Insights into ADaM Implementation Guide V1.0

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ADaM Agenda

- What is ADaM IG 1.0
- Our Process
- ADSL Implementation
- Using ADSL for Tables
- Basic Data Structure (BDS) Implementation
- Using BDS for Tables
- Future

What is ADaM and the Implementation Guide 1.0

- ADaM = Analysis Dataset Model
- Driving principle is that the design of analysis datasets/metadata provide clear communication of the purpose of the datasets
- ADaM supports the efficient creation and review of analysis datasets
- Builds on the nomenclature of SDTM

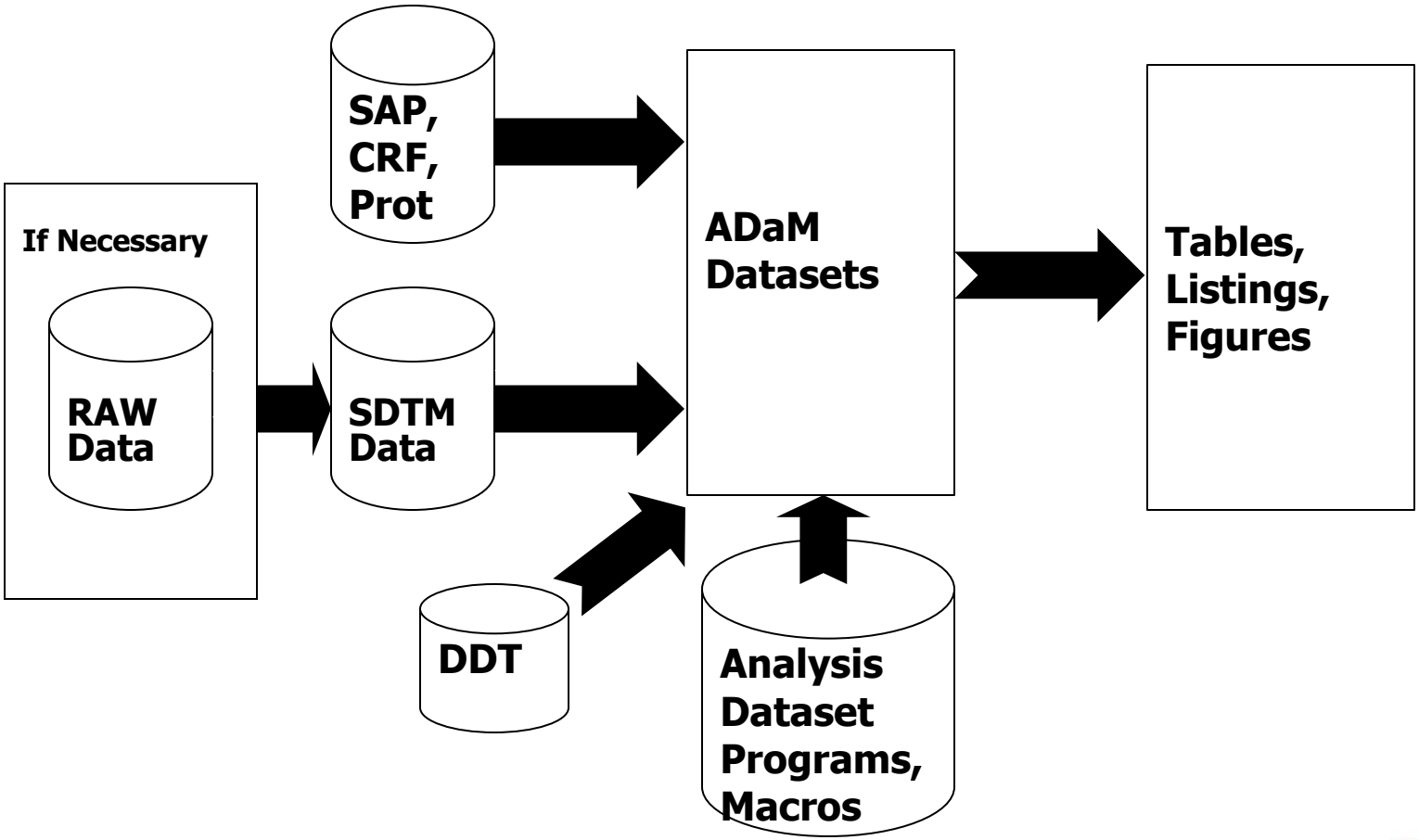
  + attributes

  + variables

  + data structures

  For statistical analysis
- ADaM IG 1.0
  - Describes two standard data structures: the subject-level analysis dataset and the basic data structure
  - ADSL (subject-level dataset) is one record per subject
  - BDS (basic data structure) is one or more records per subject, per analysis parameter, per timepoint

