INTRODUCTION
Patient-reported outcomes (PROs) are important metrics within oncology and are increasingly being adopted for use in clinical trials to measure the impact of a treatment on patients’ well-being. The Common Terminology Criteria for Adverse Events (CTCAE) is a patient-centered framework for evaluating symptoms. The PRO-CTCAE aims to complement the CTCAE by adding symptom-related endpoints.

METHODS
A systematic literature search was conducted in the Pubmed, Cochrane, and EMBASE databases using the following search terms: [PRO AND CTCAE] OR [PRO AND adverse events] OR [symptom and CTCAE] OR [PRO and clinical trials].

RESULTS
The PRO-CTCAE was developed based on the PRO-CTCAE study. The PRO-CTCAE was applied to a Phase II/III study of nivolumab (nivolumab phase trial).

CONCLUSIONS
The PRO-CTCAE is a valuable tool for evaluating symptoms in clinical trials. It provides a more comprehensive and patient-centered approach to assessing treatment outcomes.

REFERENCES

DISCLOSURES
The authors declare no conflicts of interest.

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Image of the PRO-CTCAE application

Table 1: Included Symptoms in the PRO-CTCAE

<table>
<thead>
<tr>
<th>Category</th>
<th>Example Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular</td>
<td>Chest pain, shortness of breath</td>
</tr>
<tr>
<td>GI</td>
<td>Diarrhea, constipation</td>
</tr>
<tr>
<td>Gynecological</td>
<td>Vaginal bleeding, lyeorrhea</td>
</tr>
<tr>
<td>Hematological</td>
<td>Hair loss, fatigue</td>
</tr>
<tr>
<td>Nervous System</td>
<td>Dizziness, headache</td>
</tr>
</tbody>
</table>

Figure 1: Example of the PRO-CTCAE application in a clinical trial.