INPUT SAMPLE CHOLESTEROL DATA AS SDTM LB DOMAIN

Obs	USUBJID	LBDTC	LBTESTCD	LBSTRESN
1	101	2003-09-05	HDL	48
2	101	2003-09-05	LDL	188
3	101	2003-09-05	TRIG	108
4	101	2003-09-06	HDL	49
5	101	2003-09-06	LDL	185
6	101	2003-09-06	TRIG	
7	102	2003-10-01	HDL	54
8	102	2003-10-01	LDL	200
9	102	2003-10-01	TRIG	350
10	102	2003-10-02	HDL	52
11	102	2003-10-02	LDL	
12	102	2003-10-02	TRIG	360
13	103	2003-11-10	HDL	
14	103	2003-11-10	LDL	240
15	103	2003-11-10	TRIG	900
16	103	2003-11-11	HDL	30
17	103	2003-11-11	LDL	
18	103	2003-11-11	TRIG	880
19	103	2003-11-12	HDL	32
20	103	2003-11-12	LDL	
21	103	2003-11-12	TRIG	
22	103	2003-11-13	HDL	35
23	103	2003-11-13	LDL	289
24	103	2003-11-13	TRIG	930

INPUT SAMPLE PILL DOSING DATA AS SDTM EX DOMAIN

Obs	USUBJID	EXSTDTC
1	101	2003-09-07
2	102	2003-10-07
3	103	2003-11-13

Obs	USUBJID	PARAMCD	AVAL	ADT	EXSTDTC	ABLFL
1	101	HDL	48	2003-09-05	2003-09-07	
2	101	HDL	49	2003-09-06	2003-09-07	Y
3	101	LDL	188	2003-09-05	2003-09-07	
4	101	LDL	185	2003-09-06	2003-09-07	Y
5	101	TRIG	108	2003-09-05	2003-09-07	Y
6	101	TRIG		2003-09-06	2003-09-07	
7	102	HDL	54	2003-10-01	2003-10-07	
8	102	HDL	52	2003-10-02	2003-10-07	Y
9	102	LDL	200	2003-10-01	2003-10-07	
10	102	LDL		2003-10-02	2003-10-07	
11	102	TRIG	350	2003-10-01	2003-10-07	
12	102	TRIG	360	2003-10-02	2003-10-07	Y
13	103	HDL		2003-11-10	2003-11-13	
14	103	HDL	30	2003-11-11	2003-11-13	
15	103	HDL	32	2003-11-12	2003-11-13	Y
16	103	HDL	35	2003-11-13	2003-11-13	
17	103	LDL	240	2003-11-10	2003-11-13	Y
18	103	LDL		2003-11-11	2003-11-13	
19	103	LDL		2003-11-12	2003-11-13	
20	103	LDL	289	2003-11-13	2003-11-13	
21	103	TRIG	900	2003-11-10	2003-11-13	
22	103	TRIG	880	2003-11-11	2003-11-13	Y
23	103	TRIG		2003-11-12	2003-11-13	
24	103	TRIG	930	2003-11-13	2003-11-13	

Obs	USUBJID	LBDTC	LBTESTCD	LBSTRESN
1	101	2013-06-15	HGB	1.0
2	101	2013-06-16	HGB	1.1
3	101	2013-07-15	HGB	1.2
4	101	2013-07-21	HGB	1.3
5	101	2013-08-14	HGB	1.4
6	101	2013-08-16	HGB	1.5
7	101	2014-06-01	HGB	1.6
8	101	2014-06-25	HGB	1.7
9	101	2015-06-10	HGB	1.8
10	101	2015-06-15	HGB	1.9

Obs	USUBJID	EXSTDTC
1	101	2013-06-17

Merged EX and LB data sets to make ADLB data set

Obs	USUBJID	LBDTC	LBTESTCD	LBSTRESN	EXSTDTC
1	101	2013-06-15	HGB	1.0	2013-06-17
2	101	2013-06-16	HGB	1.1	2013-06-17
3	101	2013-07-15	HGB	1.2	2013-06-17
4	101	2013-07-21	HGB	1.3	2013-06-17
5	101	2013-08-14	HGB	1.4	2013-06-17
6	101	2013-08-16	HGB	1.5	2013-06-17
7	101	2014-06-01	HGB	1.6	2013-06-17
8	101	2014-06-25	HGB	1.7	2013-06-17
9	101	2015-06-10	HGB	1.8	2013-06-17
10	101	2015-06-15	HGB	1.9	2013-06-17

