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Practical Guide to Creating ADaM Datasets for Cross-over Studies

Neha Sakhawalkar, Rang Technologies, Piscataway, NJ
Kamlesh Patel, Rang Technologies, Piscataway, NJ

ABSTRACT

Analysis datasets are categorized into Subject Level Analysis Data (ADSL), Basic Data Structure (BDS), Occurrence Data Structure (OCCDS) and Other ADaM data structures. The first three are most common and are used to analyze data in most of the studies. Parallel studies are very common and hence implementation of the ADaM data structures for those studies is relatively straightforward for experienced programmers and biostatisticians. Cross-over study design on the other hand is less commonly utilized and is more complex as compared to parallel study design. Hence, creating ADaM datasets for cross-over study design can be quite challenging. This paper aims at focusing on ADaM datasets for cross-over studies with details regarding variables, difference between derivations of these variables across the various data structures (ADSL, BDS and OCCDS) as well as an example of each data structure.

INTRODUCTION

A well-designed clinical study generally compares two or more randomly assigned groups of people where at least one of the groups receives the study drug. The way the participants get assigned in groups depends on study design. The most common study design is randomized parallel study design. In this case the participants are randomly assigned to either drug (multiple treatment groups may be created if testing different doses of study drug) or placebo arm. The participant (subject) remains in the same arm throughout the study. Another way of comparing groups in a study is by using cross-over study design. In cross-over design the patients are initially assigned to a treatment arm (drug or placebo) and later-on cross-over to another treatment arm. This implies that even though the subject is initially assigned to placebo arm he will eventually receive the drug as well. Crossover studies are longer duration studies and can be quite complicated to analyze based on how the data was collected. This paper will mainly focus on the three ADaM data structures that the analysis datasets are categorized under. This paper mainly points out the variables required for cross-over studies and includes short examples to understand the data structures.

Subject Level Analysis Data (ADSL)

The structure of ADSL is one record per subject according to CDISC standards. ADSL contains all important subject level data variables like identifier variables, demographic variables, population indicator variables, treatment variables, timing variables as well as permissible dose and trial experience variables. The identifier and demographic variables are subject specific and hence will be unique for each subject. Also, the definitions for population indicator variables such as Full Analysis Set Population Flag (FASFL) Safety Population Flag (SAFFL), Randomized Population Flag (RANDFL), etc. must be standardized for a study and hence can fit into the ADSL format of one record per subject even for cross-over studies. However, cross-over studies have multiple treatment and timing variables based on the definition of the study design. These variables are used to identify the period number and the order of treatments for subjects for all other datasets of the study. A list of the commonly utilized/ required treatment and timing variables for cross-over studies is noted in Table 1. The timing variables routinely utilized for a parallel study such TRTSDTM, TRTEDTM, TRTSDT TRTEDT are also kept in the ADSL for cross-over studies. These timing variables are generally used to record the start date of first dose and end date of the last dose for a subject in the study. Table 4 includes an example ADSL dataset for three subjects which have been used to illustrate examples for BDS and OCCDS data structures. TRT01A is the treatment for subject during Period 01 and the following treatment for Period 02 for subject is mapped in TRT02A. The number of TRTxxA depends on TRTSEQA

which has the sequence in which the treatments are administered. TRT01A and TRT02A have corresponding treatment start and end dates as well as end of treatment status (EOT01STT, EOT02STT) and end of study date (EOS01DT, EOS02DT).

