



PIONEER Consensus Definitions for Core Outcomes in Localised 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).

Biochemical recurrence

- RP: two consecutive PSA rises ≥ 0.2 ng/mL.
- FOCAL and EBRT: Phoenix criteria (nadir + 2 ng/mL) after local curative therapy (EBRT or FOCAL).

Localised disease recurrence

- RP: development of a palpable nodule on a DRE, or pelvic lesion identified on imaging in conjunction with a detectable serum PSA level.
- EBRT: abnormal DRE findings (a change in the DRE, initially becoming normal after treatment), Phoenix criteria (nadir + 2 ng/mL), positive imaging and/or residual disease on biopsy.
- FOCAL: any imaging, positive control biopsy (irrespective of the side) and/or salvage therapy.

Distant disease recurrence/metastases

Development of distant metastasis on imaging.

Need for curative R/ (applicable to active surveillance specifically)

Patients discontinued from AS and underwent treatment for various reasons including change in patient preference, increasing PSA, digital rectal examination suggestive of more advanced features, biopsy evidence of increased tumour volume or higher grade, doctor's decision, with or without new findings on MRI.

Treatment failure (applicable to ablative procedures)

- HIFU (whole gland): any record of a positive prostate biopsy after HIFU, the initiation of secondary prostate cancer treatment (e.g. hormone therapy, second HIFU procedure, radiotherapy or surgery), radiographic evidence of prostate cancer metastases or prostate cancer-related death, PSA greater than test level or phoenix criteria.
- CRYO: change in DRE, rising in PSA, positive biopsy, or radiographic evidence of progression

Positive surgical margins (surgery)

Positive when the tumour reached the inked surface of the specimen

Major surgical complications

RP: presence or absence of early (< 30 days) or late (> 30 days) complications according to Clavien Dindo grade 3, 4, and 5.

Radiation toxicity / Major radiation complication

EBRT: presence or absence of acute (< 90 days) or late (≥ 90 days) radiation toxicity as defined by a validated tool (e.g. RTOG, LENT/SOM)

Core outcomes assessed using PROMS

- Bowel dysfunction
- Faecal incontinence
- Urinary dysfunction
- Stress incontinence
- Sexual dysfunction
- Over all quality of life

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