

Background

The PHUSE Best Practices for Data Collection Initiatives project team conducted a survey in 2020 to study the variation in the collection and treatment emergence (TE) definition of adverse event (AE) data in clinical studies to reduce the variability across industry. The project team noted the need to pursue additional research to further harmonize industry practices. The PHUSE Treatment Emergence Definition project team conducted an additional survey to solicit input from respondents on various TEAE scenarios for a basic study design and the initial results are reported in this poster (13 Sept 2021 data cut; N = 216 respondents). Respondents were asked to review each scenario and indicate whether they thought the patient had a TEAE for an intervention period summary table.

Assumptions

- Two-period, two-treatment design:
- Screening period
 - Patients undergo typical screening assessments and receive no treatment
 - Intervention period
 - Patients receive active drug or control throughout entire period and there are no dosing modifications
 - There is no safety follow-up period
- Adverse event scenarios:
- Each scenario represents the reported AE(s) for a single patient
 - Event onset, recurrence, and severity can vary over time, however, changes in drug relatedness or seriousness are out of scope
 - Each event is the same medical concept for the patient and everything is known about the events

Conclusions

- A very basic study design was utilized with not uncommon scenarios, yet considerable disagreement in TE responses was noted among respondents
- Further analysis is needed to better understand the results before issuing any recommendations:
 - Differences by respondent characteristics
 - Common themes in open-text comments provided by respondents (not reported here)

Next Steps

- Conduct final survey analysis
- Develop white paper with recommendations / points to consider
- Address other sources for TE definition variation in future white papers:
 - Changes in drug relatedness and seriousness
 - More complex study designs
 - Events in presence of multiple treatments
 - Events during a safety follow-up period
 - “Last dose + X” window for post-treatment events

TE Scenarios and Initial Survey Results

