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TRTP and TRTA in BDS Application per CDISC ADaM Standards

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ABSTRACT

CDSIC ADaM Implementation Guide v1.1 (IG) [1]. has defined the standards on how to use the TRTP and TRTA terminology when developing ADaM DBS datasets, and provided users some examples to illustrate how to utilize the standards. However, the definitions and examples from ADaM IG are limited to the applications that data is expected to be in good standing. There will be some sort of challenges for crossover studies when it comes to the situation that repeated visit record, unscheduled visit record or the record out of treatment visit window occur. This paper will present a review of experiences implementing TRTP and TRTA in ADaM BDS datasets, and discuss the comprehensive utilization of TRTP and TRTA terminology step by step with some practical examples.

INTRODUCTION

Per CDISC ADaM IG, "TRTP is a record-level identifier that represents the planned treatment attributed to a record for analysis purposes. TRTP indicates how treatment varies by record within a subject and enables analysis of crossover and other designs. TRTxxP (copied from ADSL) may also be needed for some analysis purposes, and may be useful for traceability and to provide context." [2]

However, in real world practice, the pre-defined "copied from ADSL" is not always working ideally to get what we want to achieve. In terms of the data with the duplicates, unscheduled or out of visit window records, the way to handle them could be depending on how we understand the BDS data structure, and how we understand the analysis requirement. This paper focuses on implementation side of the comprehensive utilization of TRTP step by step. It assumes basic knowledge of CDISC ADaM data structure, SAS programming, ADaM Implementation Guide v1.1 (IG) and FDA Study Data Technical Conformance Guide v2.1.

Below are two cases of data which will be used throughout the discussion in this paper. One of which illustrates a clinical trial with a single treatment, the other is a cross-over study with three treatments. A group of examples will be presented in details to support such discussions.

Table 1: ADSL in a single treatment study

SUBJID	TRT01P	TRT01PN	TR01SDT	TR01EDT
201	A	1	01Jul15	01Sep15
202	B	2	01Jul15	01Sep15
203	B	2	01Jul15	01Sep15
204	A	1	01Jul15	01Sep15

Table 1 Treatment data values in ADSL

Table 1.1: ADPC in a single treatment study

SUBJID	PCTESTCD	PCSPEC	VISIT	PCDTC	PCSTRESC	PCSTRESN	PCSTRESU	PCTPT
203	BUPRENOR	PLASMA	SCREEN	2014-08-10T05:10	<20.0	.	ng/L	0 (Pre-dose)
203	BUPRENOR	PLASMA	VISIT1	2014-08-10T06:10	54.3	54.3	ng/L	0.167 Hours
203	BUPRENOR	PLASMA	VISIT 1	2014-08-10T06:20	1610	1610	ng/L	0.33 Hours
203	BUPRENOR	PLASMA	VISIT 1	2014-08-10T06:30	8840	8840	ng/L	0.5 Hours

Table 1.1 Source data SDTM.PC of a single treatment study

Table 2: ADSL in a cross-over study

SUBJID	TRT01P	TRT01PN	TRT02P	TRT02PN	TRT03P	TRT03PN	TR01SDT	TR01EDT	TR02SDT	TR02EDT	TR03SDT	TR03EDT
201	A	1	C	3	B	2	10Aug14	10Aug14	24Aug14	24Aug14	07Sep14	07Sep14
202	B	2	A	1	C	3	10Aug14	10Aug14	24Aug14	24Aug14	07Sep14	07Sep14
203	B	2	C	3	A	1	10Aug14	10Aug14	24Aug14	24Aug14	07Sep14	07Sep14
204	C	3	A	1	B	2	10Aug14	10Aug14	24Aug14	24Aug14	07Sep14	07Sep14

Table 2 Cross-over study treatment data values in ADSL

Table 2.1: Case 1 Study: Perfect source data with SDTM.PC in a cross-over study

SUBJID	PCTESTCD	PCSPEC	VISIT	PCDTC	PCSTRESC	PCSTRESN	PCSTRESU	PCTPT
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T05:10	<20.0	.	ng/L	0 (Pre-dose)
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:10	54.3	54.3	ng/L	0.167 Hours
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:20	1610	1610	ng/L	0.33 Hours
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:30	8840	8840	ng/L	0.5 Hours
201	…	…	…	…				
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T05:10	<20.0	.	ng/L	0.167 Hours
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T06:10	107	107	ng/L	0.33 Hours
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T06:20	1540	1540	ng/L	0.5 Hours
201	…	…	…	…				
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T05:10	<20.0	.	ng/L	0.167 Hours
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T06:10	111	111	ng/L	0.33 Hours
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T06:20	806	806	ng/L	0.5 Hours

