

Trial name	CALERIE 2
Dataset name	RANDSF36 (Rand SF-36 QOL instrument)
Description	RAND SF-36 QOL data from CRF. Includes responses to each item in the questionnaire and derived scores using SF-36 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/ RANDSF1, RANDSF2, RANDSF3, 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	RANDSF1.PAGENUM	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
SF36DT	Date of SF-36	DATEHDR.STUDYDT	DT		DT
SF36NDRS	Reason SF-36 not done	DATEHDR.STUDYND	N		TUND
CRFSF36	SF-36 done	SF36DT	N	=1 if SF36DT is non-missing else =0	
The following variables RANDSF1 – RANDSF36 assign scores to each SF36 item according to the official scoring algorithm. ‘Value’ refers to the value of the source variable as indicated in the CRF.					
RANDSF1	Health	RANDSF1.HEALTH	N	=100 if value=1 =75 if value=2 =50 if value=3 =25 if value=4 =0 if value=5	0=Poor 25=Fair 50=Good 75=Very good 100=Excellent
RANDSF2	Health compared to last year	RANDSF1.GHLTHNOW	N	Same as RANDSF1	0=Much worse now 25=Somewhat worse now 50=About the same 75=Somewhat better now 100=Much better now

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RANDFS3	Vigorous activities	RANDFS1.VIGORACT	N	=0 if value=1 =50 if value=2 =100 if value=3	0=Yes, limited a lot 50 = Yes, limited a little 100=No, not limited at all
RANDFS4	Moderate activities	RANDFS1.MODACT	N	Same as RANDFS3	See RANDFS3
RANDFS5	Lifting or carrying groceries	RANDFS1.LIFTCARR	N	Same as RANDFS3	See RANDFS3
RANDFS6	Climbing several flights	RANDFS1.CLIMBSEV	N	Same as RANDFS3	See RANDFS3
RANDFS7	Climbing one flight	RANDFS1.CLIMB1	N	Same as RANDFS3	See RANDFS3
RANDFS8	Bending, kneeling, stooping	RANDFS1.BENDING	N	Same as RANDFS3	See RANDFS3
RANDFS9	Walking more than a mile	RANDFS1.WALKMILE	N	Same as RANDFS3	See RANDFS3
RANDFS10	Walking several blocks	RANDFS1.WALKSBLK	N	Same as RANDFS3	See RANDFS3
RANDFS11	Walking one block	RANDFS1.WALKBLCK	N	Same as RANDFS3	See RANDFS3
RANDFS12	Bathing or dressing yourself	RANDFS1.BATHING	N	Same as RANDFS3	See RANDFS3
RANDFS13	Cut work time due to physical health	RANDFS2.CUTWORK1	N	=0 if value=1 =100 if value=2	0=Yes 100=No
RANDFS14	Accomplished less due to physical health	RANDFS2.ACCOMLE1	N	Same as RANDFS13	See RANDFS13
RANDFS15	Limited kind of work due to phys. health	RANDFS2.LIMWORK1	N	Same as RANDFS13	See RANDFS13
RANDFS16	Difficulty with work due to phys. health	RANDFS2.DIFWORK1	N	Same as RANDFS13	See RANDFS13
RANDFS17	Cut work time due to emotional problems	RANDFS2.CUTWORK2	N	Same as RANDFS13	See RANDFS13
RANDFS18	Accomplished less due to emotional probs	RANDFS2.ACCOMLE2	N	Same as RANDFS13	See RANDFS13
RANDFS19	Didn't work carefully due to emot. probs	RANDFS2.CAREFUL	N	Same as RANDFS13	See RANDFS13
RANDFS20	Phys/emot probs interfered w/ soc. acts.	RANDFS2.SOCIAL	N	Same as RANDFS1	0=Extremely 25=Quite a bit 50=Moderately 75=Slightly 100=Not at all