Our Process



ADSL

- One record per subject
- Provides the variables that describe a subject
- Variables such as population flags, treatment variables, demographic information, sub-grouping, important dates, etc.
- Allows for simple combining with any other dataset (SDTM and/or analysis datasets)
- Required in a CDISC-based submission even if no other analysis datasets are submitted

An Example RAW Dataset

	STUDYID	DOMAIN	USUBJID	SUBJID	RFSTDTC	RFENDTC	SITEID	BRTHDTC	AGE	AGEU	SEX	RACE	ARMCD	ARM	COUNTRY
1	ACP-103-0	DM	001001	001001	2008-03-0	2008-04-1	001	1940-01-0	68	YEARS	M	WHITE			USA
2	ACP-103-0	DM	001002	001002	2008-12-1	2009-02-0	001	1937-07-2	71	YEARS	M	WHITE			USA
3	ACP-103-0	DM	001004	001004	2009-03-2	2009-05-0	001	1940-05-2	68	YEARS	M	HISPANIC			USA
4	ACP-103-0	DM	001005	001005	2009-03-2	2009-04-2	001	1942-05-0	66	YEARS	F	WHITE			USA
5	ACP-103-0	DM	002001	002001	2007-06-1	2007-07-2	002	1935-01-2	72	YEARS	M	WHITE			USA
6	ACP-103-0	DM	003001	003001	2007-08-3	2007-09-2	003	1949-07-2	58	YEARS	F	WHITE			USA
7	ACP-103-0	DM	003002	003002	2008-02-1	2008-04-0	003	1929-08-0	78	YEARS	F	WHITE			USA
8	ACP-103-0	DM	003003	003003	2008-11-2	2008-12-2	003	1937-06-1	71	YEARS	F	WHITE			USA
9	ACP-103-0	DM	003006	003006	2009-02-1	2009-03-2	003	1941-06-2	67	YEARS	F	WHITE			USA
10	ACP-103-0	DM	004002	004002	2008-03-1	2008-03-2	004	1921-03-0	86	YEARS	M	WHITE			USA
11	ACP-103-0	DM	004005	004005	2009-04-2	2009-06-0	004	1940-10-1	68	YEARS	M	WHITE			USA
12	ACP-103-0	DM	005002	005002	2008-02-0	2008-03-1	005	1932-08-0	75	YEARS	M	WHITE			USA
13	ACP-103-0	DM	005003	005003	2008-03-3	2008-05-1	005	1953-08-1	54	YEARS	M	ASIAN			USA
14	ACP-103-0	DM	005005	005005	2008-06-1	2008-07-2	005	1946-08-3	61	YEARS	M	WHITE			USA
15	ACP-103-0	DM	005007	005007	2009-04-2	2009-06-1	005	1948-07-1	60	YEARS	M	WHITE			USA
16	ACP-103-0	DM	006001	006001	2007-12-0	2007-12-0	006	1928-08-0	79	YEARS	M	ASIAN			USA
17	ACP-103-0	DM	006003	006003	2008-06-2	2008-06-2	006	1928-11-0	79	YEARS	M	WHITE			USA
18	ACP-103-0	DM	008002	008002	2007-08-0	2007-09-1	008	1940-07-0	67	YEARS	F	WHITE			USA
19	ACP-103-0	DM	008004	008004	2007-09-1	2007-10-2	008	1941-11-2	65	YEARS	F	HISPANIC			USA
20	ACP-103-0	DM	008006	008006	2008-01-2	2008-03-0	008	1924-08-1	83	YEARS	F	WHITE			USA
21	ACP-103-0	DM	008007	008007	2008-03-1	2008-04-1	008	1935-05-0	72	YEARS	M	WHITE			USA
22	ACP-103-0	DM	008008	008008	2008-03-2	2008-04-3	008	1934-12-0	73	YEARS	F	WHITE			USA
23	ACP-103-0	DM	008009	008009	2008-08-2	2008-10-0	008	1928-09-3	79	YEARS	F	WHITE			USA
24	ACP-103-0	DM	008010	008010	2009-04-0	2009-05-2	008	1938-08-2	70	YEARS	M	WHITE			USA
25	ACP-103-0	DM	008012	008012	2009-04-2	2009-06-0	008	1942-05-1	66	YEARS	F	WHITE			USA

