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Trial name	**CALERIE 2**
Dataset name	**IVRSRAND (Randomized Treatment)**
Description	Randomized Treatment Assignment from IVRS system
Comments on data structure	1 record / DEIDNUM for each randomized subject
Population	All randomized subjects (n=220)
Usage notes	Merge with analysis datasets by DEIDNUM, and use TX for randomized treatment arm.
Final sort order	DEIDNUM

Variable name	**LABEL**	**Source variables**	**Definition**	**C/N?**	**Accepted values/ Format**
DEIDNUM	Subject Number	From IVRS system		C	
RANDOMDT	IVRS Randomization date			DT	
STRATA1	Sex / BMI Stratum			C	1= Female, 22-24.9 2=Female, 25-27.9 3=Male, 22-24.9 4=Male, 25-27.9
TX	Randomized Treatment arm			C	A=Caloric Restriction B=Control
RANDORD	Randomization Order		Randomization order based on RANDOMDT	N	

Trial name	**CALERIE 2**
Dataset name	**VISITS (All attended study visits)**
Description	Details of each Study Visit attended
Comments on data structure	1 record / DEIDNUM / VISIT for each subject with at least 1 study visit (including screening), for each study visit that was attended
Population	Every subject who attended any study visit, including screening (n=1069 subjects x multiple visits)
VISITs	1, 2, 3, 4, 5, 6, 7, 8, 9, 10,11,12,13 (does not include 7.1, 7.2, 8.1, 8.2, 11.1 or 12.1)
Usage notes	This dataset is useful for checking all the visits attended by each subject. It won't be needed for most analyses.
Source data files	All CRF datasets with dates: CHECKLST, DATEHDR, CONSENT, VITALS, SAFETYLB, PREGTEST, DLWHDR, DLWCHT, DXASCAN, PARHDR, FOODRCD, DTHADM1, ADMIT, OUTCMELB, BIOPSY, URINE24, RMR, RANDOM, STDYCOMP
Final sort order	DEIDNUM VISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	VISIT	N	Study Visit, based on CRF page (See Appendix 1)	VISFMT
VISSTRDT	1st date in Visit	All Dates on CRF: CHECKLST.CLINICDT DATEHDR.STUDYDT CONSENT.CONSNTDT VITALS.VITALDT SAFETYLB.SAMPDT DLWHDR.DLWDSEDT DLWCHT.DLWCOLDT DXASCAN.DXADT PARHDR.PARDT FOODRCD.FDRECDT DTHADM1.DTHADMDT ADMIT.(CTSTRDT, CTSTPDT, ADMITDT, DISCHDT) OUTCMELB.SAMPDT BIOPSY.BIOPSYDT URINE24.(URNSTRDT,URNSTPDT) RMR.RMRDT RANDOM(RANDOMDT, INVENTDT)	DT	Smallest CRF date for that DEIDNUM/VISIT	DT
VISLSTDT	Last date in Visit		DT	Largest CRF date for that DEIDNUM/VISIT	DT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
VISSTAT	Status at Visit	VISSTRDT, RTNCLINI,	N	=1 if the visit was attended ie if there are any dates for that visit in the CRF or RTNCLINI=1. else =0 if the visit was not attended	0=Not Attended 1=Attended
NEXTSTAT	Status for next visit	CHECKLST. (FAILELIG, LOSTINT, MUCHTIME, SCHEDULE, DLKSTDPR, DWINVSTD, UWILRAN, TRANPROB, CHLDCARE, REFEXPLN, OTHER) CHECKLST.RETVST, PERMDISC.PRMDISDT STDCOMP.STDCOMP		If this is the subject's final visit, this variable indicates that the subject was either ineligible (during a screening visit) or dropped out, or completed the study. Otherwise, the status is 'expected for next visit'. =1 if FAILELIG=1 Else =2 if STDCOMP<1 (and FAILELIG<1) else =3 if VISIT<13 and STDCOMP=1 else =4 if VISIT=13 and STDCOMP=1. missing if VISSTAT ≠ 1	1=Ineligible (Screening) 2=Dropped Out 3=Expected for next visit 4=Completed study
RAND	Randomized	IVRSRAND.RANDOMDT	N	=1 if RANDOMDT is non-missing else =0	0=not randomized 1=randomized
VISDUR	Duration of visit	VISSTRDT, VISLSTDT	N	=VISLSTDT – VISSTRDT	
DAYSRND	Days since randomization	VISSTRDT, IVRSRAND.RANDOMDT	N	=VISSTRDT - RANDOMDT	
DAYSINT	Days since intervention prescribed	VISSTRDT, RANDOM.INVENTDT	N	=VISSTRDT - INVENTDT	

Trial name	**CALERIE 2**
Dataset name	**SUBJECT1 (demographics, disposition)**
Description	Demographics, disposition and dates
Comments on data structure	1 record / DEIDNUM for all subjects who had at least one study visit (including screening)
Population	All subjects who had at least one study visit (including screening). (n=1069)
Usage Notes	Most analyses only involve subjects who were randomized (RAND=1) or started intervention (INTERVEN=1), so remember to use only the desired subset of records. For most analyses, it is useful to merge the analysis dataset with SUBJECT1 by DEIDNUM, to identify and keep just the randomized or intervention subjects.
Source data files	ANALDATA/VISITS, IVRSRAND, CRF/RANDOM, CONSENT, DEMOG, PERMDISC, STDYCOMP, HEIGHT,
Final sort order	DEIDNUM

Variable name	**LABEL**	**Source variables**	**C/ N?**	**Definition**	**Accepted values/ Format**
INVSITE	Investigator Site	INVSITE	C	Investigator Site	
DEIDNUM	Subject Number	DEIDNUM	C	Subject Number	
SCR1DT	Date of Screening Visit 1	VISITS.VISSTRDT, VISIT	DT	First date of Screening Visit 1 = VISSTRDT from the record with VISIT=1	
BL1DT	Date of Baseline Visit 1	VISITS.VISSTRDT, VISIT	DT	First date of Baseline Visit 1 = VISSTRDT from the record with VISIT=4	
RANDOMDT	IVRS Randomization date	IVRSRAND.RANDOMDT	DT	IVRS Randomization date	
RAND	Randomized (IVRS)	RANDOMDT	N	=1 if RANDOMDT exists Else =0	0=no 1=yes
STRATA1	Sex / BMI stratum	IVRSRAND.STRATA1	N	Sex / BMI stratum from IVRS	1= Female, 22-24.9 2=Female, 25-27.9 3=Male, 22-24.9 4=Male, 25-27.9
BMISTRAT	BMI stratum at rand.	STRATA1	N	=1 if STRATA1 in (1,3) =2 if STRATA1 in (2, 4)	1=22 – 24.9 2= 25 – 27.9
CONSNTDT	Date informed consent signed	CONSENT.CONSNTDT (CRF p. 28)	DT	Date informed consent signed	
CONSENT	Consent signed	CONSNTDT	N	=1 if CONSNTDT is non-missing else =0	
INTERVEN	Intervention started	RANDOM.SRTINVEN (CRF p.92)	N	Intervention started	0=no 1=yes

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
INVENTDT	Date Intervention started	RANDOM.INVENTDT (CRF p.92)	DT	Date Intervention started	
DAY0DT	Day 0 date	IVRSRAND.TX INVENTDT, RANDOMDT	DT	(this is the day prior to intervention start for CR group (IVRSRAND.TX='A'), and the day of randomization for Controls, (IVRSRAND.TX='B'))	
DAY1DT	Day 1 date	DAY0DT	DT	=DAY0DT + 1	
REFDT	Reference date	INTERVEN SCR1DT, DAY1DT	DT	Reference date for Study Days is screening visit 1 date for non-randomized subjects, and intervention start date for randomized subjects. = SCR1DT if INTERVEN=0 = DAY1DT if INTERVEN=1	
M1DT	Month 1 visit start date	VISITS.VISIT, VISSTRDT	DT	=VISSTRDT if VISIT=7	
M3DT	Month 3 visit start date	VISITS.VISIT, VISSTRDT	DT	=VISSTRDT if VISIT=8	
M6DT	Month 6 visit start date	VISITS.VISIT, VISSTRDT	DT	=VISSTRDT if VISIT=9	
M9DT	Month 9 visit start date	VISITS.VISIT, VISSTRDT	DT	=VISSTRDT if VISIT=10	
M12DT	Month 12 visit start date	VISITS.VISIT, VISSTRDT	DT	=VISSTRDT if VISIT=11	
M18DT	Month 18 visit start date	VISITS.VISIT, VISSTRDT	DT	=VISSTRDT if VISIT=12	
M24DT	Month 24 visit start date	VISITS.VISIT, VISSTRDT	DT	=VISSTRDT if VISIT=13	
LASTVIS	Last visit attended	VISITS.VISIT	N	= largest value of VISIT with non-missing VISSTRDT for that DEIDNUM	VISFMT (see Appendix)
LASTSTAT	Status at last visit	VISITS.NEXTSTAT	N	= NEXTSTAT at largest value of VISIT for that DEIDNUM with non-missing NEXTSTAT	1=Ineligible 2=Dropped out 3=Expected for next visit 4=Completed study
LASTDT	Date of last visit	VISITS.VISLSTDT	DT	=largest value of VISLSTDT over all VISITs for that DEIDNUM	

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
				The following set of variables pertain to Study completion / Dropout	
STDCOMP	Completed study evaluations	STDYCOMP.STDCOMP (CRF p.302)	N	Completed study (ie study evaluations) through Month 24, for subjects who were consented and started baseline. (Note: this only applies to subjects who were consented and started baseline. Missing for subjects who were screened out before starting baseline evaluations.) It is possible to complete study evaluations even for subjects who permanently discontinued the CR intervention.	0=No 1=Yes
DROPOUT	Discontinued study evaluations	STDCOMP	N	=1 if STDCOMP=0 else missing (Note: this only applies to subjects who were consented and started baseline and discontinued study evaluations before study completion. Subjects who dropped out before baseline have SCRDROP=1)	1=Dropped Out
SCRDROP	Dropped out during screening	LASTVIS, LASTSTAT	N	=1 if LASTVIS<4 and LASTSTAT is (1 or 2) else missing	
BLDROP	Dropped out during baseline	LASTVIS, LASTSTAT	N	=1 if LASTVIS=(4 or 5) and LASTSTAT =2 else missing	
RANDDROP	Dropped out after rand. before interven.	LASTVIS, LASTSTAT	N	=1 if LASTVIS=6 and LASTSTAT =2 and INTERVEN=0 else missing	
INTDROP	Dropped out after starting intervention	LASTVIS, LASTSTAT	N	=1 if LASTVIS>=6 and LASTSTAT =2 and INTERVEN=1 else missing	
SSTATUS	Status in study	SCRDROP, BLDROP, RANDDROP, INTDROP, STDCOMP, LASTSTAT, LASTVIS	N	=1 if SCRDROP=1 else =2 if BLDROP=1 else =3 if RANDDROP=1 else =4 if INTDROP=1 else =5 if LASTVIS>=6 and LASTSTAT=3 and STDCOMP<1 else =6 if STDCOMP=1	1=screening dropout 2=BL dropout 3=rand. Dropout 4=follow-up dropout 5=in follow-up 6=completed
STDENDDT	Study completion date	STDCOMP.STDENDDT	DT	Study completion date for subjects who	

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
		(p.302)		completed study evaluations through Month 24. =STDENDDT if STDCOMP=1	
DROPDT	Dropout date	STDCOMP.STDENDDT (p.302)	DT	Dropout date for subjects who dropped out after starting baseline evaluations. =STDENDDT if DROPOUT=1 (Does not apply to subjects who dropped out during screening).	
DROPREAS	Reason for dropping out	STDCOMP.REASON (p.302)	N	Reason for dropping out during/after baseline (Note: this only applies to subjects who dropped out after starting baseline evaluations. For subjects who dropped out during screening, see SDRPELIG – SDRPOTHR)	[TUEND] 1=Consent withdrawn 2=Lost to follow-up 3=Adverse Event 4=Death 98=Other
NOCMPSP	Other reason for dropping out (text)	STDCOMP.NOCOMPSP (p.302)	C	Text field. Some values were combined. If index(nocompsp,'LOW') or index(nocompsp,'BMD') then nocompsp='LOW BMD'. if index(nocompsp,'MOVE') then nocompsp='MOVED'. If index(nocompsp,'JOB') or index(nocompsp,'WORK') then nocompsp='WORK'.	
DEATHDT	Date of death	STDCOMP.DEATHDT (p.302)	DT		
PERMDISC	Permanently discontinued CR intervention	PERMDISC.PRMDISDT	N	=1 if PRMDISDT is non-missing, else missing (Note: this only applies to subjects who were randomized to the CR arm (TX=’A’)	1=Yes

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
				and started the intervention and permanently discontinued the intervention before study completion)	
TXCOMP	Completed Intervention	INTERVEN, TX, PERMDISC, STDCOMP	N	Completed intervention means: CR subjects who started intervention and completed study evaluations through Month 24 and did not permanently discontinue the intervention, or AL subjects who completed study evaluations through Month 24. Not defined for subjects who did not start intervention. = 1 if INTERVEN=1 AND TX='A' and STDCOMP=1 and PERMDISC<1 Or TX='B' and STDCOMP=1 Else =0 if INTERVEN=1 and TX='A' and PERMDISC=1 Or TX='B' and STDCOMP=0 Else missing if INTERVEN<1.	0=Did not complete Intervention 1=Completed Intervention
PRMDISDT	CR discontinuation date	PERMDISC.PRMDISDT (CRF p.300)	DT	Date of permanent discontinuation from CR intervention (only applies to subjects who were randomized to the CR arm and started the CR intervention, then permanently discontinued before completing the trial)	
PERMRSN	CR discontinuation reason	PERMDISC.PERMRSN (CRF p.300)	N	Reason for permanent discontinuation from CR intervention. (only applies to subjects who were randomized to the CR arm and started the CR intervention, then permanently discontinued)	TUPERM (see CRF p.300)
				The following set of variables are Demographic Variables	
DOBDT	Date of birth	DEMOG.DOBDT (CRF p.6)	DT		
AGE	Age at 1st screening visit	SCR1DT, DOBDT	N	= years from DOBDT to SCR1DT	2 decimal places

Variable name	**LABEL**	**Source variables**	**C/ N?**	**Definition**	**Accepted values/ Format**
AGEBL	Age at 1st baseline visit	BL1DT, DOBDT	N	=years from DOBDT to BL1DT	2 decimal places
GENDER	Sex	DEMOG.GENDER (CRFp.6)	N	1=Male 2=Female	[TUGEND]
FEMALE	Female sex	GENDER	N	=0 if GENDER=1 (Male) =1 if GENDER=2 (Female)	0=Male 1=Female
ETHNIC	Ethnic group	DEMOG.ETHNIC (CRF p.6)	N	1=Hispanic or Latino 2=Not Hispanic or Latino 3=Unknown	[TUETHN]
RACE	Race	DEMOG.RACE (CRF p.6)	N	Some of the original categories have been combined. if RACE is 1, 3, 6, 7 then recode as 8. Otherwise, retain the original value.	2=Asian 4=Black or African American 5=White 8=Other
WHITE	White race	RACE	N	=1 if RACE=5 Else =0 if RACE > 0 Else missing	
RACE3	Race (African American, White, Other)	RACE	N	=1 if RACE=4 Else = 2 if RACE in (2,8) Else = 3 if RACE =5 Else missing	1=African American 2=Other 3=White
MARSTAT	Marital status	DEMOG.MARSTAT (CRF p.6)	N	Some of the original categories have been combined. If MARSTAT= 2, 4, 5, then recode to 7, Otherwise, retain the original value.	1=Married 3=Single, never married 6=Not married, but living with partner 7=Previously married
MARRIED	Married	MARSTAT	N	=1 if MARSTAT=1 Else =0 if MARSTAT>0 Else missing.	
LIVSIT	Living situation	DEMOG.LIVSIT (CRF p.6)	N	Some of the original categories have been combined. If LIVSIT is 3, 4, 98 then recode as 5. Otherwise, retain the original value.	1=House 2=Apartment 5=Other
EDUCATE	Education	DEMOG.EDUCATE (CRF p.6)	N	Some of the original categories have been combined. if EDUCATE is 1, 2 or 3 then recode as 8.	4=Some college / Associates degree 5=College 6=Non-doctoral graduate degree

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
				Otherwise, retain the original value.	7=Doctoral degree 8=12th Grade/GED or less
FAMINC	Family income	DEMOG.FAMINC (CRF p.6)	N	1=$0 - $19,999 2=$20,000 - $39,000 3=$40,000 - $59,000 4=$60,000 - $79,000 5=$80,000 - $99,000 6=$100,000 or greater	[TUFINC]
HEIGHT	Height (cm)	HEIGHT.HGHT1 – HGHT3 (CRF p.4)	N	Mean of 3 height measurements taken at screening visit 1. = mean of (HGHT1, HGHT2, HGHT3)	
				The following variables are reasons for dropping out during the screening period.	
SDRPELIG	Failed eligibility (screening)	CHECKLST.FAILELIG	N	=1 if FAILELIG=1 and STATUS=1 in any record for that DEIDNUM Else missing	
SDRPINTR	Lost interest (screening)	CHECKLST.LOSTINT	N	=1 if LOSTINT=1 in any record for that DEIDNUM Else missing	
SDRPTIME	Too much time (screening)	CHECKLST.MUCHTIME	N	=1 if MUCHTIME=1 in any record for that DEIDNUM Else missing	
SDRPSCHD	Scheduling conflicts (screening)	CHECKLST.SCHEDULE	N	=1 if SCHEDULE=1 in any record for that DEIDNUM Else missing	
SDRPPROC	Dislikes study procedures (screening)	CHECKLST.DLKSTDPR	N	=1 if DLKSTDPR=1 in any record for that DEIDNUM Else missing	
SDRPRSCH	Unwilling to be in research study (scr)	CHECKLST.DWINVSTD	N	=1 if DWINVSTD=1 in any record for that DEIDNUM Else missing	
SDRPRAND	Unwilling to be randomized (screening)	CHECKLST.UNWILRAN	N	=1 if UNWILRAN=1 in any record for that DEIDNUM Else missing	
SDRPTRAN	Transportation problems (screening)	CHECKLST.TRANPROB	N	=1 if TRANPROB=1 in any record for that DEIDNUM	

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
				Else missing	
SDRPCHLD	Child care issues (screening)	CHECKLST.CHLDCARE	N	=1 if CHLDCARE=1 in any record for that DEIDNUM Else missing	
SDRPREFX	Refused with no explanation (screening)	CHECKLST.REFEXPLN	N	=1 if REFEXPLN=1 in any record for that DEIDNUM Else missing	
SDRPCONT	Unable to contact (screening)	CHECKLST.UNABCONT	N	=1 if UNABCONT=1 in any record for that DEIDNUM Else missing	
SDRPOTHR	Other dropout reason (screening/BL)	CHECKLST.OTHER, DROPREAS, STATUS	N	=1 if OTHER=1 in any record for that DEIDNUM, **or (DROPREAS=98 and STATUS=2)** Else missing	
BDRPCNST	Consent withdrawn during baseline period	DROPREAS, STATUS	N	=1 if DROPREAS=1 and STATUS=2 Else missing	
BDRPAEVT	Adverse Event during Baseline	DROPREAS, STATUS	N	=1 if DROPREAS=3 and STATUS=2 Else missing	

Trial name	**CALERIE 2**
Dataset name	**CLWTLONG (all clinic weights)**
Description	Weights measured in the Clinic at each study Subvisit. Each 'VISIT' (eg 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	1, 4, 5, 7, 8, 9, 10, 11, 11.1, 12, 12.1, 13 (See Appendix 1 for 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
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	

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
				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 aprt.	
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	

Trial name	**CALERIE 2**
Dataset name	**CLWTVIS (mean clinic weight at each visit)**
Description	Mean of all clinic weights over all Subvisits for each VISIT, for each subject
Comments on data structure	1 record / DEIDNUM / VISIT.
Population	All subjects who had at least one study visit (including screening visits).
VISITs	Includes all the original visits (1, 4, 5, 7, 8, 9, 10, 11, 11.1, 12, 12.1, 13) and adds VISIT 0 which combines the two baseline Visits 4 and 5 into a single baseline mean. (See Appendix for VISIT codes)
Usage Notes	Use MCLINWT for analyses requiring the mean clinic weight at each visit If separate records are needed for each of the two baseline periods, use VISITs 4 and 5. If only one overall baseline mean record is needed, use VISIT 0.
Source data files	ANALDATA/CLWTLONG
Final sort order	DEIDNUM VISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	VISIT	N	Study Visit, based on CRF pages (See Appendix 1)	VISFMT
WTDT1	1st clinic. wght date/visit	WTDT	DT	Date of first weight at that visit	DT
WTDT2	Last clinic wght date/visit	WTDT	DT	Date of last weight at that visit	DT
NWT	Number of clinic weights at visit	CLINWT	N	Number of non-missing clinic weights at that visit.	
MCLINWT	Mean clinic weight	CLINWT	N	= mean clinic weight over all records for that DEIDNUM/VISIT	
HEIGHT	Height (cm)	HEIGHT	N	Height	
MBMI	Body mass index	BMI		= mean BMI over all records for that DEIDNUM/VISIT	
BLCLINWT	Baseline clinic weight	MCLINWT, VISIT	N	Baseline clinic weight (MCLINWT from VISIT 0)	
DELTAWTB	Change in weight since baseline	MCLINWT, BLCLINWT	N	=MCLINWT – BLCLINWT	
PDELTAWT	% Change in weight since baseline	DELTAWTB, BLCLINWT	N	= 100 x DELTAWTB / BLCLINWT	

Trial name	**CALERIE 2**
Dataset name	**HOMEWT (all home weights)**
Description	All weights measured daily at home during each 2 week DLW period. Weights are merged with DLW dates, to determine days from DLW dosing to weight.
Comments on data structure	1 record / DEIDNUM / VISIT / HWGHTDT / HWTKG
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
VISITs	4, 5, 11 and 13 for all subjects, 9 and 12 for CR subjects (See Appendix for VISIT codes)
Usage notes	HOMEWT is used for doing regression of daily 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/HWGHLOG1, HWGHLOG2 ANALDATA/DLWLONG, SUBJECT1
Final sort order	DEIDNUM, VISIT, HWGHTDT, HWTKG

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	HWGHLOG1.TIMEPT	N	=4 if TIMEPT=1 =5 if TIMEPT=2 =9 if TIMEPT=5 =11 if TIMEPT=7 =12 if TIMEPT=8 =13 if TIMEPT=9	VISFMT
HWGHTDT	Date of home weight	HWGHLOG2.HWLOGDT	DT		DT
HWTDAY	Home weight day in DLW period	HWGHTDT, DLWLONG.DLWDSEDT	N	= HWGHTDT – DLWDSEDT (missing if either date is missing)	
HWEIGHT	Home weight	HWGHLOG2.HWEIGHT	N		
HWTKG	Home weight (kg)	HWEIGHT	N	=HWEIGHT x 0.45359237	

Trial name	CALERIE 2
Dataset name	**DXAA (Body Composition**
Description	DXA (Dual-energy X-ray absorptiometry) is used to measure body composition: % body fat, fat mass (FM), fat free mass (FFM), bone mineral density (BMD), bone mineral content (BMC). The DXA lab recommended corrections to some of the BMD, Area, %BF, and total mass measures, which also affected BMC, fat, FFM and lean variables. These corrections were recommended based on analysis of drift for the DXA machines. Corrections are shown in the specs below. This dataset combines DXA lab results with CRF data.
Comments on data structure	1 record / DEIDNUM/ VISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
VISITs	4, 5, 11 and 13 for all subjects, 9.1, 9.2 and 12 for CR subjects. (DXA is done twice each at baseline and Month 6, and once at the other visits) VISIT 0 combines the two baseline Visits 4 and 5 into a single baseline mean, and VISIT 9 combines the two Month 6 visits into a single Month 6 mean. (See Appendix for VISIT codes)
Usage Notes	For Whole Body fat and fat free mass, according to DXA data handling rules, use the variables FM and FFM, which are created by multiplying clinic weight by % body fat from DXA, rather than the variable BTOTFAT and BTOTFFM which are obtained by the DXA, and considered to be less accurate. BTOTPF (whole body %fat) is also used in many analyses. If separate records are needed for each of the two baseline DXAs, use VISITs 4 and 5. If only one overall baseline mean record is needed, use VISIT 0. If separate records are needed for each of the two Month 6 DXAs, use VISITs 9.1 and 9.2. If only one overall baseline mean record is needed, use VISIT 9.
Source data files	CRF/DXASCAN, LABS/DXA, ANALDATA/SUBJECT1, DLWFLAT
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	DXASCAN.PAGEID	N		
VISIT	Visit	PAGENUM, DXA.XVISITN	N	Study Visit, based on CRF pages (See Appendix 1) Or DXA.XVISITN	VISFMT
SUBVISIT	Sub-Visit	SUBVISIT	N	Study Sub-Visit, based on CRF pages (See Appendix 1)	SVISFMT

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DXADT	DXA date (CRF)	DXASCAN.DXADT	DT		
REDXADT	DXA rescan date (CRF)	DXASCAN.REDXADT	DT		
BSCANDT	DXA scan date (lab)	DXA.BSCANDT	DT		
HSCANDT	Hip scan date (lab)	DXA.HSCANDT	DT		
SSCANDT	Spine scan date	DXA.SSCANDT	DT		
RSCANDT	Forearm scan date	DXA.RSCANDT	DT		
DLWDSEDT	DLW dose date	DLWFLAT.DLWDSEDT	DT	DLW start and end dates are included to determine the lag between DLW and DXA.	
DLWENDDT	DLW end date	DLWFLAT.DLWENDDT	DT		
INRANGE	DXA is within 15 days of DLW	BSCANDT, DLWDSEDT, DLWENDDT	N	This variable is an indicator for whether the DXA is within 15 days of the DLW period. This is used for the adherence analysis, where DXA assays must be within 15 days of DLW to be included in the analysis. This is used to create FMA and FFMA. =0 if .z<BSCANDT < DLWDSEDT – 15 or BSCANDT > DLWENDDT + 15 > .z Else =1 if DLWDSEDT – 15 <= BSCANDT <= DLWENDDT + 15 Else missing if any of BSCANDT, DLWDSEDT, or DLWENDDT are missing	
CRFDXA	DXA done (CRF)	DXASCAN.DXADT, DXASCAN.REDXADT	N	=1 if DXADT is non-missing or REDXADT is non-missing else =0	
LABDXA	DXA lab data received	BSCANDT	N	=1 if BSCANDT is non-missing	
NDXA	Number of DXAs at visit	LABDXA	N	For VISIT 0 (VISITs 4 and 5 combined) and VISIT 9 (VISITs 9.1 and 9.2 combined), this variable is the sum of LABDXA from the 2 component visits,	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				indicating whether both, only 1, or no DXAs were done. For all other visits, NDXA=LABDXA.	
WBDY	Whole body scanned?	DXASCAN.SBDY,REWBDY	N	=1 if WBDY=1 or REWBDY=1 else missing	
FARM	Forearm scanned?	DXASCAN.FARM, REFARM	N	=1 if FARM=1 or REFARM=1 else missing	
SPINE	Spine scanned?	DXASCAN.SPINE, RESPINE	N	=1 if SPINE=1 or RESPINE=1 else missing	
HIP	Hip scanned?	DXASCAN.HIP, REHIP	N	=1 if HIP=1 or REHIP=1 else missing	
WBDYND	Reason whole body not scanned	DXASCAN.WBDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
FARMND	Reason forearm not scanned	DXASCAN.FARMND	N		
SPINEND	Reason spine not scanned	DXASCAN.SPINEND	N		
HIPND	Reason hip not scanned	DXASCAN.HIPND	N		
CLINWTA	Clinic weight on DXA date	CLWTLONG.CLINWT, CLWTLONG.WTDT, DXADT	N	=CLINWT if WTDT = DXADT	
CLINWTB	Clinic weight closest to DXA date	CLWTLONG.CLINWT, CLWTLONG.WTDT, DXADT	N	Closest clinic weight to DXA date within 7 days. =CLINWT on DXA date as defined above, if there is a record with WTDT=DXADT. If there is no record with WTDT = DXADT, CLINWTB is the clinic weight with the closest date to DXADT, within 7 days.	
WTDTB	Closest DXA weight date	CLWTLONG.WTDT	DT	Date of Clinic weight closest to DXA date. (Date of CLINWTB)	
DXAWTDIF	Diff. between DXA mass and clinic weight	BTOTMASS, CLIWNTB	N	Difference between DXA mass and closest clinic weight	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				= BTOTMASS – CLINWTB	
DXWTDDIF	Diff. between DXA and clinic weight date	DXADT, WTDTB	N	Difference between DXA date and closest weight date = WTDTB - BSCANDT	
NOCLINWT	No clinic weight on DXA date	CLINWTA	N	=1 if CLINWTA is missing	
*BMD Where * = the following regions:		DXA.*BMD Where * =:	N	Corrections were made to BMD values based on recommendations from the DXA lab. See DXA data handling rules document.	
BTOT	WBody Total BMD	BTOT			
BSUB	WBody Sub Total BMD	BSUB			
HEAD	Head BMD	HEAD			
LARM	Left Arm BMD	LARM			
RARM	Right Arm BMD	RARM			
LRIB	Left Rib BMD	LRIB			
RRIB	Right Rib BMD	RRIB			
TSPI	Thor Spine BMD	TSPI			
LSPI	Lumb Spine BMD	LSPI			
PELV	Pelvic BMD	PELV			
LLEG	Left Leg BMD	LLEG			
RLEG	Right Leg BMD	RLEG			
T	Trochanter BMD	T			
IT	Intertrochanter BMD	IT			
N	Neck BMD	N			
W	Wards triangle BMD	W			
HTOT	Hip Total BMD	HTOT			
L1	L1 BMD	L1			
L2	L2 BMD	L2			
L3	L3 BMD	L3			
L4	L4 BMD	L4			
STOT	Spine Total BMD	STOT			
R13	Radius 1/3 BMD	R13			
RM	Radius Mid BMD	RM			

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
RU U13 UM UU RTOT UTOT RU13 RUM RUU RUTOT	Radius ultra BMD Ulna 1/3 BMD Ulna Mid BMD Ulna ultra BMD Forearm Total BMD Ulna Total BMD Radius + Ulna 1/3 BMD Radius + Ulna Mid Radius + Ulna ultra Radius + Ulna Total	RU U13 UM UU RTOT UTOT RU13 RUM RUU RUTOT			
*AREA For * = (the same list as for BMD) (except RUTOTARE)	Same as for BMD, but Area instead of BMD	DXA.*AREA: * =Same list as for BMD,	N	Corrections were made to AREA values based on recommendations from the DXA lab. See DXA data handling rules document.	
				BMC variables (kg)	
*BMC For * = (the same list as for BMD)	Same as for BMD, but BMC instead of BMD	*BMD and *AREA for same list as BMD	N	For each *, = *BMD x *AREA / 1000	
TRNKBMC	Trunk BMC	DXA.TRNKBMC	N	= DXA.TRNKBMC / 1000	
*PF Where * = the following regions: BTOT BSUB HEAD LARM	 Wbody Total %Fat Wbody Sub Total Head %Fat Left Arm %Fat	DXA.*PF Where * = the following regions: BTOT BSUB HEAD LARM	N	Corrections were made to PF values based on recommendations from the DXA lab. See DXA data handling rules document.	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RARM TRNK LLEG RLEG AGT AND GYN	Right Arm %Fat Trunk %Fat Left Leg %Fat Right Leg %Fat Total Android+Gynoid %Fat Android %Fat Gynoid %Fat	RARM TRNK LLEG RLEG AGT AND GYN			
*MASS (for * = the same list as PF)	Same as for PF, but Mass (kg) instead of PF	DXA.*MASS Where * = same list as for PF.	N	Corrections were made to MASS values based on recommendations from the DXA lab. See DXA data handling rules document.	
*FAT (for * = the same list as PF) Except: TRUNKFAT instead of TRNKFAT)	Same as for PF, but fat (kg) instead of PF	*PF, *MASS	N	= *MASS x *PF / 100 (use *MASS and *PF as defined above) (Note: for whole body fat mass, use FM (defined below), which is based on the Clinic weight, instead of BTOTFAT)	
*FFM (for * = the same list as PF)	Same as for PF, but FFM (kg) instead of PF	*MASS, *FAT	N	= *MASS - *FAT Use *MASS and *FAT as defined above (Note: for whole body fat free mass, use FFM (defined below), which is based on the Clinic weight, instead of BTOTFFM)	
FM	Whole Body FM (clinic weight x %BF)	CLINWTB, BTOTPF, BTOTFAT	N	(Closest Clinic weight multiplied by %BF, if clinic weight is within 7 days of DXA. Otherwise, uses Fat mass from DXA)	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				=CLINWTB x BTOTPF / 100 if CLINWTB is non-missing Else = BTOTFAT if CLINWTB is missing	
FFM	Whole Body FFM (clinic weight – FM)	CLINWTB, FM, BTOTFFM	N	(Closest clinic weight – FM, if clinic weight is within 7 days of DXA. Otherwise, uses FFM from DXA). =CLINWTB – FM if CLINWTB is non-missing Else = BTOTFFM if CLINWTB is missing	
FMA	Fat mass (adherence rules)	FM, INRANGE	N	This variable is for the adherence analysis only: only FM values within 15 days of the DLW period are included in the analysis. = FM if INRANGE ≠0 (ie INRANGE = 1 or missing) Else missing if INRANGE=0	
FFMA	FFM (adherence rules)	FFM, INRANGE	N	This variable is for the adherence analysis only: only FM values within 15 days of the DLW period are included in the analysis. = FFM if INRANGE ≠0 (ie INRANGE = 1 or missing) Else missing if INRANGE=0	
THIP	Tscore hip total BMD	SEX, ETHNIC, HTOTBMD	N	See SAS code on pages 26-29	
TNECK	Tscore femoral neck BMD	SEX, ETHNIC, NBMD	N	See SAS code on pages 26-29	
TSPINE	Tscore spine total BMD	SEX, ETHNIC, L1BMD, L2BMD, L3BMD, L4BMD, STOTBMD	N	See SAS code on pages 26-29	
HBMDDROP	Drop in Hip total BMD	HTOTBMD, HBMD_BL	N	= HTOTBMD – (HTOTBMD from VISIT=4)	
SBMDDROP	Drop in Spine total BMD	STOTBMD, SBMD_BL	N	=STOTBMD – (STOTBMD from VISIT=4)	
NBMDDROP	Drop in Femoral Neck BMD	NBMD, NBMD_BL	N	= NBMD – (NBMD from VISIT=4)	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
PHBMDDRP	% drop in Hip total BMD	HBMDDROP, HBMD_BL	N	= 100 X HBMDDROP / (HTOTBMD from VISIT=4)	
PSBMDDRP	% drop in Spine total BMD	SBMDDROP, SBMD_BL	N	=100 X SBMDDROP / (STOTBMD from VISIT=4)	
PNBMDDRP	% drop in Femoral neck BMD	NBMDDROP, NBMD_BL	N	=100 X NBMDDROP / (NBMD from VISIT=4)	
BMDALERT	Flagged for low BMD at hip or spine	VISIT, PHBMDDRP, PSBMDDRP, THIP, TSPINE	N	Subjects are flagged for low BMD if there is ≥5% drop in BMD up to Month 12, or ≥10% drop in BMD after Month 12, or T-score at Hip or Spine is < -2.5. =1 if VISIT in (9,11) and max(PHBMDDRP, PSBMDDRP)>=5 Or VISIT>11 and max(PHBMDDRP,PSBMDDRP)>=10 Or .z<THIP < -2.5 Or .z<TSPINE < -2.5 Else missing	