Table 1: List of ADSL variables for a cross-over study variables

Variable Name	Variable Label	Type	Core	Notes
TRTxxP	Planned Treatment for period xx	Char	Req	The planned treatment for subjects where xx represents the different treatments planned to be administered in the cross-over study.
TRTxxPN	Planned Treatment for period xx (N)	Num	Perm	Numeric code for TRTxxP with one-to-on mapping.
TRTxxA	Actual Treatment for period xx	Char	Cond	The actual treatment administered to subjects where xx represents the actual treatments that occurred in the study.
TRTxxAN	Actual Treatment for period xx (N)	Num	Perm	Numeric code for TRTxxA with one-to-on mapping.
TRTSEQP	Planned Sequence of Treatments	Char	Req	It is required for cross-over studies to record the order/sequence of planned treatment. In most cases, this can be obtained by concatenating TRTxxP in the ascending order of xx.
TRTSEQA	Actual Sequence of Treatments	Char	Cond	It is required for cross-over studies to record the order/sequence of actual treatment if it does not match the planned treatment order.
TRxxSDT	Date of First Exposure in Period xx	Num	Req	Date when the subject was first exposed to the treatment for period xx, i.e. It would be the start date corresponding to TRTxxA.
TRxxEDT	Date of Last Exposure in Period xx	Num	Req	Date when the subject was last exposed to the treatment for period xx, i.e. it would be the end date corresponding to TRTxxA.
TRxxSDTM	Datetime of First Exposure in Period xx	Num	Req	Datetime when the subject was first exposed to the treatment for period xx, i.e. it would be the end date corresponding to TRTxxA.
TRxxEDTM	Datetime of Last Exposure in Period xx	Num	Req	Datetime when the subject was last exposed to the treatment for period xx, i.e. it would be the end date corresponding to TRTxxA.

Basic Data Structure (BDS)

The basic data structure contains one or more records per subject, per analysis parameter. Analysis timepoint is conditionally required based on analysis. The cross-over studies get particularly complicated

when it comes to the basic data structure since most important datasets belong to it. For basic data structure subjects can have multiple records per treatment period as well as multiple treatment periods in case of crossover studies. The important variables including start date, end date, visit windowing, etc. need to be updated/implemented separately for each treatment period. Another important variable is BASE, i.e. the baseline value. The SAP must state how this value needs to be handled. BASE can either be the same for the entire study collected at the beginning of first period or it can be calculated separately for each period e.g. screening visit for each period will be baseline for that period.

Treatment variables TRTP, TRTPN, TRTA and TRTAN are used for BDS datasets, unlike TRTxxA or TRTxXP in ADSL since the treatment variables are unique for each treatment period. Similarly, timing variables are also distinct for each treatment period and variables APERSDTM, APEREDTM, APERSDT, APEREDT, APERSTM, APERETM are used to record the period start datetime, date and time as well as period end datetime, date and time. Period denoting variables APERIOD and APERIODC are utilized to record the order of the treatment periods. Generally, a standardized macro is created for deriving APERIOD, APERIODC, TRTA, TRTAN, TRTP, TRTPN, APERSDTM, APEREDTM, APERSDT, APEREDT, APERSTM, and APERETM from ADSL based on the analysis dates for the dataset. The important variables required for basic data structure datasets are listed in Table 2. ADLB is used as an example of basic data structure and the subjects in ADSL (Table 4) are used to illustrate it in Table 5. BDS is more vertical hence the variables TRTA and TRTAN are used and each row represents only one period which is noted in variables APERIOD/APERIODC. Period variables can either be derived based on ADTM/ADT of the related PARAM, i.e. if ADT lies between a certain TRxxSDTM and TRxxEDTM then APERIOD will be xx. Another way of deriving APERIOD is based on a combination of VISIT and TRTSEQA. For example, if VISIT number is recorded as EVENT_2 then TRTA will be the second treatment from TRTSEQA. The approach to be used on how the data was collected. Sometimes a combination of above two methods might need to be used. The APER variables are derived from ADSL based on the value of APERIOD. If APERIOD = 2, the APERSDTM and APEREDTM for that record will be TRxxSDTM and TRxxEDTM respectively. In the ADLB example for this paper, the baseline is separately identified for each Period. Hence, one subject will have multiple BASE values if they were crossed-over to different treatment groups.

