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Adding New Rows in the ADaM Basic Data Structure: When and How

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ABSTRACT

The ADaM (Analysis Data Model) BDS (Basic Data Structure) has specific rules to follow when adding columns or rows. Because there are limitations to what can be added as a column to a BDS structure, much of our derived content must be added as rows.

This HOW uses a Vital Signs example, demonstrating the common BDS dataset need of adding analysis parameters and visits. Attendees will start with a general specification and mock-up, and use that to create metadata content that can be used for both detailed specification and within a define document. The resulting metadata will include both variable-level and parameter-level content and contain SAS® code snippets.

This is an intermediate-level HOW. Attendees are expected to be familiar with the analysis needs of clinical trials, CDISC, and submissions to FDA.

INTRODUCTION

This paper provides a brief summary on the topic of adding rows in the ADaM BDS structure. It supports the Hands-On Workshop, where attendees work to develop the structure of a BDS dataset. Content provided here is taken from ADaM documents and slides, and is meant to supplement rather than replace the hands-on component.

ADAM BASICS

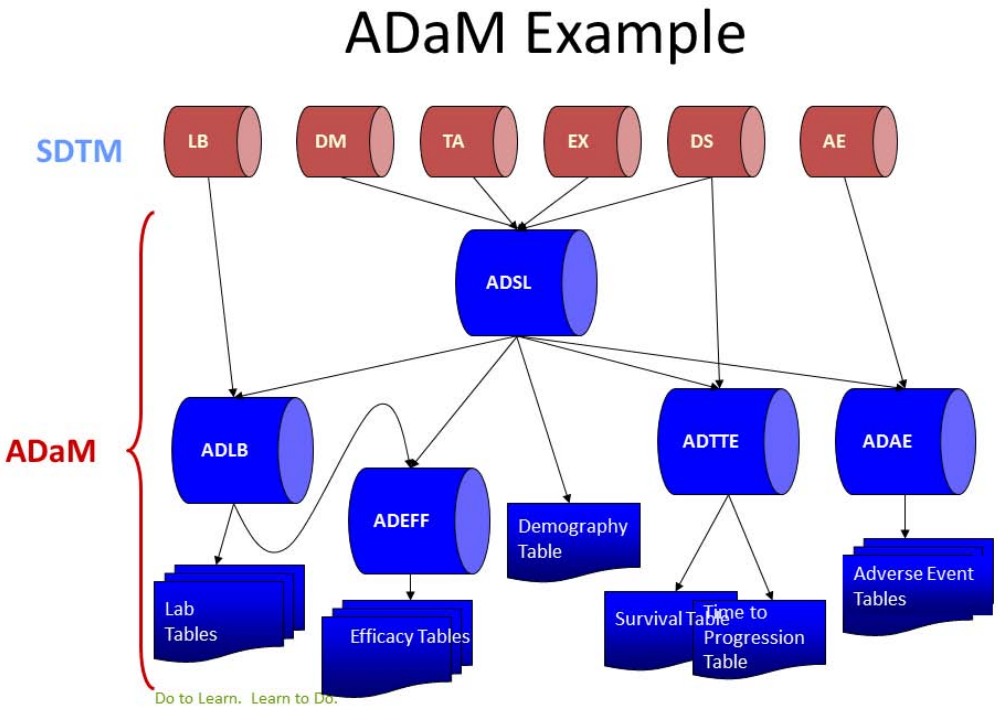
The following is an excerpt from the ADaM Implementation Guide Version 1.0, Section 4.2:

