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SDTM Basics for ADaM Dataset Creation

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Meet the Speakers



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- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*
- *This presentation is not showing the best practice but shows some variations in SDTM to think about how to create ADaM*
- *The content of this presentation is based on the personal views of the presenters and does not represent the views of the company to which the presenters belong.*



Agenda

1. SDTM and ADaM
2. Make sure to check units in SDTM
3. Unscheduled visits in SDTM
4. Similar variables in SDTM and ADaM
5. Conclusion

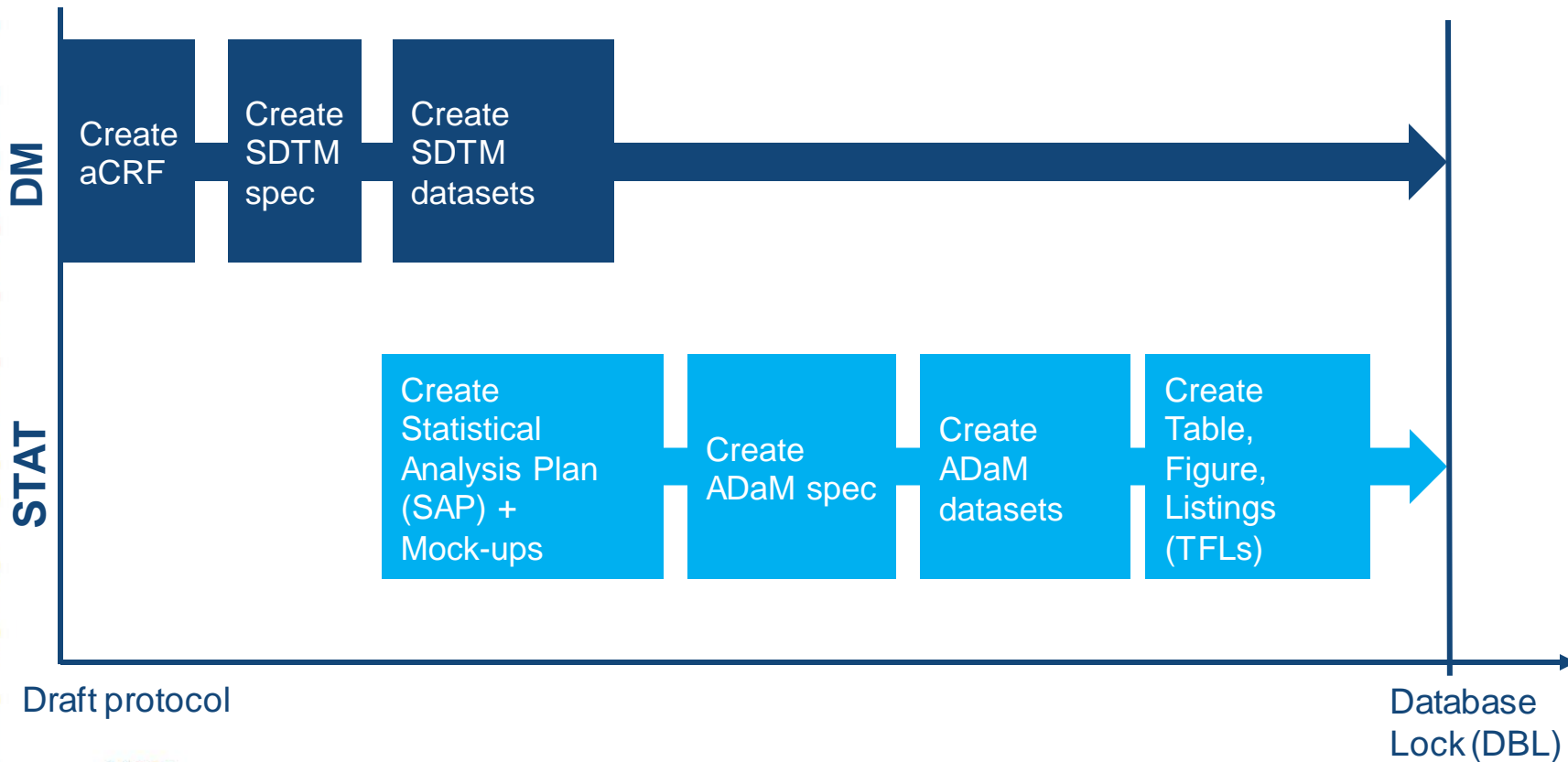
SDTM and ADaM



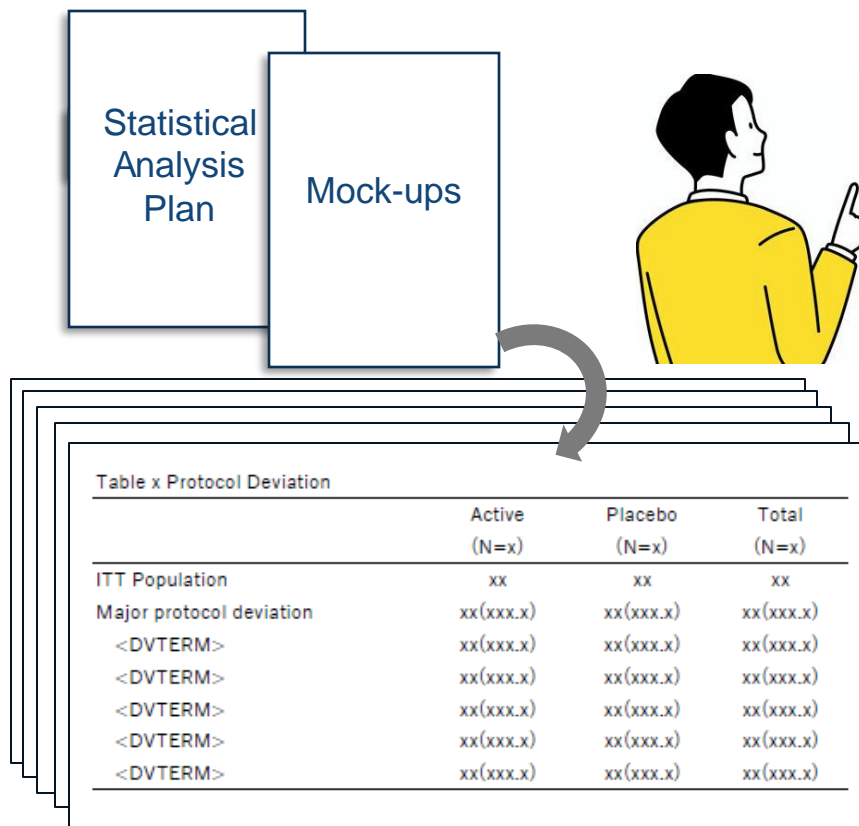