Table 2: List of BDS variables for a cross-over study variables

Variable Name	Variable Label	Type	Core	Notes
TRTP	Planned Treatment	Char	Req	The record-level identifier for planned treatment for subjects.
TRTPN	Planned Treatment (N)	Num	Perm	Numeric code for TRTP with one-to-on mapping.
TRTA	Actual Treatment	Char	Cond	The record-level identifier for actual treatment for subjects.
TRTAN	Actual Treatment (N)	Num	Perm	Numeric code for TRTA with one-to-on mapping.
APERIOD	Period	Num	Perm	Record-level timing variable denoting the analysis period within the study associated with the record.
APERIODC	Period (C)	Char	Perm	Text format of the APERIOD.
APERSDT	Period Start Date	Num	Perm	Start date for treatment period.
APERSTM	Period Start Time	Num	Perm	Start time for treatment period.
APERSDTM	Period Start Datetime	Num	Perm	Start datetime for treatment period.
APEREDT	Period End Date	Num	Perm	End date for treatment period.
APERETM	Period End Time	Num	Perm	End time for treatment period.

Variable Name	Variable Label	Type	Core	Notes
APEREDTM	Period End Datetime	Num	Perm	End datetime for treatment period.

Occurrence Data Structure (OCCDS)

For occurrence data structure subjects can have multiple records per treatment period as well as multiple treatment periods in case of crossover studies. Hence the treatment variables TRTP, TRTPN, TRTA and TRTAN are like the ones in the BDS datasets. The timing variables APERSDTM, APEREDTM, APERSDT, APEREDT, APERSTM, APERETM are used to record the period start datetime, date and time as well as period end datetime, date and time and are derived like BDS datasets. Period denoting variables APERIOD and APERIODC are utilized to record the order of the treatment periods.

Depending on the type of data represented by OCCDS, flags are used to denote the period during which the event occurred. The commonly used flag is ONTRxxFL (On-Period Flag), where xx corresponds to the period of treatment. The important variables required for occurrence data structure datasets are listed in Table 3. ADCM has been used as an example of occurrence data structure illustrated in Table 6. The period related variables (APERIOD, APERIODC, APERSDTM, APEREDTM, APERSDT, APEREDT, APERSTM, APERETM) as well as treatment related variables (TRTP, TRTPN, TRTA, TRTAN) are derived like BDS datasets. Some of the variables not used in BDS are PREFL (Pre-treatment Flag), ONPERFL (On Period Flag) and ONTRxxFL (On Treatment Flag for Period xx). These variables are illustrated in the below datasets and might be used for a dataset based on the type of analysis to be done for a study.

Table 3: List of OCCDS variables for a cross-over study variables

Variable Name	Variable Label	Type	Core	Notes
TRTP	Planned Treatment	Char	Req	The record-level identifier for planned treatment for subjects.
TRTPN	Planned Treatment (N)	Num	Perm	Numeric code for TRTP with one-to-on mapping.
TRTA	Actual Treatment	Char	Cond	The record-level identifier for actual treatment for subjects.
TRTAN	Actual Treatment (N)	Num	Perm	Numeric code for TRTA with one-to-on mapping.
APERIOD	Period	Num	Perm	Record-level timing variable denoting the analysis period within the study associated with the record.
APERIODC	Period (C)	Char	Perm	Text format of the APERIOD.
APERSDT	Period Start Date	Num	Perm	Start date for treatment period.
APERSTM	Period Start Time	Num	Perm	Start time for treatment period.
APERSDTM	Period Start Datetime	Num	Perm	Start datetime for treatment period.
APEREDT	Period End Date	Num	Perm	End date for treatment period.
APERETM	Period End Time	Num	Perm	End time for treatment period.
APEREDTM	Period End Datetime	Num	Perm	End datetime for treatment period.
ONTRxxFL	On-Period xx Flag	Char	Perm	Denotes the period during which as event occurred.

Table 4: Example ADSL dataset subset for 3 subjects for cross-over study

Obs	STUDYID	USUBJID	SUBJID	SITEID	AGE	AGEU	FASFL	SAFFL	COMPLFL	DTHFL
1	A101	A101-B2-101	101	B2	26	YEARS	Y	Y	Y	N
2	A101	A101-B2-102	102	B2	19	YEARS	Y	Y	N	N
3	A101	A101-B1-103	103	B1	32	YEARS	Y	Y	Y	N

