Insight into ADaM

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ADaM Agenda

- Definition
- Introduction
- Background
- Principles
- SDTM/ADaM Differences
- ADaM Implementation Guide v1.0
- ADSL
- ADaM Basic Data Structure

What is ADaM

- ADaM = Analysis Dataset Model
- Guideline for analysis datasets used to generate statistical analysis for submissions
- Builds on the nomenclature of SDTM

  + attributes

  + variables

  + data structures

  for statistical analysis
- ADaM v1.0 released for REVIEW 5/2008

Introduction to ADaM

- ADaM data models created by large number of reviewers experienced in regulatory submissions
- Models represent one approach – other designs may be appropriate
- Structure and content should be clear on the statistics of the product
- Be proactive and work with your reviewer from the start!!

Background

- FDA established electronic submission in 1997 (21 CFR Part11)
- 1999 – FDA standardized file format (SAS® V5 Transport Files)
  - Described the submission of metadata files (define.pdf)
- Four types of submitted data (from eCTD)
  - Data tabulations
  - Data listings
  - Analysis datasets
  - Subject profiles
- Data listings and subject profiles routinely submitted as documents
- Data tabulations / analysis datasets
  - Study Data Tabulations (SDT): SDTM 3.1.1/3.1.2
  - Statistical Analysis Datasets (SAD): ADaM
- CRT Data Description Specification: describes the metadata of the datasets submitted (SDT, SAD)
- Anticipated that XML metadata (define.xml) will replace define.pdf

ADaM Principles

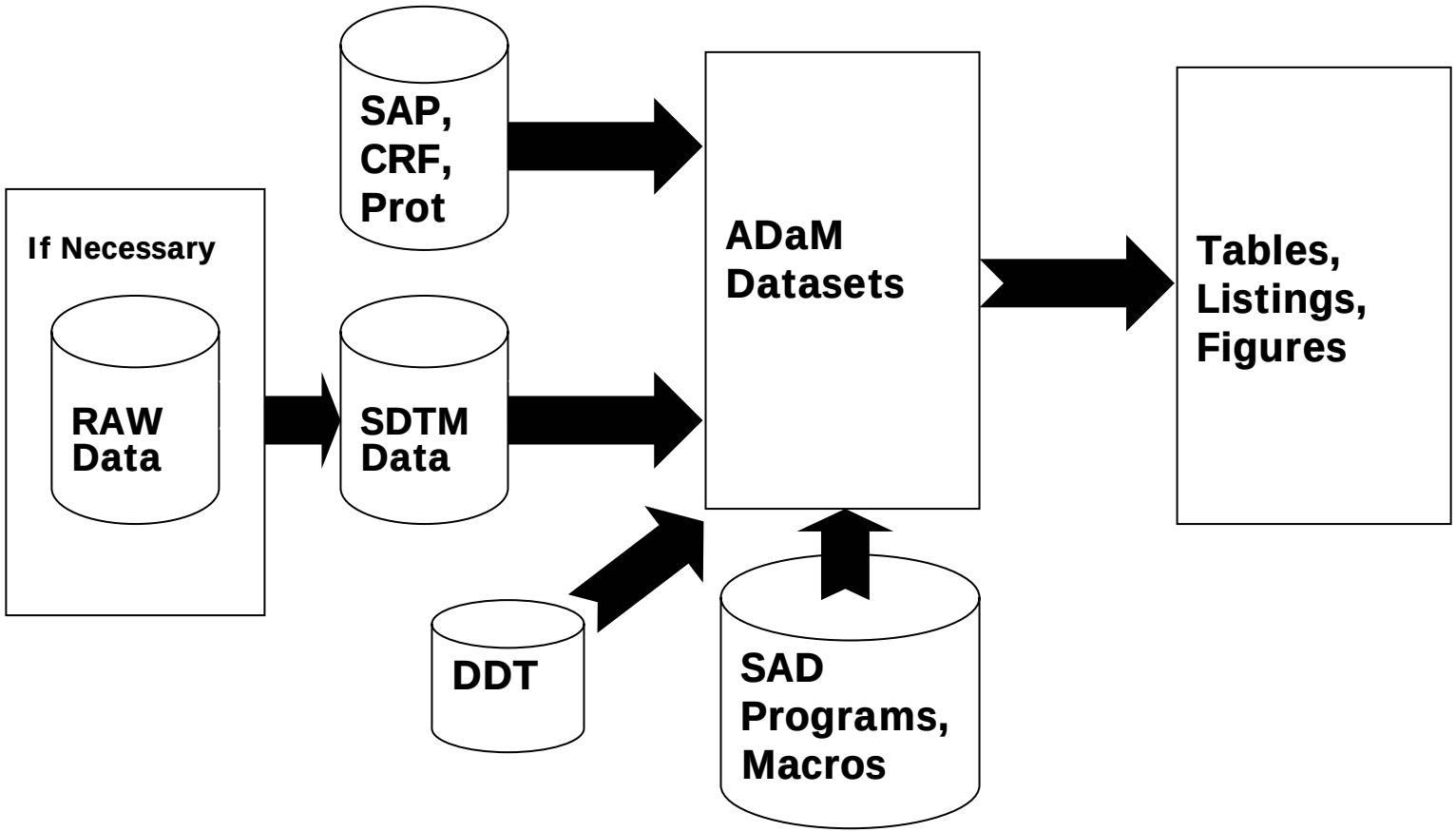
- “Standardize” delivery to FDA
- Clear documentation of the content, source and quality of the analysis datasets
- Clear documentation of the results of a clinical trial including statistical methods, transformations, assumptions, derivations, imputations
- Metadata, programs, and documentation translate SAP to the statistical results
- Useable by current tools such as SAS
- XML metadata for future analysis tool development
- “Analysis-ready” or “One Proc Away”

