

Project Summary Report

YODA Project Protocol #: 2025-0460

Alzheimer's Disease (AD) Placebo Data Harmonization for Future AD Data Initiative/Vivli Challenge

Objective

The proposed research was to generate a single analyzable dataset comprised of placebo-arm data from a number of Alzheimer's disease phase 3 clinical trials. That included two aims:

Aim 1. Generate a tall format ADaM with one row per participant, per parameter, per visit, with key demographic and baseline characteristics merged into each row. In this format, study data can be stacked together for a single data table including all placebo-arm participants across all harmonized trials.

Aim 2. Transpose the integrated, tall dataset to generate a wide-format file with one row per person per visit. A transposed, wide version of the file is useful for analyses that require one entry per participant.

A harmonized dataset is being made permissibly available via the Vivli platform.

To our knowledge, this project created one of the largest Alzheimer's disease datasets. The aggregated dataset will enable researchers to perform analyses immediately across trials without having to perform harmonization themselves, and allows them to focus on hypothesis testing, generation, and validation. We believe this dataset will spur innovation and progress in ADRD research.

Methods

All studies were stacked into a singular ADaM dataset. Specifically, the following were standardized across all visits to help facilitate analysis of the data:

1. **Visit Windowing:** A harmonized visit windowing strategy was applied across all studies. Study protocols were reviewed to define visit windows that align with the timing and structure of the data in each trial, ensuring comparability across datasets.
2. **Standardization of Outcome Labels:** Clinical outcome labels were standardized to ensure that identical outcomes across studies are consistently named and can be accurately grouped for analysis. This step facilitates cross-study comparisons and pooled analyses.
3. **Standardization of Outcome Measurements:** In addition to standardizing the labels of different outcomes within the final ADaM dataset, work was done to help standardize the outcomes themselves to make the studies as comparable as possible.
4. **Categorization of Related Outcomes:** Outcomes that were similar but not identical (e.g., ADAS-Cog11 vs. ADAS-Cog13) were grouped into broader parameter categories. This allows for meaningful classification while preserving the distinctions between closely related measurements.
5. **Redefinition of Baseline Measurements:** A consistent approach to defining baseline values was implemented across studies. Each protocol was examined to determine the most appropriate and comparable method for deriving baseline measurements for key outcomes.
6. **Standardization of Analysis Day (Reference Day):** The definition of "Day 1" or the reference day for baseline was standardized across all studies to ensure uniformity in the calculation of analysis days. This is critical for accurate temporal alignment of data during longitudinal analyses.

Results

N/A

Conclusions

The dataset was created and is ready for conclusions to be reached by the researchers who will be gaining access to the data.