SAF_Summ_ByTrt <- df3_An01_05_SAF_Summ_ByTrt |>
        dplyr::mutate(AnalysisId = 'An01_05_SAF_Summ_ByTrt',
               MethodId = 'Mth01_CatVar_Count_ByGrp',
               OutputId = 'Out14-1-1')
```

```
} else {
    df3_An01_05_SAF_Summ_ByTrt = data.frame(AnalysisId = 'An01_05_SAF_Summ_ByTrt',
               MethodId = 'Mth01_CatVar_Count_ByGrp',
               OutputId = 'Out14-1-1')
}


# Analysis An03_01_Age_Summ_ByTrt----
#Summary of Age by Treatment

#Apply Data Subset ---
df2_An03_01_Age_Summ_ByTrt <- df_pop

#Apply Method ---

# Method ID:              Mth02_ContVar_Summ_ByGrp
# Method name:            Summary by group of a continuous variable
# Method description:     Descriptive summary statistics across groups for a continuous variable

if(nrow(df2_An03_01_Age_Summ_ByTrt) != 0) {
                                df3_An03_01_Age_Summ_ByTrt <-
  cards::ard_continuous(
    data = df2_An03_01_Age_Summ_ByTrt,
    by = c('TRT01A'),
    variables = AGE
  ) |>
dplyr::mutate(operationid = dplyr::case_when(stat_name == 'N' ~ 'Mth02_ContVar_Summ_ByGrp_1_n',
                                                                    stat_name == 'mean' ~ 'Mth02_ContVar_Summ_ByGrp_2_Mean',
                                                                    stat_name == 'sd' ~ 'Mth02_ContVar_Summ_ByGrp_3_SD',
                                                                    stat_name == 'median' ~ 'Mth02_ContVar_Summ_ByGrp_4_Median',
                                                                    stat_name == 'p25' ~ 'Mth02_ContVar_Summ_ByGrp_5_Q1',
                                                                    stat_name == 'p75' ~ 'Mth02_ContVar_Summ_ByGrp_6_Q3',
                                                                    stat_name == 'min' ~ 'Mth02_ContVar_Summ_ByGrp_7_Min',
                                                                    stat_name == 'max' ~ 'Mth02_ContVar_Summ_ByGrp_8_Max'))}
if(nrow(df2_An03_01_Age_Summ_ByTrt) != 0){
df3_An03_01_Age_Summ_ByTrt <- df3_An03_01_Age_Summ_ByTrt |>
       dplyr::mutate(AnalysisId = 'An03_01_Age_Summ_ByTrt',
               MethodId = 'Mth02_ContVar_Summ_ByGrp',
               OutputId = 'Out14-1-1')
} else {
    df3_An03_01_Age_Summ_ByTrt = data.frame(AnalysisId = 'An03_01_Age_Summ_ByTrt',
               MethodId = 'Mth02_ContVar_Summ_ByGrp',
               OutputId = 'Out14-1-1')
}


# Analysis An03_01_Age_Comp_ByTrt----
#Comparison of Age by Treatment

#Apply Data Subset ---
df2_An03_01_Age_Comp_ByTrt <- df_pop

#Apply Method ---

# Method ID:              Mth04_ContVar_Comp_Anova
# Method name:            Analysis of variance group comparison for a continuous variable
# Method description:     Comparison of groups by analysis of variance (ANOVA) for a continuous variable
```

{siera}

- Automation of ADS
- Not a black box solution

{cards} and {cardx}

- **cards and cardx:** Open-source R packages that creates ARDs from ADAM.

{cards} and {cardx}