> "In the ADaM BDS, subjects, analysis parameters, and analysis timepoints define rows and are identified in standard columns. Subject, parameter and timepoint in combination may not be enough to serve as natural keys (unique record identifiers). There may be multiple rows within a given combination, depending on the number of observations collected or derived, baseline definition, etc.
>
> Standard columns exist for a variety of purposes, such as SDTM record identifiers for traceability, population and other record selection flags, analysis values, and some standard functions of analysis values. Permissible columns are not limited to those whose variable names are specified in Section 3, and may include study-specific analysis model covariates, subgrouping variables, variables supportive of traceability, and other variables needed for analysis or useful for review.
>
> However, there are some constraints on when derived data may be added as columns. Specifically, the subject of Section 4.2 is to address when functions of analysis values should be added as additional columns, and when they should be added as additional rows instead.
>
> The precise sequence of steps involved in creating a BDS analysis dataset varies according to operational and study-specific needs. For the purposes of this discussion, it is useful to think of two initial steps.
>
> The first step is to create a set of rows and columns more or less directly derived from or loaded from input SDTM domains into their appropriate places. This step may include creation of analysis parameters (PARAM etc.), analysis timepoint (AVISIT etc.) and analysis variables (AVAL and AVALC). It would also include addition of identifiers (STUDYID, SITEID, USUBJID, SUBJID) and other SDTM variables for traceability (VISIT, --SEQ, etc.).
>
> The second step consists of further derivation of additional rows and columns based on this precursor set of analysis dataset records and columns. It is this second step that is addressed in Section 4.2.
>
> To be specific, derived rows and columns are defined in Section 4.2 to be rows and columns that are created based on data already present in the analysis dataset, as opposed to data that are (1) copied or derived directly from SDTM; or (2) copied or derived directly from other analysis datasets or metadata. This section only addresses the creation of columns and rows to accommodate such internally-derived data.

This section discusses the ADaM rules that govern when such internal derivation of data should result in creation of columns, and when it should result in creation of rows. These rules are an essential part of the definition of the BDS."

ADAM IN THE CLINICAL PROCESS

The ADaM role in the clinical analysis process includes the production of both analysis datasets and reports, as shown in the diagram below:



The purpose of each ADaM Dataset is to provide what is needed to produce desired results. Recommended steps for ADaM dataset production are:

- Create results metadata (specs)
- Create analysis dataset and parameter metadata (specs)
- Create analysis data
- Create analysis results

KEY PRINCIPLES OF ADAM

Traceable

- Provide clear and unambiguous communication of science and statistics
- Think like a reviewer: Follow the trail backward from
  Result -> Analysis Dataset -> Tabulation Dataset -> (e)CRF.
  Did you do what the SAP said you'd do? If not, do you explain why?

Analyzable

- Formerly known as "one proc away"
- Separates data derivations from statistical procedure
  1. Create dataset
  2. Use dataset to derive analysis results
- Reduces programming required to (re)generate results, could be done by someone with limited programming knowledge

Useable

- Vendor-neutral tools, such as SAS, S+, JMP, Excel, etc.
- Currently this means SAS v5 transport files, a simple 2-dimensional structure
- Next: potentially XML, with more than 2-dimensions allowed

Readable

- Metadata provides additional information not available from the data itself, such as transformations, imputations and other derivations; statistical methods used; assumptions made
- Humans for now, machines in future, enormous potential for tool development

BASIC RULES FOR CREATING DATA

- Name analysis datasets as ADXxxxxx. For example ADSL, ADTTE, ADLB, etc.
- Create ADaM datasets with specific analysis results in mind.
- Only create data you need. Not all SDTM data needs to be included in an analysis dataset
- Use SDTM Conventions for naming variables and variable fragments.
- Copy variables from SDTM as needed.
- Add "N" suffix to name when creating a numeric version of a character SDTM variable
- Same name / same label / same attributes. When copying an SDTM variable, ALL attributes must remain unchanged. If anything is not the same, create a new variable.

ADSL BASICS

- ADSL = Subject-Level Analysis Dataset
- 1-record per Subject
- Source: SDTM
- Content: Basic subject-level information.
- The method to get basic subject-level information added to any other dataset
- Useful for generating table denominators
- Demography and Disposition results can usually be derived directly from ADSL

BASIC DATA STRUCTURE (BDS)

The BDS structure is one record per subject per analysis parameter (per timepoint, as needed). Because it is a flexible structure, it allows most analyses to be performed. Additionally, the vertical structure provides traceability back to predecessor datasets, such as SDTM.

BDS datasets can contain

- Observed, derived and imputed data
- Data from SDTM and/or other ADaM datasets
- Data copied from ADSL
- Analysis timing variables
- Analysis parameters
- Analysis indicators
- Covariates and sub-setting flags
- Data point traceability

BDS COLUMNS VS. ROWS

The ADaM IG section 4.2 describes a set of rules for when we are to create columns vs. rows in a BDS structured dataset:

Rule 1. A parameter-invariant function of AVAL and BASE on the same row that does not involve a transform of BASE should be added as a new column.