Obs	TRT01P	TRT01PN	TRT02P	TRT02PN	TRT01A	TRT01AN	TRT02A	TRT02AN	TRTSEQP
1	Trt-A	1	Trt-B	2	Trt-A	1	Trt-B	2	Trt-A->Trt-B
2	Trt-A	1	Trt-B	2	Trt-A	1	Trt-B	2	Trt-A->Trt-B
3	Trt-B	2	Trt-A	1	Trt-B	2	Trt-A	1	Trt-B->Trt-A

Obs	TRTSEQA	RANDDT	COMPLDT	TRTSDTM	TRTEDTM	TRTSDT
1	Trt-A->Trt-B	04FEB2016	13NOV2017	01NOV2016:14:12:00	05NOV2017:02:35:00	01NOV2016
2	Trt-A->Trt-B	03MAY2016	.	22JUN2016:21:43:00	19MAR2017:06:05:00	22JUN2016
3	Trt-B->Trt-A	08JUN2016	20DEC2017	02MAR2017:18:17:00	16NOV2017:22:01:00	02MAR2017

Obs	TRTEDT	TRT01SDT	TRT02SDT	TRT01EDT	TRT02EDT	EOSDT	EOSSTT
1	05NOV2017	01NOV2016	12MAR2017	06NOV2016	18MAR2017	13NOV2017	COMPLETED
2	19MAR2017	22JUN2016	15MAR2017	27JUN2016	.	14JUL2017	DISCONTINUED
3	16NOV2017	03MAR2017	16NOV2017	15MAR2017	20DEC2017	12JAN2018	COMPLETED

Obs	EOT01DT	EOT02DT	EOT01STT	EOT02STT
1	15DEC2016	05NOV2017	COMPLETED	COMPLETED
2	28JUN2016	.	COMPLETED	DISCONTINUED
3	03MAR2017	17NOV2017	COMPLETED	COMPLETED

Table 5: Example ADLB dataset subset for 3 subjects for Glucose test for cross-over study

Obs	STUDYID	USUBJID	SUBJID	SITEID	AGE	AGEU	FASFL	SAFFL	TRTP	TRTPN	TRTA	TRTAN	PARAM
1	A101	A101-B2-101	101	B2	26	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)
2	A101	A101-B2-101	101	B2	26	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)
3	A101	A101-B2-101	101	B2	26	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)
4	A101	A101-B2-102	102	B2	19	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)
5	A101	A101-B2-102	102	B2	19	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)
6	A101	A101-B2-102	102	B2	19	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)
7	A101	A101-B2-102	102	B2	19	YEARS	Y	Y	Trt-B	2	Trt-B	2	Glucose(mg/dl)
8	A101	A101-B2-102	102	B2	19	YEARS	Y	Y	Trt-B	2	Trt-B	2	Glucose(mg/dl)
9	A101	A101-B2-102	102	B2	19	YEARS	Y	Y	Trt-B	2	Trt-B	2	Glucose(mg/dl)
10	A101	A101-B1-103	103	B1	32	YEARS	Y	Y	Trt-B	2	Trt-B	2	Glucose(mg/dl)
11	A101	A101-B1-103	103	B1	32	YEARS	Y	Y	Trt-B	2	Trt-B	2	Glucose(mg/dl)
12	A101	A101-B1-103	103	B1	32	YEARS	Y	Y	Trt-B	2	Trt-B	2	Glucose(mg/dl)
13	A101	A101-B1-103	103	B1	32	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)
14	A101	A101-B1-103	103	B1	32	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)
15	A101	A101-B1-103	103	B1	32	YEARS	Y	Y	Trt-A	1	Trt-A	1	Glucose(mg/dl)

