

<b>Trial name</b>	<b>CALERIE 2</b>
<b>Dataset name</b>	<b>PSQI (Pittsburgh Sleep Quality Index)</b>
<b>Description</b>	Pittsburgh Sleep Quality Index data from CRF. Includes responses to each item in the questionnaire and derived scores using PSQI scoring algorithm (see QOL scoring MOP).
<b>Comments on data structure</b>	1 record / DEIDNUM / VISIT
<b>Population</b>	All subjects who had baseline evaluations, including all randomized subjects
<b>Visits</b>	Baseline Visits 1-3 , Month 6, Month 12, Month 24 <a href="#">VISIT codes</a>
<b>Source data files</b>	CRF/PSQI1, PSQI2, DATEHDR, ANALDATA/SUBJECT1
<b>Final sort order</b>	DEIDNUM VISIT

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DEIDNUM	Subject Number	DEIDNUM	C		
PAGENUM	CRF page number	PSQI1.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
PSQIDT	Date of PSQI	DATEHDR.STUDYDT	DT		DT
PSQIND	Reason PSQI not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFPSQI	PSQI done	PSQIDT, PSQINDRSN	N	=1 if PSQIDT is non-missing else =0	
FALLASLP	PSQI time to fall asleep (minutes)	PSQI1.FALLASLP	N		
ACTSLP	PSQI actual sleep (hours)	PSQI1.ACTSLP	N		
WITHIN30	PSQI question 5a	PSQI1.WITHIN30	N		TUSLP
MIDNGHMG	PSQI question 5b	PSQI1.MIDNGHMG	N		TUSLP

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
GOBTHRM	PSQI question 5c	PSQI1.GOBTHRM	N		TUSLP
BREATHE	PSQI question 5d	PSQI1.BREATHE	N		TUSLP
SNORE	PSQI question 5e	PSQI1.SNORE	N		TUSLP
COLD	PSQI question 5f	PSQI1.COLD	N		TUSLP
HOT	PSQI question 5g	PSQI1.HOT	N		TUSLP
BADDRM	PSQI question 5h	PSQI1.BADDRM	N		TUSLP
PAIN	PSQI question 5i	PSQI1.PAIN	N		TUSLP
PSQIOTHR	PSQI question 5j	PSQI1.OTHER	N		TUSLP
MEDSTKN	PSQI question 6	PSQI1.MEDSTKN	N		TUSLP
AWKESOC	PSQI question 7	PSQI2.AWKESOC	N		TUSLPB
KPENTHUS	PSQI question 8	PSQI2.KPENTHUS	N		TUSLPC
SLPQLTY	PSQI question 9	PSQI2.SLPQLTY	N		TUSLPD
BEDTM	Bed time	PSQI1.BEDHR, PSQI1.BEDMIN	TM	Create time variable of BEDHR, BEDMIN (if BEDHR is between 8-12, add 12 to BEDHR first)	TIME
WAKETM	Wake time	PSQI1.WAKEHR, PSQI1.WAKEMIN	TM	Create time variable of WAKEHR, WAKEMIN	TIME
SLEEPHRS	Hours in bed	BEDTM, WAKETM	N	If BEDTM<WAKETM =WAKETM – BEDTM in hours  else if WAKETM<BEDTM =(WAKETM+86400) – BEDTM in hours	
SLEEPEFF	Sleep efficiency	ACTSLP, SLEEPHRS	N	=100 X (ACTSLP/SLEEPHRS)	
PSQISCR1	PSQI Subjective sleep quality	SLPQLTY	N		TUSLPD
PSQISCR2	PSQI Sleep latency	FALLASLP, WITHIN30	N	Let TEMP2 =0 if 0<=FALLASLP<=15 =1 if 15<FALLASLP<=30 =2 if 30<FALLASLP<=60 =3 if FALLASLP>60	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/Format
				Let TEMP25A= sum of TEMP2 and WITHIN30 missing if either is missing  PSQISCR2: =0 if TEMP25A=0 =1 if TEMP25A is in (1 or 2) =2 if TEMP25A is in (3 or 4) =3 if TEMP25A is in (5 or 6)	
PSQISCR3	PSQI Sleep duration	ACTSLP	N	=0 if ACTSLP>7 =1 if 6<ACTSLP<=7 =2 IF 5<ACTSLP<=6 =3 if 0<=ACTSLP<=5	
PSQISCR4	PSQI Sleep efficiency	SLEEPEFF	N	=0 if SLEEPEFF>85 =1 IF 75<SLEEPEFF<=85 =2 if 65<SLEEPEFF<=75 =3 if 0<=SLEEPEFF<=65	
PSQISCR5	PSQI Sleep disturbance	PSQI1.MIDNGHMG, PSQI1.GOBTHRM, PSQI1.BREATHE, PSQI1.SNORE, PSQI1.COLD, PSQI1.HOT, PSQI1.BADDRM, PSQI1.PAIN, PSQI1.OTHER	N	Let TEMP5= sum of MIDNGHMG, GOBTHRM, BREATHE, SNORE, COLD, HOT, BADDRM, PAIN, OTHER missing if anything except OTHER is missing  PSQISCR5: =0 if TEMP5=0 =1 if 1<=TEMP5<=9 =2 if 10<=TEMP5<=18 =3 IF 19<=TEMP5<=27	
PSQISCR6	PSQI Sleeping medication	PSQI1.MEDSTKN	N		
PSQISCR7	PSQI Daytime dysfunction	AWKESOC, KPENTHUS	N	Let TEMP78=Sum of AWKESOC and KPENTHUS Missing if either is missing  PSQISCR7: =0 if TEMP78=0 =1 if TEMP78 in (1 or 2) =2 if TEMP78 in (3 or 4) =3 if TEMP78 in (5 or 6)	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
PSQISCOR	Global PSQI score	PSQICOMP1 – PSQICOMP7	N	= sum of PSQISCR1 – PSQISCR7 missing if any are missing	