ADaM Criteria and Variable Standards

- Identify observations that exist in the submitted study tabulation data (SDTM)
- Identify observations that are derived within the ADaM analysis dataset
- Identify the method used to create derived observations
- Identify observations used for analysis, in contrast to those used to support traceability or future analysis

- No more than 8 characters in length
- Start with a letter or underscore
- Be comprised of letters, underscore, digits only
- All labels must be no more than 40 characters in length

Example Process



ADaM Differences with SDTM

- Structure may not always be vertical
- Redundancy is needed for easy analysis
- Numeric variables
- Combine variables across multiple domains
- Dates are formatted to SAS dates for ease of manipulation
- Dataset Name: ADXXXXXX

ADaM IG v1.0

- Structure of an analysis dataset does not limit what analyses can be done, nor communication
- ADaM model will not support compliance testing as rigorous as SDTM due to flexibility
- Use of structured metadata may someday allow analysis to be virtual
  - Any variable or observation could be created upon request and then be associated with other variables/observations

ADaM IG v1.0 Basic Data Structure

- Two standard structures
  - ADSL: subject-level dataset
  - Multiple record per subject basic data structure
- V1.0 focuses on the standard multiple-record-per-subject (ADaM Basic Data) structure
- Basic data structure is a normalized design
  - One or more records per subject per analysis parameter per timepoint
- Variable(s) describing the subject, analysis parameter, and timepoint can be considered the most important variables in understanding the basic structure

ADaM IG v1.0 Variable Groups

- Subject Identifiers (e.g. USUBJID)
- SDTM Identifiers (e.g. --SEQ, VISITNUM)
- ADaM Timing Identifiers (e.g. AVISIT, AVISITN)
- ADaM Parameter Identifiers (e.g. PARAM, PARAMCD)
- ADaM Analysis Values (e.g. AVAL, AVALC)
- Analysis Enabling Variables (e.g. ANLFL, TRTP)
- Supportive Variables (support traceability back to import data, etc)

