EVPM ICSR(s)		Indivi	Individual Case Safety Report Form				EudraVigilance
General Information							
EudraVigilance Local Report Number		EU-E	EU-EC-10009153924				
Sender Type		Healt	Health professional				
Sender's Organisation		ASTR	ASTRAZENECA AB				
Type of Report			Spontaneous				
Primary source country			European Economic Area				
Reporter's qualification			Non-Healthcare Professional				
Case serious?			Yes				
Patient							
Age Group			Age Group (as per reporter)			Sex	
						Female	
Reaction / Event							
MedDRA LLT			Duration		Outcome		Seriousness <sup>1</sup>
Thrombosis			Fatal			death., hospital., other	
Drug Information							
Role <sup>2</sup>	Drug		Duration	Dose	1	Jnits in Interval	Action taken
COVID-19 VACCINE ASTRAZENECA (CHAD S NCOV-19) - COVID-19 VACCINE ASTRAZEN (CHADOX1 NCOV-19)							Not applicable
Drug Information (cont.)							
Info <sup>3</sup>	o <sup>3</sup> Drug		Indication P		harm. Form	Route of Admin.	
	COVID-19 VACCINE ASTRAZENECA (CHADOX NCOV-19) - COVID-19 VACCINE ASTRAZENEC (CHADOX1 NCOV-19)						Intramuscular use
Rechallenge matrix table							
Reaction/Event (MedDRA LLT)			Drug			Rechallenge? / Reaction recurred?	
			COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19) - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)				no - n/a

<sup>1</sup> 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> Drug role: S=suspect; C=concomitant; I=interacting; N=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