ADaM Overview

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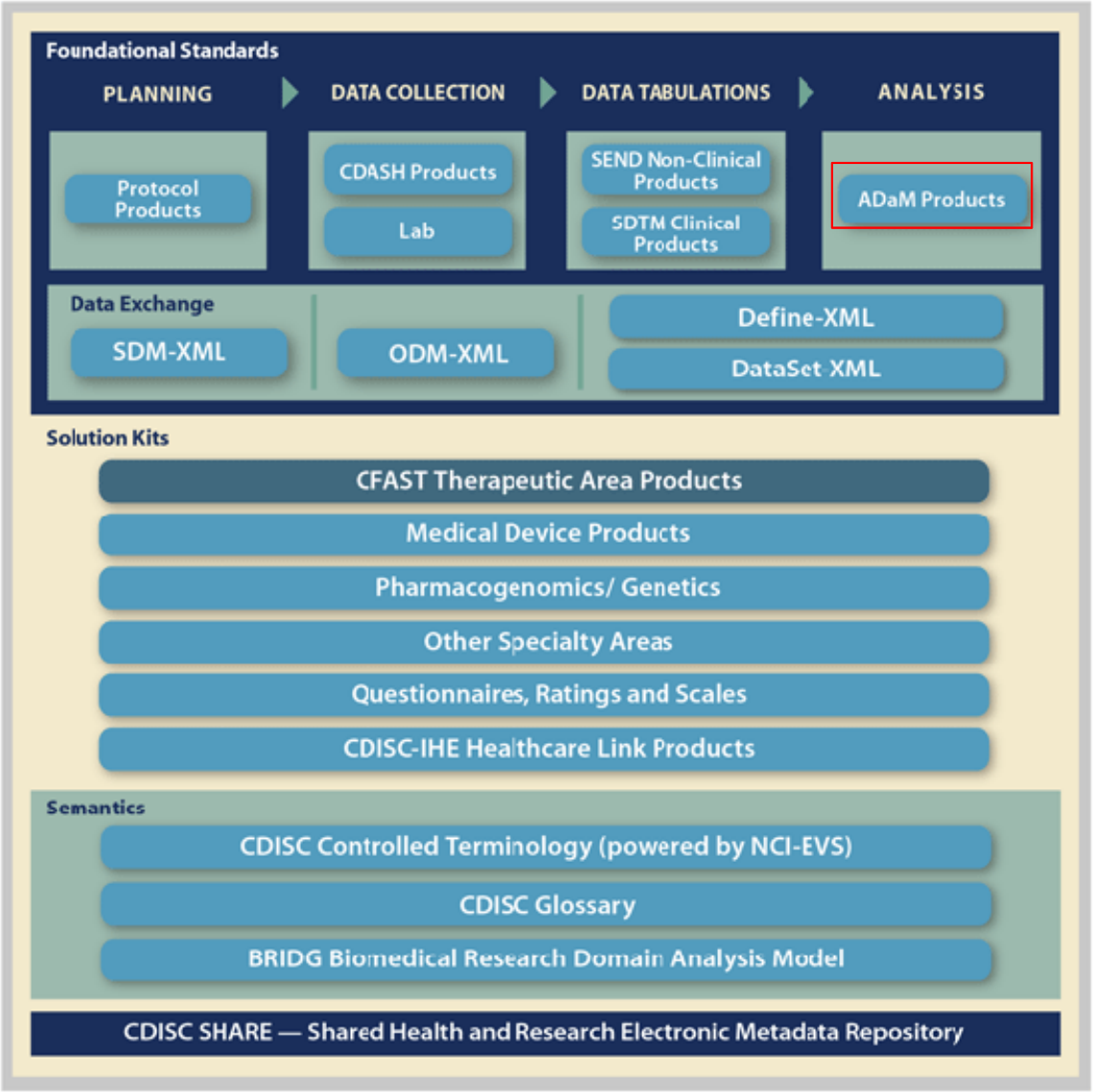
Standards & Implementations



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- ADaM Documents
- ADaM Basic
- ADaM Examples

Current ADaM Documents

- ADaM Model Document V2.1 （2009）
- ADaM OCCDS v1 (Provisional， 2015-06-01)
- ADaM IG1.1 (2016-02-12)

