

Trial name	CALERIE 2
Dataset name	DEROGATI (Derogatis interview for sexual function)
Description	Derogatis interview for sexual function data from CRF, flattened to 1 record per DEIDNUM / VISIT. Includes responses to each item in the questionnaire and derived scores using Derogatis 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/DISFEM1 – DISFEM4, DISMALE1 –DISMALE3, 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	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
DEROGDT	Date of Derogatis	DATEHDR.STUDYDT	DT		DT
DRGNDRSN	Reason Derogatis not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFDEROG	Derogatis done	DEROGDT, DRGNDRSN	N	=1 if DEROGDT is non-missing else=0 if VISSTAT=1. Else missing.	
DRG1-DRG25	Answers to Derogatis question 1-25	DEROG.QNO DEROG.RESPONSE	N	DRG[#] = RESPONSE if QNO=#	Formats are not applied to raw variables, because formats are different for male and female questionnaires. See CRF for codes.

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
N1DRG	Number non-missings for Derogatis score1	DRG1, DRG2, DRG3, DRG4, DRG5	N	= number of non-missings in (DRG1,DRG2,DRG3,DRG4,DRG5)	
N2DRG	Number non-missings for Derogatis score2	DRG6, DRG7, DRG8, DRG9, DRG10	N	=number of non-missings in (DRG6,DRG7,DRG8,DRG9,DRG10)	
N3DRG	Number non-missings for Derogatis score3	DRG11,DRG12,DRG13,DRG14,DRG15	N	=number of non-missings in (DRG11,DRG12,DRG13,DRG14,DRG15)	
N4DRG	Number non-missings for Derogatis score4	DRG16,DRG17,DRG18,DRG19,DRG20,DRG21	N	=number of non-missings in (DRG16,DRG17,DRG18,DRG19,DRG20,DRG21)	
N5DRG	Number non-missings for Derogatis score5	DRG22,DRG23,DRG24,DRG25	N	=number of non-missings in (DRG22,DRG23,DRG24,DRG25)	
NDRG	Number non-missing Derogatis responses	DRG1 – DRG25	N	=number of non-missings in DRG1-DRG25	
NMISSDRG	Number of missing Derogatis responses	DRG1 – DRG25	N	Defined only if CRFDEROG=1 =number of missings in DRG1-DRG25 missing if CRFDEROG<1.	
Scores are derived according to the official Derogatis scoring algorithm (see QOL MOP). For each score category, the score is missing if more than one of the components is missing. If one component is missing, the missing item is imputed using the mean of the non-missing items.					
DRGSCR1	Sexual cognition / fantasy score	N1DRG, DRG1, DRG2, DRG3, DRG4, DRG5	n	= missing if N1DRG<4 else if N1DRG>=4, =sum of (DRG1,DRG2,DRG3,DRG4,DRG5) multiplied by (5/N1DRG)	
DRGSCR2	Sexual arousal score	N2DRG, DRG6, DRG7, DRG8, DRG9, DRG10	N	= missing if N2DRG<4 else if N2DRG>=4, =sum of (DRG6,DRG7,DRG8,DRG9,DRG10) multiplied by (5/N2DRG)	
DRGSCR3	Sexual behavior/experiences score	N3DRG, DRG11,DRG12,DRG13,DRG14,DRG15	N	=missing if N3DRG<4 else if N3DRG>=4, =sum of (DRG11,DRG12,DRG13,DRG14,DRG15) multiplied by (5/N3DRG)	
DRGSCR4	Orgasm score	N4DRG,DRG16,DRG17,DRG18,DRG19,DRG20,DRG21	N	= missing if N4DRG<5 else if N4DRG>=5, =sum of (DRG16,DRG17,DRG18,DRG19,DRG20,DRG21) multiplied by (6/N4DRG)	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DRGSCR5	Drive and relationship score	N5DRG, DRG22, DRG23, DRG24, DRG25	N	=missing if N5DRG<3 else if N5DRG>=3, =sum of (DRG22,DRG23,DRG24,DRG25) multiplied by (4/N5DRG)	
DRGSCORE	Total Derogatis score	DRGSCR1 – DRGSCR5	N	= sum of (DRGSCR1, DRGSCR2, DRGSCR3, DRGSCR4, DRGSCR5)	