



PIONEER Consensus Definitions for Core Outcomes in Metastatic Prostate Cancer

Overall Survival

Refers to death from any cause. Reported either at a defined timepoint (e.g. 5 years) or as time to event (depending on study design).

Prostate Cancer Specific Survival

Refers prostate cancer specific death. Reported either at a defined timepoint (e.g. 5 years) or as time to event (depending on study design).

Development of castration-resistant disease (only applicable to HSPC)

Castrate level of serum testosterone < 50 ng/dL or < 1.7 nmol/L plus either;

- Biochemical progression: Three consecutive rises in PSA one week apart resulting in two 50% increases over the nadir, and a PSA > 2 ng/mL OR
- Radiological progression: The appearance of new lesions: either two or more new bone lesions on bone scan or a soft tissue lesion using RECIST (Response Evaluation Criteria in Solid Tumours).

Symptomatic progression alone must be questioned and subject to further investigation. It is not sufficient to diagnose CRPC

Biochemical progression-free survival

Castrate serum level of testosterone < 50 ng/dL or < 1.7 nmol/L plus;
Biochemical progression: Three consecutive rises in PSA one week apart resulting in two 50% increases over the nadir, and a PSA > 2 ng/mL.

Radiographic progression-free survival

Radiological progression: The appearance of new lesions: either two or more new bone lesions on imaging or a soft tissue lesion using RECIST (Response Evaluation Criteria in Solid Tumours), ideally through central review.

Clinical progression-free survival

Time to the first occurrence of symptomatic skeletal related events, pain, or other symptoms, objective evidence of an increase in extent of disease or death.

PSA response

Reduction in the PSA level from baseline by 50% or more or 90% or more, as confirmed on an additional PSA evaluation performed 3 or more weeks later and patients at castrate level (if on ADT)).

Major surgical complications

Could be one of the following procedures:

- TURP (transurethral resection of the prostate)
- Ureteral stent
- Percutaneous nephrostomy tube
- Suprapubic catheter placement
- Chronic Foley catheter
- Self-intermittent catheterization
- Extensive pelvic surgery
- Palliative radiotherapy

Symptomatic skeletal event

Symptomatic fracture, cord compression or need for surgery and/or radiation to bone

Core outcomes assessed using PROMS

- Bowel dysfunction
- Side effects of systematic therapy
- Urinary, sexual, emotional and physical dysfunction
- Pain
- Fatigue
- Performance status

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