Overview of DREAM data

July 22, 2019

This export site provides a total of 35 data files for DREAM in excel format. The data are from 535 participants who were randomized into the Primary trial and 43 participants among the 535 who were randomized into the Extension study.

There are 3 main types of data in DREAM:

1. Data derived from case report forms completed at the clinical centers (30 files)

Dataset names correspond to the form names (see table below). Annotated versions of the forms are provided with embedded variable names that are used as column headings for the excel files.

|  |  |  |
| --- | --- | --- |
| **#** | **Case Report Form\_Name** | **Dataset name**  |
| 1 | Adverse Event Log | AE |
| 2 | BASELINE HEALTH REVIEW | BR |
| 3 | Baseline Refraction and Visual Acuity Testing | BV |
| 4 | CONCOMITANT MEDICATION LOG | CM |
| 5 | Additional Information on Women Of Childbearing Potential | CP |
| 6 | MARS LETTER CONTRAST SENSITIVITY TEST | CS |
| 7 | BASELINE DIETARY SUPPLEMENT FORM | DS |
| 8 | DRY EYE TREATMENT | DT |
| 9 | ELIGIBILITY OCULAR EVALUATION FORM | EO |
| 10 | FOLLOW-UP HEALTH REVIEW | FR |
| 11 | FOLLOW-UP DIETARY SUPPLEMENT FORM | FS |
| 12 | GENERAL INFORMATION FORM | GI |
| 13 | KERATOGRAPHY ASSESSMENT | KT |
| 14 | Medical Monitor SAE Review Form | MEDICAL\_MONITOR\_SAE\_REVIEW |
| 15 | Medical History Form | MH |
| 16 | MMP-9 Testing | MM |
| 17 | MISSED VISIT FORM | MV |
| 18 | FOLLOW-UP OCULAR EVALUATION FORM | OA |
| 19 | BRIEF OCULAR DISCOMFORT INVENTORY© (BODI©) | ODI |
| 20 | OCULAR SURFACE DISEASE INDEX © | OSI |
| 21 | PATIENT DEATH FORM | PD |
| 22 | Serious Adverse Event Initial Reporting Form | SA |
| 23 | SF-36v2 | SF36 |
| 24 | Serious Adverse Event Follow-Up Reporting Form | SU |
| 25 | TELEPHONE VISIT FORM | TF |
| 26 | DRY EYE TREATMENT HISTORY FORM | TH |
| 27 | TEAR OSMOLARITY ASSESSMENT | TO |
| 28 | HEALTHCARE UTILIZATION FORM | UQ |
| 29 | Follow-up Visual Acuity Testing | VA |
| 30 | Work Productivity and Activity Impairment Questionnaire | WP |

1. Data from laboratories that analyzed samples from the DREAM patients

Datasets contain the results of testing (see table below). For laboratory results file 1 to 3, we provide a separate excel file titled “*Lab results data dictionary*” indicating the meaning of each variable. For laboratory file 4, the variable names are self-explanatory.

|  |  |  |
| --- | --- | --- |
|  | **Laboratory Result** | **Dataset name**  |
| 1 | Impression Cytology | IC\_RESULTS |
| 2 | Tear Cytokines | TC\_RESULTS |
| 3 | Autoantibodies (including those for Sjogren Syndrome) | SJO\_RESULTS |
| 4 | Fatty Acid Concentrations and Percentages | FATTY\_ACID\_SAMPLES |

1. Data from grading forms completed at the DREAM Meibography Reading Center

The one dataset name corresponds to the grading form name. An annotated version of the form is provided with embedded variable names that are used as column headings for the csv file.

|  |  |
| --- | --- |
| **Grading Form\_Name** | **Dataset name**  |
| Meibomian Gland Baseline | MB |

Most DREAM procedures were required for all patients. However, there were certain exploratory measurements that were conducted only in clinical centers that had the equipment necessary to complete the procedures. The table below lists the exploratory procedures and the number of patients who had the exploratory procedures at baseline.

|  |  |  |
| --- | --- | --- |
|  | **Dataset name**  | **N at Baseline** |
| KERATOGRAPHY ASSESSMENT (including meibography) | KT | 292 |
| TEAR CYTOKINES | TC\_RESULTS | 190 |
| TEAR OSMOLARITY  | TO | 411 |
|  |  |  |

Most missing data is attributable to missed visits. However, particularly for the laboratory data, there may be additional missing data due to the samples not drawn, losses and damage in shipping, equipment failures, etc.