

Trial name	CALERIE 2
Dataset name	DLWLONG (Doubly Labeled Water, long)
Description	Long Form DLW data (used for measuring TDEE), with 8 records for each DLW test, 1 for each urine sample, with isotope data for each sample. Urine samples are collected on day 0 (2 pre-dose, 2 post-dose), day 7 (x2) and day 14(x2), at BL1, BL2, M12 and M24 for all subjects and also at M6 and M18 for CR subjects. This dataset combines data from DLW lab with CRF data. (The raw DLW file uses masked sample id DLWSAMID instead of DEIDNUM and VISIT).
Comments on data structure	1 record per DEIDNUM / VISIT / DLWSMPNO (8 records per DLW assay, determined by DEIDNUM / VISIT. (DLWSMPNO denotes the 8 sample collection timepoints during each DLW assay).
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization.
Visits	Baseline Visits 1-3, Baseline Visits 4-7, Month 12, Month 24 for all subjects. Month 9 and Month 18 for CR subjects only. VISIT codes
Usage notes	Most analyses involving TDEE should use the TEERQ dataset, which has 1 record per DEIDNUM/VISIT, and incorporates the DLW data handling rules, and uses subject specific RQ to calculate TDEE. The DLWLONG dataset is of use for examining the isotope values within each DLW test. The TEE in DLWLONG is based on fixed RQ=0.86, which is not used in the study analyses.
Source data files	CRF/DLWHDR DLWCHT LABS/DLW
Final sort order	DEIDNUM VISIT DLWSMPNO

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DEIDNUM	Subject Number	DEIDNUM	C		
PAGENUM	CRF page number	DLWHDR.PAGEID	N		
VISIT	Visit	PAGENUM	N	Study Visit, based on CRF pages (See Appendix 1)	VISFMT
SUBVISIT	Sub-Visit	PAGENUM	N	Study Sub-Visit, based on CRF pages (See Appendix 1)	SVISFMT
DLWMIXWT	DLW mix weight (CRF) (g)	DLWHDR.DLWMIXWT	N		
DLWDSEDT	DLW dose date (CRF)	DLWHDR.DLWDSEDT	DT		DT
DLWDSETM	DLW dose date/time (CRF)	DLWHDR.DLWDSETM	DTM		DTM
CRFDLW	DLW done (CRF)	DLWDSEDT	N	=1 if DLWDSEDT is non- missing =0 if DLWDSEDT is missing Note: CRFDLW indicates that the DLW dose was taken, however there were several subjects at baseline who took the dose, but did not complete the 14 day DLW sample set, and therefore do not have results.	0=not done 1=done
DLWNDRSN	Reason DLW not done	DLWHDR.DLWND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	[TUND]

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DLWSMPNO	DLW sample number	DLWSMPNO	N	1 – 2 are the 2 pre-dose urine samples 3 – 4 are the 2 post dose samples on day 0 5 – 6 are the 2 day 7 samples 7 – 8 are the 2 day 14 samples	1=PDa 2=PDb 3=D0a 4=D0b 5=D7a 6=D7b 7=D14a 8=D14b
DLWCOLDT	Sample collection date (CRF)	DLWCHT.DLWCOLDT	DT		DT
DLWCOLTM	Sample collection dtm (CRF)	DLWCHT.DLWCOLTM	DTM		DTM
LABDLW	DLW lab data received	DLW dataset	N	=1 if record exists in DLW =0 if record does not exist in DLW	0=DLW lab data not received 1=DLW lab data received
LDOSETM	DLW dose date/time (Lab)	LABDLW.DOSETM	DTM		DTM
LCOLLTM	Sample collection dtm (Lab)	LABDLW.COLLTM	DTM		DTM
				Note: Most of the following variables exist for only 1 record per DLWLABEL, at DLWSMPNO=1, except ISO2H and ISO18O which have values at every DLWSMPNO.	
DOSEAMT	DLW mix weight (lab)	DLW.DOSEAMT	N		
ISO2H	Isotopic data 2H	DLW.ISO2H	N		
ISO18O	Isotopic data 18O	DLW.ISO18O	N		
ISODILNH	Isotope dilution spaces NH	DLW.ISODILNH	N		
ISODILNO	Isotope dilution spaces NO	DLW.ISODILNO	N		
PTBWH	% Total Body Water H	DLW.PTBWH	N		
PTBWO	% Total Body Water O	DLW.PTBWO	N		
KHTURNO	KH Fractional Turnover rate	DLW.KHTURNO	N		
KOTURNO	KO Fractional Turnover rate	DLW.KOTURNO	N		
CXRH	Correlation fractional turnover rate H	DLW.CXRH	N		
CXRO	Correlation fractional turnover rate O	DLW.CXRO	N		
RCO2P	Carbon Dioxide Production rate	DLW.RCO2P	N		
TEE	Total energy expenditure	DLW.TEE	N	TEE based on RCO2P and RQ = 0.86 (Note: this is not the value used in most analyses. We use TEERQ.TEERQ instead, which is based on individual RQ)	