

Trial name	CALERIE 2
Dataset name	VITALSA (Vital Signs)
Description	Vital signs – blood pressure, heart rate, oral temperature, and waist measurements, from CRF.
Comments on data structure	1 record per DEIDNUM / VISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
Visits	0, Baseline Visits 1-3, Baseline Visits 4-7, Month 1, Month 3, Month 6, Month 9, Month 12, Month 18, Month 24 VISIT 0 combines the two baseline Visits into a single baseline mean. VISIT codes
Source data files	CRF/VITALS , ANALDATA/SUBJECT1
Final sort order	DEIDNUM VISIT

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DEIDNUM	Subject Number	DEIDNUM			
PAGENUM	CRF page number	VITALS.PAGEID	N		
VISIT	Visit	PAGENUM	N	Study Visit, based on CRF page (See Appendix 1)	VISFMT
SUBVISIT	Sub-Visit	PAGENUM	N	Study Sub-visit, based on CRF page (See Appendix 1)	SVISFMT
VITALDT	Vitals date	VITALS.VITALDT	DT		DT
WUNDRSN	Reason Waist not done	VITALS.WUND	N		TUND
MEANWST	Mean waist measurement (cm)	WMEAS1, WMEAS2, WMEAS3	N	Mean of the 2 closest natural waist measurements	
MEANUMB	Mean umbilical measurement (cm)	UMEAS1, UMEAS2, UMEAS3	N	Mean of the 2 closest umbilical waist measurements	
PULSE	Pulse (bpm)	VITALS.PULSE	N		
PULNDRSN	Reason pulse not done	VITALS.PULND	N		TUND
TEMP	Oral Temperature (c)	VITALS.TEMP	N		
TMPNDRSN	Reason oral temp. not done	VITALS.TMPND	N		TUND
RESP	Respirations (/minute)	VITALS.RESP	N		
RSPNDRSN	Reason respirations not done	VITALS.RESPND	N		TUND

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
BPARM	Blood Pressure arm	VITALS.BPARM	N	1=Left 2=Right	TUARM
MEANSBP	Mean Systolic BP (mm Hg)	BPSYS1, BPSYS2, BPSYS3	N	Mean of the two closest Systolic BP measurements	
MEANDBP	Mean Diastolic BP (mm Hg)	BPDIA1, BPDIA2, BPDIA3	N	Mean of the two closest Diastolic BP measurements	
BPNDRSN	Reason BP not done	VITALS.BPND	N		TUND
MEANBP	Mean BP (mm Hg)	MEANSBP, MEANDBP	N	$= (\text{MEANSBP} + 2 \times \text{MEANDBP}) / 3$	
PULSEPRS	Pulse Pressure (mm Hg)	MEANSBP, MEANDBP	N	$= \text{MEANSBP} - \text{MEANDBP}$	