

|                                   |                                                                                               |
|-----------------------------------|-----------------------------------------------------------------------------------------------|
| <b>Trial name</b>                 | <b>CALERIE 2</b>                                                                              |
| <b>Dataset name</b>               | <b>DTH (Delayed-type Hypersensitivity)</b>                                                    |
| <b>Description</b>                | DTH (Delayed-type Hypersensitivity) data from CRF, flattened to 1 record per DEIDNUM / VISIT. |
| <b>Comments on data structure</b> | 1 record / DEIDNUM / VISIT                                                                    |
| <b>Population</b>                 | Subjects who attended Baseline Visit 2, including all randomized subjects.                    |
| <b>Visits</b>                     | Baseline Visits 4-7, Month 12, Month 24<br><a href="#">VISIT codes</a>                        |
| <b>Source data files</b>          | CRF/DTHADM1, DTHADM2, analdata/VISITS2, SUBJECT1                                              |
| <b>Final sort order</b>           | 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<br>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<br>DTHADM2.DIAMA | N     | =DIAMA from record with ANTIGEN=1                             |                         |
| SALIN24B      | 24 h Saline measure B      | DTHADM2.ANTIGEN<br>DTHADM2.DIAMB | N     | =DIAMB from record with ANTIGEN=1                             |                         |
| SALINE24      | Mean 24 hour Saline        | SALIN24A, SALIN24B               | N     | =Mean of SALIN24A and SALIN24B<br>Missing if both are missing |                         |
| SALIN48A      | 48 h Saline measure A      | DTHADM2.ANTIGEN<br>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<br>DTHADM2.DIAMB | N     | =DIAMB from record with ANTIGEN=5                             |                         |
| SALINE48      | Mean 48 hour Saline           | SALIN48A, SALIN48B               | N     | =Mean of SALIN48A and SALIN48B<br>Missing if both are missing |                         |
| SALINE        | Mean Saline                   | SALINE24, SALINE48               | N     | =Mean of SALINE24 and SALINE48<br>Missing if both are missing |                         |
| TETOX24A      | 24 h Tetanus Toxoid measure A | DTHADM2.ANTIGEN<br>DTHADM2.DIAMA | N     | =DIAMA from record with ANTIGEN=2                             |                         |
| TETOX24B      | 24 h Tetanus Toxoid measure B | DTHADM2.ANTIGEN<br>DTHADM2.DIAMB | N     | =DIAMB from record with ANTIGEN=2                             |                         |
| TETTOX24      | Mean 24 hour Tetanus Toxoid   | TETOX24A, TETOX24B               | N     | =Mean of TETOX24A and TETOX24B<br>Missing if both are missing |                         |
| TETOX48A      | 48 h Tetanus Toxoid measure A | DTHADM2.ANTIGEN<br>DTHADM2.DIAMA | N     | =DIAMA from record with ANTIGEN=6                             |                         |
| TETOX48B      | 48 h Tetanus Toxoid measure B | DTHADM2.ANTIGEN<br>DTHADM2.DIAMB | N     | =DIAMB from record with ANTIGEN=6                             |                         |
| TETTOX48      | Mean 48 hour Tetanus Toxoid   | TETOX48A, TETOX48B               | N     | =Mean of TETOX48A and TETOX48B<br>Missing if both are missing |                         |
| TETTOX        | Mean Tetanus Toxoid           | TETTOX24, TETTOX48               | N     | =Mean of TETTOX24 and TETTOX48<br>Missing if both are missing |                         |
| CANDI24A      | 24 h Candida measure A        | DTHADM2.ANTIGEN<br>DTHADM2.DIAMA | N     | =DIAMA from record with ANTIGEN=3                             |                         |
| CANDI24B      | 24 h Candida measure B        | DTHADM2.ANTIGEN<br>DTHADM2.DIAMB | N     | =DIAMB from record with ANTIGEN=3                             |                         |
| CANDID24      | Mean 24 hour Candida          | CANDI24A, CANDI24B               | N     | =Mean of CANDI24A and CANDI24B<br>Missing if both are missing |                         |
| CANDI48A      | 48 h Candida measure A        | DTHADM2.ANTIGEN<br>DTHADM2.DIAMA | N     | =DIAMA from record with ANTIGEN=7                             |                         |
| CANDI48B      | 48 h Candida measure B        | DTHADM2.ANTIGEN<br>DTHADM2.DIAMB | N     | =DIAMB from record with ANTIGEN=7                             |                         |
| CANDID48      | Mean 48 hour Candida          | CANDI48A, CANDI48B               | N     | =Mean of CANDI48A and CANDI48B<br>Missing if both are missing |                         |
| CANDIDA       | Mean Candida                  | CANDID24, CANDID48               | N     | =Mean of CANDID24 and CANDID48<br>Missing if both are missing |                         |
| TRICH24A      | 24 h Trichophyton measure A   | DTHADM2.ANTIGEN<br>DTHADM2.DIAMA | N     | =DIAMA from record with ANTIGEN=4                             |                         |
| TRICH24B      | 24 h Trichophyton measure B   | DTHADM2.ANTIGEN<br>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<br>Missing if both are missing                                  |                             |
| TRICH48A      | 48 h Trichophyton measure A                                                                                                                                                                                                                                                                                                                            | DTHADM2.ANTIGEN<br>DTHADM2.DIAMA                                                     | N     | =DIAMA from record with ANTIGEN=8                                                              |                             |
| TRICH48B      | 48 h Trichophyton measure B                                                                                                                                                                                                                                                                                                                            | DTHADM2.ANTIGEN<br>DTHADM2.DIAMB                                                     | N     | =DIAMB from record with ANTIGEN=8                                                              |                             |
| TRICH48       | Mean 48 hour Trichophyton                                                                                                                                                                                                                                                                                                                              | TRICH48A, TRICH48B                                                                   | N     | =Mean of TRICH48A and TRICH48B<br>Missing if both are missing                                  |                             |
| TRICH         | Mean Trichophyton                                                                                                                                                                                                                                                                                                                                      | TRICH24, TRICH48                                                                     | N     | =Mean of TRICH24 and TRICH48<br>Missing if both are missing                                    |                             |
| MEAN24        | Overall 24 hour mean                                                                                                                                                                                                                                                                                                                                   | SALIN24, TETOX24,<br>CANDI24, TRICH24                                                | N     | = mean of (SALIN24, TETOX24, CANDI24,<br>TRICH24)                                              |                             |
| MEAN48        | Overall 48 hour mean                                                                                                                                                                                                                                                                                                                                   | SALINE48, TETTOX48,<br>CANDID48, TRICH48                                             | N     | = mean of (SALINE48, TETTOX48, CANDID48,<br>TRICH48)                                           |                             |
| MEANALL       | Overall mean                                                                                                                                                                                                                                                                                                                                           | SALINE24, TETTOX24,<br>CANDID24, TRICH24<br>SALINE48, TETTOX48,<br>CANDID48, TRICH48 | N     | = mean of (SALINE24, TETTOX24, CANDID24,<br>TRICH24, SALINE48, TETTOX48, CANDID48,<br>TRICH48) |                             |
|               | <b>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 &gt;=5 mm. The (continuous) value for each analyte is set to missing if the diameter of induration is &lt;5mm.</b> |                                                                                      |       |                                                                                                |                             |
| TT24_GT5      | Tet. Tox. Diam. of Indur. 24 hrs<br>>= 5mm                                                                                                                                                                                                                                                                                                             | TETTOX24                                                                             | N     | =0 if .z<TETTOX24 < 5<br>=1 if TETTOX24 >=5<br>Missing if TETTOX24 is missing                  | 1 = '>=5 mm'<br>0 = '<5 mm' |
| TTDI24        | Tet. Tox. Diameter of Indur. at 24<br>hrs                                                                                                                                                                                                                                                                                                              | TETTOX24                                                                             | N     | =TETTOX24 if TETTOX24>=5<br>Missing if TETTOX24 is <5 (or missing)                             |                             |
| TT48_GT5      | Tet. Tox. Diam. of Indur. 48 hrs<br>>= 5mm                                                                                                                                                                                                                                                                                                             | TETTOX48                                                                             | N     | =0 if .z<TETTOX48 < 5<br>=1 if TETTOX48 >=5<br>Missing if TETTOX48 is missing                  | 1 = '>=5 mm'<br>0 = '<5 mm' |
| TTDI48        | Tet. Tox. Diameter of Indur. at 48<br>hrs                                                                                                                                                                                                                                                                                                              | TETTOX48                                                                             | N     | =TETTOX48 if TETTOX48>=5<br>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<br>=1 if CANDID24 >=5<br>Missing if CANDID24 is missing                  | 1 = '>=5 mm'<br>0 = '<5 mm' |