- Analysis Results Metadata Specification for Define-XML v2 （2015）
- ADaM Validation checks V1.3 （2015）
- Appendices
  - Examples in Commonly Used Statistical Methods（2011）
  - ADAE （2012）
  - ADTTE （2012）

ADaM documents under development

- **ADaM Data Structures for Integration**
  - Integrated ADSL(IADSL) V1.0 Draft for public review (2015)
- ADaM metadata model and its implementation
- Document to cover **multivariate analyses**

ADaM Principles 基本原则

- 分析数据集及相关元数据必须：
  - 促进清晰无歧义的交流
  - 提供分析数据和它的源数据之间的可溯源性
  - 能很容易地在常用软件工具上使用
- 分析数据集必须：
  - 伴有元数据
  - 即可分析

- 实施考虑：
  - 必须包括ADSL
  - 数据集命名遵循ADxxxxxx规范
  - 尽量使用ADaM标准变量,遵循命名规范
  - 同名、同义、 同值
  - 多个研究间的一致性

- **Analysis datasets and their associated metadata must:**
  - facilitate clear and unambiguous communication
  - provide traceability between the analysis data and its source data (ultimately SDTM)
  - be readily useable by commonly available software tools
- **Analysis datasets must:**
  - be accompanied by metadata
  - be analysis-ready

- **Practical Considerations**
  - Must include “ADSL”
  - Analysis datasets naming convention “ADxxxxxx.”
  - Variable naming conventions
  - “same name, same meaning, same values” principle
  - apply naming conventions for datasets and variables consistently

ADaM Data Structure

- **ADSL (Subject-level Analysis Dataset)**
  - Demographics 人口学
  - Population Indicators 人群标帜
  - Treatment Variables 治疗变量
  - Baseline Characteristics 基线特征
  - 。。。

- **BDS (ADaM Basic Data Structure)**
  - Analysis Parameter Variables 分析参数： PARAM, PARAMCD, AVAL,AVALC …
  - …

- **OCCDS (ADaM Occurrence Data Structure)**
  -

ADSL Variables

- Study Identifiers
  - STUDYID, USUBJID, SUBJID, SITEID, SITEGRy, SITEGRyN
- Demographics
  - SEX, RACE, RACEGRy, RACEGRyN
- Population Indicators
  - FASFL, SAFFL, ITTFL, PPROTFL, COMPLFL, RANDFL, ENRLFL
- Treatment Variables
  - ARM, ACTARM, TRTxxP, TRTxxPN, TRTxxA, TRTxxAN, TRTSEQP
- Trial Dates
  - TRTSDT,TRTSTM,TRTSDTM,TRTSDTF,TRTSTMF,TRTEDT,TRTETM,TRTEDTM,TRTEDTF,TRTETMF,TRxxSDT,TRxxSTM,TRxxSDTM,TRxxSDTF,TRxxSTMF,TRxxEDT,TRxxETM,TRxxEDTM,TRxxEDTF,TRxxETMF,
- Baseline Characteristics
  - Subgroup Variables
  - Covariates
  - Others: if to be used in several ADs

BDS Variables

- Study Identifiers
  - STUDYID, USUBJID, SUBJID, SITEID
- Treatment Variables
  - TRTP,TRTPN,TRTA,TRTAN,TRTPGy,TRTPGyN,TRTAGy,TRTA GyN
- Timing Variables
  - ADT,ATM,ADTM,ADY,ADTF,ATMF,
  - ASTDT,ASTTM,ASTDTM,ASTDY,ASTDTF,ASTTMF
  - AENDT,AENTM,AENDTM,AENDY,AENDTF,AENTMF
  - AVISIT,AVISITN,ATPT,ATPTN

BDS Variables 2

- **Analysis Parameter Variables**
  - PARAM,PARAMCD,PARAMN,PARAMTYP,PARCATy,PARCATyN
  - AVAL,AVALC,AVALCATy
  - BASE,BASEC,BASECATy,BASETYPE
  - CHG,CHGCATy,PCHG,PCHGCATy
  - R2BASE, R2AyLO,R2AyHI,SHIFTy,SHIFTyN,
  - CRITy

- **Analysis Descriptor Variables**
  - DTYPE

- **Indicator Variables**
  - ABLFL, ABLFN
  - ANLzzFL, ANLzzFN
  - ONTRTFL
  - CRITyFL, CRITyFN

Derived Columns Vs Derived Rows

- 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. creating an analysis timepoint
- 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.