Table 2.1 Source data SDTM.PC with no discrepancy

Table 2.2: Case 2 Study: Duplicates occurred in source SDTM.PC in a cross-over study

SUBJID	PCTESTCD	PCSPEC	VISIT	PCDTC	PCSTRESC	PCSTRESN	PCSTRESU	PCTPT
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T05:10	<20.0	.	ng/L	0 (Pre-dose)
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:10	54.3	54.3	ng/L	0.167 Hours
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:20	1610	1610	ng/L	0.33 Hours
201	**BUPRENOR**	**PLASMA**	**PERIOD 1**	**2014-08-10T06:30**	**8840**	**8840**	**ng/L**	**0.5 Hours**
201	**BUPRENOR**	**PLASMA**	**PERIOD 1**	**2014-08-10T06:30**	**8851**	**8851**	**ng/L**	**0.5 Hours**
201	…	…	…	…				
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T05:10	<20.0	.	ng/L	0.167 Hours
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T06:10	107	107	ng/L	0.33 Hours
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T06:20	1540	1540	ng/L	0.5 Hours
201	…	…	…	…				
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T05:10	<20.0	.	ng/L	0.167 Hours
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T06:10	111	111	ng/L	0.33 Hours
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T06:20	806	806	ng/L	0.5 Hours

Table 2.2 Source data SDTM.PC with duplicate values for one visit

Table 2.3: Case 3 Study: Out-of-Visit-Window occurred in source SDTM.AE in a cross-over study

USUBJID	AEBODSYS	AEDECOD	AESTDTC	AEENDTC
201	Skin and subcutaneous tissue disorders	Acne	**2014-08-01T13:52**	2015-08-01T12:00
201	Skin and subcutaneous tissue disorders	Acne	**2014-08-13T13:50**	2015-08-18T11:00
201	Gastrointestinal disorders	Nausea	**2014-09-06T19:15**	2015-09-08T05:46
201	Gastrointestinal disorders	Vomiting	**2014-09-07T10:35**	2015-09-07T10:36

Table 2.3 Source data SDTM.AE with event dates out-of-visit-window

Table 2.4: Case 4 Study: Unscheduled visit occurred in source SDTM.VS in a cross-over study

USUBJID	VSTESTCD	VSSTRESC	VSSTRESN	VSSTRESU	VISIT	VSDTC	VSTPTNUM	VSTPT
201	PULSE	64	64	BEATS/MIN	PERIOD 1	2014-08-10T05:08	-0.5	-0.5 HOUR PRE DOSE
201	PULSE	50	50	BEATS/MIN	PERIOD 1	2014-08-10T07:58	2	2 HOURS POST DOSE
201	PULSE	56	56	BEATS/MIN	UNSCHEDULED VISIT	2014-08-10T08:01	-	-
201	PULSE	55	55	BEATS/MIN	PERIOD 1	2014-08-10T09:58	4	4 HOURS POST DOSE
201	…	…	…	…	…			
201	PULSE	61	61	BEATS/MIN	PERIOD 2	2014-08-24T05:08	-0.5	-0.5 HOUR PRE DOSE
201	PULSE	59	59	BEATS/MIN	PERIOD 2	2014-08-24T07:58	2	2 HOURS POST DOSE
201	PULSE	60	60	BEATS/MIN	PERIOD 2	2014-08-24T09:58	4	4 HOURS POST DOSE
201	…	…	…	…	…			
201	PULSE	71	71	BEATS/MIN	PERIOD 3	2014-09-07T05:08	-0.5	-0.5 HOUR PRE DOSE
201	PULSE	55	55	BEATS/MIN	PERIOD 3	2014-09-07T07:58	2	2 HOURS POST DOSE
201	PULSE	55	55	BEATS/MIN	PERIOD 3	2014-09-07T09:58	4	4 HOURS POST DOSE
201	…	…	…	…	…			

Table 2.4 Source data SDTM.VS with unscheduled event dates.