Implementing ADSL

• We use the SDTM data to create a mapping document with the traceability/derivation information

Variable Name	Variable Label	Type	Codelist	Core	Traceability/ Derivation
STUDYID	Study Identifier	Char		Required	DM.STUDYID
USUBJID	Unique Subject Identifier	Char		Required	DM.USUBJID
SUBJID	Subject Identifier for the Study	Char		Required	DM.SUBJID
SITEID	Study Site Identifier	Char		Required	DM.SITEID
AGE	Age	Num		Required	DM.AGE
AGEU	Age Units	Char	(AGEU)	Required	DM.AGEU
SEX	Sex	Char	(SEX)	Required	DM.SEX
RACE	Race	Char	(RACE)	Required	DM.RACE
ARM	Description of Planned Arm	Char		Required	DM.ARM
TRT01P	Planned Treatment for Period 1	Char		Required	DM.ARM

Using ADSL for Tables

	Statistic	Placebo	Phenergan 12.5mg	Phenergan 25mg
Age (years)	n mean standard deviation median min max	xx xx.x xx.xx xx.x xx xx		
Age Category <65 65-75 >75	n	xx		
Sex Male Female	n	 xx xx		
Race White Hispanic Asian	n	 xx xx xx		
Race Category White Non-White	n	 xx xx		

Implementation

- During review of the table, we see the following variables will need to be added to ADSL:
  - AGEGR1N – categorization of the age into ranges
  - SEXGR1N – to order the sex in the output (Male, Female)
  - RACEGR1N – to order the race in the output (White, Hispanic, Asian)
  - RACEGR2N – to collapse races into White, Non-White groups

Variable Name	Variable Label	Type	Codelist	Core	Traceability/ Derivation
STUDYID	Study Identifier	Char		Required	DM.STUDYID
…					
AGE	Age	Num		Required	DM.AGE
AGEU	Age Units	Char	(AGEU)	Required	DM.AGEU
AGEGR1N	**Age Category - Numeric**	**Num**	**1 = <65, 2 = 65 – 74, 3 = >-75**	**Permissible**	**Derived: agegr1n = (.<age<65)*1 + (65<=age<75)*2 + (age>=75)*3**
SEX	Sex	Char	(SEX)	Required	DM.SEX
SEXGR1N	**Sex Category**	**Num**	**1 = MALE, 2 = FEMALE**	**Permissible**	**Derived: sexgr1n = (sex='M')*1 + (sex='F')*2**
RACE	Race	Char	(RACE)	Required	DM.RACE
RACEGR1N	**Race Category**	**Num**	**1 = WHITE, 2 = HISPANIC, 3 = ASIAN**	**Permissible**	**Derived: racegr1n = (race='WHITE')*1 + (race='HISPANIC')*2 + (race='ASIAN')*3**
RACEGR2N	**Race Category Pooled**	**Num**	**1 = White, 2 = Non-White**	**Permissible**	**Derived: if RACE='WHITE' then RACEGR2N=1; else RACEGR2N=2**
ARM	Description of Planned Arm	Char		Required	DM.ARM
TRT01P	Planned Treatment for Period 1	Char		Required	DM.ARM

Table Program

```
%*** Get stats for age;
proc sort data=adam.adsl out=adsl;
  by usubjid;

proc summary data=adsl;
  class trt01pn;
  var age;
  output out=stat1(where=(_type_=1)) n=n1 mean=mean1 std=std1 median=med1 min=min1 max=max1;
run;

proc transpose data=stat1 out=tran1 prefix=trt;
  id trt01pn;
  var n1 mean1 std1 med1 min1 max1;
run;
```