OCCDS

- Structure: usually one record per each record in the corresponding SDTM domain.

- Exceptional Examples
  - Screening failure
  - Topic spans several treatment periods and to be counted in each
  - multiple coding paths

OCCDS Variables

- **Identifier Variables 标识符**
  - STUDYID, USUBJID, SUBJID, SITEID， --SEQ
- **Dictionary Coding and Categorization Variables 词典编码与归类变量**
  - MedDRA: --TERM, --DECOD, --BODSYS, --LLT, --HLT, --HLGT, --SOC…
  - WHO Drug: CMTRT, CMDEOCD, CMCLAS, ATCy…
  - --CAT, --SCAT, ACATy
- **Timing Variables 时间变量**
  - --STDTC， ASTDT， ASTTM， ASTDTM， ASTDTF， ASTTMF
  - --ENDTC， AENDT， AENTM， AENDTM， AENDTF， AENTMF
  - ASTDY， --STDY， AENDY， --ENDY
  - ADURN， ADURU， --DUR
  - APERIOD， APERIODC， APHASE

OCCDS变量2

- **Indicator Variables 指示变量**
  - SDTM： --OCCUR， --PRESP
  - ANLzzFL
  - AE: TRTEMFL, AETRTEM
  - CM: ONTRTFL
  - AE/CM: PREFL, FUPFL
  - Occurrence Flag: AOCCFL, AOCCPFL, AOCCIFL, AOCCPIFL, AOCCzzFL

- **Descriptive Variables 描述变量**
  - Xxx from SDTM: AESEV …
  - numeric version: AESEVN …
  - Imputed version: ASEV, ASEVN …
  - Pooled version: SEVGRy, SEVGRyN…

ADCM - Meta

Dataset Name	Variable Name	Variable Label	Variable Type	Codelist / Controlled Terms	Source / Derivation
ADCM	STUDYID	Study Identifier	text		CM.STUDYID
ADCM	USUBJID	Unique Subject Identifier	text		CM.USUBJID
ADCM	CMSEQ	Sequence Number	integer		CM.CMSEQ
ADCM	CMTRT	Reported Name of Drug, Med or Therapy	text		CM.CMTRT
ADCM	CMMODIFY	Modified Reported Name	text		CM.CMMODIFY
ADCM	CMDECOD	Standardized Medication Name	text	WHODRUG	CM.CMDECOD WHO Drug Dictionary March 2012
ADCM	ATC1CD	ATC Level 1 Code	text	WHODRUG	ATC Level 1 Code WHO Drug Dictionary March 2012
ADCM	ATC2CD	ATC Level 2 Code	text	WHODRUG	ATC Level 2 Code WHO Drug Dictionary March 2012
ADCM	ATC3CD	ATC Level 3 Code	text	WHODRUG	ATC Level 3 Code WHO Drug Dictionary March 2012
ADCM	ATC1	ATC Level 1 Text	text	WHODRUG	ATC Level 1 Text WHO Drug Dictionary March 2012
ADCM	ATC2	ATC Level 2 Text	text	WHODRUG	ATC Level 2 Text WHO Drug Dictionary March 2012
ADCM	ATC3	ATC Level 3 Text	text	WHODRUG	ATC Level 3 Text WHO Drug Dictionary March 2012
ADCM	AOCCFL	1st Occurrence within Subject Flag	text	Y	<Producer will insert derivation here>
ADCM	AOCC01FL	First Occurrence of ATC Level 1 Flag	text	Y	<Producer will insert derivation here>
ADCM	AOCC02FL	First Occurrence of ATC Level 2 Flag	text	Y	<Producer will insert derivation here>
ADCM	AOCC03FL	First Occurrence of ATC Level 3 Flag	text	Y	<Producer will insert derivation here>
ADCM	AOCCPFL	1st Occurrence of Preferred Term Flag	text	Y	<Producer will insert derivation here>

