

Demonstrations of AutoTable

Chengxin Li

AutoCheng Clinical Data Services

March, 2026

Agenda

Introduction

Analysis Result Metadata (ARM)

ARM Applications

autoTable with ARM Driven

%ADSLEVL, %OCCFREQ, %BDSSTAT, %BDSSHIFT

Demos

Questions

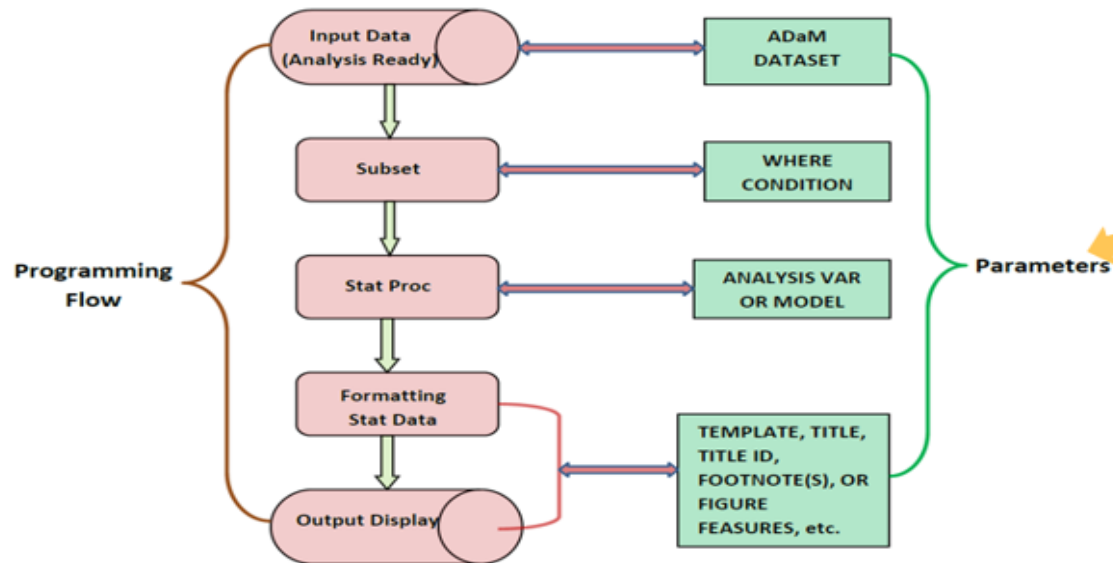
Introduction to ARM

- ❖ Three types of metadata defined in ADaM v2.1 (published in Dec. 2009)
 - Analysis Dataset Metadata
 - Analysis Variable Metadata
 - **Analysis Results Metadata (ARM)**
- ❖ Analysis Results Metadata
 - Describes the main attributes of the analysis results
 - Provides traceability between analysis results and analysis dataset to facilitate reviews
 - ARM v1.0 for Define-XML V2 supporting ARM submission published in Jan 2015
 - ARM submission for primary/secondary endpoints and main safety analyses recommended (e.g., by PMDA)
- ❖ ARM widely used in table shell annotations

ARM Applications

auto TLF Driven by ARM

- ❖ Achieving autoTLF requires ADaM or pre-processing ADaM to be analysis-ready. After applying data selection criteria WHERE statement, it's able to directly invoke SAS statistical procedure, formatting and reporting



- association exists between programming process and ARM
- macro parameters design aligned with ARM fields
- thus, macro call instance as table specs as well
- additionally, ARM define-xml generation automated and harmonized with production

- ❖ To support layout multiplicities, capture core features/patterns of table shells, thus **NO** requirements on table shell standardization or digitalization
- ❖ NO black box: parameters of one macro call are the table specifications; plain executable codes as output; submission ready/facilitated
- ❖ Targeting to supporting 95% analysis, 85% layouts

ARM Applications

Design of Freq analysis with OCCDS example

%macro OCCFREQ(

1

SAP

TableID	=	Table number
Title	=	Table titles
Footnote	=	User defined footnotes
Popu	=	Analysis population set