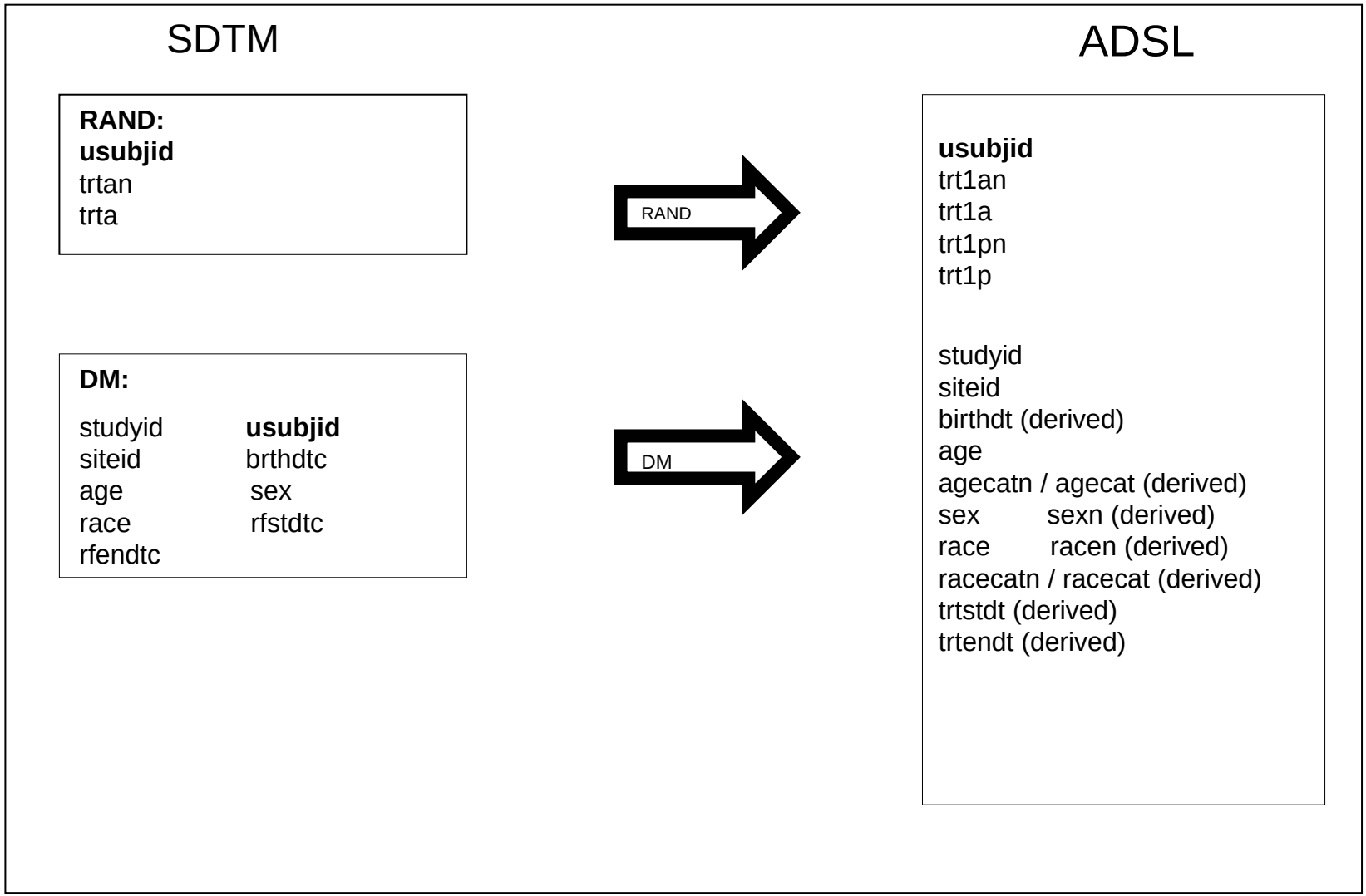
Subject-Level Dataset (ADSL)

- Minimum requirement if any analysis datasets are submitted
- One record per subject
- Contains all variables for describing the analysis population
  - Demographic data (age, sex, race, etc)
  - Baseline Characteristics
  - Disease Factors
  - Treatment code/group
  - Factors that could affect response to therapy
  - Other relevant variables (smoking, alcohol intake, etc. [i.e. used as strata])
  - Population flags
- Data in ADSL can be used as source for data used in other analysis (derive variables only once)

