

<b>Trial name</b>	<b>CALERIE 2</b>
<b>Dataset name</b>	<b>RMRA (Resting Metabolic Rate)</b>
<b>Description</b>	<p>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.</p> <p>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 (&lt; 10 usable participant minutes, RQ &lt;0.65 or &gt;1.05, or RMR &lt; 800 or &gt;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.</p>
<b>Comments on data structure</b>	1 record / DEIDNUM/ VISIT / RMRVISIT
<b>Population</b>	All randomized subjects, as well as some subjects who started baseline but dropped out before randomization
<b>VISITs</b>	<p>Baseline Visits 4-7, Month 12, Month 24 for all subjects. Month 6, Month 18 for CR subjects.</p> <p>There are 2 RMRs at Baseline Visits 4-7, denoted by RMRVISIT=1 and 2. VISIT 0 combines the two baseline Visits into a single baseline mean. <a href="#">VISIT codes</a></p>
<b>Usage notes</b>	<p>This dataset has the unadjusted RMR value, incorporating the RMR data handling rules.</p> <p>The primary endpoint, RMR adjusted for age, sex, FM and FFM, is found in the RMRRESID dataset.</p> <p>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.</p>
<b>Source data files</b>	CRF/RMR, LABS/RMRLOAD, ANALDATA/SUBJECT1, DLWFLAT
<b>Final sort order</b>	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=2 <sup>nd</sup> 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)	
<b>Variables for Participant RMR</b>					
				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	
<b>Variables for pre-test CO2 calibration</b>					
				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	
<b>Variables for post-test CO2 calibration</b>					
				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	
<b>Variables for CAL gas 1 calibration</b>					
				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 EEVENT=3	

Variable name	LABEL	Source variables	C/N?	Definition	Accepted values/ Format
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	
<b>Variables for CAL gas 2 calibration</b>					
				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	