Individual Case Safety Report Form

individual Case Safety Report Form						Ludiavigliance		
General Information								
EudraVigilance Local Report Number			EU-EC-10016891123					
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	fo³ Drug		Indication Ph		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 Drug role: S=suspect; C=concomitant; I=interacting; N=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