SAS code for DXA T-scores

SAS code for calculating BMD T-scores for total hip, femoral neck and total spine.

```
**************************************************************************************** ;
**      TOTAL HIP TSCORES                                        ** ;
**      USING HOLOGIC NHANES NORMALS                                     ** ;
**************************************************************************************** ;
IF PAT_SEX='F' THEN DO ;
      IF PAT_ETH IN ( 'B'  )  THEN THIP= ( HTOTBMD - 1.031 ) / 0.156 ;                    **  BLACK AGE 45 1.031    0.156  ** ;
            ELSE IF PAT_ETH IN ( 'H'  )  THEN THIP= ( HTOTBMD - 0.962 ) / 0.134 ;   **  MEXICAN AMERICAN AGE 35 0.962    0.134  ** ;
            ELSE IF PAT_ETH IN ( 'A' 'C' 'O' 'W' ' ' )  THEN THIP= ( HTOTBMD - 0.942 ) / 0.122 ;    **  ANY ETHNIC OTHER THAN BLACK OR HISPANIC AGE 25  ** ;
END ;
**************************************************************************************** ;
ELSE IF PAT_SEX='M' THEN DO ;
      IF PAT_ETH IN ( 'B'  )  THEN THIP= ( HTOTBMD - 1.177 ) / 0.172 ;                    ** 1.177    0.172 BLACK AGE 25  ** ;
            ELSE IF PAT_ETH IN ( 'H'  )  THEN THIP= ( HTOTBMD - 1.055 ) / 0.132 ;   ** 1.055    0.132 MEXICAN AMERICAN AGE 25  ** ;
            ELSE IF PAT_ETH IN ( 'A' 'C' 'O' 'W' ' ' )  THEN THIP= ( HTOTBMD - 1.033 ) / 0.151 ;    ** 1.033    0.151 ANY ETHNIC OTHER THAN BLACK OR HISPANIC
AGE 25 0.942    0.122 ** ;
END ;
**************************************************************************************** ;

IF PAT_SEX='F' THEN DO ;
      IF PAT_ETH IN ( 'B'  )  THEN TNECK= ( NBMD - 0.951 ) / 0.142 ;               ** 0.951    0.142 BLACK AGE 25   ** ;
            ELSE IF PAT_ETH IN ( 'H'  )  THEN TNECK= ( NBMD - 0.874 ) / 0.118 ;     ** 0.874    0.118 MEXICAN AMERICAN AGE 25   ** ;
            ELSE IF PAT_ETH IN ( 'A' 'C' 'O' 'W' ' ' )  THEN TNECK= ( NBMD - 0.849 ) /  0.111 ;     ** 0.849    0.111 ANY ETHNIC OTHER THAN BLACK OR HISPANIC
AGE 25  ** ;
END ;
**************************************************************************************** ;


ELSE IF PAT_SEX='M' THEN DO ;
      IF PAT_ETH IN ( 'B'  )  THEN TNECK= ( NBMD - 1.073 ) / 0.156 ;               **1.073    0.156  BLACK AGE 25  ** ;
            ELSE IF PAT_ETH IN ( 'H'  )  THEN TNECK= ( NBMD - 0.977 ) / 0.131 ;     ** 0.977    0.131 MEXICAN AMERICAN AGE 25  ** ;
            ELSE IF PAT_ETH IN ( 'A' 'C' 'O' 'W' ' ' )  THEN TNECK= ( NBMD - 0.930 ) /  0.136 ;     **0.930    0.136  ANY ETHNIC OTHER THAN BLACK OR HISPANIC
AGE 25  ** ;
END ;
**************************************************************************************** ;

LABEL THIP='Tscore Hip Total BMD' ;
THIP=ROUND(THIP,0.0001) ;
LABEL TNECK='Tscore Femoral Neck BMD' ;
TNECK=ROUND(TNECK,0.0001) ;
**************************************************************************************** ;
**      TOTAL SPINE TSCORES                                        ** ;
```

```
**     USING HOLOGIC NORMALS                                   ** ;
*************************************************************************** ;
IF PAT_SEX='F' THEN DO ;
IF PAT_ETH IN ( 'B'  )  THEN DO ;  ** BLACK ** ;
     IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.190)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.016)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.129)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.225)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.075)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.162)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.209)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.118)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.185)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.135)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.156)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.112)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.139)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.183)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.150)/ 0.110 ;
END ;
*************************************************************************** ;
ELSE IF PAT_ETH IN ( 'H'  )  THEN DO ;  ** HISPANIC ** ;
     IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.084)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 0.925)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.028)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.116)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 0.979)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.058)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.101)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.018)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.079)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.034)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.053)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.013)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.037)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.077)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.047)/ 0.110 ;
END ;
*************************************************************************** ;
ELSE IF PAT_ETH IN ( 'A' 'C' 'O' 'W' ' ' )  THEN DO ;   ** WHITE, ASIAN , OTHER ** ;
     IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.084)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 0.925)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.028)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.116)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 0.979)/ 0.110 ;
```

```
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.058)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.101)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.018)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.079)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.034)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.053)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.013)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.037)/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.077)/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.047)/ 0.110 ;
END ;
END ;
************************************************************************** ;
ELSE IF PAT_SEX='M' THEN DO ;
IF PAT_ETH IN ( 'A' 'C' 'O' 'W' ' ' )  THEN DO;  ** WHITE, ASIAN , OTHER ** ;
    IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.008 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.094 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.103 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.145 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.053 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.098 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.124 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.070 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.115 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.090 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.087 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.059 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.084 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.121 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.091 )/ 0.110 ;
END ;
************************************************************************** ;
ELSE IF PAT_ETH IN ( 'B'  )  THEN DO ;  ** BLACK ** ;
    IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.107 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.201 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.211 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.257 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.156 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.206 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.234 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.175 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.224 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.197 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.194 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.163 )/ 0.110 ;
```

```
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.190 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.231 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.198 )/ 0.110 ;
END ;

************************************************************************ ;
ELSE IF PAT_ETH IN ( 'H'  )  THEN DO ;  ** HISPANIC ** ;
    IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.008 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.094 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.103 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.145 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.053 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.098 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.124 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.070 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.115 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.090 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.087 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD> .Z AND L4BMD<=.Z THEN TSPINE=(STOTBMD - 1.059 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD<=.Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.084 )/ 0.110 ;
ELSE IF L1BMD<=.Z AND L2BMD> .Z AND L3BMD<=.Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.121 )/ 0.110 ;
ELSE IF L1BMD> .Z AND L2BMD> .Z AND L3BMD> .Z AND L4BMD> .Z THEN TSPINE=(STOTBMD - 1.091 )/ 0.110 ;
END ;
END ;
LABEL TSPINE='Tscore Spine Total BMD' ;
TSPINE=ROUND(TSPINE,0.0001) ;
```

Trial name	**CALERIE 2**
Dataset name	**FOODWEEK (Food diary per week)**
Description	Food diary data converted to 1 record per DEIDNUM / VISIT. Food diaries were recorded and analyzed for 6 days during each DLW period. The raw food diary dataset FOODNDS contains one record for each day with numerous variables for the nutrition intake. FOODWEEK converts the daily food diary results dataset to 1 record per DEIDNUM / VISIT. For most variables, we take the average of each variable over all days in the DEIDNUM / VISIT. However, variables for %calories from fat, protein, carbs and alcohol are calculated by dividing the total intake of the macronutrient over the entire week by the total overall caloric intake over the entire week. These results are merged with CRF data, with one record for each visit that was attended at which food diaries were expected. For the combined baseline visit (VISIT 0), all variables are calculated as the mean of the mean values from each of the two baseline visits.
Comments on data structure	1 record / DEIDNUM/ VISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
VISITs	4, 5, 11 and 13 for all subjects, 9 and 12 for CR subjects VISIT 0 combines the two baseline Visits into a single baseline mean, (See Appendix for VISIT codes)
Usage notes	The following variables are often used in analyses: KCAL, PCTFATC, PCTPROTC, PCTCARBC, PCTALCC. If separate records are needed for each of the two baseline periods, use VISITs 4 and 5. If only one overall baseline mean record is needed, use VISIT 0.
Source data files	LABS/FOODNDS, CRF/FOODRCD
Final sort order	DEIDNUM VISIT

Variable name	**LABEL**	**Source variables**	**C/ N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		$20
PAGENUM	CRF page number	FOODRCD.PAGEID	N		
VISIT	Visit	PAGENUM, FOODNDS.FFORM	N	Study Visit, based on CRF page (See Appendix 1) Or FOODNDS.FFORM (see FOODNDS specs)	VISFMT
SUBVISIT	Sub-Visit	PAGENUM, FOODNDS.FFORM	N	Study Sub-visit, based on CRF page (See Appendix 1) Or FOODNDS.FFORM (see FOODNDS specs)	SVISFMT
FOODDT1	First date of food intake	FOODNDS.INTAKEDT	DT	Smallest nonmissing INTAKEDT for that DEIDNUM/VISIT	
FOODCRF	Food diary done (CRF)	FOODRCD.FDRECDT	N	=1 if CRF indicated that at least one reliable food diary record was done. =1 if at least one record for that DEIDNUM / VISIT has	

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
				non-missing FDRECDT and RECQUAL=1 Else =0	
FOODNDS	Food diary analysis received	FOODNDS	N	=1 if there are any records in FOODNDS for that DEIDNUM/VISIT.	
FDNDRSN	Reason food diary not done	FOODDAY.FOODNDRSN	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
NNDSDAYS	Number of food diary days	FOODNDS FOODRCD.RECQUAL	N	Number of days with reliable food diary results for that DEIDNUM / VISIT. = number of records in FOODNDS with RECQUAL<=1 for that INTAKEDT for that DEIDNUM /VISIT Missing if not in FOODNDS.	
				The following variables, (TGRAMS –ALCCAL) take the mean value of the variable over all days for that DEIDNUM / VISIT that have acceptable quality (RECQUAL<=1 incuding missing RECQUAL)	
TGRAMS	Total Grams	TGRAMS	N		
KCAL	Self Reported Energy Intake (kcal/d)	KCAL	N	Use this variable for Self Reported Energy Intake	
TFAT	Self-Reported Fat intake (g/d)	TFAT	N		
TCARB	Self-Reported Carbohydrate intake (g/d)	TCARB	N		
TPROT	Self-Reported Protein intake (g/d)	TPROT	N		
ANIPROT	Animal Protein (g)	ANIPROT	N		
VEGPROT	Vegetable Protein (g)	VEGPROT	N		
ALCOHOL	Self-Reported Alcohol intake (g/d)	ALCOHOL	N		
CHOLEST	Cholesterol (mg)	CHOLEST	N		

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
TSFA	Total Saturated Fatty Acids (g)	TSFA	N		
TMUFA	Total Monounsaturated Fatty Acids (g)	TMUFA	N		
TPUFA	Total Polyunsaturated Fatty Acids (g)	TPUFA	N		
FRUCTOSE	Fructose (g)	FRUCTOSE	N		
GALACTOS	Galactose (g)	GALACTOS	N		
GLUCOSE	Glucose (g)	GLUCOSE	N		
LACTOSE	Lactose (g)	LACTOSE	N		
MALTOSE	Maltose (g)	MALTOSE	N		
SUCROSE	Sucrose (g)	SUCROSE	N		
STARCH	Starch (g)	STARCH	N		
TDFIB	Total Dietary Fiber (g)	TDFIB	N		
SOLFIB	Soluble Dietary Fiber (g)	SOLFIB	N		
INSOLFIB	Insoluble Dietary Fiber (g)	INSOLFIB	N		
PECTINS	Pectins (g)	PECTINS	N		
TVITAIU	Total Vitamin A Activity (IU)	TVITAIU	N		
BETACEQ	Beta-Carotene Equivalents (mcg)	BETACEQ	N		
RETINOL	Retinol (mcg)	RETINOL	N		
VITD	Vitamin D (calciferol) (mcg)	VITD	N		
TATOCOEQ	Total Alpha-Tocopherol Equivalents (mg)	TATOCOEQ	N		
VITETAT	Vitamin E (Total Alpha-Tocopherol) (mg)	VITETAT	N		
BTOCO	Beta-Tocopherol (mg)	BTOCO	N		

Variable name	**LABEL**	**Source variables**	**C/ N?**	**Definition**	**Accepted values/ Format**
GTOCO	Gamma-Tocopherol (mg)	GTOCO	N		
DTOCO	Delta-Tocopherol (mg)	DTOCO	N		
VITK	Vitamin K (phylloquinone) (mcg)	VITK	N		
VITC	Vitamin C (ascorbic acid) (mg)	VITC	N		
THIAMIN	Thiamin (vitamin B1) (mg)	THIAMIN	N		
RIBOFLAV	Riboflavin (vitamin B2) (mg)	RIBOFLAV	N		
NIACIN	Niacin (vitamin B3) (mg)	NIACIN	N		
PANTOAC	Pantothenic acid (mg)	PANTOAC	N		
VITB	Vitamin B-6 (mg)	VITB	N		
TFOLATE	Total Folate (mcg)	TFOLATE	N		
VITB12	Vitamin B-12 (cobalamin) (mcg)	VITB12	N		
CA	Calcium (mg)	CA	N		
P	Phosphorus (mg)	P	N		
MG	Magnesium (mg)	MG	N		
FE	Iron (mg)	FE	N		
ZN	Zinc (mg)	ZN	N		
CU	Copper (mg)	CU	N		
SE	Selenium (mcg)	SE	N		
NA	Sodium (mg)	NA	N		
K	Potassium (mg)	K	N		
SFA40	SFA 4:0 (butyric acid) (g)	SFA4_0	N		
SFA60	SFA 6:0 (caproic acid) (g)	SFA6_0	N		

Variable name	**LABEL**	**Source variables**	**C/ N?**	**Definition**	**Accepted values/ Format**
SFA80	SFA 8:0 (caprylic acid) (g)	SFA8_0	N		
SFA100	SFA 10:0 (capric acid) (g)	SFA10_0	N		
SFA120	SFA 12:0 (lauric acid) (g)	SFA12_0	N		
SFA140	SFA 14:0 (myristic acid) (g)	SFA14_0	N		
SFA160	SFA 16:0 (palmitic acid) (g)	SFA16_0	N		
SFA170	SFA 17:0 (margaric acid) (g)	SFA17_0	N		
SFA180	SFA 18:0 (stearic acid) (g)	SFA18_0	N		
SFA200	SFA 20:0 (arachidic acid) (g)	SFA20_0	N		
SFA220	SFA 22:0 (behinic acid) (g)	SFA22_0	N		
MUFA141	MUFA 14:1 (myristoleic acid) (g)	MUFA14_1	N		
MUFA161	MUFA 16:1 (palmitoleic acid) (g)	MUFA16_1	N		
MUFA181	MUFA 18:1 (oleic acid) (g)	MUFA18_1	N		
MUFA201	MUFA 20:1 (gadoleic acid) (g)	MUFA20_1	N		
MUFA221	MUFA 22:1 (erucic acid) (g)	MUFA22_1	N		
PUFA182	PUFA 18:2 (linoleic acid) (g)	PUFA18_2	N		
PUFA183	PUFA 18:3 (linolenic acid) (g)	PUFA18_3	N		
PUFA184	PUFA 18:4 (parinaric acid) (g)	PUFA18_4	N		
PUFA204	PUFA 20:4 (arachidonic acid) (g)	PUFA20_4	N		
PUFA205	PUFA 20:5 (eicosapentaeonic acid (g)	PUFA20_5	N		
PUFA225	PUFA 22:5 (docosapentaenoic acid (g)	PUFA22_5	N		
PUFA226	PUFA 22:6 (docosahexaenoic acid (g)	PUFFA22_	N		

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
TRP	Tryptophan (g)	TRP	N		
THR	Threonine (g)	THR	N		
ILE	Isoleucine (g)	ILE	N		
LEU	Leucine (g)	LEU	N		
LYS	Lysine (g)	LYS	N		
MET	Methionine (g)	MET	N		
CYS	Cystine (g)	CYS	N		
PHE	Phenylalanine (g)	PHE	N		
TYR	Tyrosine (g)	TYR	N		
VAL	Valine (g)	VAL	N		
ARG	Arginine (g)	ARG	N		
HIS	Histidine (g)	HIS	N		
ALA	Alanine (g)	ALA	N		
ASP	Aspartic Acid (g)	ASP	N		
GLU	Glutamic Acid (g)	GLU	N		
GLY	Glycine (g)	GLY	N		
PRO	Proline (g)	PRO	N		
SER	Serine (g)	SER	N		
ASPTME	Aspartame (mg)	ASPTME	N		
SACCHAR	Saccharin (mg)	SACCHAR	N		
CAFF	Caffeine (mg)	CAFF	N		
PHYTAC	Phytic Acid (mg)	PHYTAC	N		

Variable name	**LABEL**	**Source variables**	**C/ N?**	**Definition**	**Accepted values/ Format**
OXALAC	Oxalic Acid (mg)	OXALAC	N		
THRMH	3-Methylhistidine (mg)	THRMH	N		
SUCPOLY	Sucrose Polyester (g)	SUCPOLY	N		
ASH	Ash (g)	ASH	N		
WATER	Water (g)	WATER	N		
PCALFAT	Mean % calories from fat	PCALFAT	N	Note: these variables are the average of the daily %calories for each macronutrient, over the VISIT. We do not use these in the analyses. Instead, we recalculate overall % calories for each macronutrient in PCTFATC, PCTCARBC, PCTPROTC and PCTALCC, by dividing the total caloric intake of each macronutrient during the week by the total overall caloric intake.	
PCALCARB	Mean % calories from carbohydrate	PCALCARB	N		
PCALPROT	Mean % calories from protein	PCALPROT	N		
PCALC	Mean % calories from alcohol	PCALC	N		
PCALSFA	% calories from SFA	PCALSFA	N		
PCALMUFA	% calories from MUFA	PCALMUFA	N		
PCALPUFA	% calories from PUFA	PCALPUFA	N		
POLSATR	Polyunsaturated to Saturated Fat Ratio	POLSATR	N		
CHOLSATR	Cholesterol to Saturated Fatty Acid Ind	CHOLSATR	N		
TVITAAC	Tot. Vit. A Act. (Retinol Eq.) (mcg)	TVITAAC	N		
TRAN181	TRANS 18:1 trans-octadecenoic acid (g)	TRAN18_1	N		
TRAN182	TRANS 18:2 trans-octadecadienoic ac. (g)	TRAN18_2	N		
TRAN161	(trans-hexadecenoic acid (g)	TRAN16_1	N		
TTRAN	Total Trans-Fatty Acids (TRANS) (g)	TTRAN	N		
BETAC	Beta-Carotene (mcg)	BETAC	N		

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
ALPHAC	Alpha-Carotene (mcg)	ALPHAC	N		
BCRYTOX	Beta-Cryptoxanthin (mcg)	BCRYTOX	N		
LUTZEA	Lutein + Zeaxanthin (mcg)	LUTZEA	N		
LYCOP	Lycopene (mcg)	LYCOP	N		
DFE	Dietary Folate Equivalents (mcg)	DFE	N		
NFE	Natural Folate (food folate) (mcg)	NFE	N		
SF	Synthetic Folate (folic acid) (mcg)	SF	N		
TVITAREQ	Total Vitamin A Activity (Retinol Activi Tot. Vit. A Act. (Retinol Act. Eq) (mcg)	TVITAREQ	N		
KJ	Energy (kj)	KJ	N		
NIAEQ	Niacin Equivalents (mg)	NIAEQ	N		
TSUGARS	Total Sugars (g)	TSUGARS	N		
O3FA	Omega-3 Fatty Acids (g)	O3FA	N		
MN	Manganese (mg)	MN	N		
VEIU	Vitamine E (international Units) (IU)	VEIU	N		
NATATOCO	Natural Alpha-Tocopherol (mg)	NATATOCO	N		
SYNATOCO	Synthetic Alpha-Tocopherol (mg)	SYNATOCO	N		
DAIDZEIN	Daidzein (mg)	DAIDZEIN	N		
GENISTEI	Genistein (mg)	GENISTEI	N		
GLYCIT	Glycitein (mg)	GLYCIT	N		
COUMESTR	Coumestrol (mg)	COUMESTR	N		

Variable name	**LABEL**	**Source variables**	**C/ N?**	**Definition**	**Accepted values/ Format**
BIOCHA	Biochanin A (mg)	BIOCHA	N		
FORMO	Formononetin (mg)	FORMO	N		
ASUGARS	Added Sugars (g)	ASUGARS	N		
ACEK	Acesulfame Pottassium (mg)	ACEK	N		
SUCRALOS	Sucralose (mg)	SUCRALOS	N		
AVLCARB	Available Carbohydrate (g)	ACARB	N		
GLYIGLU	Glycemic Index (glucose reference)	GLYIGLU	N		
GLYIBRE	Glycemic Index (bread reference)	GLYIBRE	N		
GLYLGLU	Glycemic Load (glucose reference)	GLYLGLU	N		
GLYLBRE	Glycemic Load (bread reference)	GLYLBRE	N		
CHOLINE	Choline (mg)	CHOLINE	N		
BETAINE	Betaine (mg)	BETAINE	N		
ERYTHRTL	Erythritol (g)	ERYTHRTL	N		
INOSITOL	Inositol (g)	INOSITOL	N		
ISOMALT	Isomalt (g)	ISOMALT	N		
LACTITOL	Lactitol (g)	LACTITOL	N		
MALTITOL	Maltitol (g)	MALTITOL	N		
MANNITOL	Mannitol (g)	MANNITOL	N		
PINITOL	Pinitol (g)	PINITOL	N		
SORBITOL	Sorbitol (g)	SORBITOL	N		
XYLITOL	Xylitol (g)	XYLITOL	N		
NITROGEN	Nitrogen (g)	NITROGEN	N		

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
TOTCLA	Total (CLA 18:2) (g)	TOTCLA	N		
CLACIS9	CLA cis-9, trans-11 (g)	CLACIS9	N		
CLATR10	CLA trans-10, cis-12 (g)	CLATR10	N		
TAGATOSE	Tagatose (mg)	TAGATOSE	N		
FATCAL	Fat calories (kcal/day)	FATCAL	N		
PROTCAL	Protein calories (kcal/day)	PROTCAL	N		
CARBCAL	Carbohydrate calories (kcal/day)	CARBCAL	N		
ALCCAL	Alcohol calories (kcal/day)	ALCCAL	N		
				The following set of variables (TKCAL –TALCCAL), take the Sum of the variable over all records with that DEIDNUM / VISIT	
TKCAL	Total calories for the week	KCAL	N	Sum of KCAL for that DEIDNUM/VISIT	
TFATCAL	Total fat calories for the week	FATCAL	N	Sum of FATCAL for that DEIDNUM/VISIT	
TPROTCAL	Total protein calories for the week	PROTCAL	N	Sum of PROTCAL for that DEIDNUM/VISIT	
TCARBCAL	Total carb. Calories for the week	CARBCAL	N	Sum of CARBCAL for that DEIDNUM/VISIT	
TALCCAL	Total alcohol calories for the week	ALCCAL	N	Sum of ALCCAL for that DEIDNUM/VISIT	
				Overall %calories from fat, protein, carbs and alcohol are calculated by dividing the total caloric intake of each macronutrient during the week by the total overall caloric intake. Use these instead of PCALFAT, PCALPROT, PCALCARB, PCALC.	
PCTFATC	Self-Reported % calories from fat	TFATCAL, TKCAL	N	= 100 x TFATCAL / TKCAL	
PCTPROTC	Self-reported % calories from protein	TPROTCAL, TKCAL	N	= 100 x TPROTCAL / TKCAL	
PCTCARBC	Self-reported % calories from carbs	TCARBCAL, TKCAL	N	= 100 x TCARBCAL / TKCAL	

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
PCTALCC	Self-reported % calories from alcohol	TALCCAL, TKCAL	N	= 100 x TALCCAL / TKCAL	

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	4, 5, 11 and 13 for all subjects, 9 and 12 for CR subjects (See Appendix for 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	0=not done 1=done

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				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.	
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]
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		

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
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)	

Trial name	**CALERIE 2**
Dataset name	**TEERQ (TEE from DLW with individual RQ)**
Description	DLW data (used to measure TDEE), flattened to 1 record per DEIDNUM / VISIT. TEE is recalculated using individual RQ, which is calculated using self-reported macronutrient intake and changes in daily and clinic weights during the DLW period. (See Adherence data handling rules document for details of derivation of RQ and TEE). DLW results are merged with CRF data, so there are records for each visit that was attended at which DLW was expected, even if there are no DLW results; however, baseline records for non-randomized subjects with no DLW results are excluded from this dataset.
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	4, 5, 11 and 13 for all subjects, 9 and 12 for CR subjects VISIT 0 combines the two baseline Visits into a single baseline mean, (See Appendix for VISIT codes)
Usage notes	Use TEERQ (which is based on individual RQ) for analyses of TEE. If separate records are needed for each of the two baseline periods, use VISITs 4 and 5. If only one overall baseline mean record is needed, use VISIT 0.
Source data files	ANALDATA /DLWLONG, SUBJECT1, DXAA, FOODWEEK, CLWTLONG, HOMEWT
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	PAGENUM	N		
VISIT	Visit	VISIT	N	Study Visit, based on CRF pages (See Appendix 1)	VISFMT
SUBVISIT	Sub-Visit	SUBVISIT	N	Study Sub-Visit, based on CRF pages (See Appendix 1)	SVISFMT
DLWMIXWT	DLW mix weight (CRF) (g)	DLWLONG.DLWMIXWT	N		
DLWDSEDT	DLW dose date (CRF)	DLWLONG.DLWDSEDT	DT		DT
DLWDSETM	DLW dose date/time (CRF)	DLWLONG.DLWDSETM	DTM		DTM
CRFDLW	DLW dose taken (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	0=DLW not done 1=DLW dose taken

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
				at baseline who took the dose, but did not complete the 14 day DLW sample set, and therefore do not have results. See DLWCMPLT.	
DLWNDRSN	Reason DLW not done	DLWLONG.DLWNDRSN	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
PDADTM	Date/time of PDa sample	DLWLONG.DLWCOLDTM DLWLONG.DLWSMPNO	DTM	=DLWCOLDTM from DLWSMPNO=1	
PDBDTM	Date/time of PDb sample		DTM	=DLWCOLDTM from DLWSMPNO=2	
D0ADTM	Date/time of D0a sample		DTM	=DLWCOLDTM from DLWSMPNO=3	
D0BDTM	Date/time of D0b sample		DTM	=DLWCOLDTM from DLWSMPNO=4	
D7ADTM	Date/time of D7a sample		DTM	=DLWCOLDTM from DLWSMPNO=5	
D7BDTM	Date/time of D7b sample		DTM	=DLWCOLDTM from DLWSMPNO=6	
D14ADTM	Date/time of D14a sample		DTM	=DLWCOLDTM from DLWSMPNO=7	
D14BDTM	Date/time of D14b sample		DTM	=DLWCOLDTM from DLWSMPNO=8	
DLWENDDT	DLW end date	D14ADTM	DT	= datepart of D14ADT	
DLWMDT	DLW midpoint date	DLWDSEDT, DLWENDDT	DT	=mean of DLWDSEDT and DLWENDDT	
DLWDUR	Duration of DLW period (days)	DLWDSEDT, DLWENDDT	N	=days from DLWDSETM to D14BDTM	
DLWCMPLT	DLW completed (CRF)	DLWDSEDT, D14ADTM, D14BDTM	N	Completed means dose was given, and a 14 day sample was collected. =1 if DLWDSEDT and at least one of (D14ADTM, D14BDTM) are non-missing else =0 if CRFDLW is non-missing else missing	0=DLW not complete 1=DLW complete
LABDLW	DLW lab data received	DLWLONG.LABDLW	N		0=DLW lab data not received 1=DLW lab data

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format received
ISODILNH	Isotope dilution spaces NH	DLWLONG.ISODILNH	N		
ISODILNO	Isotope dilution spaces NO	DLWLONG.ISODILNO	N		
NHNO	NH/NO ratio	ISODILNH, ISODILNO	N	=ISODILNH / ISODILNO	
PTBWH	% Total Body Water H	DLWLONG.PTBWH	N		
PTBWO	% Total Body water O	DLWLONG.PTBWO	N		
KHTURNO	KH Fractional Turnover rate	DLWLONG.KHTURNO	N		
KOTURNO	KO Fractional Turnover rate	DLWLONG.KOTURNO	N		
KOKH	KO/KH ratio	KHTURNO, KOTURNO	N	= KOTURNO / KHTURNO	
CXRH	Correlation fractional turnover rate H	DLWLONG.CXRH	N		
CXRO	Correlation fractional turnover rate O	DLWLONG.CXRO	N		
RCO2P	Carbon Dioxide Production rate	DLWLONG.RCO2P	N		
	The following set of variables from AGEVIS – DBPROT are used to derive FQ and RQ using the algorithm described in the Adherence MOP.				
AGEVIS	Age at visit (years)	SUBJECT1.DOBDT, DLWDSEDT	N	= Years from DOBDT to DLWDSEDT	
FEMALE	Female	SUBJECT1.GENDER	N	=0 if GENDER=1 =1 if GENDER=2	
CLINWTB	Clinic weight closest to DXA date	DXAA.CLINWTB	N		
FM	Fat mass (clinic weight x %BF)	DXAA.FM	N		
FFM	FFM (clinic weight –FM)	DXAA.FFM	N		
INRANGE	DXA is within 15 days of DLW	DXAA.INRANGE	N	According to the Adherence MOP, only DXA measurements that are within 15 days of the DLW can be used for calculating RQ. FMA and FFMA are missing if INRANGE<1.	
FMA	Fat mass (Adherence rules)	DXAA.FMA	N		
FFMA	FFM (adherence rules)	DXAA.FFMA	N		
	The total self-reported caloric intake from the food diary was considered unreliable, so we derived a provisional				

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
	predicted energy intake for each subject at each visit, using a prediction equation derived from baseline data (modeling TEE on age, sex, FM and FFM). This is used to create AFAT – AALC below.				
EIPRED	Predicted EI	AGEVIS, FEMALE, FM, FFM, EIMODEL.INTERCEPT, B_AGE, B_FEMALE, B_FM, B_FFM	N	= 539.808 + (4.24511 x AGEVIS) + (66.7494 x FEMALE) + (-4.77314 x FM) + (36.8911 x FFM)	
NNDSDAYS	Number of food diary days	FOODWEEK.NNDSDAYS	N	Number of food diary days for that DEIDNUM / VISIT	
KCAL	Self Reported Energy Intake (kcal/d)	FOODWEEK.KCAL	N		
TFAT	Self-Reported Fat intake (g/d)	FOODWEEK.TFAT	N		
TCARB	Self-Reported Carbohydrate intake (g/d)	FOODWEEK.TCARB	N		
TPROT	Self-Reported Protein intake (g/d)	FOODWEEK.TPROT	N		
ALCOHOL	Self-Reported Alcohol intake (g/day)	FOODWEEK.ALCOHOL	N		
	The total grams of fat, protein, carbs and alcohol reported in the food diary were considered unreliable, but the relative proportions of fat, protein, carbs and alcohol were considered reliable. Therefore, according to the Adherence MOP, we recalculated adjusted values of the daily intakes of each macronutrient, based on the predicted total daily caloric intake, rather than the reported daily intake.				
AFAT	Adjusted daily fat intake (g/day)	TFAT, KCAL, EIPRED	N	= TFAT x (EIPRED / KCAL)	
ACARB	Adjusted daily carb. intake (g/day)	TCARB, KCAL, EIPRED	N	= TCARB x (EIPRED / KCAL)	
APROT	Adjusted daily protein intake (g/day)	TPROT, KCAL, EIPRED	N	= TPROT x (EIPRED / KCAL)	
AALC	Adjusted daily alcohol intake (g/day)	ALCOHOL, KCAL, EIPRED	N	= ALCOHOL x (EIPRED / KCAL)	
DHWTG	g/d weight loss (daily weights)	HOMEWT.HWTKG	N	For each subject and visit, linear regression was done on all daily weights (HOMEWT.HWTKG) during the DLW period and within 7 days before the start or after the end of the DLW period to obtain the daily rate of weight change from daily weights. DHWTG is the slope from this regression.	
NHWT	# of home weights in regression	HOMEWT.HWTKG	N		

