While randomized controlled clinical trials are the gold standard for demonstrating efficacy, there is a need to facilitate comparison of trial findings with real-world populations. This is evident in the 3rd Century Core Set with the FDA’s large post-licensure initiatives, such as iME4GisFish in Europe.2 In this study we propose the use of common model transformation and standardized clinical vocabulary to facilitate replication of the study setup from an Alzheimer’s trial, publicly available in the Clinical Data Exchange, Standards Consortium: Study Data Tabulation Model (CDISC SDTM) format, in a real-world data Electronic Medical Record data source.3 For data transformation, the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) was used.4

Results

Various ADAS subtests and MMSE data were extracted and compared. Figure 2 shows a comparison between the two datasets. The CDISC clinical trial dataset from CDISC, of mild to moderate AD patients, was compared with a real-world population. This allowed for comparison of adverse events against a population not present in the original placebo controlled clinical trial dataset from CDISC, of mild to moderate AD patients. Within this study, we assessed the ability to measure both efficacy and safety measures between a clinical trial and real-world populations.

Conclusions

By leveraging standard OMOP vocabularies and common data modeling, cohort replication and analysis can be executed rapidly and consistently. This has potential applications for enhancing the conduct of synthetic control arms for clinical development and for extrapolation of clinical trial findings to real-world treatment practices.

Table 1: Demographics

Age at Index

Baseline Cohort

Real-world Cohort

Mean (SD)

Women

Men

Missing/EMR

Drugs in Current Use

Baseline Cohort

Real-world Cohort

Mean (SD)

Men

Women

Missing/EMR

Table 1: Demographics

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