

Trial name	CALERIE 2
Dataset name	POMSA (Profile of Mood States)
Description	Profile of Mood States data from CRF, flattened to one record per DEIDNUM / VISIT. Raw data has 1 record for each of the 65 questions per DEIDNUM / VISIT. Includes responses to each item in the questionnaire and derived scores using POMS scoring algorithm (see QOL scoring MOP).
Comments on data structure	1 record / DEIDNUM / VISIT
Population	All subjects who had baseline evaluations, including all randomized subjects
Visits	Baseline Visits 1-3 , Month 6, Month 12, Month 24 VISIT codes
Source data files	CRF/POMS, DATEHDR, ANALDATA/SUBJECT1
Final sort order	DEIDNUM VISIT

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DEIDNUM	Subject Number	DEIDNUM	C		
PAGENUM	CRF page number	POMS.PAGEID	N		
VISIT	Visit	PAGENUM	N	Study Visit, based on CRF page (See Appendix)	VISFMT
SUBVISIT	Sub-Visit	PAGENUM	N	Study Sub-visit, based on CRF page (See Appendix)	SVISFMT
POMSDT	Date of POMS	DATEHDR.STUDYDT	DT		DT
POMSND	Reason POMS not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFPOMS	POMS done	POMSDT	N	=1 if POMSDT is non-missing else =0	
POMS1 – POMS65	Response for POMS questionnaire item 1 – 65	POMS.POMSQ, POMS.POMSA	N	POMS[N]=POMSA if POMSQ=N.	TUPOMB
POMS22R	POMS Item 22 reversed	POMS22	N	=4 – POMS22	
POMS54R	POMS Item 54 reversed	POMS54	N	=4 – POMS54	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
NTENSION	N non-missings for POMS tension score	POMS2, 10, 16, 20, 22R, 26, 27, 34, 41	N	Number of non-missings in POMS2, 10, 16, 20, 22R, 26, 27, 34, 41	
NDEPRESS	N non-missings for POMS depression score	POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62	N	Number of non-missings in POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62	
NANGER	N non-missings for POMS anger score	POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57	N	Number of non-missings in POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57	
NVIGOR	N non-missings for POMS vigor score	POMS7, 15, 19, 38, 51, 56, 60, 63	N	Number of non-missings in POMS7, 15, 19, 38, 51, 56, 60, 63	
NFATIGUE	N non-missings for POMS fatigue score	POMS4, 11, 29, 40, 46, 49, 65	N	Number of non-missings in POMS4, 11, 29, 40, 46, 49, 65	
NCONFUSE	N non-missings for POMS confusion score	POMS8, 28, 37, 50, 54R, 59, 64	N	Number of non-missings in POMS8, 28, 37, 50, 54R, 59, 64	
The following POMS scores are derived using the POMS scoring algorithm in the QOL Scoring MOP. For each item, the score is missing if >10% of the components are missing. Otherwise, any missing items are imputed using the mean of the non-missing items.					
TENSION	POMS Tension score	NTENSION, POMS2, 10, 16, 20, 22R, 26, 27, 34, 41	N	If NTENSION=9 =sum of POMS2, 10, 16, 20, 22R, 26, 27, 34, 41 else missing	
DEPRESS	POMS Depression score	NDEPRESS, POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62	N	If NDEPRESS = 15, =sum of POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62 else if NDEPRESS=14 =sum of non-missing POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62 plus the average of the non-missing POMS else missing	
ANGER	POMS Anger score	NANGER, POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57	N	If NANGER=12 =sum of POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57 else if NANGER=11 =sum of non-missing POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57 plus the average of the non-missing POMS else missing	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
VIGOR	POMS Vigor score	NVIGOR, POMS7, 15, 19, 38, 51, 56, 60, 63	N	If NVIGOR=8, =sum of POMS7, 15, 19, 38, 51, 56, 60, 63 else missing	
FATIGUEP	POMS Fatigue score	NFATIGUE, POMS4, 11, 29, 40, 46, 49, 65	N	If NFATIGUE=7, =sum of POMS4, 11, 29, 40, 46, 49, 65 else missing	
CONFUSE	POMS Confusion score	NCONFUSE, POMS8, 28, 37, 50, 54R, 59, 64	N	If NCONFUSE=7, =sum of POMS8, 28, 37, 50, 54R, 59, 64 else missing	
DISTURB	Total POMS mood disturbance score	TENSION, DEPRESS, ANGER, VIGOR, FATIGUEP, CONFUSE	N	=sum of (TENSION, DEPRESS, ANGER, FATIGUEP, CONFUSE) minus VIGOR missing if any of the above are missing	