|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **ADVERSE EVENT (Page 1 of 2)** | | | | |
| Type of Adverse Event & description  *(if more than one AE occurred, fill out a separate form for each)* | | **Adverse Event:** |  | |
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| **Adverse Event Description** | | |
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| **Date of Onset** | | Date of onset | | Date Study team became aware |
| \_\_ \_\_- \_\_ \_\_- \_\_ \_\_ \_\_ \_\_  MM DD YYYY | | \_\_ \_\_- \_\_ \_\_- \_\_ \_\_ \_\_ \_\_  MM DD YYYY |
| **Time of Onset** | | Time of onset | | Time Study team became aware |
| \_\_ \_\_: \_\_ \_\_  H H M M | | \_\_ \_\_: \_\_ \_\_  H H M M |
| **Date / Time of Resolution**  **OR** 🞎 Check if ongoing | | Date of Resolution | | Time of Resolution |
| \_\_ \_\_- \_\_ \_\_- \_\_ \_\_ \_\_ \_\_  MM DD YYYY | | \_\_ \_\_: \_\_ \_\_  H H M M |
|  |  | | | |
| **ADVERSE EVENT (CONTINUED) (Page 2 of 2)** | | | | |
| Most Extreme Intensity | 1🞎 Mild 2🞎 Moderate 3🞎 Severe | | | |
| Study Relationship | 1🞎 Not Related 2🞎 Unlikely 4🞎 Possibly 3🞎 Probably 5🞎 Definitely | | | |
| Drug Relationship | 1🞎 Not Related 2🞎 Unlikely 4🞎 Possibly 3🞎 Probably 5🞎 Definitely | | | |
| Expectedness | 1🞎 Expected 2🞎 Unexpected | | | |
| Treatment Action Taken  (*check* ***all*** *that apply*) | 1🞎 None 2🞎 Surgery required 3🞎 Medication 4🞎 Hospitalization  5🞎 Other (*specify*) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | |
| Outcome | 1🞎 Resolved 2🞎 Resolved with sequelae *(specify in comments section)*  3🞎 Death 4🞎 Unresolved 5🞎 Unknown | | | |
| **Serious?**  ***(Defined as fatal, life-threatening, significant disability, congenital abnormality, prolonged or new hospitalization)***  ***If serious, report to IRB/FDA per guidelines*** | **0🞎 No 1🞎 Yes**    **If yes, please check all that apply:**  **1🞎 Fatal 2🞎 Life-threatening 3🞎 Significant disability**  **4🞎 Prolonged hospitalization 5🞎 New hospitalization** | | | |
| Comments |  | | | |