ADCM - Data

Row	STUDYID	USUBJID	CMSEQ	CMTRT	CMMODIFY	CMDECOD	ATC1CD	ATC1	ATC2CD
1	ABC	ABC-001	1	TYLENOL	TYLENOL	PARACETAMOL	N	NERVOUS SYSTEM	N02
2	ABC	ABC-001	2	TYLENOL	TYLENOL	PARACETAMOL	N	NERVOUS SYSTEM	N02
3	ABC	ABC-001	3	TYLENOL	TYLENOL	PARACETAMOL	N	NERVOUS SYSTEM	N02
4	ABC	ABC-001	4	TYLENOL	TYLENOL	PARACETAMOL	N	NERVOUS SYSTEM	N02
5	ABC	ABC-001	5	CONTAC MS	CONTAC MS	CONTAC MS	N	NERVOUS SYSTEM	N02
6	ABC	ABC-001	6	FLONASE	FLONASE	FLUTICASONE PROPIONATE	R	RESPIRATORY SYSTEM	R01
7	ABC	ABC-002	1	ROBITUSSIN COUGH	ROBITUSSIN	NOVAHISTINE DMX	R	RESPIRATORY SYSTEM	R05
8	ABC	ABC-002	2	MOTRIN	MOTRIN	IBUPROFEN	M	MUSCULO-SKELETAL SYSTEM	M01
9	ABC	ABC-002	3	IBUPROFEN	IBUPROFEN	IBUPROFEN	M	MUSCULO-SKELETAL SYSTEM	M01
10	ABC	ABC-003	1	ZOLLOFT	ZOLOFT	SERTRALIN	N	NERVOUS SYSTEM	N06

Row	ATC2	ATC3CD	ATC3	AOCCFL	AOCCPFL
1 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS	Y	Y
2 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS		
3 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS		
4 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS		
5 (cont)	ANALGESICS	N02B	OTHER ANALGESICS AND ANTIPYRETICS		Y
6 (cont)	NASAL PREPARATIONS	R01A	DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOP		Y
7 (cont)	COUGH AND COLD PREPARATIONS	R05FA	COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS		Y
8 (cont)	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	M01A	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-S		Y
9 (cont)	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS	M01A	ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-S		
10 (cont)	PSYCHOANALEPTICS	N06A	ANTIDEPRESSANTS		Y

Row	AOCC01FL	AOCC02FL	AOCC03FL	CMINDC	CMDOSFRM	CMDOSE	CMDOSU	CMDOSFRQ	CMROUTE	CMSTDTC*	ASTDT*	CMENDTC*
1 (cont)	Y	Y	Y	HEADACHE	TABLET	100	mg	ONCE	ORAL	2011-01-02	02Jan2011	2011-01-02
2 (cont)				HEADACHE	TABLET	100	mg	ONCE	ORAL	2011-01-04	04Jan2011	2011-01-04
3 (cont)				HEADACHE	TABLET	100	mg	ONCE	ORAL	2011-01-10	10Jan2011	2011-01-10
4 (cont)				HEADACHE	TABLET	100	mg	ONCE	ORAL	2011-01-15	15Jan2011	2011-01-15
5 (cont)				COLD	TABLET	200	mg	ONCE	ORAL	2011-01-17	17Jan2011	2011-01-17
6 (cont)	Y	Y	Y	COUGH	TABLET	50	mg	QD	ORAL	2009-02-01	01Feb2009	
7 (cont)		Y	Y	INFECTION	SUSPENSION	500	mg	QID	ORAL	2011-03-01	01Mar2011	2011-03-15
8 (cont)	Y	Y	Y	LEG PAIN	TABLET	500	mg	PRN	ORAL	2011-05-14	14May2011	2011-06-01
9 (cont)				ARTHRITIS	TABLET	250	mg	QD	ORAL	2011-06-10	10Jun2011	
10 (cont)	Y	Y	Y	ANXIETY	TABLET	50	mg	QD	ORAL	2001-03		

Other Points to Consider

- not everything from ADSL needs to be copied to BDS
- Noted that length can vary between SDTM and ADaM variable
- Allow y to go from 1-99

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- ADaM Documents
- ADaM Basic
- ADaM Examples

Examples

- ADSL (ADSL)
- AEAE (OCCDS)
- ADVS (BDS)

