

Making PRO Data Work: Remote Monitoring, Real-Time Visualization, and Timely Intervention in Oncology Trials and Patient Care

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Abstract

Clinician assessment of adverse events in oncology systematically underestimates the severity and frequency of symptoms that patients actually experience, creating risks in both drug development and routine care. Electronic patient-reported outcome (ePRO) systems help to address this gap by enabling frequent remote symptom monitoring, bringing the patient voice into the care pathway between clinic visits. Published studies confirm that automated data-driven alerting in response to ePRO data entries can drive better patient outcomes including reduced emergency department visits, delayed physical function deterioration, and improved symptom control, with early intervention the likely mechanism. Translating this evidence into practice demands deliberate attention to how data are visualized, communicated, and acted upon. This perspectives article examines, primarily in the context of oncology clinical trials, the tools and design principles that translate ePRO data into timely clinical action, including heatmap visualizations that reveal symptom trajectories at a glance, predefined alert thresholds that trigger proactive responses, and patient-facing self-management support delivered at the moment of reporting. The regulatory, ethical and methodological case for embedding active monitoring within oncology trial design is also considered.

Plain Language Summary

When cancer patients experience side effects from their treatment, doctors often underestimate how severe those symptoms are. This means that problems can go unnoticed and unaddressed, sometimes until they become serious enough to require emergency care.

Digital tools that allow patients to report their symptoms regularly from home offer an improved way forward. When patients complete short electronic questionnaires at home about how they are feeling, their care team can monitor responses in real time and receive automatic alerts if symptoms persist or reach a worrying level. Research shows that this kind of remote monitoring leads to better outcomes for patients, such as fewer emergency department visits and longer time to deterioration in physical function. The likely reason is simple: problems are identified and treated earlier, before they escalate. This article looks at the practical tools that make remote symptom monitoring work effectively, both in clinical trials as well as routine care. These include visual displays that allow clinicians to spot worsening trends quickly, automatic alerts that prompt the care team to act without delay, and in-app guidance that helps patients manage milder symptoms themselves while waiting for clinical support.

We also discuss why building this kind of monitoring into cancer trials is not just good practice, but an ethical responsibility to the patients who take part.

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Keywords

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A foundational challenge in oncology clinical trials is that standard tools for assessing treatment tolerability do not adequately capture the patient's experience. Clinician-reported adverse event assessment using the Common Terminology Criteria for Adverse Events (CTCAE)¹ consistently under-reports and under-rates symptom severity compared to patient accounts.² Veitch and colleagues found that every one of 50 adverse events reported by at least 10% of patients in a phase I population was under-reported by physicians, with 19 items recorded by clinicians at 1% or less while patients reported the same symptoms at rates of 10% to 31%.³ A separate European study of 1,933 patients found adverse event severity was underestimated by clinicians in comparison to patient self-reports.⁴

This discordance has real consequences. In early phase trials, inaccurate dose-toxicity characterization increases the risk of patients being exposed to unnecessarily high doses carried forward into later development. In phase 3, where tolerability data informs labelling and real-world prescribing, the same systematic under-reporting means that patients and clinicians may be inadequately prepared for the true symptom burden of treatment. Patient-reported outcome measures (PROMs) are therefore essential at every stage of oncology drug development, from optimal dose selection through to the accurate characterization of the patient experience in confirmatory trials.

This article considers how patient-reported data are collected, monitored, and acted upon in cancer trials, with key considerations for translation into routine care also addressed. Drawing on recent regulatory guidance, landmark trial evidence, and practical implementation experience, we examine the case for integrating ePRO-based remote symptom monitoring into oncology drug development, from early dose-finding through to confirmatory trials and routine care. We address what data should be collected and why, how it should be visualized and communicated to drive timely clinical action, its relationship to formal safety reporting, and the ethical and methodological considerations that arise when monitoring is embedded within trial design.

The value of PROMs in remote cancer treatment oversight and monitoring

A systematic review and meta-analysis of 45 randomized controlled cancer trials in over 13,000 patients⁵ found that integrating quality of life measures such as the EORTC QLQ-C30⁶ into cancer care was associated with a reduction in overall mortality (Hazard Ratio: 0.84) and improved health-related quality of life at 12 weeks. Rationale suggested included (i) earlier identification and management of symptoms before they escalate; (ii) the reflective act of completing PROMs prompting patients to raise concerns they might otherwise not mention; (iii) improved quality of clinician-patient communication; and (iv) the potential of electronic collection to support remote monitoring and proactive care coordination.