```r
ard_categorical(
  data = adsl,
  by = TRT01A,
  variables = c(AGEGR1, SEX, RACE, ETHNIC)
)
```

{cards} data frame: 81 x 11

	group1	group1_level	variable	variable_level	stat_name	stat_label	stat
1	TRT01A	Placebo	AGEGR1	>64	n	n	72
2	TRT01A	Placebo	AGEGR1	>64	N	N	86
3	TRT01A	Placebo	AGEGR1	>64	p	%	0.837
4	TRT01A	Placebo	AGEGR1	18-64	n	n	14
5	TRT01A	Placebo	AGEGR1	18-64	N	N	86
6	TRT01A	Placebo	AGEGR1	18-64	p	%	0.163
7	TRT01A	Placebo	SEX	F	n	n	53
8	TRT01A	Placebo	SEX	F	N	N	86
9	TRT01A	Placebo	SEX	F	p	%	0.616
10	TRT01A	Placebo	SEX	M	n	n	33

https://www.danieldsjoberg.com/ARD-PHUSE-workshop-2025/slides/01-intro-cards/#/exercise-2-demographics-ard-1

{cards} and {cardx}

```
pharmaverseadam::adsl |>
  dplyr::filter(ARM %in% c("Xanomeline High Dose", "Xanomeline Low Dose")) |>
  cardx::ard_stats_t_test(by = ARM, variables = AGE)
```

