

Form 1- Part B: Initial Report of a Suspected Serious Adverse (SAE)

Version 1.0, 08 October 2020

Section Header	Num.	Question Text	Question Responses	Required
		Instructions: To be completed by a study physician (coordinator) for each suspected serious adverse event (SAE) upon reception of form DCF10a.		
		Coordinator ID		
		Child ID	Pre-filled	
		Child age (months)	Pre-filled	
		Date	Calculated automatically	
		Suspected SAE number	Pre-filled	
		Did the child receive study drug within 14 days before symptoms onset?	1, Yes 2, No, Stop this is not a suspected SAE.	
Suspected SAE characteristics		Suspected serious adverse event characteristics (select all that apply)		
		Resulted in death	1, Yes 2, No	
		Life threatening	1, Yes 2, No	
		Hospitalization/prolongation of hospitalization	1, Yes 2, No	
		Persistent or significant disability or incapacity	1, Yes 2, No	
		If other, specify	Free text	
Preliminary causality assessment		Causality to the study	1, Not related 2, Unlikely related 3, Possibly related 4, Probably related 5, Definitely related 4, Not assessable	