- **Study Data Tabulation Model (SDTM)** provides a standard for organizing and formatting data to streamline processes in collection, management, analysis, and reporting.
- **Analysis Data Model (ADaM)** defines dataset and metadata standards that support:
 - Efficient generation, replication, and review of clinical trial statistical analyses
 - Traceability between analysis results, analysis data, and data represented in SDTM

<https://www.cdisc.org/standards/foundational>

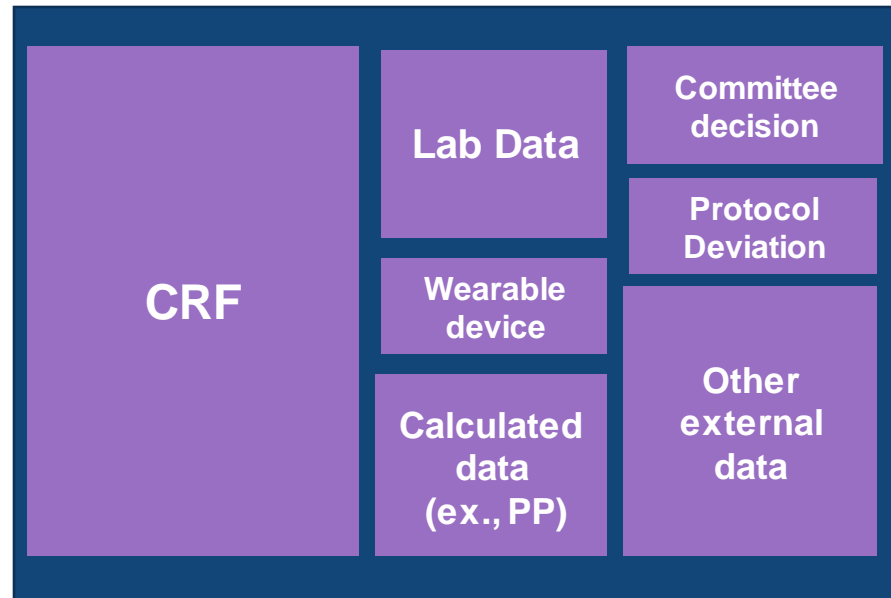
General Process Flow before DBL



SDTM → ADaM



SDTM





Make sure to check units in SDTM

Make sure to check units in SDTM

LB domain

LBTEST	LBORRES	LBORRESU	LBSTRESN	LBSTRESU	LBNAM
Calcium	4.688	mEq/L	2.3441	mmol/L	Hospital A
Calcium	4.986	mEq/L	2.4938	mmol/L	Hospital A
Calcium	9.695	mg/dL	2.4189	mmol/L	Hospital B
Calcium	9.595	mg/dL	2.394	mmol/L	Hospital B