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
DCWTG	g/d weight loss (clinic weights)	CLWTLONG.CLINWT	N	For each subject and visit, linear regression was done on all clinic weights (CLWTLONG.CLINWT) during the DLW period and within 7 days before the start or after the end of the DLW period to obtain the daily rate of weight change from clinic weights. DCWTG is the slope from this regression.	
NCWT	# of clinic weights in regression	CLWTLONG.CLINWT	N		
DWTG	Delta body weight (g/day)	DHWTG, DCWTG	N	The mean of the two slopes is used to derive the daily rate of weight change. = mean of DHWTG and DCWTG	
DBFAT	Delta body fat (g/day)	DWTG	N	Daily rate of change in body fat, assuming 74% of weight loss is fat =DWTG x 0.74	
DBPROT	Delta body protein (g/day)	DWTG	N	Daily rate of change in body protein, assuming 26% of weight loss is FFM, and 21% of that is protein. =DWTG x 0.26 x 0.21	
FQ	FQ (food quotient)	AFAT, ACARB, APROT, AALC,	N	={ (AFAT x 1.427) + (ACARB x 0.829) + (APROT x 0.774) + (AALC x 0.972) } / { (AFAT x 2.019) + (ACARB x 0.829) + (APROT x 0.966) + (AALC x 1.459) }	
RQUNADJ	Unadjusted Respiratory Quotient	AFAT, ACARB, APROT, AALC, DBFAT, DBPROT	N	={ [(AFAT – DBFAT) x 1.427] + (ACARB x 0.829) + [(APROT – DBPROT) x 0.774] + (AALC x 0.972) } / { [(AFAT – DBFAT) x 2.019] + (ACARB x 0.829) + [(APROT – DBPROT) x 0.966] + (AALC x 1.459) }	
RQ	Adjusted Respiratory Quotient	RQUNADJ, VISIT, TX	N	Subject Specific Respiratory Quotient, imputed from the closest visit if missing (this is the RQ value used to calculate TEERQ)	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
				If RQUNADJ is nonmissing, = RQUNADJ Else if RQUNADJ is missing and RCO2P is non-missing: If VISIT=4, use RQUNADJ from VISIT=5 if it exists If VISIT=5, use RQUNADJ from VISIT=4 if it exists If VISIT > 5 : If TX='A' and : VISIT=9: use RQUNADJ from VISIT 11 if it exists Else use RQUNADJ from VISIT 12 if it exists VISIT=11: use the mean* of RQUNADJ from VISITS 9 and 12 If at least one of them exists. Else use RQUNADJ from VISIT 13 if it exists VISIT=12: use the mean* of RQUNADJ from VISITS 11 and 13 If at least one of them exists. Else use RQUNADJ from VISIT 9 VISIT=13: use RQUNADJ from VISIT 12 if it exists, Else use RQUNADJ from VISIT 11 Else If TX='B' and: VISIT=11: use RQUNADJ from VISIT 13 if it exists, Else use the mean* RQUNADJ from VISITS 4 and 5	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
				VISIT=13: use RQUNADJ from VISIT 11 if it exists, Else use the mean* RQUNADJ from VISITS 4 and 5 *If any of the components are missing, take the mean of the non-missing components.	
TEERQ	TEE (using individual RQ)	RCO2P, RQ	N	Use this variable for TEE. = 22.4 x RCO2P x [1.2321 + (3.815 / RQ)] 5 baseline values were hardcoded because there were problems with the DLW values. (By decision of the QC committee, 5 baseline values were hardcoded)	
TEE86	TEE (using RQ=0.86)	RCO2P	N	TEE based on RCO2P and RQ = 0.86 (Note: this is not the value used in most analyses. We use TEERQ instead, which is based on individual RQ) = 22.4 x RCO2P x [1.2321 + (3.815 / 0.86)] (By decision of the QC committee, 5 baseline values were hardcoded)	
FFMHYDR	Hydration of FFM	ISODILNO, DXAA.FFM	N	=ISODILNO / FFM	
FFMO18	FFM from O18 Dilution space	ISODILNO	N	=ISODILNO / 0.73	

Trial name	**CALERIE 2**
Dataset name	**PCTCR (Long term %CR adherence by interval)**
Description	This dataset applies the Adherence MOP to calculate long term Adherence (%CR with respect to baseline energy intake) during each interval from Baseline to each follow-up visit and between consecutive and non-consecutive follow-up visits. This calculation involves TEE at each visit and changes in FM and FFM between visits.
Comments on data structure	1 record / DEIDNUM / INTERVAL
Population	All randomized subjects who had at least one follow-up visit
Source data files	ANALDATA/SUBJECT1, IVRSRAND, TEERQ, DXAA
Final sort order	DEIDNUM INTERVAL

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
DEIDNUM	Subject Number	DEIDNUM	C		
INTERVAL	Interval	INTERVAL	N	Each record represents an interval between two visits.	1='BL – M6' 2='BL – M12' 3='BL – M18' 4='BL – M24' 5='M6 – M12' 6='M6 – M18' 7='M6 – M24' 8='M12 – M18 9='M12 – M24' 10='M18 – M24'
TEEBL	TEE at Baseline (kcal/day)	TEERQ.TEERQ	N	=TEERQ from the record with VISIT=0 (TEE based on individual RQ)	
MEANEE	Mean TEE during interval (Kcal/day)	TEERQ,TEERQ	N	The Mean TEE for an interval is the weighted average of TEERQ at the start and end of the interval, and all visits in between. Baseline to Month 6 (CR arm only): TEE_{BL-M6} = (Baseline TEERQ + (5 x M6 TEERQ)) / 6 M6 – M12 (CR arm only): TEE_{M6-M12} = (M6 TEERQ + M12 TEERQ) / 2 Baseline to M12 (CR arm):	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
				TEE_{BL-M12} = ((TEE_{BL-M6} x days from BL to M6) + (TEE_{M6-M12} x days from M6 to M12)) / days from BL to M12. Baseline to M12 (AL arm): TEE_{BL-M12} = mean of BL TEERQ and M12 TEERQ Etc, See Adherence MOP for full details.	
				The next 4 variables use FMA and FFMA, which are FM and FFM from DXA, only if within 15 days of the DLW period.	
STARTFM	FM at start of interval (kg)	DXAA.FMA	N	=FMA from the visit at the start of the interval	
ENDFM	FM at end of interval (kg)	DXAA.FMA	N	=FMA from the visit at the end of the interval	
STARTFFM	FFM at start of interval (kg)	DXAA.FFMA	N	=FFMA from the visit at the start of the interval	
ENDFFM	FFM at end of interval (kg)	DXAA.FFMA	N	=FFMA from the visit at the end of the interval	
STARTDT	Date at start of interval	DXAA.BSCANDT	DT	=BSCANDT from the visit at the start of the interval	
ENDDT	Date at end of interval	DXAA.BSCANDT	DT	=BSCANDT from the visit at the end of the interval	
DELTAFM	Change in FM over interval (kg)	STARTFM, ENDFM	N	= ENDFM – STARTFM.	
DELTAFFM	Change in FFM over interval (kg)	STARTFFM, ENDFFM	N	= ENDFFM – STARTFFM	
DELTAWT	Change in weight over interval (kg)	DELTAFM, DELTAFFM	N	= DELTAFM + DELTAFFM	
DURATION	Duration of interval (days)	STARTDT, ENDDT	N	= ENDDT – STARTDT	
TOTDES	Total change in energy stores (kcal)	DELTAFM, DELTAFFM	N	Assuming 9300 kcal/kg of FM and 1100 kcal/kg of FFM. = (DELTAFM x 9300) + (DELTAFFM x 1100)	
DES	Daily change in energy stores (kcal/day)	TOTDES, DURATION	N	= TOTDES / DURATION If both TOTDES and DURATION both exist, and DURATION>0.	
EI	Energy Intake during interval (kcal/day)	MEANEE, DES	N	= MEANEE + DES If both MEANEE and DES exist. Else missing.	
PCTCR	% CR during interval (vs. Baseline)	EI, TEEBL	N	= 100 x (TEEBL – EI) / TEEBL If both TEEBL and EI exist. Else missing.	
ECWTCHG	Energy content of wgt, change (kcal/kg)	TOTDES, DELTAWT	N	Assuming 9300 kcal/kg of FM and 1100 kcal/kg of FFM. = TOTDES / DELTAWT	

Trial name	**CALERIE 2**
Dataset name	**PCTCRVIS(Long term %CR by visit)**
Description	This dataset takes long term adherence data from PCTCR (which has 1 record per DEIDNUM / INTERVAL), and converts it to 1 record per DEIDNUM / VISIT such that the %CR for each visit is the %CR during the most recent 6 month interval for CR subjects, or most recent 12 month interval for AL subjects. For AL subjects at month 6, we use the %CR from BL-M12, and at month 18 we use the %CR from M12 to M24.
Comments on data structure	1 record / DEIDNUM / VISIT
Population	All subjects who had at least one follow-up visit
Visits	11 and 13 for subjects in both arms, 9, 12 for CR subjects only
Source data files	ANALDATA/PCTCR
Final sort order	DEIDNUM VISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit		N	CR subjects have records with VISIT = 9, 11, 12, 13 AL subjects have records with VISIT= 11, 13	
				All variables pertain to the interval since the last visit to the current visit. If TX='A' (CR): if VISIT=9 (M6), use data from INTERVAL=1 (BL-M6) if VISIT=11 (M12), use data from INTERVAL=5 (M6-M12) If VISIT=12 (M18), use data from INTERVAL=8 (M12 – M18) If VISIT=13 (M24), use data from INTERVAL=10 (M18-M24) If TX='B' (AL): If VISIT= 9 (M6) or 11 (M12), use data from INTERVAL=2 (BL-M12) If VISIT= 12 (M18) or 13 (M24), use data from INTERVAL=9 (M12–M24)	
MEANEEV	Mean TEE since last visit (kcal/day)	MEANEE	N		
DESV	Delta energy stores (kcal/d)	DES	N		
EIV	Daily EI (kcal/day)	EI	N		
PCTCRV	% CR since last visit	PCTCR	N		
ECWTCHGV	Energy content weight change (kcal/kg)	ECWTCHG	N	Assuming 9300 kcal/kg of FM and 1100 kcal/kg of FFM	

Trial name	**CALERIE 2**
Dataset name	**PCTCRST (Short Term %CR during DLW Period)**
Description	This dataset calculates Total Energy Intake (TEI) and short term %CR during each 2 week DLW period at each visit, using TEE from DLW, the daily change in weight (from regression of daily and clinic weights), and the treatment and visit specific energy content of weight change (median) to calculate daily change in energy stores.
Comments on data structure	1 record / DEIDNUM / VISIT
Population	All randomized subject
Visits	0, 11, 13 for all subjects, 9 , 12 for CR subjects
Source data files	ANALDATA/ IVRSRAND, TEERQ, PCTCRVIS
Final sort order	DEIDNUM VISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	TEERQ.VISIT	N		
MECWTCHG	Energy content weight change (kcal/kg)	PCTCRVIS.ECWTCHGV	N	Median energy content of weight change by treatment arm and interval. For VISITs 9, 11, 12 and 13: = median calculated energy content of weight change from the most recent 6 (CR arm) or 12 (AL arm) month interval, among all subjects in that treatment arm for that interval. For VISIT 0: =Median ECWTCHG from BL-M12 (VISIT 11) among all AL subjects.	
TEERQ	TEE (using individual RQ)	TEERQ.TEERQ	N		
DWTG	Short term change in body weight (g/day)	TEERQ.DWTG	N	Daily change in body weight (g/day) during DLW period For each DEIDNUM / VISIT, mean of the slopes from separate linear regressions of daily weights and clinic weights during the DLW period (+/- 7 days).	
TEEBL	Baseline TEE (kcal/day)	TEERQ.TEERQ	N	=TEERQ from VISIT=0	
DESST	Short term Delta energy	DWTG, MECWTCHG	N	Daily change in body energy stores during DLW period	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
	stores (kcal/d)			(kcal/day) Using daily change in body weight, multiplied by energy content of weight change. =DWTG x MECWTCHG / 1000	
TEIST	Short term daily EI (kcal/d)	TEERQ, DESST	N	Daily Energy Intake during DLW period (kcal/day) = TEERQ + DESST	
PCTCRST	Short term %CR during DLW period	TEIST, TEEBL	N	= 100 x (TEEBL – TEIST) / TEEBL	

Trial name	**CALERIE 2**
Dataset name	**PARVISIT (7 Day Physical Activity Recall, by VISIT)**
Description	There are two 7 day PAR recalls recorded in the CRF for every 2 week DLW period. For each day in the recall period, the minutes of activity at moderate, hard and very hard intensity in the morning, afternoon and evening, as well as the time the subject went to sleep and woke up, are recorded. The PARVISIT dataset converts raw 7 day PAR data from the CRF, which has 1 record per day, to 1 record per VISIT, with the average minutes/day and kcal/day spent in moderate, hard or very hard activity, and overall time and energy spent in physical activity. MET-hrs per day at each activity level are calculated using the PAR MOP, and then multiplied by the RMR at that VISIT to derive energy expenditure at each activity level, and total daily energy expenditure.
Comments on data structure	1 record DEIDNUM / VISIT The raw PAR data is first flattened from 1 record per DEIDNUM / day to 1 record per DEIDNUM / SUBVISIT (where each SUBVISIT corresponds to 1 week), by taking the mean of each variable over all days in the week. Then this intermediate dataset is flattened to 1 record per DEIDNUM / VISIT by taking the mean of each averaged variable over all SUBVISITs in the VISIT. (Each VISIT (except VISIT0) consists of two Weeks). This is done because a week is the main unit of observation for 7 day PAR recalls.
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
VISITs	4, 5, 11 and 13 for all subjects, 9 and 12 for CR subjects VISIT 0 combines the two baseline Visits into a single baseline mean, (See Appendix for VISIT codes)
Usage notes	If separate records are needed for each of the two baseline periods, use VISITs 4 and 5. If only one overall baseline mean record is needed, use VISIT 0.
Source data files	CRF/PARHDR, PARCHT, PARQ, ANALDATA/RMRA
Final sort order	DEIDNUM VISIT

Notes on data derivation at the day level: The raw CRF data has minutes of activity at moderate, hard and very hard intensity in the morning, afternoon and evening, as well as the time the subject went to sleep and woke up, for each day. Using the PAR MOP and data handling rules, if < 10 minutes are reported in any category, they are reset to 0. All remaining activity values are rounded to the closest 15 minutes. These values are then summed up, to obtain the total minutes and hours of moderate, hard and very hard activity, and sleep for each day. Light activity hours are calculated as 24 – sum of total sleep, moderate, hard, and very hard activity hours.

Several subjects had missing data for sleep times. After querying, many of them were confirmed as not having slept at all on those days. Since that could not be reported on the CRF, these subjects had total sleep hours hardcoded to 0. Applying the data handing rules, for subjects whose missing sleep times could not be confirmed, as long as they had any work or activity times recorded for that day, sleep hours were calculated as 24 – total of all reported hours. Days with nothing recorded at all were excluded.

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	VISIT	N	Study Visit, based on CRF page (See Appendix 1)	VISFMT
PARDT	Date of 1ST PAR recall	PARHDR.PARDT	DT	= smallest non-missing PARDT for that DEIDNUM / VISIT	
CRFPAR	PAR collected	PARHDR.PARDT	N	= 1 if PARDT is non-missing for at least one day during that VISIT.	
PARNDRSN	Reason PAR not collected	PARHDR.PARND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required If more than one 7 day PAR during the VISIT has a reason, use the smallest value	TUND
MOREACT	More active than usual	PARQ.LSTWK	N	=1 if LSTWK=1 for any records for that DEIDNUM/VISIT	
LESSACT	Less active than usual	PARQ.LSTWK	N	=1 if LSTWK=2 for any records for that DEIDNUM/VISIT	
PARPROB	Any problems with PAR?	PARQ.PARPROB	N	=largest PARPROB for that DEIDNUM / VISIT	
NOTVLD	PAR not valid	PARQ.PARVLD	N	=1 if PARVLD=0 for any records for that DEIDNUM/ VISIT. Else missing.	
NDAYS	Number of days in PAR recall		N	= total number of days with PAR data for that DEIDNUM/VISIT	
MMODHRS	Mean moderate activity hours per day	MORMOD, AFTRMOD, EVEMOD	N	For MMODHRS – MVHRDHRS: first we take the sum of the source variables within each day (min/day), then divide by 60 to get hrs/day. Next, the daily value is averaged over all days in that week. Finally, the weekly average is averaged over all weeks in the VISIT. Also, see notes on data derivation at the day level (above this table) for additional information on rounding, etc.	
MHARDHRS	Mean hard activity hours per day	MORHARD, AFTRHARD, EVEHARD	N		
MVHRDHRS	Mean very hard activity hours per day	MORVHRD, AFTRVHRD, EVEVHRD	N		

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
MSLPHRS	Mean sleep hours per day	TOTSLEEP	N	TOTSLEEP for each day is derived from in bed time and get up time. This is averaged over all days in the week, and this average is averaged over all weeks in the VISIT. Also, see notes on data derivation at the day level (above this table) for additional information on missing sleep data.	
MLGTHRS	Mean light hours per day	MSLPHRS, MMODHRS, MHARDHRS, MVHRDHRS	N	=24 – sum (MSLPHRS, MMODHRS, MHARDHRS, MVHRDHRS)	
PARACTHR	Mean activity hours per day	MMODHRS, MHARDHRS, MVHRDHRS	N	Mean hours per day of moderate, hard or very hard intensity activity = sum of MMODHRS, MHARDHRS, MVHRDHRS	
PAREXHRS	Mean exercise hours per day	MHARDHRS, MVHRDHRS	N	Mean hours per day of hard or very hard intensity activity. = sum of MHARDHRS, MVHRDHRS	
MSLPMIN	Mean sleep minutes per day	MSLPHRS	N	= source variable x 60	
MLGTMIN	Mean light minutes per day	MLGTHRS	N		
MMODMIN	Mean moderate minutes per day	MMODHRS	N		
MHARDMIN	Mean hard minutes per day	MHARDHRS	N		
MVHRDMIN	Mean very hard minutes per day	MVHRDHRS	N		
PARACTMN	Mean activity minutes per day	MMODMIN, MHARDMIN, MVHRDMIN	N	Mean minutes per day of moderate, hard or very hard intensity activity. =sum of MMODMIN, MHARDMIN, MVHRDMIN	
PAREXMIN	Mean exercise minutes per day	MHARDMIN, MVHRDMIN	N	Mean minutes per day of hard or very hard intensity activity. =sum of MHARDMIN, MVHRDMIN	
				MET-hrs are calculated using instructions in the PAR MOP	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
SLPMETS	Mean sleep MET-hrs per day	MSLPHRS	N	=MSLPHRS	
LGTMETS	Mean light MET-hrs per day	MLGTHRS	N	=MLGTHRS x 1.5	
MODMETS	Mean moderate MET-hrs per day	MMODHRS	N	=MMODHRS x 4	
HARDMETS	Mean hard MET-hrs per day	MHARDHRS	N	=MHARDHRS x 6	
VHRDMETS	Mean very hard MET-hrs per day	MVHRDHRS	N	=MVHRDHRS x 10	
TOTMETS	Mean total MET-hrs per day	SLPMETS, LGTMETS, MODMETS, HARDMETS, VHRDMETS	N	=sum of SLPMETS, LGTMETS, MODMETS, HARDMETS, VHRDMETS	
				Energy expenditure for each activity level is calculated by multiplying METS by RMR (from the same VISIT)	
SLEEPCAL	Mean sleep kcal/day	SLPMETS, RMRA.RMR	N	=SLPMETS x RMR/24	
LIGHTCAL	Mean light kcal/d	LGTMETS, RMRA,RMR	N	=LGTMETS x RMR/24	
MODCAL	Mean moderate kcal/day	MODMETS, RMRA.RMR	N	=MODMETS x RMR/24	
HARDCAL	Mean hard kcal/day	HARDMETS, RMRA.RMR	N	=HARDMETS x RMR/24	
VHARDCAL	Mean very hard kcal/day	VHRDMETS RMRA.RMR	N	=VHRDMETS x RMR/24	
PARCAL1	PAR activity kcal/day (light – very hard)	LIGHTCAL, MODCAL, HARDCAL, VHARDCAL	N	=sum of LIGHTCAL, MODCAL, HARDCAL, VHARDCAL	
PARCAL2	PAR activity kcal/day (mod – very hard)	MODCAL, HARDCAL, VHARDCAL	N	=sum of MODCAL, HARDCAL, VHARDCAL	
PAREXCAL	PAR exercise kcal/day (hard, very hard)	HARDCAL, VHARDCAL	N	=sum of HARDCAL, VHARDCAL	
PARTDEE	Mean daily energy expenditure from PAR	TOTMETS, RMRA.RMR	N	=TOTMETS x RMR/24	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
	The following variables, WESLPHRS – WDTDEE are derived similarly to the above variables, but only among weekend (or weekday) days.				
WESLPHRS	Weekend sleep hours per day	WESLPHRS	N	See note above	
WELGTMIN	Weekend light minutes per day	WELGTMIN	N		
WEMODMIN	Weekend moderate minutes per day	WEMODMIN	N		
WEHRDMIN	Weekend hard minutes per day	WEHRDMIN	N		
WEVHDMIN	Weekend very hard minutes per day	WEVHDMIN	N		
WEACTMIN	Weekend activity minutes per day	WEACTMIN	N		
WEEXMIN	Weekend exercise minutes per day	WEEXMIN	N		
WEMETS	Weekend MET-hrs per day	WEDLYMETS	N		
WETDEE	Weekend TDEE	WETDEE	N		
WDSLPHRS	Weekday sleep hours per day	WDSLPHRS	N	See note above	
WDLGTMIN	Weekday light minutes per day	WDLGTMIN	N		
WDMODMIN	Weekday moderate minutes per day	WDMODMIN	N		
WDHRDMIN	Weekday hard minutes per day	WDHRDMIN	N		
WDVHDMIN	Weekday very hard minutes per day	WDVHDMIN	N		
WDACTMIN	Weekday activity minutes per day	WDACTMIN	N		
WDEXMIN	Weekday exercise minutes per day	WDEXMIN	N		
WDMETS	Weekday MET-hrs per day	WDDLYMETS	N		
WDTDEE	Weekday TDEE	WDTDEE	N		

Trial name	**CALERIE 2**
Dataset name	**RMRA (Resting Metabolic Rate)**
Description	This dataset converts the raw minute-by-minute RMR data to 1 record per RMR test. Each record in the raw data has a flag (EEVENT) indicating whether the record is a usable participant minute, a QC minute, or to be discarded. For each RMR test, there are 2 separate 'runs' of RMR data. The first run has PTQC='PT' and involves about 4 minutes of pre-test CO2 calibration (EEVENT=2), followed by about 30 minutes of participant data (EEVENT=5 for usable data). The second run has PTQC='QC', and has three kinds of calibration tests: approximately 4 minutes of post-test CO2 calibration (EEVENT=2), approximately 4 minutes of CAL gas 1 (EEVENT=3) and approximately 4 minutes of CAL gas 2 (EEVENT=4). Unusable minutes are flagged with EEVENT=1. This dataset flattens all that information into 1 record per test. Raw RMR values are calculated as the mean RMR from all usable participant (non QC) RMR values. Then RMR data handling rules are applied to set RMR values to missing if exclusion criteria are met (< 10 usable participant minutes, RQ <0.65 or >1.05, or RMR < 800 or >4000). RMR results are merged with CRF data, so there is a record for all study visits that were attended at which RMR was expected, even if there are no RMR results. There were some RMR assays that were done that did not have usable results.
Comments on data structure	1 record / DEIDNUM/ VISIT / RMRVISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
VISITs	5, 11 and 13 for all subjects, 9 and 12 for CR subjects There are 2 RMRs at baseline (VISIT 5), denoted by RMRVISIT=1 and 2 VISIT 0 combines the two baseline Visits into a single baseline mean, (See Appendix for VISIT codes)
Usage notes	This dataset has the unadjusted RMR value, incorporating the RMR data handling rules. The primary endpoint, RMR adjusted for age, sex, FM and FFM, is found in the RMRRESID dataset. If separate records are needed for each of the two baseline RMRs, use VISIT 5 (with RMRVISIT=1 and 2). If only one overall baseline mean record is needed, use VISIT 0.
Source data files	CRF/RMR, LABS/RMRLOAD, ANALDATA/SUBJECT1, DLWFLAT
Final sort order	DEIDNUM VISIT RMRVISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
PAGENUM	CRF page number	RMR.PAGEID	N		
VISIT	Visit	PAGENUM, RMRLOAD.RFORM	N	Study Visit, based on CRF page (See Appendix 1) Or RMRLOAD.RFORM (see RMRLOAD specs)	VISFMT
SUBVISIT	Sub-Visit	SUBVISIT	N	Study Sub-Visit, based on CRF page (See Appendix 1)	SVISFMT

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
		RMRLOAD.RFORM		Or RMRLOAD.RFORM	
RMRVISIT	RMR sub-visit	RMR.RMRVISIT RMRLOAD.RFORM	N	1= first RMR at a visit 2=2nd Baseline RMR	[TURMR] 1=RMR1 2=RMR2
RMRDTCRF	RMR date (CRF)	RMR.RMRDT	DT		
RMRDTM	RMR start date/time	RMRLOAD.RMRTM	DTM		Datetime13
CRFRMR	RMR performed (CRF)	RMR.RMRDT	N	=1 if RMRDT is non-missing else =0	
RMRNDRSN	Reason RMR not performed	RMR.RMRND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	[TUND]
RMRLOAD	RMR data uploaded	RMRLOAD	N	=1 if there are any usable participant records in RMRLOAD (EEVENT=5) for that DEIDNUM/VISIT/RMRVISIT else =0 (not all subjects who had RMR performed had usable results)	
Variables for Participant RMR					
				Variables NPT – RMR are calculated from usable participant data, ie records with EEVENT=5.	
NPT	Number of usable RMR minutes	RMRLOAD	N	= number of records in RMRLOAD with EEVENT=5 for that DEIDNUM/VISIT/RMRVISIT	
MVO2	Mean VO2	RMRLOAD.VO2	N	= mean VO2 for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	
MVCO2	Mean VCO2	RMRLOAD.VCO2	N	= mean VCO2 for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	
MRER	Mean RER	RMRLOAD.RER	N	= mean RER for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	
MVE	Mean VE	RMRLOAD.VE	N	= mean VE for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	
MO2P	Mean O2 %	RMRLOAD.O2P	N	= mean O2P for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
MCO2P	Mean CO2 %	RMRLOAD.CO2P	N	= mean CO2P for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	
SVO2	Total VO2	RMRLOAD.VO2	N	= sum of VO2 for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	
SVCO2	Total VCO2	RMRLOAD.VCO2	N	= sum of VCO2 for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	
RQRAW	RQ (before data handling rules)	SVO2, SVCO2	N	= SVCO2 / SVO2	
RMRRAW	RMR (before data handling rules)	RMRLOAD.REE	N	= mean REE for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=5	
RQ_RMR	RQ (using data handling rules)	RQRAW NPT, RMRRAW		RMR Data handling rules make RQ missing if any of the exclusion criteria are met. =RQRAW Missing if any of the following is true: 1) NPT<10 2) RQRAW < 0.65 or > 1.05 3) RMRRAW < 800 or > 4000	
RMR	RMR (using data handling rules)	RQRAW NPT, RMRRAW	N	This is the RMR value used for analyses. It incorporates RMR Data handling rules which make RMR missing if any of the exclusion criteria are met. Note, the Primary endpoint is RMR Residuals, which is in the RMRRESID dataset. =RMRRAW Set to missing if any of the following is true: 1) NPT<10 2) RQRAW < 0.65 or > 1.05 3) RMRRAW < 800 or > 4000	
Variables for pre-test CO2 calibration					
				Variables NQC1 – PRERQ are calculated from records for Pre-test CO2 calibration (PTQC='PT' and EEVENT=2)	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
NQC1	Minutes in pre-test CO2 calibration	RMRLOAD	N	= number of records in RMRLOAD for that DEIDNUM/VISIT/RMRVSIT among records with PTQC='PT' and EEVENT=2	
SVO2PRE	Total VO2 for pre-test CO2 calibration	RMRLOAD.VO2	N	= sum of VO2 for that DEIDNUM/VISIT/RMRVISIT among records with PTQC='PT' and EEVENT=2	
PREO2	Mean VO2 for pre-test CO2 calibration	SVO2PRE, NQC1	N	= SVO2PRE / NQC1 (IF NQC1>0)	
SVCO2PRE	Total VCO2 for pre-test CO2 calibration	RMRLOAD.VCO2	N	= sum of VCO2 for that DEIDNUM/VISIT/RMRVISIT among records with PTQC='PT' and EEVENT=2	
PRECO2	Mean VCO2 for pre-test CO2 calibration	SVCO2PRE, NQC1	N	= SVCO2PRE / NQC1 (IF NQC1>0)	
PRERQ	Pre-test RQ for CO2 calibration	SVO2PRE, SVCO2PRE	N	=SVCO2PRE / SVO2PRE	
Variables for post-test CO2 calibration					
				Variables NQC2 – POSTRQ are calculated from records for Post-test CO2 calibration (PTQC='QC' and EEVENT=2)	
NQC2	Minutes in post-test CO2 calibration	RMRLOAD	N	= number of records in RMRLOAD for that DEIDNUM/VISIT/RMRVSIT among records with PTQC='QC' and EEVENT=2	
SVO2POST	Total VO2 for post-test CO2 calibration	RMRLOAD.VO2	N	= sum of VO2 for that DEIDNUM/VISIT/RMRVISIT among records with PTQC='QC' and EEVENT=2	
POSTO2	Mean VO2 for post-test CO2 calibration	SVO2POST, NQC2	N	=SVO2POST / NQC2 (IF NQC2>0)	
SVCO2POS	Total VCO2 for post-test CO2 calibration	RMRLOAD.VCO2	N	= sum of VCO2 for that DEIDNUM/VISIT/RMRVISIT among records with PTQC='QC' and EEVENT=2	
POSTCO2	Mean VCO2 for post-test CO2 calibration	SVCO2POST, NQC2	N	=SVCO2POST / NQC2 (IF NQC2>0)	
POSTRQ	Post-test RQ for CO2 calibration	SVO2POST, SVCO2POST	N	=SVCO2POST / SVO2POST	
Variables for CAL gas 1 calibration					
				Variables NQC3 – C1PSTCO2 are calculated from records for post-test CAL gas 1 calibration (EEVENT=3)	
NQC3	Minutes post-test CAL gas 1 calibration	RMRLOAD	N	= number of records in RMRLOAD for that DEIDNUM/VISIT/RMRVSIT among records with	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				EEVENT=3	
C1PREO2	Mean O2 % for pre-test CAL gas 1		N	=20.94 if NQC3 >0, else missing	
C1PRECO2	Mean CO2 % for pre-test CAL gas 1		N	=0 if NQC3>0, else missing	
C1PSTO2	Mean O2 % for post-test CAL gas 1	RMRLOAD.O2P	N	= mean of O2P for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=3	
C1PSTCO2	Mean CO2 % for post-test CAL gas 1	RMRLOAD.CO2P	N	=mean of CO2P for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=3	
Variables for CAL gas 2 calibration					
				Variables NQC4 – C2PSTCO2 are calculated from records for post-test CAL gas 2 calibration (EEVENT=4)	
NQC4	Minutes post-test CAL gas 2 calibration	RMRLOAD	N	= number of records in QC4 for that DEIDNUM/VISIT/RMRVSIT among records with EEVENT=4	
C2PSTO2	Mean O2 % for post-test CAL gas 2	RMRLOAD.O2P	N	= mean of O2P for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=4	
C2PSTCO2	Mean CO2 % for post-test CAL gas 2	RMRLOAD.CO2P	N	=mean of CO2P for that DEIDNUM/VISIT/RMRVISIT among records with EEVENT=4	

Trial name	**CALERIE 2**
Dataset name	**CORETMPA (Core temperature)**
Description	This dataset converts the raw data from the core temperature file to 1 record per DEIDNUM / VISIT. Core temperature is measured for each minute for the approximately 26 hour duration of core temperature monitoring. A minute is considered usable if the temperature is between 35 -39 degrees C. The raw data has 1 record for each 15 minute interval, and variables for the number of usable minutes in that interval, and the sum of the usable temperatures in the interval. Capsule ingestion time is defined as the last minute of the first interval with a usable temperature. The Core temperature data handling rules are implemented: data for the first 30 minutes after capsule ingestion are excluded, and only the first 26 hours of usable records are used. Average core temperature for the 24 hour period, daytime and nighttime are calculated. Coretemp results are merged with CRF data, so there is a record for all study visits that were attended at which core temp was expected, even if there are no core temp results. There were several core temp assays that were done that did not have usable results.
Comments on data structure	1 record / DEIDNUM / VISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
VISITs	5, 9, 11, 13 for both treatment arms (See Appendix for VISIT codes)
Usage notes	CORETEMP is one of the primary endpoint variables.
Source data files	LABS/CORETEMP, CRF/ADMIT, ANALDATA/ RMRA, 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	ADMIT.PAGEID	N		
VISIT	Visit	PAGENUM, CORETEMP.CFORM	N	Study Visit, based on CRF page (See Appendix 1) Or CORETEMP.CFORM (see CORETEMP specs)	VISFMT
SUBVISIT	Sub-Visit	SUBVISIT	N	Study Sub-visit, based on CRF page (See Appendix 1) Or CORETEMP.CFORM (see CORETEMP specs)	SVISFMT
CRFSTRDT	Core Temp start date (CRF)	ADMIT.CTSTRDT	DT		
CTND	Reason Core Temp not done.	ADMIT.CTND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure	[TUND]