2

Programming

INDATA	=	Input analysis dataset
WHERE	=	Data selection criteria
ADSL	=	Input ADSL dataset
SUBJSUM	=	No. SUBJECT/EVENT with TEAE
ANALVAR	=	Analysis variables
ADSL_ARM	=	Treatment period variable from ADSL
INDATA_ARM	=	Treatment group variable from INDATA
SUBGROUP	=	Subgroup analysis variable
FreqThreshold	=	Frequency threshold minimum cut-off, e.g., non-SAE ISS)

autoTable Scopes

❖ Non-inferential Analyses

SAS Macro	Input Dataset	Analyses
%OCCFREQ	Any OCCDS, e.g., ADAE, ADCM, ADMH	Any frequency analyses
%BDSSTAT	Any BDS, e.g., ADLB, ADEG, ADVS	Any descriptive analyses with continuous/character variables
%BDSSHIFT	Any BDS, e.g., ADLB, ADEG	Shift table analyses, specifically
%ADSLEVL	ADSL	Subject evaluation analyses, e.g., tables of baseline, demographic, disposition, population, etc.

❖ Inferential Analyses

%ANCOVA, %MMRM, %CMH, %TTE

Macro Output

Seq	Item	Note
1	Table	table output in formats of RTF, PDF, or XLSX
2	SAS Codes	Plain executable submission-ready SAS code dynamically resolved from the macro call. Executing the generated code reproduces the identical table
3	RDS	Final results dataset used for qc, or implementing any other special table layout
4	ARMDS	Aggregated dataset of table specifications with ARM structure Facilitate ARM define-xml generations
5	Log file	Macro execution logs

Demos with Detailed Parameters and Options

- ❖ Multi-options defined along with parameters
 - ✓ Table level, applied to the whole table, e.g., page break pattern
 - ✓ Parameter level, applied to a component of the parameter, e.g., sort order
 - ✓ **Table Layout Features and Patterns Additionally Captured**
- ❖ Simulated ADaMs used (ADSL, ADAE, ADLB), and table shells used here for demonstration purpose only
- ❖ Demographic table with %ADSLEVL
- ❖ SOC, PT, and Sev table with %OCCFREQ
- ❖ Observed values, CHG/PCHG by Visit table with %BDSSTAT
- ❖ Shift table with %BDSSHIFT

Demos with Details Parameters and Options

❖ Demographic Table with %ADSLEVL

```
%ADSLEVL(  
  TABLEID=%NRBQUOTE(t_demo2\LCHLBL=Category), /*TableID required; LCHLBL option to update the default display label*/  
  TITLE=, /*opt., separated with # if multiple. if both TITLE and FOOTNOTE NULL indicating user with utility macro*/  
  FOOTNOTE=, /*opt., separated with # if multiple*/  
  
  POPU=SAFFL, /*POPU parameter for big N summary as well*/  
  
  ADSL=%str(ADaM.ADSL),  
  WHERE =%str(SAFFL='Y'), /*data selection criteria from ADSL, applied to all analysis variables listed in ANALVAR parameters*/  
  
  ADSL_ARM=%NRBQUOTE(TRT01A\PRELOADFMT=$TRTA.\INFORMAT=TRTAN.\THCLIST=Xanomeline|[TRT11 TRT12 TRT19] ~ TRT21 ~ TRT99\THCFMT=$TRTSHEADER.),  
  /*PRELOADFMT option for trt grouping, THCLIST option for spanning header, THCFMT option for further formatting*/  
  
  ANALVAR=%NRBQUOTE(AGEGR1\CATSUM=OLI\DISP=%nrbquote(Age (years), n (%)) # /*CATSUM option for variable layout pattern*/  
    AGE\DISP=Age (years) # /*DISP option for variable label display, by default, with variable label*/  
    ARACE\CATSUM=OLI\preloadfmt=$RACE.\informat=RACEN.\DISP=%nrbquote(Race, n (%)) #  
    AETHNIC\CATSUM=OLI\DISP=%nrbquote(Ethnicity, n (%)) #  
    WEIGHTBL # HEIGHTBL # BMIBL # AOUNTRY\DISP=Country\informat=COUNTRYN. /*informat option for sort*/  
  ) /*CHAR var triggering freq summary, NUM var triggering DSTAT summary*/  
);
```

