

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	Baseline Visits 1-3 , Month 6, Month 12, Month 24 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	