## **Individual Case Safety Report Form**

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General Information								
EudraVigilance Local Report Number		EU-E	EU-EC-10016891126					
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-F	Non-Healthcare Professional					
Case serious?		Yes	Yes					
Patient								
Age Group			Age Group (as per reporter)			Sex		
Reaction / Event								
MedDRA LLT		Duration		Outcome		Seriousness <sup>1</sup>		
Vaccination adverse reaction			Fatal		Fatal		death.	
Drug Information								
Role <sup>2</sup>	Drug		Duration	Dose	U	Inits in Interval	Action taken	
S	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)					Unknown		
Drug Information (cont.)								
Info <sup>3</sup>	Drug		Indication	Indication		arm. Form	Route of Admin.	
	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)		N/A		Solution for injection		Intramuscular use	
Rechallenge matrix table								
Reaction/Event (MedDRA LLT)			Drug			Rechallenge? / Reaction recurred?		
Vaccination adverse reaction			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

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

<sup>3</sup> 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