

Participant ID |__|__|__|__|__|

Participant's Initials |__|__|__|

Sex |__| (m/f)

ADVERSE EVENTS FORM

AE#	Report date (DD/MM/YYYY)	Description of adverse event	Event onset date (DD/ MM/YYYY)	Event end date (DD/ MM/YYYY)	Severity (Grade)	Relation- ship *	Action	Outcome	Reported as SAE	Indicate which AE is considered related to
	___/___/___		___/___/___	___/___/___						
	___/___/___		___/___/___	___/___/___						
	___/___/___		___/___/___	___/___/___						
	___/___/___		___/___/___	___/___/___						
	___/___/___		___/___/___	___/___/___						
	___/___/___		___/___/___	___/___/___						
	___/___/___		___/___/___	___/___/___						

Relationship is attributed by a physician. All local AEs are causally related to vaccination

Relationship to vaccine administration	Grade	Action	Outcome	Reported as SAE
0 = Not related 1 = Unlikely related 2 = Possibly related 3 = Probably related 4 = Definitely related.	1 = Present but easily tolerated 2 = Interferes with daily activities 3 = Prevents from daily activities 4 = Life-threatening, patients at risk of death (Report as SAE)	0 = No action taken 1 = Medication 2 = Non- Drug therapy 3 = Hospitalisation * * Report as SAE	1 = Resolved 2 = Resolving 3 = Not Resolved 4 = Resolved with sequelae 5 = Fatal 6 = Unknown	1 = Yes 2 = No