

<b>Trial name</b>	<b>CALERIE 2</b>
<b>Dataset name</b>	<b>RANDSF36 (Rand SF-36 QOL instrument)</b>
<b>Description</b>	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).
<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/ RANDSF1, RANDSF2, RANDSF3, DATEHDR, ANALDATA/SUBJECT1
<b>Final sort order</b>	DEIDNUM VISIT

<b>Variable name</b>	<b>LABEL</b>	<b>Source variables</b>	<b>C/N?</b>	<b>Definition</b>	<b>Accepted values/ Format</b>
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	
	<b>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.</b>				
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	<b>0=Poor 25=Fair 50=Good 75=Very good 100=Excellent</b>
RANDSF2	Health compared to last year	RANDSF1.GHLTHNOW	N	Same as RANDSF1	<b>0=Much worse now 25=Somewhat worse now 50=About the same 75=Somewhat better now 100=Much better now</b>

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RANDSF3	Vigorous activities	RANDSF1.VIGORACT	N	=0 if value=1 =50 if value=2 =100 if value=3	<b>0=Yes, limited a lot</b> <b>50 = Yes, limited a little</b> <b>100=No, not limited at all</b>
RANDSF4	Moderate activities	RANSDF1.MODACT	N	Same as RANDSF3	See RANDSF3
RANDSF5	Lifting or carrying groceries	RANDSF1.LIFTCARR	N	Same as RANDSF3	See RANDSF3
RANDSF6	Climbing several flights	RANDSF1.CLIMBSEV	N	Same as RANDSF3	See RANDSF3
RANDSF7	Climbing one flight	RANDSF1.CLIMB1	N	Same as RANDSF3	See RANDSF3
RANDSF8	Bending, kneeling, stooping	RANDSF1.BENDING	N	Same as RANDSF3	See RANDSF3
RANDSF9	Walking more than a mile	RANDSF1.WALKMILE	N	Same as RANDSF3	See RANDSF3
RANDSF10	Walking several blocks	RANDSF1.WALKSBLK	N	Same as RANDSF3	See RANDSF3
RANDSF11	Walking one block	RANDSF1.WALKBLCK	N	Same as RANDSF3	See RANDSF3
RANDSF12	Bathing or dressing yourself	RANDSF1.BATHING	N	Same as RANDSF3	See RANDSF3
RANDSF13	Cut work time due to physical health	RANDSF2.CUTWORK1	N	=0 if value=1 =100 if value=2	<b>0=Yes</b> <b>100=No</b>
RANDSF14	Accomplished less due to physical health	RANDSF2.ACCOMLE1	N	Same as RANDSF13	See RANDSF13
RANDSF15	Limited kind of work due to phys. health	RANDSF2.LIMWORK1	N	Same as RANDSF13	See RANDSF13
RANDSF16	Difficulty with work due to phys. health	RANDSF2.DIFWORK1	N	Same as RANDSF13	See RANDSF13
RANDSF17	Cut work time due to emotional problems	RANDSF2.CUTWORK2	N	Same as RANDSF13	See RANDSF13
RANDSF18	Accomplished less due to emotional probs	RANDSF2.ACCOMLE2	N	Same as RANDSF13	See RANDSF13
RANDSF19	Didn't work carefully due to emot. probs	RANDSF2.CAREFUL	N	Same as RANDSF13	See RANDSF13
RANDSF20	Phys/emot probs interfered w/ soc. acts.	RANDSF2.SOCIAL	N	Same as RANDSF1	<b>0=Extremely</b> <b>25=Quite a bit</b> <b>50=Moderately</b> <b>75=Slightly</b> <b>100=Not at all</b>

