Individual Case Safety Report Form

EVPINITCSK(S)			Individual Case Safety Report Form				Eudravigilarice	
General Information								
EudraVigilance Local Report Number		EU-E0	EU-EC-10016890671					
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	Yes					
Patient								
Age Group			Age Group (as per reporter)			Sex		
Reaction / Event								
MedDRA LLT		Duration			Outcome		Seriousness ¹	
Vaccination adverse reaction					Fatal		death.	
Drug Information								
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	Drug		Indication		Pharm. Form		Route of Admin.	
	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)			Solution for injection		on for injection	Intramuscular use	
Rechallenge matrix table								
Reaction/Event (MedDRA LLT)			Drug			Rechallenge? / Reaction recurred?		
Vaccinat	ion adverse reaction		AXZEVRIA - COVID-19 VACCINE ASTRAZENECA HADOX1 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