ADSL Required Variables

- Study Identifiers
  - STUDYID
  - USUBJID
  - SITEID
- Subject Demographics
  - AGE
  - SEX
  - RACE
- Treatment Variables
  - ARM
  - TRTxP
- Trial Dates
  - TRTSTDT
  - TRTENDT
- Other Common Variables (non-required)
  - FASFL
  - SAFFL
  - ITTFL
  - PPROTFL
  - COMPLFL

From SDTM to ADSL



ADSL Example

	STUDYID	DOMAIN	USUBJID	SITEID	REGION	AGE	AGECAT	AGECATN	BRTHDT	SEX	SEXN	RACE	RACEN	RACEOTH	RACECAT	RACECATN	RA
1	STUDY - ABC	ADSL	001001	001	USA	68	65 - 75	2	02JAN1940	M	1	WHITE	1		White	1	Y
2	STUDY - ABC	ADSL	001002	001	USA	71	65 - 75	2	28JUL1937	M	1	WHITE	1		White	1	Y
3	STUDY - ABC	ADSL	001004	001	USA	68	65 - 75	2	25MAY1940	M	1	HISPANIC	4		Non-White	2	Y
4	STUDY - ABC	ADSL	001005	001	USA	66	65 - 75	2	04MAY1942	F	2	WHITE	1		White	1	Y
5	STUDY - ABC	ADSL	002001	002	USA	72	65 - 75	2	28JAN1935	M	1	WHITE	1		White	1	Y
6	STUDY - ABC	ADSL	003001	003	USA	58	< 65	1	21JUL1949	F	2	WHITE	1		White	1	Y
7	STUDY - ABC	ADSL	003002	003	USA	78	> 75	3	05AUG1929	F	2	WHITE	1		White	1	Y
8	STUDY - ABC	ADSL	003003	003	USA	71	65 - 75	2	17JUN1937	F	2	WHITE	1		White	1	Y
9	STUDY - ABC	ADSL	003006	003	USA	67	65 - 75	2	29JUN1941	F	2	WHITE	1		White	1	Y
10	STUDY - ABC	ADSL	004002	004	USA	86	> 75	3	07MAR1921	M	1	WHITE	1		White	1	Y
11	STUDY - ABC	ADSL	004005	004	USA	68	65 - 75	2	10OCT1940	M	1	WHITE	1		White	1	Y
12	STUDY - ABC	ADSL	005002	005	USA	75	65 - 75	2	09AUG1932	M	1	WHITE	1		White	1	Y
13	STUDY - ABC	ADSL	005003	005	USA	54	< 65	1	18AUG1953	M	1	ASIAN	3		Non-White	2	Y
14	STUDY - ABC	ADSL	005005	005	USA	61	< 65	1	31AUG1946	M	1	WHITE	1		White	1	Y
15	STUDY - ABC	ADSL	005007	005	USA	60	< 65	1	12JUL1948	M	1	WHITE	1		White	1	Y
16	STUDY - ABC	ADSL	006001	006	USA	79	> 75	3	04AUG1928	M	1	ASIAN	3		Non-White	2	Y
17	STUDY - ABC	ADSL	006003	006	USA	79	> 75	3	02NOV1928	M	1	WHITE	1		White	1	Y
18	STUDY - ABC	ADSL	008002	008	USA	67	65 - 75	2	09JUL1940	F	2	WHITE	1		White	1	Y
