

Trial name	CALERIE 2
Dataset name	DTH (Delayed-type Hypersensitivity)
Description	DTH (Delayed-type Hypersensitivity) data from CRF, flattened to 1 record per DEIDNUM / VISIT.
Comments on data structure	1 record / DEIDNUM / VISIT
Population	Subjects who attended Baseline Visit 2, including all randomized subjects.
Visits	Baseline Visits 4-7, Month 12, Month 24 VISIT codes
Source data files	CRF/DTHADM1, DTHADM2, analdata/VISITS2, 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	DTHADM1.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
DTHADMDT	Date of DTH injection	DTHADM1.DTHADMDT	DT		
DTHDONE	DTH injection given	DTHADMDT	N	=1 if DTHADMDT is non-missing else =0	
DTHNDRSN	Reason DTH not done	DTHADM1.DTHND	N		TUND
WKSHTCMP	DTH worksheet completed	WKSHTCMP	N		
EXCLMET	DTH exclusion criteria met	EXCLMET	N		
ARM	Arm injected	ARM	N		TUDTHA
SALIN24A	24 h Saline measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=1	
SALIN24B	24 h Saline measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=1	
SALINE24	Mean 24 hour Saline	SALIN24A, SALIN24B	N	=Mean of SALIN24A and SALIN24B Missing if both are missing	
SALIN48A	48 h Saline measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=5	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
SALIN48B	48 h Saline measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=5	
SALINE48	Mean 48 hour Saline	SALIN48A, SALIN48B	N	=Mean of SALIN48A and SALIN48B Missing if both are missing	
SALINE	Mean Saline	SALINE24, SALINE48	N	=Mean of SALINE24 and SALINE48 Missing if both are missing	
TETOX24A	24 h Tetanus Toxoid measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=2	
TETOX24B	24 h Tetanus Toxoid measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=2	
TETTOX24	Mean 24 hour Tetanus Toxoid	TETOX24A, TETOX24B	N	=Mean of TETOX24A and TETOX24B Missing if both are missing	
TETOX48A	48 h Tetanus Toxoid measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=6	
TETOX48B	48 h Tetanus Toxoid measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=6	
TETTOX48	Mean 48 hour Tetanus Toxoid	TETOX48A, TETOX48B	N	=Mean of TETOX48A and TETOX48B Missing if both are missing	
TETTOX	Mean Tetanus Toxoid	TETTOX24, TETTOX48	N	=Mean of TETTOX24 and TETTOX48 Missing if both are missing	
CANDI24A	24 h Candida measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=3	
CANDI24B	24 h Candida measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=3	
CANDID24	Mean 24 hour Candida	CANDI24A, CANDI24B	N	=Mean of CANDI24A and CANDI24B Missing if both are missing	
CANDI48A	48 h Candida measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=7	
CANDI48B	48 h Candida measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=7	
CANDID48	Mean 48 hour Candida	CANDI48A, CANDI48B	N	=Mean of CANDI48A and CANDI48B Missing if both are missing	
CANDIDA	Mean Candida	CANDID24, CANDID48	N	=Mean of CANDID24 and CANDID48 Missing if both are missing	
TRICH24A	24 h Trichophyton measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=4	
TRICH24B	24 h Trichophyton measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=4	