Obs	PARAMCD	ADTM	ADT	ATM	AVISIT	AVISITN	APERIOD	APERIODC
1	L00068P	01NOV2016:12:25:00	01NOV2016	12:25:00	Baseline	1	1	Period 01
2	L00068P	05NOV2016:11:12:00	05NOV2016	11:12:00	End of Treatment	2	1	Period 01
3	L00068P	14DEC2016:11:15:00	14DEC2016	11:15:00	Day 35 Post-Discharge	3	1	Period 01
4	L00068P	22JUN2016:08:55:00	22JUN2016	8:55:00	Baseline	1	1	Period 01
5	L00068P	28JUN2016:04:49:00	28JUN2016	4:49:00	End of Treatment	2	1	Period 01
6	L00068P	31AUG2016:10:04:00	31AUG2016	10:04:00	Day 35 Post-Discharge	3	1	Period 01
7	L00068P	15MAR2017:11:02:00	15MAR2017	11:02:00	Baseline	1	2	Period 02
8	L00068P	19MAR2017:04:37:00	19MAR2017	4:37:00	End of Treatment	2	2	Period 02
9	L00068P	14JUL2017:10:23:00	14JUL2017	10:23:00	Day 35 Post-Discharge	4	2	Period 02
10	L00068P	02MAR2017:13:45:00	02MAR2017	13:45:00	Baseline	1	1	Period 01
11	L00068P	03MAR2017:12:43:00	03MAR2017	12:43:00	End of Treatment	2	1	Period 01
12	L00068P	10APR2017:10:01:00	10APR2017	10:01:00	Day 35 Post-Discharge	3	1	Period 01
13	L00068P	16NOV2017:07:07:00	16NOV2017	7:07:00	Baseline	1	2	Period 02

Obs	PARAMCD	ADTM	ADT	ATM	AVISIT	AVISITN	APERIOD	APERIODC
14	L00068P	17NOV2017:05:21:00	17NOV2017	5:21:00	End of Treatment	2	2	Period 02
15	L00068P	20DEC2017:09:49:00	20DEC2017	9:49:00	Day 35 Post-Discharge	4	2	Period 02

Obs	APHASE	APERSDTM	APERSDT	APERSTM	APEREDTM	APEREDT	APERETM	AVAL	ABLFL
1	PRE-TREATMENT	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00	93	Y
2	TREATMENT 01	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00	78	
3	FOLLOW-UP	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00	93	
4	PRE-TREATMENT	22JUN2016:21:43:00	22JUN2016	21:43:00	31AUG2016:10:04:00	31AUG2016	10:04:00	97	Y
5	TREATMENT 01	22JUN2016:21:43:00	22JUN2016	21:43:00	31AUG2016:10:04:00	31AUG2016	10:04:00	102	
6	FOLLOW-UP	22JUN2016:21:43:00	22JUN2016	21:43:00	31AUG2016:10:04:00	31AUG2016	10:04:00	88	
7	PRE-TREATMENT	15MAR2017:16:07:00	15MAR2017	16:07:00	15MAY2017:10:51:00	15MAY2017	10:51:00	96	Y
8	TREATMENT 02	15MAR2017:16:07:00	15MAR2017	16:07:00	15MAY2017:10:51:00	15MAY2017	10:51:00	110	
9	FOLLOW-UP	15MAR2017:16:07:00	15MAR2017	16:07:00	15MAY2017:10:51:00	15MAY2017	10:51:00	91	
10	PRE-TREATMENT	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00	88	Y
11	TREATMENT 01	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00	89	
12	FOLLOW-UP	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00	73	
13	PRE-TREATMENT	16NOV2017:09:42:00	16NOV2017	9:42:00	20DEC2017:09:55:00	20DEC2017	9:55:00	92	Y
14	TREATMENT 02	16NOV2017:09:42:00	16NOV2017	9:42:00	20DEC2017:09:55:00	20DEC2017	9:55:00	101	
15	FOLLOW-UP	16NOV2017:09:42:00	16NOV2017	9:42:00	20DEC2017:09:55:00	20DEC2017	9:55:00	87	