19	STUDY - ABC	ADSL	008004	008	USA	65	65 - 75	2	24NOV1941	F	2	HISPANIC	4		Non-White	2	Y
20	STUDY - ABC	ADSL	008006	008	USA	83	> 75	3	19AUG1924	F	2	WHITE	1		White	1	Y
21	STUDY - ABC	ADSL	008007	008	USA	72	65 - 75	2	02MAY1935	M	1	WHITE	1		White	1	Y
22	STUDY - ABC	ADSL	008008	008	USA	73	65 - 75	2	08DEC1934	F	2	WHITE	1		White	1	Y
23	STUDY - ABC	ADSL	008009	008	USA	79	> 75	3	30SEP1928	F	2	WHITE	1		White	1	Y
24	STUDY - ABC	ADSL	008010	008	USA	70	65 - 75	2	24AUG1938	M	1	WHITE	1		White	1	Y
25	STUDY - ABC	ADSL	008012	008	USA	66	65 - 75	2	17MAY1942	F	2	WHITE	1		White	1	Y
26	STUDY - ABC	ADSL	009001	009	USA	64	< 65	1	15NOV1942	F	2	WHITE	1		White	1	Y
27	STUDY - ABC	ADSL	009002	009	USA	72	65 - 75	2	31JAN1935	F	2	WHITE	1		White	1	Y
28	STUDY - ABC	ADSL	009003	009	USA	78	> 75	3	19FEB1929	M	1	WHITE	1		White	1	Y
29	STUDY - ABC	ADSL	009005	009	USA	58	< 65	1	18FEB1950	M	1	WHITE	1		White	1	Y
30	STUDY - ABC	ADSL	009006	009	USA	82	> 75	3	28SEP1925	M	1	WHITE	1		White	1	Y
31	STUDY - ABC	ADSL	009007	009	USA	61	< 65	1	16MAY1947	F	2	WHITE	1		White	1	Y
32	STUDY - ABC	ADSL	009008	009	USA	55	< 65	1	22MAR1953	F	2	WHITE	1		White	1	Y
33	STUDY - ABC	ADSL	010002	010	USA	72	65 - 75	2	22JAN1935	M	1	WHITE	1		White	1	Y
34	STUDY - ABC	ADSL	010004	010	USA	69	65 - 75	2	15JUN1938	M	1	WHITE	1		White	1	Y
35	STUDY - ABC	ADSL	010005	010	USA	85	> 75	3	24JUN1922	M	1	WHITE	1		White	1	Y
36	STUDY - ABC	ADSL	010007	010	USA	73	65 - 75	2	01NOV1934	M	1	WHITE	1		White	1	Y
37	STUDY - ABC	ADSL	010009	010	USA	85	> 75	3	04SEP1922	M	1	WHITE	1		White	1	Y
38	STUDY - ABC	ADSL	010010	010	USA	72	65 - 75	2	13APR1936	F	2	WHITE	1		White	1	Y
39	STUDY - ABC	ADSL	010012	010	USA	72	65 - 75	2	05APR1936	M	1	WHITE	1		White	1	Y
40	STUDY - ABC	ADSL	010014	010	USA	82	> 75	3	27APR1926	M	1	WHITE	1		White	1	Y
41	STUDY - ABC	ADSL	010015	010	USA	57	< 65	1	11APR1951	M	1	WHITE	1		White	1	Y

