



The Clinical Data
Science Conference

US 2025

16–19 March
Renaissance Orlando at SeaWorld Florida

Selecting GeARS: Analysis Results Standard Implementation Options for Accelerated Analysis and TFL Automation

Paper & Presentation # DS09

March 18, 2025

Richard Marshall, Principal Data Standards & Automation Architect

Bhavin Busa, Principal & Co-Founder

Analysis Results Standard (ARS) Resources

■ Model documentation:

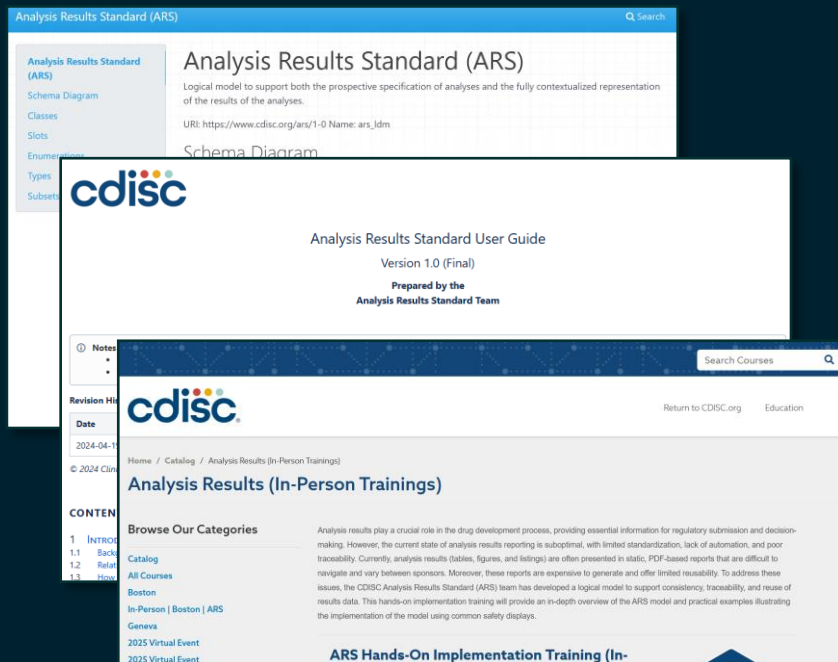
<https://cdisc-org.github.io/analysis-results-standard/>

■ User Guide:

<https://wiki.cdisc.org/display/ARSP/Analysis+Results+Standard+User+Guide+v1.0>

■ CDISC Hands-On Training:

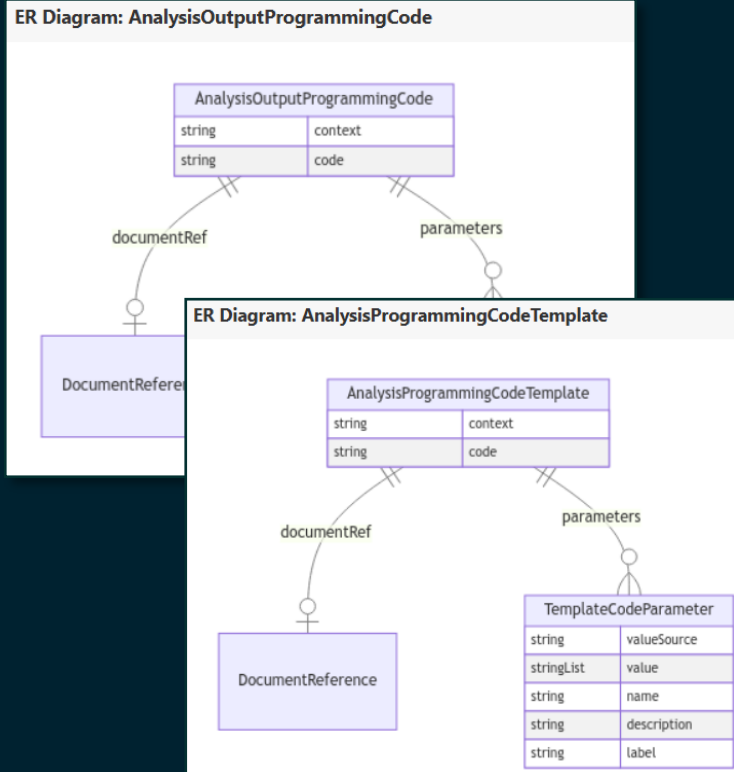
<https://learnstore.cdisc.org/>



Analysis Results
(In-Person
Trainings)