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				5=Not required	
CRFCT	Core Temperature done (CRF)	CRFSTRDT	N	=1 if CRFSTRDT is non-missing else =0	
CTRMRLAG	Elapsed time from RMR to core temp start	RMRA.RMRDTCRF, CRFSTRDT	N	This is used to determine which core temp tests are within 30 days of RMR, for data handling rules. = days from RMRDTCRF to CRFSTRDT	
OUTRANGE	Core Temp more than 30 days from RMR	CTRMRLAG	N	This is a flag to identify Core Temps that will be set to missing by data handling rules. =1 if abs(CTRMRLAG)>30 Else missing	
CT	Core Temperature data received	CORETEMP	N	=1 if the record exists in CORETEMP	
CTSTRTTM	CoreTemp start dtm (monitor)	CORETEMP.STARTTM	DTM	Core Temperature start date/time from monitor =smallest non-missing STARTTM for that DEIDNUM VISIT	
CTSTOPTM	CoreTemp stop dtm (monitor)	CORETEMP.STOPTM	DTM	Core temperature stop date/time from monitor =largest STOPTM for that DEIDNUM VISIT	
INGESTTM	Date/time capsule ingested	CORETEMP.STOPTM, CORETMEP.USEDRECS	DTM	Capsule ingestion time is defined as the end of the first 15 minute interval that has any minute with temperature from 35 – 39 degrees C. =smallest non-missing STOPTM for that DEIDNUM / VISIT that has USEDRECS>0	
LSTUSDTM	Dtm of last usable record	CORETEMP.STARTTM CORETEMP.USEDRECS	DTM	Date/time of last usable record from monitor = largest non-missing STARTTM for that DEIDNUM / VISIT that has USEDRECS>0	
CTDUR	Core Temp duration (monitor) (hours)	CTSTRTTM, CTSTOPTM	N	=hours from CTSTRTTM to CTSTOPTM	
USEDDUR	Duration of usable records (hours)	INGESTTM, LSTUSDTM	N	=hours from INGESTTM to LSTUSDTM	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
Variables for 24 hour average core temperature, using data handling rules.		Variables NTOTA24 – VARA24 are calculated from records that start at least 30 minutes after INGESTTM and are within the first 1560 usable minutes after that point (1500 for VISIT 9), using the cumulative sum of USEDRECS in each interval. A24 is an indicator for records that meet these criteria.			
NTOTA24	Total number of Core Temp minutes	NUMRECS, A24	N	Total number of Core Temp minutes, excluding first 30 minutes, up to 26 hours = sum of NUMRECS over all records with A24=1 for that DEIDNUM/VISIT	
NUSEDA24	Number of usable Core Temp minutes	USEDRECS, A24	N	Number of usable Core Temp minutes, excluding first 30 minutes, up to 26 hours = sum of USEDRECS over all records with A24=1 for that DEIDNUM/VISIT	
CTUNADJ	Unadjusted 24 hour core temperature	TEMPSUM, NUSEDA24, A24, OUTRANGE	N	Average 24 hour core temperature before applying data handling rules. This is NOT used in the analyses. = sum of TEMPSUM over all records with A24=1 for that DEIDNUM/VISIT / NUSED24A	
CORETEMP	Average 24 hour Core Temperature	CTUNADJ OUTRANGE, NUSEDA24	N	Average 24 hour core temperature (excluding first 30 minutes, up to 26 hours) with data handling rules applied: make missing if core temperature is not within 30 days of RMR, or there are fewer than 720 usable minutes. This is used for primary endpoint analyses. =CTUNADJ Set to missing if OUTRANGE=1 or NUSEDA24<720	
VARA24	Variance of 24 hour Core Temperature	TEMPSQ, NUSEDA24, CORETEMP, OUTRANGE	N	Variance of 24 hour Core Temperature (excluding first 30 minutes, up to 26 hours) =((sum of TEMPSQ over all records with A24=1 for that DEIDNUM VISIT) / NUSEDA24) – (CORETEMP^2)	

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
				Missing if OUTRANGE=1 or NUSEDA24<720	
Variables for Daytime average core temperature, using data handling rules.		**Variables NTOTD – VARD are calculated from records that start at least 30 minutes after INGESTTM and start between 8 am to 10:30 pm. DAY is an indicator for records that meet these criteria.**			
NTOTD	Number of daytime Core Temp minutes	NUMRECS, DAY	N	Total number of Daytime Core Temp minutes (between 8 am to 10:30 pm) = sum of NUMRECS over all records with DAY=1 for that DEIDNUM VISIT	
NUSEDD	Number of usable daytime Core Temp min.	USEDRECS, DAY	N	Number of usable Daytime Core Temp minutes (between 8 am to 10:30 pm) = sum of USEDRECS over all records with DAY=1 for that DEIDNUM VISIT	
CTDUNADJ	Unadjusted daytime Core Temperature	TEMPSUM, NUSEDD, DAY	N	Average Daytime core temperature (8am to 10:30 pm) before applying data handling rules. This is NOT used in the analyses. =(sum of TEMPSUM over all records with DAY=1 for that DEIDNUM VISIT) / NUSEDD	
CORTEMPD	Average daytime Core Temperature	CTDUNADJ, OUTRANGE, NUSEDD	N	Average Daytime core temperature (8am to 10:30 pm) with data handling rules applied: make missing if core temperature is not within 30 days of RMR, or there are fewer than 220 usable minutes. =CTDUNADJ Missing if OUTRANGE=1 or NUSEDD<220	
VARD	Variance of daytime Core Temp	TEMPSQ, NUSEDD, CORTEMPD, DAY, OUTRANGE	N	Variance of daytime Core Temp between 8 am to 10:30 pm =((sum of TEMPSQ over all records with DAY=1 for that DEIDNUM VISIT) / NUSEDD) – (CORTEMPD^2) Missing if OUTRANGE=1 or NUSEDD<220	
Variables for Nighttime average core temperature, using data handling rules.		**Variables NTOTN – VARN are calculated from records that start at least 30 minutes after INGESTTM and start between 2 am to 5 am. NIGHT is an indicator for records that meet these**			

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
		criteria.			
NTOTN	Number of nighttime Core Temp minutes	NUMRECS, NIGHT	N	Total number of Nighttime Core Temp minutes (between 2 am – 5 am) = sum of NUMRECS over all records with NIGHT =1 for that DEIDNUM VISIT	
NUSEDN	Number of usable night Core Temp min.	USEDRECS,NIGHT	N	Number of usable Nighttime Core Temp minutes (between 2 am – 5 am) = sum of USEDRECS over all records with NIGHT =1 for that DEIDNUM VISIT	
CTNUNADJ	Unadjusted nighttime Core Temperature	TEMPSUM, NUSEDN, NIGHT	N	Average Nighttime Core Temperature (between 2 am – 5 am) before applying data handling rules. This is NOT used in the analyses. =(sum of TEMPSUM over all records with NIGHT =1 for that DEIDNUM VISIT) / NUSEDN	
CORTEMPN	Average nighttime Core Temperature	CTNUNADJ, OUTRANGE, NUSEDN	N	Average Nighttime core temperature (between 2am – 5am) with data handling rules applied: make missing if core temperature is not within 30 days of RMR, or there are fewer than 45 usable minutes. =CTNUNADJ Missing if OUTRANGE=1 or NUSEDN<45	
VARN	Variance of nighttime Core Temp	TEMPSQ, NUSEDN, CORTEMPN, NIGHT, OUTRANGE,	N	Variance of Nighttime core temperature (between 2 am – 5 am) =((sum of TEMPSQ over all records with NIGHT =1 for that DEIDNUM VISIT)/ NUSEDN) – (CORTEMPN^2) Missing if OUTRANGE=1 or NUSEDN<45	

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, 4, 5, 7, 8, 9, 10, 11, 12, 13 VISIT 0 combines the two baseline Visits into a single baseline mean, (See Appendix for 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	= (MEANSBP + 2x MEANDBP) / 3	
PULSEPRS	Pulse Pressure (mm Hg)	MEANSBP, MEANDBP	N	= MEANSBP – MEANDBP	

Trial name	**CALERIE 2**
Dataset name	**VO2MAX (VO2 Max – treadmill test)**
Description	Maximal oxygen uptake test done on treadmill. Results are reported on the CRF. All subjects who took the test have peak VO2. VO2 max exists only if the subject met VO2 max criteria.
Comments on data structure	1 record / DEIDNUM/ VISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
Visits	5, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/VOMAX, 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	PAGENUM	N		
VISIT	Visit	VISIT	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
VOMAXDTM	VO2 Max date/time	DATEHDR.STUDYTM	DTM		
CRFVO2	VO2 Max performed	VOMAXDTM	N	=1 if VOMAXDTM is non-missing else =0	
VO2NDRSN	Reason VO2 max not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
MEALTM	Date/time of last meal	VOMAX.MEALTM	DTM		
VO2LAG2	Hours from last meal to VO2 max	VOMAXDTM, MEALTM	N	Hours from MEALTM to VOMAXDTM	
RESTRHYM	Rest ECG rhythm	VOMAX.RESTRHYM	N	1=Sinus 2=Atrial fibrillation 98=Other	TURHYT
VCONDUCT	Rest ECG ventricular conduction	VOMAX.VCONDUCT	N	1=Normal 2=LBBB 3=RBBB	TUVCON

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RESTRATE	Resting heart rate	VOMAX.RESTRATE	N		
AGERATE	Age predicted heart rate	VOMAX.AGERATE	N		
HRATEMAX	Heart rate (max)	VOMAX.HRATEMAX	N		
				Reasons for termination:	
SYMLTD	Symptom limited termination	VOMAX.SYMLTD	N		1=Yes
ANGISEM	Termination for angina	VOMAX.ANGISEM	N		1=Yes
CANGINA	Heart Rate at true cardiac angina	VOMAX.CANGINA	N		
ECGCHNG	Heart Rate during ischemic ECG	VOMAX.ECGCHNG	N		
ARRYTHM	Termination for arrhythmia	VOMAX.ARRYTHM	N		1=Yes
CHGBP	Termination for BP changes	VOMAX.CHGBP	N		1=Yes
VENISCH	Termination for ventricular ischemia	VOMAX.VENISCH	N		1=Yes
PAINCRMP	Termination for orthopedic complaints	VOMAX.PAINCRMP	N		1=Yes
VO2OTHR	Termination for other reason	VOMAX.OTHER	N		1=Yes
REASONSP	Specify other reason	VOMAX.REASONSP	C	Text string	
ECTOPY	Frequent ventricular ectopy	VOMAX.ECTOPY	N		0=No 1=Yes
EXERCISE	Ventricular ectopy during exercise	VOMAX.EXERCISE	N		1=Yes
RECOVERY	Ventricular ectopy during recovery	VOMAX.RECOVERY	N		1=Yes
PVOMEAS1	Peak VO2 (mL/kg/min)	VOMAX.PVOMEAS1	N		
PVOMEAS2	Peak VO2 (L/min)	VOMAX.PVOMEAS2	N		
MEETCRIT	Met VO2 max criteria	VOMAX.MEETCRIT	N	Subject met at least 2 of the 3 VO2 max criteria: a) Achieved a plateau in VO2 (changes <=150 mL between the final two stages),	0=No 1=Yes

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
				b) RER >=1.1 c) HR max +/- 5 bpm of age-predicted max.	
VOMEAS1	VO2 max (mL/kg/min)	VOMAX.VOMEAS1	N		
VOMEAS2	VO2 max (L/min)	VOMAX.VOMEAS2	N		
EXERTIME	Exercise time (minutes)	VOMAX.EXERMIN, VOMAX.EXERSEC	N	= the sum of EXERMIN and EXERSEC/60	
VOSYS	Systolic BP at VO2 max	VOMAX.VOSYS	N		
VODIA	Diastolic BP at VO2 max	VOMAX.VODIA	N		
BORG	Borg RPE score at VO2 max	VOMAX.BORG	N		
PEAKRER	Peak RER	VOMAX.PEAKRER	N		
VEPEAK	VE at VO2 peak / VO2 max (L/min)	VOMAX.VEPEAK	N		
VEVOPEAK	VE/VO2 at VO2 peak /VO2 max (L/min)	VOMAX.VEVOPEAK	N		

Trial name	**CALERIE 2**
Dataset name	**HANDGRPA (Handgrip strength)**
Description	Handgrip strength data from CRF, transposed to 1 record per DEIDNUM / VISIT.
Comments on data structure	1 record / DEIDNUM/ VISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
Visits	5, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/HANDGRIP, 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	HANDGRIP.PAGEID	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
HGRPDTM	Date/time of handgrip test	DATEHDR.STUDYTM	DTM		DATETIME
HGRPCRF	Handgrip test performed	HANDGRIP.RIGHT, HANDGRIP.LEFT	N	=1 if RIGHT or LEFT is non-missing for at least one record for that DEIDNUM / VISIT else =0	
HGNDRSN	Reason handgrip test not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
DYNO	Dynometer handle position	HANDGRIP.DYNO	N		
DOMHND	Dominant hand	HANDGRIP.DOMHND	N	1=Left 2=Right 3=Ambidextrous	TUDOMH
RHPF1	Peak force 1, right hand	HANDGRIP.TESTNO, HANDGRIP.RIGHT	N	= RIGHT if TESTNO=1	
RHPF2	Peak force 2, right hand	HANDGRIP.TESTNO, HANDGRIP.RIGHT	N	= RIGHT if TESTNO=2	

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
RHPF3	Peak force 3, right hand	HANDGRIP.TESTNO, HANDGRIP.RIGHT	N	= RIGHT if TESTNO=3	
LHPF1	Peak force 1, left hand	HANDGRIP.TESTNO, HANDGRIP.LEFT	N	= LEFT if TESTNO=1	
LHPF2	Peak force 2, left hand	HANDGRIP.TESTNO, HANDGRIP.LEFT	N	= LEFT if TESTNO=2	
LHPF3	Peak force 3, left hand	HANDGRIP.TESTNO, HANDGRIP.LEFT	N	= LEFT if TESTNO=3	
RHPFMEAN	Mean peak force, right hand	RHPF1 – RPHF3	N	= average of RHPF1, RHPF2, RHPF3	
LHPFMEAN	Mean peak force, left hand	LHPF1 – LHPF3	N	= average of LHPF1, LHPF2, LHPF3	
PFRDIF	Right hand peak force discrepancy	RHPF1 – RHPF3	N	Discrepancy between two largest peak force values, right hand = absolute value of the difference between the two largest values of RHPF1, RHPF2, RHPF3	
PFLDIF	Left hand peak force discrepancy	LHPF1 – LHPF3	N	Discrepancy between two largest peak force values, left hand = absolute value of the difference between the two largest values of LHPF1, LHPF2, LHPF3	

Trial name	**CALERIE 2**
Dataset name	**ISOMETRA (Isometrics)**
Description	Isometric / Isokinetic Knee Extension and Flexion measurements from CRF, flattened to 1 record per DEIDNUM / VISIT. (The CRF dataset has 20 records per DEIDNUM / VISIT, 1 for each measure, with values for each leg.) Includes all original measurements and derived values, eg, mean of repeated measurements for each leg, mean of each measurement for both legs, etc.
Comments on data structure	1 record / DEIDNUM/ VISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
Visits	5, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/ISOMETRC, DATEHDR, ANALDTA/SUBJECT1, CLWTVIS, DXAA
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	ISOMETRC.PAGEID	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
ISODTM	Date/time of Isometrics	DATEHDR.STUDYTM	DTM		Datetime
ISOCRF	Isometrics performed	ISODTM	N	=1 if RIGHTLEG or LEFTLEG is non-missing for any record for that DEIDNUM / VISIT else = 0	
ISONDRSN	Reason Isometrics not performed	STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
RKIP	Recent injury or pain -right knee	ISOMETRC.RKIP	N		
LKIP	Recent injury or pain -left knee	ISOMETRC.LKIP	N		
	The following 40 variables (KE60PTR – IKF3L) are directly from the CRF				
KE60PTR	60’/s right knee extension peak torque	ISOMETRC.GRAVEFF,	N	60^o/s knee extension peak torque, right leg	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
		ISOMETRC.RIGHTLEG		= RIGHTLEG if GRAVEFF=1	
KE60TWR	60º/s right knee extension total work		N	60^{0}/s knee extension total work, right leg = RIGHTLEG if GRAVEFF=2	
KE60APR	60’/s right knee extension average power		N	60^{0}/s right knee extension average power, right leg = RIGHTLEG if GRAVEFF=3	
KF60PTR	60’/s right knee flexion peak torque		N	60^{0}/s knee flexion peak torque, right leg = RIGHTLEG if GRAVEFF=4	
KF60TWR	60’/s right knee flexion total work		N	60^{0}/s knee flexion total work, right leg = RIGHTLEG if GRAVEFF=5	
KF60APR	60’/s right knee flexion average power		N	60^{0}/s knee flexion average power, right leg = RIGHTLEG if GRAVEFF=6	
KE180PTR	180’/s right knee extension peak torque		N	180^{0}/s knee extension peak torque, right leg = RIGHTLEG if GRAVEFF=7	
KE180TWR	180’/s right knee extension total work		N	180^{0}/s knee extension total work, right leg = RIGHTLEG if GRAVEFF=8	
KE180APR	180’/s right knee ext. average power		N	180^{0}/s knee extension average power, right leg = RIGHTLEG if GRAVEFF=9	
KE180WFR	180’/s right knee ext work fatigue index		N	180^{0}/s knee extension work fatigue index, right leg = RIGHTLEG if GRAVEFF=10	
KF180PTR	180’/s right knee flexion peak torque		N	180^{0}/s knee extension work fatigue index, right leg = RIGHTLEG if GRAVEFF=11	
KF180TWR	180’/s right knee flexion total work		N	180^{0}/s knee flexion total work, right leg = RIGHTLEG if GRAVEFF=12	
KF180APR	180’/s right knee flexion average power		N	180^{0}/s knee flexion average power, right leg = RIGHTLEG if GRAVEFF=13	
KF180WFR	180’/s right knee flex work fatigue ind.		N	180^{0}/s knee flexion work fatigue index, right leg = RIGHTLEG if GRAVEFF=14	
IKE1R	Isometric right knee ext. peak torque 1		N	Isometric knee extension peak torque 1, right leg = RIGHTLEG if GRAVEFF=15	
IKE2R	Isometric right knee ext. peak torque 2		N	Isometric knee extension peak torque 2, right leg = RIGHTLEG if GRAVEFF=16	
IKE3R	Isometric right knee ext. peak torque 3		N	Isometric knee extension peak torque 3, right leg = RIGHTLEG if GRAVEFF=17	
IKF1R	Isometric right knee flex. peak torque 1		N	Isometric knee flexion peak torque 1, right leg = RIGHTLEG if GRAVEFF=18	
IKF2R	Isometric right knee flex. peak torque 2	ISOMETRC.GRAVEFF,	N	Isometric knee flexion peak torque 2, right leg	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
		ISOMETRC.RIGHTLEG		= RIGHTLEG if GRAVEFF=19	
IKF3R	Isometric right knee flex. peak torque 3		N	Isometric knee flexion peak torque 3, right leg = RIGHTLEG if GRAVEFF=20	
KE60PTL	60’/s left knee extension peak torque	ISOMETRC.GRAVEFF, ISOMETRC.LEFTLEG	N	60^0/s knee extension peak torque, left leg = LEFTLEG if GRAVEFF=1	
KE60TWL	60’/s left knee extension total work		N	60^0/s knee extension total work, left leg = LEFTLEG if GRAVEFF=2	
KE60APL	60’/s left knee extension average power		N	60^0/s knee extension average power, left leg = LEFTLEG if GRAVEFF=3	
KF60PTL	60’/s left knee flexion peak torque		N	60^0/s knee flexion peak torque, left leg = LEFTLEG if GRAVEFF=4	
KF60TWL	60’/s left knee flexion total work		N	60^0/s knee flexion total work, left leg = LEFTLEG if GRAVEFF=5	
KF60APL	60’/s left knee flexion average power		N	60^0/s knee flexion average power, left leg = LEFTLEG if GRAVEFF=6	
KE180PTL	180’/s left knee extension peak torque		N	180^0/s knee extension peak torque, left leg = LEFTLEG if GRAVEFF=7	
KE180TWL	180’/s left knee extension total work		N	180^0/s knee extension total work, left leg = LEFTLEG if GRAVEFF=8	
KE180APL	180’/s left knee extension average power		N	180^0/s knee extension average power, left leg = LEFTLEG if GRAVEFF=9	
KE180WFL	180’/s left knee ext. work fatigue index		N	180^0/s knee extension work fatigue index, left leg = LEFTLEG if GRAVEFF=10	
KF180PTL	180’/s left knee flexion peak torque		N	180^0/s knee flexion peak torque, left leg = LEFTLEG if GRAVEFF=11	
KF180TWL	180’/s left knee flexion total work		N	180^0/s knee flexion total work, left leg = LEFTLEG if GRAVEFF=12	
KF180APL	180’/s left knee flexion average power		N	180^0/s knee flexion total work, left leg = LEFTLEG if GRAVEFF=13	
KF180WFL	180’/s left knee flex. work fatigue ind.		N	180^0/s knee flexion work fatigue index, left leg = LEFTLEG if GRAVEFF=14	
IKE1L	Isometric left knee ext. peak torque 1		N	Isometric knee extension peak torque 1, left leg = LEFTLEG if GRAVEFF=15	
IKE2L	Isometric left knee ext. peak torque 2		N	Isometric knee extension peak torque 2, left leg = LEFTLEG if GRAVEFF=16	
IKE3L	Isometric left knee ext. peak torque 3		N	Isometric knee extension peak torque 3, left leg = LEFTLEG if GRAVEFF=17	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
IKF1L	Isometric left knee flex. peak torque 1			Isometric knee flexion peak torque 1, left leg = LEFTLEG if GRAVEFF=18	
IKF2L	Isometric left knee flex. peak torque 2			Isometric knee flexion peak torque 2, left leg = LEFTLEG if GRAVEFF=19	
IKF3L	Isometric left knee flex. peak torque 3			Isometric knee flexion peak torque 3, left leg = LEFTLEG if GRAVEFF=20	
	The following variables are derived from the raw variables.				
IKERMEAN	Mean peak torque iso. right knee ext.	IKE1R, IKE2R, IKE3R	N	Mean peak torque, isometric knee extension, right leg = average of IKE1R, IKE2R, IKE3R	
IKFRMEAN	Mean peak torque iso. right knee flex.	IKF1R, IKF2R, IKF3R	N	Mean peak torque, isometric knee flexion, right leg = average of IKF1R, IKF2R, IKF3R	
IKELMEAN	Mean peak torque iso. left knee ext.	IKE1L, IKE2L, IKE3L	N	Mean peak torque, isometric knee extension, left leg = average of IKE1L, IKE2L, IKE3L	
IKFLMEAN	Mean peak torque iso. left knee flex.,	IKF1L, IKF2L, IKF3L	N	Mean peak torque, isometric knee flexion, left leg = average of IKF1L, IKF2L IKF3L	
IKERMAX	Max peak torque iso. right knee ext.	IKE1R, IKE2R, IKE3R	N	Highest peak torque, isometric knee extension, right leg = max of IKE1R, IKE2R, IKE3R	
IKFRMAX	Max peak torque iso. right knee flex.	IKF1R, IKF2R, IKF3R	N	Highest peak torque, isometric knee flexion, right leg = max of IKF1R, IKF2R, IKF3R	
IKELMAX	Max peak torque iso. left knee ext.	IKE1L, IKE2L, IKE3L	N	Highest peak torque, isometric knee extension, left leg = max of IKE1L, IKE2L, IKE3L	
IKFLMAX	Max peak torque iso. left knee flex.	IKF1L, IKF2L, IKF3L	N	Highest peak torque, isometric knee flexion, left leg = max of IKF1L, IKF2L IKF3L	
IKERDIF	Isometric right knee ext. discrepancy	IKE1R, IKE2R, IKE3R	N	Discrepancy between two largest values of isometric knee extension, right leg =Absolute value of the difference between the two largest values of IKE1R, IKE2R, IKE3R	
IKFRDIF	Isometric right knee flex. discrepancy	IKF1R, IKF2R, IKF3R	N	Discrepancy between two largest values of isometric knee flexion, right leg =Absolute value of the difference between the two largest values of IKF1R, IKF2R, IKF3R	
IKELDIF	Isometric left knee ext. discrepancy	IKE1L, IKE2L, IKE3L	N	Discrepancy between two largest values of isometric knee extension, left leg =Absolute value of the difference between the two largest values of IKE1L, IKE2L, IKE3L	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
IKFLDIF	Isometric left knee flex. discrepancy	IKF1L, IKF2L, IKF3L	N	Discrepancy between two largest values of isometric knee flexion, left leg =Absolute value of the difference between the two largest values of IKF1L, IKF2L, IKF3L	
MLEGLEAN	Avg. left and right leg lean mass (kg)	DXAA.LLEGLEAN, DXAA.RLEGLEAN	N	Average of left and right leg lean mass (kg) = mean (LLEGLEAN, RLEGLEAN)	
KE60PTM	Avg. 60°/s knee extension peak torque	KE60PTR, KE60PTL	N	60°/sec knee extension, peak torque, average of both legs (N.m) = mean (KE60PTR, KE60PTL)	
KE60PTWT	60°/s knee ext. peak torque / body wt.	KE60PTM, MCLINWT	N	Average 60°/sec knee extension, peak torque, relative to body weight (N.m/kg) =KE60PTM / MCLINWT	
KE60PTLL	60°/s knee ext. peak torque / leg lean	KE60PTM, MLEGLEAN	N	Average 60°/sec knee extension, peak torque, relative to leg lean mass (N.m/kg) =KE60PTM / MLEGLEAN	
KE60TWM	Avg. 60°/s knee extension total work	KE60TWR, KE60TWL	N	60°/sec knee extension, total work, average of both legs (N.m) = mean (KE60TWR, KE60TWL)	
KE60APM	Avg. 60°/s knee extension average power	KE60APR, KE60APL	N	60°/sec knee extension, average power, average of both legs (watts) = mean (KE60APR, KE60APL)	
KF60PTM	Avg. 60°/s knee flexion peak torque	KF60PTR, KF60PTL	N	60°/sec knee flexion, peak torque, average of both legs (N.m) = mean (KF60PTR, KF60PTL)	
KF60PTWT	60°/s knee flex peak torque / body wt.	KF60PTM, MCLINWT	N	60°/sec knee flexion, peak torque, relative to body weight (N.m/kg) =KF60PTM / MCLINWT	
KF60PTLL	60°/s knee flex. peak torque / leg lean	KF60PTM, MLEGLEAN	N	60°/sec knee flexion, peak torque, relative to leg lean mass (N.m/kg) =KF60PTM / MLEGLEAN	
KF60TWM	Avg. 60°/s knee flexion total work	KF60TWR, KF60TWL	N	60°/sec knee flexion, total work, average of both legs (N.m) = mean (KF60TWR, KF60TWL)	
KF60APM	Avg. 60°/s knee flexion average power	KF60APR, KF60APL	N	60°/sec knee flexion, average power, average of both	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
				legs (watts) = mean (KF60APR, KF60APL)	
KE180PTM	Avg. 180°/s knee extension peak torque	KE180PTR, KE180PTL	N	180°/sec knee extension, peak torque, average of both legs (N.m) = mean (KE180PTR, KE180PTL)	
KE180PTW	180°/s knee ext. peak torque / body wt.	KE180PTM, MCLINWT	N	180°/sec knee extension, peak torque, relative to body weight (N.m/kg) =KE180PTM / MCLINWT	
KE18PTLL	180°/s knee ext. peak torque / leg lean	KE180PTM, MLEGLEAN	N	180°/sec knee extension, peak torque, relative to leg lean mass (N.m/kg) =KE180PTM / MLEGLEAN	
KE180TWM	Avg. 180°/s knee extension, total work	KE180TWR, KE180TWL	N	180°/sec knee extension, total work, average of both legs (N.m) = mean (KE180TWR, KE180TWL)	
KE180APM	Avg. 180°/s knee extension average power	KE180APR, KE180APL	N	180°/sec knee extension, average power, average of both legs (watts) = mean (KE180APR, KE180APL)	
KE180WFI	Avg. 180°/s knee ext, work fatigue index	KE180WFR, KE180WFL	N	180°/sec knee extension, work fatigue index, average of both legs (%) = mean (KE180WFR, KE180WFL)	
KF180PTM	Avg. 180°/s knee flexion, peak torque	KF180PTR, KF180PTL	N	180°/sec knee flexion, peak torque, average of both legs (N.m) = mean (KF180PTR, KF180PTL)	
KF180PTW	180°/s knee flex. peak torque / body wt.	KF180PTM, MCLINWT	N	180°/sec knee flexion, peak torque, relative to body weight (N.m/kg) =KF180PTM / MCLINWT	
KF18PTLL	180°/s knee flex. peak torque / leg lean	KF180PTM, MLEGLEAN	N	180°/sec knee flexion, peak torque, relative to leg lean mass (N.m/kg) =KF180PTM / MLEGLEAN	
KF180TWM	Avg. 180°/s knee flexion total work	KF180TWR, KF180TWL	N	180°/sec knee flexion, total work, average of both legs (N.m) = mean (KF180TWR, KF180TWL)	
KF180APM	Avg. 180°/s knee flexion average power	KF180APR, KF180APL	N	180°/sec knee flexion, average power, average of both legs (watts)	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
				= mean (KF180APR, KF180APL)	
KF180WFI	Avg. 180°/s knee flex work fatigue index	KF180WFR, KF180WFL	N	180°/sec knee flexion, work fatigue index, average of both legs (%) = mean (KF180WFR, KF180WFL)	
IKEPTMAX	Avg. iso. knee ext. max peak torque	IKERMAX, IKELMAX	N	Isometric knee extension, highest peak torque, average of both legs (N.m) =mean (IKERMAX, IKELMAX)	
IKEPT_WT	Iso knee ext max peak torque / body wt	IKEPTMAX, MCLINWT	N	Isometric knee extension, highest peak torque, relative to body weight (N.m/kg) = IKEPTMAX / MCLINWT	
IKEPT_LL	Iso knee ext max peak torque / leg lean	IKEPTMAX, MLEGLEAN	N	Isometric knee extension, highest peak torque, relative to leg lean mass (N.m/kg) = IKEPTMAX / MLEGLEAN	
IKFPTMAX	Avg. iso. knee flex. max peak torque	IKFRMAX, IKFLMAX	N	Isometric knee flexion, highest peak torque, average of both legs (N.m) =mean (IKFRMAX, IKFLMAX)	
IKFPT_WT	Iso knee flex max peak torque / body wt	IKFPTMAX, MCLINWT	N	Isometric knee flexion, highest peak torque, relative to body weight (N.m/kg) = IKFPTMAX / MCLINWT	
IKFPT_LL	Iso knee flex max peak torque / leg lean	IKFPTMAX, MLEGLEAN	N	Isometric knee flexion, highest peak torque, relative to leg lean mass (N.m/kg) = IKFPTMAX / MLEGLEAN	
SUMPT	Composite strength score peak torque	KE60PTM, KF60PTM, KE180PTM, KF180PTM, IKEPTMAX, IKFPTMAX	N	Composite strength score, absolute peak torque (N.m) = sum of KE60PTM, KF60PTM, KE180PTM, KF180PTM, IKEPTMAX, IKFPTMAX Missing if any component is missing	
SUMPT_WT	Comp. strength score peak torque / body wt	KE60PTWT, KF60PTWT,	N	Composite strength score, absolute peak torque relative to body weight (N.m/kg)	

Variable name	**LABEL**	**Source variables**	**C/N ?**	**Definition**	**Accepted values/ Format**
		KE180PTWT, KF180PTWT, IKEPT_WT, IKFPT_WT		=sum of KE60PTWT, KF60PTWT, KE180PTWT, KF180PTWT, IKEPT_WT, IKFPT_WT Missing if any component is missing	
SUMPT_LL	Comp strength score peak torque/leg lean	KE60PTLL, KF60PTLL, KE180PTLL, KF180PTLL, IKEPT_LL, IKFPT_LL	N	Composite strength score, absolute peak torque relative to leg lean mass (N.m/kg) =sum of KE60PTLL, KF60PTLL, KE180PTLL, KF180PTLL, IKEPT_LL, IKFPT_LL Missing if any component is missing	
WFIM	Average work fatigue index (%)	KE180WFI, KF180WFI	N	Average work fatigue index (%) = mean of KE180WFI, KF180WFI	

Trial name	**CALERIE 2**
Dataset name	**OCLABLNG (outcome lab results, stacked)**
Description	Outcome lab results from Vermont lab, stacked.
Comments on data structure	1 record / DEIDNUM/ VISIT / ASSAY
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
Visits	5, 9, 11, 11.1, 12, 13 Most assays only have records at VISITs 5, 11 and 13, but a few also have records at VISITs 9, 11.1, or 12.
Source data files	LABS/OUTCLAB, ANALDATA/SUBJECT1
Final sort order	DEIDNUM VISIT ASSAY

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	OUTCLAB.OFORM	N	=5 if OFORM=0 or 70 or 80 =8 if OFORM=3 =9 if OFORM=6 =11 if OFORM=12 or 72 or 82 =11.1 if OFORM=17 =12 if OFORM=18 =12.1 if OFORM=23 =13 if OFORM=24 or 74 or 84 else missing See VISIT codes in appendix	VISFMT
SUBVISIT	Sub-Visit	VISIT	N	=11 if VISIT=5 =17 if VISIT=8 =23 if VISIT=9 =28 if VISIT=11 =30 if VISIT=11.1 =31 if VISIT=12 =34 if VISIT=12.1 =38 if VISIT=13 See codes in appendix	SVISFMT
LABTYPE	Vermont Lab type	OFORM	N	=1 if OFORM in (0, 3, 6, 12, 17, 18, 23, 24) =2 if OFORM in (70, 72, 74)	1: ‘Scheduled lab’ 2: ‘Off-cycle’

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				=3 if OFORM in (80, 82, 84) =4 if OFORM=98 =5 if OFORM=99	3: 'Tissue' 4: 'Reliability' 5: 'Unscheduled'
OCOLDT	Sample collection date	OCOLDT	DT	= datepart of OCOLDT	DT
ASSAY	Outcome assay	ASSAY	C		see following table
ASSAYTYP	Type of assay	ASSAY	C	see following table	
OUNIT	Outcome units	UNIT	C		
QUALITY	Outcome quality	QUAL	N		0=Unknown 1=Normal result 2=Sample not received 3=Insufficient quantity 4=Poor quality –no result 5=Poor quality –result obtained 6=Out of range – low 7=Out of range – high 8=Off-cycle exclusion
RESLTRAW	Outcome result, original	RES	N	Original lab result (uncorrected for values below detectable limits). This was not used in analyses. =RES. Make missing if value is in (-888, -999), which are missing codes.	
RESULT	Result, corrected	RESLTRAW QUALITY, LOVAL	N	Corrected Result using QC committee decision. Use this value for analyses. For values that are coded QUALITY=6 (Out of range – low), use the lowest detectable value. If QUALITY=6, = LOVAL Else = RESLTRAW	
HAVERSLT	Have assay result	QUALITY, RESULT	N	=1 if RESULT is non-missing or QUALITY is in (6,7)	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				else =0	
LOVAL	Lower limit	LOVAL	N		
HIVAL	Upper limit	HIVAL	N		
ALERT	Abnormal value alert	RESULT, LOVAL, HIVAL	N	=1 if RESULT is non-missing and : LOVAL is non-missing and RESULT<LOVAL Or HIVAL is non-missing and RESULT>HIVAL Else =0 IF RESULT is non-missing Else missing if RESULT is missing	

Formatted values and ASSAYTYP for each value of ASSAY in OCLABLNG.