Mock-up

Calcium (mg/dL)	Active	Placebo
Baseline		
N	x	x
Mean (SD)	x.xx (x.xxx)	x.x (x.xxx)
Median	x.xx	x.xx
Min, Max	x.xx, x.xx	x.xx, x.xx
<Visit>		
N	x	x
Mean (SD)	x.xx (x.xxx)	x.x (x.xxx)
Median	x.xx	x.xx
Min, Max	x.xx, x.xx	x.xx, x.xx

2 Examples

1: Create a row for the value in the needed units and make **--DRVFL =Y**

LB domain

LBTEST	LBORRES	LBORRESU	LBSTRESN	LBSTRESU	LBDRVFL	VISIT	LBNAM
Calcium	4.688	mEq/L	2.3441	mmol/L		Week 1	Hospital A
Calcium			9.3947	mg/dL	Y	Week 1	Hospital A
Calcium	4.986	mEq/L	2.4938	mmol/L		Week 2	Hospital A
Calcium			9.9955	mg/dL	Y	Week 2	Hospital A
Calcium	9.695	mg/dL	2.4189	mmol/L		Week 1	Hospital B
Calcium			9.695	mg/dL	Y	Week 1	Hospital B
Calcium	9.595	mg/dL	2.394	mmol/L		Week 2	Hospital B
Calcium			9.595	mg/dL	Y	Week 2	Hospital B

2 Examples

2: Create a SUPP domain and store the value in the needed units

LB domain

LBSEQ	LBTEST	LBORRES	LBORRESU	LBSTRESN	LBSTRESU	LBNAM
1	Calcium	4.688	mEq/L	2.3441	mmol/L	Hospital A
2	Calcium	4.986	mEq/L	2.4938	mmol/L	Hospital A
3	Calcium	9.695	mg/dL	2.4189	mmol/L	Hospital B
4	Calcium	9.595	mg/dL	2.394	mmol/L	Hospital B

SUPPLB domain

RDOMAIN	IDVAR	IDVARVAL	QNAM	QLABEL	QVAL
LB	LBSEQ	1	LBCNRES	Result in conventional unit	9.3947
LB	LBSEQ	1	LBCNRESU	Conventional unit	mg/dL
LB	LBSEQ	2	LBCNRES	Result in conventional unit	9.9955
LB	LBSEQ	2	LBCNRESU	Conventional unit	mg/dL
LB	LBSEQ	3	LBCNRES	Result in conventional unit	9.695
LB	LBSEQ	3	LBCNRESU	Conventional unit	mg/dL
LB	LBSEQ	4	LBCNRES	Result in conventional unit	9.595
LB	LBSEQ	4	LBCNRESU	Conventional unit	mg/dL

Another option

- Convert units in ADaM

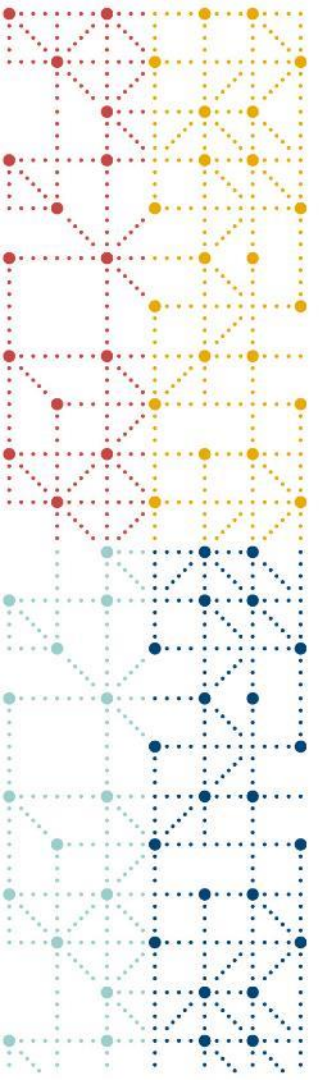
ADLB

PARAM	PARAMCD	AVAL
Parameter	Parameter Code	Analysis Value
Calcium (mg/dL)	CA	9.3947
Calcium (mg/dL)	CA	9.9955
Calcium (mg/dL)	CA	9.6949
Calcium (mg/dL)	CA	9.5947