```
{cards} data frame: 14 x 9
   group1 variable   context   stat_name stat_label      stat
1     ARM      AGE stats_t_…    estimate  Mean Dif…    -1.286
2     ARM      AGE stats_t_…   estimate1  Group 1 …    74.381
3     ARM      AGE stats_t_…   estimate2  Group 2 …    75.667
4     ARM      AGE stats_t_…   statistic  t Statis…     -1.03
5     ARM      AGE stats_t_…     p.value    p-value     0.304
6     ARM      AGE stats_t_…   parameter  Degrees …   165.595
7     ARM      AGE stats_t_…    conf.low  CI Lower…     -3.75
8     ARM      AGE stats_t_…   conf.high  CI Upper…     1.179
9     ARM      AGE stats_t_…      method     method Welch Tw…
10    ARM      AGE stats_t_… alternative  alternat… two.sided
11    ARM      AGE stats_t_…          mu    H0 Mean          0
12    ARM      AGE stats_t_…      paired  Paired t…     FALSE
13    ARM      AGE stats_t_…   var.equal  Equal Va…     FALSE
14    ARM      AGE stats_t_…  conf.level  CI Confi…      0.95
```

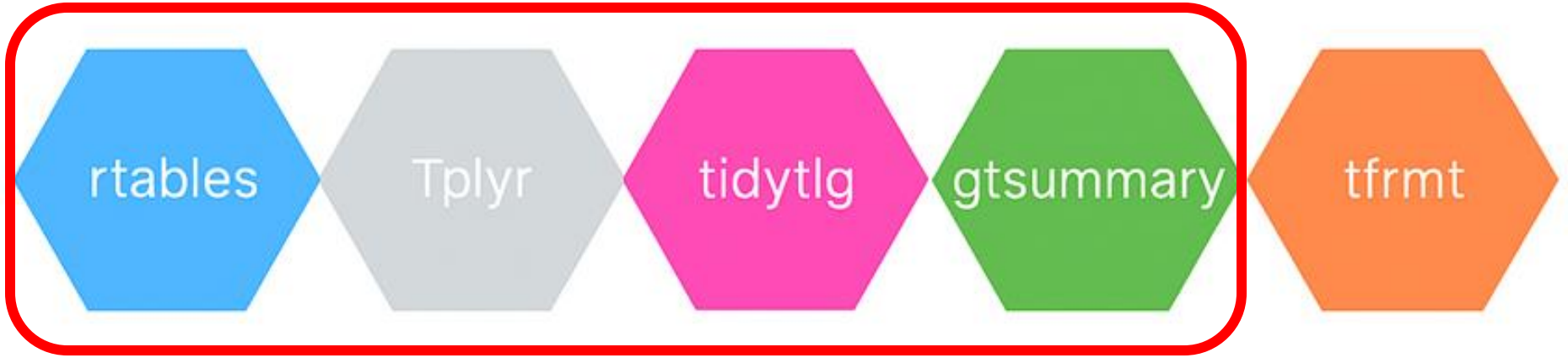
https://www.danieldsjoberg.com/ARD-PHUSE-workshop-2025/slides/02-intro-cardx/#/cardx-t-test-example

{cards} and {cardx}

- Allows creation of ARD without ARM-TS
- Does not offer an automated solution to creating ARDs

R packages for creating tables

- Data frame-first packages

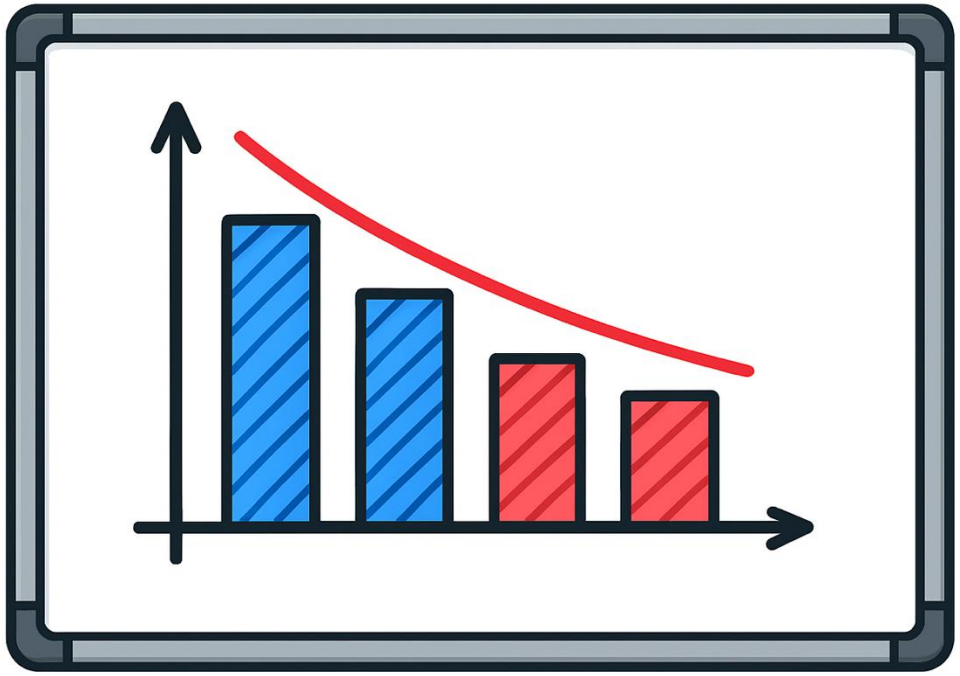


R packages for creating tables

- ARD-first packages

{gtsummary}

- **gtsummary**: Open-source R package to summarize and present study results.



{gtsummary}

Data Set → tbl_summery()

ARD → tbl_ard_summery()

Characteristic	Placebo N = 86	High Dose N = 84
Age		
Mean (SD)	75 (9)	74 (8)
Median (IQR)	76 (69, 82)	76 (71, 80)
Range	52 - 89	56 - 88
Baseline BMI (kg/m^2)		
Mean (SD)	23.6 (3.7)	25.3 (4.2)
Median (IQR)	23.4 (21.2, 25.6)	24.8 (22.7, 27.9)
Range	15.1 - 33.3	13.7 - 34.5
Discontinuation, n (%)		
Completed	58 (67.4%)	27 (32.1%)
Adverse Event	8 (9.3%)	40 (47.6%)
Withdrew Consent	9 (10.5%)	8 (9.5%)
Sponsor Decision	2 (2.3%)	3 (3.6%)
Lack of Efficacy	3 (3.5%)	1 (1.2%)
I/E Not Met	1 (1.2%)	2 (2.4%)
Physician Decision	1 (1.2%)	2 (2.4%)
Death	2 (2.3%)	0 (0.0%)
Protocol Violation	1 (1.2%)	1 (1.2%)
Lost to Follow-up	1 (1.2%)	0 (0.0%)

→ ARD

https://www.danieldsjoberg.com/ARD-PHUSE-workshop-2025/slides/03-tables-gtsummary/#/gtsummary-runs-on-ards

{gtsummary}