TRTP and TRTA IN SINGLE TREATMENT STUDY

In CDISC standards per ADaM IG 1.1, “At least one treatment variable is required in a BDS dataset. This requirement is satisfied by any of the subject-level or record-level treatment variables (e.g. TRTxxP or TRTP). One is allowed to use any treatment variable in analysis of BDS. Any subject-level treatment variable may be copied into the BDS dataset from ADSL. [3]”.

When a clinical trial is defined as a single treatment study, it’s relatively easier to practice the ADaM standards by directly following the ADaM IG. Let’s look at the Table 1 and Table 1.1 case.

Table 1: ADSL in a single treatment study

SUBJID	TRT01P	TRT01PN	TR01SDT	TR01EDT
201	A	1	1--Jul-15	1--Sep-15
202	B	2	1--Jul-15	1--Sep-15
203	B	2	1--Jun-15	1--Aug-15
204	A	1	1--Jun-15	1--Aug-15

Table 1 Treatment data values in ADSL

For the single treatment study, we can get TRTP for ADPC by merging the ADSL and PC though Subject ID, and create the TRTP value in ADPC by copying the TRT01P from ADSL.

Table 1.1: ADaM.ADPC in a single treatment study with TRTP added

SUBJID	PCTESTCD	PCSPEC	VISIT	PCDTC	PCSTRESC	PCSTRESN	PCSTRESU	PCTPT	TRTP
203	BUPRENOR	PLASMA	SCREEN	2014-08-10T05:10	<20.0	.	ng/L	0 (Pre-dose)	**B**
203	BUPRENOR	PLASMA	VISIT1	2014-08-10T06:10	54.3	54.3	ng/L	0.167 Hours	**B**
203	BUPRENOR	PLASMA	VISIT 1	2014-08-10T06:20	1610	1610	ng/L	0.33 Hours	**B**
203	BUPRENOR	PLASMA	VISIT 1	2014-08-10T06:30	8840	8840	ng/L	0.5 Hours	**B**

Table 1.1 ADaM.ADPC of a single treatment study

This COPY method is applicable to all single treatment studies, we don't need to do any pre-work of data manipulation when add TRTP to ADaM BDS datasets.

The illustrations above can be applied to the practice of TRTA variable in BDS dataset.

TRTP and TRTA IN CROSS-OVER TREATMENT STUDY

The beauty part of TRTP is that TRTP as a record-level identifier can represent the planned treatment attributed to a record for analysis purposes, and most importantly can indicate how treatment varies by record within a subject and enables the analysis of a crossover study design.

When a study is designed as a cross-over multi-period treatment, how we should best utilize the ADaM IG regarding TRTP standards? Though there is no requirement that TRTP will correspond to the TRTxxP as defined by the record's value of APERIOD, if populated, TRTP must match at least one value of the character planned treatment variables in ADSL (e.g., TRTxxP, TRTSEQP, TRxxPGy). As noted by IG, at least one treatment variable is required even in non-randomized trials. This requirement is satisfied by any subject-level or record-level treatment variables (e.g., TRTxxP, TRTP, TRTA). Even if not used for analysis, any ADSL treatment variable may be included in the BDS dataset.

The best practice of TRTP per ADaM IG is that users should assign the correct value to TRTP for all the analyzed records. To achieve this, some other comprehensive techniques need be taken into consideration. For example, variables in ADaM BDS datasets such ANLxxFL, AVISIT, APERIOD etc. may also contribute to the decision on how to define the TRTP value.

Table 2 is an illustration of ADSL data of a cross-over study. By examining the data, it is a study with three treatment period. Each subject has three treatments along with three treatment start and stop dates.

