ADVERSE EVENT (AE) REPORT FORM
(For all countries)

Report Type: ❒ Initial ❒ Follow-up Follow-up No:

Date of AE Report:

Please fill and return this form to Alde Expression Lifesciences Pvt Ltd, Plot No. S4-3 to S4-6, Industrial Area IIE Escort Farm, kashipur Uttarakhand – 244713

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 occurence:**	**Tel. No:**

2. Adverse Event Information

AE term(s):

Course of event:

❒ Onset of AE or date and time when AE occurred*:*	**Date:**	**Time:**
❒ Onset of AE or date and time when event became serious, if applicable:	**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:_____

Lab test Details (with dates, results and normal range): _____

3. Drug Details

Name of the drug:_____**Strength:**_____**Indication:**_____

Route of Admin:_____**Dosage form:**_____**Dose:**_____

Frequency:_____**Expiry date: DD/MM/YYYY**

Start date:(dd.mmm.yyyy) Stop date:(dd.mmm.yyyy) Ongoing:

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❒ Drug stop temporarily: Date:_____ ❒ Drug restarted: Date:_____ ❒ Drug withdrawn permanently ❒ Dosage not changed ❒ Unknown ❒ Not applicable							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 (*Supplement attached Yes/No)*							
(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 Manufacturer:**			
Alde Expression Lifesciences Pvt Ltd, **Plot No. S4-3 to S4-6, Industrial Area IIE Escort Farm, Kashipur Uttarakhand – 244713** **Email: pv@aldeexpression.com** **24*7 mobile number: 9958165585**				**Date received by receiver:** __ / __ / _____ **Name and sign of receiver:** **Safety Report ID:**			