ABSTRACT

Industry standards have evolved over time for data collection (CDASH), observed data (SDTM), and analysis datasets (ADaM). Although substantial progress has been made, additional standardization can improve product development. This poster will cover two specific needs. First, further advancement is needed to develop industry standards for analysis and reporting. Development of standard Tables, Figures, and Listings (TFLs) and associated analyses will lead to improved standardization from collection through data storage. (You need to know how to analyze and display results before finalizing how to collect and store data.) The development of standard TFLs will also lead to improved product lifecycle by ensuring reviewers receive the desired analyses for the consistent and efficient evaluation of patient safety and drug effectiveness. Second, additional improvement is needed with respect to data traceability from collection to analysis. This poster will display how Eli Lilly & Company plans to address this gap.

Status of Industry Standards

Why Standardize Tables/Figures/Listing?

- Need to know how the data will be displayed to ensure proper collection and storage
- Ensures reviewers receive the desired displays
- Enables consistent and efficient evaluation of patient safety and drug effectiveness
- Facilitates the incorporation of advice from subject matter experts
  - Creates forum to communicate improved methodology
  - For safety, leads to improved signal detection

What TFLs Can Be Standardized?

Demographics
- Create consistent definitions of adverse events and treatment emergent adverse events

Adverse Events
- Create consistent definitions of adverse events and treatment emergent adverse events

Vital Signs, Laboratory Measures, ECGs
- Consistent approach for central tendency
- Consistent approach for outliers/shifts
- Consistent advice on reference ranges or thresholds

TFLs for Common Events of Special Interest
- Hepatotoxicity
- Hypersensitivity

CONCLUSIONS

- There is a HUGE opportunity for increased efficiency by standardizing common TFLs across the industry
- Standardizing common TFLs for safety may improve safety signal detection
- Improving data traceability will facilitate the review process