Demographics Display

ADSL where ITTFL=Y

Table 14.2.1
Demographics
ITT Population

AGE

TRT01P

	Placebo N=xx	CDE_01 n(%)	Total n(%)
Age			
Mean	xx.x	xx.x	xx.x
Standard Deviation	xx.x	xx.x	xx.x
Min	xx	xx	xx
Max	xx	xx	xx
Age Group, n (%)			
<65	xx (xx.x)	xx (xx.x)	xx (xx.x)
65-80	xx (xx.x)	xx (xx.x)	xx (xx.x)
>80	xx (xx.x)	xx (xx.x)	xx (xx.x)

AGEGR1N

Demographics Display – codes

- Age
  - proc means data=ADSL;
  - where ITTFL='Y';
  - class TRT01P;
  - var AGE;
  - run;

- t-test:
  - Proc ttest data=adsl;
  - where ITTFL='Y';
  - class TRT01P;
  - var AGE;
  - run;

- Age Group
  - proc freq data=ADSL;
  - where ITTFL='Y';
  - table TRT01P*AGEGR1N;
  - run;

- Chisq:
  - proc freq data=ADSL;
  - where ITTFL='Y';
  - table TRT01P*AGEGR1N/chisq;
  - run;

Example: Demographics

DM=Demographics

RFICDTC

Informed Consent Date ☐☐ ☐☐☐ ☐☐☐☐
Day Month Year

Demographics

BRTHDTC

Date of Birth ☐☐ ☐☐☐ ☐☐☐☐
Day Month Year

SEX

Sex ☐ Male ☐ Female

RACE

Race ☐ White

RACE, when more than one selected, RACE=MULTIPLE and individual responses are RACE1, RACE2, etc. in SUPPDM

☐ Black or African American

☐ Asian

☐ American Indian or Alaska Native

☐ Native Hawaiian or Other Pacific Islander

☐ Other, specify: RACEOTH in SUPPDM

Example - ADSL

SDTM.DM

DOMAIN	USUBJID	ARM	RFICDTC	BRTHDTC	RFXSTDTC	RFXENDTC	AGE	AGEU	SEX	RACE
DM	01-701-1015	Placebo	2013-12-26	1951-04-03	2014-01-02	2014-07-02	63	YEARS	F	WHITE
DM	01-701-1023	Placebo	2012-07-22	1948-10-26	2012-08-05	2012-09-01	64	YEARS	M	WHITE
DM	01-701-1033	CDE_001	2014-03-10	1940-08-06	2014-03-18	2014-03-31	74	YEARS	M	WHITE
DM	01-701-1047	Placebo	2013-01-22	1928-04-03	2013-02-12	2013-03-09	85	YEARS	F	WHITE
DM	01-701-1097	CDE_001	2013-12-23	1946-01-20	2014-01-01	2014-07-09	68	YEARS	M	WHITE

ADaM.ADSL

USUBJID	TRT01P	TRTSDT	TRTEDT	AGE	AGEGR1	AGEGR1N	AGEU	SEX	RACE	RACEN	SAFFL	ITTFL
01-701-1015	Placebo	02-Jan-2014	02-Jul-2014	63	<65	1	YEARS	F	WHITE	1	Y	Y
01-701-1023	Placebo	05-Aug-2012	01-Sep-2012	64	<65	1	YEARS	M	WHITE	1	Y	Y
01-701-1033	CDE_001	18-Mar-2014	31-Mar-2014	74	65-80	2	YEARS	M	WHITE	1	Y	Y
01-701-1047	Placebo	12-Feb-2013	09-Mar-2013	85	>80	3	YEARS	F	WHITE	1	Y	Y
01-701-1097	CDE_001	01-Jan-2014	09-Jul-2014	68	65-80	2	YEARS	M	WHITE	1	Y	Y

Examples

- ADSL (ADSL)
- AEAE (OCCDS)
- ADVS (BDS)

AE Display

ADAE where SAFFL=Y and TRTEMFL=Y
ADSL where SAFFL=Y

Table 14.2.7.1

Summary of Treatment Emergent Adverse Events by System Organ Class and Preferred Term