Table Program (cont.)

```
%*** Summarize age category;
proc summary data=adsl;
  class trt01pn agegr1n;
  var age;
  output out=stat2(where=(_type_=3)) n=n2;
run;

proc sort data=stat2;
  by agegr1n;

proc transpose data=stat2 out=tran2 prefix=trt;
  by agegr1n;
  id trt01pn;
  var n2;
run;

...for sexgr1n, racegr1n, racegr2n
```

BDS – Basic Data Structure

- Contains one or more records per subject, per analysis parameter, per analysis timepoint
- Analysis timepoint is conditionally required depending on the analysis
- Contains a central set of variables of data being analyzed
  - Value being analyzed (e.g. AVAL)
  - Description of the value being analyzed (e.g. PARAM)
- ADaM dataset structures do NOT have counterparts in SDTM (e.g. Findings Domain)
- A record in the BDS structure can represent an observed, derived or imputed value
- BDS is flexible in that additional rows and columns can be added to support the analysis and/or provide traceability
- Typically, there are multiple BDS datasets in a study.

Example RAW Dataset

	STUDYID	DOMAIN	USUBJID	VSSEQ	VSTESTCD	VSTEST	VSCAT	VSPOS	VSORRES	VSORRESU	VSSTRESC	VSSTRESN	VSSTRESU	VSSTAT	VSLOC	VSBLFL	VSDRVFL	VISIT	VISITNUM	VSDTC
1	ACP-103-0	VS	001001	1	TEMP	Oral Temp			97.6	° F	36.44	36.44	C		Right		Y	Screening	1	2008-03-0
2	ACP-103-0	VS	001001	2	RESP	Respirati			16	breaths p	16	16	breaths p		Right			Screening	1	2008-03-0
3	ACP-103-0	VS	001001	3	SYSBP	Systolic	1 Minute	STANDING	110	mmHg	110	110	mmHg		Right			Screening	1	2008-03-0
4	ACP-103-0	VS	001001	4	DIABP	Diastolic	1 Minute	STANDING	74	mmHg	74	74	mmHg		Right			Screening	1	2008-03-0
5	ACP-103-0	VS	001001	5	PULSE	Pulse Rat	1 Minute	STANDING	68	beats per	68	68	beats per		Right			Screening	1	2008-03-0
6	ACP-103-0	VS	001001	6	SYSBP	Systolic	5 Minute	SUPINE	116	mmHg	116	116	mmHg		Right			Screening	1	2008-03-0
7	ACP-103-0	VS	001001	7	DIABP	Diastolic	5 Minute	SUPINE	76	mmHg	76	76	mmHg		Right			Screening	1	2008-03-0
8	ACP-103-0	VS	001001	8	PULSE	Pulse Rat	5 Minute	SUPINE	60	beats per	60	60	beats per		Right			Screening	1	2008-03-0
9	ACP-103-0	VS	001001	9	WT	Weight			167	lbs	75.75	75.75	kg		Right	Y	Y	Study Day	2	2008-03-0
10	ACP-103-0	VS	001001	10	HT	Height			69.5	in	176.53	176.53	cm		Right	Y	Y	Study Day	2	2008-03-0
11	ACP-103-0	VS	001001	11	TEMP	Oral Temp			97.6	° F	36.44	36.44	C		Right	Y	Y	Study Day	2	2008-03-0
12	ACP-103-0	VS	001001	12	RESP	Respirati			16	breaths p	16	16	breaths p		Right	Y		Study Day	2	2008-03-0
13	ACP-103-0	VS	001001	13	BMI	Body Mass			24.31		24.31	24.31			Right	Y	Y	Study Day	2	2008-03-0
14	ACP-103-0	VS	001001	14	SYSBP	Systolic	1 Minute	STANDING	110	mmHg	110	110	mmHg		Right	Y		Study Day	2	2008-03-0
15	ACP-103-0	VS	001001	15	DIABP	Diastolic	1 Minute	STANDING	74	mmHg	74	74	mmHg		Right	Y		Study Day	2	2008-03-0
16	ACP-103-0	VS	001001	16	PULSE	Pulse Rat	1 Minute	STANDING	74	beats per	74	74	beats per		Right	Y		Study Day	2	2008-03-0
17	ACP-103-0	VS	001001	17	SYSBP	Systolic	5 Minute	SUPINE	120	mmHg	120	120	mmHg		Right	Y		Study Day	2	2008-03-0
18	ACP-103-0	VS	001001	18	DIABP	Diastolic	5 Minute	SUPINE	76	mmHg	76	76	mmHg		Right	Y		Study Day	2	2008-03-0
19	ACP-103-0	VS	001001	19	PULSE	Pulse Rat	5 Minute	SUPINE	56	beats per	56	56	beats per		Right	Y		Study Day	2	2008-03-0
20	ACP-103-0	VS	001001	20	TEMP	Oral Temp			97.4	° F	36.33	36.33	C		Right		Y	Study Day	3	2008-03-1
21	ACP-103-0	VS	001001	21	RESP	Respirati			16	breaths p	16	16	breaths p		Right			Study Day	3	2008-03-1
22	ACP-103-0	VS	001001	22	SYSBP	Systolic	1 Minute	STANDING	98	mmHg	98	98	mmHg		Right			Study Day	3	2008-03-1
23	ACP-103-0	VS	001001	23	DIABP	Diastolic	1 Minute	STANDING	72	mmHg	72	72	mmHg		Right			Study Day	3	2008-03-1

