

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	Baseline Visits 4-7, Month 6, Month 12, Month 24 <u>for both treatment arms</u> 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 5=Not required	[TUND]

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
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, CORETEMP.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	
USEDUR	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) Missing if OUTRANGE=1 or NUSEDA24<720	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
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, OUTFRANGE, 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 OUTFRANGE=1 or NUSEDD<220	
VARD	Variance of daytime Core Temp0	TEMPSQ, NUSEDD, CORTEMPD, DAY, OUTFRANGE	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 OUTFRANGE=1 or NUSEDD<220	

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