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RANDSF21	Bodily pain	RANDSF2.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	<b>0=Very severe</b> <b>20=Severe</b> <b>40=Moderate</b> <b>60=Mild</b> <b>80=Very mild</b> <b>100=None</b>
RANDSF22	Pain interfered with normal work	RANDSF2.INTERFE	N	Same as RANDSF1	<b>0=Extremely</b> <b>25=Quite a bit</b> <b>50=Moderately</b> <b>75=A little bit</b> <b>100=Not at all</b>
RANDSF23	Full of pep	RANDSF3.PEP	N	Same as RANDSF21	<b>0=None of the time</b> <b>20=A little of the time</b> <b>40=Some of the time</b> <b>60=A good bit of the time</b> <b>80=Most of the time</b> <b>100=All of the time</b>
RANDSF24	Nervous	RANDSF3.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	<b>0=All of the time</b> <b>20=Most of the time</b> <b>40=A good bit of the time</b> <b>60=Some of the time</b> <b>80=A little of the time</b> <b>100=None of the time</b>
RANDSF25	Down in the dumps	RANDSF3.DOWN	N	Same as RANDSF24	See RANDSF24
RANDSF26	Calm and peaceful	RANSF3.CALM	N	Same as RANDSF21	See RANDSF21
RANDSF27	Lot of energy	RANDSF3.ENERG	N	Same as RANDSF21	See RANDSF21
RANDSF28	Downhearted and blue	RANDSF3.BLUE	N	Same as RANDSF24	See RANDSF24
RANDSF29	Worn out	RANDSF3.WORN	N	Same as RANDSF24	See RANDSF24
RANDSF30	Happy	RANDSF3.HAPPY	N	Same as RANDSF21	See RANDSF21
RANDSF31	Tired	RANDSF3.TIRED	N	Same as RANDSF24	See RANDSF24
RANDSF32	Phys/emot probs interfered w/ soc. acts.	RANDSF3.EMOTPROB	N	=0 if value=1 =25 if value=2 =50 if value=3 =75 if value=4 =100 if value=5	<b>0=All of the time</b> <b>25=Most of the time</b> <b>50=Some of the time</b> <b>75=A little of the time</b> <b>100=None of the time</b>

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RANDSF33	Get sick easily	RANDSF3.SICK	N	Same as RANDSF32	0=Definitely True 25=Mostly true 50=Don't know 75=Mostly false 100=Definitely false
RANDSF34	As healthy as anybody	RANDSF3.HEALTHYA	N	Same as RANDSF1	0=Definitely false 25=Mostly false 50=Don't know 75=Mostly true 100=Definitely true
RANDSF35	Expect health to get worse	RANDSF3.EHWORSE	N	Same as RANDSF32	See RANDSF33
RANDSF36	Health is excellent	RANDSF3.HEXCEL	N	Same as RANDSF1	See RANDSF34
NSF36	Number of non-missing SF-36 responses	RANDSF1 – RANDSF36	N	Number of non-missings among RANDSF1 – RANDSF36	
NMISSF36	Number of missing SF-36 responses	RANDSF1 – RANDSF36	N	Defined only if CRFSF36=1 Number of missings among RANDSF1 – RANDSF36 Missing if CRFSF36<1.	
PFSCORE	SF-36 Physical functioning	RANDSF3,4,5,6,7,8,9,10,11,12	N	=Average of RANDSF3,4,5,6,7,8,9,10,11,12 if >= 8 of the components are non-missing. Else missing	
RLPHSCOR	SF-36 Role limits. due to phys. health	RANDSF13,14,15,16	N	=average of RANDSF13,14,15,16 if all 4 components are non-missing else missing	
RLEPSCOR	SF-36 Role limits. due to emot. probs.	RANDSF17,18,19	N	=average of RANDSF17,18,19 if all 3 components are non-missing, else missing	
EFSCORE	SF-36 Energy / fatigue	RANDSF23,27,29,31	N	=average of RANDSF23,27,29,31 if all 4 components are non-missing, else missing	
EWBSCORE	SF-36 Emotional well being	RANDSF24,25,26,28,30	N	=average of RANDSF24,25,26,28,30 if all 5 components are non-missing, else missing	
SFSCORE	SF-36 Social functioning	RANDSF20, 32	N	=average of RANDSF20,32 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	RANDSF21,22	N	=average of RANDSF21,22 if NP=2 if both components are non-missing, else missing	
GHSCORE	SF-36 General health	RANDSF1,33,34,35,36	N	=average of RANDSF1,33,34,35,36 if all 5 components are non-missing, else missing	