Implementing BDS (Vital Sign Example)

•We use the SDTM data to create the mapping document traceability/derivation

Variable Name	Variable Label	Type	Codelist	Core	Traceability/ Derivation
STUDYID	Study Identifier	Char		Required	VS.STUDYID
USUBJID	Unique Subject Identifier	Char		Required	VS.USUBJID
TRTP	Planned Treatment	Char		Required	ADSL.TRT01P
PARAM	Parameter	Char		Required	VS.VSTEST
PARAMCD	Parameter Code	Char		Required	VS.VSTESTCD
AVAL	Analysis Value	Num		Required*	VS.VSSTRESC
AVALC	Analysis Value - Character	Char		Required*	VS.VSSTRESN

Using BDS for Tables

Vital Sign	Visit	Statistic	Placebo	Phenergan 12.5mg	Phenergan 25mg
Systolic Blood Pressure (Supine)	Screening Day 1 Day 8 Change from Baseline at Day 8	n mean standard deviation median min max (same stats)	xx xx.x xx.xx xx.x xx xx		
Diastolic Blood Pressure (Supine) [Do Respiratory last same stats]	Screening Day 1 Day 8 Change from Baseline at Day 8	n mean standard deviation median min max (same stats)	xx xx.x xx.xx xx.x xx xx		

Implementation

- By review of the table, the following variables will need to be added to the BDS for Vital Signs:
  - BASE – Baseline value (numeric)
  - CHG – Change from baseline (numeric)

Variable Name	Variable Label	Type	Codelist	Core	Traceability/ Derivation
STUDYID	Study Identifier	Char		Required	VS.STUDYID
USUBJID	Unique Subject Identifier	Char		Required	VS.USUBJID
TRTP	Planned Treatment	Char		Required	ADSL.TRT01P
PARAM	Parameter	Char		Required	VS.VSTEST
PARAMCD	Parameter Code	Char		Required	VS.VSTESTCD
AVAL	Analysis Value	Num		Required*	VS.VSSTRESC
AVALC	Analysis Value - Character	Char		Required*	VS.VSSTRESN
BASE	**Baseline Value**	**Num**		**Conditional**	**Derived: if visitn=2 then base=vsstresn**
CHG	**Change from Baseline**	**Num**		**Permissible**	**Derived: aval - base**

ADSL / Basic Data Structure – MORE!!

- There are a number of other variables described in the implementation guide for both the ADSL and BDS datasets
- Impossible to go over all metadata in 15 minutes…