Rule 2. A transformation of AVAL that does not meet the conditions of Rule 1 should be added as a new parameter, and AVAL should contain the transformed value

Rule 3. A function of one or more rows within the same parameter for the purpose of creating an analysis timepoint should be added as a new row for the same parameter.

Rule 4. A function of multiple rows within a parameter should be added as a new parameter.

Rule 5. A function of more than one parameter should be added as a new parameter

Rule 6. When there is more than one definition of baseline, each additional definition of baseline requires the creation of its own set of rows.

EXAMPLE 1

Consider the following SDTM (partial) data set.

STUDYID	DOMAIN	USUBJID	VSTESTCD	VISIT	VSSTRESN	VSSTRESU
BP3304	VS	BP3304-A01	DIABP	Screening	80	mmHg
BP3304	VS	BP3304-A01	DIABP	Visit 1	79	mmHg
BP3304	VS	BP3304-A01	DIABP	Visit 1	78	mmHg
BP3304	VS	BP3304-A01	DIABP	Visit 1	79	mmHg
BP3304	VS	BP3304-A01	DIABP	visits	XX	mmHg
BP3304	VS	BP3304-A01	DIABP	Follow-Up	110	mmHg

And imagine we already have constructed ADSL (partial view). Appendix I contains then variable metadata corresponding to the ADaM variables used in the examples.

USUBJID	MITTFL	ARMCD	TRT01P	TRTSDT	TRTEDT	HYPDUR	HYPDURC
BP3304-A01	Y	A	100 MG BP3304	6/30/2009	1/11/2010	11.76	> 10 years

Suppose that change from baseline analysis is required as specified in the following mock table.

14.2.1.1 Diastolic Blood Pressure
Modified Intent-to-Treat Population

	BP3304 (N = xx)		Placebo (N = xx)	
	Observed	Change from Baseline	Observed	Change from Baseline
Baseline				
N	XX		XX	
Mean (SD)	XXX.XX (XX.XXX)		XXX.XX (XX.XXX)	
Median	XXX.XX		XXX.XX	
Min, Max	XXX.XX, XXX.XX		XXX.XX, XXX.XX	
Week 4				
N	XX	XX	XX	XX
Mean (SD)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)	XXX.XX (XX.XXX)
Median	XXX.XX	XXX.XX	XXX.XX	XXX.XX
Min, Max	XXX.XX, XXX.XX	XXX.XX, XXX.XX	XXX.XX, XXX.XX	XXX.XX, XXX.XX
LS Mean (SE)		XX.X (XX.XXX)		XX.X (XX.XXX)
95% CI for LS Mean		(XX.X, XX.X)		(XX.X, XX.X)
p-value				X.XXXX
95% CI for LS Mean Difference				(XX.X, XX.X)

Reference: Listing 16.2.6.2
Note: Baseline is defined as the last value collected before the first dose of study drug. Least squares means, standard errors, and confidence intervals come from a last observation carried forward (LOCF) analysis using an analysis of covariance (ANCOVA) model with fixed effects for treatment and baseline therapy strata and a covariate for baseline blood pressure. SD = Standard Deviation, Min = Minimum, Max = Maximum LS = Least Squares, SE = Standard Error, CI = Confidence Interval.

A partial view of the ADVS ADaM dataset to perform this analysis could look like:

	USUBJID	MITTFL	AVISIT	PARAMCD	AVAL	BASE	CHG	DTYPE
1	BP3304-A01	Y	Pre	DBP	79			
2	BP3304-A01	Y	Pre	DBP	78			
3	BP3304-A01	Y	Pre	DBP	79			
4	BP3304-A01	Y	Baseline	DBP	78.667	78.667	0	AVERAGE
5	BP3304-A01	Y	Week 4	DBP	76	78.667	-2.667	
6	BP3304-A01	Y	Follow-Up	DBP	110	78.667	31.333	
7	BP3304-A01	Y	End of Study	DBP	110	78.667	31.333	LOCF