The PRO-TECT trial⁷ examined whether targeted, symptom-focused electronic monitoring could drive additional and more proximate clinical benefits. Conducted across 52 community oncology practices in the United States, 1,191 patients with metastatic cancer were randomized to weekly electronic symptom monitoring using items from the patient-reported outcomes version of the CTCAE (PRO-CTCAE) item bank,⁸ or to usual care (with no formal patient-reported outcomes collection). While the trial showed no difference in overall survival between groups, it demonstrated significant benefits in several critical areas: patients using the electronic patient-reported outcome (ePRO) solution had fewer emergency department visits (1.02 vs 1.30 visits at 12 months), longer time to physical function deterioration (12.6 vs 8.5 months), and better overall symptom control. The mechanism behind these improvements was straightforward: the ePRO system automatically alerted care teams when patients reported severe or worsening symptoms. This early warning system enabled proactive intervention before symptoms deteriorated to the point of requiring emergency care. The recognized value of this proactive data monitoring was reflected in a reported 91.5% completion rate for the weekly surveys, completed for up to one year,⁷ with patients reporting the ePRO solution relevant to their care,⁹ a finding also supported by other studies.¹⁰ This study demonstrates the value of remote symptom monitoring to improve cancer care, and leads us to consider how this should also be a feature of patient care and oversight in today's clinical trials.

Core oncology patient-reported outcome measures

The FDA guidance for core patient-reported outcomes in cancer trials identifies five core domains that should be assessed using well-defined, specific PRO measures: disease-related symptoms, symptomatic adverse events, overall side effect

impact summary measure, physical function and role function measures.¹¹ These are all relevant and important measures for trial purposes, but some provide less immediate value in informing ongoing mitigation of symptom burden to drive optimal patient outcomes. Specifically, physical function and role function measures, such as the subscales of the EORTC QLQ-C30, generally measure more slowly changing functional states that don't cleanly map to a specific clinical intervention. Certain physical function items, for example, may provide an early signal of cumulative toxicity burden or disease progression, which may be more appropriate for periodic review as opposed to regular oversight and clinical action. Further, it is unclear whether the overall side effect impact summary measure (e.g., FACT GP5 measuring overall bother associated with the cumulative side effect profile)¹² has added value for triggering clinical interventions. For this reason, we consider that the FDA core PROM set is appropriately comprehensive for trial purposes, but that remote monitoring programs should prioritize a leaner, intervention-oriented subset focused on patient-report and clinical oversight of disease-related symptoms and symptomatic adverse events.

Actionable data insights

To drive effective remote monitoring of symptoms in cancer trials and routine care, data must be provided and presented in a way that drives clinically actionable insights quickly and easily. Regnault and colleagues explored a range of descriptive and longitudinal modelling approaches using PRO-CTCAE data from the DREAMM-2 multiple myeloma trial, primarily in the context of trial reporting and publication.¹³ They identified that descriptive methods, including maximum post-baseline ratings, mean change from baseline over time, and visual methods such as stacked bar charts and cumulative frequency plots, offer accessible summaries of symptom burden and its evolution across a study. For remote monitoring specifically, where data must inform near-real-time clinical decisions rather than post-hoc trial reporting, patient-level visualization and alerting becomes critical to drive ease of use and timely intervention.^{14,15}

ePRO affords the opportunity to provide real-time reporting of data recorded by patients, to drive actionable insights. Key to this includes thoughtfully presented clinician-facing visualizations to drive timely decision making, and automated site alerts to enable timely action without taking significant time away from the care team in both routine care and clinical research.

Heatmap visualization

Heatmaps offer a particularly effective visualization format for longitudinal symptom data.¹⁶ They compress multiple dimensions of information such as symptom type, severity, and time, into a single, immediately interpretable display (Figure 1). Color coding (and numeric coding) allows clinicians to detect patterns and trends at a glance, without needing to interrogate underlying data tables or navigate multiple charts. Worsening trajectories across cycles are visible instantly as a shift from green to amber to red. At this individual patient level, heatmaps make it easy to identify which symptoms are persistent versus transient, whether severity is persistent or escalating over successive cycles, and whether multiple symptoms are clustering simultaneously – a pattern that may signal cumulative toxicity burden even when no single symptom



Figure 1. Patient-level heatmap visualization of PRO-CTCAE data (using synthetic data). Each cell displays the PRO-CTCAE severity grade for a given symptom at each assessment timepoint (0 = absent; 1 = mild; 2 = moderate; 3 = severe; 4 = very severe), with cell color corresponding to grade: blank = 0; green = 1; amber = 2; light red = 3; dark red = 4

has reached a threshold that would trigger a formal alert. This combination of simplicity and information density makes heatmaps well suited not only to clinical monitoring but also to patient-clinician conversations at the point of care, where a shared visual reference can facilitate more focused and productive discussion of symptom management.