ARS Programming Code Classes

- AnalysisOutputProgrammingCode
 - AnalysisOutputCodeParameter
- AnalysisProgrammingCodeTemplate
 - TemplateCodeParameter



Create Reference Document

Name *
table140701.sas

Label
Enter Label

Description
Program for generation of table 14.7.01

Location
./programs/table140701.sas

Cancel Create

```
referenceDocuments:
- id: table140701_sas
  location: ./programs/table140701.sas
  name: table140701.sas
  description: "Program for generation
    of table 14.7.01"
```

Table 14.7.01

Summary of TEAE by System Organ Class and Preferred Term

Safety Population

Class	Placebo (N=XX)	n

Programming Code

Context
SAS Version 9.4

☒ From existing document reference

Reference Document
table140701.sas

outputs:

```
- id: Out14-7-01
  name: Table 14.7.01
  label: Summary of TEAE by System Organ Class and Preferred Term
  programmingCode:
    context: SAS Version 9.4
  documentRef:
    referenceDocumentId: table140701_sas
```

Output Programming Code

■ To link an output to an external program file:

1. Define the program as a reference document.
2. Reference the document as the programming code for the output.



outputs:

```
- id: Out14-7-01  
  name: Table 14.7.01
```

```
  label: Summary of TEAE by System Organ Class and Preferred Term
```

Table 14.7.01		
Summary of TEAE by System Organ Class and Preferred Term		
Safety Population		
Class	Placebo (N=XX)	n

outputs:

```
- id: Out14-7-01  
  name: Table 14.7.01  
  label: Summary of TEAE by System Organ Class and Preferred Term  
  programmingCode:  
    context: SAS Version 9.4  
    documentRef:  
      referenceDocumentId: table140701_sas
```

▼ Programming Code

Context

SAS Version 9.4

☐ From existing document reference

Code

Xaesum;

where ...

▼ Programming Code

Context

SAS Version 9.4

☒ From existing document reference

Reference Document

table140701.sas

Output Programming Code

■ Specify programming code directly:

1. To run a program file.
2. As individual programming statements.
3. As a call to an existing macro.

Table 14.7.01

Summary of TEAE by System Organ Class and Preferred Term

Safety Population

Class	Placebo (N=XX)	n
-------	----------------	---

```

outputs:
- id: Out14-7-01
  name: Table 14.7.01
  label: Summary of TEAE by System Organ Class and Preferred Term
  programmingCode:
    context: SAS Version 9.4
    code: '%aesum(bysoc=&bysoc, bypt=&bypt, popvar=&popvar)'
    parameters:
      - name: bysoc
        label: Summarize by SOC (Y/N)
        value: Y
      - name: bypt
        label: Summarize by PT (Y/N)
        value: Y
      - name: popvar
        label: Population variable
        description: >
          Records are selected for inclusion when
          the named variable has a value of Y.
        value: SAFFL

```

▼ Programming Code

Context

SAS Version 9.4

☐ From existing document reference

Code

%aesum(bysoc=&bysoc, bypt=&bypt, popvar=&popvar)

Parameter 1

Parameter Name

bysoc

Parameter Label

Summarize by SOC (Y/N)

Parameter Value

Y

Parameter 2

Parameter Name

bypt

Parameter Label

Summarize by PT (Y/N)

Parameter Value

Y

Parameter 3

Parameter Name

popvar

Parameter Label

Population variable

Parameter Value

SAFFL

Parameter Description

Records are selected for inclusion when the

Parameterized Output Programming Code

- Parameter values may be specified.
- Facilitates integration with an existing macro library.
- How the parameter values are passed to the macro call depends on the implementation preferences

Summary of Demographic and Baseline Characteristics				
Safety Population				
Characteristics	Placebo (N=XX)	Xanomeline Low Dose (N=XX)	Xanomeline High Dose (N=XX)	p-value
Age				0.XXX
n	XX	XX	XX	
Mean (SD)	XX.X (XX.XX)	XX.X (XX.XX)	XX.X (XX.XX)	
Median	XX.X	XX.X	XX.X	
Q1, Q3	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
Min, Max	XX.X, XX.X	XX.X, XX.X	XX.X, XX.X	
Age Group				0.XXX

analyses:

```

- id: An03_02_AgeGrp_Comp_ByTrt
  name: Comparison of Age Group by Treatment
  programmingCode:
    context: SAS Version 9.4
    code: 'proc freq data=ADSL; grpvar=&GRPVAR, anvar=&ANVAR;
    parameter TRT01A * AGEGRP / chisq;
    - name: ANDS;
      label: Analysis dataset
      value: ADSL
    - name: GRPVAR
      label: Grouping variable
      value: TRT01A
    - name: ANVAR
      label: Analysis variable
      value: AGEGRP
  