```r
library(gtsummary)
ADSL <- cards::ADSL |> dplyr::filter(startsWith(ARM, "Xanomeline"))
ADAE <- cards::ADAE |> dplyr::filter(startsWith(TRTA, "Xanomeline"))

tbl <- ADSL |>
  tbl_summary(
    by = ARM,
    include = c(AGE, RACE),
    type = AGE ~ "continuous2",
    statistic = all_continuous() ~ c("{mean} ({sd})", "{min}, {max}")
  ) |>
  add_overall()
```

Characteristic	Overall N = 168[1]	Xanomeline High Dose N = 84[1]	Xanomeline Low Dose N = 84[1]
Age			
Mean (SD)	75 (8)	74 (8)	76 (8)
Min, Max	51, 88	56, 88	51, 88
Race			
AMERICAN INDIAN OR ALASKA NATIVE	1 (0.6%)	1 (1.2%)	0 (0.0%)
BLACK OR AFRICAN AMERICAN	15 (8.9%)	9 (10.7%)	6 (7.1%)
WHITE	152 (90.5%)	74 (88.1%)	78 (92.9%)

[1] n (%)

https://www.danieldsjoberg.com/ARD-PHUSE-workshop-2025/slides/03-tables-gtsummary/#/simple-summary-table

{gtsummary}

```
1 gather_ard(tbl) |> purrr::pluck("tbl_summary")
```

{cards} data frame: 79 x 12

	group1	group1_level	variable	variable_level	stat_name	stat_label	stat
1	TRT01P	Placebo	AGEGR1	>64	n	n	72
2	TRT01P	Placebo	AGEGR1	>64	N	N	86
3	TRT01P	Placebo	AGEGR1	>64	p	%	0.837
4	TRT01P	Placebo	AGEGR1	18-64	n	n	14
5	TRT01P	Placebo	AGEGR1	18-64	N	N	86
6	TRT01P	Placebo	AGEGR1	18-64	p	%	0.163
7	TRT01P	Xanomeli…	AGEGR1	>64	n	n	73
8	TRT01P	Xanomeli…	AGEGR1	>64	N	N	84
9	TRT01P	Xanomeli…	AGEGR1	>64	p	%	0.869
10	TRT01P	Xanomeli…	AGEGR1	18-64	n	n	11

https://www.danieldsjoberg.com/ARD-PHUSE-workshop-2025/slides/03-tables-gtsummary/#/simple-summary-table-1

{gtsummary}

- Uses ADaM or ARD as input
- ARD is created as a byproduct of every {gtsummary}
- ARD created using {gtsummary} can be compared with ARD created using {cards}

{tfrmt}:

- **tfrmt:** Open-source R package for defining display-related metadata which can then be used to easily format existing data.

{tfrmt}:

	Placebo		Xanomeline Low Dose		Xanomeline High Dose		fisher_pval	
	n_pct	AEs	n_pct	AEs	n_pct	AEs	p_low	p_high
ANY BODY SYSTEM	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
CARDIAC DISORDERS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
GASTROINTESTINAL DISORDERS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
APPLICATION SITE PRURITUS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
APPLICATION SITE ERYTHEMA	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
APPLICATION SITE IRRITATION	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
INFECTIONS AND INFESTATIONS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
NERVOUS SYSTEM DISORDERS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
DIZZINESS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
PRURITUS	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
ERYTHEMA	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx
RASH	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	XXX (xx.x %)	[XXX]	x.xxx	x.xxx

https://gsk-biostatistics.github.io/tfrmt/articles/examples.html

{tfrmt}:

```
tfrmt(
  # specify columns in the data
  group = AEBODSYS,
  label = AETERM,
  column = c(col2, col1),
  param = param,
  value = value,
  sorting_cols = c(ord1, ord2),
  # specify value formatting
  body_plan = body_plan(
    frmt_structure(group_val = ".default", label_val = ".default",
                   frmt_combine("{n} {pct}",
                                n = frmt("XXX"),
                                pct = frmt_when(
                                  "==100" ~ "",
                                  "==0" ~ "",
                                  TRUE ~ frmt("(xx.x %)")))),
    frmt_structure(group_val = ".default", label_val = ".default",
                   AEs = frmt("[XXX]")),
    frmt_structure(group_val = ".default", label_val = ".default",
                   pval = frmt_when(">0.99" ~ ">0.99",
                                    "<0.001" ~ "<0.001",
                                    "<0.05" ~ frmt("x.xxx*"),
                                    TRUE ~ frmt("x.xxx", missing ="--")))
  ),
  # Nest Preferred terms under SOC
  row_grp_plan = row_grp_plan(label_loc = element_row_grp_loc(location = "indented")),

  # Specify column styling plan
  col_style_plan = col_style_plan(
    col_style_structure(align = c(".",",","," "), col = c(p_low, p_high))
```

```
# columns
col_plan = col_plan(
  ## defines the spanning column order, and then beneath them the order of their contents
  -starts_with("ord"),