Table 2: ADSL in a cross-over three-treatment study

SUBJID	TRT01P	TRT01PN	TRT02P	TRT02PN	TRT03P	TRT03PN	TR01SDT	TR01EDT	TR02SDT	TR02EDT	TR03SDT	TR03EDT
201	A	1	C	3	B	2	10Aug14	10Aug14	24Aug14	24Aug14	07Sep14	07Sep14
202	B	2	A	1	C	3	10Aug14	10Aug14	24Aug14	24Aug14	07Sep14	07Sep14
203	B	2	C	3	A	1	10Aug14	10Aug14	24Aug14	24Aug14	07Sep14	07Sep14
204	C	3	A	1	B	2	10Aug14	10Aug14	24Aug14	24Aug14	07Sep14	07Sep14

Table 2 Cross-over study treatment values in ADSL

Below Table 2.1 is the first case, source SDTM.PC data shows that Subject 201 has the three-period data available and no discrepancy with the data collection. Such case allows us to identify the subject for his each record in SDTM.PC clearly in the ADSL data.

Table 2.1: Case 1 Study: ADPC in a cross-over study

SUBJID	PCTESTCD	PCSPEC	VISIT	PCDTC	PCSTRESC	PCSTRESN	PCSTRESU	PCTPT	TRTP
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T05:10	<20.0	.	ng/L	0 (Pre-dose)	**A**
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:10	54.3	54.3	ng/L	0.167 Hours	**A**
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:20	1610	1610	ng/L	0.33 Hours	**A**
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:30	8840	8840	ng/L	0.5 Hours	**A**
201	…	…	…	…					
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T05:10	<20.0	.	ng/L	0.167 Hours	**C**
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T06:10	107	107	ng/L	0.33 Hours	**C**
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T06:20	1540	1540	ng/L	0.5 Hours	**C**
201	…	…	…	…					
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T05:10	<20.0	.	ng/L	0.167 Hours	**B**
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T06:10	111	111	ng/L	0.33 Hours	**B**
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T06:20	806	806	ng/L	0.5 Hours	**B**

Table 2.1 ADPC with the source PC data having no discrepancy

However, when the BDS data is not in perfect collection format, some special attention then needs be given to it. Table 2.2 is a case that duplicate records are identified in the source SDTM.PC. In order to determine the value of TRTP correctly, ANL01FL has been taken into consideration. TRTP has been assigned the value “A” for the record with ANL01Fl=”Y” which tells that this record will be required for analysis. The other duplicate record has been left empty with TRTP.

Table 2.2: Case 2 Study: ADPC in a cross-over study

SUBJID	PCTESTCD	PCSPEC	VISIT	PCDTC	PCSTRESC	PCSTRESN	PCSTRESU	PCTPT	TRTP	ANL01FL
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T05:10	<20.0	.	ng/L	0 (Pre-dose)	A	Y
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:10	54.3	54.3	ng/L	0.167 Hours	A	Y
201	BUPRENOR	PLASMA	PERIOD 1	2014-08-10T06:20	1610	1610	ng/L	0.33 Hours	A	Y
201	**BUPRENOR**	**PLASMA**	**PERIOD 1**	**2014-08-10T06:30**	**8840**	**8840**	**ng/L**	**0.5 Hours**		
201	**BUPRENOR**	**PLASMA**	**PERIOD 1**	**2014-08-10T06:30**	**8851**	**8851**	**ng/L**	**0.5 Hours**	A	Y
201	…	…	…	…						
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T05:10	<20.0	.	ng/L	0.167 Hours	C	Y
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T06:10	107	107	ng/L	0.33 Hours	C	Y
201	BUPRENOR	PLASMA	PERIOD 2	2014-08-24T06:20	1540	1540	ng/L	0.5 Hours	C	Y
201	…	…	…	…						
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T05:10	<20.0	.	ng/L	0.167 Hours	B	Y
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T06:10	111	111	ng/L	0.33 Hours	B	Y
201	BUPRENOR	PLASMA	PERIOD 3	2014-09-07T06:20	806	806	ng/L	0.5 Hours	B	Y

Table 2.2 ADPC with source PC having duplicate values for one visit

The more challenge comes when the BDS data is not clearly collected per time-period for a cross-over study. Table 2.3 illustrates an example of ADAE. The criteria with CRF Adverse Event collection often does not have the requirement to include study visit or study period, giving the fact that AEs should be collected anytime it takes place. For the analysis purpose, the frequency of AEs in each treatment period is demanded, and this can be achieved by adding TRTP.

