

Adverse Event/Device Effect Record For UoL Sponsored Medical Device Studies

Subject ID <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>	Subject Initials <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/> <input style="width: 20px; height: 20px; border: 1px solid black;" type="text"/>
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	Adverse event/ Device Effect Description	Start Date (DD/MMM/YYYY)	End Date (DD/MMM/YYYY)	Relationship to Procedure: 1=not related OR 2=unlikely OR 3=possible OR 4=probable OR 5=causal relationship	Relationship to Device 1=not related OR 2=unlikely OR 3=possible OR 4=probable OR 5=causal relationship	SAE or Device Deficiency? Y/N	Expectedness Assessment 1=Expected 2=Unexpected	Outcome 1=Resolved 2=Resolved with sequelae 3= Ongoing 4= Fatal 5= Unknown
1		--/--/----	--/--/----					
2		--/--/----	--/--/----					
3		--/--/----	--/--/----					
4		--/--/----	--/--/----					
5		--/--/----	--/--/----					
6		--/--/----	--/--/----					
7		--/--/----	--/--/----					