	USUBJID	ADT	ABLFL	ANL01FL	ASEQ
1	BP3304-A01	6/30/2009		N	1
2	BP3304-A01	6/30/2009		N	2
3	BP3304-A01	6/30/2009		N	3
4	BP3304-A01	6/30/2009	Y	Y	4
5	BP3304-A01	7/28/2009		Y	5
6	BP3304-A01	12/15/2009		Y	6
7	BP3304-A01	12/15/2009		Y	7

Notice the application of two of the rules:

- Column CHG, the change of baseline, applies rule 1
- Baseline computation (average of 3 records) and for End of Study (LOCF) analyses applies rule 3

EXAMPLE 2

Now suppose the required analysis is a bit different.

14.2.5.1 Time to Achievement of Diastolic Blood Pressure ≤ 90 mmHg
Modified Intent-to-Treat Population

	BP3304 (N=xx) n (%)	Placebo (N=xx) n (%)
N	XX	XX
No. with DBP ≤ 90 mmHg	XX (XX.X)	XX (XX.X)
No. of Censored	XX (XX.X)	XX (XX.X)
Time to DBP ≤ 90 mmHg (Weeks)		
Median	XX.XX	XX.XX
95% CI of Median	(XX.XX, XX.XX)	(XX.XX, XX.XX)
25-75%ile	XX.XX – XX.XX	XX.XX – XX.XX
Min, Max	XX.X, XX.X+	XX.X, XX.X+

Reference: Listing 16.2.6.2

Note: Time to diastolic blood pressure ≤ 90 mmHg is calculated using Kaplan-Meier methods. 95% CI for median is computed using Brookmeyer and Crowley's method.

+ = censored value, C.I. = Confidence interval, DBP = diastolic blood pressure.

The corresponding ADaM data set may look like:

	USUBJID	TRTP	ADT	PARAM	PARAMCD	**AVAL**	STARTDT
1	BP3304-A01	100 MG BP3304	7/28/2009	First DBP < 90 mmHg	DBP90	4.14	6/30/2009
2	BP3304-A01	100 MG BP3304	12/15/2009	Last DBP Collected	LASTDBP	24.14	6/30/2009
3	BP3304-A01	100 MG BP3304	7/28/2009	Weeks to DBP<=90	TTE	4.14	

	USUBJID	MITTFL	CNSR	EVNTDESC	DTYPE	SRCDOM	SRCVAR	SRCSEQ
1	BP3304-A01	Y		DBP <=90 reached		ADVS	ADT	5
2	BP3304-A01	Y		Censored at last DBP		ADVS	ADT	6
3	BP3304-A01	Y	0	DBP <=90 reached	TTE			

In this case all patients have a last DBP assessment, in other words, a record for parameter LASTDBP. Those who have reached DBP < 90 will also have parameter DBP90 populated with the earliest occurrence. The TTE row is computed using rule 5: selecting the time of parameter DBP90 if available (this constitutes an event), or selecting the parameter LASTDBP (this constitutes a censored observation). The actual analysis is done using the parameter code TTE.

CONCLUSION

The rules listed in ADaMIG section 4.2 and repeated here in this paper help us make the determination of when to add rows and when to add columns. Because much of the time we need to create new rows, we can use variables such as DTYPE to provide information about how each row was derived. For those used to working with a more horizontal dataset and adding columns, it can be a little intimidating to instead have to add rows. The rules and examples in section 4 of the ADaMIG, the examples in this paper, and the exercises in the Hands-On Workshop corresponding to this paper can all be of help when adding rows.