ADSL Example

	Variable	Type	Len	DLen	Format	InFormat	Label
1	STUDYID	Char	11	11	$11.	.	Study Identifier
2	DOMAIN	Char	8	8	$8.	.	Domain Abbreviation
3	USUBJID	Char	15	15	$15.	.	Unique Subject Identifier
4	SITEID	Char	4	4	$4.	.	Study Site Identifier
5	REGION	Char	8	8	$8.	.	Region
6	AGE	Num	8	10	BEST10.	.	Age
7	AGECAT	Char	10	10	$10.	.	Age category
8	AGECATN	Num	8	10	BEST10.	.	Age category - Numeric
9	BRTHDT	Num	8	9	DATE9.	.	Birth Date
10	SEX	Char	1	1	$1.	.	Sex
11	SEXN	Num	8	10	BEST10.	.	Sex (Numeric code)
12	RACE	Char	41	41	$41.	.	Race
13	RACEN	Num	8	10	BEST10.	.	Race (Numeric code)
14	RACEOTH	Char	50	50	$50.	.	Other Race, Specify
15	RACECAT	Char	12	12	$12.	.	Race category
16	RACECATN	Num	8	10	BEST10.	.	Race category - Numeric
17	RANDFL	Char	1	1	$1.	.	Randomized Population Flag
18	SAFFL	Char	1	1	$1.	.	Safety Population Flag
19	ITTFL	Char	1	1	$1.	.	Intent-To-Treat Population Flag
20	PPROTFL	Char	1	1	$1.	.	Per-Protocol Population Flag
21	PKFL	Char	1	1	$1.	.	PK Population Flag
22	COMPLFL	Char	1	1	$1.	.	Completers Population Flag
23	TERMFL	Char	1	1	$1.	.	Patient terminated study Flag
24	TERMDT	Num	8	9	DATE9.	.	Termination Date
25	TRT1A	Char	30	30	$30.	.	Actual Treatment Group
26	TRT1AN	Num	8	10	BEST10.	.	Actual Treatment Group Numeric Code
27	TRT1P	Char	30	30	$30.	.	Planned Treatment for Period 1
28	TRT1PN	Num	8	10	BEST10.	.	Planned Treatment for Period 1 Numeric
29	RANDDT	Num	8	9	DATE9.	.	Randomization Date
30	TRTSTDT	Num	8	9	DATE9.	.	Date of First Exposure to Treatment
31	TRTENDT	Num	8	9	DATE9.	.	Date of Last Exposure to Treatment
32	RFSTDTC	Char	19	19	$19.	.	Reference Start Date (char)
33	RFSTDT	Num	8	9	DATE9.	.	Reference Start Date
34	RFENDTC	Char	19	19	$19.	.	Reference End Date (char)
35	RFENDT	Num	8	9	DATE9.	.	Reference End Date
36	RFENDY	Num	8	8	8.	.	Reference End Day
37	ICDTC	Char	15	15	$15.	.	Informed Consent Date
38	ICDT	Num	8	9	DATE9.	.	Informed Consent Date - Numeric
39	ETERMSP	Char	200	200	$200.	.	Reason for terminating the study early
40	ETERMN	Num	8	10	BEST10.	.	Reason for terminating early, Numeric

