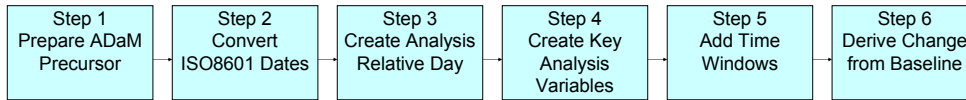


Extension of the Six Steps Approach: How to go from an SDTM findings domain to an ADaM-compliant analysis dataset

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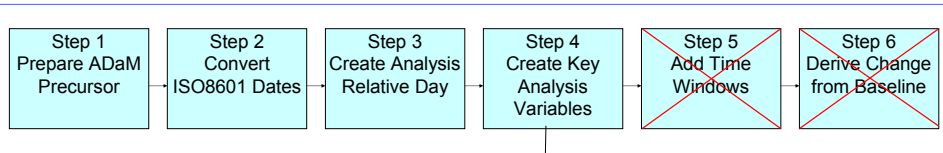
SIX STEPS TO CONSTRUCT AN ADaM BASIC DATA STRUCTURE (BDS) ANALYSIS DATASET[†]



EXTENSION OF THE BASIC STEPWISE APPROACH

ANALYSIS OF PREDEFINED LIMITS OF CHANGE (PDLc)

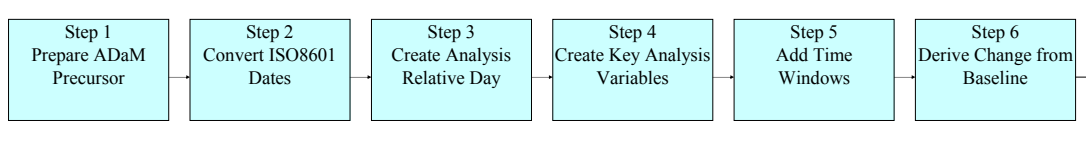
EXAMPLE 1: PREDEFINED LIMIT CRITERION IS MET WHEN THE POST-BASELINE SERUM SODIUM RESULT > 146 MMOL/L



Step PDLc CRIT1FL

PARAMCD	ADY	PARAM	AVAL	CRIT1	CRIT1FL
NA	-18	Sodium (mmol/L)	141		
NA	1	Sodium (mmol/L)	140		
NA	14	Sodium (mmol/L)	145		
NA	46	Sodium (mmol/L)	149	Sodium > 146 mmol/L	Y

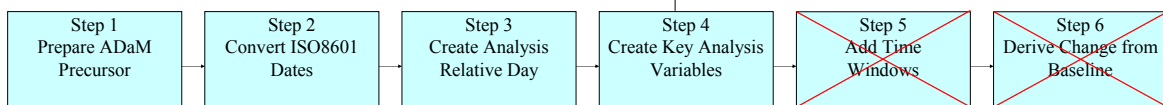
EXAMPLE 2: PREDEFINED LIMIT CRITERION IS MET WHEN THE POST-BASELINE SITTING SYSTOLIC BLOOD PRESSURE ≥ 180 MMHG WITH A 20 MMHG INCREASE FROM BASELINE



PARAMCD	ADY	AVISIT	ABLFL	AVAL	BASE	CHG	CRIT1	CRIT1FL
SYSBP	-18	Baseline		104	120	-6		
SYSBP	1	Baseline	Y	120	120	0		
SYSBP	14	Treatment 1		180	120	60	Result ≥ 180 mm Hg and change from baseline > 20 mm Hg	Y

Step PDLc CRIT1FL

TIME TO EVENT ANALYSIS



Step CENSOR

USUBJID	PARAMCD	PARAM	STARTDT	ADT	AVAL	CNSR	EVNTDESC
1001-0001	DEATH	Time to Death (days)	01JAN2007	15JAN2007	15	0	DEATH
1001-0002	DEATH	Time to Death (days)	01JAN2007	17JUN2007	168	1	COMPLETED THE STUDY
1001-0003	DEATH	Time to Death (days)	01JAN2007	30APR2007	120	1	LOST TO FOLLOW-UP
1001-0004	DEATH	Time to Death (days)	01JAN2007	17JUN2007	168	1	COMPLETED THE STUDY
1001-1005	DEATH	Time to Death (days)	01JAN2007	30JAN2007	30	0	DEATH
1001-1006	DEATH	Time to Death (days)	01JAN2007	04JAN2007	4	1	ADVERSE EVENT

Step 1: Merge of SDTM datasets (AE, DS) with the SUPQUAL in order to build the ADaM precursors.
Step 2: Conversion of the ISO 8061 dates to valid SAS dates (e.g. for ADT and STARTDT).
Step 3: Creation of the relative day (ADY).
Step 4: Derivation of PARAMCD, PARAM and AVAL.
Step CENSOR: Creation of additional time to event variables CNSR and EVNTDESC.

[†]Q. Wang, C.H. Herremans How to go From an SDTM Findings Domain to an ADaM-Compliant Analysis Dataset: An Example. , Proceedings of PhSUE 2007, CD05, 8p [Pharmaceutical Users Software Exchange 2010 Conference (PhUSE), Berlin, Germany, October 14-17, 2010]. <http://www.lexiansen.com/phuse/2010/cd/cd05.pdf>