Advanced SDTM / ADaM : Case Studies and Practical Applications

Presented by Dr. Eunhye Lee, Associate STAT Director,
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Meet the Speaker

Eunhye Lee

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Eunhye Lee is the Associate STAT Director at LSK Global PS, Korea's CRO. With over 16 years of experience as a biostatistician, she has more than 10 years of expertise in CDISC SDTM/ADaM for clinical trials and currently manages the LSK CDISC Parts.

She holds a BA in Mathematics and Statistics from Sungkyunkwan University, as well as an MS and Ph.D. in Biostatistics and Computing from Yonsei University.

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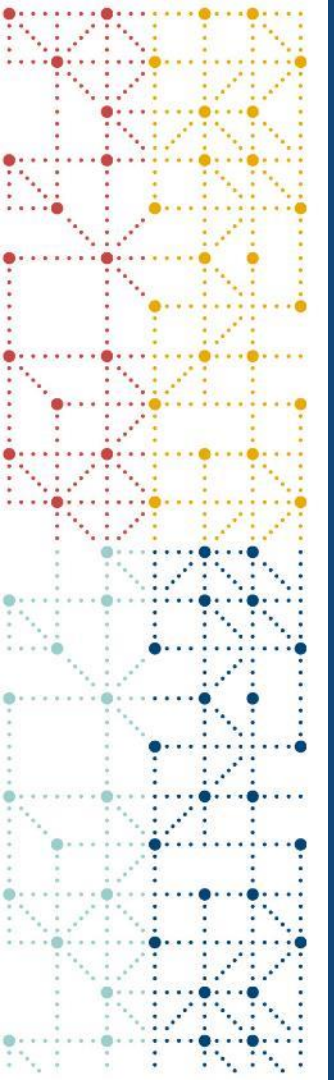
- *The views and opinions expressed in this presentation are those of the author and do not necessarily reflect the official policy or position of CDISC.*

Agenda

1. CDISC for Complex Study Designs
   - SDTM Trial Design
   - ADaM Period Variables
2. Case Study
   - TDM Example
   - Crossover Trial



CDISC for Complex Study Design

SDTM - Trial Design Model

ADaM - Period Variable

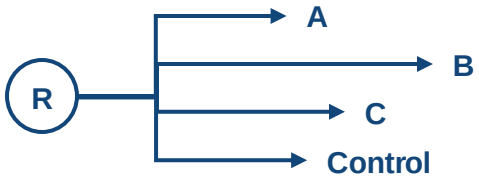
Complex Study Designs

- A clinical study can follow multiple masking techniques and/or multiple interventions based on conditional treatment assignment
  - Double-blind / Single-blind / Open-label
  - Multiple interventions / Sequential interventions / Combination therapies
  - Adaptive designs / Multi-arm studies
- The FDA needs a clear view of complex trial designs to make sure the design is appropriate and the data is valid for the trial's objectives.
- The Trial Design Model (TDM) in the SDTM provides a standardized way to describe the features of a clinical trial.

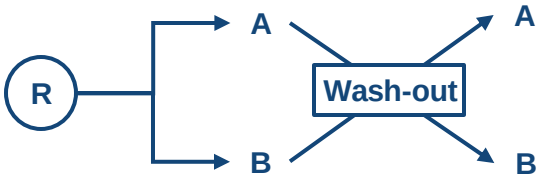
Complex Study Designs

Parallel study design

Double blind *Open label*



Adaptive or SMART study designs

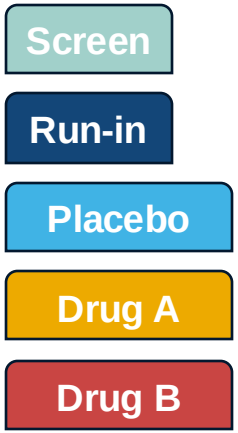


Crossover study designs

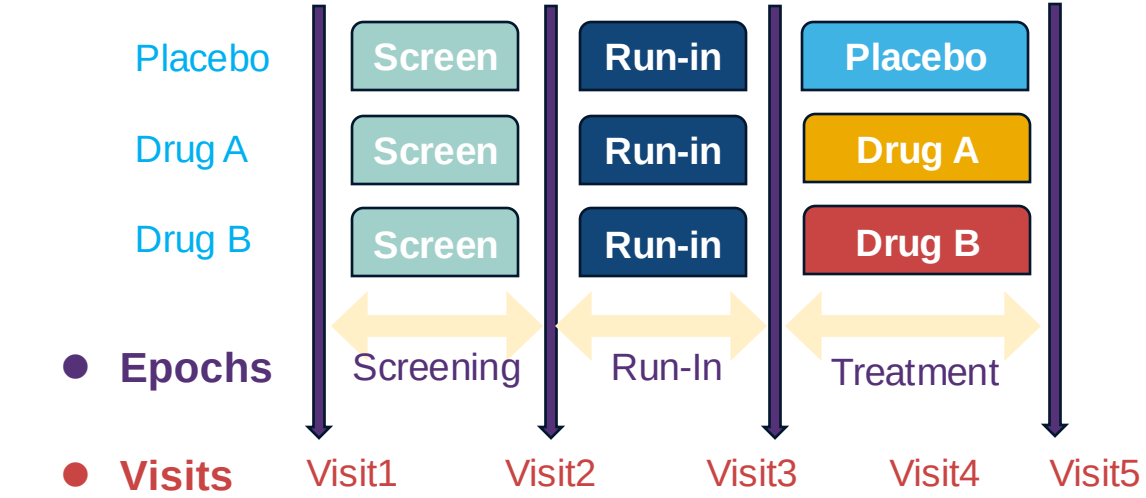
Trial Design Model (TDM)

- The Trial Design Model (TDM) is built on the concepts and identification of Elements, Arms, Epochs, and Visits