Demos with Details Parameters and Options

❖ Demographic Table Output with %ADSLEVL

Category	XANOMELINE			Placebo (N=86)	All Subjects (N=254)
	Low Dose (N=84)	High Dose (N=84)	Pooled (N=168)		
Age (years), n (%)					
<65	8 (9.5)	11 (13.1)	19 (11.3)	14 (16.3)	33 (13.0)
65-80	47 (56.0)	55 (65.5)	102 (60.7)	42 (48.8)	144 (56.7)
>80	29 (34.5)	18 (21.4)	47 (28.0)	30 (34.9)	77 (30.3)
Age (years)					
n	84	84	168	86	254
Mean (SD)	75.7 (8.29)	74.4 (7.89)	75.0 (8.09)	75.2 (8.59)	75.1 (8.25)
Median	77.5	76.0	77.0	76.0	77.0
Min, Max	51, 88	56, 88	51, 88	52, 89	51, 89

Demos with Details Parameters and Options

❖SOC, PT, and Sev Table with %OCCFREQ

```
%OCCFREQ(  
  TABLEID=%NRBQUOTE(t_teae_socptsev), /*left column header autogenerated by default, further customized if needed*/  
  Title  =%str(Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity # (Safety Analysis Set)),  
  Footnote=%NRBQUOTE(TEAE: treatment-emergent adverse event. #  
    Note: Adverse events (AEs) are coded using MedDRA version 27.0.),  
    /*commonly titles/footnotes loaded with company utility macro instead of manual input here*/  
  Popu   =%str(SAFFL),  
  Indata =ADaM.ADAE, /*or WORK.ADAE if preprocessed*/  
  ADSL   =ADaM.ADSL,  
  SUBJSUM=, /*%str(EVENT\DISP=No. of Events # USUBJ\DISP=Subjects with at least one TEAE)*/  
  
  ANALVAR=%NRBQUOTE(ASEV\WHERE=AOCIFL='Y'\preloadfmt=$ASEV.\informat=ASEVN.\CATSUM=OLI\disp=TEAE #  
    AESOC\DISP=System Organ Class\INDENT=0\SUMOFF=Y # /*INDENT option defining embedded layer associations*/  
    ASEV\WHERE=AOCISIFL='Y'\preloadfmt=$ASEV.\informat=ASEVN.\INDENT=1 #  
    AEDECOD\DISP=Preferred Term\INDENT=1\SUMOFF=Y #  
    ASEV\WHERE=AOCPIFL='Y'\preloadfmt=$ASEV.\informat=ASEVN.\INDENT=2  
  ),  
  
  ADSL_ARM=%str(TRT01A),  
  INDATA_ARM=%NRBQUOTE(TRTA\PRELOADFMT=$TRTA.\INFORMAT=TRTAN.\THCLIST="Xanomeline"| [TRT11 TRT12 TRT19] ~ TRT21 ~ TRT99\THCFMT=$TRTSHEADER.)  
); /*THCLIST for table spanning header, TCHFMT further formatting header display if needed*/
```

Demos with Details Parameters and Options

❖SOC, PT, and Sev Table with %OCCFREQ

Table 14.3.1.2 Treatment-Emergent Adverse Events by System Organ Class, Preferred Term and Severity
(Safety Analysis Set)

