

HEALTH PROFESSIONAL PROSTATE TOXICITY DATA

To be completed by the Doctor or Research Nurse ONLY

Study number

RQ□□□□□-□

Patient initials

□□□□

Date of birth (dd/mm/yyyy)

□□/□□/□□□□

Date completed (dd/mm/yyyy)

□□/□□/□□□□

Name + Signature of Person completing the CRF

Time point

- | | |
|---|--|
| <input type="checkbox"/> Pre-radiotherapy (RT) | <input type="checkbox"/> 2 years after RT start |
| <input type="checkbox"/> End of RT | <input type="checkbox"/> 3 years after RT start* |
| <input type="checkbox"/> 6 weeks after end of RT* | <input type="checkbox"/> 4 years after RT start* |
| <input type="checkbox"/> 1 year after RT start | *if available |

Rectum/ Bowel

If information: **Not Known** fill boxes with 9's, if **Not Applicable** fill boxes with 8's

Proctitis

- 0 = None
- 1 = Rectal discomfort, intervention not indicated
- 2 = Symptoms (e.g. rectal discomfort, passing blood or mucus); medical intervention indicated; limiting instrumental activities of daily living (ADL)
- 3 = Severe symptoms; faecal urgency or stool incontinence; limiting self care ADL
- 4 = Life-threatening e.g. perforation; urgent intervention indicated

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Perforation

- 0 = None
- 2 = Symptomatic; medical intervention indicated
- 3 = Severe symptoms; elective operative intervention indicated
- 4 = Life-threatening; urgent intervention indicated

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Bowel Obstruction

- 0 = None
- 1 = Asymptomatic; clinical or diagnostic observations only; intervention not indicated
- 2 = Symptomatic; altered GI function e.g. vomiting, diarrhoea; IV fluids <24 h
- 3 = Hospitalization indicated; elective operative intervention; disabling
- 4 = Life-threatening; urgent intervention indicated, e.g. total colectomy

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Bowel fistula

- 0 = None
- 1 = Asymptomatic; clinical or diagnostic observations only; intervention not indicated
- 2 = Symptomatic; altered GI function
- 3 = Severely altered GI function; total parenteral nutrition (TPN) or hospitalization indicated; elective operative intervention indicated
- 4 = Life-threatening consequences; urgent intervention indicated

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Bowel stenosis

- 0 = None
- 1 = Asymptomatic; clinical or diagnostic observations only; intervention not indicated
- 2 = Symptomatic; altered GI function
- 3 = Severely altered GI function; tube feeding or hospitalization indicated; elective operative intervention indicated
- 4 = Life-threatening consequences; urgent operative intervention indicated

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Bowel Ulceration

- 0 = None
- 1 = Asymptomatic/ radiographic/ endoscopic findings only; intervention not indicated
- 2 = Symptomatic; altered GI function
- 3 = Symptomatic and severely altered GI function; total parenteral nutrition (TPN) indicate, deep ulcer; elective operative or endoscopic intervention indicated; disabling
- 4 = Life threatening consequences; urgent operative intervention indicated

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Diarrhoea

- 0 = None
- 1 = Increase of <4 stools per day over baseline; mild increase in ostomy output compare to baseline
- 2 = Increase of 4-6 stools per day over baseline; moderate increase in ostomy output compared to Baseline
- 3 = Increase of ≥7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care activities of daily living (ADL)
- 4 = Life threatening consequences; urgent intervention indicated

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Flatus

- 0 = None
- 1 = Mild symptoms; intervention not indicated
- 2 = Moderate; persistent; psychosocial sequelae

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Rectal bleeding

- 0 = No bleeding
- 1 = Mild; no intervention
- 2 = Moderate symptoms; medical intervention/minor cauterization indicated
- 3 = Transfusion, interventional radiology, endoscopic or operative intervention indicated
- 4 = Life threatening/ major or urgent intervention indicated

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Management of Sphincter Control

- 0 = No problem
- 1 = Occasional use of incontinence pads
- 2 = Daily use of incontinence pads
- 3 = Severe symptoms, elective operative intervention indicated

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Bladder/Urethra

If information: **Not Known** fill boxes with 9's, if **Not Applicable** fill boxes with 8's

Haematuria

- 0 = None
- 1 = Asymptomatic; clinical or diagnostic observations only; no intervention indicated
- 2 = Symptomatic; urinary catheter or bladder irrigation indicated; limiting instrumental ADL
- 3 = Gross hematuria; transfusion, IV medication or hospitalization indicated; elective endoscopic, radiologic or operative intervention indicated; limiting self care ADL
- 4 = Life threatening/ urgent radiologic or operative intervention indicated