- **Elements**



- **Arms**
- **Epochs**
- **Visits**



Trial Design Model (TDM) Domain in SDTM

It is sensible to create the **TE**, followed by **TA** and **TV.**

- **TE (Elements)**

DOMAIN	ETCD	ELEMENT
TE	SCRN	Screen
TE	RUNIN	Run-in
TE	PLAC	Placebo
TE	DRUGA	Drug A
TE	DRUGB	Drug B

- **TA (Arms/Elements/Epoch)**

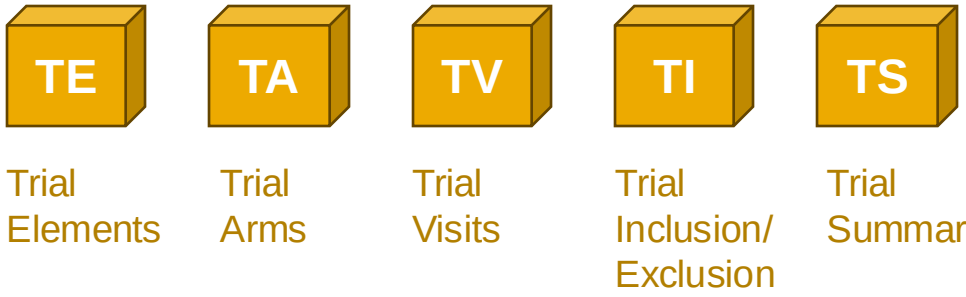
DOMAIN	ARMCD	ARM	ETCD	EPOCH
TA	DRUGA	Drug A	SCRN	SCREENING
TA	DRUGA	Drug A	RUNIN	RUN-IN
TA	DRUGA	Drug A	DRUGA	TREATMENT
TA	DRUGB	Drug B	SCRN	SCREENING
TA	DRUGB	Drug B	RUNIN	RUN-IN
TA	DRUGB	Drug B	DRUGB	TREATMENT
TA	PLAC	PLACEBO	…	…

- **TV (Visit)**

DOMAIN	VISITNUM	VISIT
TV	1	Visit 1
TV	2	Visit 2
TV	3	Visit 3
TV	4	Visit 4
TV	5	Visit 5

Trial Design Model (TDM) in SDTM

- TDM domain is a special purpose data set, which provides the clear description about the study design but do not contain subject data.



- Creating Trial Design Datasets for complex study designs can be *challenging* because they are being created retrospectively from the **protocol**.

.. Constructing the Trial design datasets is more a matter of **ART** than it is pure Science ..

(Wood and Lenzen, 2011)

SDTM TDM in Crossover Trial

- **Elements**

Screen

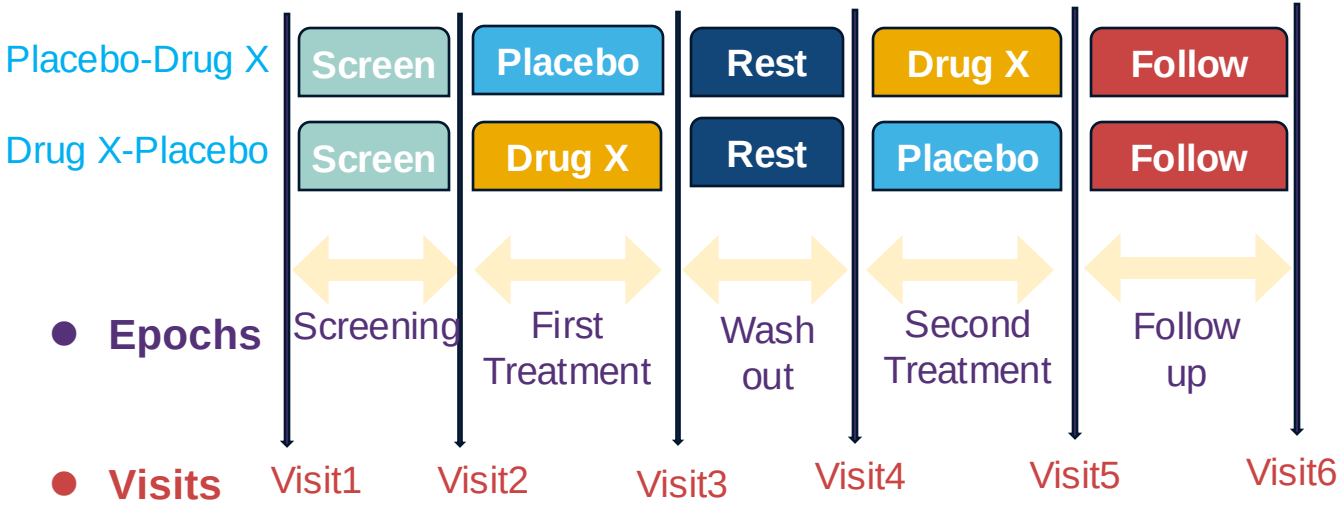
Rest

Placebo

Drug X

Follow

- **Arms**



SDTM TDM in Crossover Trial

- **TE (Elements)**

DOMAIN	ETCD	ELEMENT
TE	SCRN	Screen
TE	REST	Rest
TE	PLAC	Placebo
TE	DRUGX	Drug X
TE	FU	Follow-up

- **TA (Arms/Elements/Epoch)**

DOMAIN	ARMCD	ARM	ETCD	EPOCH
TA	P-D	Placebo-Drug X	SCRN	SCREENING
TA	P-D	Placebo-Drug X	PLAC	TREATMENT1
TA	P-D	Placebo-Drug X	REST	WASHOUT
TA	P-D	Placebo-Drug X	DRUGX	TREATMENT2
TA	P-D	Placebo-Drug X	FU	FOLLOW-UP
TA	D-P	Drug X-Placebo	SCRN	SCREENING
TA	D-P	Drug X-Placebo	DRUGX	TREATMENT1
TA	…	…	…	...

