Individual Case Safety Report Form

EVPIVITCSR(S)			individual Case Safety Report Form				Eudravigilance
General Information							
EudraVigilance Local Report Number		EU-E	EU-EC-10016892588				
Sender Type		Health	Health professional				
Sender's Organisation		ASTRAZENECA AB					
Type of Report		Spont	Spontaneous				
Primary source country		Non-European Economic Area					
Reporter's qualification		Non-Healthcare Professional					
Case serious?		Yes					
Patient							
Age Group			Age Group (as per reporter)			Sex	
Reaction	on / Event						
MedDRA LLT		Duration			Outcome		Seriousness ¹
Vaccination adverse reaction			Fatal		Fatal		death.
Drug Ir	nformation						
Role ²	Drug		Duration	Dose	U	nits in Interval	Action taken
S	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)						Unknown
Drug Ir	nformation (cont.)						
Info ³	Info ³ Drug		Indication Pt		arm. Form	Route of Admin.	
VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)			N/A			on for injection	Intramuscular use
Rechal	lenge matrix table						
Reaction/Event (MedDRA LLT)			Drug			Rechallenge? / Reaction recurred?	
Vaccinati			'AXZEVRIA - COVID-19 VACCINE ASTRAZENECA CHADOX1 NCOV-19)			no - n/a	

Seriousness: death=results in death; life threat.=life threatening; hospital.=requires hospitalization/prolongation of hospitalization; disability=results in disability/incapacity; congen.=congenital anomaly/birth defect; other=other medically important information; (blank)=non-serious

 $^{2 \}quad \text{Drug role: } \textbf{S} \text{=-suspect; } \textbf{C} \text{=-concomitant; } \textbf{I} \text{=-interacting; } \textbf{N} \text{=-not administered}$

³ Additional Information on Drug: 1=Counterfeit; 2= Overdose; 3=Drug taken by the father; 4=Drug taken beyond expiry date; 5=Batch and lot tested and found within specifications; 6=Batch and lot tested and found not within specifications; 7=Medication error; 8=Misuse; 9=Abuse; 10=Occupational exposure; 11=Off label use; (blank) = no additional information