

# Patient Reported Outcomes in Cancer Clinical Trials: Measuring the Human Element

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## Abstract

Cancer clinical trials have long been the cornerstone of medical research, providing critical insights into the effectiveness of novel treatments and therapies. Traditionally, clinical endpoints in these trials have relied heavily on objective measures, such as tumor size reduction or progression-free survival. While these measures are undeniably valuable, they often fall short in capturing the full impact of cancer and its treatment on patients' lives. This is where Patient Reported Outcomes (PROs) come into play, offering a more comprehensive and patient-centered approach to understanding the human element of cancer clinical trials. PROs encompass a wide range of self-reported data, including patient perspectives on symptoms, functioning, quality of life and treatment side effects. By collecting and analyzing PROs in clinical trials, researchers can gain a deeper understanding of how patients experience cancer and its treatments beyond mere clinical metrics. This patient-centric data is invaluable in assessing treatment efficacy, making informed decisions and improving the overall cancer care journey.

**Keywords:** Cancer clinical trials • Patient-centered • Patient reported outcomes

## Introduction

PROs provide a direct line of communication between patients and healthcare professionals. By asking patients about their symptoms, physical and emotional well-being and overall quality of life, healthcare providers can better tailor their care to individual needs. This leads to more personalized and patient-centered treatment plans, which ultimately improves the patient's overall experience and outcomes. Involving patients in treatment decisions is increasingly emphasized in modern healthcare [1]. PROs help inform these decisions by giving patients the opportunity to express their preferences and values. Understanding how treatments impact a patient's daily life and overall well-being can guide physicians and patients in selecting the most appropriate course of action.

While clinical endpoints like tumour shrinkage are essential, they don't always tell the whole story. PROs offer a real-world perspective on how treatments affect patients. For instance, they can shed light on how well a drug controls symptoms, alleviates side effects, or maintains or improves quality of life. This information is crucial for evaluating the true efficacy of a treatment. Regulatory bodies, such as the U.S. Food and Drug Administration (FDA), now emphasize the importance of including PRO data in cancer clinical trials. PROs provide insights that can influence regulatory decisions on drug approvals, label claims and recommended uses. This has led to a paradigm shift in the design and conduct of clinical trials.

## Description

Developing standardized PRO instruments that can be consistently used

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across different trials is a complex task. Researchers need to ensure that the measures are both reliable and relevant to the specific cancer type, stage and treatment under investigation. Collecting PRO data can be burdensome for patients, especially during the already stressful experience of cancer treatment. Researchers must consider how to minimize the burden while still obtaining comprehensive and accurate data. Interpreting PRO data is not always straightforward [2,3]. Researchers need to determine how changes in PROs relate to clinical outcomes and whether these changes are clinically meaningful. This necessitates well-defined analytical methodologies. Patient-reported information is sensitive and maintaining patient privacy is of utmost importance. Researchers must handle PRO data securely and in compliance with ethical guidelines. Incorporating PROs into cancer clinical trials is a significant step towards a more holistic and patient-centric approach to cancer care.

Leveraging technology, including smartphone apps and wearables, can make data collection more convenient and engaging for patients. This can lead to real-time data capture and better adherence to reporting. Expanding the use of PROs to post-market surveillance and real-world evidence studies can provide insights into long-term treatment outcomes, helping researchers understand how treatments affect patients in their everyday lives. Identifying patients at higher risk for severe symptoms or reduced quality of life through PRO data can enable healthcare providers to offer tailored supportive care, improving overall patient well-being [4,5]. Collaborative efforts among healthcare providers, researchers and patients are crucial in developing and implementing PROs effectively. Patient education on the importance of reporting their experiences is also essential to gather meaningful data.

## Conclusion

In conclusion, Patient Reported Outcomes are a vital tool for measuring the human element in cancer clinical trials. They offer insights into the patient experience, treatment impact and quality of life that complement traditional clinical endpoints. Integrating PROs into research has the potential to revolutionize the way we understand and approach cancer care, ensuring that the human element remains at the forefront of medical progress. As cancer research continues to evolve, the importance of PROs cannot be overstated, as they illuminate the patient's voice in the fight against cancer.

## References

1. Fernández de Palencia Espinosa, Ma Ángeles, Ma Sacramento Díaz Carrasco and

- Andrés Sánchez Salinas, et al. "Potential drug–drug interactions in hospitalised haematological patients." *J Oncol Pharm Pract* 23 (2017): 443-453.
2. Bohn, Laura M. and Cullen L. Schmid. "Serotonin receptor signaling and regulation via  $\beta$ -arrestins." *Crit Rev Biochem Mol Biol* 45 (2010): 555-566.
  3. Desandes, Emmanuel, Jacqueline Clavel, Claire Berger and Jean-Louis Bernard, et al. "Cancer incidence among children in France, 1990–1999." *Pediatr Blood Cancer* 43 (2004): 749-757.
  4. François, A., B. Ksas, P. Gourmelon and N. M. Griffiths. "Changes in 5-HT-mediated pathways in radiation-induced attenuation and recovery of ion transport in rat colon." *Am J Physiol Gastrointest* 278 (2000): G75-G82.
  5. Mohammad-Zadeh, L. F., L. Moses and S. M. Gwaltney-Brant. "Serotonin: A review." *J Vet Pharmacol Ther* 31 (2008): 187-199.

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