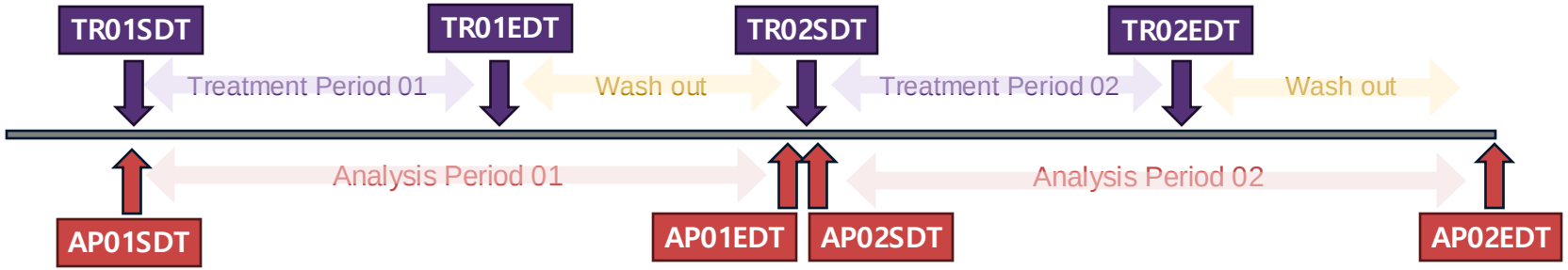
- **TV (Visit)**

DOMAIN	VISITNUM	VISIT
TV	1	Visit 1
TV	2	Visit 2
TV	3	Visit 3
TV	4	Visit 4
TV	5	Visit 5
TV	6	Visit 6

ADaM Variables in Crossover Trial

- **Treatment and Date Variables in ADSL**
  - TRTSEQP, TRTSEQA
  - TRT01P, TRT02P, TRT01A, TRT02A
  - TR01SDT, TR01EDT, TR02SDT, TR02EDT

USUBJID	TRTSEQP	TRT01P	TRT02P
1001	**Placebo-Drug X**	Placebo	Drug X



TR01SDT	TR01EDT	TR02SDT	TR02EDT	AP01SDT	AP01EDT	AP02SDT	AP02EDT

ADaM Variables in Crossover Trial

- **Analysis Period Variables**
  - APERIOD, APERIODC, ASPER, ASPERC
  - AP01SDT, AP01EDT, AP02SDT, AP02EDT in ADSL
- **Analysis Phase Variables**
  - APHASE ：Similar concept to EPOCH in SDTM
  - PH1SDT, PH2EDT in ADSL, PHSDT, PHEDT in non-ADSL

Variable	Variable Values							
APHASE	Screening	Treatment						Follow-up
APHASEN	1	2						3
APERIOD		1			2			
APERIODC		Crossover Period 1			Crossover Period 2			
ASPER		1	2	3	1	2	3	
ASPERC		Escalation	Maintenance	De-escalation	Escalation	Maintenance	De-escalation	

Case Study

TDM Example

Crossover Trial

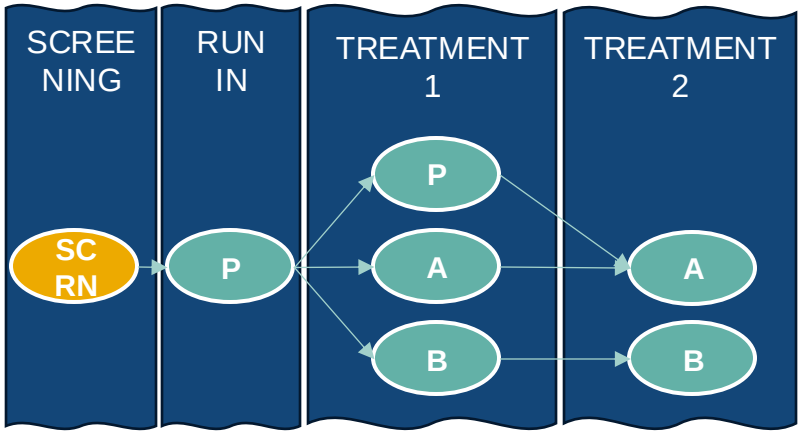
TDM Example 1

- TA (Arms/Elements/Epoch)

DOMAIN	ARMCD	ARM	TAETORD	ETCD	EPOCH
TA	P-A	Placebo-DrugA	1	SCRN	SCREENING
TA	P-A	Placebo-DrugA	2	P	RUN-IN
TA	P-A	Placebo-DrugA	3	P	TREATMENT1
TA	P-A	Placebo-DrugA	4	A	TREATMENT2
TA	A-A	DrugA-DrugA	1	SCRN	SCREENING
TA	A-A	DrugA-DrugA	2	P	RUN-IN
TA	A-A	DrugA-DrugA	3	A	TREATMENT1
TA	A-A	DrugA-DrugA	4	A	TREATMENT2
TA	B-B	DrugB-DrugB	1	SCRN	SCREENING
TA	B-B	DrugB-DrugB	2	P	RUN-IN
TA	B-B	DrugB-DrugB	3	B	TREATMENT1
TA	B-B	DrugB-DrugB	4	B	TREATMENT2

- TE (Elements)