Real-time alerting

Electronic data capture enables the automation of data-driven alerts and notifications, such as email messages direct to the clinician or care team. These can be used to instantly inform the care team when certain data patterns are observed – for example, one or more symptom severity ratings of severe or greater, one or more symptoms increasing in severity by two or more categories, etc. These can be used to drive the timely implementation of clinical interventions to mitigate symptoms experienced by the particular patient, without the need to monitor reports on a regular basis.

To ensure consistency across sites, alert thresholds and the required actions they trigger should be defined prospectively in the trial protocol, rather than left to ad hoc clinical judgement.^{17,18} The PRO-TECT trial provides a useful model: automated email alerts were sent to a designated clinical nurse whenever a patient reported a prespecified level of symptom severity or worsening, with the alert containing the relevant PRO scores to enable the nurse to assess the situation and respond appropriately. Practices were also provided with standardized clinician-level symptom management materials based on clinical practice guidelines to support their response to such alerts. In designing alert systems for clinical trials, sponsors should also consider the workflow implications for site staff, ensuring that alert responses are integrated into existing nursing and care coordination processes and defined in the protocol. Staff working in oncology trials have raised concerns about alert volume, accountability for response, and workflow integration, reinforcing the importance of prospective planning and clearly defined escalation pathways.¹⁹

Symptom and side effect self-management

It's important to remember that the interface that patients use to report their symptoms and side effects (e.g., web solution or mobile app) provides a powerful opportunity to engage the patient with self-management tools and information. For example, when reporting mouth ulcers in the symptom log, the application could also direct the patient to approved self-help information on how to manage and alleviate these ahead of potential contact by the care team to put further interventions in place.

This engagement layer serves several purposes simultaneously. It provides patients with actionable guidance at the moment they are most aware of a symptom, reducing the window between symptom onset and first-line self-management. It supports self-efficacy, the confidence to understand and respond to their own symptoms, which the PRO-TECT investigators identified as a likely contributor to the trial's observed benefits. This feature may also reduce the volume of urgent clinical contacts for symptoms that can be adequately managed by the patient with appropriate guidance, allowing the care team to focus their attention on cases requiring direct intervention. Content delivered through this channel should be clinically approved, condition and treatment specific, and aligned with the alert thresholds defined in the protocol, so that self-management guidance and clinical escalation work as complementary parts of a coherent symptom management pathway rather than as parallel and potentially contradictory sources of advice.

PRO-CTCAE and CTCAE: Complementary Data, Not Competing Records

A question that frequently arises when PRO-CTCAE data are collected alongside standard clinician-reported safety data is whether the two datasets need to be reconciled. The short answer is that they do not, and attempting to do so would misrepresent the purpose of each. The regulatory framework is instructive here. ICH GCP E6(R3) section 2.12.3 states that investigators should be provided with timely access to data by the sponsor and be responsible for its timely review, explicitly including PRO data among the data sources that can have an impact on participant safety.²⁰ Section 2.12.1 further requires that investigators ensure the integrity of data under their responsibility. The EMA, in Appendix 2 to its guideline on the evaluation of anticancer medicinal products,²¹ recommends that where PRO collection gives rise to medically concerning levels of symptoms, an a priori plan for the management of such alerts should be included in the protocol and communicated to trial staff. Further, the FDA's Core PROs in Cancer Trials guidance¹¹ is equally clear that PRO-CTCAE data are intended to complement, not replace, standard CTCAE safety reporting. Taken together, these regulatory positions establish that PRO-CTCAE data carries meaningful oversight obligations, but within a framework that treats it as a distinct and complementary source of evidence rather than a parallel safety record requiring formal alignment with CTCAE.

The two instruments capture fundamentally different things: CTCAE reflects the clinician's judgement about which adverse events are medically significant and how they should be graded, while PRO-CTCAE captures the patient's own

experience of symptoms, including those that may not surface in a clinical consultation. Some patient-reported symptoms will reflect disease rather than treatment toxicity; others may be combined by the clinician into a single recorded adverse event; and some will not reach the threshold for formal AE recording. Discordance between the two datasets is therefore expected and appropriate, not a data quality problem requiring resolution.

It is important to note that a patient-reported symptom, however severe, does not itself constitute a serious adverse event in the regulatory sense. That determination requires clinical judgement by the investigator. The role of PRO-CTCAE data in this context is to prompt timely clinical review, which in turn determines whether formal SAE reporting is warranted. Our recommended best practice is for investigators to review PRO-CTCAE data ahead of clinical consultations and CTCAE assessments, using it to inform and enrich their safety evaluation. Alert thresholds, expected response actions, and frequency of review should be defined prospectively in the protocol, with appropriate systems in place to document that review has taken place.

