

	<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> </div> <div style="text-align: center;">Site Number</div>		<div style="display: flex; justify-content: space-around;"> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> </div> <div style="text-align: center;">Subject Number</div>				
	Prostate Cancer						

Adverse Events including SREs		
1 AEs including SREs		
1.1	Were any adverse events experienced?	<input type="radio"/> [Y] Yes AEYN <input type="radio"/> [N] No
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"/> [SRE-related] SRE-related AECAT <input type="radio"/> [Not SRE-related] Not SRE-related
1.5	If SRE-related, Indicate type of event	<input type="radio"/> [PATHOLOGICAL FRACTURE] Pathological Fracture AESCAT <input type="radio"/> [NON-PATHOLOGICAL FRACTURE] Non-Pathological Fracture <input type="radio"/> [SPINAL CORD COMPRESSION] Spinal Cord Compression <input type="radio"/> [OTHER SRE-RELATED EVENT] Other SRE-Related Event
1.6	What is the best description of the cause of the fracture?	<input type="radio"/> [BONE METASTASIS] Bone Metastasis AECAUSE <input type="radio"/> [OSTEOPOROSIS] Osteoporosis <input type="radio"/> [TRAUMA] Trauma <input type="radio"/> [OTHER] Other <input type="radio"/> [UNKNOWN] Unknown
1.7	What is the toxicity grade of the adverse event?	<input type="radio"/> [1] Grade 1 AETOXGR <input type="radio"/> [2] Grade 2 <input type="radio"/> [3] Grade 3 <input type="radio"/> [4] Grade 4 <input type="radio"/> [5] Grade 5
1.8	Start Date (DD-MMM-YYYY)	<div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> <div style="border: 1px solid black; width: 40px; height: 30px;"></div> </div> AESTDAT



Protocol Prostate Cancer

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Site Number

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Subject Number

Adverse Events including SREs

1 AEs including SREs

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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Site Number

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Adverse Events including SREs

1 AEs including SREs

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