Code for Demographic Table

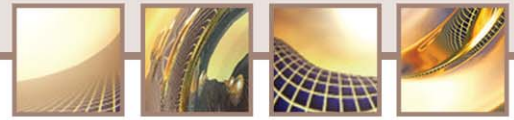
```
***  get ADSL data  *** ;
data demo ;
    set adsl ;
    where saffl='Y' ;
run ;

***  create means output   *** ;
proc means data=demo ;
   var age ;
   output out=demo1  n=n mean=mean  std=std median=median min=min max=max…
run  ;

 proc freq data=demo ;
      table trt1an * agecatn / list out=demo2 ;
 run;

proc freq data=demo ;
      table trt1an * sexn / list out=demo3 ;
 run;
 …

data final;
     set demo1 demo2 demo3  … ;
 run ;

***  after computations, format data as needed and print report  *** ;
```

ADaM “Basic” Data Structure

- Normalized design
- One record
  - Per subject +
  - Per analysis parameter +
  - Per analysis timepoint
- Will be used for the majority of analyses
- Similar to the SDTM Findings domain in structure
  - But NOT limited to findings data

ADaM “Basic” Data Structure Required Variables

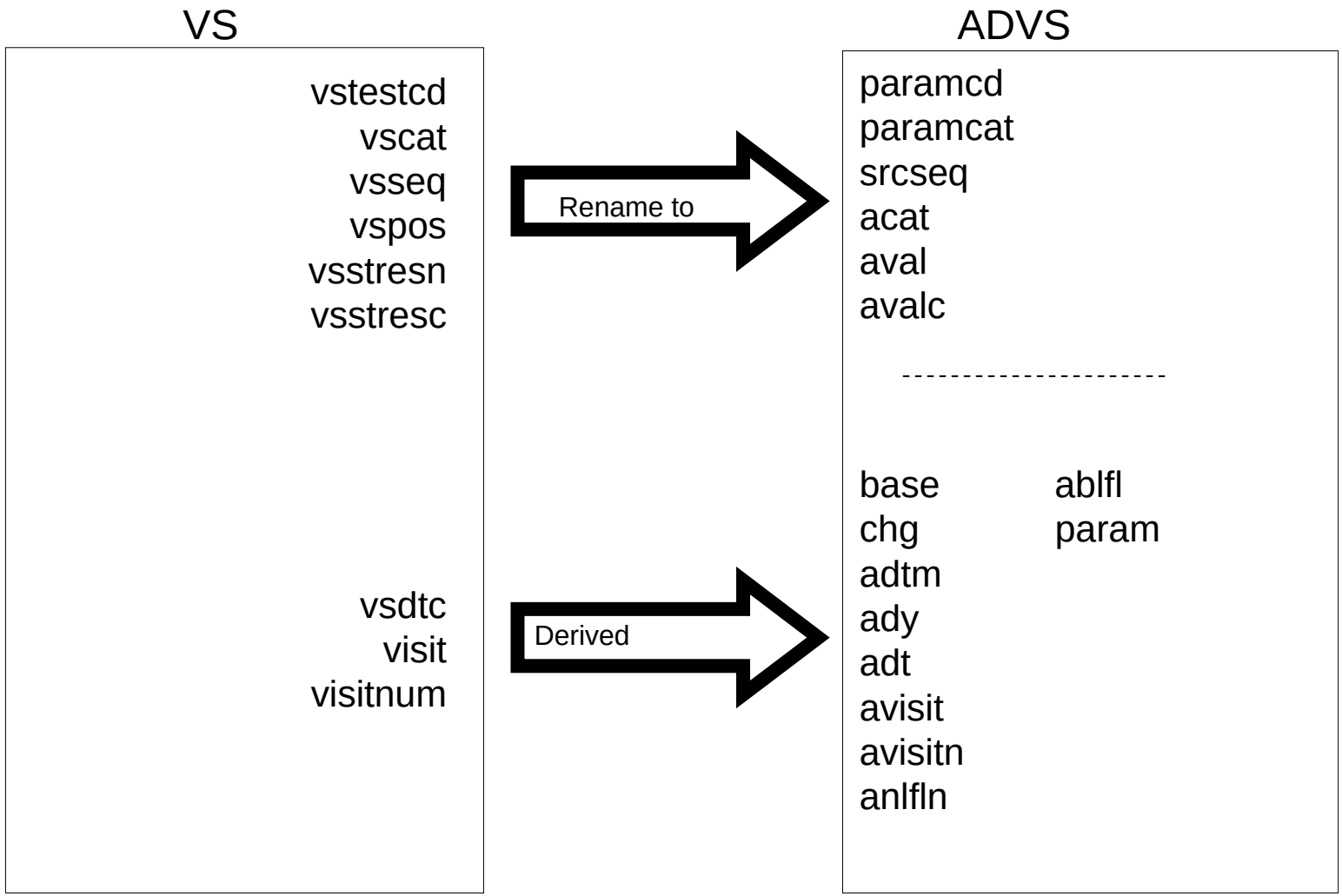
- Subject Identifier Variables
  - STUDYID
  - USUBJID
- Treatment Variables
  - TRTxP
  - TRTxPN
- Analysis Parameter Variables
  - PARAM
  - PARAMCD
  - AVAL and/or AVALC



ADaM “Basic” Data Structure Likely Variables

- Timing Variables
  - ADT (analysis date)
  - ADY (analysis relative day)
  - AVISIT (analysis timepoint description)
  - AVISITN (analysis timepoint number)
- Analysis Parameter Variables
  - BASE (baseline value)
  - CHG (change from baseline)
  - PCHG (percent change from baseline)
- Analysis Descriptor Variables
  - DTYPE (derivation type: LOCF, WOCF, AVERAGE, etc)
- Indicator Variables
  - ABLFL (baseline record flag)
  - ANLFL (analyzed record flag)

