Individual Case Safety Report Form

individual Case Safety Report Form						Ludravigilarice	
General Information							
EudraVigilance Local Report Number			EU-EC-10016891129				
Sender Type		Health	Health professional				
Sender's Organisation		ASTR	ASTRAZENECA AB				
Type of Report		Spont	Spontaneous				
Primary source country		Non-E	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			Fata		Fatal		death.
Drug Ir	nformation						
Role ²	Drug		Duration	Dose	U	Inits in Interval	Action taken
S	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)						Unknown
Drug Ir	nformation (cont.)						
Info ³	nfo³ Drug		Indication Pl		arm. Form	Route of Admin.	
	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)		N/A So		Soluti	on for injection	Intramuscular use
Rechal	lenge matrix table						
Reaction/Event (MedDRA LLT)			Drug			Rechallenge? / Reaction recurred?	
Vaccinati	ion adverse reaction	VAXZEVRIA - 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