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APPENDIX I – ADAM METADATA

	Variable Name	Variable Label	Variable Type	Display Format	Codelist / Controlled Terms	Source / Derivation
ADSL	STUDYID	Study Identifier	char			DM.STUDYID
ADSL	USUBJID	Unique Subject Identifier	char			DM.USUBJID
ADSL	SUBJID	Subject Identifier for the Study	char			DM.SUBJID
ADSL	SITEID	Study Site Identifier	char			DM.SITEID
ADSL	COUNTRY	Country	char			DM.COUNTRY
ADSL	AGE	Age	num			DM.AGE
ADSL	AGEU	Age Units	char		(AGEU)	DM.AGEU
ADSL	AGEGR1	Age Group 1	char			Set to 'Y' if age > 65
ADSL	SEX	Sex	char		(SEX)	DM.SEX
ADSL	ETHNIC	Ethnicity	char		(ETHNIC)	DM. ETHNIC
ADSL	RACE	Race	char		(RACE)	DM.RACE
ADSL	ENRLFL	Enrolled Population Flag	Char		Y,N	Has signed informed consent (Subject has a record where DSDECOD = 'INFORMED CONSENT OBTAINED')
ADSL	RANDFL	Randomized Population Flag	Char		Y,N	Has been randomized (Subject has a record where DSDECOD='RANDOMIZED')
ADSL	SAFFL	Safety Population Flag	char		Y,N	Set to 'Y' if patient had at least one dose of Study medication: (At least one record with EX.EXDOSTOT >. then 'Y'; else 'N'.)
ADSL	PPROTFL	Per-Protocol Population Flag	char		Y,N	Set to 'Y' if patient had at least 112 doses (80% of planned) of study medication, 'N' otherwise. If count of occurrences of EX.EXDOSTOT > 0 is at least112 then 'Y'; else 'N'.
ADSL	MITTFL	Modified Intent-To-Treat Population Flag	char		Y,N	Set to 'Y' if patient is in the safety population and had baseline and at least one post-baseline diastolic pressure measurement. For non-missing VS.VSORRES where VS.TESTCD='DIABP' patient has VSBLFL='Y' and another record with VS.VSDTC > TRTSTDT
ADSL	COMPTRFL	Completer Treatment Flag	char		Y,N	Set to 'Y' if DS.EPOCH='TREATMENT PHASE' and DS.DSDECOD='COMPLETED'; else set to 'N'
ADSL	COMPFUFL	Completer Follow-up Flag	char		Y,N	Set to 'Y' if DS.EPOCH='FOLLOW-UP' and DS.DSDECOD='COMPLETED'; else set to 'N'
ADSL	ARMCD	Planned Arm Code	char		A,B	DM.ARM

	Variable Name	Variable Label	Variable Type	Display Format	Codelist / Controlled Terms	Source / Derivation
ADSL	ARM	Description of Planned Arm	char		A,B	DM.ARM
ADSL	TRT01P	Planned Treatment for Period 1	char		100 MG BP3304, PLACEBO	Set to ARM
ADSL	TRT01PN	Planned Treatment for Period 1 (N)	num		1,2	Set to 1 if TRT01P='100 MG BP3304', set to 2 if TRT01P='PLACEBO'
ADSL	RANDDT	Date of Randomization	num	DATE9.		INPUT(DS.DSDTC, YYMMDD10.) where DS.DSDECOD='RANDOMIZED'
ADSL	TRTSDT	Date of First Exposure to Treatment	num	DATE9.		Set to the numeric version of smallest non-missing EX.EXSTDTC when EXDOSTOT>0.
ADSL	TRTSDTF	Date of First Exposure Imput. Flag	char		M, D,Y	No imputation. Always blank
ADSL	TRTEDT	Date of Last Exposure to Treatment	num	DATE9.		Set to the datepart of numeric version of largest non-missing EX.EXENDTC when EXDOSTOT>0. Imputation rules?.
ADSL	TRTEDTF	Date of Last Exposure Imput. Flag	char		M, D,Y	No imputation. Always blank
ADSL	HEIGHT	Height (cm)	num			Set to VS.VSSTRESN where VS.VSBLFL='Y' and VS.VSTEST="HEIGHT"
ADSL	WEIGHT	Weight (kg)	num			Set to VS.VSSTRESN where VS.VSBLFL='Y' and VS.VSTEST="WEIGHT"
ADSL	BMI	Body mass index	num			Set to WEIGHT / [(HEIGHT/100)**2]
ADSL	NMITBS	Not Baseline DIABP	char			Set to 'Y' when there is No Baseline DIABP
ADSL	NMITPBS	Not Post-Baseline DIABP	char			Set to 'Y' when there is No Post-Baseline DIABP
ADSL	NMITSAF	Not in Safety Population	char			Set to 'Y' when SAFFL ne 'Y' .
ADSL	NPPRMIT	Not in MITT Population	char			Set to 'Y' when MITTFL is not 'Y'
ADSL	NPPRDOS	Received <80% of Sched Doses	char			Set to 'Y' when number of doses is < 112. Count number of days under exposure as then sum of all EX.EXSTDTC to EXENDTC per subject.
ADSL	NPPRVIOL	Mayor Protocol Violation	char			Set to 'Y' when DS.DSCAT='DISPOSITION EVENT' and DS.DSDECOD ='PROTOCOL VIOLATION' while DS.EPOCH='Treatment'
ADSL	DISCREAS	Reason for discontinuation	char			Set to DS.DSDECOD when DS.DSCAT='DISPOSITION EVENT'
ADSL	NRNDREAS	Reason for not Randomized	char			Set to DS.DSDECOD when DS.DSCAT='DISPOSITION EVENT' and the subject does not have any record where DS.DSDECOD='RANDOMIZED'
ADSL	BLTHSTR	Baseline Therapy Strata	num		1,2	When SC.SCTESTCD='STRATUM' then set to 1 if SC.SCSTRESC='STRATUM 1'; Set to 2 if SC.SCSTRESC='STRATUM 2'
ADSL	ALCHIST	Alcohol History	char			Set to SC.SCSTRESC when SC.SCTESTCD='ALCOHOL'.
ADSL	TOBHIST	Tobacco History	char			Set to SC.SCSTRESC when SC.SCTESTCD='TOBACCO'.

