LAKANA trial

Data collection form 15: Protocol deviation - Site-level Deviation Form.

Version 2.0

Section Header	Num.	Question Text	Question Responses	Required
	[0]	Complete this form for site-level events that deviate from standard operating procedures and are not associated with any specific participant. This may include deviations from standard procedures for handling study drug or specimens.		
	[1]	Supervisor ID		Yes
Timing Information	[2]	Date of reporting	Date	Yes
	[3]	Protocol deviation start date	Date	Yes
	[4]	Protocol deviation end date	Date	Yes
Details of the deviation from planned study protocol	[5]	Indicate deviation category	0, Inadequate process for obtaining consent 1, Other deviation in the provision of information about the trial 2, Incorrect enrolment 3, Deviation in the implementation of household visits 4, Use of expired medication or medication not approved for use 4a, Other deviation in the storage, transport, or provision of study drug 5, Incorrect measurement of trial outcomes 7, Data entry or management errors 6, Deviation in laboratory assessments/procedures 8, Error in Serious Adverse Event Reporting	Yes

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			8a Other deviation that may have violated the participant's rights or place her / him at an increased risk of adverse consequences 9, Other.	
	[6]	Specify other	Free text	Yes
	[7]	Description of deviation and how the issue was identified	Free text	Yes
	[8]	Describe steps taken to resolve or avoid recurrence of the deviation:		Yes
	[9]	Does this deviation meet immediate IRB reporting requirements?	*Automatically completed:* *= Yes if answer to Q5= 0 or 4 or 8a* *Otherwise = No*	
	[10]	Did the deviation result in an adverse or serious adverse event?	1, Yes, Complete SAE Form DCF10a | 0, No | 99, Unknown	
	[11]	Will the affected subject continue to participate in the study?	1, Yes | 0, No	Yes
General information	[12]	Additional notes:		