Modified ADLB dataset with the following variables
ABLFL = Baseline Record Flag; PARAMCD = Parameter Code
ADT = Analysis Date; AVAL = Analysis Value
AWTARGET = Analysis Window Target
AWRANGE = Analysis Window Valid Relative Range
AVISIT = Analysis Visit
ADY = Analysis Relative Day
AWTDIFF = Analysis Window Diff from Target
ANL01FL = Analysis Record Flag 01

Obs	USUBJID	PARAMCD	ADT	EXSTDTC	ADY	AVISIT	AWTARGET	ADY	AWTDIFF	AWRANGE	ANL01FL
1	101	HGB	2013-06-15	2013-06-17	-2	Baseline	-1	-2	1	Up to ADY -1	
2	101	HGB	2013-06-16	2013-06-17	-1	Baseline	-1	-1	0	Up to ADY -1	Y
3	101	HGB	2013-07-15	2013-06-17	29	Month 1	30	29	1	25 <= ADY <= 35	Y
4	101	HGB	2013-07-21	2013-06-17	35	Month 1	30	35	5	25 <= ADY <= 35	
5	101	HGB	2013-08-14	2013-06-17	59	Month 2	60	59	1	55 <= ADY <= 65	Y
6	101	HGB	2013-08-16	2013-06-17	61	Month 2	60	61	1	55 <= ADY <= 65	
7	101	HGB	2014-06-01	2013-06-17	350	Year 1	365	350	15	350 <= ADY <= 380	
8	101	HGB	2014-06-25	2013-06-17	374	Year 1	365	374	9	350 <= ADY <= 380	Y
9	101	HGB	2015-06-10	2013-06-17	724	Year 2	730	724	6	715 <= ADY <= 745	
10	101	HGB	2015-06-15	2013-06-17	729	Year 2	730	729	1	715 <= ADY <= 745	Y

Input sample systolic blood pressure (SBP) values as SDTM VS domain

Obs	USUBJID	VSTESTCD	VISITNUM	VSSTRESN
1	101	SBP	1	160
2	101	SBP	2	150
3	101	SBP	3	140
4	101	SBP	4	130
5	101	SBP	5	120
6	202	SBP	1	141
7	202	SBP	2	151
8	202	SBP	3	161
9	202	SBP	4	171
10	202	SBP	5	181

De-normalize, Normalized SBP values to a flat structure for statistical modelling

Obs	USUBJID	_NAME_	_LABEL_	VISIT1	VISIT2	VISIT3	VISIT4	VISIT5
1	101	VSSTRESN	Numeric Result/Finding in Standard Units	160	150	140	130	120
2	202	VSSTRESN	Numeric Result/Finding in Standard Units	141	151	161	171	181

Input sample systolic blood pressure (SBP) values as SDTM VS domain & missing values

Obs	USUBJID	VSTESTCD	VISITNUM	VSSTRESN
1	101	SBP	1	160
2	101	SBP	3	140
3	101	SBP	4	130
4	101	SBP	5	120
5	202	SBP	1	141
6	202	SBP	2	151
7	202	SBP	3	161
8	202	SBP	4	171
9	202	SBP	5	181

De-normalize, Normalized SBP values to a flat structure for statistical modelling without ID statement

Obs	USUBJID	_NAME_	_LABEL_	VISIT1	VISIT2	VISIT3	VISIT4	VISIT5
1	101	VSSTRESN	Numeric Result/Finding in Standard Units	160	140	130	120	
2	202	VSSTRESN	Numeric Result/Finding in Standard Units	141	151	161	171	181

De-normalize, Normalized SBP values to a flat structure for statistical modelling with ID statement

Obs	USUBJID	_NAME_	_LABEL_	VISIT1	VISIT3	VISIT4	VISIT5	VISIT2
1	101	VSSTRESN	Numeric Result/Finding in Standard Units	160	140	130	120	
2	202	VSSTRESN	Numeric Result/Finding in Standard Units	141	161	171	181	151

Two-Way frequency table of the variables AVAL TRTP
AVAL = analysis value 0= pt lived 1= pt died
TRTP = Planned Treatment