	Variable Name	Variable Label	Variable Type	Display Format	Codelist / Controlled Terms	Source / Derivation
ADSL	HYPDUR	Duration of Hypertension (years)	char			Set to the numeric value of the duration from SC.SCSTRESC when SC.SCTESTCD = 'HYPERTENSIVE' and DS.DSSTDTC when DS.DSDECOD = 'INFORMED CONSENT OBTAINED'
ADSL	HYPDURC	Duration of Hypertension Category	char			Set to '<10 years' if HYPDUR <= 10, set to '>10 years' if HYPDUR >10
ADVS						
ADVS	STUDYID	Study ID	Text	$8.		VS.STUDYID
ADVS	USUBJID	Unique Subject Identifier	Text	$15.		VS.USUBJID
ADVS	SITEID	Study Site Identifier	Text	$10.		VS.SITEID
ADVS	TRTP	Planned Treatment	Text	$15.	100 MG BP3304, PLACEBO	If VS.VSSTDTC is between ADSL.TRTSDT and ADSL.TRTEDT then assign to ADSL.TRT01P, else missing.
ADVS	TRTPN	Planned Treatment (N)	Integer	1.0	1, 2	Set to 2 if TRTP='PLACEBO'; set to 1 if TRTP='100 MG BP3304'
ADVS	MITTFL	Modified Intent-To-Treat Population Flag	Text	$1.	Y,N	ADSL.MITTFL
ADVS	ADT	Date of VItals Result	Integer	DATE9.		Set to numeric version of VS.VSDTC when AVISIT comes from VS.VISIT; when AVISIT='END OF STUDY', set to the date of the last visit with a non-missing AVAL for PARAM
ADVS	ADY	Relative Day of VItals Result	Integer	4.0		ADT - TRTSDT + 1
ADVS	AVISIT	Analysis Visit	Text	$15.	Baseline, WEEK 4, WEEK 8, WEEK 12, WEEK 16, WEEK 20, WEEK 24, End of Study	Map based on visit windows in Section 3 of SAP using ADY. Set to 'Baseline' and 'End of Study' for corresponding added visit as described in parameter-level metadata
ADVS	AVISITN	Analysis Timepoint Number	Integer	1.0	1, 2, 3, 4, 5, 6, 7, 8	1=Baseline, 2=Week 4, 3=Week 8, 4=Week 12, 5=Week 16, 6=Week 20, 7=Week 24, 8=End of Study
ADVS	PARAM	Parameter Description	Text	$40.		Derive by concatenating VS.VSTEST, VS.VSSTRESU for the VS.VSTEST in ('SYSBP' 'DIABP').
ADVS	PARAMCD	Parameter Code	Text	$8.		VS.VSTESTCD for the VS.VSTEST in ('SYSBP' 'DIABP').
ADVS	AVAL	Analysis Value	Float			Set to VS.VSSTRESN