DOMAIN	ETCD	ELEMENT
TE	SCRN	Screen
TE	P	Placebo
TE	A	DrugA
TE	B	DrugB



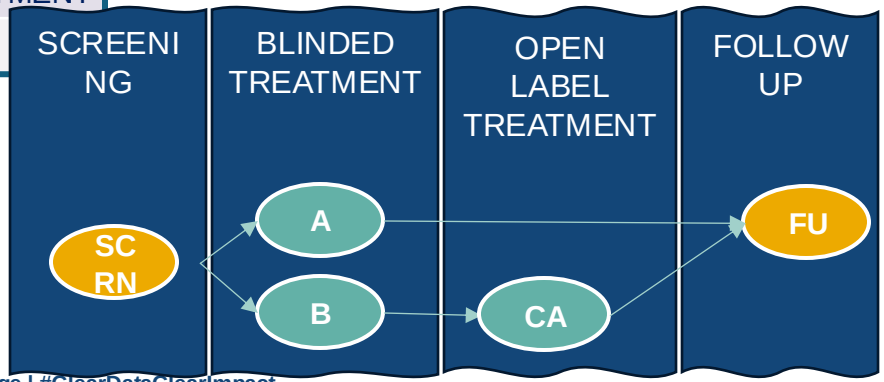
TDM Example 2

- **TA (Arms/Elements/Epoch)**

DOMAIN	ARMCD	ARM	TAETORD	ETCD	EPOCH
TA	A	DrugA	1	SCRN	SCREENING
TA	A	DrugA	2	A	BLINDED TREATMENT
TA	A	DrugA	5	FU	FOLLOW-UP
TA	B	DrugB	1	SCRN	SCREENING
TA	B	DrugB	2	B	BLINDED TREATMENT
TA	B	DrugB	4	CA	OPEN LABEL TREATMENT
TA	B	DrugB	5	FU	FOLLOW-UP

- **TE (Elements)**

DOMAIN	ETCD	ELEMENT
TE	SCRN	Screening
TE	A	DrugA
TE	B	DrugB
TE	CA	Open Label DrugA
TE	FU	Follow-up

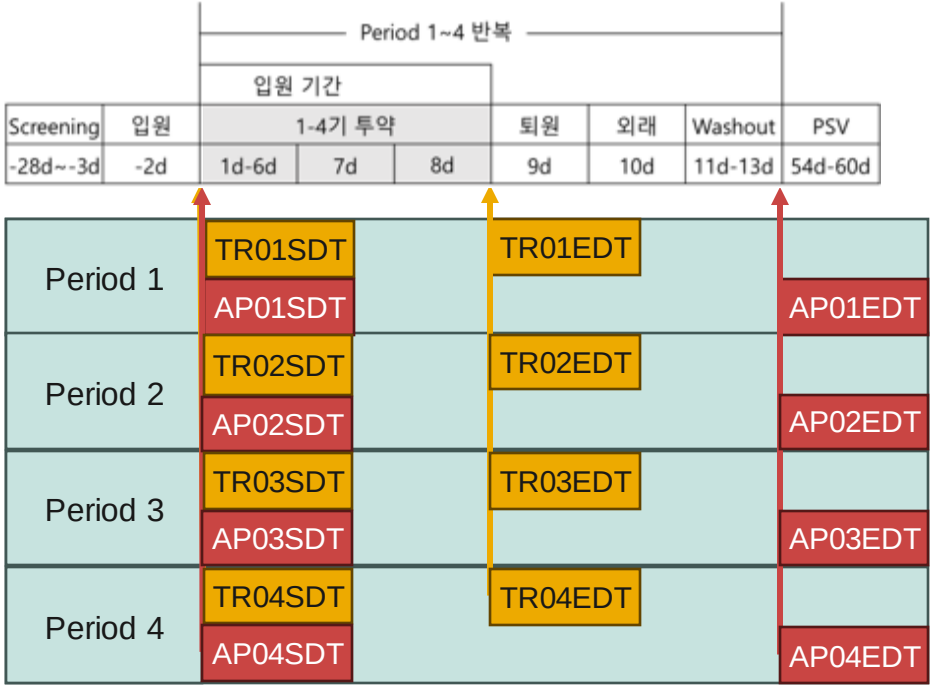


Crossover Trial – Example 1

- **Study Design** – open label, multiple dose, 4-sequence, 4-period
-

	Period 1	Period 2	Period 3	Period 4
Sequence 1	A	B	D	C
Sequence 2	B	C	A	D
Sequence 3	C	D	B	A
Sequence 4	D	A	C	B

- Number of subjects in each sequence = 6
- Total number of subjects = 24



Crossover Trial – Example 1

- **Analysis Result** - Demographic

TABLE 14.1.3
Demographic and Baseline Characteristics
Randomized Set

	Sequence 1 (A→B→D→C) (N=6)	Sequence 2 (B→C→A→D) (N=6)	Sequence 3 (C→D→B→A) (N=6)	Sequence 4 (D→A→C→B) (N=6)	Total (N=24)
Age (years)					
n	6	6	6	6	24
Mean(SD)	30.00(2.90)	27.83(4.36)	27.67(4.84)	32.00(6.36)	29.38(4.81)
Median	29.00	27.00	27.50	30.50	28.50
Min, Max	27.00, 34.00	23.00, 33.00	22.00, 34.00	24.00, 41.00	22.00, 41.00
P-value [1]					0.3712 (a)
Smoking History, n(%)					
Non-Smoker	3(50.00)	6(100.00)	6(100.00)	6(100.00)	21(87.50)
Smoker	0	0	0	0	0
Ex-Smoker	3(50.00)	0	0	0	3(12.50)
P-value [2]					0.0395 (f)

- **ADaM** – ADSL

SUBJID	TRTSEQP	TRT01P	TRT02P	TRT03P	TRT04P
S001	ABDC	A	B	D	C
S002	CDBA	C	D	B	A
S003	BCAD	B	C	A	D
S004	DACB	D	A	C	B

TR01SDT	TR01EDT	TR02SDT	...	TR04EDT

Treatment Date Variables

AP01SDT	AP01EDT	AP02SDT	...	AP04EDT

Analysis Period Variables

Crossover Trial – Example 1

- **Analysis Result** – Adverse Events

TABLE 14.2.1
Overall Summary of TEAEs
Safety Set

	Group A (N=24)	Group B (N=24)	Group C (N=24)	Group D (N=24)	Total (N=96)
Subjects with TEAEs	4(16.67) [8]	8(33.33) [12]	7(29.17) [16]	4(16.67) [5]	23(23.96) [41]
95% Confidence Interval	[1.76, 31.58]	[14.47, 52.19]	[10.98, 47.35]	[1.76, 31.58]	[15.42, 32.50]
P-value					0.3516
Intensity					
Mild	7	11	15	5	38
Moderate	1	1	1	0	3
Severe	0	0	0	0	0
Relationship to Study Drug					
Definitely related	0	0	0	0	0
Probably related	2	6	3	1	12
Possibly related	3	3	6	2	14
Definitely not related, None	3	3	7	2	15
Unknown, Unassessable	0	0	0	0	0
Subjects with Serious TEAEs	0	0	0	0	0
Exact 95% Confidence Interval	[0.00, 14.25]	[0.00, 14.25]	[0.00, 14.25]	[0.00, 14.25]	[0.00, 3.77]

