

<b>Trial name</b>	<b>CALERIE 2</b>
<b>Dataset name</b>	<b>HEMATOL (Hematology)</b>
<b>Description</b>	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 $\geq 5\%$ ). Also includes a flag for subjects who had any anemia surveillance form.
<b>Comments on data structure</b>	1 record / DEIDNUM/ VISIT HCOLDT
<b>Population</b>	All subjects who started baseline evaluations, including all randomized subjects
<b>Visits</b>	Baseline Visits 1-3 , Week 2, Month 1, Week 6, Week 8, Month 3, Month 4, Month 6, Month 9, Month 12, Month 18, Month 24, as well as unscheduled lab draws.  Visits Week 2, Week 6, Week 8, Month 4, were discontinued from the protocol, so only early subjects had those visits. <a href="#">VISIT codes</a>
<b>Source data files</b>	SFLABLNG, IVRSRAND
<b>Final sort order</b>	DEIDNUM VISIT HCOLDT

<b>Variable name</b>	<b>LABEL</b>	<b>Source variables</b>	<b>C/N ?</b>	<b>Definition</b>	<b>Accepted values/ Format</b>
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'