	Variable Name	Variable Label	Variable Type	Display Format	Codelist / Controlled Terms	Source / Derivation
ADVS	BASE	Baseline Value	Float			For numeric tests only: AVAL where ABLFL='Y'
ADVS	CHG	Change from Baseline	Float			For numeric tests: AVAL-BASE
ADVS	CRIT1	Analysis Criterion 1	Text	20		See parameter-level metadata.
ADVS	CRIT1FL	Criterion 1 Evaluation Result Flag	Text	$1.	Y	See parameter-level metadata.
ADVS	DTYPE	Derivation Type	Text	$10.	LOCF, missing	Blank for records coming from SDTM. Set to 'LOCF' for LOCF values, as described in the parameter-level metadata.
ADVS	ABLFL	Baseline Record Flag	Text	$1.	Y,N	Set to 'Y' for last row with non-missing AVAL prior to TRTSTDT
ADVS	ANL01FL	Analyzed Record Flag 1	Text	$1.	Y,N	Set to 'Y' for post-baseline rows with a non-missing AVAL
ADVS	ONTRTFL	On Treatment Record Flag	Text	$1.	Y,N	If VS.VSDTC is between TRTSDT and TRTEDT then set to 'Y', otherwise missing
ADVS	ONTRTFN	On Treatment Numeric Indicator	Integer	1.0	0,1	Set to 1 when ONTRTFL is 'Y'; set to 0 when ONTRTFL is either 'N' or missing
ADVS	BLTHSTR	Baseline Therapy Strata	Integer	1.0	1, 2	ADSL.BLTHSTR
ADVS	VSSEQ	Sequence Number	Num			VS.VSSEQ
ADVS	ASEQ	Analysis Sequence Number	Num			Add sequence number starting at 1 for each new subject
ADVST						
ADVST	STUDYID	Study ID	Text	$8.		ADVS.STUDYID
ADVST	USUBJID	Unique Subject Identifier	Text	$15.		ADVS.USUBJID
ADVST	SITEID	Study Site Identifier	Text	$10.		ADVS.SITEID
ADVST	TRTP	Planned Treatment	Text	$15.	100 MG BP3304, PLACEBO	ADVS.TRTP
ADVST	TRTPN	Planned Treatment (N)	Integer	1.0	1, 2	ADVS.TRTPN
ADVST	MITTFL	Modified Intent-To-Treat Population Flag	Text	$1.	Y,N	ADVS.MITTFL
ADVST	PPROTFL	Per-Protocol Population Flag	char		Y,N	ADSL.PPROTFL
ADVST	PARAM	Parameter Description	Text	$40.		See SAP and parameter-level metadata for numeric and categorical definitions
ADVST	PARAMCD	Parameter Code	Text	$8.		See SAP and parameter-level metadata for numeric and categorical definitions
ADVST	AVAL	Analysis Value	Float			(ADT - STARTDT + 1)/7

	Variable Name	Variable Label	Variable Type	Display Format	Codelist / Controlled Terms	Source / Derivation
ADVST	STARTDT	Time to Event Origin/Date	Integer	DATE9.		ADVS.RANDDT
ADVST	ADT	Analysis Date	Integer	DATE9.		ADVS.ADT
ADVST	CNSR	Censoring Indicator	Integer	1.0	0,1	See SAP and parameter-level metadata for numeric and categorical definitions
ADVST	EVNTDESC	Event or Censoring Description	Text			See SAP and parameter-level metadata for numeric and categorical definitions
ADVST	CRIT1	Analysis Criterion 1	Text	20		ADVS.CRIT1
ADVST	CRIT1FL	Criterion 1 Evaluation Result Flag	Text	$1.	Y	ADVS.CRIT1FL
ADVST	PARAMTYP	Parameter Type	Text	$10.	DERIVED, missing	See parameter-level metadata.
ADVST	SRCDOM	Source Domain	Text	$8.	ADVS	Set to 'ADVS'
ADVST	SRCVAR	Source Variable	Text	$8.	ADT	Set to 'ADT'
ADVST	SRCSEQ	Source Sequence Number	Integer		ASEQ	Set to ADVS.ASEQ