Standardized or Arbitrary? Evaluation of Life Expectancy Eligibility Criteria in Metastatic Prostate Cancer Trials

Authors: Natalie Sarah Chea*, Elia Abou Chawareb, Blake Adnani, Sophie Zaaijer, Omid Yazdanpanah, Shera Feinstein, Arash Rezazadeh Kalebasty, David I. Lee, Mohammed Shahait

Department of Urology at University of California, Irvine

*Email: nschea@uci.edu

Background:

Life expectancy (LE) is a critical determinant of eligibility in prostate cancer clinical trials, reflecting patient fitness through age, comorbidity burden, and overall health status. However, LE estimation may rely on subjective clinical judgment or objective models, and the extent to which standardized methods are applied in clinical trials remains unclear. Lack of consistent LE assessment limits evaluation of trial representativeness and generalizability. We therefore examined the frequency, methodology, and thresholds of LE assessment in metastatic hormone-sensitive prostate cancer trials.

Methods:

We conducted a systematic review of interventional metastatic hormone-sensitive prostate cancer trials (n=85) registered on ClinicalTrials.gov over the past 10 years. Trial characteristics, sponsorship, and eligibility criteria were extracted. LE requirements were assessed for presence, specified thresholds, and methodology (validated tools vs clinician judgment or unspecified).

Results:

Of 85 trials, 19 (22.4%) included an explicit LE threshold, while 66 (77.6%) did not reference LE. Among trials specifying LE criteria, 17 (89.5% of the cohort requiring LE) did not define the method of LE assessment, and none required use of a validated prediction tool (e.g., G8 or Charlson Comorbidity Index). Two trials (2.4%) explicitly relied on clinician judgment.

Minimum LE thresholds varied, most commonly ≥3 months (19 trials, 22.4%) and ≥6 months (17 trials, 20.0%), with additional thresholds including ≥12 and ≥24 months. Trials incorporating LE criteria were predominantly Phase II (n=12) and Phase III (n=3) and more frequently observed in academic or government-sponsored studies (n=15) than in industry-sponsored trials (n=4).

Conclusion:

Only 22% of metastatic prostate cancer trials explicitly incorporate LE thresholds, with the majority lacking any reference to LE. Among those that do, assessment methods are overwhelmingly unspecified, and no trials mandate validated predictive tools. This lack of standardization introduces variability in

patient selection, potentially limiting generalizability and contributing to disparities in trial enrollment. Adoption of objective, validated LE assessment tools should be considered to improve trial design and applicability to real-world populations.