

PEDIG - Public Dataset Readme File for the Myopia Treatment Study 1

A Randomized Trial of Low-Dose Atropine Eyedrops for the Control of Myopia Progression.

Link to public website: <https://www.jaeb.org/projects>

The primary manuscript was submitted to the New England Journal of Medicine and has not yet been published.

Important:

Use of these publicly-available data requires that you include the following attribution and disclaimer in any use of these data:

"The source of the data is A Randomized Trial of Low-Dose Atropine for the Treatment of Myopia: Myopia Treatment Study 1. The study was funded by the National Eye Institute of the National Institutes of Health Grants EY11751, EY18810 and EY23198; and was conducted by the Pediatric Eye Disease Investigator Group (PEDIG). The analyses, content and conclusions presented herein are solely the responsibility of the authors and have not been reviewed or approved by the PEDIG group, the NEI, or the NIH."

Contents of this dataset zip file:

1. **Protocol** – the final protocol in PDF format (MTS1ProtocolV5.1 06Apr2020)
2. **Case Report Forms** – The Case Report Forms (CRF) folder contains a PDF for each CRF used to collect data during the study. The data from these forms are in the tables in the Data Tables folder. The tables used in each CRF are listed in the Data Glossary document (MTS1_DataGlossary_13Jan2023). Fields that were deemed unnecessary for analyses are not included in public data tables (e.g. tracking and administrative information) and any information that could be used to identify the participants.
3. **Data Tables** – The Data Tables folder contains the data collected from the study in .txt format, pipe (|) delimited. All Patient IDs and dates have been de-identified. Dates are de-identified using the expert determination-based approach – using a single random offset of up to 365 days to each participant's set of treatment dates, which preserves the dates relationships to each other. Some data which may contain identifiable information is excluded from the data files.
4. **Data Glossary** – The data glossary (MTS1_DataGlossary_13Jan2023) is to be used in conjunction with the txt files in the Data Tables folder. It contains one table per table txt file and gives a description of each field.

Notes:

A summary table at the beginning of the Data Glossary document lists each data table, and defines 1) whether the table data are one record per **PtID** or one record per **PtID per Visit**, and 2) lists the associated CRFs associated with that table.

The unique patient identifier (**PtID** field) identifies data for a specific participant between tables.

The unique visit identifier (**Visit** field) identifies data for a specific visit for that participant PtID between tables if applicable.