ePRO IN ONCOLOGY: PATIENT PREFERENCE, COMPLIANCE, & BEST PRACTICES

Sarah Tressel Gary, PhD and Susan M. Dallabrida, PhD

ONCOLOGY PATIENT PREFERENCE

Patient-reported outcomes (PROs) and electronic PRO (ePRO) are increasingly becoming an important aspect of cancer clinical trials and patient care, especially with regard to measuring drug efficacy, patient quality of life, and drug safety. Several studies have found that oncology patients find electronic handheld diaries and tablets easy to use, helpful, and preferable over paper, thus alleviating any concern as to whether patient burden, health status, or age impact the feasibility of using ePRO with oncology patients.

> Oncology patients think that electronic symptoms reporting positively impacts their clinical care. 87% of patients think that symptom assessments are important to complete because it helps the clinical team know their symptom severity and 79% agreed, the clinical team takes the symptom scores into account in deciding treatment.¹

> Metastatic breast cancer patients reported that tablets were easy to read (94%) and navigate (99%), helped them to remember and report symptoms (74%), and would recommend to other patients (94%).²

> Non-small cell lung cancer patients preferred electronic versions (60%) of the EQ-5D and Functional Assessment of Cancer Therapy-Lung Cancer (FACT-L) over paper formats (12%).³

> One study found that 52% preferred touch screen to paper, 24% had no preference, and 24% preferred paper. There were no missed responses with the electronic version, whereas paper contained over 1000 missing or unusable responses.⁴
ONCOLOGY PATIENT COMPLIANCE

Patient compliance with completion of ePRO assessments is important for obtaining accurate and high-quality data when conducting clinical trials. Several published studies and ERT’s own experience have found stable and high compliance in cancer patients when using ePRO.

Electronic symptoms reporting in prostate cancer, breast cancer, and multiple myeloma patients at site visits showed stable and high compliance (96-100%) using the ERT eCOA Tablet. This was also true for compliance levels among all patients in the study, who ranged from age 28 to 89.

In a breast cancer study with over 450 patients from 16 countries the overall compliance for three questionnaires (EORTC QLQ-C30, EORTC QLQ-BM22, EQ-5D) was 97.8%. Completion percentages remained consistent for subsequent visits, even as the number of patients remaining in the pool of participants decreased (EORTC QLQ C30, Fig. 1).

Thus, even though the number of patients in the trial decreased over time, completion of all three questionnaires was unaffected. From ages 28 to 89, there was consistent compliance with overall percent completion (inclusive of all visits) for all questionnaires between 92.1% and 100% (EORTC QLQ-C30, Fig 2).
In a prostate cancer study with over 1000 patients from 21 countries the overall compliance with the expected questionnaire completion was 98.4%. Percent completion was 99.4% (BPI-SF, Fig 3), 97.2% (FACT-P) and 96.9% (EQ-5D). Percent completion on visits where one questionnaire was to be completed was 99.8%, and percent completion on visits where multiple questionnaires were to be completed was 97.6%. Percent completion by country ranged from 93.8% to 100%, with 7 countries having 100% completion for all three questionnaires (BPI-SF, Fig 4).
In a multiple myeloma study with over 400 patients from 15 countries the overall compliance (inclusive of all visits) for the three questionnaires was 95.9%. The overall percent completion was 96.2% (EORTC QLQ-C30), 97.7% (EORTC QLQ-MY20, Fig 5), and 93.8% (EQ-5D).
Percent completion was very high in breast cancer, prostate cancer, and multiple myeloma with patients completing electronic questionnaires on an ERT touch-screen eCOA Tablet. Percent completion was not affected by the number of clinic visits. Oncology patients demonstrated no drop off in percent completion of questionnaires as a function of time. The percent of questionnaires completed remained high on visits where three questionnaires were completed versus one questionnaire, indicating that completing the three questionnaires in a visit was not unduly burdensome. Whether a country was developed or developing did not affect patient percent completion of the questionnaires.

Compliance with the completion of home-based electronic daily diaries in cancer pain was evaluated in a large global study with adult patients who had chronic pain due to cancer. Patients completed a daily diary which included a pain numerical rating scale and there were alarms and icons to remind patients to complete the diary. The overall compliance for the daily diary, even as the number of patients decreased over time, remained high and stable over the course of the trial, with an overall compliance of 96% (Fig. 6).
CONCLUSION

Oncology patients prefer electronic data capture and demonstrate a willingness and ability to consistently complete questionnaires for the duration of their participation in a clinical trial, independent of type of cancer, age, country, questionnaire, or length of commonly used oncology questionnaires. Collection of ePRO using either at-home ERT eCOA HandHeld devices or a clinic-based ERT eCOA Tablet yielded a highly complete data set in cancer patients demonstrating that this is an effective and feasible approach for recording symptoms and quality of life assessments.

Learn how you can accelerate your oncology research with eCOA technology that doesn’t get in the way. To learn more, go to ert.com or email info@ert.com.