Assessment of Completion Time to Optimize the Administration of Common Patient-Reported Outcome Measures (PROMs) in Oncology Clinical Trials

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INTRODUCTION

- In oncology clinical trials, patient reported outcome measure (PROM) endpoints provide a valuable complement to traditional endpoints such as tumour response and survival and are central to the patient's understanding of treatment benefits.
- Despite their valuable insight, there is low representation of PROM endpoints in oncology medication labeling[1].
- The FDA draft guidance relating to core patient reported outcomes (PROs) in oncology[2] illustrates some of the weaknesses in common PROM strategies and recommends specificity in measurement selection and assessment scheduling dependent on treatment duration.
- Methods to lessen patient burden are also central to the agency's recommendations and invaluable in informing PROM selection and scheduling strategies in clinical trials, but the burden of PROM completion is poorly understood.
- Here we examine completion times, often seen as an indicator of burden, for commonly used PROMs in oncology to better understand how measure selection translates to patient time investment in clinical trials.

METHODS

PROM completion times were examined for 2881 patients recruited into 7 global ongoing studies in breast cancer (N= 1795) and non-small cell lung cancer (N = 1086).

Data on the following PROMs were analysed:

- European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire - Core Questionnaire (QLQ C30)
- EORTC Breast Cancer Module (QLQ BR23) for participants with breast cancer EORTC Lung Cancer Module (QLQ LC13) for participants with non-small cell lung cancer
- Patient-Reported Outcomes – Common Terminology Criteria for Adverse Events (PRO-CTCAE)
- Single item side effects measure
- EuroQol EQ-5D-5L.

PROMs were completed electronically on a tablet device at clinics during site visits using a single item per screen presentation. Completion time was estimated from the PROM start and completion electronic timestamps at baseline (BL) and end of treatment (EoT) assessments.

RESULTS

TABLE 1: Completion Times (seconds/item)

	Baseline						End of Treatment					
	QLQ C30	QLQ BR23	QLQ LC13	PRO-CTCAE	Side effects	EQ-5D-5L	QLQ C30	QLQ BR23	QLQ LC13	PRO-CTCAE	Side effects	EQ-5D-5L
Median (s)	8	8	6	7	16	14	7	6	7	6	14	10
IQR (s)	6	5	5	6	15	13	6	4	8	5	13	11

- Per item completion time (seconds) was greater across visits for the single-item side effect measure, followed by the EQ-5D-5L.
- Shorter but similar completion times were found for the EORTC QLQ C30, the EORTC QLQ BR23, the EORTC QLQ LC13, and the PRO-CTCAE.
- Median completion times were shorter for the EoT assessment compared to BL, likely due to increased patient familiarity.

FIGURE 1: Completion Times (seconds/item) at Baseline

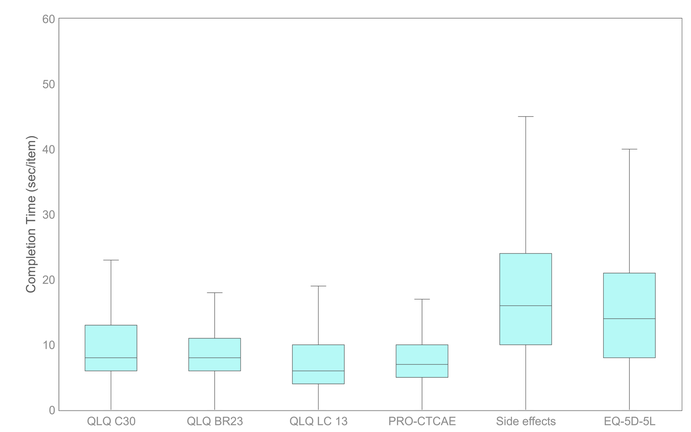
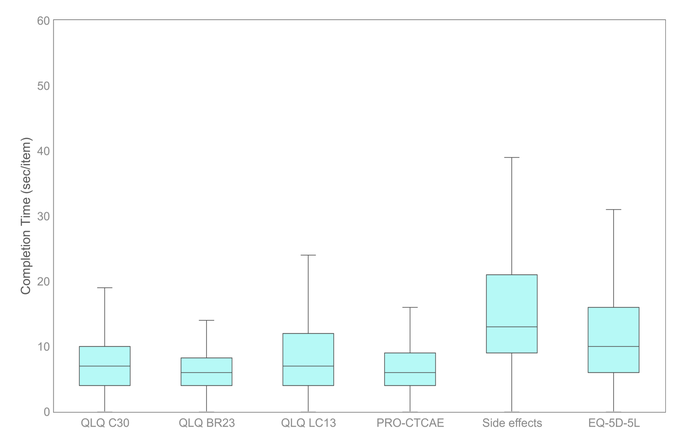


FIGURE 2: Completion Times (seconds/item) at End of Treatment



DISCUSSION

Careful PROM selection and scheduling in oncology trials are essential for the management of patient time and PROM completion burden. FDA recommended core PROM measurement sets for oncology[2] may require greater use of PROM subscales and at-home assessments. Based on our EoT data, the estimated completion time for the EORTC QLQ C30 physical functioning subscale along with selected PRO-CTCAE items and the side-effect impact measure is approximately 120s. These results provide confidence that a measurement strategy utilizing core PROM sets may not be over-burdensome or too time consuming to patients.

REFERENCES

1 Gnanasakthy, A., Barrett, A., Evans, E., D'Alessio, D., and Romano, C. D. (2019). A review of patient-reported outcomes labeling for oncology drugs approved by the FDA and the EMA (2012-2016). Value Health 22 (2), 203–209

2 FDA. Core patient-reported outcomes in cancer clinical trials: draft guidance for industry, 2021. https://www.fda.gov/ regulatory-information/search-fda-guidance-documents/core-patient-reported-outcomes-cancer-clinical-trials

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