Table 6: Example ADCM dataset subset for 3 subjects for cross-over study

Obs	STUDYID	SUBJID	SITEID	TRTP	TRTPN	TRTA	TRTAN	FASFL	SAFFL	CMSTDTC	CMENDTC
1	A101	101	B2	Trt-A	1	Trt-A	1	Y	Y	2016-11-01T00:15:00	2016-11-01T00:15:00
2	A101	101	B2	Trt-A	1	Trt-A	1	Y	Y	2016-11-01T06:14:00	2016-11-01T06:14:00
3	A101	101	B2	Trt-A	1	Trt-A	1	Y	Y	2016-11-01T12:27:00	2016-11-01T12:27:00
4	A101	101	B2	Trt-A	1	Trt-A	1	Y	Y	2016-11-01T18:25:00	2016-11-01T18:25:00
5	A101	101	B2	Trt-A	1	Trt-A	1	Y	Y	2016-11-01T23:50:00	2016-11-01T23:50:00
6	A101	101	B2	Trt-A	1	Trt-A	1	Y	Y	2016-11-02T06:18:00	2016-11-02T06:18:00
7	A101	102	B2	Trt-B	2	Trt-B	2	Y	Y	2017-03-15T00:06:00	2017-03-15T00:06:00
8	A101	103	B1	Trt-B	2	Trt-B	2	Y	Y	2017-03-02T01:22:00	2017-03-02T01:22:00
9	A101	103	B1	Trt-B	2	Trt-B	2	Y	Y	2017-03-02T08:11:00	2017-03-02T08:11:00
10	A101	103	B1	Trt-B	2	Trt-B	2	Y	Y	2017-03-02T14:53:00	2017-03-02T14:53:00
11	A101	103	B1	Trt-B	2	Trt-B	2	Y	Y	2017-03-02T19:57:00	2017-03-02T19:57:00
12	A101	103	B1	Trt-B	2	Trt-B	2	Y	Y	2017-03-03T01:57:00	2017-03-03T01:57:00
13	A101	103	B1	Trt-B	2	Trt-B	2	Y	Y	2017-03-03T09:29:00	2017-03-03T09:29:00
14	A101	103	B1	Trt-A	1	Trt-A	1	Y	Y	2017-11-16T02:32:00	2017-11-16T02:32:00

Obs	CMTRT	CMDECOD	PREFL	ONPERFL	ONTR01FL	ONTR02FL	APERIOD	APERIODC
1	Morphine	MORPHINE	Y				1	Period 01
2	Morphine	MORPHINE	Y				1	Period 01
3	Morphine	MORPHINE	Y				1	Period 01
4	Morphine	MORPHINE					1	Period 01
5	Morphine	MORPHINE					1	Period 01
6	Morphine	MORPHINE					1	Period 01
7	Dilaudid	HYDROMORPHONE HYDROCHLORIDE					2	Period 02

Obs	CMTRT	CMDECOD	PREFL	ONPERFL	ONTR01FL	ONTR02FL	APERIOD	APERIODC
8	Dilaudid	HYDROMORPHONE HYDROCHLORIDE	Y				1	Period 01
9	Dilaudid	HYDROMORPHONE HYDROCHLORIDE	Y				1	Period 01
10	Dilaudid	HYDROMORPHONE HYDROCHLORIDE	Y				1	Period 01
11	Dilaudid	HYDROMORPHONE HYDROCHLORIDE					1	Period 01
12	Dilaudid	HYDROMORPHONE HYDROCHLORIDE					1	Period 01
13	Dilaudid	HYDROMORPHONE HYDROCHLORIDE					1	Period 01
14	Dilaudid	HYDROMORPHONE HYDROCHLORIDE					2	Period 02

Obs	APERSDTM	APERSDT	APERSTM	APEREDTM	APEREDT	APERETM
1	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00
2	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00
3	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00
4	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00
5	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00
6	01NOV2016:14:12:00	01NOV2016	14:12:00	14DEC2016:11:15:00	14DEC2016	11:15:00
7	15MAR2017:16:07:00	15MAR2017	16:07:00	15MAY2017:10:51:00	15MAY2017	10:51:00
8	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00
9	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00
10	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00
11	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00
12	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00
13	02MAR2017:18:17:00	02MAR2017	18:17:00	10APR2017:10:01:00	10APR2017	10:01:00
14	16NOV2017:09:42:00	16NOV2017	9:42:00	20DEC2017:09:55:00	20DEC2017	9:55:00

CONCLUSION

This paper presents the implementation of ADaM data structures in cross-over studies. This implementation is based on the author's experience and the implementation can be affected by the study design or the way in which data is collected. This paper can be followed as a guideline to the three data structures of analysis datasets for a cross-over study.

REFERENCES

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CONTACT INFORMATION

Name: Neha Sakhawalkar

Email: sakh.neha@gmail.com