However, we can not this time simply copy the TRT01P from ADSL [Table 1.1] or merge by TRTxxP from ADSL [Table 2.1] or by VISIT period from SDTM.AE [Table 2.1 and Table 2.2]. Instead, some pre-calculation need be processed to obtain the visit period in SDTM.AE before assigning the TRTP values. Importantly the pre-process of visit period should follow the definition defined by Statistical Analysis Plan.

In this Case 3 study, to derive the AVISIT per SAP rule –
IF Period 1 Start Date <= AE Start Date < Period 2 Start Date THEN AVISIT = Period 1
ELSE IF Period 2 Start Date <= AE Start Date < Period 3 Start Date THEN AVISIT = Period 2
ELSE IF AE Start Date >= Period 3 Start Date THEN AVISIT = Period 3

After the AVIST values have been appropriately retrieved, the TRTP can be obtained by merging into ADSL.

Table 2.3: Case 3 Study: ADAE in a cross-over study

USUBJID	AEBODSYS	AEDECOD	AESTDTC	AEENDTC	AVISIT	TRTP
201	Skin and subcutaneous tissue disorders	Acne	**2014-08-01T13:52**	2015-08-01T12:00	**PERIOD 1**	**A**
201	Skin and subcutaneous tissue disorders	Acne	**2014-08-13T13:50**	2015-08-18T11:00	**PERIOD 1**	**A**
201	Gastrointestinal disorders	Nausea	**2014-09-06T19:15**	2015-09-08T05:46	**PERIOD 2**	**C**
201	Gastrointestinal disorders	Vomiting	**2014-09-07T10:35**	2015-09-07T10:36	**PERIOD 3**	**B**

Table 2.3 Source data SDTM.AE with event dates out-of-visit-window

SAS code for the above AVISIT derivation in Table 2.3 can be done like this –

IF TR01SDT<= AESTDT< TR02SDT **THEN** AVISIT = Period 1
ELSE IF TR02SDT <= AESTDT < TR03SDT **THEN** AVISIT = Period 2
ELSE IF AESTDT >= TR03SDT **THEN** AVISIT = Period 3

You can also apply this rule to derive APERIOD to achieve the same goal as APERIOD can replace the AVISIT to be used to identify the BDS record –

IF TR01SDT<= AESTDT< TR02SDT **THEN** APERIOD = 1
ELSE IF TR02SDT <= AESTDT < TR03SDT **THEN** APERIOD = 2
ELSE IF AESTDT >= TR03SDT **THEN** APERIOD = 3

Note that the TR01SDT, TR02SDT and TR03SDT in ADSL have been used to identify the time period in AE data. The derivation rule is simply an example for your reference. You may also want to use TR01EDT, TR02EDT and TR03EDT for the derivation. The point is to follow the SAP to make the derivation correct for analysis purpose.

Another challenge with BDS data is that unscheduled visits exist in the data almost everywhere. Let's bypass the data discrepancy checks at this point, assume we use the data as is. When it comes to deal with an unscheduled visit, first we need to identify how SAP defines the usage of the unscheduled. If an unscheduled visit has been defined not to be included in the analysis, simply leave TRTP empty. If an unscheduled visit has been defined to be included in the analysis, it's critical to figure out which AVISIT this unscheduled visit belongs to. In order to identify which TRTP this unscheduled record should go to, AVISIT or APERIOD value need be created first for the unscheduled record per SAP.

For the Case 4 study, the unscheduled visit has been processed to AVISIT = PERIOD 1, AVISITNUM=2 and per SAP it should be included into analysis because it's the last available analysis value for PERIOD 1 TIMEPOINT 2.

