Adverse Event/Device Effect Record

For UoL Sponsored Medical Device Studies

| **Event Number** | **Adverse event/ Device Effect Description** | **Start Date**(DD/MMM/YYYY) | **End Date**(DD/MMM/YYYY) | **Relationshipto Procedure\***(\*key below) | **Relationshipto Device**(\*key below) | **SAE or Device Deficiency?**(Yes/No) | **Expectedness****Assessment**(1=Expected2=Unexpected) | **Outcome**(‡key below) |
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**\***1=not related, 2=unlikely, 3=possibly related, 4=probably, **5=**causal relationship

‡ 1=Resolved, 2= Resolved with sequelae, 3=ongoing, 4=Fatal, 5=Unknown