I System Organ Class Preferred Term Analysis Severity/Intensity	Xanomeline			Placebo (N=86)	All Subjects (N=254)
	Low Dose (N=84)	High Dose (N=84)	Pooled (N=168)		
TEAE					
Mild	0	2 (2.4)	2 (1.2)	3 (3.5)	5 (2.0)
Moderate	41 (48.8)	37 (44.0)	78 (46.4)	41 (47.7)	119 (46.9)
Severe	36 (42.9)	40 (47.6)	76 (45.2)	25 (29.1)	101 (39.8)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS					
Mild	1 (1.2)	0	1 (0.6)	1 (1.2)	2 (0.8)
Moderate	39 (46.4)	37 (44.0)	76 (45.2)	19 (22.1)	95 (37.4)
Severe	7 (8.3)	3 (3.6)	10 (6.0)	1 (1.2)	11 (4.3)
APPLICATION SITE PRURITUS					
Mild	0	0	0	0	0
Moderate	18 (21.4)	20 (23.8)	38 (22.6)	6 (7.0)	44 (17.3)
Severe	4 (4.8)	2 (2.4)	6 (3.6)	0	6 (2.4)

Demos with Details Parameters and Options

❖ Observed Values, CHG by Visit Table with %BDSSTAT

```
%BDSSTAT (  
  TABLEID=%NRBQUOTE(t_lab_saf2\LCHLBL=%NRBQUOTE(Visit^n  Statistics)\AVARDPAT=SH\LCPCHG=1%),  
  /*analysis variables transposed to header display with option setting, left column width/label adjustable*/  
  POPU=SAFFL,  
  
  INDATA=ADaM.ADLB,  
  where=%str(AVISITN>=0),  
  ADSL=ADaM.ADSL,  
  
  ANALVAR=%NRBQUOTE(BASE\disp=Baseline # AVAL\DISP=Observed Value # CHG),  
  /*multi BASE/AVAL/CHG/PCHG for study PART1 and PART2 easily achieved e.g., with WHERE suboption: BASETYPE='...'*/  
  
  BYVAR=%str(PARAM\DPAT=TV # AVISIT),      /*DPAT option supporting more flexible table shells*/  
  
  ADSL_ARM=TRT01A,  
  INDATA_ARM=%NRBQUOTE(TRTA\PRELOADFMT=$TRTA.\INFORMAT=TRTAN.)  
);
```

Demos with Details Parameters and Options

❖ Observed Values, CHG by Visit Table with %BDSSTAT

Parameter = Hemoglobin (mmol/L)

I Visit Statistics	Xanomeline Low Dose (N=84)		Xanomeline High Dose (N=84)		Pooled Xanomeline (N=168)		Placebo (N=86)		All Subjects (N=254)	
	Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value	Change from Baseline	Observed Value	Change from Baseline
Baseline										
n	81		81		162		85		247	
Mean (SD)	8.62 (0.768)		8.87 (0.783)		8.75 (0.784)		8.62 (0.828)		8.70 (0.800)	
Median	8.56		8.87		8.75		8.63		8.69	
Min, Max	6.6, 10.2		7.4, 10.6		6.6, 10.6		6.4, 10.4		6.4, 10.6	
Week 2										
n	80	77	80	77	160	154	83	82	243	236
Mean (SD)	8.45 (0.763)	-0.16 (0.462)	8.72 (0.829)	-0.21 (0.425)	8.58 (0.805)	-0.18 (0.443)	8.44 (0.765)	-0.16 (0.416)	8.53 (0.793)	-0.17 (0.433)
Median	8.44	-0.06	8.66	-0.25	8.53	-0.19	8.50	-0.19	8.50	-0.19
Min, Max	6.5, 10.5	-1.2, 0.7	7.1, 10.9	-1.3, 1.2	6.5, 10.9	-1.3, 1.2	6.8, 10.4	-1.1, 0.9	6.5, 10.9	-1.3, 1.2
Week 4										
n	71	69	71	69	142	138	79	78	221	216
Mean (SD)	8.35 (0.780)	-0.30 (0.501)	8.62 (0.780)	-0.21 (0.452)	8.49 (0.789)	-0.25 (0.477)	8.37 (0.815)	-0.23 (0.436)	8.45 (0.798)	-0.25 (0.462)
Median	8.19	-0.25	8.56	-0.25	8.38	-0.25	8.32	-0.31	8.38	-0.25
Min, Max	6.1, 10.1	-2.4, 0.9	7.4, 10.8	-1.2, 1.0	6.1, 10.8	-2.4, 1.0	6.5, 10.1	-1.1, 1.1	6.1, 10.8	-2.4, 1.1

