



Prostate Cancer

Site Number

Subject Number

Adverse Events including SREs

1 AEs including SREs

1.1	Were any adverse events experienced?	<input type="radio"/> <small>[Y]</small> Yes <input type="radio"/> <small>[N]</small> No	AEYN
1.2	What is the adverse event identifier?		AESPID
1.3	What is the adverse event term?		AETERM
1.4	What is the category of the adverse event?	<input type="radio"/> <small>[SRE-related]</small> SRE-related <input type="radio"/> <small>[Not SRE-related]</small> Not SRE-related	AECAT
1.5	If SRE-related, Indicate type of event	<input type="radio"/> <small>[PATHOLOGICAL FRACTURE]</small> Pathological Fracture <input type="radio"/> <small>[NON-PATHOLOGICAL FRACTURE]</small> Non-Pathological Fracture <input type="radio"/> <small>[SPINAL CORD COMPRESSION]</small> Spinal Cord Compression <input type="radio"/> <small>[OTHER SRE-RELATED EVENT]</small> Other SRE-Related Event	AESCAT
1.6	What is the best description of the cause of the fracture?	<input type="radio"/> <small>[BONE METASTASIS]</small> Bone Metastasis <input type="radio"/> <small>[OSTEOPOROSIS]</small> Osteoporosis <input type="radio"/> <small>[TRAUMA]</small> Trauma <input type="radio"/> <small>[OTHER]</small> Other <input type="radio"/> <small>[UNKNOWN]</small> Unknown	AECAUSE
1.7	What is the toxicity grade of the adverse event?	<input type="radio"/> <small>[1]</small> Grade 1 <input type="radio"/> <small>[2]</small> Grade 2 <input type="radio"/> <small>[3]</small> Grade 3 <input type="radio"/> <small>[4]</small> Grade 4 <input type="radio"/> <small>[5]</small> Grade 5	AETOXGR
1.8	Start Date (DD-MMM-YYYY)	<input type="text"/>	AESTDAT



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1.9	What is the anatomical location of the adverse event?	<input type="radio"/> [PELVIC BONE] Pelvic Bone <input type="radio"/> [LUMBAR SPINE] Lumbar Spine <input type="radio"/> [LIMB, LOWER] Lower Extremity <input type="radio"/> [LIMB, UPPER] Upper Extremity	AELOC										
1.10	What is the side of the anatomical location of the adverse event?	<input type="radio"/> [RIGHT] Right <input type="radio"/> [LEFT] Left <input type="radio"/> [BILATERAL] Bilateral	AELAT										
1.11	Is the adverse event still ongoing?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AEONGO										
1.12	End Date (DD-MMM-YYYY)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>											AEENDAT
1.13	Was the adverse event serious?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AESER										
1.14	Did the adverse event result in death?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AESDTH										
1.15	Death Date (DD-MMM-YYYY)	<table border="1"><tr><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td></tr></table>											DTHDAT
1.16	Was the adverse event life threatening?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AESLIFE										
1.17	Did the adverse event result in initial or prolonged hospitalization for the subject?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AESHOSP										
1.18	Did the adverse event result in disability or permanent damage?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AESDISAB										



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1.19	Was the adverse event associated with a congenital anomaly or birth defect?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AESCONG
1.20	Was the adverse event a medically important event not covered by other serious criteria?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AESMIE
1.21	Was this adverse event related to study treatment?	<input type="radio"/> [Y] Yes <input type="radio"/> [N] No	AEREL
1.22	What action was taken with study treatment?	<input type="radio"/> [DOSE INCREASED] Dose Increased <input type="radio"/> [DOSE NOT CHANGED] Dose not Changed <input type="radio"/> [DOSE REDUCED] Dose Reduced <input type="radio"/> [DRUG INTERRUPTED] Drug Interrupted <input type="radio"/> [DRUG WITHDRAWN] Drug Withdrawn <input type="radio"/> [NOT APPLICABLE] Not Applicable <input type="radio"/> [UNKNOWN] Unknown	AEACN
1.23	What is the outcome of this adverse event?	<input type="radio"/> [RECOVERING/RESOLVING] Recovering/Resolving <input type="radio"/> [NOT RECOVERED/NOT RESOLVED] Not Recovered/Not Resolved <input type="radio"/> [RECOVERED/RESOLVED] Recovered/Resolved <input type="radio"/> [RECOVERED/RESOLVED WITH SEQUELAE] Recovered/Resolved with Sequelae <input type="radio"/> [FATAL] Fatal <input type="radio"/> [UNKNOWN] Unknown	AEOUT