Methods for Reporting the Patient-Reported Outcomes Version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE) Data in Cancer Clinical Trials

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BACKGROUND

The National Cancer Institute’s PRO-CTCAE has been developed to integrate patient perspectives on symptomatic adverse events in cancer trials.

As an initial new assessment, there are currently no standard approaches for analyzing and reporting PRO-CTCAE data.

• Benchmark at prior example papers using standard bar charts and recommended that future directions consider baseline and more frequent reports of PRO-CTCAE data to allow for greater longitudinal analysis.

OBJECTIVE

• To provide a systematic and easy-to-apply approach that can be used to report PRO-CTCAE data in clinical trial oncology.

METHODS

-Challenges of Analyzing and Reporting PRO-CTCAE Data

The PRO-CTCAE measurement system consists of a large-term library

– 547 PRO-CTCAE items for 68 PRO-CTCAE terms are mapped to the TRA-CTCAE MedLink.

• For irregular reinduction and expression, two PRO-CTCAE terms are mapped to each other.

• Each term may have 1 to 3 attribute items, where the term is defined as frequency, severity, interference, presence, or amount.

• The presentation provides a simple and informative solution to PRO-CTCAE data.

The order of the score level makes it easy to dichotomize the scores. In our experience, it can be easily seen that approximately 20% of the patients have constipation score ≥ 3, and approximately 90% have constipation score ≥ 1.

• The visual presentation makes it easy to identify prevalent symptoms. For example, symptoms like pain, swelling, or redness are responsive to treatments.

RESULTS

Reporting of Baseline PRO-CTCAE Data

• As shown in Figure 2, horizontal bars make it easy to look at 20-30 items per page to show the toxicities/symptoms burden in the clinical trial patient population.

• The stacked bar chart provides a unified display of PRO-CTCAE terms with various attitude levels.

• High granularity is retained in stacked bars because the percentage of each score level is presented.

• The visual presentation makes it easy to identify prevalent symptoms.

• The order of the score level makes it easy to dichotomize the scores. In our experience, it can be easily seen that approximately 20% of the patients have constipation score ≥ 3, and approximately 90% have constipation score ≥ 1.

• Sample sizes presented beside each bar allow for assessing completion/compliance.

Reporting of Postbaseline PRO-CTCAE Data

To compare treatment differences, we define as outcome in three categories: improved, no change (e.g., stable), or worsened from baseline (Figure 3).

• It is important to assess the improvement or change in adverse events when the direction of treatment impact on the symptom is unknown. It is also possible that the treatment improves some symptoms while worsening others.

• The visual presentation makes it easy to identify symptoms that are responsive to treatment.

• In Figure 4 and 5, both improved and worsened scores are relative to baseline and are depicted longitudinally and on one figure.

• The purpose of the stacked bar chart is to allow the percentage of patients with a changed (improved or worsened) symptom score (the longer the bar, the lesser the percentage in the “no change” category).

• Treatment groups are displayed side-by-side for easy comparison.

• High granularity is retained in divergent stacked bars (Figure 5) because the percentage of each change score level is presented.

• The proposed order of the improving/worsening category makes it easy to see the percentage of improvement (or worsened scores) using visual cutoff criteria (e.g., frequency, severity, presence, or amount).

• Sample sizes presented beside each bar allow for assessing completion/compliance.

CONCLUSIONS

• The presentation provides a simple and informative solution to PRO-CTCAE data reporting that considers both the baseline and longitudinal analysis and corresponding attitude levels that can be used for regulatory submission.

• Programs have been developed using the SAS software, which is preferred for data analysis.

• The visualization of the results makes it easy to identify symptoms that matter to patients and are responsive to therapies.

REFERENCES


CONTACT INFORMATION

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Figure 1. Example PRO-CTCAE items and scoring

Figure 2. Percentage of Patients With PRO-CTCAE Responses at Baseline, by Item and System Organ Class

Figure 3. Stacked Bar Chart for the Percentage of Categories of Change From Baseline to Week 4 in General Disorders

Figure 4. Divergent Lollipop Chart for Percentage of Patients With Improvement or Worsening in Constipation Severity, by Treatment and Visit

Figure 5. Divergent Stacked Bar Chart for Percentage of Patients With Improvement or Worsening in Constipation Severity, by Treatment and Visit

Figure 6. Divergent Stacked Bar Chart for Percentage of Patients With Improvement or Worsening in Constipation Severity, by Treatment and Visit

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