Variable name	LABEL	Source variables	C/N ?	Definition	Accepted values/ Format
TRICH24	Mean 24 hour Trichophyton	TRICH24A, TRICH24B	N	=Mean of TRICH24A and TRICH24B Missing if both are missing	
TRICH48A	48 h Trichophyton measure A	DTHADM2.ANTIGEN DTHADM2.DIAMA	N	=DIAMA from record with ANTIGEN=8	
TRICH48B	48 h Trichophyton measure B	DTHADM2.ANTIGEN DTHADM2.DIAMB	N	=DIAMB from record with ANTIGEN=8	
TRICH48	Mean 48 hour Trichophyton	TRICH48A, TRICH48B	N	=Mean of TRICH48A and TRICH48B Missing if both are missing	
TRICH	Mean Trichophyton	TRICH24, TRICH48	N	=Mean of TRICH24 and TRICH48 Missing if both are missing	
MEAN24	Overall 24 hour mean	SALIN24, TETOX24, CANDI24, TRICH24	N	= mean of (SALIN24, TETOX24, CANDI24, TRICH24)	
MEAN48	Overall 48 hour mean	SALINE48, TETTOX48, CANDID48, TRICH48	N	= mean of (SALINE48, TETTOX48, CANDID48, TRICH48)	
MEANALL	Overall mean	SALINE24, TETTOX24, CANDID24, TRICH24 SALINE48, TETTOX48, CANDID48, TRICH48	N	= mean of (SALINE24, TETTOX24, CANDID24, TRICH24, SALINE48, TETTOX48, CANDID48, TRICH48)	
The remaining variables were derived for use in the Immune Function manuscript: For each analyte, at each of 24 and 48 hours , a dichotomous variable is created with value 0 if the diameter of induration is 0 - 5 mm and 1 if >=5 mm. The (continuous) value for each analyte is set to missing if the diameter of induration is <5mm.					
TT24_GT5	Tet. Tox. Diam. of Indur. 24 hrs >= 5mm	TETTOX24	N	=0 if .z<TETTOX24 < 5 =1 if TETTOX24 >=5 Missing if TETTOX24 is missing	1 = '>=5 mm' 0 = '<5 mm'
TTDI24	Tet. Tox. Diameter of Indur. at 24 hrs	TETTOX24	N	=TETTOX24 if TETTOX24>=5 Missing if TETTOX24 is <5 (or missing)	
TT48_GT5	Tet. Tox. Diam. of Indur. 48 hrs >= 5mm	TETTOX48	N	=0 if .z<TETTOX48 < 5 =1 if TETTOX48 >=5 Missing if TETTOX48 is missing	1 = '>=5 mm' 0 = '<5 mm'
TTDI48	Tet. Tox. Diameter of Indur. at 48 hrs	TETTOX48	N	=TETTOX48 if TETTOX48>=5 Missing if TETTOX48 is <5 (or missing)	
TTDIMAX	Maximum Tet. Tox. Diameter	TTDI24, TTDI48	N	= max(TTDI24, TTDI48)	
TTDIMEAN	Average Tet. Tox. Diameter	TTDI24, TTDI48	N	= mean(TTDI24, TTDI48)	
CD24_GT5	Candida Diam. of Indur. 24 hrs >= 5mm	CANDID24	N	=0 if .z<CANDID24 < 5 =1 if CANDID24 >=5 Missing if CANDID24 is missing	1 = '>=5 mm' 0 = '<5 mm'

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DTH

CDI24	Candida Diameter of Indur. at 24 hrs	CANDID24	N	=CANDID24 if CANDID24>=5 Missing if CANDID24 is <5 (or missing)	
CD48_GT5	Candida Diam. of Indur. 48 hrs >= 5mm	CANDID48	N	=0 if .z<CANDID48 < 5 =1 if CANDID48 >=5 Missing if CANDID48 is missing	1 = '>=5 mm' 0 = '<5 mm'
CDI48	Candida Diameter of Indur. at 48 hrs	CANDID48	N	=CANDID48 if CANDID48>=5 Missing if CANDID48 is <5 (or missing)	
CDIMAX	Maximum Candida Diameter	CDI24, CDI48	N	= max(CDI24, CDI48)	
CDIMEAN	Average Candida Diameter	CDI24, CDI48	N	= mean(CDI24, CDI48)	
TR24_GT5	Trich. Diam. of Indur. 24 hrs >= 5mm	TRICH24	N	=0 if .z<TRICH24 < 5 =1 if TRICH24 >=5 Missing if TRICH24 is missing	1 = '>=5 mm' 0 = '<5 mm'
TRDI24	Trich. Diameter of Indur. at 24 hrs	TRICH24	N	=TRICH24 if TRICH24>=5 Missing if TRICH24 is <5 (or missing)	
TR48_GT5	Trich. Diam. of Indur. 48 hrs >= 5mm	TRICH48	N	=0 if .z<TRICH48 < 5 =1 if TRICH48 >=5 Missing if TRICH48 is missing	1 = '>=5 mm' 0 = '<5 mm'
TRDI48	Trich. Diameter of Indur. at 48 hrs	TRICH48	N	=TRICH48 if TRICH48>=5 Missing if TRICH48 is <5 (or missing)	
TRDIMAX	Maximum Trich. Diameter	TRDI24, TRDI48	N	TRDIMAX = max(TRDI24, TRDI48)	
TRDIMEAN	Average Trich. Diameter	TRDI24, TRDI48	N	TRDIMEAN = mean(TRDI24, TRDI48)	
TOTDIAM	Total Diameter Across Antigens	TTDIMEAN, CDIMEAN, TRDIMEAN	N	= TTDIMEAN + CDIMEAN + TRDIMEAN Missing if any component is missing	
NANTI24	Num. Positive Antigens at 24 hrs	TT24_GT5, CD24_GT5, TR24_GT5	N	= TT24_GT5 + CD24_GT5 + TR24_GT5 Missing if any component is missing	
NANTI48	Num. Positive Antigens at 48 hrs	TT48_GT5, CD48_GT5, TR48_GT5	N	=TT48_GT5 + CD48_GT5 + TR48_GT5 Missing if any component is missing	
NANTIMAX	Num. Positive Antigens Based on Max	TTDIMAX, CDIMAX, TRDIMAX	N	= (TTDIMAX >= 5) + (CDIMAX >= 5) + (TRDIMAX >= 5) Missing if any component is missing	