

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	Baseline Visits 1-3, Week 2, Month 1, Week 6, Week 8, Month 3, Month 4, month 5, Month 6, Month 9, Month 12, Month 24 Visits Week 2, Week 6, Week 8, Month 4, Month 5 were discontinued from the protocol, so only early subjects had those visits. VISIT codes
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	