SDTM VS to ADVS



ADaM Basic Data Structure Example

	STUDYID	DOMAIN	USUBJID	SITEID	RANDFL	SAFFL	ITTFL	TRT1A	TRT1AN	PARAMCD	PARAM	PARAMCAT	ACAT	AVALC	AVAL	ABLFL	AVISIT	AVISI
1	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	1 Minute	STANDING	74	74		Screening	
2	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	5 Minute	SUPINE	76	76		Screening	
3	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	1 Minute	STANDING	68	68		Screening	
4	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	5 Minute	SUPINE	60	60		Screening	
5	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	RESP	Respirati			16	16		Screening	
6	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	1 Minute	STANDING	110	110		Screening	
7	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	5 Minute	SUPINE	116	116		Screening	
8	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	TEMP	Oral Temp			36.44	36.44		Screening	
9	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	BMI	Body Mass			24.31	24.31	Y	Day 1 (Ba	
10	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	1 Minute	STANDING	74	74	Y	Day 1 (Ba	
11	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	5 Minute	SUPINE	76	76	Y	Day 1 (Ba	
12	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	HT	Height (c			176.53	176.53	Y	Day 1 (Ba	
13	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	1 Minute	STANDING	74	74	Y	Day 1 (Ba	
14	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	5 Minute	SUPINE	56	56	Y	Day 1 (Ba	
15	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	RESP	Respirati			16	16	Y	Day 1 (Ba	
16	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	1 Minute	STANDING	110	110	Y	Day 1 (Ba	
17	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	5 Minute	SUPINE	120	120	Y	Day 1 (Ba	
18	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	TEMP	Oral Temp			36.44	36.44	Y	Day 1 (Ba	
19	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	WT	Weight (k			75.75	75.75	Y	Day 1 (Ba	
20	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	1 Minute	STANDING	72	72		Day 8	
21	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	5 Minute	SUPINE	76	76		Day 8	
22	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	1 Minute	STANDING	58	58		Day 8	
23	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	5 Minute	SUPINE	56	56		Day 8	
24	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	RESP	Respirati			16	16		Day 8	
25	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	1 Minute	STANDING	98	98		Day 8	
26	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	5 Minute	SUPINE	110	110		Day 8	
27	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	TEMP	Oral Temp			36.33	36.33		Day 8	
28	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	1 Minute	STANDING	60	60		Day 15	
29	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	5 Minute	SUPINE	68	68		Day 15	
30	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	1 Minute	STANDING	60	60		Day 15	
31	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	5 Minute	SUPINE	56	56		Day 15	
32	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	RESP	Respirati			16	16		Day 15	
33	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	1 Minute	STANDING	100	100		Day 15	
34	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	5 Minute	SUPINE	112	112		Day 15	
35	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	TEMP	Oral Temp			36.50	36.5		Day 15	
36	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	1 Minute	STANDING	60	60		Day 29	
37	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	DIABP	Diastolic	5 Minute	SUPINE	64	64		Day 29	
38	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	1 Minute	STANDING	58	58		Day 29	
39	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	PULSE	Pulse Rat	5 Minute	SUPINE	54	54		Day 29	
40	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	RESP	Respirati			16	16		Day 29	
41	STUDY - A	ADVS	001001	001	Y	Y	Y	Drug 40mg	2	SYSBP	Systolic	1 Minute	STANDING	96	96		Day 29	

Code For Vitals Signs Table

```
***  get vitals data needed for the table  *** ;
proc sort data=advs(keep=usubjid trt1an avisitn avisit paramcd acat aval chg saffl adt anlfl
                        where=(anlfl='Y' and saffl='Y' and adt^=.))
            out=vitals ;
   by usubjid avisitn paramcd acat ;
run ;

*** create means output for vitals result *** ;
proc means data=vitals ;
   var aval ;
   by paramcd avisitn avisit acat ;
   output out=vitals1  n=n mean=mean  std=std median=median min=min max=max…
run  ;

proc means data=vitals ;
   var chg ;
   by paramcd avisitn avisit acat ;
   output out=vitals2  n=n mean=mean  std=std median=median min=min max=max…
run  ;

data final ;
   set vitals1 vitals2 ;
run ;

***  after computations, format data as needed and print report  *** ;
```

Experience

- There is a learning curve moving to IG 1.0
  - Similar to CRF data to SDTM, there are certain types of data structures that don't "fit" the ADaM basic data structure clearly/cleanly
  - AEs, MH
- ADSL could become unwieldy with a large number of variables
- Certain SDTM structures are quite easy to move to ADaM IG 1.0 (i.e. VS, EG, LB datasets)
- ADaM basic data structure liked by programmers, not as much by statisticians/QC'ers
- Standards, Standards, Standards!!

References

- “Analysis Data Model: Version 2.1”, CDISC Analysis Dataset Modeling Team, 18DEC2007
- “ADaM Implementation Guide Version 1.0”, CDISC ADaM Team, 30MAY2008

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Questions?