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RANDFS21	Bodily pain	RANDFS2.BODPAIN	N	=100 if value=1 =80 if value=2 =60 if value=3 =40 if value=4 =20 if value=5 =0 if value=6	0=Very severe 20=Severe 40=Moderate 60=Mild 80=Very mild 100=None
RANDFS22	Pain interfered with normal work	RANDFS2.INTERFE	N	Same as RANDFS1	0=Extremely 25=Quite a bit 50=Moderately 75=A little bit 100=Not at all
RANDFS23	Full of pep	RANDFS3.PEP	N	Same as RANDFS21	0=None of the time 20=A little of the time 40=Some of the time 60=A good bit of the time 80=Most of the time 100=All of the time
RANDFS24	Nervous	RANDFS3.NERV	N	=0 if value=1 =20 if value=2 =40 if value=3 =60 if value=4 =80 if value=5 =100 if value=6	0=All of the time 20=Most of the time 40=A good bit of the time 60=Some of the time 80=A little of the time 100=None of the time
RANDFS25	Down in the dumps	RANDFS3.DOWN	N	Same as RANDFS24	See RANDFS24
RANDFS26	Calm and peaceful	RANSF3.CALM	N	Same as RANDFS21	See RANDFS21
RANDFS27	Lot of energy	RANDFS3.ENERG	N	Same as RANDFS21	See RANDFS21
RANDFS28	Downhearted and blue	RANDFS3.BLUE	N	Same as RANDFS24	See RANDFS24
RANDFS29	Worn out	RANDFS3.WORN	N	Same as RANDFS24	See RANDFS24
RANDFS30	Happy	RANDFS3.HAPPY	N	Same as RANDFS21	See RANDFS21
RANDFS31	Tired	RANDFS3.TIRED	N	Same as RANDFS24	See RANDFS24
RANDFS32	Phys/emot probs interfered w/ soc. acts.	RANDFS3.EMOTPROB	N	=0 if value=1 =25 if value=2 =50 if value=3 =75 if value=4 =100 if value=5	0=All of the time 25=Most of the time 50=Some of the time 75=A little of the time 100=None of the time

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RANDFS33	Get sick easily	RANDFS3.SICK	N	Same as RANDFS32	0=Definitely True 25=Mostly true 50=Don't know 75=Mostly false 100=Definitely false
RANDFS34	As healthy as anybody	RANDFS3.HEALTHYA	N	Same as RANDFS1	0=Definitely false 25=Mostly false 50=Don't know 75=Mostly true 100=Definitely true
RANDFS35	Expect health to get worse	RANDFS3.EHWORSE	N	Same as RANDFS32	See RANDFS33
RANDFS36	Health is excellent	RANDFS3.HEXCEL	N	Same as RANDFS1	See RANDFS34
NSF36	Number of non-missing SF-36 responses	RANDFS1 – RANDFS36	N	Number of non-missings among RANDFS1 – RANDFS36	
NMISSF36	Number of missing SF-36 responses	RANDFS1 – RANDFS36	N	Defined only if CRFSF36=1 Number of missings among RANDFS1 – RANDFS36 Missing if CRFSF36<1.	
PFSCORE	SF-36 Physical functioning	RANDFS3,4,5,6,7,8,9,10,11,12	N	=Average of RANDFS3,4,5,6,7,8,9,10,11,12 if >= 8 of the components are non-missing. Else missing	
RLPHSCOR	SF-36 Role limits. due to phys. health	RANDFS13,14,15,16	N	=average of RANDFS13,14,15,16 if all 4 components are non-missing else missing	
RLEPSCOR	SF-36 Role limits. due to emot. probs.	RANDFS17,18,19	N	=average of RANDFS17,18,19 if all 3 components are non-missing, else missing	
EFSCORE	SF-36 Energy / fatigue	RANDFS23,27,29,31	N	=average of RANDFS23,27,29,31 if all 4 components are non-missing, else missing	
EWBSCORE	SF-36 Emotional well being	RANDFS24,25,26,28,30	N	=average of RANDFS24,25,26,28,30 if all 5 components are non-missing, else missing	
SFSCORE	SF-36 Social functioning	RANDFS20, 32	N	=average of RANDFS20,32 if NSF=2 if both components are non-missing, else missing	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
PAINSCOR	SF-36 Pain	RANDFS21,22	N	=average of RANDFS21,22 if NP=2 if both components are non-missing, else missing	
GHSCORE	SF-36 General health	RANDFS1,33,34,35,36	N	=average of RANDFS1,33,34,35,36 if all 5 components are non-missing, else missing	