- Period and Treatment Group

	Period 1	Period 2	Period 3	Period 4
Sequence 1	A	B	D	C
Sequence 2	B	C	A	D
Sequence 3	C	D	B	A
Sequence 4	D	A	C	B

Group A : A

- **TEAEs in Each Group** :
An adverse event that occurs the same as or later than the first IP administration date/time in the corresponding Treatment Group Period and before first IP administration date/time in the subsequent Period.

Crossover Trial – Example 1

- **ADaM** – ADAE (Occurrence Data Structure)

ADaM ADSL | *SDTM AE* | *ADaM ADAE Derived Variables*

SUBJID	TRTSEQA	TRT01A	TRT02A	TRT03A	TRT04A	AP01SDT	AP02SDT	AP03SDT	...	AESEQ	AEDECOD	ASTDT	TRTA	APERIOD	APERIODC	TRTEMFL
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01		1	Fever	2020-01-04	**A**	**1**	**Period 1**	Y
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01		2	Headache	2020-01-20	**B**	**2**	**Period 2**	Y
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01		3	Pruritus	2020-01-27	**B**	**2**	**Period 2**	Y
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01		4	Skin mass	2020-02-04	**D**	**3**	**Period 3**	Y

VARIABLE_NAME	VARIABLE_LABEL	DERIVATION
ASTDT	Analysis Start Date	Convert AESTDTC to numeric format
TRTA	Actual Treatment	Set to **TRT01A** if AP01SDT<=**ASTDT**<=AP01EDT Set to **TRT02A** if AP02SDT<=**ASTDT**<=AP02EDT Set to **TRT03A** if AP03SDT<=**ASTDT**<=AP03EDT Set to **TRT04A** if AP04SDT<=**ASTDT**<=AP04EDT
TRTEMFL	Treatment Emergent Flag	Set to 'Y' on the events where AP01SDT<=ASTDT<=AP01EDT or AP02SDT<=ASTDT<=AP02EDT or AP03SDT<=ASTDT<=AP03EDT or AP04SDT<=ASTDT<=AP04EDT Else set to 'N'

Crossover Trial – Example 1

- **ADaM** – ADAEDIFF (Basic Data Structure)

To assess the adverse events ***difference between treatment groups***,

we can use GENMOD procedure using generalized estimating equations (GEE) and GLIMMIX procedure using generalized liner random models.

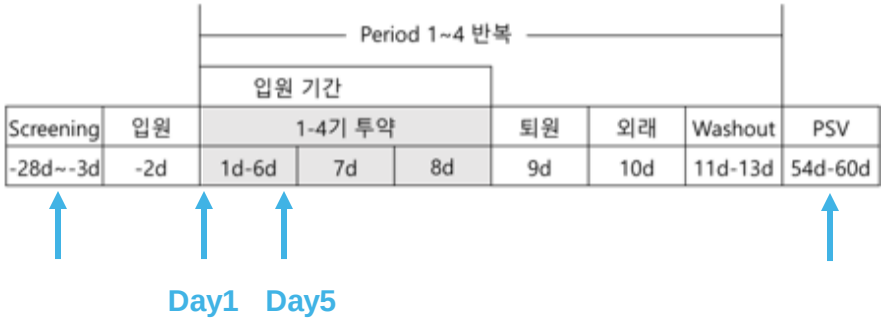
SUBJID	APERIOD	TRTSEQP	TRTA	CARRY	AVAL	AVALC
S001	1	ABDC	A	Z	0	Not Occurred
S001	2	ABDC	B	A	0	Not Occurred
S001	3	ABDC	D	B	0	Not Occurred
S001	4	ABDC	C	D	1	Occurred
S002	1	CDBA	C	Z	0	Not Occurred
S002	2	CDBA	D	C	1	Occurred
S002	3	CDBA	B	D	0	Not Occurred
S002	4	CDBA	A	B	0	Not Occurred
S003	1	BCAD	B	Z	0	Not Occurred
S003	2	BCAD	C	B	0	Not Occurred
S003	3	BCAD	A	C	0	Not Occurred
S003	4	BCAD	D	A	0	Not Occurred
S004	1	DACB	D	Z	0	Not Occurred
S004	2	DACB	A	D	0	Not Occurred
S004	3	DACB	C	A	0	Not Occurred
S004	4	DACB	B	C	1	Occurred

Crossover Trial – Example 1

- **Analysis Result** – Laboratory

TABLE 14.2.16
Summary of Hematology Tests
Safety Set
[RBC]

	Group A (N=24)	Group B (N=24)	Group C (N=24)	Group D (N=24)	Total (N=96)
Screening					
n					24
Mean(SD)					5.170(0.284)
Median					5.195
Min, Max					4.510, 5.820
Day 1, Pre-dose 0 hour (Baseline)					
n	24	24	24	24	96
Mean(SD)	4.875(0.318)	4.823(0.374)	4.820(0.404)	4.794(0.366)	4.828(0.362)
Median	4.875	4.760	4.840	4.755	4.825
Min, Max	4.120, 5.490	4.010, 5.700	4.100, 5.850	4.240, 5.510	4.010, 5.850
Day 5, Pre-dose 0 hour					
n	24	24	24	24	96
Mean(SD)	4.772(0.294)	4.783(0.240)	4.843(0.394)	4.850(0.313)	4.812(0.312)
Median	4.790	4.795	4.835	4.890	4.820
Min, Max	4.110, 5.430	4.160, 5.250	3.980, 5.750	4.280, 5.430	3.980, 5.750
Post-Study Visit					
n					24
Mean(SD)					4.365(0.259)
Median					4.340
Min, Max					3.870, 4.860



