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**REVIEW ARTICLE**

**Patient-Reported Outcomes in Phase II Cancer Clinical Trials: Lessons Learned and Future Directions**

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With increasing limits on the resources available to conduct cancer clinical trials, the inclusion of patient-reported outcomes (PROs) in treatment and symptom management trials must be prioritized. Although it has been suggested on occasion that phase III trials should take precedence over phase II trials, we argue that there is a clear and important role for PRO assessment in phase II trials going forward. To illustrate the value realized from including PROs in phase II trials, we provide case examples from cancer treatment and supportive care. The benefits of including PROs in symptom management intervention research are exemplified using phase II trials targeting cognitive impairment. The inclusion of PROs in phase II cancer clinical trials adds important information about the impact of treatment in health-related quality of life, and advances the science of PRO measurement. These contributions significantly enhance the design of phase III trials, ultimately leading to the efficient utilization of clinical trial resources.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

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