**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 #\_\_\_\_\_\_ |

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| --- | --- | --- |
| **Serious Adverse Event and Grade:** |  | **Dose level/randomization**: **[ ]  NA** |
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| --- | --- |
| **Medical History**:  | **Prior SAE’s (attr. & grade) [x]  NA** |

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| **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: |  / / |