  span_structure(
    col2 = c(
      "Xanomeline High Dose (N=84)" = `Xanomeline High Dose`,
      "Xanomeline Low Dose (N=84)" = `Xanomeline Low Dose`,
      "Placebo (N=86)" = Placebo
    ),
    col1 = c(`n (%)` = `n_pct` ,
             `[AEs]` = `AEs`)
  ),
  span_structure(
    col2 = c("Fisher's Exact p-values" = fisher_pval),
    col1 = c(
      # add a line break to help with table formatting
      `Placebo vs.\n Low Dose` = `p_low` ,
     `Placebo vs.\n High Dose` = `p_high`
    )
  ))
) %>%
print_to_gt(data_ae2)  %>%
tab_options(
  container.width = 1000
)
```

https://gsk-biostatistics.github.io/tfrmt/articles/examples.html

{tfrmt}:

	Placebo (N=86)		Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Fisher's Exact p-values	
	n (%)	[AEs]	n (%)	[AEs]	n (%)	[AEs]	Placebo vs. Low Dose	Placebo vs. High Dose
ANY BODY SYSTEM	65 (75.6 %)	[281]	77 (91.7 %)	[412]	76 (90.5 %)	[433]	0.007*	0.014*
CARDIAC DISORDERS	12 (14.0 %)	[26]	13 (15.5 %)	[30]	15 (17.9 %)	[30]	0.831	0.534
GASTROINTESTINAL DISORDERS	17 (19.8 %)	[26]	14 (16.7 %)	[22]	20 (23.8 %)	[36]	0.692	0.580
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	21 (24.4 %)	[46]	47 (56.0 %)	[118]	40 (47.6 %)	[124]	<0.001	0.002*
APPLICATION SITE PRURITUS	6 (7.0 %)	[10]	22 (26.2 %)	[32]	22 (26.2 %)	[35]	<0.001	<0.001
APPLICATION SITE ERYTHEMA	3 (3.5 %)	[3]	12 (14.3 %)	[20]	15 (17.9 %)	[23]	0.015*	0.002*
