

TEMPO AE, Con Med and Covance Lab Data Dictionary

version 5/2010

	SAS Variable Name	Label	Type	Length	Format	Range/Codelist/Description
		<b>Adverse Experience Log (AE) L100</b>				
	DATASRC	Data Source	Char	4		0007
	PDDOCID	PD-DOC ID	Char	8		De-identified ID
	SITE	Site Number	Num	8		
	ae02	COSTART AE TEXT (coded with the COSTART 1998 dictionary)	Char	64		Verbatim as captured on CRF has been replaced by the COSTART text of the coded term.
	ae01	AE#	Num	8		
	ae03	AE Status	Num	8		1=began in double-blind 2=began in active treatment
	ae04	Pre-Existing Condition	Num	8		1=Yes 2=No
	ae07	Duration Less than 1 day	Num	8		in Hours
	ae08	Severity	Num	8		1=Mild 2=Moderate 3=Severe
	ae09	Serious	Num	8		1=Yes 2=No
	ae10	Classification	Num	8		1=fatal 2=life-threatening 3=permanently disabling 4=requires or prolongs hospitalization 5= results in congenital anomaly 6=cancer 7=drug overdose
	ae11	Study Drug Dosing Change	Num	8		1=As per protocol 2=Study drug temporarily discontinued 3= Dose halved in active treatment phase 4=Study drug stopped
	ae12	Subject Outcome	Num	8		1=Recovered 2=Under treatment/observation 3=Sequelae 4=Unkown/lost to follow-up 5=Death
	ae13	Corrective Drug Therapy	Num	8		1=Yes 2=No
	ae14	Suspected Study Drug Relationship	Num	8		1=Unknown 2=Unrelated 3=Possibly related 4=Probably related
	ae15	AE Follow-up	Num	8		1=to be followed 2= not to be followed 3=unrecovered at week 26 N=not final visit

TEMPO AE, Con Med and Covance Lab Data Dictionary

version 5/2010

derived	aestartdays	Days from BL to AE start date (AE Log)	Num	8		AE Start date - Enrollment date	
derived	aestopdays	Days from BL to AE stop date (AE Log)	Num	8		AE Stop date - Enrollment date	
derived	duratdys	AE Duration	Num	8		duratdys = stop date - start date +1	
derived	aestartyr	AE start year	Num	8			
derived	aestopyr	AE stop year	Num	8			
		<b>Concomitant Medication Log/PD (MEDP) L200</b>			NOTE: There are 2 observations that do not have a start date. These will have a missing WEEK. Usually occurs when the medication was started a long time prior to the start of the study; can not say this is always the case.		
	DATASRC	Data Source	Char	4		0007	
	PDDOCID	PD-DOC ID	Char	8		De-identified ID	
	medp01	WHO Drug name (coded with WHO 1999 dictionary)	char	\$100		Verbatim as captured on CRF has been replaced by the WHO Drug Dictionary name of the coded term.	
	SITE	Site Number	Num	8			
	medp02	Total Daily Dose	Char	10			
	medp03	Unit	Char	20			
	medp04	Frequency	Char	20			
	medp05	Route of Administration	Char	20			
	medp08	Ongoing	Num	8		1=Yes 2=No 3=Withdrawing	
	medp09	Indication (PD)	Char	15		Parkinson	
derived	medpstartdays	Days from BL to con med start date (Con Med Log-PD)	Num	8		Con Med start date - Enrollment date (PD) A negative number means the medication was began prior to enrolling in the study.	
derived	medpstopdays	Days from BL to con med stop date (Con Med Log-PD)	Num	8		Con Med Stop date - Enrollment date (PD) A negative number means the medication was stopped prior to entering the study.	
derived	duratdys	Time on Medication (PD indication)	Num	8		duratdys=med stop date - med start date +1	
derived	medpstartyr	Medication start year	Num	8			
derived	medpstopyr	Medication stop year	Num	8			
		<b>Concomitant Medication Log (CMED) L300</b>			NOTE: There are 20 observations that do not have a start date. These will have a missing WEEK. Usually occurs when the medication was started a long time prior to the start of the study; can not say this is always the case.		
	DATASRC	Data Source	Char	4		0007	
	PDDOCID	PD-DOC ID	Char	8		De-identified ID	