Make sure to check units in SDTM

- Find out if the units of values that are stored in SDTM are matching with the ones defined in SAP.
- If not, discuss with those who create SDTM how values of different units would be stored in SDTM.
- Decide that values in SDTM can be simply copied to ADaM without unit conversion or units of values have to be converted in ADaM.



Unscheduled visits in SDTM

How unscheduled visits are populated in SDTM?

Subject 1111
VISIT1
Unscheduled Visit
Unscheduled Visit
VISIT2
VISIT3
Unscheduled Visit



SDTM

VISITNUM	VISIT	LBDMC
1	VISIT1	2022-04-01
999	UNSCHEDULED	2022-04-02
999	UNSCHEDULED	2022-04-02
2	VISIT2	2022-04-08
3	VISIT3	2022-04-15
999	UNSCHEDULED	2022-04-15

Same values are populated for all UNSCHEDULED for VISITNUM

- Provides no differentiation between the unplanned visits
- Chronological sorting is hard

How unscheduled visits are populated in SDTM?

Subject 1111
VISIT1
Unscheduled Visit
Unscheduled Visit
VISIT2
VISIT3
Unscheduled Visit



SDTM

VISITNUM	VISIT	LBDTC
1	VISIT1	2022-04-01
1.01	VISIT1 Unscheduled 1	2022-04-02
1.02	VISIT1 Unscheduled 2	2022-04-02
2	VISIT2	2022-04-08
3	VISIT3	2022-04-15
3.01	VISIT3 Unscheduled 1	2022-04-15

a one-to-one relationship between visits and values of VISITNUM that are consistent across domains

VISIT&VISITNUM are referred for creating analysis visits

VISITNUM	VISIT	AVISITN	AVISIT	ADT	ADY	ANL01FL
1	VISIT1	1	VISIT1	2022-04-01	7	Y
1.01	VISIT1 Unscheduled 1	1	VISIT1	2022-04-02	8	
1.02	VISIT1 Unscheduled 2	1	VISIT1	2022-04-02	8	
2	VISIT2	2	VISIT2	2022-04-08	15	Y
3	VISIT3	3	VISIT3	2022-04-15	23	Y
3.01	VISIT3 Unscheduled 1	3	VISIT3	2022-04-15	23	



Similar variables in SDTM and ADaM

Timing Variables in ADaM

- Variable names start with letter A are directly associated with AVAL/AVALC

Example:

ADT	Analysis Date
ADTM	Analysis Datetime
ADY	Analysis Relative Day
ASTDT AENDT	Analysis Start Date Analysis End Date
ASTDY AENDY	Analysis Start Relative Day Analysis End Relative Day

- Supportive timing variables

ADY and --DY

ADY=Number of days from a reference date to ADT, directly related to AVAL or AVALC.

AVISIT	AVISITN	ADT	ADY	AVAL	ANL01FL	TRTSDT
Baseline	0	2022-03-18	-14	50.0	Y	2022-04-01
VISIT1	1	2022-04-08	8	45.4	Y	2022-04-01
VISIT2	2	2022-04-15	15	46.3	Y	2022-04-01
VISIT3	3	2022-04-22	22	55.1	Y	2022-04-01
VISIT3	3	2022-04-23	23	54.6		2022-04-01
VISIT4	4	2022-04-29	29	50.3	Y	2022-04-01

If $ADT < TRTSDT$ then $ADY = ADT - TRTSDT$
else if $ADT \geq TRTSDT$ then $ADY = ADT - TRTSDT + 1$

$2022/04/08 - 2022/04/01 + 1 = 8$

ADY and --DY

SDTM variable: **--DY** = Actual study day of visit/collection/exam expressed in integer days relative to the sponsor-defined DM.RFSTDTC.