ASSAY	Formatted value	ASSAYTYP
ADIPOHMW	Adinopectin, HMW (ng/mL)	ENDOCRINE
ADIPOTOT	Adinopectin, Total (ng/mL)	ENDOCRINE
CHHDLR	Cholesterol Ratio	LIPIDS
CHOL	Cholesterol - Total (mg/dL)	LIPIDS
CORT	Cortisol (ug/dL)	ENDOCRINE
CPEP	C-Peptide S – fasting (pmol/L)	GLUCOSE
CPEP120	C-Peptide S - 120 minute (pmol/L)	GLUCOSE
CPEP30	C-Peptide S - 30 minute (pmol/L)	GLUCOSE
CPEP60	C-Peptide S (pmol/L) - 60 minute (pmol/L)	GLUCOSE
CPEP90	C-Peptide S (pmol/L) - 90 minute (pmol/L)	GLUCOSE
CPEPT	C-Peptide– fasting (ng/mL)	GLUCOSE
CPEPT120	C-Peptide - 120 minute (ng/mL)	GLUCOSE
CPEPT30	C-Peptide - 30 minute (ng/mL)	GLUCOSE

ASSAY	Formatted value	ASSAYTYP
CPEPT60	C-Peptide - 60 minute (ng/mL)	GLUCOSE
CPEPT90	C-Peptide - 90 minute (ng/mL)	GLUCOSE
CRP	CRP (C-Reactive Protein) (ug/mL)	INFLAMMATION
CTX	CTX (Serum beta Crosslaps (beta C-Terminal Telopeptide) (ug/L)	COLLAGEN TURNOVER
DHES	DHEA-S (ug/dL)	ENDOCRINE
DIPH	Diphtheria Antibody (IU/mL)	ANTIBODY RESPONSE
DIPH3	Diphtheria Antibody (24M visit 3) (IU/mL)	ANTIBODY RESPONSE
FRTES	Free testosterone (ng/dL)	SEX
FSH	Follicle Stimulating Hormone (mIU/mL)	SEX
GH	GH (Growth Hormone) (pg/mL)	GROWTH HORMONES
HAAB	Hepatitis A Antibody (IU/L)	ANTIBODY RESPONSE
HAAB3	Hepatitis A Antibody (24M Visit 3) (IU/L)	ANTIBODY RESPONSE
HDL	HDL Cholesterol (mg/dL)	LIPIDS
ICAM1	ICAM1 (Intercellular Adhesion Molecule 1) (ng/mL)	INFLAMMATION
IGF1	IGF1 (Insulin-like Growth Factor 1) (ng/mL)	GROWTH HORMONES / ENDOCRINE
IGFBP1	IGFBP1 (Insulin-like Growth Factor binding protein 1) (pg/mL)	GROWTH HORMONES
IGFBP3	IGFBP3 (Insulin-like Growth Factor binding protein 3) (ng/mL)	GROWTH HORMONES / ENDOCRINE
IL1B	IL1B (Interleukin 1 beta) (pg/mL)	INFLAMMATION
IL6	IL6 (Interleukin 6) (pg/mL)	INFLAMMATION
IL8	IL8 (Interleukin 8) (pg/mL)	INFLAMMATION
INS0	Insulin –fasting (ug/mL)	INFLAMMATION
INS120	Insulin - 120 minute (ug/mL)	INFLAMMATION
INS30	Insulin - 30 minute (ug/mL)	INFLAMMATION
INS60	Insulin - 60 minute (ug/mL)	INFLAMMATION
INS90	Insulin - 90 minute (ug/mL)	INFLAMMATION
LDL	LDL Cholesterol (mg/dL)	LIPIDS

ASSAY	Formatted value	ASSAYTYP
LEPTIN	Leptin (pg/mL)	INFLAMMATION
LH	Luteinizing Hormone (mIU/mL)	SEX
MCP1	MCP1 (Monocyte Chemoattractant Protein 1) (pg/mL)	INFLAMMATION
NOREP1	Norepinephrine 1 (pg/mL)	ENDOCRINE
NOREP2	Norepinephrine 2 (pg/mL)	ENDOCRINE
PDGFAB	PDGFAB (Platelet Derived Growth Factor AB) (pg/mL)	GROWTH HORMONES / ENDOCRINE
PINP	PINP (N-terminal propeptide of type 1 procollagen) (ug/L)	COLLAGEN TURNOVER
PRA	PRA (Plasma Renin Activity) (ng/ml/hr)	ENZYMES
SGL0	Glucose - fasting (mg/dL)	GLUCOSE
SGL120	Glucose – 120 minute (mg/dL)	GLUCOSE
SGL30	Glucose – 30 minute (mg/dL)	GLUCOSE
SGL60	Glucose – 60 minute (mg/dL)	GLUCOSE
SGL90	Glucose – 90 minute (mg/dL)	GLUCOSE
SHBG	Sex Hormone Binding Globulin (nmol/L)	SEX
T3	T3 (Triiodothyronine) Total (ng/dL)	ENDOCRINE
TESTO	Total Testosterone (ng/dL)	SEX
TETA	Tetanus Toxoid Antibody (IU/mL)	ANTIBODY RESPONSE
TETA3	Tetanus Toxoid Antibody (24M visit 3) (IU/mL)	ANTIBODY RESPONSE
TGFB1	TGFB1 (pg/mL)	GROWTH HORMONES
TNFA	TNF-a (Tumor Necrosis Factor alpha) (pg/mL)	INFLAMMATION
TRIG	Triglyceride (mg/dL)	LIPIDS
TSH	Thyroid Stimulating Hormone (uIU/mL)	ENDOCRINE

ASSAY	Formatted Value	ASSAYTYP
STRP01	Streptococcus pneumonia IgG Serotype 1	ANTIBODY RESPONSE
STRP02	Streptococcus pneumonia IgG Serotype 2	ANTIBODY RESPONSE

ASSAY	**Formatted Value**	**ASSAYTYP**
STRP03	Streptococcus pneumonia IgG Serotype 3	ANTIBODY RESPONSE
STRP04	Streptococcus pneumonia IgG Serotype 4	ANTIBODY RESPONSE
STRP05	Streptococcus pneumonia IgG Serotype 5	ANTIBODY RESPONSE
STRP06B	Streptococcus pneumonia IgG Serotype 6B	ANTIBODY RESPONSE
STRP07F	Streptococcus pneumonia IgG Serotype 7F	ANTIBODY RESPONSE
STRP08	Streptococcus pneumonia IgG Serotype 8	ANTIBODY RESPONSE
STRP09N	Streptococcus pneumonia IgG Serotype 9N	ANTIBODY RESPONSE
STRP09V	Streptococcus pneumonia IgG Serotype 9V	ANTIBODY RESPONSE
STRP10A	Streptococcus pneumonia IgG Serotype 10A	ANTIBODY RESPONSE
STRP11A	Streptococcus pneumonia IgG Serotype 11A	ANTIBODY RESPONSE
STRP12F	Streptococcus pneumonia IgG Serotype 12F	ANTIBODY RESPONSE
STRP14	Streptococcus pneumonia IgG Serotype 14	ANTIBODY RESPONSE
STRP15B	Streptococcus pneumonia IgG Serotype 15B	ANTIBODY RESPONSE
STRP17F	Streptococcus pneumonia IgG Serotype 17F	ANTIBODY RESPONSE
STRP18C	Streptococcus pneumonia IgG Serotype 18C	ANTIBODY RESPONSE
STRP19A	Streptococcus pneumonia IgG Serotype 19A	ANTIBODY RESPONSE
STRP19F	Streptococcus pneumonia IgG Serotype 19F	ANTIBODY RESPONSE
STRP20	Streptococcus pneumonia IgG Serotype 20	ANTIBODY RESPONSE
STRP22F	Streptococcus pneumonia IgG Serotype 22F	ANTIBODY RESPONSE
STRP23F	Streptococcus pneumonia IgG Serotype 23F	ANTIBODY RESPONSE
STRP33F	Streptococcus pneumonia IgG Serotype 33F	ANTIBODY RESPONSE
STRP01V3	Streptococcus pneumonia IgG Serotype 1	ANTIBODY RESPONSE
STRP02V3	Streptococcus pneumonia IgG Serotype 2	ANTIBODY RESPONSE
STRP03V3	Streptococcus pneumonia IgG Serotype 3	ANTIBODY RESPONSE
STRP04V3	Streptococcus pneumonia IgG Serotype 4	ANTIBODY RESPONSE

ASSAY	Formatted Value	ASSAYTYP
STRP05V3	Streptococcus pneumonia IgG Serotype 5	ANTIBODY RESPONSE
STRP06BV3	Streptococcus pneumonia IgG Serotype 6B	ANTIBODY RESPONSE
STRP07FV3	Streptococcus pneumonia IgG Serotype 7F	ANTIBODY RESPONSE
STRP08V3	Streptococcus pneumonia IgG Serotype 8	ANTIBODY RESPONSE
STRP09NV3	Streptococcus pneumonia IgG Serotype 9N	ANTIBODY RESPONSE
STRP09V3	Streptococcus pneumonia IgG Serotype 9V	ANTIBODY RESPONSE
STRP10AV3	Streptococcus pneumonia IgG Serotype 10A	ANTIBODY RESPONSE
STRP11AV3	Streptococcus pneumonia IgG Serotype 11A	ANTIBODY RESPONSE
STRP12FV3	Streptococcus pneumonia IgG Serotype 12F	ANTIBODY RESPONSE
STRP14V3	Streptococcus pneumonia IgG Serotype 14	ANTIBODY RESPONSE
STRP15BV3	Streptococcus pneumonia IgG Serotype 15B	ANTIBODY RESPONSE
STRP17FV3	Streptococcus pneumonia IgG Serotype 17F	ANTIBODY RESPONSE
STRP18CV3	Streptococcus pneumonia IgG Serotype 18C	ANTIBODY RESPONSE
STRP19AV3	Streptococcus pneumonia IgG Serotype 19A	ANTIBODY RESPONSE
STRP19FV3	Streptococcus pneumonia IgG Serotype 19F	ANTIBODY RESPONSE
STRP20V3	Streptococcus pneumonia IgG Serotype 20	ANTIBODY RESPONSE
STRP22FV3	Streptococcus pneumonia IgG Serotype 22F	ANTIBODY RESPONSE
STRP23FV3	Streptococcus pneumonia IgG Serotype 23F	ANTIBODY RESPONSE
STRP33FV3	Streptococcus pneumonia IgG Serotype 33F	ANTIBODY RESPONSE

Trial name	**CALERIE 2**
Dataset name	**OCLABFLT (outcome labs, flat)**
Description	Outcome labs from Vermont lab, flattened to 1 record per DEIDNUM / VISIT. Lab results are merged with CRF data, so there is a record for all study visits that were attended at which lab tests was expected, even if there are no lab results.
Comments on data structure	1 record / DEIDNUM/ VISIT
Population	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
Visits	0, 9, 11, 11.1, 12, 12.1, 13 (See Appendix for VISIT codes)
Usage notes	Most assays are only done at visits 0, 11 and 13, but a few others, including antibody response are done at visits 11.1, 12, 12.1, and only CTX is done at visit 9.
Source data files	CRF/OUTCMELB, ANALDATA/SUBJECT1, VO2MAX, OCLABLNG
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	OUTCMELB.PAGEID	N		
VISIT	Visit	PAGENUM, OCLABLNG.VISIT	N	Study Visit, based on CRF page (See Appendix), and OCLABLNG.VISIT	VISFMT
SUBVISIT	Sub-Visit	OUTCMELB.PAGENUM, OCLABLNG.SUBVISIT	N	Study Sub-visit, based on CRF page (See Appendix), and OCLABLNG.SUBVISIT	SVISFMT
LMEALTM	Date/time of last meal	OUTCMELB.LMEALTM	DTM		Datetime13
SAMPDT	Sample collection date	OUTCMELB.SAMPDT	DT		Date
SAMPTM	Sample collection date/time	OUTCMELB.SAMPTM	DTM		Datetime13
LMEALHRS	Last meal to sample collection (hours)	LMEALTM, SAMPTM	N	=SAMPTM – LMEALTM (hours)	
CRFCAT	Catecholamine collection done (CRF)	OUTCMELB.OTCMSAMP OUTCMELB.SAMPCOL	N	=1 if OTCMSAMP=1 and SAMPCOL=1 else =0 if OTCMSAMP=1 and (SAMPCOL<1 or SAMPND is non-missing)	
CATNDRSN	Reason catecholamine not collected	OUTCMELB.OTCMSAMP OUTCMELB.SAMPND	N	=SAMPND if OUTCMSAMP=1	TUND
CRFBLD	Outcome blood collection done (CRF)	OUTCMELB.OTCMSAMP	N	=1 if OTCMSAMP=2 and SAMPCOL=1	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
		OUTCMELB.SAMPCOL		else =0 if OTCMSAMP=2 and (SAMPCOLM<1 or SAMPND is non-missing)	
BLDNDRSN	Reason outcome blood not collected	OUTCMELB.OTCMSAMP OUTCMELB.SAMPND	N	=SAMPND if OUTCMSAMP=2	TUND
CRFOGTT	OGTT performed	OUTCMELB.OTCMSAMP OUTCMELB.SAMPCOL	N	=1 if OTCMSAMP=3 and SAMPCOL=1 else =0 if OTCMSAMP=3 and (SAMPCOL<1 or SAMPND is non-missing)	
OGTTNDRS	Reason OGTT not performed	OUTCMELB.OTCMSAMP OUTCMELB.SAMPND	N	=SAMPND if OUTCMSAMP=3	
OGTTHRS	Hours from treadmill test to OGTT	SAMPTM, VOMAXDTM	N	=SAMPTM – VOMAXDTM (in hours, rounded to 2 decimal places)	
VACNDRSN	Reason vaccines not given	OUTCMELB.OTCMSAMP OUTCMELB.SAMPND	N	=SAMPND if OUTCMSAMP=4	
HEPA	Hepatitis A Vaccine given	OUTCMELB.HEPA	N	Defined only if Visit in (11.1, 12.1) (Months 17 and 23) =1 if HEPA=1 else =0	
TD	Tetanus/diphtheria vaccine given	OUTCMELB.TD	N	Defined only if VISIT=11.1 (Month 17) =1 if TD=1 else =0	
PV	Pneumococcal vaccine given	OUTCMELB.PV	N	Defined only if VISIT=11.1 (Month 17) =1 if PV=1 else =0	
VMNTLAB	Have Vermont lab data	VERTMONTLAB	N	=1 if there is at least one record from OCLABLNG for that DEIDNUM/VISIT. Else =0	
		For ADIPOHMW – TGFB1, the source variables are from OCLABLNG			
ADIPOHMW	Adiponectin, HMW (ng/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = ADIPOHMW	
ADIPOTOT	Adiponectin, Total (ng/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = ADIPOTOT	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
CHHDLR	Cholesterol Ratio	ASSAY, RESULT	N	= RESULT if ASSAY = CHHDLR	
CHOL	Cholesterol Total (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = CHOL	
CORT	Cortisol (ug/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = CORT	
CPEP	C-Peptide S – fasting (pmol/L)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEP	
CPEP30	C-Peptide S - 30 minute (pmol/L)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEP30	
CPEP60	C-Peptide S - 60 minute (pmol/L)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEP60	
CPEP90	C-Peptide S - 90 minute (pmol/L)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEP90	
CPEP120	C-Peptide S - 120 minute (pmol/L)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEP120	
CPEPT	C-Peptide– fasting (ng/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEPT	
CPEPT30	C-Peptide - 30 minute (ng/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEPT30	
CPEPT60	C-Peptide - 60 minute (ng/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEPT60	
CPEPT90	C-Peptide - 90 minute (ng/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEPT90	
CPEPT120	C-Peptide - 120 minute (ng/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = CPEPT120	
CRP	CRP (C-Reactive Protein) (ug/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = CRP	
CRP_GRP	CRP grouped	ASSAY, QUALITY	N	If ASSAY=CRP: =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
DHES	DHEA-S (ug/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = DHES	
FRTES	Free Testosterone (ng/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = FRTES	
FSH	Follicle Stimulating Hormone (mIU/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = FSH	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
GH	GH (Growth Hormone) (pg/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = GH	
HDL	HDL Cholesterol (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = HDL	
ICAM1	ICAM1 (ng/mL)	ASSAY, RESULT	N	(Intercellular Adhesion Molecule 1) = RESULT if ASSAY = ICAM1	
IGF1	IGF1 (ng/mL)	ASSAY, RESULT	N	(Insulin-like Growth Factor 1) = RESULT if ASSAY = IGF1	
IL1B	IL1B (Interleukin 1 beta) (pg/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = IL1B	
IL1B_GRP	IL1B grouped	ASSAY, QUALITY	N	If ASSAY=IL1B =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
IL6	IL6 (Interleukin 6) (pg/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = IL6	
IL6_GRP	IL6 grouped	ASSAY, QUALITY	N	If ASSAY=IL6 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
IL8	IL8 (Interleukin 8) (pg/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = IL8	
LDL	LDL Cholesterol (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = LDL	
LEPTIN	Leptin (pg/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = LEPTIN	
LH	LH (Luteinizing Hormone) (mIU/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = LH	
MCP1	MCP1 (pg/mL)	ASSAY, RESULT	N	(Monocyte Chemoattractant Protein 1) = RESULT if ASSAY = MCP1	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
NOREP1	Norepinephrine 1 (pg/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = NOREP1	
NOREP2	Norepinephrine 2 (pg/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = NOREP2	
NOREP	Norepinephrine (pg/mL)	NOREP1, NOREP2	N	=mean (NOREP1, NOREP2)	
SGL0	Glucose - fasting (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = SGL0	
SGL30	Glucose – 120 minute (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = SGL30	
SGL60	Glucose – 30 minute (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = SGL60	
SGL90	Glucose – 60 minute (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = SGL90	
SGL120	Glucose – 90 minute (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = SGL120	
SHBG	Sex Hormone Binding Globulin (nmol/L)	ASSAY, RESULT	N	= RESULT if ASSAY = SHBG	
T3	T3 (Triiodothyronine) total (ng/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = T3	
TESTO	Total Testosterone (ng/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = TESTO	
TNFA	TNF-a (pg/mL)	ASSAY, RESULT	N	(Tumor Necrosis Factor alpha) = RESULT if ASSAY = TNFA	
TRIG	Triglyceride (mg/dL)	ASSAY, RESULT	N	= RESULT if ASSAY = TRIG	
TSH	Thyroid Stimulating Hormone (uIU/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = TSH	
CTX	CTX (ug/L)	ASSAY, RESULT	N	(Serum beta Crosslaps (beta C-Terminal Telopeptide) = RESULT if ASSAY = CTX	
HAAB	Hepatitis A Antibody (IU/L)	ASSAY, RESULT	N	= RESULT if ASSAY = HAAB or HAAB3	
HAAB_GRP	Hepatitis A Antibody grouped	ASSAY, QUALITY	N	If ASSAY=HAAB or HAAB3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
IGFBP1	IGFBP1 (pg/mL)	ASSAY, RESULT	N	(Insulin-like Growth Factor binding protein 1) = RESULT if ASSAY = IGFBP1	
IGFBP3	IGFBP3 (ng/mL)	ASSAY, RESULT	N	(Insulin-like Growth Factor binding protein 3) = RESULT if ASSAY = IGFBP3	
INS0	Insulin –fasting (ug/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = INS0	
INS30	Insulin - 30 minute (ug/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = INS30	
INS60	Insulin - 60 minute (ug/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = INS60	
INS90	Insulin - 90 minute (ug/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = INS90	
INS120	Insulin - 120 minute (ug/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = INS120	
PDGFAB	PDGFAB (pg/mL)	ASSAY, RESULT	N	(Platelet Derived Growth Factor AB) = RESULT if ASSAY = PDGFAB	
PINP	PINP (ug/L)	ASSAY, RESULT	N	(N-terminal propeptide of type 1 procollagen) = RESULT if ASSAY = PINP	
PRA	PRA (Plasma Renin Activity) (ng/ml/hr)	ASSAY, RESULT	N	= RESULT if ASSAY = PRA	
PRA_GRP	PRA grouped	ASSAY, QUALITY	N	If ASSAY=PRA =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
TETA	Tetanus Toxoid Antibody (IU/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = TETA or TETA3	
TETA_GRP	Tetanus Toxoid Antibody grouped	ASSAY, QUALITY	N	If ASSAY=TETA or TETA3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
TGFB1	TGFB1 (pg/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = TGFB1	
	The following variables are derived variables for glucose and insulin sensitivity.				
AUCGLUC	AUC Glucose from OGTT (mg·hr/dL)	SGL0, SGL30, SGL60, SGL90, SGL120	N	=0.25 x (SGL0 + 2 x SGL30 + 2 x SGL60 + 2 x SGL90 + SGL120)	
AUCINS	AUC Insulin from OGTT (IU·hr/mL)	INS0, INS30, INS60, INS90, INS120	N	= 0.25 x (INS0 + 2 x INS30 + 2 x INS60 + 2 x INS90 + INS120)	
HOMAIR	HOMA-IR	INS0, SGL0	N	= INS0 x SGL0 / 405	
HOMABETA	HOMA-beta (%)	INS0, SGL0	N	= (360 x INS0) / (SGL0 -63)	
INSRESP	Insulin response	INS0, INS30, SGL0, SGL30	N	= (INS30 – INS0) / (SGL30 – SGL0)	
INSSENS	Insulin sensitivity	INS0	N	= 1 / INS0	
ODINDEX	Oral Disposition Index (DIo)	INSRESP, INSSENS	N	= INSRESP x INSSENS	
DIPH	Diphtheria Antibody (IU/mL)	ASSAY, RESULT	N	= RESULT if ASSAY = DIPH or DIPH3	
DIPH_GRP	Diphtheria grouped	ASSAY, QUALITY	N	If ASSAY=DIPH or DIPH3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP01	Streptococcus pneumonia IgG Serotype 1	ASSAY, RESULT	N	= RESULT if ASSAY = STRP01 or STRP01V3	
S01_GRP	STRP01 grouped	ASSAY, QUALITY	N	If ASSAY=STRP01 or STRP01V3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP02	Streptococcus pneumonia IgG Serotype 2	ASSAY, RESULT	N	= RESULT if ASSAY = STRP02 or STRP02V3	
S02_GRP	STRP02 grouped	ASSAY, QUALITY	N	If ASSAY=STRP02 or STRP02V3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
STRP03	Streptococcus pneumonia IgG Serotype 3	ASSAY, RESULT	N	= RESULT if ASSAY = STRP03 or STRP03V3	
S03_GRP	STRP03 grouped	ASSAY, QUALITY	N	If ASSAY=STRP03 or STRP03V3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP04	Streptococcus pneumonia IgG Serotype 4	ASSAY, RESULT	N	= RESULT if ASSAY = STRP04 or STRP04V3	
S04_GRP	STRP04 grouped	ASSAY, QUALITY	N	If ASSAY=STRP04 or STRP04V3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP05	Streptococcus pneumonia IgG Serotype 5	ASSAY, RESULT	N	= RESULT if ASSAY = STRP05 or STRP05V3	
S05_GRP	STRP05 grouped	ASSAY, QUALITY	N	If ASSAY=STRP05 or STRP05V3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP06B	Streptococcus pneumonia IgG Serotype 6B	ASSAY, RESULT	N	= RESULT if ASSAY = STRP06B or STRP06BV3	
S06B_GRP	STRP06B grouped	ASSAY, QUALITY	N	If ASSAY=STRP06B or STRP06BV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP07F	Streptococcus pneumonia IgG Serotype 7F	ASSAY, RESULT	N	= RESULT if ASSAY = STRP07F or STRP07FV3	
S07F_GRP	STRP07F grouped	ASSAY, QUALITY	N	If ASSAY=STRP07F or STRP07FV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP08	Streptococcus pneumonia IgG Serotype 8	ASSAY, RESULT	N	= RESULT if ASSAY = STRP08 or STRP08V3	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
S08_GRP	STRP08 grouped	ASSAY, QUALITY	N	If ASSAY=STRP08 or STRP08V3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP09N	Streptococcus pneumonia IgG Serotype 9N	ASSAY, RESULT	N	= RESULT if ASSAY = STRP09N or STRP09NV3	
S09N_GRP	STRP09N grouped	ASSAY, QUALITY	N	If ASSAY=STRP09N or STRP09NV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP09V	Streptococcus pneumonia IgG Serotype 9V	ASSAY, RESULT	N	= RESULT if ASSAY = STRP09V or STRP09VV3	
S09V_GRP	STRP09V grouped	ASSAY, QUALITY	N	If ASSAY=STRP09V or STRP09VV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP10A	Streptococcus pneumonia IgG Serotype 10A	ASSAY, RESULT	N	= RESULT if ASSAY = STRP10A or STRP10AV3	
S10A_GRP	STRP10A grouped	ASSAY, QUALITY	N	If ASSAY=STRP10A or STRP10AV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP11A	Streptococcus pneumonia IgG Serotype 11A	ASSAY, RESULT	N	= RESULT if ASSAY = STRP11A or STRP11AV3	
S11A_GRP	STRP11A grouped	ASSAY, QUALITY	N	If ASSAY=STRP11A or STRP11AV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP12F	Streptococcus pneumonia IgG Serotype 12F	ASSAY, RESULT	N	= RESULT if ASSAY = STRP12F or STRP12FV3	
S12F_GRP	STRP12F grouped	ASSAY, QUALITY	N	If ASSAY=STRP12F or STRP12FV3 =1 if QUALITY=6 =2 if QUALITY=1	1=below detectable limit 2=Normal

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
				=3 if QUALITY=7 Else missing	3=above detectable limit
STRP14	Streptococcus pneumonia IgG Serotype 14	ASSAY, RESULT	N	= RESULT if ASSAY = STRP14 or STRP14V3	
S14_GRP	STRP14 grouped	ASSAY, QUALITY	N	If ASSAY=STRP14 or STRP14V3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP15B	Streptococcus pneumonia IgG Serotype 15B	ASSAY, RESULT	N	= RESULT if ASSAY = STRP15B or STRP15BV3	
S15B_GRP	STRP15B grouped	ASSAY, QUALITY	N	If ASSAY=STRP15B or STRP15BV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP17F	Streptococcus pneumonia IgG Serotype 17F	ASSAY, RESULT	N	= RESULT if ASSAY = STRP17F or STRP17FV3	
S17F_GRP	STRP17F grouped	ASSAY, QUALITY	N	If ASSAY=STRP17F or STRP17FV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP18C	Streptococcus pneumonia IgG Serotype 18C	ASSAY, RESULT	N	= RESULT if ASSAY = STRP18C or STRP18CV3	
S18C_GRP	STRP18C grouped	ASSAY, QUALITY	N	If ASSAY=STRP18C or STRP18CV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP19A	Streptococcus pneumonia IgG Serotype 19A	ASSAY, RESULT	N	= RESULT if ASSAY = STRP19A or STRP19AV3	
S19A_GRP	STRP19A grouped	ASSAY, QUALITY	N	If ASSAY=STRP19A or STRP19AV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
STRP19F	Streptococcus pneumonia IgG Serotype 19F	ASSAY, RESULT	N	= RESULT if ASSAY = STRP19F or STRP19FV3	
S19F_GRP	STRP19F grouped	ASSAY, QUALITY	N	If ASSAY=STRP19F or STRP19FV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP20	Streptococcus pneumonia IgG Serotype 20	ASSAY, RESULT	N	= RESULT if ASSAY = STRP20 or STRP20V3	
S20_GRP	STRP20 grouped	ASSAY, QUALITY	N	If ASSAY=STRP20 or STRP20V3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP22F	Streptococcus pneumonia IgG Serotype 22F	ASSAY, RESULT	N	= RESULT if ASSAY = STRP22F or STRP22FV3	
S22F_GRP	STRP22F grouped	ASSAY, QUALITY	N	If ASSAY=STRP22F or STRP22FV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP23F	Streptococcus pneumonia IgG Serotype 23F	ASSAY, RESULT	N	= RESULT if ASSAY = STRP23F or STRP23FV3	
S23F_GRP	STRP23F grouped	ASSAY, QUALITY	N	If ASSAY=STRP23F or STRP23FV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit
STRP33F	Streptococcus pneumonia IgG Serotype 33F	ASSAY, RESULT	N	= RESULT if ASSAY = STRP33F or STRP33FV3	
S33F_GRP	STRP33F grouped	ASSAY, QUALITY	N	If ASSAY=STRP33F or STRP33FV3 =1 if QUALITY=6 =2 if QUALITY=1 =3 if QUALITY=7 Else missing	1=below detectable limit 2=Normal 3=above detectable limit

Trial name	**CALERIE 2**
Dataset name	**SFLABLNG (safety lab data, stacked)**
Description	Safety labs stacked with 1 record for each assay. Safety labs were collected at all study visits, and if needed at unscheduled visits. For all protocol scheduled lab visits, lab results are merged with CRF data.
Comments on data structure	1 record / DEIDNUM/ VISIT/ COLDT / TESTCODE (stacked tests)
Population	All subjects who had baseline evaluations, including all randomized subjects
Visits	4, 6.1, 7, 7.1, 7.2, 8, 8.1, 8.2, 9, 10, 11, 12, 13 Unscheduled safety labs do not have a VISIT value. (See Appendix for VISIT codes)
Usage notes	Some assays have numeric results (RESULTN), and others have qualitative, character results (RESULTC). There are a few assays (eg INSM, TLDLC, TSG) which usually have numeric results, but in some cases have character results if the results are outside the detectable range. Records with missing VISIT were unscheduled safety labs, eg, if a subject had abnormal results at a visit and needed to retest.
Source data files	CRF/SAFETYLB, LABS/SAFETY ANALDATA/SUBJECT1
Final sort order	DEIDNUM VISIT COLDT TESTCODE

Variable name	**LABEL**	**Source variables**	**C/N ?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
PAGENUM	CRF page number	SAFETYLB.PAGEID	N		
VISIT	Visit	PAGENUM, SAFETY.SFORM	N	Study Visit, based on CRF page for CRF data Or SFORM for SAFETY data =4 if SFORM=BASELINE =7 if SFORM=MONTH 1 =8 if SFORM=MONTH 3 =9 if SFORM=MONTH 6 =10 if SFORM=MONTH 9 =11 if SFORM=MONTH 12 =12 if SFORM=MONTH 18 =13 if SFORM=MONTH 24 Missing for off-schedule visit	VISFMT

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
				See appendix for codes.	
SUBVISIT	Sub-Visit	PAGENUM, SAFETY.SFORM	N	Study Sub-visit, based on CRF page for CRF data Or SFORM for SAFETY data =5 if SFORM=BASELINE =14 if SFORM=MONTH 1 =17 if SFORM=MONTH 3 =20 if SFORM=MONTH 6 =24 if SFORM=MONTH 9 =25 if SFORM=MONTH 12 =31 if SFORM=MONTH 18 =35 if SFORM=MONTH 24 Missing for off-schedule visit See appendix for codes.	SVISFMT
COLDT	Sample collection date (lab)	SAFETY.COLDT	DT		Date
CRFSFBLD	Blood collection done (CRF)	SAFETYLB.BLSMPCOL SAFETYLB.BLSMPND	N	Only defined if the record was in SAFETYLB: =1 if BLSMPCOL=1 else =0 if BLSMPCOL=0 or BLSMPND is non-missing else missing	
BLSMPND	Reason blood not collected	SAFETYLB.BLSMPND	N		TUND
CRFSFURN	Urine collection done (CRF)	SAFETYLB.URSMPCOL SAFETYLB.URSMPND	N	Only defined if the record was in SAFETYLB: =1 if URSMPCOL=1 else =0 if URSMPCOL=0 or URSMPND is non-missing else missing	
URSMPND	Reason urine not collected	SAFETYLB.URSMPND	N		TUND
SFTYLAB	Safety lab data received	SAFETY.SAMPTM	N	=1 if the record was in SAFETY else =0	
TESTCODE	Test code	SAFETY.TESTCODE	C		
TESTSHRT	Test name	SAFETY.TESTCODE	C		
RESULTC	Test result (qualitative)	SAFETY.RESULTS	C		
RESULTN	Test result (quantitative)	SAFETY.RESULTN	N		

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
SUNIT	Test units	SAFETY.UNIT	C		
LOWREF	Lower normal bound	SAFETY.LOWREF	N	Convert from C to N	
HIGHREF	Upper normal bound	SAFETY.HIGHREF	N	Convert from C to N	
ALERTHL	Calculated abnormal test result (H/L)	RESULTN, LOWREF, HIGHREF, ALERT	N	= -1 if (RESULTN is non missing and LOWREF is non-missing and RESULTN<LOWREF) Else =1 if (RESULTN is non missing and HIGHREF is non-missing and RESULTN>HIGHREF) Else=0 if RESULTN is non-missing or RESULTC is non-missing Else missing	-1 = Low 0 = Normal 1= High

