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| ***Instructions****: Complete this report for any serious adverse event experienced by a study participant enrolled in this study as soon as it is identified. A serious adverse event is defined in the protocol. Please complete this form and send it to CONRAD within 24 hours, along with a copy of the AE Form.* | | | | | | | |
| **Serious Adverse Event (SAE)** | | | | | | | |
|  | Event: | | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Diagnosis preferred. If no diagnosis, describe symptoms, include anatomical position. Must match AE CRF.) | | | | |
|  | Participant age: | | years | | | | |
|  | Date participant enrolled in the study: | | /  /  dd MMM yy | | | | |
|  | Date of 1st Dose: | | /  /  dd MMM yy | | | | |
|  | Time and date of last product use: | | /  /  :  dd MMM yy (24 hour clock) | | | | |
|  | Start/onset Date: | | /  /  dd MMM yy | | | | |
|  | Corresponding AE#: | |  | | | | |
|  | Corresponding CM# used: | | or  None | | | | |
|  | Why was the adverse event considered serious? *(Mark all that apply):* | | | | | | |
|  | Death *(specify cause of death)*  Life threatening adverse experience (immediate risk of death from event)  Required inpatient hospitalization (Minimum 24 hour inpatient hospitalization) or prolongation of existing hospitalization; provide dates of hospitalization:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Persistent or significant disability/incapacity (disruption of participant’s ability to conduct normal life functions)  Congenital anomaly/birth defect  Important medical event that may jeopardize the participant or important medical event that may require medical or surgical intervention to prevent one of the above definitions  Other *(specify):\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_* | | | | | | |
|  | Date SAE reported to the sponsor: | | /  /  dd MMM yy | | Initials & Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
|  | Date SAE reported to local ethics committee: | | /  /  dd MMM yy | | Initials & Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |
|  | | Case Narrative: Description of the clinical presentation/course of the event, precipitating events, relevant medical history, onset date of event symptoms, investigational product compliance information with start and stop dates included, responses to queries posed by principal investigator or medical monitor and any other assessments (e.g., pertinent laboratory data, physical exam) which help explain the event. **It is not necessary to include information that has been recorded elsewhere on these forms** | | | | |
|  | | Person completing this form: printed name and signature | | | | |
|  | | Printed name | | Signature | | \_\_ \_\_/\_\_ \_\_ \_\_/\_\_ \_\_  dd mmm yy |
|  | | Investigator’s printed name and signature | | | | |
|  | | Printed name | | Signature | | \_\_ \_\_/\_\_ \_\_ \_\_/\_\_ \_\_  dd mmm yy |
| Please email this form as a PDF to [conradsafety@evms.edu](mailto:conradsafety@evms.edu) | | | | | | |