## **Individual Case Safety Report Form**

EVPM ICSR(s)			Individual Case Safety Report Form				Eudravigliance
General Information							
EudraVigilance Local Report Number		EU-E	EU-EC-10016891127				
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-H	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	nits in Interval	Action taken
S	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)	)					Unknown
Drug Information (cont.)							
Info <sup>3</sup>	Drug	Indication			Pharm. 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?	
			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

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

<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