Trial name	**CALERIE 2**
Dataset name	**SFLABFLT (Safety lab, flat)**
Description	Safety lab data flattened to 1 record per DEIDNUM / VISIT, with a variable for each Safety assay. Some assays have numeric results, while others have character value results. A few assays, (INSM, TLDLC, TSG) have both numeric and character results – eg, if the result is beyond detectable limits, the numeric value is missing, and character results are given. This dataset only contains records for Safety labs collected at protocol specified time-points, and does not include unscheduled safety labs, or safety labs for weeks 2, 6, 8 or months 4 and 5, which were dropped from the protocol. See SFLABLNG for unscheduled safety labs.
Comments on data structure	1 record / DEIDNUM / VISIT
Population	All subjects who had baseline evaluations, including all randomized subjects
Visits	0, 7, 8, 9, 10, 11, 12, 13 (See Appendix for VISIT codes)
Usage notes	Note that for INSM, TLDLC, and TSG, which normally have numeric values, some subjects have character values instead (INSM_C, TLDLC_C, TSG_C) because the results were beyond detectable limits, or some other reason. This dataset does not include unscheduled safety labs, or safety labs for weeks 2, 6, 8 or months 4 and 5, which were dropped from the protocol. See SFLABLNG for unscheduled or other non-protocol safety labs.
Source data files	ANALDATA / SFLABLNG
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	PAGENUM	N		
VISIT	Visit	VISIT	N		VISFMT
SUBVISIT	Sub-visit	SUBVISIT	N		SVISFMT
COLDT	Sample collection date (lab)	COLDT	DT		Date
CRFSFBLD	Blood collection done (CRF)	CRFSFBLD	N		
BLSMPND	Reason blood not collected	BLSMPND	N		TUND
CRFSFURN	Urine collection done (CRF)	CRFSFURN	N		
URSMPND	Reason urine not collected (CRF)	URSMPND	N		TUND
SFTYLAB	Safety lab data received	SFTYLAB	N		

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
AMMB	Ammonium Biurate	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='AMMB'	
AMMTPH	Triple Phosphate	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='AMMTPH'	
AMURPH	Amorphous Urates or Phosphates	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='AMURPH'	
BACUA	Bacteria	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='BACUA'	
BASOAA	Basophils, Absolute (10^3/Ul)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='BASOAA'	
BASOPA	Basophils (%)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='BASOPA'	
CALC	Calcium Oxalate	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='CALC'	
EOSNAA	Eosinophils, Absolute (10^3/Ul)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='EOSNAA'	
EOSNPA	Eosinophils (%)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='EOSNPA'	
FIBER	Fiber	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='FIBER'	
HCT	Hematocrit (%)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='HCT'	
HGB	Hemoglobin (g/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='HGB'	
HYLC	Hyaline Cast	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='HYLC'	
INSM	Insulin (Uu/Ml)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='INSM'	
INSM_C	Insulin – character result	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='INSM'	
LYMPAA	Lymphocytes, Absolute (10^3/Ul)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='LYMPAA'	
LYMPPA	Lymphocytes (%)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='LYMPPA'	
MCH	Mean Corpuscular Hemoglobin (pg)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='MCH'	
MCHC	Mean Corpuscular Hgb Conc (g/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='MCHC'	
MCV	Mean Cell Volume (Fl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='MCV'	
MONOAA	Monocytes, Absolute (10^3/Ul)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='MONOAA'	
MONOPA	Monocytes (%)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='MONOPA'	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
MUCUS	Mucus	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='MUCUS'	
NEUTAA	Neutrophils, Absolute (10^3/Ul)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='NEUTAA'	
NEUTPA	Neutrophils (%)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='NEUTPA'	
NRBCAA	Nucleated RBC, Absolute (10^3/Ul)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='NRBCAA'	
NRBCPA	Nucleated RBC (%)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='NRBCPA'	
PLT	Platelet Count (10^3/Ul)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='PLT'	
PLTASS	Platelet Assessment	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='PLTASS'	
POLLEN	Pollen	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='POLLEN'	
RBC	Red Blood Cells (10^6/Ul)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='RBC'	
RBCC	RBC Cast	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='RBCC'	
RBCMOR	RBC Morphology	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='RBCMOR'	
RBCUA	RBC Urine	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='RBCUA'	
SEP	Squamous Epithelial Cells	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='SEP'	
SPERM	Sperm	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='SPERM'	
STARCH2	Starch	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='STARCH'	
TALB	Albumin (g/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TALB'	
TALP	Alkaline Phosphatase (IU/L)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TALP'	
TALT	ALT (SGPT) (IU/L)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TALT'	
TAST	AST (SGOT) (IU/L)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TAST'	
TBLD	UA Blood	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='TBLD'	
TBUN	Blood Urea Nitrogen (mg/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TBUN'	
TCAL	Calcium (mg/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TCAL'	

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
TCHL	Cholesterol (mg/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TCHL’	
TCK	Creatine Kinase (IU/L)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TCK’	
TCRE	Creatinine (mg/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TCRE’	
TCRPHR	Cardiac CRP (mg/L)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TCRPHR’	
TEP	Transitional Epithelial Cells	TESTCODE, RESULTC	C	=RESULTC if TESTCODE=’TEP’	
TFE	Iron (ug/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TFE’	
TGFRB	Egfr (Afr. American) (Ml/min/1.73*m$^{2)}$	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TGFRB’	
TGFRW	Egfr (Ml/min/1.73*m$^{2)}$	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TGFRW’	
TGGT	Gamma Glutamyl Transferase (IU/L)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TGGT’	
TGLS	Serum Glucose (mg/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TGLS’	
TGLUA	UA Glucose	TESTCODE, RESULTC	C	=RESULTC if TESTCODE=’TGLUA’	
THCGS	BHCG	TESTCODE, RESULTC	C	=RESULTC if TESTCODE=’THCGS’	
THDL	HDL (mg/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’THDL’	
TK	Potassium (mEq/L)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TK’	
TKET	UA Ketones	TESTCODE, RESULTC	C	=RESULTC if TESTCODE=’TKET’	
TLDLC	LDL Calc (mg/Dl)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TLDLC’	
TLDLC_C	LDL - character value	TESTCODE, RESULTC	C	=RESULTC if TESTCODE=’TLDLC’	
TMAG	Magnesium (mg/dL)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TMAG’	
TNA	Sodium (mEq/L)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TNA’	
TPH	pH	TESTCODE, RESULTN	N	=RESULTN if TESTCODE=’TPH’	
TPROTEIN	Urine Protein	TESTCODE, RESULTC	C	=RESULTC if TESTCODE=’TPROT’	
TRICHOM	Trichomonas	TESTCODE, RESULTC	C	=RESULTC if TESTCODE=’TRICH’	

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
TSG	Specific gravity (SGU)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TSG'	
TSG_C	Specific gravity – character value	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='TSG'	
TTBL	Total Bili (mg/dL)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TTBL'	
TTP	Total Protein (g/dL)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TTP'	
TTRG	Triglycerides (mg/dL)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TTRG'	
TUA	Uric Acid (mg/dL)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='TUA'	
UACRY	Uric Acid Crystal	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='UACRY'	
WBC	White Blood Cells (10^3/uL)	TESTCODE, RESULTN	N	=RESULTN if TESTCODE='WBC'	
WBCC	WBC Cast	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='WBCC'	
WBCMOR	WBC Morphology	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='WBCMOR'	
WBCUA	WBC Urine	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='WBCUA'	
YSTUA	Yeast	TESTCODE, RESULTC	C	=RESULTC if TESTCODE='YSTUA'	

Trial name	**CALERIE 2**
Dataset name	**BDI (Beck Depression Inventory)**
Description	Beck Depression Inventory data from CRF. The raw data has 3 records per DEIDNUM / VISIT, 1 record for each of 3 pages of the questionnaire. This is flattened to 1 record per DEIDNUM / VISIT. Includes responses to each item on the questionnaire, and derived scores. Scores are derived using the official BDI 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	4, 7, 8, 9, 10, 11, 12, 13 (See Appendix for VISIT codes)
Source data files	CRF/BDIQ, DATEHDR, SUBJECT1, DEPRESS, ANALDATA/IVRSRAND
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	BDIQ.PAGEID	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
BDIDT	Date of BDI	DATEHDR.STUDYDT	DT		DT
BDINDRSN	Reason BDI not done	DATEHDR..STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFBDI	BDI done	BDIDT, BDINDRSN	N	=1 if BDIDT is non-missing else =0	
	The following 21 variables (SADNESS – SEXINTR) are the responses to each item on the questionnaire.				**See CRF for formatted values**
SADNESS	Sadness	BDIQ.SADNESS	N		TUSAD
PESSIMIS	Pessimism	BDIQ.PESSIMIS	N		TUPESS

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
FAILURE	Past failure	BDIQ.FAILURE	N		TUFAIL
PLEASURE	Loss of pleasure	BDIQ.PLEASURE	N		TUPLEA
GUILTY	Guilty feelings	BDIQ.GUILTY	N		TUGUIL
PUNISH	Punishment feelings	BDIQ.PUNISH	N		TUPUNI
DISLIKE	Self-dislike	BDIQ.DISLIKE	N		TUDISL
		BDIQ refers to			
CRITICAL	Self-criticalness	BDIQ.CRITICAL	N		TUCRIT
SUICIDAL	Suicidal thoughts or wishes	BDIQ.SUICIDAL	N		TUSUIC
CRYING	Crying	BDIQ.CRYING	N		TUCRY
AGITATIO	Agitation	BDIQ.AGITATIO	N		TUAGIT
INTEREST	Loss of interest	BDIQ.INTEREST	N		TUINTR
INDECISI	Indecisiveness	BDIQ.INDECISI	N		TUINDE
WORTHLES	Worthlessness	BDIQ.WORTHLES	N		TUWORT
ENERGY	Loss of energy	BDIQ.ENERGY	N		TUENER
SLEEPING	Changes in sleeping pattern	BDIQ.SLEEPING	N		TUSLEE
IRRITABI	Irritability	BDIQ.IRRITABI	N		TUIRRI
APPETITE	Changes in appetite	BDIQ.APPETITE	N		TUAPPE
CONCENTR	Concentration difficulty	BDIQ.CONCENTR	N		TUCONC
FATIGUEB	Tiredness or fatigue	BDIQ.FATIGUE	N		TUFATI
SEXINTR	Loss of interest in sex	BDIQ.SEXINTR	N		TUSEXI
SLEEP_R	Sleeping – recoded	SLEEPING	N	SLEEPING is recoded according to scoring algorithm. =0 if SLEEPING = 0	

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
				=1 if SLEEPING in 1, 2 =2 if SLEEPING IN 3, 4 =3 if SLEEPING in 5, 6	
APPETI_R	Appetite – recoded	APPETITE	N	APPETITE is recoded according to scoring algorithm. =0 if APPETITE = 0 =1 if APPETITE in 1, 2 =2 if APPETITE IN 3, 4 =3 if APPETITE in 5, 6	
NBDI	Number of non-missing BDI items	SADNESS - - SEXINTR	N	=Number of non-missing variables among SADNESS – SEXINTR	
NMISSBDI	Number of missing BDI items	SADNESS - - SEXINTR	N	Defined only if CRFBDI=1. =Number of missing variables among SADNESS – SEXINTR missing if CRFBDI<1.	
SUMBDI	Total BDI score	SADNESS – ENERGY, IRRITABI, CONCENTR-SEXINTR, SLEEP_R, APPETI_R, NUMMISS	N	Total BDI Score: missing if >10% of items (>2) are missing. If 1 item is missing, impute value using mean of all non-missing items. Missing if NBDI<19 Else, if NBDI>=19, =(Sum of non-missing variables: SADNESS, PESSIMIS, FAILURE, PLEASURE, GUILTY, PUNISH, DISLIKE, CRITICAL, SUICIDAL, CRYING, AGITATIO, INTEREST, INDECISI, WORTHLES, ENERGY, IRRITABI, CONCENTR, FATIGUEB, SEXINTR, SLEEP_R, APPETI_R) multiplied by (21 / NBDI).	
BDIGRP	BDI grouped result	SUMBDI	N	=1 if 0<= SUMBDI <=13 =2 if 14 <= SUMBDI <=19 =3 if 20 <= SUMBDI <=28 =4 if 29 <= SUMBDI <=63	1=minimal depression 2=mild depression 3=moderate depression 4=severe depression

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
BDIALERT	Flagged for depression (BDI Score >=21)	SUMBDI	N	=1 if SUMBDI >= 20 else missing	
BDISURV	Depression report received	DEPRESS, IVRSRAND.TX	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 DEPRESS for that DEIDNUM else =0	-1='NA' 0='No' 1='Yes'

Trial name	**CALERIE 2**
Dataset name	**BSQA (Body Shape Questionnaire)**
Description	Body Shape Questionnaire data from CRF, flattened to 1 record per DEIDNUM/VISIT. Raw data is stacked with 1 record for each of the 34 questions. Includes responses to each item on the questionnaire, and derived scores. Scores are derived using the official BSQ 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/BSQ, 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	BSQ.PAGEID	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
BSQDT	Date of BSQ	DATEHDR.STUDYDT	DT		DT
BSQNDRSN	Reason BSQ not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFBSQ	BSQ done	BSQDT, BSQNDRSN	N	=1 if BSQDT is non-missing else =0 if VISSTAT=1. Else missing	
BSQ1 – BSQ34	Response for BSQ questionnaire item 1 – 34	BSQ.BSQQUES, BSQ.BSQANSW		BSQ[N]=BSQANSW IF BSQQUES=N	TUBSQW
NBSQ	Total non-missing BSQ items	BSQ1 – BSQ34	N	Number of non-missings in BSQ1 – BSQ34	
NMISSBSQ	Total missing BSQ items	BSQ1 – BSQ34	N	Defined only if CRFBSQ=1. Number of missings in BSQ1 – BSQ34 Missing if CRFBSQ < 1	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
BSQSCORE	BSQ score	BSQ1 – BSQ34	N	Missing if >10% of items are missing (NMISSBSQ>3.) If 1-3 items are missing, impute them using the mean of the non-missing items. = sum of all the non missing BSQ1 – BSQ34 plus NMISSBSQ x the mean of all the non-missing BSQ1 – BSQ34	

Trial name	**CALERIE 2**
Dataset name	**DEROGATI (Derogatis interview for sexual function)**
Description	Derogatis interview for sexual function data from CRF, flattened to 1 record per DEIDNUM / VISIT. Includes responses to each item in the questionnaire and derived scores using Derogatis 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/DISFEM1 – DISFEM4, DISMALE1 – DISMALE3, 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	PAGEID	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
DEROGDT	Date of Derogatis	DATEHDR.STUDYDT	DT		DT
DRGNDRSN	Reason Derogatis not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFDEROG	Derogatis done	DEROGDT, DRGNDRSN	N	=1 if DEROGDT is non-missing else=0 if VISSTAT=1. Else missing.	
DRG1-DRG25	Answers to Derogatis question 1-25	DEROG.QNO DEROG.RESPONSE	N	DRG[#] = RESPONSE if QNO=#	Formats are not applied to raw variables, because formats are different for male and female questionnaires. See

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
					CRF for codes.
N1DRG	Number non-missings for Derogatis score1	DRG1, DRG2, DRG3, DRG4, DRG5	N	= number of non-missings in (DRG1,DRG2,DRG3,DRG4,DRG5)	
N2DRG	Number non-missings for Derogatis score2	DRG6, DRG7, DRG8, DRG9, DRG10	N	=number of non-missings in (DRG6,DRG7,DRG8,DRG9,DRG10)	
N3DRG	Number non-missings for Derogatis score3	DRG11,DRG12,DRG13 ,DRG14,DRG15	N	=number of non-missings in (DRG11,DRG12,DRG13,DRG14,DRG15)	
N4DRG	Number non-missings for Derogatis score4	DRG16,DRG17,DRG18 ,DRG19,DRG20,DRG21	N	=number of non-missings in (DRG16,DRG17,DRG18,DRG19,DRG20,DRG21)	
N5DRG	Number non-missings for Derogatis score5	DRG22,DRG23,DRG24 ,DRG25	N	=number of non-missings in (DRG22,DRG23,DRG24,DRG25)	
NDRG	Number non-missing Derogatis responses	DRG1 – DRG25	N	=number of non-missings in DRG1-DRG25	
NMISSDRG	Number of missing Derogatis responses	DRG1 – DRG25	N	Defined only if CRFDEROG=1 =number of missings in DRG1-DRG25 missing if CRFDEROG<1.	
	Scores are derived according to the official Derogatis scoring algorithm (see QOL MOP). For each score category, the score is missing if more than one of the components is missing. If one component is missing, the missing item is imputed using the mean of the non-missing items.				
DRGSCR1	Sexual cognition / fantasy score	N1DRG, DRG1, DRG2, DRG3, DRG4, DRG5	n	= missing if N1DRG<4 else if N1DRG>=4, =sum of (DRG1,DRG2,DRG3,DRG4,DRG5) multiplied by (5/N1DRG)	
DRGSCR2	Sexual arousal score	N2DRG, DRG6, DRG7, DRG8, DRG9, DRG10	N	= missing if N2DRG<4 else if N2DRG>=4, =sum of (DRG6,DRG7,DRG8,DRG9,DRG10) multiplied by (5/N2DRG)	
DRGSCR3	Sexual behavior/experiences score	N3DRG, DRG11,DRG12,DRG13 ,DRG14,DRG15	N	=missing if N3DRG<4 else if N3DRG>=4, =sum of (DRG11,DRG12,DRG13,DRG14,DRG15) multiplied by (5/N3DRG)	
DRGSCR4	Orgasm score	N4DRG,DRG16,DRG17,DRG18,DRG19,DRG20,DRG21	N	= missing if N4DRG<5 else if N4DRG>=5, =sum of (DRG16,DRG17,DRG18,DRG19,DRG20,DRG21)	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				multiplied by (6/N4DRG)	
DRGSCR5	Drive and relationship score	N5DRG, DRG22, DRG23, DRG24, DRG25	N	=missing if N5DRG<3 else if N5DRG>=3, =sum of (DRG22,DRG23,DRG24,DRG25) multiplied by (4/N5DRG)	
DRGSCORE	Total Derogatis score	DRGSCR1 – DRGSCR5	N	= sum of (DRGSCR1, DRGSCR2, DRGSCR3, DRGSCR4, DRGSCR5)	

Trial name	**CALERIE 2**
Dataset name	**FCI (Food Craving Inventory)**
Description	Food Craving Inventory data from CRF, flattened to 1 record per DEIDNUM / VISIT. The original CRF data has 1 record for each of the 28 questions per DEIDNUM/VISIT. Includes responses to each item in the questionnaire and derived scores using FCI 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/CRAVE, 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	CRAVE.PAGEID	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
FCIDT	Date of FCI	DATEHDR.STUDYDT	DT		DT
FCINDRSN	Reason FCI not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFFCI	FCI done	FCIDT, FCINDRSN	N	=1 if FCIDT is non-missing else =0 if VISSTAT=1. Else missing.	
FCI1 – FCI28	Response for FCI questionnaire item 1 – 28	CRAVE.FCIQ CRAVE.FCIA	N	FCI[N]=FCIA if FCIQ=N.	TUCRVB
NFCI	Total non-missing FCI items	FCI1 – FCI28	N	Number of non-missings in FCI1 – FCI28	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
NMISSFCI	Total missing FCI items	FCI1 – FCI28	N	Defined only if CRFFCI=1 Number of missings in FCI1 – FCI28 Missing if CRFFCI<1	
CARBS	FCI Carbohydrates	FCI5, 9, 12, 14, 18, 21, 22, 28	N	Sum of FCI5, 9, 12, 14, 18, 21, 22, 28 Missing if any of the components are missing	
SWEETS	FCI Sweets	FCI1, 8, 13, 16, 17, 23, 24, 25	N	Sum of FCI1, 8, 13, 16, 17, 23, 24, 25 Missing if any of the components are missing	
FATS	FCI Fats	FCI3, 4, 6, 10, 15, 19, 26, 27	N	Sum of FCI3, 4, 6, 10, 15, 19, 26, 27 Missing if any of the components are missing	
FASTFOOD	FCI Fast Foods	FCI2, 7, 11, 20	N	Sum of FCI2, 7, 11, 20 Missing if any of the components are missing	

Trial name	**CALERIE 2**
Dataset name	**FCQSTATA (Food Cravings Questionnaire – State)**
Description	Food Cravings Questionnaire – State, from CRF, flattened to 1 record per DEIDNUM / VISIT. Raw data has 1 record for each of the 15 questions per DEIDNUM / VISIT. Includes responses to each item in the questionnaire and derived scores using FCQSTATE 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/FCQSTATE, 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	FCQSTATE.PAGEID	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
FCQSDT	Date of FCQ - State	DATEHDR.STUDYDT	DT		DT
FCQSNDRS	Reason FCQ State not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFFCQS	FCQ – State done	FCQSDT	N	=1 if FCQSDT is non-missing else =0	
FCQS1 – FCQS15	Response for FCQSTATE item~~s~~ 1 – 15	FCQSTATE.STATEQ FCQSTATE.STATEA	N	FCQS[N]=STATEA if STATEQ=N.	TUFCQD
NFCQS	Total non-missing FCQSTATE items	FCQS1 – FCQS15	N	Number of non-missings in FCQS1 – FCQS15	
NMISFCQS	Total missing FCQSTATE items	FCQS1 – FCQS15	N	Defined only if CRFFCQS=1 Number of missings in FCQS1 – FCQS15 Missing if CRFFCQS<1	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
DESIRE	FCQSTATE Desire score	FCQS1, 2, 3	N	Sum of FCQS1, 2, 3 Missing if any of these FCQSs is missing	
ANTPOS	FCQSTATE Anticipation positive score	FCQS4, 5, 6	N	Sum of FCQS4, 5, 6 Missing if any of these FCQSs is missing	
ANTNEG	FCQSTATE Anticipation negative score	FCQS7, 8, 9	N	Sum of FCQS7, 8, 9 Missing if any of these FCQSs is missing	
LACKCTRL	FCQSTATE Lack of control score	FCQS10, 11, 12	N	Sum of FCQS10, 11, 12 Missing if any of these FCQSs is missing	
HUNGER	FCQSTATE Hunger / physiological score	FCQS13, 14, 15	N	Sum of FCQS13, 14, 15 Missing if any of these FCQSs is missing	

Trial name	**CALERIE 2**
Dataset name	**FCQTRTA (Food Cravings Questionnaire – Trait)**
Description	Food Cravings Questionnaire – Trait data from CRF, flattened to one record per DEIDNUM. This questionnaire is only filled out at baseline. Raw data has 1 record for each of the 39 questions per DEIDNUM. Includes responses to each item in the questionnaire and derived scores using FCQTRAIT scoring algorithm (see QOL scoring MOP).
Comments on data structure	1 record / DEIDNUM
Population	All subjects who had baseline evaluations, including all randomized subjects
Visits	4 (See Appendix for VISIT codes)
Source data files	CRF/FCQTRAIT, DATEHDR, ANALDATA/SUBJECT1
Final sort order	DEIDNUM

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
PAGENUM	CRF page number	FCQTRAIT.PAGEID	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
FCQTDT	Date of FCQ - Trait	DATEHDR.STUDYDT	DT		DT
FCQTNDRS	Reason FCQ Trait not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFFCQT	FCQ – Trait done	FCQTDT,	N	=1 if FCQTDT is non-missing else =0	
FCQT1 – FCQT39	Response for FCQTRAIT item 1 – 39	FCQTRAIT.TRAIT FCQTRAIT.TRAITA	N	FCQT[N]=TRAITA if TRAIT=N.	TUFCQB
NFCQT	Total non-missing FCQTRAIT items	FCQT1 – FCQT39	N	Number of non-missings in FCQT1 – FCQT39	
NMISFCQT	Total missing FCQTRAIT items	FCQT1 – FCQT39	N	Defined only if CRFFCQT=1 Number of missings in FCQT1 – FCQT39	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				Missing if CRFFCQT<1	
INTENT	FCQTRAIT Intent score	FCQT5, 18, 23	N	Sum of FCQT5, 18, 23 Missing if any of these FCQTs is missing	
POSANTC	FCQTRAIT Positive Anticipation score	FCQT9, 10, 15, 24, 38	N	Sum of FCQT9, 10, 15, 24, 38 Missing if any of these FCQTs is missing	
NEGANTC	FCQTRAIT Negative Anticipation score	FCQT16, 19, 21	N	Sum of FCQT16, 19, 21 Missing if any of these FCQTs is missing	
CONTROL	FCQTRAIT Control score	FCQT2, 3, 22, 25, 26, 29	N	Sum of FCQT2, 3, 22, 25, 26, 29 Missing if any of these FCQTs is missing	
THOUGHTS	FCQTRAIT Thoughts score	FCQT6, 8, 27, 28, 31, 32, 33	N	Sum of FCQT6, 8, 27, 28, 31, 32, 33 Missing if any of these FCQTs is missing	
HUNGER_T	FCQTRAIT Hunger / Physiological score	FCQT11, 12, 13, 14	N	Sum of FCQT11, 12, 13, 14 Missing if any of these FCQTs is missing	
EMOTIONS	FCQTRAIT Emotions/negative affect score	FCQT20, 30, 34, 39	N	Sum of FCQT20, 30, 34, 39 Missing if any of these FCQTs is missing	
CUES	FCQTRAIT Cues /environment score	FCQT1, 35, 36, 37	N	Sum of FCQT1, 35, 36, 37 Missing if any of these FCQTs is missing	
GUILT	FCQTRAIT Guilt score	FCQT4, 7, 17	N	Sum of FCQT4, 7, 17 Missing if any of these FCQTs is missing	

Trial name	**CALERIE 2**
Dataset name	**MAEDSA (Multiaxial Assessment of Eating Disorder Symptoms)**
Description	MAEDS data from CRF, flattened to 1 record per DEIDNUM / VISIT. Raw data has 1 record for each of the 56 questions per DEIDNUM / VISIT. Includes responses to each item in the questionnaire and derived scores using MAEDS 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	4, 8, 9, 11, 12, 13 (See Appendix for VISIT codes)
Source data files	CRF/MAEDS, DATEHDR, EDISORD 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	MAEDS.PAGEID	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
MAEDSDT	Date of MAEDS	DATEHDR.STUDYDT	DT		DT
MAEDSND	Reason MAEDS not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFMAEDS	MAEDS done	MAEDSDT, MAEDSND	N	=1 if MAEDSDT is non-missing else =0	
MAEDS1 – MAEDS56	Answer to MAEDS question 1-56	MAEDS.MAEDQ, MAEDS.MAEDA	N	MAEDS[#] = MAEDA if MAEDQ= #	TUMAEZ
MAEDS11R, MAEDS12R, MAEDS23R, MAEDS32R, MAEDS56R	Reverse scored MAEDS question *n*	MAEDS11, MAEDS12, MAEDS23, MAEDS32, MAEDS56	N	MAEDS[#]_R = 8 – MAEDS[#]	

Variable name	**LABEL**	**Source variables**	**C/N ?**	**Definition**	**Accepted values/ Format**
N1MAEDS	Number of non-missings for MAEDS score1	MAEDS2,MAEDS11R,MAEDS12R,MAEDS13,MAEDS16,MAEDS24,MAEDS29,MAEDS30,MAEDS33,MAEDS39,MAEDS51	N	= number of non-missing in (MAEDS2,MAEDS11R,MAEDS12R,MAEDS13,MAEDS16,MAEDS24,MAEDS29,MAEDS30,MAEDS33,MAEDS39,MAEDS51)	
N2MAEDS	Number of non-missings for MAEDS score2	MAEDS5, MAEDS19,MAEDS22, MAEDS26, MAEDS27, MAEDS48, MAEDS49, MAEDS54	N	=number of non-missing in (MAEDS5,MAEDS19,MAEDS22,MAEDS26,MAEDS27,MAEDS48,MAEDS49,MAEDS54)	
N3MAEDS	Number of non-missings for MAEDS score3	MAEDS6, MAEDS9, MAEDS15, MAEDS17, MAEDS21, MAEDS35, MAEDS37	N	= number of non-missing in (MAEDS6,MAEDS9,MAEDS15,MAEDS17,MAEDS21,MAEDS35,MAEDS37)	
N4MAEDS	Number of non-missings for MAEDS score4	MAEDS7, MAEDS20, MAEDS23R, MAEDS25, MAEDS28, MAEDS36, MAEDS40, MAEDS43, MAEDS47, MAEDS55, MAEDS56R	N	=number of non-missing in (MAEDS7,MAEDS20,MAEDS23R,MAEDS25,MAEDS28,MAEDS36,MAEDS40,MAEDS43,MAEDS47,MAEDS55,MAEDS56R)	
N5MAEDS	Number of non-missings for MAEDS score5	MAEDS1, MAEDS3, MAEDS14, MAEDS32R, MAEDS42, MAEDS44, MAEDS45, MAEDS50, MAEDS53	N	= number of non-missing in (MAEDS1,MAEDS3,MAEDS14,MAEDS32R,MAEDS42,MAEDS44,MAEDS45,MAEDS50,MAEDS53)	
N6MAEDS	Number of non-missings for MAEDS score6	MAEDS4, MAEDS8, MAEDS10, MAEDS18, MAEDS31, MAEDS34, MAEDS38, MAEDS41, MAEDS46, MAEDS52	N	=number of non-missing in (MAEDS4,MAEDS8,MAEDS10,MAEDS18,MAEDS31,MAEDS34,MAEDS38,MAEDS41,MAEDS46,MAEDS52)	
	The following MAEDS scores are derived using the MAEDS scoring algorithm in the QOL Scoring MOP. For each item, the score is missing if >10% of the components are missing. Otherwise, any missing items are imputed using the mean of the non-missing items.				
MAEDSCR1	MAEDS depression score	MAEDS2, MAEDS11, MAEDS12, MAEDS13, MAEDS16, MAEDS24, MAEDS29, MAEDS30,	N	= missing if N1MAEDS< 10 else if N1MAEDS >=10, = round(sum of	

Variable name	**LABEL**	**Source variables**	**C/N ?**	**Definition**	**Accepted values/ Format**
		MAEDS33, MAEDS39, MAEDS51		(MAEDS2,MAEDS11,MAEDS12,MAEDS13,MAEDS16,MAEDS24,MAEDS29,MAEDS30,MAEDS33,MAEDS39,MAEDS51) multiplied by (11 / N1MAEDS))	
MAEDSCR2	MAEDS binge eating score	MAEDS5, MAEDS19, MAEDS22, MAEDS26, MAEDS27, MAEDS48, MAEDS49, MAEDS54	N	= missing if N2MAEDS< 8 else if N2MAEDS=8, =round (sum of (MAEDS5,MAEDS19,MAEDS22,MAEDS26,MAEDS27,MAEDS48,MAEDS49,MAEDS54))	
MAEDSCR3	MAEDS purgative behavior score	MAEDS6, MAEDS9, MAEDS15, MAEDS17, MAEDS21, MAEDS35, MAEDS37	N	Missing if N3MAEDS<7 Else if N3MAEDS=7, = round(sum of (MAEDS6,MAEDS9,MAEDS15,MAEDS17,MAEDS21,MAEDS35,MAEDS37))	
MAEDSCR4	MAEDS fear of fatness score	MAEDS7, MAEDS20, MAEDS23, MAEDS25, MAEDS28, MAEDS36, MAEDS40, MAEDS43, MAEDS47, MAEDS55, MAEDS56	N	Missing if N4MAEDS<10 Else if N4MAEDS>=10, = round(sum of (MAEDS7,MAEDS20,MAEDS23,MAEDS25,MAEDS28,MAEDS36,MAEDS40,MAEDS43,MAEDS47,MAEDS55,MAEDS56) multiplied by (11/N4MAEDS))	
MAEDSCR5	MAEDS score for restrictive eating	MAEDS1, MAEDS3, MAEDS14, MAEDS32, MAEDS42, MAEDS44, MAEDS45, MAEDS50, MAEDS53	N	Missing if N5MAEDS<9 Else if N5MAEDS=9, = round (sum of (MAEDS1,MAEDS3,MAEDS14,MAEDS32,MAEDS42,MAEDS44,MAEDS45,MAEDS50,MAEDS53))	
MAEDSCR6	MAEDS score for avoidance of fear foods	MAEDS4, MAEDS8, MAEDS10, MAEDS18, MAEDS31, MAEDS34, MAEDS38, MAEDS41, MAEDS46, MAEDS52		Missing if N6MAEDS<9 Else if N6MAEDS>=9, = round (sum of (MAEDS4,MAEDS8,MAEDS10,MAEDS18,MAEDS31,MAEDS34,MAEDS38,MAEDS41,MAEDS46,MAEDS52) multiplied by (10 / N6MAEDS))	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
TDEP	MAEDS T-score for Depression	MAEDSCR1, GENDER	N	If GENDER=1: = round (21.631 + 1.0925 X MAEDSCR1) else if GENDER=2: If MAEDSCR1=12 → =32 If MAEDSCR1=36 → =55 Else = round (19.9605 + 0.9592 x MAEDSCR1)	
TBNG	MAEDS T-score for Binge Eating	MAEDSCR2, GENDER	N	If GENDER=1: = round (18.6637 + 1.5284 x MAEDSCR2) else if GENDER=2: If MAEDSCR2=52 → =83 If MAEDSCR2=55 → =88 Else = round (17.9706 + 1.2637 x MAEDSCR2)	
TPRG	MAEDS T-score for Purgative behavior	MAEDSCR3, GENDER	N	If GENDER=1: = round (24.1607 + 2.4478 x MAEDSCR3) else if GENDER=2: = round (31.6787 + 1.6344 x MAEDSCR3)	
TFEARFAT	MAEDS T-score for Fear of Fatness	MAEDSCR4, GENDER	N	If GENDER=1: If MAEDSCR4=16 → =33 If MAEDSCR4=47 → =66 If MAEDSCR4=77 → =97 Else = round (17.029 + 1.0309 x MAEDSCR4) Else if GENDER=2: If MAEDSCR4=61 → =59 If MAEDSCR4=65 → =62 If MAEDSCR4=77 → =72 Else = round (13.9675 + 0.7467 x MAEDSCR4)	
TRST	MAEDS T-score for Restrictive Eating	MAEDSCR5, GENDER	N	If GENDER=1: If MAEDSCR5=27 → =60 Else = round (20.3533 + 1.4877 x MAEDSCR5) Else if GENDER=2: If MAEDSCR5=14 → =39 If MAEDSCR5=55 → =82 Else = round (23.4649 + 1.0734 x MAEDSCR5)	

Variable name	**LABEL**	**Source variables**	**C/N ?**	**Definition**	**Accepted values/ Format**
TAVD	MAEDS T-score Avoidance of Fear Foods	MAEDSCR6, GENDER	N	If GENDER=1: = round (29.0132 + 0.8812 x MAEDSCR6) Else if GENDER=2: = round (20.6425 + 0.8106 x MAEDSCR6)	
MAEDSFLG	Record flagged for eating disorder	TDEP, TBNG, TPRG, TFAT, TRST, TAVD	N	=1 if any of TDEP, TBNG, TPRG, TFAT, TRST, TAVD > 70 else missing	