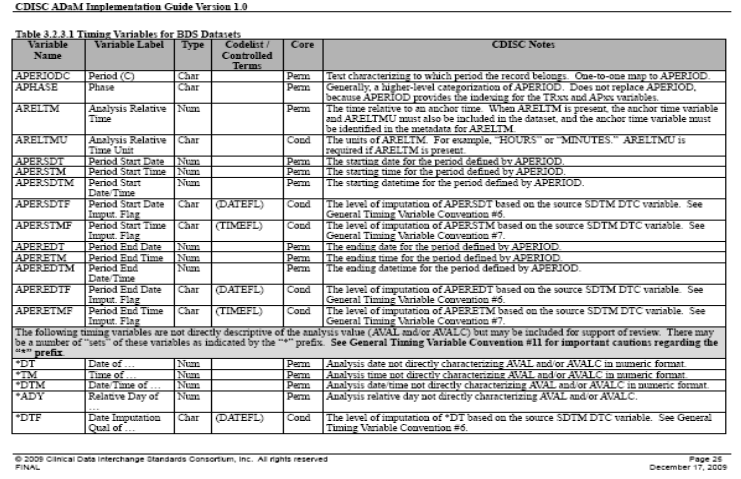


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Table 3.2.3.1 Timing Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
APERIODC	Period (C)	Char		Perm	Text characterizing to which period the record belongs. One-to-one map to APERIOD.
APHASE	Phase	Char		Perm	Generally, a higher-level categorization of APERIOD. Does not replace APERIOD, because APERIOD provides the indexing for the TRxx and APxx variables.
ARELTM	Analysis Relative Time	Num		Perm	The time relative to an anchor time. When ARELTM is present, the anchor time variable and ARELTMU must also be included in the dataset, and the anchor time variable must be identified in the metadata for ARELTM.
ARELTMU	Analysis Relative Time Unit	Char		Cond	The units of ARELTM. For example, "HOURS" or "MINUTES." ARELTMU is required if ARELTM is present.
APERSDT	Period Start Date	Num		Perm	The starting date for the period defined by APERIOD.
APERSTM	Period Start Time	Num		Perm	The starting time for the period defined by APERIOD.
APERSDTM	Period Start Date/Time	Num		Perm	The starting datetime for the period defined by APERIOD.
APERSDTF	Period Start Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of APERSDT based on the source SDTM DTC variable. See General Timing Variable Convention #6.
APERSTMF	Period Start Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of APERSTM based on the source SDTM DTC variable. See General Timing Variable Convention #7.
APEREDT	Period End Date	Num		Perm	The ending date for the period defined by APERIOD.
APERETM	Period End Time	Num		Perm	The ending time for the period defined by APERIOD.
APEREDTM	Period End Date/Time	Num		Perm	The ending datetime for the period defined by APERIOD.
APEREDTF	Period End Date Imput. Flag	Char	(DATEFL)	Cond	The level of imputation of APEREDT based on the source SDTM DTC variable. See General Timing Variable Convention #6.
APERETMF	Period End Time Imput. Flag	Char	(TIMEFL)	Cond	The level of imputation of APERETM based on the source SDTM DTC variable. See General Timing Variable Convention #7.
The following timing variables are not directly descriptive of the analysis value (AVAL and/or AVALC) but may be included for support of review. There may be a number of "sets" of these variables as indicated by the "*" prefix. **See General Timing Variable Convention #11 for important cautions regarding the "*" prefix.**					
*DT	Date of …	Num		Perm	Analysis date not directly characterizing AVAL and/or AVALC in numeric format.
*TM	Time of …	Num		Perm	Analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*DTM	Date/Time of …	Num		Perm	Analysis date/time not directly characterizing AVAL and/or AVALC in numeric format.
*ADY	Relative Day of …	Num		Perm	Analysis relative day not directly characterizing AVAL and/or AVALC.
*DTF	Date Imputation Qual of …	Char	(DATEFL)	Cond	The level of imputation of *DT based on the source SDTM DTC variable. See General Timing Variable Convention #6.