TEMPO AE, Con Med and Covance Lab Data Dictionary

version 5/2010

	cmed01	WHO Drug name (coded with WHO 1999 dictionary)	Char	\$100		Verbatim as captured on CRF has been replaced by the WHO Drug Dictionary name of the coded term.
	SITE	Site Number	Num	8		
	cmed02	Total Daily Dose	Char	\$10		
	cmed03	Unit	Char	\$20		
	cmed04	Frequency	Char	\$20		
	cmed05	Route of Administration	Char	\$20		
	cmed08	Ongoing	Num	8		1=Yes 2=No 3=Withdrawing
	cmed09	Indication (non-PD)	Char	\$50		
<b>derived</b>	cmedstartdays	Days from BL to con med start date (Con Med Log - non-PD)	Num	8		Con Med start date - Enrollment date (non-PD) A negative number means the medication was began prior to enrolling in the study.
<b>derived</b>	cmedstopdays	Days from BL to con med stop date (Con Med Log - non-PD)	Num	8		Con Med Stop date - Enrollment date (non-PD) A negative number means the medication was stopped prior to entering the study.
<b>derived</b>	duratdys	Time on Medication	Num	8		duratdys=med stop date - med start date +1
<b>derived</b>	cmedstartyr	Medication start year	Num	8		
<b>derived</b>	cmedstopyr	Medication stop year	Num	8		
		<b>Covance Lab Data (LAB)</b>				
	DATASRC	Data Source	Char	4		0007
	PDDOCID	PD-DOC ID	Char	8		De-identified ID
	gender	Gender	Num	8		1 = Male 2 = Female
	race	Race	Num	8		1 = Caucasian 2 = Black 3 = Hispanic 4=Asian 5=American Indian 6=Other
<b>derived</b>	age	Age at time of lab draw	Num	8		Lab date - date of birth (If age is GT 89 set to missing)
<b>derived</b>	agegt89	Age greater than 89?	Num	8		0=No, 1=Yes
	weeklabs	Calculated week from time of enrollment	Num	8		This is the calculated week. It equals the integer of labdays/7 and ranges from -1 to 30 with most of the values in-between. The variable week will correspond to the visitno.

TEMPO AE, Con Med and Covance Lab Data Dictionary

version 5/2010

	VISITNO	Visit Number	Char	10		SCR = screening visit BAS = baseline visit W14 = week 14 visit W26 = week 26 visit
	week	Visit week	Num	8		-1 = screening visit 0 = baseline visit 14 = week 14 visit 26 = week 26 visit
	labq03	Test Code	Char	8		
	labq04	Lab Test	Char	25		
	labq05	Character Test Result	Char	46		
	labq07	Units	Char	15		
	labq08	Numeric Test Result	Num	8		Numeric Test Result
	labq10	Abnormal Flag	Char	2		L = Low out of normal range H= High out of normal range HT=High telephone alert LT=Low telephone alert
	labq11	Numeric recode of Q03	Num	8		This is the Test Code (Q3) recoded to numbers 1-59. if labq03='CMT17' then labq11=01 ; if labq03='CMT18' then labq11=02 ; if labq03='HMT12' then labq11=03 ; if labq03='HMT95' then labq11=04 ; if labq03='HMT11' then labq11=05 ; if labq03='HMT10' then labq11=06 ; if labq03='HMT19' then labq11=07 ; if labq03='RCT392' then labq11=08 ; if labq03='RCT1' then labq11=09 ; if labq03='HMT96' then labq11=10 ; if labq03='HMT9' then labq11=12 ; if labq03='RCT9' then labq11=13 ; if labq03='RCT13' then labq11=14 ; if labq03='HMT3' then labq11=15 ; if labq03='RCT16' then labq11=16 ; if labq03='HMT18' then labq11=17 ; if labq03='CMT3' then labq11=18 ; if labq03='RCT12' then labq11=19 ; if labq03='RCT183' then labq11=20 ; etc.
	labq12	Low LNR	Num	8		Low end of Normal range
	labq13	High UNR	Num	8		High end of Normal range
<b>derived</b>	labdays	Days from BL to lab date (Covance lab data)	Num	8		Lab date - Enrollment date