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|  **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:** |  |
|  |  |
| **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 |  |