|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **What was the date of withdrawal?** | | | | D | D | | M | M | Y | Y | Y | | Y | | | |  | | |
| **Please select the primary reason of withdrawal** | | | | | | | | | | | |  | | | | | |  |
| **1. Adverse Event (AE)** | |  | | | |  | | | | | | | |  | |
|  | Related AE Number: | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | |  | |
| **2. Death** | |  | | | |  | | | | | | | |  | |
|  | Primary cause of death: | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | |  | |
|  | Related SAE Number: | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | |  | |
| **3. Withdrawal by participant** | |  | | | |  | | | | | | | | |
|  | *If possible please give reason:* | \_\_\_\_\_\_­­­­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | |
| **4. Lack of efficacy** | |  | | | | | | | | | | | | |
| **5. Lost to follow up** | |  | | | | | | | | | | | | |
| **6. Non-compliance with study drug** | | |  | | |  | | | | | | | | |
| **7. Investigator decision** | |  | | | |  | | | | | | | |  | |
|  | Please give reason: | **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | |
| **8. Pregnancy** | |  | | | | | | | | | | | | |
| **9. Progressive disease** | |  | | | | | | | | | | | | |
| **10. Protocol violation** | |  | | | |  | | | | | | | |  | |
|  | Please specify: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | | | |
| **11. Sponsor decision** | |  | | | | | | | | | | | | |
| **12. Other** | |  | | | |  | | | | | | |  | |
|  | Please specify: | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | | |  | |