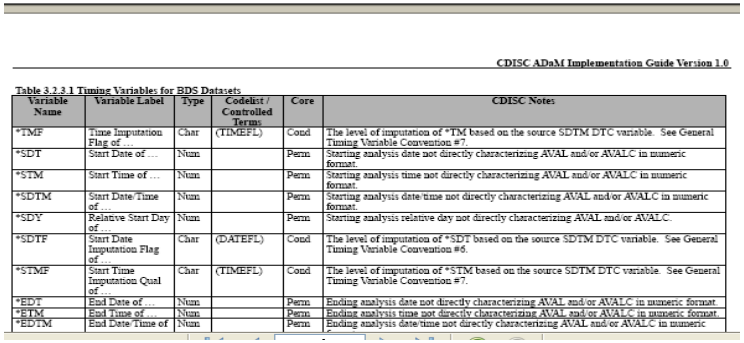

Table 3.2.3.1 Timing Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
*TMF	Time Imputation Flag of …	Char	(TIMEFL)	Cond	The level of imputation of *TM based on the source SDTM DTC variable. See General Timing Variable Convention #7.
*SDT	Start Date of …	Num		Perm	Starting analysis date not directly characterizing AVAL and/or AVALC in numeric format.
*STM	Start Time of …	Num		Perm	Starting analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*SDTM	Start Date/Time of …	Num		Perm	Starting analysis date/time not directly characterizing AVAL and/or AVALC in numeric format.
*SDY	Relative Start Day of …	Num		Perm	Starting analysis relative day not directly characterizing AVAL and/or AVALC.
*SDTF	Start Date Imputation Flag of …	Char	(DATEFL)	Cond	The level of imputation of *SDT based on the source SDTM DTC variable. See General Timing Variable Convention #6.
*STMF	Start Time Imputation Qual of …	Char	(TIMEFL)	Cond	The level of imputation of *STM based on the source SDTM DTC variable. See General Timing Variable Convention #7.
*EDT	End Date of …	Num		Perm	Ending analysis date not directly characterizing AVAL and/or AVALC in numeric format.
*ETM	End Time of …	Num		Perm	Ending analysis time not directly characterizing AVAL and/or AVALC in numeric format.
*EDTM	End Date/Time of …	Num		Perm	Ending analysis date/time not directly characterizing AVAL and/or AVALC in numeric

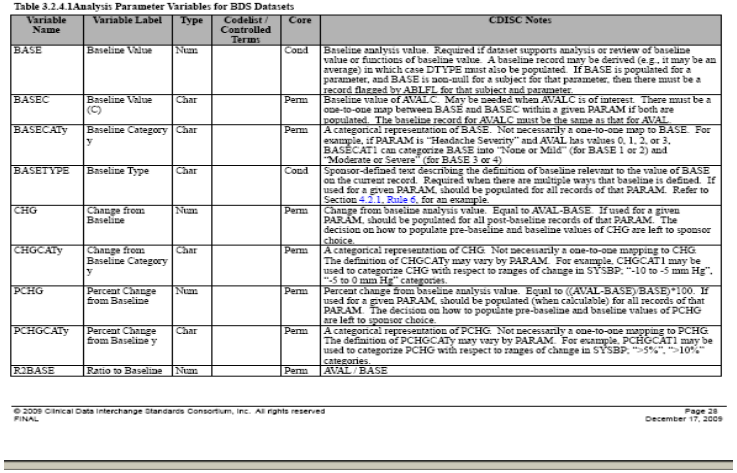

Table 3.2.4.1 Analysis Parameter Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
BASE	Baseline Value	Num		Cond	Baseline analysis value. Required if dataset supports analysis or review of baseline value or functions of baseline value. A baseline record may be derived (e.g., it may be an average) in which case DTYPE must also be populated. If BASE is populated for a parameter, and BASE is non-null for a subject for that parameter, then there must be a record flagged by ABLFL for that subject and parameter.
BASEC	Baseline Value (C)	Char		Perm	Baseline value of AVALC. May be needed when AVALC is of interest. There must be a one-to-one map between BASE and BASEC within a given PARAM if both are populated. The baseline record for AVALC must be the same as that for AVAL.
BASECATy	Baseline Category y	Char		Perm	A categorical representation of BASE. Not necessarily a one-to-one map to BASE. For example, if PARAM is "Headache Severity" and AVAL has values 0, 1, 2, or 3, BASECAT1 can categorize BASE into "None or Mild" (for BASE 1 or 2) and "Moderate or Severe" (for BASE 3 or 4)
BASETYPE	Baseline Type	Char		Cond	Sponsor-defined text describing the definition of baseline relevant to the value of BASE on the current record. Required when there are multiple ways that baseline is defined. If used for a given PARAM, should be populated for all records of that PARAM. Refer to Section 4.2.1, Rule 6, for an example.
CHG	Change from Baseline	Num		Perm	Change from baseline analysis value. Equal to AVAL–BASE. If used for a given PARAM, should be populated for all post-baseline records of that PARAM. The decision on how to populate pre-baseline and baseline values of CHG are left to sponsor choice.
CHGCATy	Change from Baseline Category y	Char		Perm	A categorical representation of CHG. Not necessarily a one-to-one mapping to CHG. The definition of CHGCATy may vary by PARAM. For example, CHGCAT1 may be used to categorize CHG with respect to ranges of change in SYSBP; "-10 to -5 mm Hg", "-5 to 0 mm Hg" categories.
PCHG	Percent Change from Baseline	Num		Perm	Percent change from baseline analysis value. Equal to ((AVAL-BASE)/BASE)*100. If used for a given PARAM, should be populated (when calculable) for all records of that PARAM. The decision on how to populate pre-baseline and baseline values of PCHG are left to sponsor choice.
PCHGCATy	Percent Change from Baseline y	Char		Perm	A categorical representation of PCHG. Not necessarily a one-to-one mapping to PCHG. The definition of PCHGCATy may vary by PARAM. For example, PCHGCAT1 may be used to categorize PCHG with respect to ranges of change in SYSBP; "-5%", "-10%" categories.
R2BASE	Ratio to Baseline	Num		Perm	AVAL / BASE