Crossover Trial – Example 1

- **ADaM** – ADLB (Basic Data Structure)

ADaM ADSL

SUBJID	TRTSEQA	TRT01A	TRT02A	TRT03A	TRT04A	AP01SDT	AP02SDT	AP03SDT	…
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	
S001	ABDC	A	B	D	C	2020-01-02	2020-01-17	2020-02-01	

SDTM LB

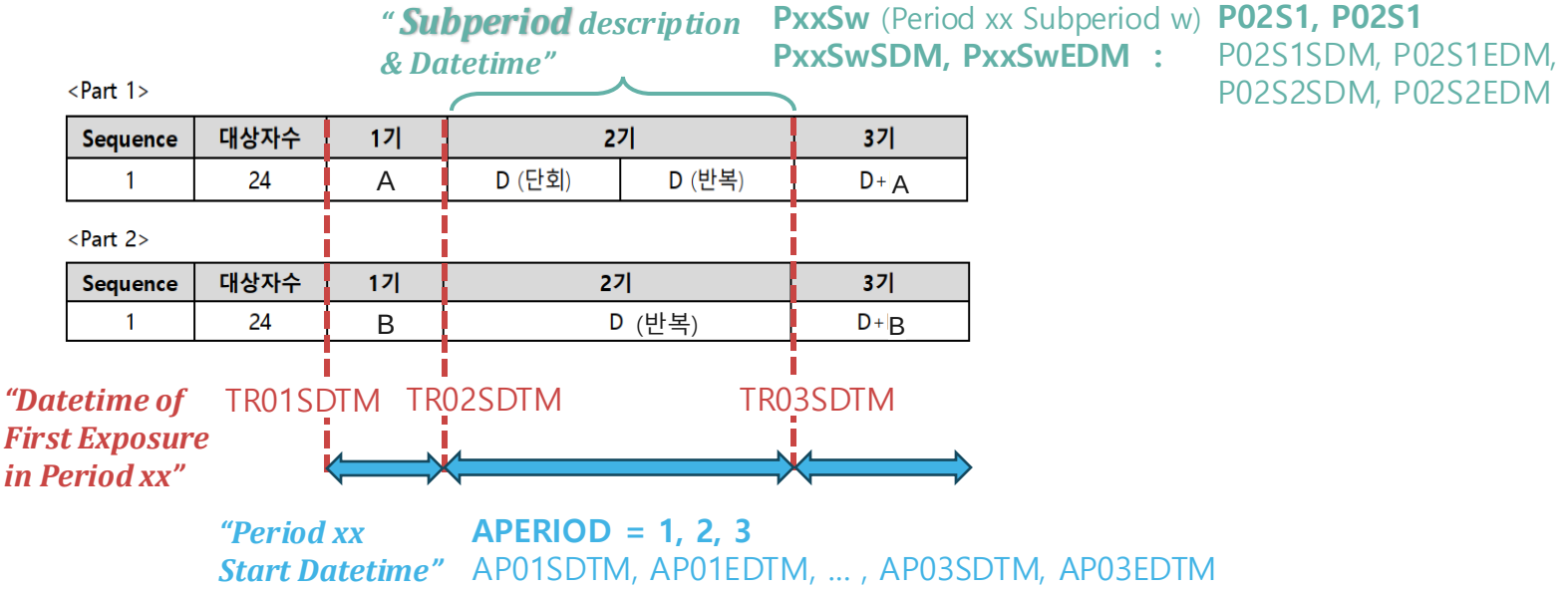
ADaM ADLB Derived Variables

PARAM	AVISIT	ADT	AVAL	APERIOD	APERIODC	TRTA
RBC	Screening	2019-12-02	7.46			
RBC	Day 1	2020-01-02	6.59	**1**	**Period 1**	**A**
RBC	Day 5	2020-01-07	9.12	**1**	**Period 1**	**A**
RBC	Day 1	2020-01-17	7.24	**2**	**Period 2**	**B**
RBC	Day 5	2020-01-22	5.97	**2**	**Period 2**	**B**
RBC	Day 1	2020-02-01	6.42	**3**	**Period 3**	**D**
RBC	Day 5	2020-02-06	6.04	**3**	**Period 3**	**D**
RBC	Day 1	2020-02-16	6.52	**4**	**Period 4**	**C**
RBC	Day 5	2020-02-21	5.46	**4**	**Period 4**	**C**
RBC	Post Study	2020-02-28	6.79			

Set to **TRT01A** if AP01SDT<=**ADT**<=AP01EDT
Set to **TRT02A** if AP02SDT<=**ADT**<=AP02EDT
Set to **TRT03A** if AP03SDT<=**ADT**<=AP03EDT
Set to **TRT04A** if AP04SDT<=**ADT**<=AP04EDT

Crossover Trial – Example 2

- **Study Design** – Open label, 2-part, one-sequence, 3-period



Crossover Trial – Example 2

- Analysis Results

Table 14.1.4
Demographic and Baseline Characteristics
Demographic Analysis Set

	Part 1 (N=24)	Part 2 (N=24)	Total (N=48)
Age (years)			
n	24	24	48
Mean(SD)	29.13(7.67)	30.04(9.19)	29.58(8.39)
Median	26.50	26.00	26.00
Min, Max	20.00, 44.00	20.00, 49.00	20.00, 49.00
P-value [1]			0.8361 (w)
Sex, n(%)			
Male	24(100.00)	24(100.00)	48(100.00)
Female	0	0	0
P-value [2]			NC