VISITNUM	VISIT	LB DTC	LB DY
0	SCREENING	2022-03-18	-14
1	VISIT1	2022-04-08	8
2	VISIT2	2022-04-15	15
3	VISIT3	2022-04-22	22
3	VISIT3	2022-04-23	23
4	VISIT4	2022-04-29	29

Suppose DM.RFSTDTC=TRTSDT then the calculation is the same as ADY

Check SDTM anchor date

AVISIT	AVISITN	ADT	ADY	AVAL	ANL01FL	TRTSDT
Baseline	0	2022-03-18	-14	50.0	Y	2022-04-01
VISIT1	1	2022-04-08	8	45.4	Y	2022-04-01
VISIT2	2	2022-04-15	15	46.3	Y	2022-04-01
VISIT3	3	2022-04-22	22	55.1	Y	2022-04-01
VISIT3	3	2022-04-23	23	54.6		2022-04-01
VISIT4	4	2022-04-29	29	50.3	Y	2022-04-01

VISITNUM	VISIT	LBDTC	LBDY
0	SCREENING	2022-03-18	-14
1	VISIT1	2022-04-08	8
2	VISIT2	2022-04-15	15
3	VISIT3	2022-04-22	22
3	VISIT3	2022-04-23	23
4	VISIT4	2022-04-29	29

ADY and LBDY may have the same values

ADY and --DY

- ADaM relative day variables need not be anchored by DM.RFSTDTC.

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
ADY		Analysis Relative Day	integer	8		Derived (Source: Sponsor) ADY = ADT - TRTSDT + 1, if ADT >= TRTSDT. ADY = ADT - TRTSDT, if ADT < TRTSDT.

Variable	Where Condition	Label / Description	Type	Length or Display Format	Controlled Terms or ISO Format	Origin / Source / Method / Comment
ADY		Analysis Relative Day	integer	8		Predecessor: LB.LBDY

Similar variables in SDTM and ADaM

SDTM	
--BLFL	Baseline Flag
--DY	Study Day of Visit/Collection/Exam

ADaM	
ABLFL	Baseline Record Flag
ADY	Analysis Relative Day

AVISIT	AVISITN	ADT	ADY	ANL01FL	ABLFL	AVAL	BASE
Baseline	0	2022-03-18	-15	Y	Y	50.0	50.0
VISIT1	1	2022-04-08	8	Y		52.1	50.0
VISIT2	2	2022-04-15	15	Y		53.2	50.0
VISIT3	3	2022-04-22	22	Y		55.5	50.0
VISIT3	3	2022-04-23	23			54.3	50.0
VISIT4	4	2022-04-29	29	Y		54.2	50.0

Variable	Label / Description	Type	Length or Display Format	Origin / Source / Method / Comment
ADY	Analysis Relative Day	integer	8	Predecessor: LB.LBDY
BASE	Baseline Value	float	8	Derived: AVAL where ABLFL=Y
ABLFL	Baseline Record Flag	text	1	Predecessor: LB.LBBLFL

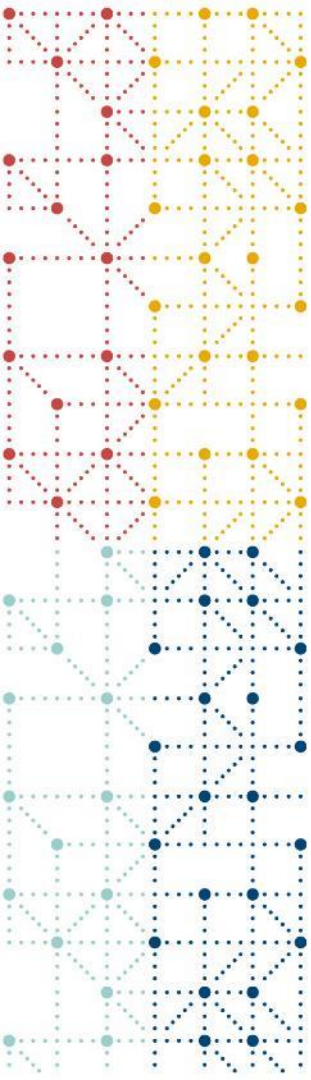
Similar variables in SDTM and ADaM

- Know that there are similar variables in SDTM and ADaM and know the specification of those variables in the studies.
- Check the specification of those variables and decide if values can be copied to ADaM or derivation is necessary for analysis variables.



Conclusion

- Since ADaM datasets are created based on SDTM datasets, it is important for those who create ADaM to know what the structures of datasets would be or how certain values would be populated or derived in SDTM beforehand.
- If certain items are missing or modification is necessary, it should be addressed at the time of SDTM creation so that successful and efficient creation of ADaM datasets are guaranteed.



Thank You!

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