Trial name	CALERIE 2
Dataset name	**CLWTLONG (all clinic weights)**
Description	Weights measured in the Clinic at each study Subvisit. Each 'VISIT' (e.g. BL1, Month 12) consists of 1-4 Subvisits
Comments on data structure	1 record / DEIDNUM / SUBVISIT. Each 'VISIT' (eg BL1, Month 12) consists of 1-4 Subvisits
Population	All subjects who had at least one study visit (including screening visits). Clinic weights are measured at each Subvisit. See appendix for list of Visits and Subvisits.
Visits	Screening Visit 1, Baseline Visits 1-3 , Baseline Visits 4-7 , Month 1, Month 3, Month 6, Month 9, Month 12, Month 17, Month 18, Month 23, Month 24 Visits Month 17, Month 23 were discontinued from the protocol, so only early subjects had those visits. VISIT codes
Usage Notes	Most analyses involving weight should be done with the CLWTVIS dataset, which has 1 record per DEIDNUM/VISIT, with the mean clinic weight at each visit. CLWTLONG is used for doing regression of clinic weights to derive the daily rate of weight change during each DLW period, which is used to calculate RQ in TEERQ.
Source data files	…CRF/DATEHDR, WEIGHT, WGHTLOSS …ANALDATA/SUBJECT1, VISITS2, IVRSRAND …EXTRAWT/EXTRACLINWT
Final sort order	DEIDNUM SUBVISIT

Note: Because some subjects had weights measured at visits that did not correspond to any CRF pages, these extra weights were collected in a separate data file, EXTRACLINWT, which is appended to the weights that were collected in the CRF. Some variables (PAGENUM, WTDTM) are missing for records from EXTRACLINWT.

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
DEIDNUM	Subject Number	DEIDNUM	C		
PAGENUM	CRF page number	DATEHDR.PAGEID	N	(missing for records from EXTRACLINWT)	
VISIT	Visit	PAGENUM	N	Study Visit, based on CRF page (See Appendix 1)	VISFMT
SUBVISIT	Sub-Visit	SUBVISIT	N	Study Sub-Visit, based on CRF page (See Appendix 1)	SVISFMT
WTNDRSN	Reason weight not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	[TUND]
WTDT	Clinic weight date	DATEHDR.STUDYDT OR EXTRACLINWT.STUDYDT	DT		DT

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
WGHT1	Clinic weight 1 (kg)	WEIGHT.WGHT1 OR EXTRACLINWT.WGHT1	N	Note: 2 or 3 clinic weights are taken on each occasion. If the first two are more than 0.1 kg apart, a third measurement is taken.	
WGHT2	Clinic weight 2 (kg)	WEIGHT.WGHT2 OR EXTRACLINWT.WGHT2	N		
WGHT3	Clinic weight 3 (kg)	WEIGHT.WGHT3 OR EXTRACLINWT.WGHT3	N	WGHT3 is only done if the first 2 weights are more than 0.1 kg apart.	
GWGHT	Gown weight (kg)	WEIGHT.GWGHT OR EXTRACLINWT.GWGHT	N		
MEANWT	Mean clinic weight	WGHT1, WGHT2, WGHT3	N	= mean of WGHT1 and WGHT2 if WGHT3 is missing else = mean of the closest two of WGHT1, WGHT2, WGHT3	
CLINWT	Adjusted clinic weight	MEANWT, GWGHT	N	= MEANWT – GWGHT	
HEIGHT	Height (cm)	SUBJECT1.HEIGHT	N		
BMI	Body mass index	CLINWT, HEIGHT	N	$=CLINWT / [(HEIGHT/100)^2]$	
BMIALERT	Record flagged for Low BMI	BMI, VISIT, SUBJECT1.CONSENT	N	Low BMI means BMI < 22 at screening visit 1, or <18.5 any time after screening. =1 if (VISIT=1 and CONSENT=1 and .z<BMI<22) or (VISIT>3 and .z < BMI < 18.5) else missing	
BMISURV	Excessive weight loss report received	IVRSRAND.TX WGHTLOSS.DEIDNUM	N	= -1 (for all records for a DEIDNUM) if TX='B' else =1 (for all records for a DEIDNUM) if there is at least one record in WGHTLOSS for that DEIDNUM else =0	-1='NA' 0='No' 1='Yes'
EXTRAWT	Additional weight (not in CRF)		N	=1 if record was in EXTRACLINWT	