Trial name	**CALERIE 2**
Dataset name	**POMSA (Profile of Mood States)**
Description	Profile of Mood States data from CRF, flattened to one record per DEIDNUM / VISIT. Raw data has 1 record for each of the 65 questions per DEIDNUM / VISIT. Includes responses to each item in the questionnaire and derived scores using POMS 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/POMS, 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	POMS.PAGEID	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
POMSDT	Date of POMS	DATEHDR.STUDYDT	DT		DT
POMSND	Reason POMS not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFPOMS	POMS done	POMSDT	N	=1 if POMSDT is non-missing else =0	
POMS1 – POMS65	Response for POMS questionnaire item 1 – 65	POMS.POMSQ, POMS.POMSA	N	POMS[N]=POMSA if POMSQ=N.	TUPOMB
POMS22R	POMS Item 22 reversed	POMS22	N	=4 – POMS22	
POMS54R	POMS Item 54 reversed	POMS54	N	=4 – POMS54	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
NTENSION	N non-missings for POMS tension score	POMS2, 10, 16, 20, 22R, 26, 27, 34, 41	N	Number of non-missings in POMS2, 10, 16, 20, 22R, 26, 27, 34, 41	
NDEPRESS	N non-missings for POMS depression score	POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62	N	Number of non-missings in POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62	
NANGER	N non-missings for POMS anger score	POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57	N	Number of non-missings in POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57	
NVIGOR	N non-missings for POMS vigor score	POMS7, 15, 19, 38, 51, 56, 60, 63	N	Number of non-missings in POMS7, 15, 19, 38, 51, 56, 60, 63	
NFATIGUE	N non-missings for POMS fatigue score	POMS4, 11, 29, 40, 46, 49, 65	N	Number of non-missings in POMS4, 11, 29, 40, 46, 49, 65	
NCONFUSE	N non-missings for POMS confusion score	POMS8, 28, 37, 50, 54R, 59, 64	N	Number of non-missings in POMS8, 28, 37, 50, 54R, 59, 64	
	The following POMS scores are derived using the POMS scoring algorithm in the QOL Scoring MOP. For each item, the score is missing if >10% of the components are missing. Otherwise, any missing items are imputed using the mean of the non-missing items.				
TENSION	POMS Tension score	NTENSION, POMS2, 10, 16, 20, 22R, 26, 27, 34, 41	N	If NTENSION=9 =sum of POMS2, 10, 16, 20, 22R, 26, 27, 34, 41 else missing	
DEPRESS	POMS Depression score	NDEPRESS, POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62	N	If NDEPRESS = 15, =sum of POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62 else if NDEPRESS=14 =sum of non-missing POMS5, 9, 14, 18, 21, 23, 32, 35, 36, 44, 45, 48, 58, 61, 62 plus the average of the non-missing POMS else missing	
ANGER	POMS Anger score	NANGER, POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57	N	If NANGER=12 =sum of POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57 else if NANGER=11 =sum of non-missing POMS3, 12, 17, 24, 31, 33, 39, 42, 47, 52, 53, 57 plus the average of the non-missing POMS	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				else missing	
VIGOR	POMS Vigor score	NVIGOR, POMS7, 15, 19, 38, 51, 56, 60, 63	N	If NVIGOR=8, =sum of POMS7, 15, 19, 38, 51, 56, 60, 63 else missing	
FATIGUEP	POMS Fatigue score	NFATIGUE, POMS4, 11, 29, 40, 46, 49, 65	N	If NFATIGUE=7, =sum of POMS4, 11, 29, 40, 46, 49, 65 else missing	
CONFUSE	POMS Confusion score	NCONFUSE, POMS8, 28, 37, 50, 54R, 59, 64	N	If NCONFUSE=7, =sum of POMS8, 28, 37, 50, 54R, 59, 64 else missing	
DISTURB	Total POMS mood disturbance score	TENSION, DEPRESS, ANGER, VIGOR, FATIGUEP, CONFUSE	N	=sum of (TENSION, DEPRESS, ANGER, FATIGUEP, CONFUSE) minus VIGOR missing if any of the above are missing	

Trial name	**CALERIE 2**
Dataset name	**PSQI (Pittsburgh Sleep Quality Index)**
Description	Pittsburgh Sleep Quality Index data from CRF. Includes responses to each item in the questionnaire and derived scores using PSQI 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/PSQI1, PSQI2, 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	PSQI1.PAGEID	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
PSQIDT	Date of PSQI	DATEHDR.STUDYDT	DT		DT
PSQIND	Reason PSQI not done	DATEHDR.STUDYND	N	1=Participant refused 2=Clinician unable to obtain 3=Insufficient time 4=Instrument failure 5=Not required	TUND
CRFPSQI	PSQI done	PSQIDT, PSQINDRSN	N	=1 if PSQIDT is non-missing else =0	
FALLASLP	PSQI time to fall asleep (minutes)	PSQI1.FALLASLP	N		
ACTSLP	PSQI actual sleep (hours)	PSQI1.ACTSLP	N		
WITHIN30	PSQI question 5a	PSQI1.WITHIN30	N		TUSLP
MIDNGHMG	PSQI question 5b	PSQI1.MIDNGHMG	N		TUSLP

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
GOBTHRM	PSQI question 5c	PSQI1.GOBTHRM	N		TUSLP
BREATHE	PSQI question 5d	PSQI1.BREATHE	N		TUSLP
SNORE	PSQI question 5e	PSQI1.SNORE	N		TUSLP
COLD	PSQI question 5f	PSQI1.COLD	N		TUSLP
HOT	PSQI question 5g	PSQI1.HOT	N		TUSLP
BADDRM	PSQI question 5h	PSQI1.BADDRM	N		TUSLP
PAIN	PSQI question 5i	PSQI1.PAIN	N		TUSLP
PSQIOTHR	PSQI question 5j	PSQI1.OTHER	N		TUSLP
MEDSTKN	PSQI question 6	PSQI1.MEDSTKN	N		TUSLP
AWKESOC	PSQI question 7	PSQI2.AWKESOC	N		TUSLPB
KPENTHUS	PSQI question 8	PSQI2.KPENTHUS	N		TUSLPC
SLPQLTY	PSQI question 9	PSQI2.SLPQLTY	N		TUSLPD
BEDTM	Bed time	PSQI1.BEDHR, PSQI1.BEDMIN	TM	Create time variable of BEDHR, BEDMIN (if BEDHR is between 8-12, add 12 to BEDHR first)	TIME
WAKETM	Wake time	PSQI1.WAKEHR, PSQI1.WAKEMIN	TM	Create time variable of WAKEHR, WAKEMIN	TIME
SLEEPHRS	Hours in bed	BEDTM, WAKETM	N	If BEDTM<WAKETM =WAKETM – BEDTM in hours else if WAKETM<BEDTM =(WAKETM+86400) – BEDTM in hours	
SLEEPEFF	Sleep efficiency	ACTSLP, SLEEPHRS	N	=100 X (ACTSLP/SLEEPHRS)	
PSQISCR1	PSQI Subjective sleep quality	SLPQLTY	N		TUSLPD
PSQISCR2	PSQI Sleep latency	FALLASLP, WITHIN30	N	Let TEMP2 =0 if 0<=FALLASLP<=15 =1 if 15<FALLASLP<=30 =2 if 30<FALLASLP<=60 =3 if FALLASLP>60	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				Let TEMP25A= sum of TEMP2 and WITHIN30 missing if either is missing PSQISCR2: =0 if TEMP25A=0 =1 if TEMP25A is in (1 or 2) =2 if TEMP25A is in (3 or 4) =3 if TEMP25A is in (5 or 6)	
PSQISCR3	PSQI Sleep duration	ACTSLP	N	=0 if ACTSLP>7 =1 if 6<ACTSLP<=7 =2 IF 5<ACTSLP<=6 =3 if 0<=ACTSLP<=5	
PSQISCR4	PSQI Sleep efficiency	SLEEPEFF	N	=0 if SLEEPEFF>85 =1 IF 75<SLEEPEFF<=85 =2 if 65<SLEEPEFF<=75 =3 if 0<=SLEEPEFF<=65	
PSQISCR5	PSQI Sleep disturbance	PSQI1.MIDNGHMG, PSQI1.GOBTHRM, PSQI1.BREATHE, PSQI1.SNORE, PSQI1.COLD, PSQI1.HOT, PSQI1.BADDRM, PSQI1.PAIN, PSQI1.OTHER	N	Let TEMP5= sum of MIDNGHMG, GOBTHRM, BREATHE, SNORE, COLD, HOT, BADDRM, PAIN, OTHER missing if anything except OTHER is missing PSQISCR5: =0 if TEMP5=0 =1 if 1<=TEMP5<=9 =2 if 10<=TEMP5<=18 =3 IF 19<=TEMP5<=27	
PSQISCR6	PSQI Sleeping medication	PSQI1.MEDSTKN	N		
PSQISCR7	PSQI Daytime dysfunction	AWKESOC, KPENTHUS	N	Let TEMP78=Sum of AWKESOC and KPENTHUS Missing if either is missing PSQISCR7: =0 if TEMP78=0 =1 if TEMP78 in (1 or 2) =2 if TEMP78 in (3 or 4) =3 if TEMP78 in (5 or 6)	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
PSQISCOR	Global PSQI score	PSQICOMP1 – PSQICOMP7	N	= sum of PSQISCR1 – PSQISCR7 missing if any are missing	

Trial name	**CALERIE 2**
Dataset name	**PSSA (Perceived Stress Scale)**
Description	Perceived Stress Scale data from CRF. Includes responses to each item in the questionnaire and derived scores using PSS 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/PSS, 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	PSS.PAGEID	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
PSSDT	Date of PSS	DATEHDR.STUDYDT	DT		DT
PSSNDRSN	Reason PSS not done	DATEHDR.STUDYND	N		TUND
CRFPSS	PSS done	PSSDT	N	=1 if PSSDT is non-missing else =0	
CTRLTHNG	Unable to control things	PSS.CTRLTHNG	N		TUPSS
HANDPROB	Able to handle personal problems	PSS.HANDPROB	N		TUPSS
GOYOWAY	Things were going your way	PSS.GOYOWAY	N		TUPSS
PILEHIGH	Difficulties piling up high	PSS.PILEHIGH	N		TUPSS
HANDPRBR	Able to handle problems, reversed	HANDPROB	N	=4 – HANDPROB	
GOYOWAYR	Things going your way, reversed	GOYOWAY	N	=4 – GOYOWAY	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
NPSS	Number of non-missing PSS items	CTRLTHNG, HANDPROB, GOYOWAY, PILEHIGH	N	= number of non-missings in CTRLTHNG, HANDPROB, GOYOWAY, PILEHIGH	
NMISSPSS	Number of missing PSS items	CTRLTHNG, HANDPROB, GOYOWAY, PILEHIGH	N	Defined only if CRFPSS=1. = number of missings in CTRLTHNG, HANDPROB, GOYOWAY, PILEHIGH missing if CRFPSS<1.	
PERSTRSS	Perceived stress score	CTRLTHNG, HANDPROBR, GOYOWAYR, PILEHIGH	N	If NTOTAL=4, =sum of CTRLTHNG, HANDPROBR, GOYOWAYR, PILEHIGH else missing	

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	4, 9, 11, 13 (See Appendix for 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
RANDSF3	Vigorous activities	RANDSF1.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**
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	**0=Yes** **100=No**
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	**0=Extremely** **25=Quite a bit** **50=Moderately** **75=Slightly** **100=Not at all**
RANDSF21	Bodily pain	RANDSF2.BODPAIN	N	=100 if value=1	**0=Very severe**

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				=80 if value=2 =60 if value=3 =40 if value=4 =20 if value=5 =0 if value=6	**20=Severe** **40=Moderate** **60=Mild** **80=Very mild** **100=None**
RANDSF22	Pain interfered with normal work	RANDSF2.INTERFE	N	Same as RANDSF1	**0=Extremely** **25=Quite a bit** **50=Moderately** **75=A little bit** **100=Not at all**
RANDSF23	Full of pep	RANDSF3.PEP	N	Same as RANDSF21	**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**
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	**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**
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	**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
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	

Trial name	**CALERIE 2**
Dataset name	**TFEQ (Eating Inventory)**
Description	Eating Inventory (formerly Three Factor Eating Questionnaire) data from CRF, flattened to one record per DEIDNUM / VISIT. Raw data is stacked with 1 record for each of the first 36 questions per DEIDNUM/VISIT. Includes scored values for each item in the questionnaire and derived scores using TFEQ 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/TFEQA, TFEQB, 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	TFEQA.PAGEID	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
TFEQDT	Date of TFEQ	DATEHDR.STUDYDT	DT		DT
TFEQNDRS	Reason TFEQ not done	DATEHDR.STUDYND	N		TUND
CRFTFEQ	TFEQ done	TFEQDT	N	=1 if TFEQDT is non-missing else =0	
TFEQ1 – TFEQ9, TFEQ11-TFEQ15, TFEQ17 – TFEQ20 TFEQ22 – TFEQ24,	TFEQ item *N*	TFEQA.EATINV, TFEQA.EATINVQ	N	TFEQ[N] = EATINV if EATINVQ=N	0=False 1=True

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
TFEQ26 – TFEQ29, TFEQ32 – TFEQ36					
TFEQ10, TFEQ16, TFEQ21, TFEQ25, TFEQ30, TFEQ31	TFEQ item *N* (reverse scored)	TFEQA.EATINV, TFEQA.EATINVQ	N	TFEQ[N] = 1 – EATINV if EATINVQ=N	0=True 1=False
TFEQ37	TFEQ item 37 (rescored)	TFEQB.WTCONTR	N	=0 if WTCONTR = 1 or 2 =1 if WTCONTR = 3 or 4	0=Rarely or Sometimes 1=Usually or Always
TFEQ38	TFEQ item 38 (rescored)	TFEQB.WTFLUCT	N	=0 if WTFLUCT = 1 or 2 =1 if WTFLUCT = 3 or 4	See TFEQ37
TFEQ39	TFEQ item 39 (rescored)	TFEQB.OFTHUNG	N	=0 if OFTHUNG = 1 or 2 =1 if OFTHUNG = 3 or 4	See TFEQ37
TFEQ40	TFEQ item 40 (rescored)	TFEQB.FEELGUIL	N	=0 if FEELGUIL = 1 or 2 =1 if FEELGUIL = 3 or 4	See TFEQ37
TFEQ41	TFEQ item 41 (rescored)	TFEQB.EATDIFF	N	=0 if EATDIFF = 1 or 2 =1 if EATDIFF = 3 or 4	0=Easy or slightly difficult 1=Moderately or very difficult
TFEQ42	TFEQ item 42 (rescored)	TFEQB.CONSEAT	N	=0 if CONSEAT = 1 or 2 =1 if CONSEAT = 3 or 4	0=Not at all or slightly 1=Moderately or extremely
TFEQ43	TFEQ item 43 (rescored)	TFEQB.STOCKING	N	=0 if STOCKING = 1 or 2 =1 if STOCKING = 3 or 4	0=Almost never or seldom 1=Usually or almost always
TFEQ44	TFEQ item 44 (rescored)	TFEQB.LOWCAL	N	=0 if LOWCAL = 1 or 2 =1 if LOWCAL = 3 or 4	0=Unlikely or slightly likely 1=Moderately or very likely
TFEQ45	TFEQ item 45 (rescored)	TFEQB.SPLURG	N	=0 if SPURG = 1 or 2 =1 if SPURG = 3 or 4	0=Never or rarely 1=Often or always
TFEQ46	TFEQ item 46 (rescored)	TFEQB.EATSLOW	N	=0 if EATSLOW = 1 or 2 =1 if EATSLOW = 3 or 4	See TFEQ44

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
TFEQ47	TFEQ item 47 (rescored)	TFEQB.DESSERT	N	=0 if DESSERT = 3 OR 4 =1 if DESSERT = 1 OR 2	0=At least once a week or almost every day 1=Almost never or seldom
TFEQ48	TFEQ item 48 (rescored)	TFEQB.EATLESS	N	=0 if EATSLOW = 1 or 2 =1 if EATSLOW = 3 or 4	See TFEQ44
TFEQ49	TFEQ item 49 (rescored)	TFEQB.BINGES	N	=0 if EATSLOW = 1 or 2 =1 if EATSLOW = 3 or 4	0=Never or rarely 1=Sometimes or at least once a week
TFEQ50	TFEQ item 50 (rescored)	TFEQB.BEHAVIOR	N	=0 if EATSLOW = 1 or 2 =1 if EATSLOW = 3 or 4	0=Not or little like me 1=Pretty good or perfect description of me
TFEQ51	TFEQ item 51 (rescored)	TFEQB.RESTRAIN	N	=0 if RESTRAIN = 0, 1 or 2 =1 if RESTRAIN = 3, 4 or 5	0=Always, usually or often eat whatever you want whenever you want, 1=Often limit food intake, but often give in, or usually limit food intake but rarely give in, or constantly limit food intake and never give in
NTFEQ	Total non-missing TFEQ items	TFEQ1 – TFEQ51	N	Number of non-missings in TFEQ1 – TFEQ51	
NMISTFEQ	Total missing TFEQ items	TFEQ1 – TFEQ51	N	Defined only If CRFTFEQ=1. Number of missings in TFEQ1 – TFEQ51 Missing if CRFTFEQ<1	
RESTRAIN	TFEQ Restraint score (Factor 1)	TFEQ4, 6, 10, 14, 18, 21, 23, 28, 30, 32, 33, 35, 37, 38, 40, 42, 43, 44, 46, 48, 50	N	If <= 2 of the components are missing, impute each of the missing items as the average of the non-missing components. RESTRAINT = sum of all the component items (including imputed)	Rounded to closest 0.1

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
				Missing if >2 of the components are missing	
DISINHIB	TFEQ Disinibition score (Factor 2)	TFEQ1, 2, 7, 9, 11, 13, 15, 16, 20, 25, 27, 31, 36, 45, 49, 51	N	If one of the components is missing, impute the missing item as the average of the non-missing components. DISINHIB2 =sum of all the component items (including imputed) Missing if >1 of the components are missing	Rounded to closest 0.1
PHUNGER	TFEQ Perceived Hunger score (Factor 3)	TFEQ3, 5, 8, 12, 17, 19, 22, 24, 26, 29, 34, 39, 41, 47	N	If one of the components is missing, impute the missing item as the average of the non-missing components. PHUNGER=sum of all the component items (including imputed) missing if >1 of the components are missing.	Rounded to closest 0.1
FLEXRSTR	Flexible Restraint	TFEQ4, 6, 23, 28, 35, 42, 48	N	=sum of all the component items missing if any component is missing	Rounded to closest 0.1
RIGDRSTR	Rigid Restraint	TFEQ14, 32, 37, 38, 40, 43, 44	N	=sum of all the component items missing if any component is missing	Rounded to closest 0.1
HABITDIS	Habitual Disinhibition	TFEQ11, 36, 45, 49, 51	N	=sum of all the component items missing if any component is missing	Rounded to closest 0.1
SITUADIS	Situational Disinhibition	TFEQ2, 7, 13, 15, 16	N	=sum of all the component items missing if any component is missing	Rounded to closest 0.1
EMOTDIS	Emotional Disinhibition	TFEQ9, 20, 27	N	=sum of all the component items missing if any component is missing	Rounded to closest 0.1
INTHUNGR	Internal Hunger	TFEQ3, 5, 12, 24, 34, 39	N	=sum of all the component items missing if any component is missing	Rounded to closest 0.1
EXTHUNGR	External Hunger	TFEQ8, 19, 22, 26, 41, 47	N	=sum of all the component items missing if any component is missing	Rounded to closest 0.1

Trial name	**CALERIE 2**
Dataset name	**WELQA (Weight Efficacy Lifestyle Questionnaire)**
Description	Eating Inventory (formerly Three Factor Eating Questionnaire) data from CRF, flattened to one record per DEIDNUM / VISIT. Raw data is stacked with 1 record for each of 20 questions per DEIDNUM / VISIT. Includes scored values for each item in the questionnaire and derived scores using TFEQ 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	4, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/ WELQ, 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	WELQ.PAGEID	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
WELQDT	Date of WELQ	DATEHDR.STUDYDT	DT		DT
WELQNDRS	Reason WELQ not done	DATEHDR.STUDYND	N		TUND
CRFWELQ	WELQ done	WELQDT	N	=1 if WELQDT is non-missing else =0	
WELQ1 – WELQ20	Response for WELQ item 1 – 20	WELQ.WELQUES, WELQ.WELANSW	N	ITEM[N]=WELANSW IF WELQUES=N	(This is not an actual format, just explanation) [0= Not confident at all that you can resist the desire to eat :

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
					9 = Very confident that you can resist the desire to eat]
NWELQ	Total non-missing WELQ items	WELQ1 – WELQ20	N	Number of non-missings in WELQ1 – WELQ20	
NMISWELQ	Total missing WELQ items	WELQ1 – WELQ20	N	Defined only if CRFWELQ=1. Number of missings in WELQ1 – WELQ20 Missing if CRFWELQ<1	
NEGEMOT	WELQ Negative emotions score	WELQ1, 6, 11, 16	N	Sum of WELQ1, 6, 11, 16 Missing if any of the components are missing	
AVAILABL	WELQ Availability score	WELQ2, 7, 12, 17	N	Sum of WELQ2, 7, 12, 17 Missing if any of the components are missing	
SOCPRESS	WELQ Social Pressure score	WELQ3, 8, 13, 18	N	Sum of WELQ3, 8, 13, 18 Missing if any of the components are missing	
PHYSDISC	WELQ Physical Discomfort score	WELQ4, 9, 14, 19	N	Sum of WELQ4, 9, 14, 19 Missing if any of the components are missing	
POSACT	WELQ Positive Activities score	WELQ5, 10, 15, 20	N	Sum of WELQ5, 10, 15, 20 Missing if any of the components are missing	
GLSCORE	WELQ Global Score	WELQ1 - 20	N	Sum of WELQ1 – 20 Missing if any of the components are missing	

Trial name	**CALERIE 2**
Dataset name	**CANTABA (CANTAB Neuropsychological assessment)**
Description	CANTAB (cognitive function test) data, flattened to one record per DEIDNUM / VISIT. The test is administered via computer software (non-CRF) and included in the raw database. Raw CANTAB data has 33 record per DEIDNUM / FORM. Includes each item in the questionnaire (there were no composite scores defined for CANTAB).
Comments on data structure	1 record / DEIDNUM / VISIT
Population	Subjects who attended Baseline Visit 2, including all randomized subjects.
Visits	5, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	CANTAB, SUBJECT1
Final sort order	DEIDNUM VISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit		n	=5 if FORM=’BASELINE2’ =9 if FORM=’MONTH 6’ =11 if FORM=’MONTH 12’ =13 if FORM=’MONTH 24’	VISFMT
CANTABDT	Date of CANTAB	CANTAB.SESIONDT	DT	Use smallest value of SESIONDT for that DEIDNUM/VISIT	DT
CANTAB	CANTAB done	CANTABDT	N	=1 if CANTABDT is non-missing else =0	
MOTME	MOT mean error	CANTAB.MEASURE, CANTAB.RAWSCORE	N	=RAWSCORE if MEASURE=1	
MOTML	MOT mean latency	‘’	N	=RAWSCORE if MEASURE=2	
RTISRT	RTI simple reaction time	‘’	N	=RAWSCORE if MEASURE=3	
RTIFCRT	RTI 5 choice reaction time	‘’	N	=RAWSCORE if MEASURE=4	
RTISAS	RTI simple accuracy score	‘’	N	=RAWSCORE if MEASURE=5	
RTIFCAS	RTI 5 choice accuracy score	‘’	N	=RAWSCORE if MEASURE=6	

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
VRMFRTC	VRM Free Recall –total correct	‘’	N	=RAWSCORE if MEASURE=7	
VRMFRTNW	VRM Free Recall – total novel words	‘’	N	=RAWSCORE if MEASURE=8	
VRMFRTP	VRM Free Recall – total perseverations	‘’	N	=RAWSCORE if MEASURE=9	
VRMRTCI	VRM Recognition total correct immed.	‘’	N	=RAWSCORE if MEASURE=10	
VRMRTFPI	VRM Recog total false positive immed.	‘’	N	=RAWSCORE if MEASURE=11	
VRMRTCD	VRM Recognition total correct delayed	‘’	N	=RAWSCORE if MEASURE=12	
VRMRTFPD	VRM Recog. total false positives delayed	‘’	N	=RAWSCORE if MEASURE=13	
DMSPCS	DMS % correct simultaneous	‘’	N	=RAWSCORE if MEASURE=14	
DMSPCAD	DMS % correct all delays	‘’	N	=RAWSCORE if MEASURE=15	
DMSPC0MD	DMS % correct 0 MS delay	‘’	N	=RAWSCORE if MEASURE=16	
DMSPC4MD	DMS % correct 4000 MS delay	‘’	N	=RAWSCORE if MEASURE=17	
DMSPC12M	DMS % correct 12000 MS delay	‘’	N	=RAWSCORE if MEASURE=18	
SWMBE	SWM between errors	‘’	N	=RAWSCORE if MEASURE=19	
SWMWE	SWM within errors	‘’	N	=RAWSCORE if MEASURE=20	
SWMTE	SWM total errors	‘’	N	=RAWSCORE if MEASURE=21	
SWMS	SWM strategy	‘’	N	=RAWSCORE if MEASURE=22	
RVPTH	RVP total hits	‘’	N	=RAWSCORE if MEASURE=23	
RVPTM	RVP total misses	‘’	N	=RAWSCORE if MEASURE=24	
RVPTFA	RVP total false alarms	‘’	N	=RAWSCORE if MEASURE=25	
RVPTCR	RVP total correct rejections	‘’	N	=RAWSCORE if MEASURE=26	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
RVPML	RVP mean latency	‘’	N	=RAWSCORE if MEASURE=27	
RVPPH	RVP Probability of hit	RVPTH, RVPTM	N	If abs(RVPTH + RVPTM) > 0, = RVPTH / (RVPTH + RVPTM) Else missing	
RVPPF	RVP Probability of false alarm	RVPTFA, RVPTCR	N	If abs(RVPTFA + RVPTCR) > 0, = RVPTFA / (RVPTFA + RVPTCR) Else missing	
RVPSI	RVP Sensitivity Index	RVPPH, RVPPF	N	= 0.5 + ((RVPPH – RVPPF) + (RVPPH – RVPPF)**2) / (4 * RVPPH * (1-RVPPF))	
IEDTE	IED total errors	CANTAB.MEASURE, CANTAB.RAWSCORE	N	=RAWSCORE if MEASURE=28	
IEDEB2	IED errors Block 2	‘’	N	=RAWSCORE if MEASURE=29	
IEDEB5	IED errors Block 5	‘’	N	=RAWSCORE if MEASURE=30	
IEDEB7	IED errors Block 7	‘’	N	=RAWSCORE if MEASURE=31	
IEDEB9	IED errors Block 9	‘’	N	=RAWSCORE if MEASURE=32	
IEDCST	IED completed stage trials	‘’	N	=RAWSCORE if MEASURE=33	
NCANTAB	Number of non-missing CANTAB items	MOTME – IEDCST (excluding RVPPH, RVPPF, RVPSI)	N	Number of non-missings in MOTME--IEDCST	
NMISSCTB	Number of missing CANTAB items	MOTME – IEDCST (excluding RVPPH, RVPPF, RVPSI)	N	Only defined if CANTAB=1 Number of missings in MOTME—IEDCST Missing if CANTAB<1.	

Trial name	**CALERIE 2**
Dataset name	**COGBIAS (Cognitive Bias assessment)**
Description	Cognitive Bias assessment data from non-CRF form, flattened to 1 record per DEIDNUM / VISIT. Raw Cognitive Bias data has multiple records per DEIDNUM / VISIT, across 4 raw datasets. Includes summary scores recorded on the form.
Comments on data structure	1 record / DEIDNUM / VISIT
Population	Subjects who attended Baseline Visit 2, including all randomized subjects.
Visits	5, 9, 11, 13 (See Appendix for VISIT codes)
Source data files	ENCODING, STROOP, POLYSEME, WORDSTEM, DATEHDR, ANALDATA/SUBJECT1
Final sort order	DEIDNUM VISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit		n	=5 if FORM='BASELINE2' =9 if FORM='MONTH 6' =11 if FORM='MONTH 12' =13 if FORM='MONTH 24'	VISFMT
CBIASDT	Date of Cognitive Bias	DATEHDR.STUDYDT	DT		DT
COGBIAS	Cognitive Bias done	CBIASDT	N	=1 if CBIASDT is non-missing else =0	
CBIASNDR	Reason Cognitive Bias not done	DATEHDR.STUDYND	N		TUND
		Variables from ENCODING			
ENCCTRLM	Encoding Control Mean Time	ENCODING.CATEGORY, ENCODING.MEAN	N	=MEAN if CATEGORY=1	
ENCDPRSM	Encoding Depressive Mean Time	ENCODING.CATEGORY, ENCODING.MEAN	N	=MEAN if CATEGORY=2	
ENCFOODM	Encoding Food Mean Time	ENCODING.CATEGORY, ENCODING.MEAN	N	=MEAN if CATEGORY=3	
ENCBODYM	Encoding Body Shape Mean Time	ENCODING.CATEGORY, ENCODING.MEAN	N	=MEAN if CATEGORY=4	
ENCFDBDM	Encoding Food + Body	ENCODING.CATEGORY,	N	=MEAN if CATEGORY=5	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
	Mean Time	ENCODING.MEAN			
Variables from STROOP					
STRCTRLM	Stroop Control Mean time	STROOP.CATEGORY, STROOP.MEANTIME	N	=MEANTIME if CATEGORY=1	
STRCTRLN	Stroop Control # correct	STROOP.CATEGORY, STROOP.NUM	N	=NUM if CATEGORY=1	
STRCTRLP	Stroop Control % correct	STROOP.CATEGORY, STROOP.PERCENT	N	=PERCENT if CATEGORY=1	
STRDPRSM	Stroop Depressive Mean time	STROOP.CATEGORY, STROOP.MEANTIME	N	=MEANTIME if CATEGORY=2	
STRDPRSN	Stroop Depressive # correct	STROOP.CATEGORY, STROOP.NUM	N	=NUM if CATEGORY=2	
STRDPRSP	Stroop Depressive % correct	STROOP.CATEGORY, STROOP.PERCENT	N	=PERCENT if CATEGORY=2	
STRFOODM	Stroop Food Mean time	STROOP.CATEGORY, STROOP.MEANTIME	N	=MEANTIME if CATEGORY=3	
STRFOODN	Stroop Food # correct	STROOP.CATEGORY, STROOP.NUM	N	=NUM if CATEGORY=3	
STRFOODP	Stroop Food % correct	STROOP.CATEGORY, STROOP.PERCENT	N	=PERCENT if CATEGORY=3	
STRBODYM	Stroop Body Size Mean time	STROOP.CATEGORY, STROOP.MEANTIME	N	=MEANTIME if CATEGORY=4	
STRBODYN	Stroop Body Size # correct	STROOP.CATEGORY, STROOP.NUM	N	=NUM if CATEGORY=4	
STRBODYP	Stroop Body Size % correct	STROOP.CATEGORY, STROOP.PERCENT	N	=PERCENT if CATEGORY=4	
STRFDBDM	Stroop Food + Body Mean time	STROOP.CATEGORY, STROOP.MEANTIME	N	=MEANTIME if CATEGORY=5	
STRFDBDN	Stroop Food + Body # correct	STROOP.CATEGORY, STROOP.NUM	N	=NUM if CATEGORY=5	
STRFDBDP	Stroop Food + Body % correct	STROOP.CATEGORY, STROOP.PERCENT	N	=PERCENT if CATEGORY=5	
Variables from POLYSEME					
PLSFDBDM	Polyseme Body/Food related Mean time	POLYSEME.CATEGORY, POLYSEME.MEANTIME	N	=MEANTIME if CATEGORY=1	
PLSFDBDN	Polyseme Body/Food	POLYSEME.CATEGORY,	N	=NUM if CATEGORY=1	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
	related # BS/F	POLYSEME.NUM			
PLSFDBDP	Polyseme Body/Food related % BS/F	POLYSEME.CATEGORY, POLYSEME.PERCENT	N	=PERCENT if CATEGORY=1	
PLSOTHM	Polyseme Other Mean time	POLYSEME.CATEGORY, POLYSEME.MEANTIME	N	=MEANTIME if CATEGORY=2	
PLSOTHN	Polyseme Other # BS/F	POLYSEME.CATEGORY, POLYSEME.NUM	N	=NUM if CATEGORY=2	
PLSOTHP	Polyseme Other % BS/F	POLYSEME.CATEGORY, POLYSEME.PERCENT	N	=PERCENT if CATEGORY=2	
Variables from WORDSTEM					
WSTCTRLM	Word Stem Control Mean time	WORDSTEM.CATEGORY, WORDSTEM.MEANTIME	N	=MEANTIME if CATEGORY=1	
WSTCTRLN	Word Stem Control # Match	WORDSTEM.CATEGORY, WORDSTEM.NUM	N	=NUM if CATEGORY=1	
WSTCTRLP	Word Stem Control % Match	WORDSTEM.CATEGORY, WORDSTEM.PERCENT	N	=PERCENT if CATEGORY=1	
WSTDPRSM	Word Stem Depressive Mean time	WORDSTEM.CATEGORY, WORDSTEM.MEANTIME	N	=MEANTIME if CATEGORY=2	
WSTDPRSN	Word Stem Depressive # Match	WORDSTEM.CATEGORY, WORDSTEM.NUM	N	=NUM if CATEGORY=2	
WSTDPRSP	Word Stem Depressive % Match	WORDSTEM.CATEGORY, WORDSTEM.PERCENT	N	=PERCENT if CATEGORY=2	
WSTFOODM	Word Stem Food Mean time	WORDSTEM.CATEGORY, WORDSTEM.MEANTIME	N	=MEANTIME if CATEGORY=3	
WSTFOODN	Word Stem Food # Match	WORDSTEM.CATEGORY, WORDSTEM.NUM	N	=NUM if CATEGORY=3	
WSTFOODP	Word Stem Food % Match	WORDSTEM.CATEGORY, WORDSTEM.PERCENT	N	=PERCENT if CATEGORY=3	
WSTBODYM	Word Stem Body Shape Mean time	WORDSTEM.CATEGORY, WORDSTEM.MEANTIME	N	=MEANTIME if CATEGORY=4	
WSTBODYN	Word Stem Body Shape # Match	WORDSTEM.CATEGORY, WORDSTEM.NUM	N	=NUM if CATEGORY=4	
WSTBODYP	Word Stem Body Shape % Match	WORDSTEM.CATEGORY, WORDSTEM.PERCENT	N	=PERCENT if CATEGORY=4	
WSTFDBDM	Word Stem Food + Body Mean time	WORDSTEM.CATEGORY, WORDSTEM.MEANTIME	N	=MEANTIME if CATEGORY=5	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
WSTFDBDN	Word Stem Food + Body # Match	WORDSTEM.CATEGORY, WORDSTEM.NUM	N	=NUM if CATEGORY=5	
WSTFDBDP	Word Stem Food + Body % Match	WORDSTEM.CATEGORY, WORDSTEM.PERCENT	N	=PERCENT if CATEGORY=5	
NCBIAS	Number of COGBIAS items	ENCCTRLMT, ENCDPRSMT, ENCFOODMT, ENCBODYMT, ENCFDBDMT, STRCTRLNUM, STRDPRSNUM, STRFOODNUM, STRBODYNUM, STRFDBDNUM, PLSFDBDNUM, PLSOTHNUM, WSTCTRLNUM, WSTDPRSNUM, WSTFOODNUM, WSTBODYNUM, WSTFDBDNUM	n	= number of non-missing values among { ENCCTRLMT, ENCDPRSMT, ENCFOODMT, ENCBODYMT, ENCFDBDMT, STRCTRLNUM, STRDPRSNUM, STRFOODNUM, STRBODYNUM, STRFDBDNUM, PLSFDBDNUM, PLSOTHNUM, WSTCTRLNUM, WSTDPRSNUM, WSTFOODNUM, WSTBODYNUM, WSTFDBDNUM }	0 – 17
NMISSCBS	Number of missing COGBIAS items	NITEMS	N	=17-NITEMS	