Demos with Details Parameters and Options

- ❖ Shift Table (from BASE to Post-BASE) with %BDSSHIFT
- ✓ The shift table layouts often show multiplicities
- ✓ With settings, the SHIFT table engine can easily implement:
 - ❑ Either BASELINE or POST-BASELINE transposed
 - ❑ Denominator with N, m, or n
 - ❑ Combinations of TRTA, PARAM, AVISIT, and even SUBGROUP, printed in title, left column, and spanning header, respectively
 - ❑ Multiple shifts presented into one table
- ✓ One typical examples demonstrated below

Demos with Details Parameters and Options

❖ Shift Table (from BASE to Post-BASE) with %BDSSHIFT

```
/*category overall baseline count--m as denominator, and postbase transposed*/
%BDSSHIFT(
  TABLEID=t_lab_shift3,
  POPU=SAFFL,

  INDATA=%str(ADaM.ADLB),
  WHERE =%NRBQUOTE(PARAMCD in ('ALT', 'AST', 'CK')),

  ADSL=%str(ADaM.ADSL),

  ANALVAR=%NRBQUOTE(BNRIND\preloadfmt=$NRIND.\informat=NRINDN. ~ ANRIND\preloadfmt=$NRIND.\informat=NRINDN.\denom=m),

  BYVAR=%str(PARAMCD\DPAT=TV # AVISIT\DPAT=LC),

  ADSL_ARM=%str(TRT01A),
  INDATA_ARM=%str(TRTA\DPAT=LC)
);
```

Demos with Details Parameters and Options

❖ Shift Table (from BASE to Post-BASE) with %BDSSHIFT

Parameter: Alanine Aminotransferase (U/L)

Treatment Group	I Baseline Category	Post-Baseline Category, n (%)			
		Low	Normal	High	Total
<u>Xanomeline</u> Low Dose (N=84)	Week 2				
	Low	2 (2.6)	1 (1.3)	0	3 (3.8)
	Normal	0	73 (93.6)	0	73 (93.6)
	High	0	1 (1.3)	1 (1.3)	2 (2.6)
	Total	2 (2.6)	75 (96.2)	1 (1.3)	78 (100)
	Week 4				
	Low	2 (2.9)	0	0	2 (2.9)
	Normal	2 (2.9)	64 (91.4)	0	66 (94.3)
	High	0	1 (1.4)	1 (1.4)	2 (2.9)
	Total	4 (5.7)	65 (92.9)	1 (1.4)	70 (100)

autoTLF Roadmap

- ❖ Non-Inferential Tables (completed)

 - %ADSLEVL, %OCCFREQ, %BDSSTAT, %BDSSHIFT**

- ❖ Inferential Tables (half-done)

 - %MMRM, %ANCOVA, %CMH, %TTE**

- ❖ AI/ML Powered (initiated)

 - AI Agents**

- ❖ Figures and Listings (planned)

- ❖ **R/Python** Packages (tracking R/Python growths)

Philosophy: Keep the solution simple and applicable in productions

Conclusion

- ❖ Design Goal to cover %95 analyses + %85 layouts is conservative
- ❖ Much more efficient than the copy-paste-update programming model by switching the focus to the table specifications only
- ❖ Achievable in minutes to generate a table with table output, RDS, and plain executable submission-ready code
- ❖ Summarizing programming routine practices and following programming styles, seeing and knowing, thus easily transitioned
- ❖ Compatible with legacy workflow, table-shell standardization or digitalization NOT a prerequisite. However, it can facilitate the generations if standardization or digitalization already conducted



Questions

For further demonstration request or collaboration,
please contact the author at:

Chengxin Li

AutoCheng Clinical Data Services LLC

Chengxin.li@autoclindata.com