Analysis Population: Safety

AEBODSYS
AEDECOD

TRTA

SYSTEM ORGAN CLASS Preferred Term	Treatment A (N = xxx) n (%)	Treatment B (N = xxx) n (%)
Number of subjects reporting at least one adverse event	x (x.x)	x (x.x)
BLOOD AND LYMPHATIC SYSTEM DISORDERS		
At least one event	x (x.x)	x (x.x)
Anaemia	x (x.x)	x (x.x)
…	x (x.x)	x (x.x)

AOCCFL=Y

AOCCSFL=Y

AOCCPFL=Y

AE Display – codes

- Any AE
  - Proc freq data=ADAE;
  - where SAFFL=‘Y’ and TRTEMFL=‘Y’ and AOCCFL=‘Y’;
  - table TRTA;
  - Run;

- By SOC
  - Proc freq data=ADAE;
  - where SAFFL=‘Y’ and TRTEMFL=‘Y’ and AOCCSFL=‘Y’;
  - table TRTA*AEBODSYS;
  - Run;

- By Preferred Name:
  - Proc freq data=ADAE;
  - where SAFFL=‘Y’ and TRTEMFL=‘Y’ and AOCCPFL=‘Y’;
  - table TRTA*AEDECOD;
  - By AEBODSYS;
  - Run;

Example: Adverse Events

Adverse Event

AE=Adverse Events

Have there been any adverse events since signature of informed consent? ◯ Yes, complete details ◯ No NOT SUBMITTED

Adverse Event (diagnosis if known or main sign/symptom)

AETERM

AESER

Serious AE ◯ No ◯ Yes*, complete seriousness criteria below (tick all that apply)

- ☐ Results in death
- ☐ Is life-threatening
- ☐ Requires/prolongs hospitalization
- ☐ Persistent/significant disability/incapacity
- ☐ Is a congenital anomaly/birth defect
- ☐ Other medically important condition

AESDTH
AESHOSP
AESCONG
AESLIFE
AESDISAB
AESMIE

Start date AESTDTC

Day Month Year

End date AEENDTC

Day Month Year

Toxicity grade/

- ◯ Grade 1
- ◯ Grade 2
- ◯ Grade 3
- ◯ Grade 4
- ◯ Grade 5

AETOXGR

Relationship with study treatment AEREL

◯ Related ◯ Unrelated

Causality factor(s) other than study treatment (tick all that apply) AERELNST

- ☐ None
- ☐ Disease under study
- ☐ Protocol procedure
- ☐ Medical History
- ☐ Concomitant medication
- ☐ Concomitant procedure
- ☐ Other, specify: _____

Action(s) taken with study treatment (tick all that apply) AEACN

- ☐ None/continued
- ☐ Permanently discontinued
- ☐ Not applicable

Other action(s) taken (tick all that apply) AEACNOTH

- ☐ None
- ☐ Concomitant medication
- ☐ Concomitant procedure
- ☐ Led to study termination

Outcome (tick only one) AEOUT

- ◯ Change in toxicity grade, severity or seriousness
- ◯ Resolved
- ◯ Resolved with sequelae
- ◯ Ongoing
- ◯ Fatal
- ◯ Unknown

Example - ADAE

SDTM.AE

USUBJID	AESEQ	AETERM	AEDECOD	AEBODSYS	AESTDTC	AEENDTC	AESEV
01-701-1015	3	DIARRHOEA	DIARRHOEA	GASTROINTESTINAL DISORDERS	2014-01	2014-01-09	MILD
01-701-1097	1	ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2014-01-03	2014-01-03	MILD
01-701-1097	2	PRURITUS GENERALISED	PRURITUS GENERALISED	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	2014-02-20	2014-02-20	MODERATE
01-701-1097	3	APPLICATION SITE VESICLES	APPLICATION SITE VESICLES	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	2014-02-20	2014-03	