Table 2.4a: Case 4 Study: ADVS in a cross-over study

SUBJID	VSTESTCD	VSSTRESN	VSSTRESU	VISIT	VSDTC	VSTPTNUM	AVISTNUM	AVIST	TRTP	ANL01FL
201	PULSE	64	BEATS/MIN	PERIOD 1	2014-08-10T05:08	-0.5	-0.5	PERIOD 1	A	Y
201	PULSE	50	BEATS/MIN	PERIOD 1	2014-08-10T07:58	2	2	PERIOD 1		
201	PULSE	56	BEATS/MIN	**UNSCHEDULED VISIT**	2014-08-10T08:01	**-**	**2**	**PERIOD 1**	**A**	Y
201	PULSE	55	BEATS/MIN	PERIOD 1	2014-08-10T09:58	4	4	PERIOD 1	A	Y
201	…	…	…	…				…		
201	PULSE	61	BEATS/MIN	PERIOD 2	2014-08-24T05:08	-0.5	-0.5	PERIOD 2	C	Y
201	PULSE	59	BEATS/MIN	PERIOD 2	2014-08-24T07:58	2	2	PERIOD 2	C	Y
201	PULSE	60	BEATS/MIN	PERIOD 2	2014-08-24T09:58	4	4	PERIOD 2	C	Y
201	…	…	…	…				…		
201	PULSE	71	BEATS/MIN	PERIOD 3	2014-09-07T05:08	-0.5	-0.5	PERIOD 3	B	Y
201	PULSE	55	BEATS/MIN	PERIOD 3	2014-09-07T07:58	2	2	PERIOD 3	B	Y
201	PULSE	55	BEATS/MIN	PERIOD 3	2014-09-07T09:58	4	4	PERIOD 3	B	Y
201	…	…	…	…				…		

Table 2.4a Source data SDTM.VS with unscheduled event dates.

You can also replace the AVISIT by APERIOD to achieve the same goal as APERIOD can also be used to identify the BDS record, see Table 2.4b. However, when it's merged to ADSL to get TRTP value, the ADSL.TRTxxPN should be used instead of TRTxxP.

Table 2.4b: Case 4 Study: ADVS in a cross-over study

SUBJID	VSTESTCD	VSSTRESN	VSSTRESU	VISIT	VSDTC	VSTPTNUM	AVISTNUM	APERIOD	TRTP	ANL01FL
201	PULSE	64	BEATS/MIN	PERIOD 1	2014-08-10T05:08	-0.5	-0.5	1	A	Y
201	PULSE	50	BEATS/MIN	PERIOD 1	2014-08-10T07:58	2	2	1		
201	PULSE	56	BEATS/MIN	**UNSCHEDULED VISIT**	2014-08-10T08:01	**-**	**2**	**1**	**A**	Y
201	PULSE	55	BEATS/MIN	PERIOD 1	2014-08-10T09:58	4	4	1	A	Y
201	…	…	…	…				…		
201	PULSE	61	BEATS/MIN	PERIOD 2	2014-08-24T05:08	-0.5	-0.5	2	C	Y
201	PULSE	59	BEATS/MIN	PERIOD 2	2014-08-24T07:58	2	2	2	C	Y
201	PULSE	60	BEATS/MIN	PERIOD 2	2014-08-24T09:58	4	4	2	C	Y
201	…	…	…	…				…		
201	PULSE	71	BEATS/MIN	PERIOD 3	2014-09-07T05:08	-0.5	-0.5	3	B	Y
201	PULSE	55	BEATS/MIN	PERIOD 3	2014-09-07T07:58	2	2	3	B	Y
201	PULSE	55	BEATS/MIN	PERIOD 3	2014-09-07T09:58	4	4	3	B	Y
201	…	…	…	…				…		

Table 2.4b Source data SDTM.VS with unscheduled event dates.

All the illustrations above can be also applied to the practice of TRTA variable in BDS dataset.

CONCLUSION

This paper has presented a review of experiences implementing TRTP and TRTA in ADaM BDS datasets, discussed comprehensive utilization of CDISC ADaM supporting variables such as AVISIT, APERIOD and "ANLxxFL" etc. when developing "TRTP", "TRTA". The examples and discussions have demonstrated the step-by-step approach of how to appropriately derive the ADaM TRTP in BDS datasets per CDISC ADaM IG v1.1. Suggestions on how to handle the BDS data with discrepancies have also been covered.

The purpose of this paper is focused on the discussion of the TRTP and TRTA terminology per CDISC ADaM IG. The details regarding the concept of what is CDISC ADaM are not covered in this paper.

REFERENCES

[1] Analysis Data Model (ADaM) Implementation Guide Version 1.1 ＜CDISC Analysis Data Model Team＞, 2016-02-12.

[2] Analysis Data Model (ADaM) Implementation Guide Version 1.1 ＜CDISC Analysis Data Model Team＞, page 32.

[3] Analysis Data Model (ADaM) Implementation Guide Version 1.1 ＜CDISC Analysis Data Model Team＞, page 32.

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