

Trial name	CALERIE 2
Dataset name	BDI (Beck Depression Inventory)
Description	Beck Depression Inventory data from CRF. The raw data has 3 records per DEIDNUM / VISIT, 1 record for each of 3 pages of the questionnaire. This is flattened to 1 record per DEIDNUM / VISIT. Includes responses to each item on the questionnaire, and derived scores. Scores are derived using the official BDI 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 1, Month 3, Month 6, Month 9, Month 12, Month 18, Month 24 VISIT codes
Source data files	CRF/BDIQ, DATEHDR, SUBJECT1, DEPRESS, ANALDATA/IVRSRAND
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	BDIQ.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
BDIDT	Date of BDI	DATEHDR.STUDYDT	DT		DT
BDINDRSN	Reason BDI not done	DATEHDR..STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFBDI	BDI done	BDIDT, BDINDRSN	N	=1 if BDIDT is non-missing else =0	
The following 21 variables (SADNESS – SEXINTR) are the responses to each item on the questionnaire.					See CRF for formatted values
SADNESS	Sadness	BDIQ.SADNESS	N		TUSAD
PESSIMIS	Pessimism	BDIQ.PESSIMIS	N		TUPESS

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
FAILURE	Past failure	BDIQ.FAILURE	N		TUFAIL
PLEASURE	Loss of pleasure	BDIQ.PLEASURE	N		TUPLEA
GUILTY	Guilty feelings	BDIQ.GUILTY	N		TUGUIL
PUNISH	Punishment feelings	BDIQ.PUNISH	N		TUPUNI
DISLIKE	Self-dislike	BDIQ.DISLIKE	N		TUDISL
		BDIQ refers to			
CRITICAL	Self-criticalness	BDIQ.CRITICAL	N		TUCRIT
SUICIDAL	Suicidal thoughts or wishes	BDIQ.SUICIDAL	N		TUSUIC
CRYING	Crying	BDIQ.CRYING	N		TUCRY
AGITATIO	Agitation	BDIQ.AGITATIO	N		TUAGIT
INTEREST	Loss of interest	BDIQ.INTEREST	N		TUINTR
INDECISI	Indecisiveness	BDIQ.INDECISI	N		TUINDE
WORTHLES	Worthlessness	BDIQ.WORTHLES	N		TUWORT
ENERGY	Loss of energy	BDIQ.ENERGY	N		TUENER
SLEEPING	Changes in sleeping pattern	BDIQ.SLEEPING	N		TUSLEE
IRRITABI	Irritability	BDIQ.IRRITABI	N		TUIRRI
APPETITE	Changes in appetite	BDIQ.APPETITE	N		TUAPPE
CONCENTR	Concentration difficulty	BDIQ.CONCENTR	N		TUCONC
FATIGUEB	Tiredness or fatigue	BDIQ.FATIGUE	N		TUFATI
SEXINTR	Loss of interest in sex	BDIQ.SEXINTR	N		TUSEXI
SLEEP_R	Sleeping – recoded	SLEEPING	N	SLEEPING is recoded according to scoring algorithm. =0 if SLEEPING = 0	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				=1 if SLEEPING in 1, 2 =2 if SLEEPING IN 3, 4 =3 if SLEEPING in 5, 6	
APPETI_R	Appetite – recoded	APPETITE	N	APPETITE is recoded according to scoring algorithm. =0 if APPETITE = 0 =1 if APPETITE in 1, 2 =2 if APPETITE IN 3, 4 =3 if APPETITE in 5, 6	
NBDI	Number of non-missing BDI items	SADNESS - - SEXINTR	N	=Number of non-missing variables among SADNESS – SEXINTR	
NMISSBDI	Number of missing BDI items	SADNESS - - SEXINTR	N	Defined only if CRFBDI=1. =Number of missing variables among SADNESS – SEXINTR missing if CRFBDI<1.	
SUMBDI	Total BDI score	SADNESS – ENERGY, IRRITABI, CONCENTR-SEXINTR, SLEEP_R, APPETI_R, NUMMISS	N	Total BDI Score: missing if >10% of items (>2) are missing. If 1 item is missing, impute value using mean of all non-missing items. Missing if NBDI<19 Else, if NBDI>=19, =(Sum of non-missing variables: SADNESS, PESSIMIS, FAILURE, PLEASURE, GUILTY, PUNISH, DISLIKE, CRITICAL, SUICIDAL, CRYING, AGITATIO, INTEREST, INDECISI, WORTHLES, ENERGY, IRRITABI, CONCENTR, FATIGUEB, SEXINTR, SLEEP_R, APPETI_R) multiplied by (21 / NBDI).	
BDIGRP	BDI grouped result	SUMBDI	N	=1 if 0<= SUMBDI <=13 =2 if 14 <= SUMBDI <=19 =3 if 20 <= SUMBDI <=28 =4 if 29 <= SUMBDI <=63	1=minimal depression 2=mild depression 3=moderate depression 4=severe depression

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
BDIALERT	Flagged for depression (BDI Score >=21)	SUMBDI	N	=1 if SUMBDI >= 20 else missing	
BDISURV	Depression report received	DEPRESS, IVRSRAND.TX	N	= -1 (for all records for a DEIDNUM) if TX='B' else =1 (for all records for a DEIDNUM) if there is at least one record in DEPRESS for that DEIDNUM else =0	-1='NA' 0='No' 1='Yes'