

**Safety Reporting Form**

Send to: [connectsafety.sm@thermofisher.com](mailto:connectsafety.sm@thermofisher.com) and [pv@connectpharm.com](mailto:pv@connectpharm.com)

Section 1: General Information/ Report Type	
Study Protocol Number:	Report Version: <input type="checkbox"/> Initial <input type="checkbox"/> Follow-up version #: _____
Date of Report: ____ / ____ / ____ DD / MMM / YYYY	Date Investigator became aware: ____ / ____ / ____ DD / MMM / YYYY
SAE: <input type="checkbox"/> Yes <input type="checkbox"/> No      AESI: <input type="checkbox"/> Yes <input type="checkbox"/> No      Other safety report type (describe): _____	

Section 2: Participant Information	
Date of Birth: ____ / ____ MMM / YYYY	Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female
Age at time of event	
Participant Number:	Height: _____ Weight: _____
Race: <input type="checkbox"/> Asian <input type="checkbox"/> Black/African American <input type="checkbox"/> White/Caucasian <input type="checkbox"/> Native Hawaiian/ other Pacific Islander <input type="checkbox"/> American Indian or Alaska Native <input type="checkbox"/> Other: _____	

Section 3: Investigational Product Administration: <i>No change from previous report</i> <input type="checkbox"/>	
Investigational product:	
Date of first Administration: ____ / ____ / ____ DD / MMM / YYYY	Date of last Administration prior to SAE Onset: ____ / ____ / ____ DD / MMM / YYYY
Did site unblind treatment for the participant due to this event? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not applicable	



<input type="checkbox"/> Drug withdrawn. If withdrawn, did the event abate after discontinuation? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not applicable Did event reoccur after restart of investigational product? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Not applicable <input type="checkbox"/> Dose reduced	<input type="checkbox"/> Dose interrupted <input type="checkbox"/> Dose not changed <input type="checkbox"/> Unknown <input type="checkbox"/> Not applicable
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**Section 5: Relevant medical history: *No change from previous report***

Unknown  None  See below:

Disease Term:	Start Date: _____ / _____ / _____ DD / MMM / YYYY	Ongoing: <input type="checkbox"/> Yes <input type="checkbox"/> No	End Date: _____ / _____ / _____ DD / MMM / YYYY
Disease Term:	Start Date: _____ / _____ / _____ DD / MMM / YYYY	Ongoing: <input type="checkbox"/> Yes <input type="checkbox"/> No	End Date: _____ / _____ / _____ DD / MMM / YYYY
Disease Term:	Start Date: _____ / _____ / _____ DD / MMM / YYYY	Ongoing: <input type="checkbox"/> Yes <input type="checkbox"/> No	End Date: _____ / _____ / _____ DD / MMM / YYYY
Disease Term:	Start Date: _____ / _____ / _____ DD / MMM / YYYY	Ongoing: <input type="checkbox"/> Yes <input type="checkbox"/> No	End Date: _____ / _____ / _____ DD / MMM / YYYY
Disease Term:	Start Date: _____ / _____ / _____ DD / MMM / YYYY	Ongoing: <input type="checkbox"/> Yes <input type="checkbox"/> No	End Date: _____ / _____ / _____ DD / MMM / YYYY

**Section 6: Relevant concomitant medications: *No change from previous report***

Unknown  None  See below:

Name of Drug	Indication for Use	Dose	Dosage Unit	Dosage Form	Frequency	Route	Start Date DD/MMM/YYYY	End Date DD/MMM/YYYY

Section 7: Relevant diagnostic test results: <i>No change from previous report</i> <input type="checkbox"/>					
<input type="checkbox"/> Unknown <input type="checkbox"/> None <input type="checkbox"/> See below:					
Name of diagnostic test	Test Date DD/MMM/YYYY	Result	Unit	Upper Limit of Normal	Lower Limit of Normal

**Section 8: Narrative**

**Details of event occurrence and treatment (*please provide a description and treatment in chronological order*):**

A large, empty rectangular box with a black border, intended for the user to provide a detailed narrative description of the event occurrence and treatment in chronological order.

Section 9: Investigator/Reporter Information		
Site Address:	Investigator name:  Phone:  Email:	Reporter name:  Phone:  Email:
Investigator Signature: I, the undersigned investigator, attest that I have reviewed this Safety Report and agree with the content.		
Investigator Signature:		Date: ____ / ____ / ____ DD / MMM / YYYY