APPLICATION SITE IRRITATION	3 (3.5 %)	[7]	9 (10.7 %)	[18]	9 (10.7 %)	[16]	0.078	0.078
INFECTIONS AND INFESTATIONS	16 (18.6 %)	[35]	9 (10.7 %)	[16]	13 (15.5 %)	[20]	0.194	0.685
NERVOUS SYSTEM DISORDERS	8 (9.3 %)	[11]	20 (23.8 %)	[40]	25 (29.8 %)	[41]	0.013*	<0.001
DIZZINESS	2 (2.3 %)	[3]	8 (9.5 %)	[13]	11 (13.1 %)	[15]	0.056	0.009*
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	8 (9.3 %)	[12]	9 (10.7 %)	[14]	10 (11.9 %)	[22]	0.803	0.626
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	20 (23.3 %)	[45]	39 (46.4 %)	[111]	40 (47.6 %)	[104]	0.002*	0.001*
PRURITUS	8 (9.3 %)	[11]	21 (25.0 %)	[31]	26 (31.0 %)	[38]	0.008*	<0.001
ERYTHEMA	8 (9.3 %)	[12]	14 (16.7 %)	[22]	14 (16.7 %)	[22]	0.175	0.175
RASH	5 (5.8 %)	[9]	13 (15.5 %)	[18]	9 (10.7 %)	[15]	0.048*	0.277

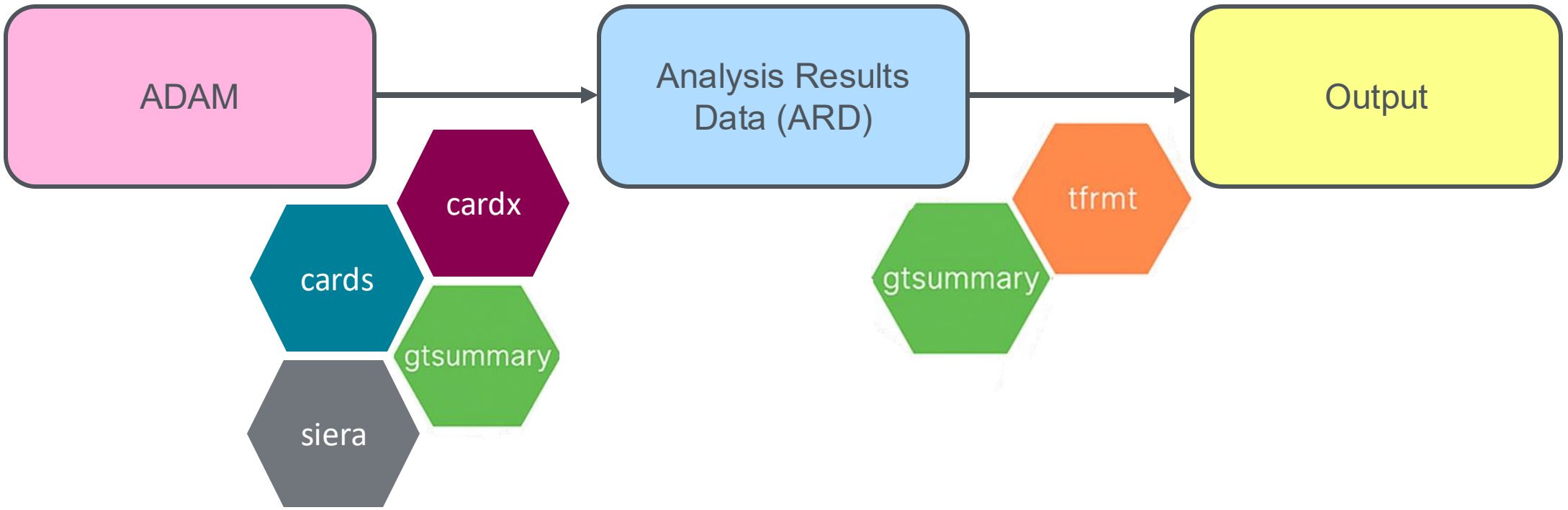
https://gsk-biostatistics.github.io/tfrmt/articles/examples.html

{tfrmt}:

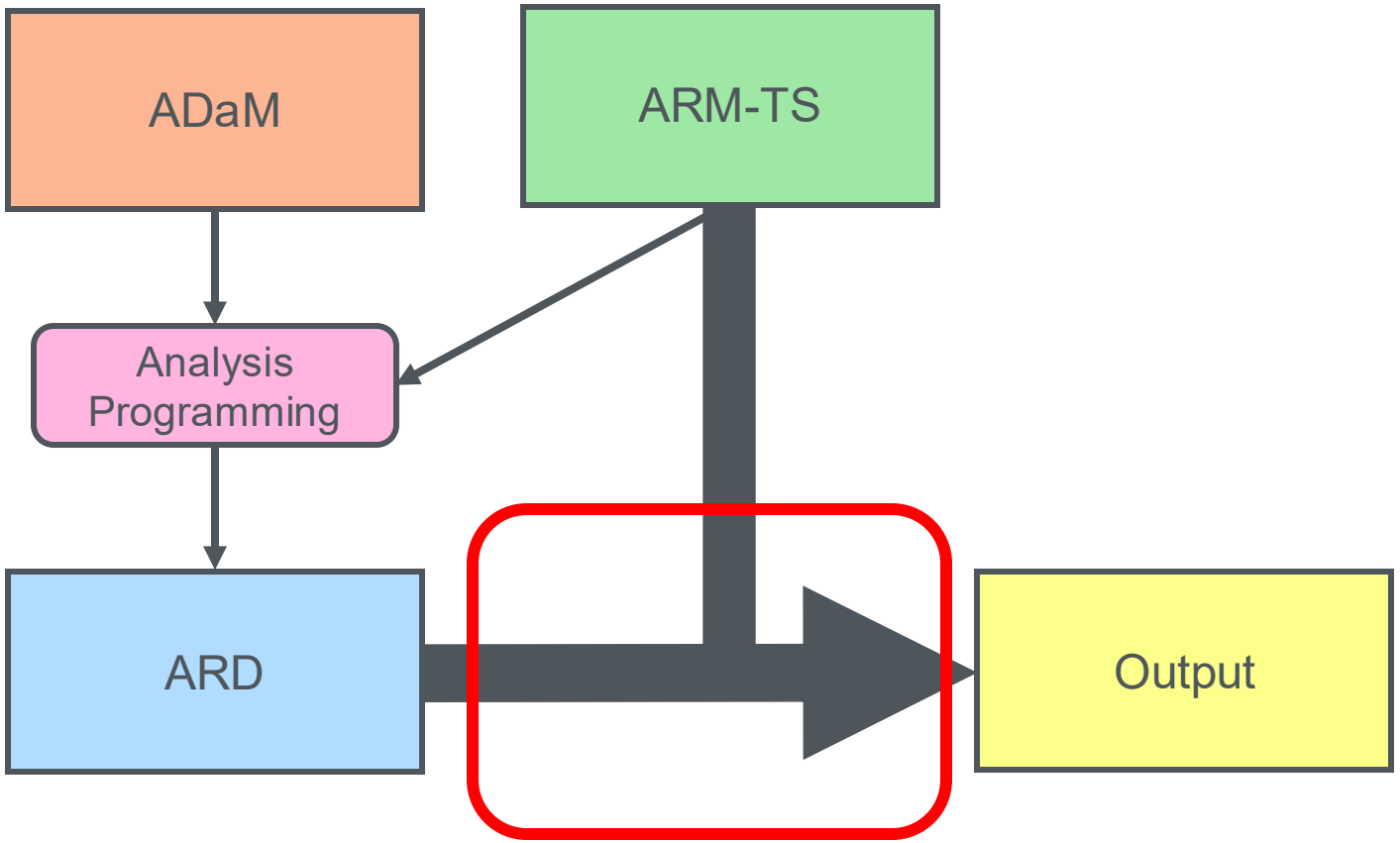
- Uses ARD as input
- Analysis is separated from layout
- Metadata object (template) can be created with limited or no available data
- Mock shell can be created from metadata object (template)
  - Metadata object (template) can be created prior to start of analysis programming
  - Enforces conformity to mock shells

https://gsk-biostatistics.github.io/tfrmt/articles/examples.html

ARS Flow



ARS Flow



What impact will this have on statistical programming?

- CDISC 360
- Pharmaverse
- R vs SAS
- FDA
- Drive change

Q&A

Thank you