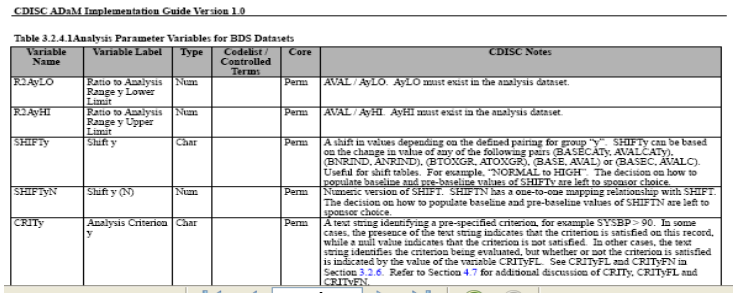

Table 3.2.4.1 Analysis Parameter Variables for BDS Datasets

Variable Name	Variable Label	Type	Codelist / Controlled Terms	Core	CDISC Notes
R2AyLO	Ratio to Analysis Range y Lower Limit	Num		Perm	AVAL / AyLO. AyLO must exist in the analysis dataset.
R2AyHI	Ratio to Analysis Range y Upper Limit	Num		Perm	AVAL / AyHI. AyHI must exist in the analysis dataset.
SHIFTy	Shift y	Char		Perm	A shift in values depending on the defined pairing for group "y". SHIFTy can be based on the change in value of any of the following pairs (BASECATy, AVALCATy), (BNRIND, ANRIND), (BTOXGR, ATOXGR), (BASE, AVAL) or (BASEC, AVALC). Useful for shift tables. For example, "NORMAL to HIGH". The decision on how to populate baseline and pre-baseline values of SHIFTy are left to sponsor choice.
SHIFTyN	Shift y (N)	Num		Perm	Numeric version of SHIFT. SHIFTN has a one-to-one mapping relationship with SHIFT. The decision on how to populate baseline and pre-baseline values of SHIFTN are left to sponsor choice.
CRITy	Analysis Criterion y	Char		Perm	A text string identifying a pre-specified criterion, for example SYSBP > 90. In some cases, the presence of the text string indicates that the criterion is satisfied on this record, while a null value indicates that the criterion is not satisfied. In other cases, the text string identifies the criterion being evaluated, but whether or not the criterion is satisfied is indicated by the value of the variable CRITyFL. See CRITyFL and CRITyFN in Section 3.2.6. Refer to Section 4.7 for additional discussion of CRITy, CRITyFL and CRITyFN.

Future Developments

- A specification document for an ADAE dataset
- A document providing details of applying the BDS to time-to-event analysis
- A document providing details of applying the BDS for analyses such as analysis of covariance
- A document providing a detailed description of the ADaM metadata model and its implementation
- A document defining ADaM compliance
- A document addressing integration of multiple studies.

References

- “Analysis Data Model (ADaM) Implementation Guide V1.0 Final,” CDISC Analysis Data Model Team, 17DEC2009
- “CDISC Analysis Data Model V2.1,” CDISC Team