Table 14.2.1
Overall Summary of TEAEs
Safety Analysis Set

	Part 1				Part 2		
	A (N=24)	Drug Single dose (N=24)	Drug Multi-dose (N=24)	Drug +A (N=24)	B (N=24)	Drug Multi-dose (N=24)	Drug +B (N=24)
Subjects with TEAEs	5(20.83)	6(25.00)	16(66.67)	12(50.00)	4(16.67)	12(50.00)	10(41.67)
95% Confidence Interval	[4.59, 37.08]	[7.68, 42.32]	[47.81, 85.53]	[30.00, 70.00]	[1.76, 31.58]	[30.00, 70.00]	[21.94, 61.39]
P-value [1]				0.0030 (c)			0.0437 (c)
Severity							
Mild	6	6	40	18	4	37	17
Moderate	0	0	0	1	0	0	1
Severe	0	0	0	0	0	0	0
Relationship to IPs							
Related	6	4	40	17	3	37	16
Not Related	0	2	0	2	1	0	2

Crossover Trial – Example 2

- **ADaM** – ADSL

<Part 1>

Sequence	대상자수	1기	2기		3기
1	24	A	D (단회)	D (반복)	D+A

SUBJID	TRT01A	TRT02A	TRT03A	TRTSEQA
S001	A	D	DA	A-D-DA

"Datetime of First Exposure in Period xx"

TR01SDTM	TR01EDTM	TR02SDTM	TR02EDTM	TR03SDTM	TR03EDTM
2021-07-24T08:30:00	2021-07-24T08:30:00	2021-07-25T08:30:00	2021-07-31T20:30:00	2021-08-01T08:30:00	2021-08-01T08:30:00

"Period xx Start Datetime"

AP01SDTM	AP01EDT	AP02SDTM	AP02EDT	AP03SDTM	AP03EDT
2021-07-24T08:30:00	2021-07-24	2021-07-25T08:30:00	2021-07-31	2021-08-01T08:30:00	2021-08-01

" Subperiod description & Datetime"

P02S1	P02S1SDM	P02S1EDT	P02S2	P02S2SDM	P02S2EDT
Treatment in Period 2-1	2021-07-25T08:30:00	2021-07-27	Treatment in Period 2-2	2021-07-29T07:36:00	2021-07-31

Crossover Trial – Example 2

- **ADaM** – ADAE

ADaM ADSL

SUBJID	TRTSEQA	TR01SDTM	TR02SDTM	TR03SDTM	P02S1SDM	P02S2SDM
S001	A-D-DA	2021-07-24T08:30:00	2021-07-25T08:30:00	2021-08-01T08:30:00	2021-07-25T08:30:00	2021-07-29T07:36:00
S007	A-D-DA	2021-07-24T08:38:00	2021-07-25T08:38:00	2021-08-01T08:38:00	2021-07-25T08:38:00	2021-07-29T07:38:00

<Part 1>

Sequence	대상자수	1기	2기		3기
1	24	A	D (단회)	D (반복)	D+A

SDTM AE

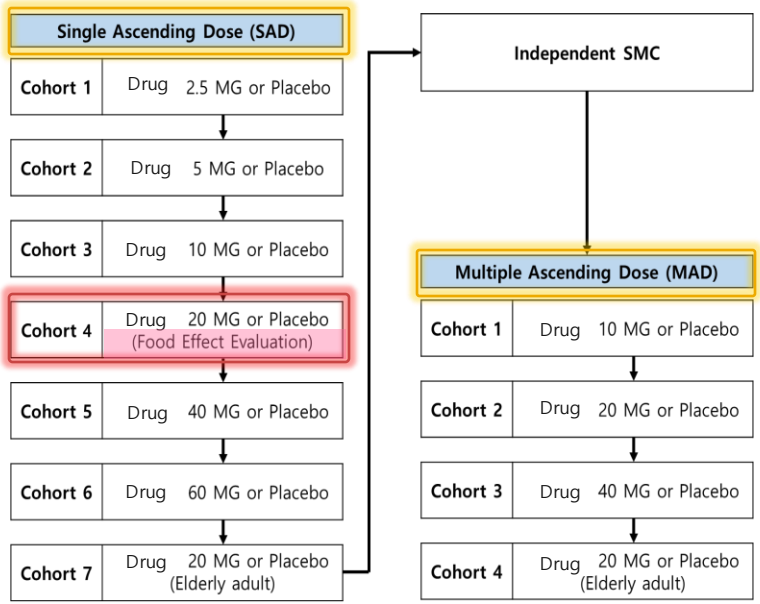
AESEQ	AEDECOD
1	Nausea
2	Abdominal pain upper
3	Diarrhoea
4	Diarrhoea
5	Nausea
1	Nausea
2	Diarrhoea
3	Diarrhoea
4	Abdominal discomfort
5	Diarrhoea
6	Headache
7	Diarrhoea

