**DSMC Serious Adverse Event Report Form**

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| --- | --- | --- | --- | --- |
| IRB # and Protocol Name: | | | | |
| Subject Initials |  | Study ID: |  | PI: |
| Enrolling MD: |
| Initial Report  Follow Up #\_\_\_\_\_\_ | | | | |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Serious Adverse Event and Grade:** | |  | | | | **Dose level/randomization**:  **NA** | | | | | |
| |  |  | | --- | --- | | **Medical History**: | **Prior SAE’s (attr. & grade)  NA** | | | | | | | | | | | | |
| **Onset Date**: | |  | | | Resolution Date: | | | |  | | |
| **Is the event unexpected in terms of nature, severity or frequency?** | | Yes  No | | **Relationship to protocol treatment:** | | | | Not Related  Unlikely Related  Possibly Related  Probably Related  Definitely Related | | | |
| **Study Drug Name:** | **NA** | | | **Date of prior dose before the event**: | | | | |  | | |
| **Brief Description of the Event:** | | | | | | | | | | | |
| **Action with Protocol Treatment**:  Dose not changed  Dose reduction  Temporarily delayed  Discontinued Permanently  N/A | | | | | | | **Outcome:**  Recovered  Recovered with sequelae  Recovering  Not Recovered  Unknown | | | | |
| Reporter Name: | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please print | | | | Date: | | | |  |
| Investigator Name: | | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Please print | | | |  | | |  | |
| Investigator Signature: | | |  | | | | Date: | | | / / | |