

16.3.1 CRFs for Deaths, Serious Adverse Events, and Withdrawals for Adverse Events

| Deaths | Other SAE | Unsolicited AE Leading to Discontinuation | Pregnancy |
|---------------|------------------|--|------------------|
| - | US2011089 | - | US2011089 |
| - | US2021031 | - | - |
| - | US2031097 | - | - |
| - | US2041007 | - | US2041007 |
| - | US2041119 | - | - |
| - | US2071083 | - | - |
| - | US2081123 | - | - |

Case report forms are available on request.