A Note on Over-Reporting and Ethical Considerations

A legitimate concern with integrating active remote symptom monitoring into clinical trials is that timely clinical intervention in response to PRO alerts may itself alter the side effect profile that the trial is designed to characterize. If patients in a monitored arm receive earlier and more proactive symptom management, their reported symptom burden may appear lower than it would under standard care, potentially presenting the tolerability profile of a new treatment in a more favorable light than real-world practice would reflect. This is not a trivial methodological concern, particularly where tolerability is a key endpoint or where the data will inform labelling. However, it must be weighed against a fundamental ethical principle: patients enrolled in clinical trials are entitled to the best available care, and withholding timely response to clinically significant symptoms in order to preserve measurement purity would be ethically indefensible. The appropriate mitigation is methodological rather than clinical. In randomized controlled trials, the effect of active monitoring on symptom management is balanced across arms, meaning that any intervention-related attenuation of symptom severity affects both the experimental and comparator groups equally. Beyond this, and for single arm studies, statistical approaches that explicitly account for concomitant symptom management interventions, such as recording and adjusting for the use of supportive medications, can further protect the integrity of the tolerability assessment. The goal is not to observe symptoms unimpeded, but to measure them rigorously while managing them responsibly. This ethical stance is reinforced by the EMA's oncology guideline (Appendix 2),²¹ as described above. The guidance identifies the need for a pre-defined plan for the effective management of "PRO alerts" that should be included in the study protocol and communicated to trial staff.

Beyond the ethical considerations, timely and effective reporting and management of symptoms and side effects is associated with higher patient retention. A survey of 334 cancer trial patients revealed that experiencing bothersome adverse treatment effects was amongst the highest factors contributing to the burden of trial participation, with high burden scores associated with a higher probability of withdrawing from the study early.²² This finding was reinforced by another study that showed that higher symptom burden at time of clinical trial enrolment was related to shorter time participating on the trial.²³

When patients feel that their symptoms are being actively monitored and managed, they are more likely to view the balance between trial burden and benefit as acceptable, which supports continued participation and adherence to trial procedures, including ePRO completion.⁷ Active monitoring and timely intervention are therefore not just ethically sound but operationally advantageous, supporting data completeness and sustained patient engagement that sponsors depend upon for robust trial inference making.

Considerations for Implementation in Routine Cancer Care

While the PRO-TECT trial provides compelling evidence for ePRO-based remote monitoring in routine oncology practice,⁷ translating this into sustainable everyday care requires deliberate attention to distinct implementation challenges. Basch and colleagues have outlined practical tenets addressing these, including protected staff time for alert management, clear escalation workflows, proactive enrolment of all eligible patients regardless of assumed digital ability, and ongoing tracking of completion rates and alert response times.²⁴ Real-world implementation across 33 European cancer centers confirmed that sustained deployment requires nurses with dedicated time and responsibility for alert management.¹⁰ This study reported that only 8 of 33 centers achieved Electronic Health Record interoperability, underscoring that integration into existing clinical systems remains a widely underestimated barrier.¹⁰ Among ePRO applications no longer in use, lack of funding and resources was the most common reason for discontinuation.²⁵ Finally, provider bias around patient age and socioeconomic status has been shown to influence whether remote monitoring is offered, and patients without a personal device or reliable connectivity risk being excluded from its benefits unless alternative modalities such as telephone-based reporting are provided.^{23,26}

Conclusion

The evidence tells us that collecting PRO data in oncology trials and clinical care improves outcomes for patients.⁷ What remains variable is the rigor and consistency with which that data are monitored, and acted upon. The tools exist to support systematic ePRO-based remote monitoring, timely symptom intervention, and meaningful visualization of patient experience data across the full treatment journey. Realizing this potential requires deliberate documentation of study requirements at the protocol level, investment in site training and workflow integration, and a growing commitment that the patient's voice through patient-reported outcome data collection is a vital component of oncology drug development and care delivery.

For sponsors, the starting point is recognizing that PRO data are not an optional supplementary endpoint but an essential component of oncology drug development, both clinically and from a regulatory standpoint. Having made that commitment, the next step is to go further than treating ePRO as a passive data collection exercise. Benefit accrues not from collection alone but from the full pathway: systematic electronic capture, real-time visibility for the care team, predefined alert thresholds, and a clinical workflow that facilitates timely response. PRO data that is collected but neither monitored nor acted upon represents not just a missed opportunity for patients, but a failure of the ethical principle that should sit at the heart of modern oncology trial design and patient care.

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Data sharing not applicable to this article as no datasets were generated or analyzed.

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