Trial name	**CALERIE 2**
Dataset name	**AE (Adverse Events)**
Description	Adverse Events recorded in CRF, with MedDRA information merged in.
Comments on data structure	1 record / DEIDNUM / AESPEC / AESTRDT (1 record for each AE reported).
Population	All subjects who completed screening and signed informed consent form and started baseline evaluations. (includes subjects who were not randomized).
Visits	4, 5, 7, 8, 9, 10, 11, 12, 13 (See Appendix for VISIT codes)
Usage notes	Adverse Events were not necessarily reported at the closest timepoint, therefore the TIMEPT or VISIT variable is not accurate. Instead, we used AEDAYS0 (days from DAY0 to the AE start date) to determine timing of AEs.
Source data files	CRF/AELOG, MEDRA
Final sort order	DEIDNUM / AESPEC / AESTRDT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
AENUM	AE #	AELOG.AENUM	N		
VISIT	Visit	AELOG.TIMEPT	N	=4 if TIMEPT=1 =5 if TIMEPT=2 =7 if TIMEPT=3 =8 if TIMEPT=4 =9 if TIMEPT=5 =10 if TIMEPT=6 =11 if TIMEPT=7 =12 if TIMEPT=8 =13 if TIMEPT=9	VISFMT
AESPEC	Adverse event (site)	AELOG.AESPEC	C		
AESER	Serious?	AELOG.AESER	N		
AEINTEN	AE intensity	AELOG.AEINTEN	N		TUTEN
AECAUSE	AE causality	AELOG.AECAUSE	N		TUCAUS
ACNONE	No action taken	AELOG.ACNONE	N		
ACTEMPD	Intervention temporarily discontinued	AELOG.ACTEMPD	N		

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
ACMEDREQ	Medical therapy required	AELOG.ACMEDREQ	N		
ACPERMD	Intervention permanently discontinued	AELOG.ACPERMD	N		
ACOTHR	Other action taken	AELOG.ACOTHR	N		
AEOUTCME	AE Outcome	AELOG.AEOUTCME	N		TUOCME
AESTRDT	AE start date	AELOG.AESTRDT	DT		
AESTPDT	AE end date	AELOG.AESTPDT	DT		
AECONT	AE continuing	AELOG.AECONT	N		
AEDAYS0	Days from day 0	SUBJECT1.DAY0DT, AESTRDT	N	= AESTRDT – DAY0DT	
AEDUR	Duration of AE (days)	AESTRDT, AESTPDT	N	= AESTPDT – AESTRDT (in days)	
AE_LLT	MedDRA Lowest Level Term	MEDRA.LLT_NAME	C	=MEDRA.LLT_NAME. if LLT_NAME is missing, let LLT_NAME=AESPEC	
AE_PRFT	MedDRA Preferred Term	MEDRA.PT_NAME	C	=MEDRA.PT_NAME. if PT_NAME is missing, let PT_NAME=AESPEC	
AE_SOC	MedDRA System Organ Class	MEDRA.SOC_NAME	C	=MEDRA.SOC_NAME if SOC_NAME is missing, let SOC_NAME='Not coded yet'	

Trial name	**CALERIE 2**
Dataset name	**SAE (Serious Adverse Events)**
Description	All Serious Adverse events
Comments on data structure	1 record / DEIDNUM / SAESTRDT
Population	Subjects who had any Serious Adverse Event after signing informed consent form.
Source data files	CRF/ SAEFORM, MEDRA, analdata/SUBJECT1
Final sort order	DEIDNUM SAESTRDT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
SAENUM	SAE #	SAEFORM.PAGEREP	N		
SAEDIAG	Serious Adverse event (site)	SAEFORM.SAEDIAG	C		
SAESTRDT	SAE start date	SAEFORM.SAESTRDT	DT		
SAESTPDT	SAE end date	SAEFORM.SAESTPDT	DT		
SAEDAYS0	Days from day 0	SUBJECT1.DAY0DT, SAESTRDT	N	= SAESTRDT – DAY0DT	
SAEDUR	Duration of SAE (days)	SAESTRDT, SAESTPDT	N	= SAESTPDT – SAESTRDT (in days)	
DEATH	Death	SAEFORM.DEATH	N		
LIFETHRT	Life-threatening	SAEFORM.LIFETHRT	N		
DISINCAP	Persistent/sig. disability or incapacity	SAEFORM.DISINCAP	N	Persistent or significant disability or incapacity	
PRLGHOSP	Prolonged or required hospitalization	SAEFORM.PRLGHOSP	N		
CONGDEF	Congenital anomaly or birth defect	SAEFORM.CONGDEF	N		
OTHRSIG	Other event requiring med/surg interven	SAEFORM.OTHRSIG	N	Other significant event requiring medical and/or surgical intervention	
SAECAUS	Causality	SAEFORM.SAECAUS	N		TUCAUS
SAEINTEN	SAE intensity	SAEFORM.SAEINTEN	N		TUTEN

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
SAEOTCME	SAE outcome	SAEFORM.SAEOTCME	N		TUOCME
DEATHDT	Date of death	SAEFORM.DEATHDT	DT		
SACNONE	No action taken	SAEFORM.ACNONE	N		
SACTEMPD	Intervention temporarily discontinued	SAEFORM.ACTEMPD	N		
SACMEDRQ	Medical therapy required	SAEFORM.ACMEDREQ	N		
SACPERMD	Intervention permanently discontinued	SAEFORM.ACPERMD	N		
SACOTHR	Other action taken	SAEFORM.ACOTHR	N		
SACOTHSP	Specify other action	SAEFORM.ACOTHSP	C		
SAE_LLT	MedDRA Lowest Level Term	MEDRA.LLT_NAME	C	=MEDRA.LLT_NAME. if LLT_NAME is missing, let LLT_NAME=AESPEC	
SAE_PRFT	MedDRA Preferred Term	MEDRA.PT_NAME	C	=MEDRA.PT_NAME. if PT_NAME is missing, let PT_NAME=AESPEC	
SAE_SOC	MedDRA System Organ Class	MEDRA.SOC_NAME	C	=MEDRA.SOC_NAME if SOC_NAME is missing, let SOC_NAME='Not coded yet'	

Trial name	**CALERIE 2**
Dataset name	**DTH (Delayed-type Hypersensitivity)**
Description	DTH (Delayed-type Hypersensitivity) data from CRF, flattened to 1 record per DEIDNUM / VISIT.
Comments on data structure	1 record / DEIDNUM / VISIT
Population	Subjects who attended Baseline Visit 2, including all randomized subjects.
Visits	5, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/DTHADM1, DTHADM2, analdata/VISITS2, 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	DTHADM1.PAGEID	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
DTHADMDT	Date of DTH injection	DTHADM1.DTHADMDT	DT		
DTHDONE	DTH injection given	DTHADMDT	N	=1 if DTHADMDT is non-missing else =0	
DTHNDRSN	Reason DTH not done	DTHADM1.DTHND	N		TUND
WKSHTCMP	DTH worksheet completed	WKSHTCMP	N		
EXCLMET	DTH exclusion criteria met	EXCLMET	N		
ARM	Arm injected	ARM	N		TUDTHA
SALIN24A	24 h Saline measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=1	
SALIN24B	24 h Saline measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=1	
SALINE24	Mean 24 hour Saline	SALIN24A, SALIN24B	N	=Mean of SALIN24A and SALIN24B Missing if both are missing	
SALIN48A	48 h Saline measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=5	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
SALIN48B	48 h Saline measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=5	
SALINE48	Mean 48 hour Saline	SALIN48A, SALIN48B	N	=Mean of SALIN48A and SALIN48B Missing if both are missing	
SALINE	Mean Saline	SALINE24, SALINE48	N	=Mean of SALINE24 and SALINE48 Missing if both are missing	
TETOX24A	24 h Tetanus Toxoid measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=2	
TETOX24B	24 h Tetanus Toxoid measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=2	
TETTOX24	Mean 24 hour Tetanus Toxoid	TETOX24A, TETOX24B	N	=Mean of TETOX24A and TETOX24B Missing if both are missing	
TETOX48A	48 h Tetanus Toxoid measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=6	
TETOX48B	48 h Tetanus Toxoid measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=6	
TETTOX48	Mean 48 hour Tetanus Toxoid	TETOX48A, TETOX48B	N	=Mean of TETOX48A and TETOX48B Missing if both are missing	
TETTOX	Mean Tetanus Toxoid	TETTOX24, TETTOX48	N	=Mean of TETTOX24 and TETTOX48 Missing if both are missing	
CANDI24A	24 h Candida measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=3	
CANDI24B	24 h Candida measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=3	
CANDID24	Mean 24 hour Candida	CANDI24A, CANDI24B	N	=Mean of CANDI24A and CANDI24B Missing if both are missing	
CANDI48A	48 h Candida measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=7	
CANDI48B	48 h Candida measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=7	
CANDID48	Mean 48 hour Candida	CANDI48A, CANDI48B	N	=Mean of CANDI48A and CANDI48B Missing if both are missing	
CANDIDA	Mean Candida	CANDID24, CANDID48	N	=Mean of CANDID24 and CANDID48 Missing if both are missing	
TRICH24A	24 h Trichophyton measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=4	
TRICH24B	24 h Trichophyton measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=4	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
TRICH24	Mean 24 hour Trichophyton	TRICH24A, TRICH24B	N	=Mean of TRICH24A and TRICH24B Missing if both are missing	
TRICH48A	48 h Trichophyton measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=8	
TRICH48B	48 h Trichophyton measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=8	
TRICH48	Mean 48 hour Trichophyton	TRICH48A, TRICH48B	N	=Mean of TRICH48A and TRICH48B Missing if both are missing	
TRICH	Mean Trichophyton	TRICH24, TRICH48	N	=Mean of TRICH24 and TRICH48 Missing if both are missing	
MEAN24	Overall 24 hour mean	SALIN24, TETOX24, CANDI24, TRICH24	N	= mean of (SALIN24, TETOX24, CANDI24, TRICH24)	
MEAN48	Overall 48 hour mean	SALINE48, TETTOX48, CANDID48, TRICH48	N	= mean of (SALINE48, TETTOX48, CANDID48, TRICH48)	
MEANALL	Overall mean	SALINE24, TETTOX24, CANDID24, TRICH24 SALINE48, TETTOX48, CANDID48, TRICH48	N	= mean of (SALINE24, TETTOX24, CANDID24, TRICH24, SALINE48, TETTOX48, CANDID48, TRICH48)	
	The remaining variables were derived for use in the Immune Function manuscript: For each analyte, at each of 24 and 48 hours , a dichotomous variable is created with value 0 if the diameter of induration is 0 - 5 mm and 1 if >=5 mm. The (continuous) value for each analyte is set to missing if the diameter of induration is <5mm.				
TT24_GT5	Tet. Tox. Diam. of Indur. 24 hrs >= 5mm	TETTOX24	N	=0 if .z<TETTOX24 < 5 =1 if TETTOX24 >=5 Missing if TETTOX24 is missing	1 = '>=5 mm' 0 = '<5 mm'
TTDI24	Tet. Tox. Diameter of Indur. at 24 hrs	TETTOX24	N	=TETTOX24 if TETTOX24>=5 Missing if TETTOX24 is <5 (or missing)	
TT48_GT5	Tet. Tox. Diam. of Indur. 48 hrs >= 5mm	TETTOX48	N	=0 if .z<TETTOX48 < 5 =1 if TETTOX48 >=5 Missing if TETTOX48 is missing	1 = '>=5 mm' 0 = '<5 mm'
TTDI48	Tet. Tox. Diameter of Indur. at 48 hrs	TETTOX48	N	=TETTOX48 if TETTOX48>=5 Missing if TETTOX48 is <5 (or missing)	
TTDIMAX	Maximum Tet. Tox. Diameter	TTDI24, TTDI48	N	= max(TTDI24, TTDI48)	
TTDIMEAN	Average Tet. Tox. Diameter	TTDI24, TTDI48	N	= mean(TTDI24, TTDI48)	
CD24_GT5	Candida Diam. of Indur. 24 hrs >= 5mm	CANDID24	N	=0 if .z<CANDID24 < 5 =1 if CANDID24 >=5 Missing if CANDID24 is missing	1 = '>=5 mm' 0 = '<5 mm'

CDI24	Candida Diameter of Indur. at 24 hrs	CANDID24	N	=CANDID24 if CANDID24>=5 Missing if CANDID24 is <5 (or missing)	
CD48_GT5	Candida Diam. of Indur. 48 hrs >= 5mm	CANDID48	N	=0 if .z<CANDID48 < 5 =1 if CANDID48 >=5 Missing if CANDID48 is missing	1 = '>=5 mm' 0 = '<5 mm'
CDI48	Candida Diameter of Indur. at 48 hrs	CANDID48	N	=CANDID48 if CANDID48>=5 Missing if CANDID48 is <5 (or missing)	
CDIMAX	Maximum Candida Diameter	CDI24, CDI48	N	= max(CDI24, CDI48)	
CDIMEAN	Average Candida Diameter	CDI24, CDI48	N	= mean(CDI24, CDI48)	
TR24_GT5	Trich. Diam. of Indur. 24 hrs >= 5mm	TRICH24	N	=0 if .z<TRICH24 < 5 =1 if TRICH24 >=5 Missing if TRICH24 is missing	1 = '>=5 mm' 0 = '<5 mm'
TRDI24	Trich. Diameter of Indur. at 24 hrs	TRICH24	N	=TRICH24 if TRICH24>=5 Missing if TRICH24 is <5 (or missing)	
TR48_GT5	Trich. Diam. of Indur. 48 hrs >= 5mm	TRICH48	N	=0 if .z<TRICH48 < 5 =1 if TRICH48 >=5 Missing if TRICH48 is missing	1 = '>=5 mm' 0 = '<5 mm'
TRDI48	Trich. Diameter of Indur. at 48 hrs	TRICH48	N	=TRICH48 if TRICH48>=5 Missing if TRICH48 is <5 (or missing)	
TRDIMAX	Maximum Trich. Diameter	TRDI24, TRDI48	N	TRDIMAX = max(TRDI24, TRDI48)	
TRDIMEAN	Average Trich. Diameter	TRDI24, TRDI48	N	TRDIMEAN = mean(TRDI24, TRDI48)	
TOTDIAM	Total Diameter Across Antigens	TTDIMEAN, CDIMEAN, TRDIMEAN	N	= TTDIMEAN + CDIMEAN + TRDIMEAN Missing if any component is missing	
NANTI24	Num. Positive Antigens at 24 hrs	TT24_GT5, CD24_GT5, TR24_GT54	N	= TT24_GT5 + CD24_GT5 + TR24_GT5 Missing if any component is missing	
NANTI48	Num. Positive Antigens at 48 hrs	TT48_GT5, CD48_GT5, TR48_GT5	N	=TT48_GT5 + CD48_GT5 + TR48_GT5 Missing if any component is missing	
NANTIMAX	Num. Positive Antigens Based on Max	TTDIMAX, CDIMAX, TRDIMAX	N	= (TTDIMAX >= 5) + (CDIMAX >= 5) + (TRDIMAX >= 5) Missing if any component is missing	

Trial name	**CALERIE 2**
Dataset name	**ECGA (12-Lead ECG)**
Description	ECG data from CRF. ECGs were done at every study visit as a safety measure.
Comments on data structure	1 record / DEIDNUM / SUBVISIT
Population	All subjects who started baseline evaluations, including all randomized subjects
Visits	4, 6.1, 7, 7.1, 7.2, 8, 8.1, 8.2, 9, 10, 11, 12, 13 (See Appendix for VISIT codes) (visits 6.1, 7.1, 7.2, 8.1 and 8.2 were discontinued from the protocol, so only early subjects had those visits)
Source data files	CRF/ECG, DATEHDR, analdata/SUBJECT1, VISITS2
Final sort order	DEIDNUM SUBVISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
PAGENUM	CRF page number	ECG.PAGEID	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
ECGDT	Date of ECG	DATEHDR.STUDYDT	DT		DT
ECGNDRSN	Reason ECG not done	DATEHDR.STUDYND	N		TUND
CRFECG	ECG done	ECG.ECGFIND	N	=1 if ECGFIND is non-missing else =0	
ECGFIND	ECG finding	ECG.ECGFIND	N		TUECG 1=Normal 2=Abnormal, not clinically significant 3=Abnormal, clinically significant
ECGSPEC	ECG finding details	ECG.ECG2SP, ECG.ECG3SP	C	(free text) =ECG3SP if non-missing else = ECG2SP if non-missing else missing	

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
ECGALERT	Flagged for ECG abnormality	ECGFIND	N	=1 if ECGFIND=3 else missing	

Trial name	**CALERIE 2**
Dataset name	**RXCAL (Prescribed Caloric intake)**
Description	Prescribed Caloric intake for subjects who were randomized to CR arm and started intervention
Comments on data structure	1 record / DEIDNUM
Population	Subjects who were randomized to the CR arm and started the CR intervention
Source data files	From CTS system (not part of the study database).
Final sort order	DEIDNUM

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
RXCAL	Prescribed EI (kcal/d)	RXCAL	N		

Trial name	**CALERIE 2**
Dataset name	**BIOPSYA (Biopsy collection details)**
Description	Information from CRF on whether subjects gave consent for muscle and fat biopsies, and dates of biopsies, flattened to one record per DEIDNUM / VISIT.
Comments on data structure	1 record / DEIDNUM/ VISIT
Population	All subjects who had Baseline Visit 2, including all randomized subjects
Visits	5, 11, 13 (See Appendix for VISIT codes)
Source data files	CRF/BIOPSY, CONSENTD, 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	BIOPSY.PAGEID	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
MSCCNSNT	Consented to muscle biopsy	CONSENTED.SAMPTYPE CONSENTED.CNSNTDTL	N	=1 if SAMPTYPE=3 and CNSNTDTL in (1,2) else =0 if SAMPTYPE=3 and CNSNTDTL=3	
FATCNSNT	Consented to fat biopsy	CONSENTED.SAMPTYPE CONSENTED.CNSNTDTL	N	=1 if SAMPTYPE=4 and CNSNTDTL in (1,2) else =0 if SAMPTYPE=4 and CNSNTDTL=3	
MBIOPDT	Date of muscle biopsy	BIOPSY.BIOPSY, BIOPSY.BIOPSYDT	DT	=BIOPSYDT if BIOPSY=1	Date
FBIOPDT	Date of fat biopsy	BIOPSY.BIOPSY, BIOPSY.BIOPSYDT	DT	=BIOPSYDT if BIOPSY=2	date
MBPNDRSN	Reason muscle biopsy not done	BIOPSY.BIOPSY, BIOPSY.BIOPSYND	N	=BIOPSYND if BIOPSY=1	TUND
FBPNDRSN	Reason fat biopsy not done	BIOPSY.BIOPSY, BIOPSY.BIOPSYND	N	=BIOPSYND if BIOPSY=1	TUND
CRFMBPSY	Muscle biopsy done (CRF)	MBIOPDT, MSCCNSNT	N	Only defined if consent was given for muscle biopsy. =1 if MBIOPDT is non-missing else=0 if MSCCNSNT=1	

Variable name	LABEL	Source variables	C/ N?	Definition	Accepted values/ Format
				else missing	
CRFFBPSY	Fat biopsy done (CRF)	FBIOPDT, FATCNSNT	N	Only defined if consent was given for fat biopsy. =1 if FBIOPDT is non-missing else=0 if FATCNSNT=1 else missing	

Trial name	**CALERIE 2**
Dataset name	**HEMATOL (Hematology)**
Description	Contains hematology values from safety lab, and determines if subjects met the protocol definition for anemia (HGB, HCT or RBC < lower level of normal, or HCT drop from baseline >=5%). Also includes a flag for subjects who had any anemia surveillance form.
Comments on data structure	1 record / DEIDNUM/ VISIT HCOLDT
Population	All subjects who started baseline evaluations, including all randomized subjects
Visits	4, 7, 8, 9, 10, 11, 12, 13 (and 6.1, 7.1, 7.2, 8.1 for early subjects), as well as unscheduled lab draws (See Appendix for VISIT codes)
Source data files	SFLABLNG, IVRSRAND
Final sort order	DEIDNUM VISIT HCOLDT

Variable name	**LABEL**	**Source variables**	**C/N ?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	SFLABLNG.VISIT	N		VISFMT
SUBVISIT	Sub-Visit	SFLABLNG.SUBVISIT	N		SVISFMT
SFORM	Lab Visit name	SFLABLNG.SFORM	C		
HCOLDT	Sample collection date (lab)	SFLABLNG.COLDT	DT		Date
HHCT	Hematocrit (%)	SFLABLNG.TESTCODE SFLABLNG.RESULTN	N	=RESULTN from record with TESTCODE=’HCT’	
HCTLLN	Hematocrit lower level of normal	SFLABLNG.TESTCODE SFLABLNG.LOWREF	N	=LOWREF from record with TESTCODE=’HCT’	
HHGB	Hemoglobin (g/dl)	SFLABLNG.TESTCODE SFLABLNG.RESULTN	N	=RESULTN from record with TESTCODE=’HGB’	
HGBLLN	Hemoglobin lower level of normal	SFLABLNG.TESTCODE SFLABLNG.LOWREF	N	=LOWREF from record with TESTCODE=’HGB’	
HRBC	Red Blood Cells (10/uL)	SFLABLNG.TESTCODE SFLABLNG.RESULTN	N	=RESULTN from record with TESTCODE=’RBC’	
RBCLLN	Red Blood Cells lower level of normal	SFLABLNG.TESTCODE SFLABLNG.LOWREF	N	=LOWREF from record with TESTCODE=’RBC’	

Variable name	**LABEL**	**Source variables**	**C/N ?**	**Definition**	**Accepted values/ Format**
BLHCT	Baseline Hematocrit (%)	HCT, VISIT	N	=HCT from record with VISIT=4 for that DEIDNUM	
HCTDROP	Hematocrit drop (abs %)	HCT, BLHCT	N	=BLHCT – HCT	
ANEMIA	Record flagged for anemia	HCT, HCTLLN, HGB, HGBLLN, RBC, RBCLLN, HCTDROP	N	Flagged for anemia if any of HCT, HGB or RBC are < their lower level of normal, or the drop in Hematocrit since baseline is >=5. =1 if .z<HCT<HCTLLN or .z<HGB<HGBLLN or .z<RBC<RBCLLN or HCTDROP>=5 else missing	
ANEMSURV	Anemia surveillance report received	IVRSRAND.TX_NUM ANEMIA1.DEIDNUM	N	= -1 (for all records for a DEIDNUM) if TX_NUM=’B’ else =1 (for all records for a DEIDNUM) if there is at least one record in ANEMIA1 for that DEIDNUM else =0	-1=’NA’ 0=’No’ 1=’Yes’

Trial name	**CALERIE 2**
Dataset name	**PAL (Physical Activity Level)**
Description	Merges TEE data from TEERQ and RMRA, to calculate Physical Activity Level (TEE/RMR).
Comments on data structure	1 record / DEIDNUM / VISIT
Population	All subject / visits with usable TEE and RMR (includes all randomized subjects)
Visits	0, 4, 5, 9, 11, 12, 13 (See Appendix for VISIT codes)
Source data files	Analdata/TEERQ, RMRA
Final sort order	DEIDNUM VISIT

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	TEERQ.VISIT	N		
TEERQ	TEE (using individual RQ)	TEERQ.TEERQ	N		
MRMR	RMR	RMRA.RMR	N	For visits 0, 4 and 5, the mean of the two baseline RMRs is used. For all other visits, the RMR from that visit is used.	
PAL	PAL (TDEE/RMR)	TEERQ, MRMR	N	=TEERQ / MRMR	
PA*	Derived Physical Activity	TEERQ, MRMR	N	= (0.9 x TEERQ) - MRMR	

*PA is also referred to as Activity Related Energy Expenditure (AREE)

Trial name	**CALERIE 2**
Dataset name	**BONELAB (Bone markers)**
Description	**Bone markers (PTH, TRAP5b, BAP)**
Comments on data structure	**1 record / DEIDNUM / VISIT**
Population	**Subjects who were randomized.**
Visits	**0, 9, 11, 13**
Source data files	**BONELABS**
Final sort order	**DEIDNUM / VISIT**

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	SUBJNO	C		
VISIT	Visit	VISNUM	N	=0 if VISNUM=0 =9 if VISNUM=6 =11 if VISNUM=12 =13 if VISNUM=24	VISFMT
PTH	PTH (pg/mL)	PTH	N	if BONELABS.PTH is in (-888, -999) then let PTH=. Else PTH=BONELABS.PTH	
PTHDT	PTH Assay date	PTHDT	Date		DATE9
TRAP5B	TRAP5b (U/L)	TRAP5B	N	if BONELABS.TRAP5B is in (-888, -999) then let TRAP5B=. Else TRAP5B=BONELABS.TRAP5B	
TRAP5BDT	TRAP5b Assay Date	TRAP5BDT	Date		DATE9
BAP	BAP (U/L)	BAP	N	if BONELABS.BAP is in (-888, -999) then let BAP=. Else BAP=BONELABS.BAP	
BAPDT	BAP Assay Date	BAPDT	Date		DATE9

Trial name	**CALERIE 2**
Dataset name	**RMRRESID (RMR Residuals)**
Description	**RMR adjusted for FM, FFM, age and sex, based on Baseline regression model.** **See Residual_data_handling_rules.docx for details.**
Comments on data structure	**1 record / DEIDNUM / VISIT**
Population	**Subjects who were randomized.**
Visits	**0, 9, 11, 12, 13**
Usage Notes	**RMRRESID.RMRRESID is one of the Primary Endpoints of the study**
Source data files	**RMRA, SUBJECT1, DXAA**
Final sort order	**DEIDNUM / VISIT**

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	RMRA.VISIT	N	Study Visit, based on CRF page (See Appendix)	VISFMT
RMRPRED	Predicted RMR	SUBJECT1.DOBDT, SUBJECT1.FEMALE DXAA.BSCANDT DXAA.FM DXAA.FFM	N	RMRPRED = INT + (AGE x B_AGE) + (FEMALE x B_FEMALE) + (FM x B_FM) + (FFM x B_FFM) where Age at each VISIT is derived as AGE=yrdif(DOBDT, BSCANDT, 'ACTUAL'). The values INT, B_AGE, B_FEMALE, B_FM and B_FFM are parameter estimates derived from the Baseline regression of RMR on AGEBL, FEMALE, FM and FFM.*	
RMRRESID	RMR Residual	RMRA.RMR RMRPRED	N	RMR adjusted for age, sex, FM and FFM*. This is one of the Primary endpoints of the study. = RMR - RMRPRED	

*See Residual_data_handling_rules.docx for details.

Trial name	**CALERIE 2**
Dataset name	**TEERESID (TEE Residuals)**
Description	**TEE adjusted for FM, FFM, age and sex, based on Baseline regression model. See Residual_data_handling_rules.docx for details.**
Comments on data structure	**1 record / DEIDNUM / VISIT**
Population	**Subjects who were randomized.**
Visits	**0, 9, 11, 12, 13**
Source data files	**TEERQ, SUBJECT1, DXAA**
Final sort order	**DEIDNUM / VISIT**

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	TEERQ.VISIT	N	Study Visit, based on CRF page (See Appendix)	VISFMT
TEEPRED	Predicted TEE	SUBJECT1.DOBDT, SUBJECT1.FEMALE TEERQ.DLWDSEDT DXAA.FM DXAA.FFM	N	TEEPRED = INT + (AGE x B_AGE) + (FEMALE x B_FEMALE) + (FM x B_FM) + (FFM x B_FFM) where Age at each VISIT is derived as AGE=yrdif(DOBDT, DLWDSEDT, 'ACTUAL'). The values INT, B_AGE, B_FEMALE, B_FM and B_FFM are parameter estimates derived from the Baseline regression of TEE on AGEBL, FEMALE, FM and FFM.*	
TEERESID	TEE Residual	TEERQ.TEERQ TEEPRED	N	TEE adjusted for age, sex, FM and FFM*. = TEERQ - TEEPRED	

*See Residual_data_handling_rules.docx for details.

Trial name	**CALERIE 2**
Dataset name	**AREERESD (AREE Residuals)**
Description	**AREE (Activity Related Energy Expenditure)* adjusted for FM, FFM, age and sex, based on Baseline regression model. See Residual_data_handling_rules.docx for details.**
Comments on data structure	**1 record / DEIDNUM / VISIT**
Population	**Subjects who were randomized.**
Visits	**0, 9, 11, 12, 13**
Source data files	**PAL, SUBJECT1, DXAA**
Final sort order	**DEIDNUM / VISIT**

Variable name	**LABEL**	**Source variables**	**C/N?**	**Definition**	**Accepted values/ Format**
DEIDNUM	Subject Number	DEIDNUM	C		
VISIT	Visit	PAL.VISIT	N	Study Visit, based on CRF page (See Appendix)	VISFMT
AREEPRED	Predicted AREE*	SUBJECT1.DOBDT, SUBJECT1.FEMALE DXAA.BSCANDT DXAA.FM DXAA.FFM	N	AREEPRED = INT + (AGE x B_AGE) + (FEMALE x B_FEMALE) + (FM x B_FM) + (FFM x B_FFM) where Age at each VISIT is derived as AGE=yrdif(DOBDT, BSCANDT, ‘ACTUAL’). The values INT, B_AGE, B_FEMALE, B_FM and B_FFM are parameter estimates derived from the Baseline regression of AREE on AGEBL, FEMALE, FM and FFM.**	
AREERESD	AREE Residual	PAL.PA AREEPRED	N	AREE adjusted for age, sex, FM and FFM**. = PA - AREEPRED	

*AREE (Activity Related Energy Expenditure) is also known as Physical Activity Level, and defined as (0.9 x TEE) - RMR

**See Residual_data_handling_rules.docx for details.

Appendix: Visit Codes

CRF pages	Value of SUBVISIT	Formatted value (SVISFMT)	Value of VISIT	Formatted value of VISIT (VISFMT)
28 – 91*			0*	Baseline Mean*
[3, 21]	1	SCR V1**	1	SCR V1**
[22 , 25]	2	SCR V2**	2	SCR V2**
26	3	SCR V3**	3	SCR V3,4**
27	4	SCR V4**		
[28 , 32]	5	BL V1	4	BL Sub 1
[33, 69]	6	BL V2		
[70, 73]	7	BL V3		
[74, 79]	8	BL V4	5	BL Sub 2
[80, 84]	9	BL V5		
85	10	BL V6		
[86 , 91]	11	BL V7		
92	12	Rand.	6	Randomization
93	13	Week 2	6.1	Week 2
[94, 98]	14	Month 1	7	Month 1
99	15	Week 6	7.1	Week 6
100	16	Week 8	7.2	Week 8
[101, 108]	17	Month 3	8	Month 3
109	18	Month 4	8.1	Month 4
110	19	Month 5	8.2	Month 5
[111 , 112]	20	Month 6 V1	9	Month 6
[113, 146]	21	Month 6 V2		
[147, 150]	22	Month 6 V3		
[151, 155]	23	Month 6 V5		
[156, 160]	24	Month 9	10	Month 9
[161, 199]	25	Month 12 V1	11	Month 12
[200, 204]	26	Month 12 V2		
[205, 206]	27	Month 12 V3		
[207, 209]	28	Month 12 V4		
210	29	Month 12 V5		
211	30	Month 17	11.1	
[212, 215]	31	Month 18 V1	12	Month 18
[216, 225]	32	Month 18 V2		

CRF pages	**Value of SUBVISIT**	**Formatted value (SVISFMT)**	**Value of VISIT**	**Formatted value of VISIT (VISFMT)**
28 – 91*			0*	Baseline Mean*
[226 , 228]	33	Month 18 V4		
229	34	Month 23	12.1	
[230 , 268]	35	Month 24 V1	13	Month 24
[269, 273]	36	Month 24 V2		
[274, 275]	37	Month 24 V3		
[276, 278]	38	Month 24 V4		
279	39	Month 24 V5		

*Visit 0 (Baseline Mean) is usually created by taking the average of values from VISITs 4 and 5 (Baseline submissions 1 and 2), rather than using CRF pages.

** Screening Visits 1-4 to determine study eligibility prior to randomization