```

Programming Code	
Context	SAS Version 9.4
From existing document reference	
Code	proc freq data=ADSL; grpvar=
Parameter 1	
Parameter Name	ANDS
Parameter Label	Analysis dataset
Parameter Value	ADSL
Parameter 2	
Parameter Name	GRPVAR
Parameter Label	Grouping variable
Parameter Value	TRT01A
Parameter 3	
Parameter Name	ANVAR
Parameter Label	Analysis variable
Parameter Value	AGEGRP

Analysis Programming Code

- Programming code can be specified at the analysis level.
- Specifies programming statements to generate result values for a specific analysis.
- May be for reference.
 - ARS support ARM for Define-XML
- May be parameterized.



▼ Programming Code

Name * **Default**

Count TEAE by SOC/PT

Categorical Continuation

Label

☒ n

Context

SAS Version 9.4 ☐ From existing document reference

Code

%socpt_count(bysoc=&bysoc, bypt=&bypt, popvar=&popvar);

Parameter Name	Parameter Label	Parameter Value	Parameter Value Source
bysoc	Summarize by SOC (Y/N)	Y, N	Enter Parameter Value ...
bypt	Summarize by PT (Y/N)	Y, N	Enter Parameter Value ...
popvar	Population variable	SAFFL	Enter Parameter Value ...

Parameter Description

Records are selected for inclusion when the named variable has a value of Y.

methods:

```
- id: MTH_SO
name: Count TEAE by SOC/PT
operations:
- id: MTH_SO
name: Count TEAE by SOC/PT
order: 1
resultPattern: XXX
```

codeTemplate:

```
context: SAS Version 9.4
code: '%socpt_count(bysoc=&bysoc, bypt=&bypt, popvar=&popvar);'
parameters:
- name: bysoc
value:
- Y
- N
- name: bypt
value:
- Y
- N
- name: popvar
value: SAFFL
```

Template Programming Code

- Specified for analysis methods
- Can be a document reference or code statements
- Usually parameterized
- How the template programming code is applied for analyses that reference the analysis method depends on implementation preferences.
- Analysis-specific parameter values must be recorded with the analysis definition

▼ Programming Code

Context

SAS Version 9.4

☐ From existing document reference

Code

`%CatVar_Count_ByGrp(anid=&anid,gfids=&gfids);`

Parameter Name	Parameter Label	Parameter Value	Parameter Value Source
anid	Analysis Id	Enter Parameter Value	#/id
Parameter Name	Parameter Label	Parameter Value	Parameter Value Source
gfids	Grouping Factor Identifie	Enter Parameter Value	#/orderedGroupings/[*]/i

methods:

```

- id: Mth01_CatVar_Count_ByGrp
  name: Count by group for a categorical variable
  operations:
    - id: Mth01_CatVar_Count_ByGrp_1_n
      name: Count of subjects
      label: n
      order: 1
      resultPattern: (N=XXX)
  codeTemplate:
    context: SAS Version 9.4
    code: "%CatVar_Count_ByGrp(anid=&anid,gfids=&gfids);"
    parameters:
      - name: anid
        description: Analysis Id
        valueSource: '#/id'
      - name: gfids
        description: Grouping Factor Identifiers
        valueSource: '#/orderedGroupings/[*]/groupingId'

```

Metadata-based Parameterization

- Template programming code parameter values may be specified as a reference to a metadata element
- This means analysis-specific parameters values can be retrieved at runtime
- Generation of analysis result values can be automated based on the selection of analysis method

Automated Analysis

Demo Video





Richard Marshall

Principal Data Standards & Automation Architect

rmarshall@clymbclinical.com

Bhavin Busa

Principal & Co-Founder

bhavin@clymbclinical.com



EMAIL

info@clymbclinical.com



WEBSITE

www.clymbclinical.com



PHONE

781-692-3613