Individual Case Safety Report Form

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General Information							
EudraVigilance Local Report Number		EU-E	EU-EC-10016891364				
Sender Type		Health professional					
Sender's Organisation		ASTRAZENECA AB					
Type of Report		Spontaneous					
Primary source country		Non-European Economic Area					
Reporter's qualification		Non-Healthcare Professional					
Case serious?		Yes					
Patient							
Age Group		Age Group (as per reporter)			Sex		
Reaction / Event							
MedDRA LLT		Duration			Outcome		Seriousness ¹
Vaccination adverse reaction		Fatal			Fatal		death.
Drug Information							
Role ²	Drug		Duration	Dose	U	Inits in Interval	Action taken
S	S VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)					Unknown	
Drug Ir	nformation (cont.)						
Info ³	Info³ Drug		Indication PI		narm. 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?		
Vaccinati		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