

ADVERSE EVENT (AE) REPORT FORM			
Report Type:		☐ Initial	☐ Follow-up
		Follow-up No:	
Date of AE Report:			
1. Patient Information			
Initials/identifier:		Date of Birth (e.g. 01 Jan 1940) _____	Ethnic Origin: ☐ White ☐ Asian ☐ Black/African American ☐ Other ☐ Please Specify
Sex: ☐ Male ☐ Female		Height (cm):	Weight (kg):
Pregnant: ☐ Yes ☐ No		Country of occurrence:	Tel. No:
2. Adverse Event Information			
AE term(s):			
Course of event:			
☐ Onset of AE (when AE occurred):		Date:	Time:
Present Status:			
☐ Ongoing → AE currently treated ☐ Yes ☐ No			
☐ Resolved Please Specify Date: Time:			
Case description: Detailed description of the event (Include related signs/symptoms, course, outcome)			
Reason for seriousness:			
☐ resulted in death ☐ life-threatening ☐ required inpatient hospitalization or prolongation of existing hospitalization ☐ resulted in persistent or significant disability/ incapability (as per reporter's opinion)/ congenital anomaly/ birth defect ☐ other medically important event (reporter's discretion)			
Intensity: ☐ Mild ☐ Moderate ☐ Severe			
Reporter's Causality: [] certainly [] probably [] possibly [] unlikely [] conditional [] unassessable [] not related			
Outcome of AE:			
☐ Completely recovered/resolved ☐ Ongoing ☐ Fatal ☐ Lost to follow-up			
☐ Unknown ☐ Recovered with sequelae → specify:			
If outcome is fatal:			
Cause of death: _____ Date: _____ Time: _____			
Report of Autopsy available? ☐ No ☐ Yes (Please attach copy to this report)			
Further information:			
3. Drug Details			
Name of the drug:		Strength:	Indication:
Route of Admin:		Dosage form:	Dose:
Frequency:		Expiry date:	
Start date:		Stop date:	Ongoing: ☐ Yes ☐ No
Action taken with suspect drug:			
☐ None			
☐ Dosage changed temporarily: Date: _____ ☐ Dosage reduced ☐ Dosage increased			

☐ Drug stop temporarily: Date: _____ ☐ Drug restarted: Date: _____ ☐ Drug withdrawn permanently ☐ Dosage not changed ☐ Unknown ☐ Not applicable							
Additional suspect drug (if any) details as above:							
Event abated after drug stopped or dose reduced:			Event reappeared after reintroduction of suspect drug:		If yes, did reaction recur?		
☐ Yes ☐ No ☐ Not applicable			☐ Yes ☐ No ☐ Not applicable		☐ Yes ☐ No ☐ Not applicable		
4. Patient's Relevant Medical History (<i>Supplement attached Yes/No</i>)							
(E.g. concomitant diseases, previous history of present condition, allergy, drug or alcohol abuse)							
5. Concomitant Drugs							
Drug Name (generic)	Dose/ Unit	Route	Frequency	Start date	Stop date	Ongoing	Causal relationship to event
						☐	☐ None ☐ Possible
	Indication:						
						☐	☐ None ☐ Possible
	Indication:						
						☐	☐ None ☐ Possible
6. Reporter Details							
Name: Address: Country: Tel. No: Email:				Occupation: ☐ Physician ☐ Pharmacist ☐ Nurse ☐ Consumer ☐ Other, specify: Also reported to: ☐ Regulatory Authority ☐ Distributor ☐ None Date : __/__/____, Signature:			
7. Send this report to:				8. To be filled by the company:			
ALDE Expression Lifesciences First Floor, 71/2C, Rama Rd, Moti Nagar, Block C, Najafgarh Road Industrial Area, New Delhi, Delhi, 110015, India (E-mail : pv@aldeexpression.com)				Date received by receiver: __/__/____ Name and sign of receiver: Safety Report ID:			

Note: A supplement paper can be added in case of further information to be reported.