**CALERIE Phase 2: Documentation of Analysis Datasets for Public Use Database**
**DTH**

|          |                                       |                              |   |                                                                                          |                             |
|----------|---------------------------------------|------------------------------|---|------------------------------------------------------------------------------------------|-----------------------------|
| CDI24    | Candida Diameter of Indur. at 24 hrs  | CANDID24                     | N | =CANDID24 if CANDID24>=5<br>Missing if CANDID24 is <5 (or missing)                       |                             |
| CD48_GT5 | Candida Diam. of Indur. 48 hrs >= 5mm | CANDID48                     | N | =0 if .z<CANDID48 < 5<br>=1 if CANDID48 >=5<br>Missing if CANDID48 is missing            | 1 = '>=5 mm'<br>0 = '<5 mm' |
| CDI48    | Candida Diameter of Indur. at 48 hrs  | CANDID48                     | N | =CANDID48 if CANDID48>=5<br>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<br>=1 if TRICH24 >=5<br>Missing if TRICH24 is missing               | 1 = '>=5 mm'<br>0 = '<5 mm' |
| TRDI24   | Trich. Diameter of Indur. at 24 hrs   | TRICH24                      | N | =TRICH24 if TRICH24>=5<br>Missing if TRICH24 is <5 (or missing)                          |                             |
| TR48_GT5 | Trich. Diam. of Indur. 48 hrs >= 5mm  | TRICH48                      | N | =0 if .z<TRICH48 < 5<br>=1 if TRICH48 >=5<br>Missing if TRICH48 is missing               | 1 = '>=5 mm'<br>0 = '<5 mm' |
| TRDI48   | Trich. Diameter of Indur. at 48 hrs   | TRICH48                      | N | =TRICH48 if TRICH48>=5<br>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<br>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<br>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<br>Missing if any component is missing                   |                             |
| NANTIMAX | Num. Positive Antigens Based on Max   | TTDIMAX, CDIMAX, TRDIMAX     | N | = (TTDIMAX >= 5) + (CDIMAX >= 5) + (TRDIMAX >= 5)<br>Missing if any component is missing |                             |