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Urinary tract obstruction

- 0 = None
- 1 = Asymptomatic; clinical or diagnostic observations only
- 2 = Symptomatic but no hydronephrosis, sepsis or renal dysfunction; urethral dilation, urinary or suprapubic catheter indicated
- 3 = Symptomatic and altered organ function (e.g. hydronephrosis, or renal dysfunction); elective radiologic, endoscopic or operative intervention indicated
- 4 = Life-threatening consequences; urgent intervention indicated

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Urinary Incontinence

- 0 = None
- 1 = Occasional (e.g. with coughing or sneezing), pads not indicated
- 2 = Spontaneous; pads indicated; limiting instrumental activities of daily living (ADL)
- 3 = Intervention indicated (e.g., clamp, collagen injections); operative intervention indicated; limiting self care ADL

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Urinary frequency

- 0 = None
 1 = Present
 2 = Limiting instrumental activities of daily living (ADL); medical management indicated

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Urinary urgency

- 0 = None
 1 = Present
 2 = Limiting instrumental ADL; medical management indicated

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Urinary retention

- 0 = None
 1 = Urinary, suprapubic or intermittent catheter placement not indicated; able to void with some residual
 2 = Placement of urinary, suprapubic or intermittent catheter placement indicated; medication Indicated
 3 = Elective operative or radiologic intervention indicated; substantial loss of affect kidney function or mass
 4 = Life-threatening; organ failure; urgent operative intervention indicated

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Fistula

- 0 = None
 2 = Non-invasive intervention indicated; urinary or suprapubic catheter placement indicated
 3 = Limiting self care ADL; elective radiologic, endoscopic or operative intervention indicated; permanent urinary diversion indicated
 4 = Life-threatening; urgent radiologic or operative intervention indicated

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Ureter/Kidney

If information: **Not Known** fill boxes with 9's, if **Not Applicable** fill boxes with 8's

Obstruction

- 0 = No obstruction
 1 = Asymptomatic, endoscopic or radiographic findings only
 2 = Symptomatic, no hydronephrosis, sepsis or renal dysfunction; no intervention
 3 = Symptomatic, altered organ function e.g. hydronephrosis or renal dysfunction, operative intervention indicated
 4 = Life-threatening consequences, organ failure or operative intervention

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Creatinine / acute kidney injury

- 0 = Normal
 1 = Creatinine 1 – 1.5 above baseline
 2 = Creatinine >1.5 – 3 times above baseline
 3 = >3 times above baseline
 4 = > 6 x upper limit of normal

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Glomerular Filtration Rate/ chronic kidney disease

- 0 = Normal
 1 = eGFR (estimated Glomerular Filtration Rate) or CrCl (creatinine clearance) <LLN – 60 ml/min
 2 = eGFR or CrCl 59 - 30 ml/min
 3 = eGFR or CrCl 29 - 15 ml/min
 4 = eGFR or CrCl <15 ml/min; dialysis or renal transplant indicated

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Sexual Dysfunction

Also for patients with hormonal therapy

Libido

- 0 = Normal
 1 = Decrease in interest, not affecting relationship
 2 = Decrease in interest, adversely affecting relationship
 7 = Did not wish to answer

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Erectile Dysfunction

- 0 = None
- 1 = Decrease in erectile function (i.e. frequency/ rigidity of erections) but intervention not indicated (e.g. medication or use of mechanical device, penile pump)
- 2 = Decrease in erectile function (i.e. frequency/ rigidity of erections) and erectile aids are indicated
- 3 = Decrease in erectile function (i.e. frequency/ rigidity of erections) but erectile aids not helpful and penile prosthesis indicated

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Ejaculation Disorder

- 0 = None
- 1 = Diminished ejaculation
- 2 = Anejaculation or retrograde ejaculation

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Orgasmic Dysfunction

- 0 = None
- 1 = Decrease in orgasmic response not adversely affecting relationship
- 2 = Decrease in orgasmic response and adversely affecting relationship

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Other

Radiation Dermatitis

- 0 = None
- 1 = Faint erythema or dry desquamation
- 2 = Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin folds and creases; moderate edema
- 3 = Moist desquamation in areas other than skin folds and creases; bleeding induced by minor trauma or abrasion
- 4 = Life-threatening consequences; skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site; skin graft indicated

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Pneumonitis (must be discussed with a physician)

- 0 = None
- 1 = Asymptomatic; clinical or diagnostic observations only; intervention not indicated
- 2 = Symptomatic; medical intervention indicated; limiting instrumental activities of daily living (ADL)
- 3 = Severe symptoms; limiting self care ADL; oxygen indicated
- 4 = Life-threatening respiratory compromise; urgent intervention indicated (e.g., tracheotomy or intubation)

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