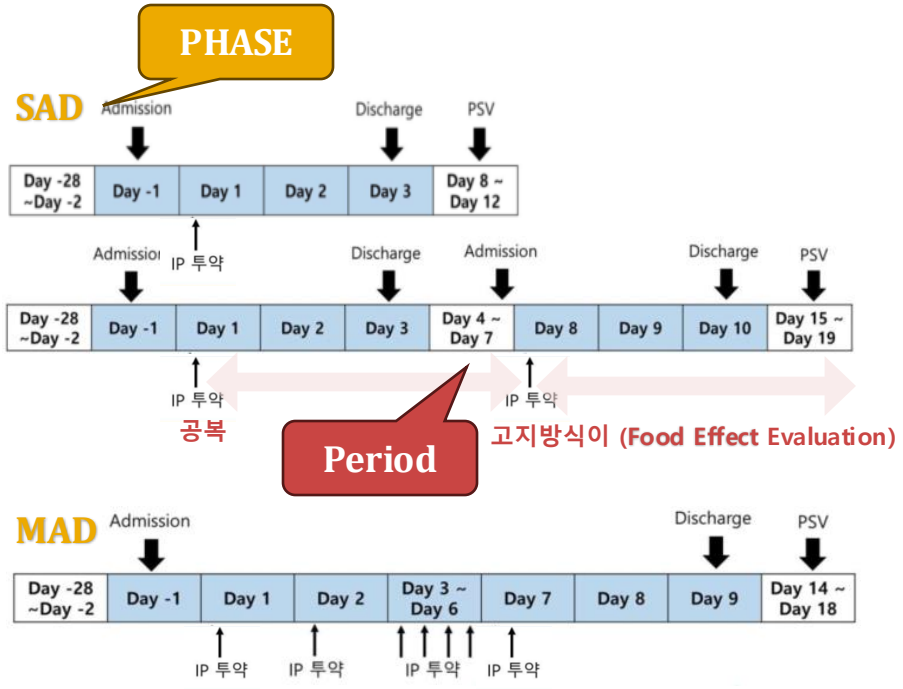
ADaM ADAE Derived Variables

ASTDTM	TRTA	APERIOD	APERIODC	ASPER	ASPERC
2021-07-24T08:50:00	A	1	Period 1		
2021-07-29T10:00:00	D	2	Period 2	2	Period 2-2
2021-07-30T12:00:00	D	2	Period 2	2	Period 2-2
2021-07-31T14:35:00	D	2	Period 2	2	Period 2-2
2021-08-01T09:30:00	DA	3	Period 3		
2021-07-24T09:00:00	A	1	Period 1		
2021-07-25T11:20:00	D	2	Period 2	1	Period 2-1
2021-07-29T10:00:00	D	2	Period 2	2	Period 2-2
2021-07-29T22:00:00	D	2	Period 2	2	Period 2-2
2021-07-30T15:00:00	D	2	Period 2	2	Period 2-2
2021-08-01T09:40:00	DA	3	Period 3		
2021-08-01T13:00:00	D+A	3	Period 3		

Crossover Trial – Example 3

- **Study Design** –single and multiple ascending dose





Crossover Trial – Example 3

- **ADaM** – ADEG

SUBJID	TRTA	PARAM	EGDTC	VISIT	AVISIT	APHASE	APERIODC	APERIOD	AVAL	ABLFL	BASE	CHG
S039	SAD-Drug 20 mg (Food Effect Evaluation)	QTcF	2020-12-24T14:51	Screening		SAD	Period 1	1	391		366	
S039	SAD-Drug 20 mg (Food Effect Evaluation)	QTcF	2021-01-13T08:15	Day 1	Day 1, Pre-dose (Baseline)	SAD	Period 1	1	366	Y	366	
S039	SAD-Drug 20 mg (Food Effect Evaluation)	QTcF	2021-01-13T10:33	Day 1	Day 1 (2h)	SAD	Period 1	1	386		366	20
S039	SAD-Drug 20 mg (Food Effect Evaluation)	QTcF	2021-01-13T12:41	Day 1	Day 1 (4h)	SAD	Period 1	1	388		366	22
S039	SAD-Drug 20 mg (Food Effect Evaluation)	QTcF	2021-01-13T14:38	Day 1	Day 1 (6h)	SAD	Period 1	1	387		366	21
S039	SAD-Drug 20 mg (Food Effect Evaluation)	F_QTcF	2021-01-20T08:11	Day 8	Day 8, Pre-dose (Baseline)	SAD	Period 2	2	395	Y	395	
S039	SAD-Drug 20 mg (Food Effect Evaluation)	F_QTcF	2021-01-20T10:33	Day 8	Day 8 (2h)	SAD	Period 2	2	383		395	-12
S039	SAD-Drug 20 mg (Food Effect Evaluation)	F_QTcF	2021-01-20T12:50	Day 8	Day 8 (4h)	SAD	Period 2	2	381		395	-14
S039	SAD-Drug 20 mg (Food Effect Evaluation)	F_QTcF	2021-01-20T14:38	Day 8	Day 8 (6h)	SAD	Period 2	2	385		395	-10
S039	SAD-Drug 20 mg (Food Effect Evaluation)	F_QTcF	2021-01-27T09:38	Post Study Visit	Post Study Visit	SAD	Period 2	2	377		395	-18
S094	MAD-Drug 20 mg	QTcF	2021-08-03T11:12	Screening		MAD			398		419	
S094	MAD-Drug 20 mg	QTcF	2021-08-20T08:22	Day 1	Day 1, Pre-dose (Baseline)	MAD			419	Y	419	
S094	MAD-Drug 20 mg	QTcF	2021-08-20T10:42	Day 1	Day 1 (2h)	MAD			402		419	-17
S094	MAD-Drug 20 mg	QTcF	2021-08-20T12:54	Day 1	Day 1 (4h)	MAD			406		419	-13
S094	MAD-Drug 20 mg	QTcF	2021-08-20T14:45	Day 1	Day 1 (6h)	MAD			411		419	-8
S094	MAD-Drug 20 mg	QTcF	2021-08-23T08:16	Day 4	Day 4, Pre-dose	MAD			416		419	-3
S094	MAD-Drug 20 mg	QTcF	2021-08-26T08:21	Day 7	Day 7, Pre-dose	MAD			384		419	-35
S094	MAD-Drug 20 mg	QTcF	2021-08-26T10:40	Day 7	Day 7 (2h)	MAD			394		419	-25
S094	MAD-Drug 20 mg	QTcF	2021-08-26T12:52	Day 7	Day 7 (4h)	MAD			398		419	-21
S094	MAD-Drug 20 mg	QTcF	2021-08-26T14:44	Day 7	Day 7 (6h)	MAD			388		419	-31
S094	MAD-Drug 20 mg	QTcF	2021-08-28T08:11	Day 9	Day 9	MAD			396		419	-23
S094	MAD-Drug 20 mg	QTcF	2021-09-02T09:34	Post Study Visit	Post Study Visit	MAD			402		419	-17

Thank You!

Contact

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