ADaM.ADAE

USUBJID	AESEQ	AETERM	AEDECOD	AEBODSYS	ASTDT	AENDT	ASEV	ASEVN	AOCCFL	AOCCSFL	AOCCPFL	TRTEMFL	TRTA
01-701-1015	3	DIARRHOEA	DIARRHOEA	GASTROINTESTINAL DISORDERS	*01-Jan-2014*	09-Jan-2014	MILD	1	Y	Y	Y	Y	Placebo
01-701-1097	1	ERYTHEMA	ERYTHEMA	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	03-Jan-2014	03-Jan-2014	MILD	1	Y	Y	Y	Y	Placebo
01-701-1097	2	PRURITUS GENERALISED	PRURITUS GENERALISED	SKIN AND SUBCUTANEOUS TISSUE DISORDERS	20-Feb-2014	20-Feb-2014	MODERATE	2			Y	Y	Placebo
01-701-1097	3	APPLICATION SITE VESICLES	APPLICATION SITE VESICLES	GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	20-Feb-2014	*31-Mar-2014*	*SEVERE*	*3*		Y	Y	Y	CDE_001

TOC

- ADSL (ADSL)
- AEAE (OCCDS)
- ADVS (BDS)

MMRM - Pulse

ADVS where ITTFL=Y and PARAMCD=PULSE and ANL01FL=Y and ABLFL ^= Y

CHG /BASE

AVISITN

TRTPN

Table 14.x.x

Mixed-effects Model Repeated Measures Analysis of Change from Baseline of **Pulse**

ITT Population

	Placebo	CDE_01	Difference (CDE_01 vs Placebo)
Week 2			
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min; Max	xx; xx	xx; xx	xx; xx
LS Mean (SE)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x
P value			x.xxx
...			
Week 8			
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min, Max	xx	xx	xx
LS Mean (SE)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
95% CI	xx.x; xx.x	xx.x; xx.x	xx.x; xx.x
P value			x.xxx

MMRM – Pulse - codes

- proc mixed data=ADVS;
- where ITTFL='Y' and PARAMCD='PULSE' and ANL01FL='Y' and ABLFL ^= Y;
  - class USUBJID AVISITN TRTPN;
  - model PCHG = TRTPN AVISITN TRTPN*AVISITN BASE / outp=PRED ddfm=KR;
  - repeated AVISITN / subject=USUBJID type=UN;
  - lsmeans TRTPN / diff cl;
  - run;

Example: Vital Signs

VS=Vital Signs

Vital Signs

VSTEST

Blood Pressure:	___ / ___ mmHg (Systolic / Diastolic)	VSORRES / VSORRESU when VSTESTCD = SYSBP, DIABP
Pulse:	___ Beats/minute	VSORRES / VSORRESU when VSTESTCD = PULSE
Height	___ cm	VSORRES / VSORRESU when VSTESTCD = HEIGHT
Weight	___ . ___ kg	VSORRES / VSORRESU when VSTESTCD = WEIGHT
Body Mass Index:	___ . ___ Kg/m^2	VSORRES / VSORRESU when VSTESTCD = BMI

Example - ADVS

SDTM.VS

USUBJID	VSSEQ	VSTESTCD	VSTEST	VSSTRESC	VSSTRESN	VSSTRESU	VISIT	VISITNUM
01-701-1015	1	PULSE	Pulse	57	57	BEATS/MIN	SCREENING	0
01-701-1015	2	PULSE	Pulse	56	56	BEATS/MIN	BASELINE	2
01-701-1015	3	PULSE	Pulse	58	58	BEATS/MIN	WEEK 2	4
01-701-1015	4	PULSE	Pulse	59	59	BEATS/MIN	WEEK 4	6
01-701-1015	5	PULSE	Pulse	55	55	BEATS/MIN	WEEK 6	8

ADaM.ADVS

USUBJID	VSSEQ	PARAMCD	PARAM	AVAL	BASE	CHG	AVISIT	AVISITN	ANL01FL	ABLFL	TRTP	ITTFL
01-701-1015	1	PULSE	Pulse (BEATS/MIN)	56	56	0	Baseline	0	Y	Y	Placebo	Y
01-701-1015	2	PULSE	Pulse (BEATS/MIN)	58	56	2	Week 2	2	Y		Placebo	Y
01-701-1015	3	PULSE	Pulse (BEATS/MIN)	59	56	3	Week 4	4	Y		Placebo	Y
01-701-1015	4	PULSE	Pulse (BEATS/MIN)	55	56	-1	Week 6	6	Y		Placebo	Y
01-701-1015	5	PULSE	Pulse (BEATS/MIN)	57	56	1	Week 8	8	Y		Placebo	Y

Ask

Thank You谢谢!

Strength *through collaboration.*

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