The FREQ Procedure

Frequency Percent	Table of AVAL by TRTP		
AVAL(Analysis Value)	TRTP(Planned Treatment)		
	a	b	Total
0	9 11.25	18 22.50	27 33.75
1	31 38.75	22 27.50	53 66.25
Total	40 50.00	40 50.00	80 100.00

Statistics for Table of AVAL by TRTP

Statistic	DF	Value	Prob
Chi-Square	1	4.5283	0.0333
Likelihood Ratio Chi-Square	1	4.5939	0.0321
Continuity Adj. Chi-Square	1	3.5779	0.0586
Mantel-Haenszel Chi-Square	1	4.4717	0.0345
Phi Coefficient		-0.2379	
Contingency Coefficient		0.2315	
Cramer's V		-0.2379	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	9
Left-sided Pr <= F	0.0288
Right-sided Pr >= F	0.9914
Table Probability (P)	0.0202
Two-sided Pr <= P	0.0576

Sample Size = 80

Two-Way frequency table of the variables AVAL TRTP
AVAL = analysis value unknown= pt lived 1= pt died
TRTP = Planned Treatment

The FREQ Procedure

Frequency Percent	Table of AVAL by TRTP		
AVAL(Analysis Value)	TRTP(Planned Treatment)		
	a	b	Total
0	9 11.84	14 18.42	23 30.26
1	31 40.79	22 28.95	53 69.74
Total	40 52.63	36 47.37	76 100.00
Frequency Missing = 4			

Statistics for Table of AVAL by TRTP

Statistic	DF	Value	Prob
Chi-Square	1	2.4114	0.1205
Likelihood Ratio Chi-Square	1	2.4208	0.1197
Continuity Adj. Chi-Square	1	1.6974	0.1926
Mantel-Haenszel Chi-Square	1	2.3797	0.1229
Phi Coefficient		-0.1781	
Contingency Coefficient		0.1754	
Cramer's V		-0.1781	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	9
Left-sided Pr <= F	0.0963
Right-sided Pr >= F	0.9646
Table Probability (P)	0.0608
Two-sided Pr <= P	0.1402

Sample Size = 76
Frequency Missing = 4

Obs	USUBJID	AESTDTC	AEENDTC	AETERM
1	101	2004-01-01	2004-01-02	Headache
2	101	2004-01-15	2004-02-03	Back Pain
3	102	2003-11-03	2003-12-10	Rash
4	102	2004-01-03	2004-01-10	Abdominal Pain
5	102	2004-04-04	2004-04-04	Constipation

Concomitant Medication (CM) data set

Obs	USUBJID	CMSTDTC	CMENDTC	CMTRT
1	101	2004-01-01	2004-01-01	Acetaminophen
2	101	2003-10-20	2004-03-20	Tylenol w/ Codeine
3	101	2003-12-12	2003-12-12	Sudaphed
4	102	2003-12-07	2003-12-18	Hydrocortizone Cream
5	102	2004-01-06	2004-01-08	Simethicone
6	102	2004-01-09	2004-03-10	Esomeprazole

Obs	USUBJID	AESTDTC	AEENDTC	AETERM	CMSTDTC	CMENDTC	CMTRT
1	101	2004-01-01	2004-01-02	Headache	2004-01-01	2004-01-01	Acetaminophen
2	101	2004-01-01	2004-01-02	Headache	2003-10-20	2004-03-20	Tylenol w/ Codeine
3	101	2004-01-15	2004-02-03	Back Pain	2003-10-20	2004-03-20	Tylenol w/ Codeine
4	102	2004-01-03	2004-01-10	Abdominal Pain	2004-01-09	2004-03-10	Esomeprazole
5	102	2004-01-03	2004-01-10	Abdominal Pain	2004-01-06	2004-01-08	Simethicone
6	102	2003-11-03	2003-12-10	Rash	2003-12-07	2003-12-18	Hydrocortizone Cream
7	102	2004-04-04	2004-04-04	Constipation			

Obs	USUBJID	AETERM
1	101	Headache
2	102	Rash
3	102	Fatal MI
4	102	Abdominal Pain
5	102	Constipation

Obs	USUBJID	DEATHFL
1	101	0
2	102	0

Obs	USUBJID	AETERM	DEATHFL
1	101	Headache	0
2	102	Rash	0
3	102	Fatal MI	1
4	102	Abdominal Pain	1
5	102	Constipation	1

Obs	USUBJID	AETERM
1	101	Headache
2	102	Rash
3	102	Fatal MI
4	102	Abdominal Pain
5	102	Constipation

Obs	USUBJID	DEATHFL
1	101	0
2	102	0

Obs	USUBJID	AETERM	DEATHFL
1	101	Headache	0
2	102	Rash	0
3	102	Fatal MI	1
4	102	Abdominal Pain	0
5	102	Constipation	0

Vital signs - Diastolic / Systolic BP data set

Obs	USUBJID	VSTESTCD	VSSTRESN	VISITNUM
1	101	DBP	160	0
2	101	SBP	90	0
3	101	DBP	140	1
4	101	SBP	87	1
5	101	DBP	130	2
6	101	SBP	85	2
7	101	DBP	120	3
8	101	SBP	80	3
9	202	DBP	141	0
10	202	SBP	75	0
11	202	DBP	161	1
12	202	SBP	80	1
13	202	DBP	171	2
14	202	SBP	85	2
15	202	DBP	181	3
16	202	SBP	90	3

Sorted - Vital signs - Diastolic / Systolic BP data set

Obs	Unique Subject Identifier	Vitals Signs Test Short Name	Numeric Result/Finding in Standard Units	VISITNUM
1	101	DBP	160	0
2	101	DBP	140	1
3	101	DBP	130	2
4	101	DBP	120	3
5	101	SBP	90	0
6	101	SBP	87	1
7	101	SBP	85	2
8	101	SBP	80	3
9	202	DBP	141	0
10	202	DBP	161	1
11	202	DBP	171	2
12	202	DBP	181	3
13	202	SBP	75	0
14	202	SBP	80	1
15	202	SBP	85	2
16	202	SBP	90	3

ADVS dataset - Change from baseline BP (visit0) & % change from baseline

Obs	USUBJID	AVISITN	PARAMCD	AVAL	ABLFL	BASE	CHG	PCHG
1	101	0	DBP	160	Y	160		
2	101	1	DBP	140		160	-20	-12.5000
3	101	2	DBP	130		160	-30	-18.7500
4	101	3	DBP	120		160	-40	-25.0000
5	101	0	SBP	90	Y	90		
6	101	1	SBP	87		90	-3	-3.3333
7	101	2	SBP	85		90	-5	-5.5556
8	101	3	SBP	80		90	-10	-11.1111
9	202	0	DBP	141	Y	141		
10	202	1	DBP	161		141	20	14.1844
11	202	2	DBP	171		141	30	21.2766
12	202	3	DBP	181		141	40	28.3688
13	202	0	SBP	75	Y	75		
14	202	1	SBP	80		75	5	6.6667
15	202	2	SBP	85		75	10	13.3333
16	202	3	SBP	90		75	15	20.0000

CE data set - SDTM Clinical events domain

Obs	USUBJID	CETERM	CEPRESP	CEOCCUR	CESTDTC
1	101	Seizure	Y	Y	2004-05-05
2	102	Seizure	Y	N	
3	103	Seizure	Y		
4	104	Seizure	Y	Y	2004-06-07

DM data set - SDTM demographics Domain

Obs	USUBJID	RFENDTC
1	101	2004-08-05
2	102	2004-08-10
3	103	2004-08-12
4	104	2004-08-20

EX data set - STDM Drug Exposure Domain

Obs	USUBJID	EXSTDTC
1	101	2004-01-01
2	102	2004-01-03
3	103	2004-01-06
4	104	2004-01-09

Adseiz data set - CDISC ADaM Basic Data Structure Time to Event

Obs	USUBJID	PARAM	AVAL	CNSR	ADT	RFENDTC	EXSTDTC	CETERM	CEPRESP	CEOCCUR	CESTDTC
1	101	Time to Seizure (days)	126	0	05MAY2004	2004-08-05	2004-01-01	Seizure	Y	Y	2004-05-05
2	102	Time to Seizure (days)	221	1	10AUG2004	2004-08-10	2004-01-03	Seizure	Y	N	
3	103	Time to Seizure (days)				2004-08-12	2004-01-06	Seizure	Y		
4	104	Time to Seizure (days)	151	0	07JUN2004	2004-08-20	2004-01-09	Seizure	Y	Y	2004-06-07