EVPM ICSR(s)		Individual Case Safety Report Form				EudraVigilance		
General Information								
EudraVig	ilance Local Report Number	EU-E	EU-EC-10009403566					
Sender Type		Health professional						
Sender's Organisation		ASTRAZENECA AB						
Type of Report		Spontaneous						
Primary source country		European Economic Area						
Reporter's qualification		Non-Healthcare Professional						
Case serious?		No						
Patient								
Age Group		Age Group (as per reporter)			Sex			
18-64 Years						Female		
Reaction / Event								
MedDRA LLT		Duration		Outcome		•	Seriousness ¹	
Falling down					Unknown			
Accident NOS		Unknow			Unknown			
Fever		1.0 Days		Recovered/Resolved				
Weakness		1.0 Days		Recovered/Resolved		solved		
Circumstance or information capable of leading to medication error					Unknown			
Drug Information								
Role ²	Drug		Duration	Dose	e Units in Interval		Action taken	
S	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)					Unknown		
Drug Information (cont.)								
Info ³	Drug		Indication		Pharm. Form		Route of Admin.	
	VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)		N/A				Intramuscular use	
Rechallenge matrix table								
Reaction/Event (MedDRA LLT)		Drug			Rechallenge? / Reaction recurred?			
Accident NUS		VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)			no - n/a			
		VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)				no - n/a		
Falling down		VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)				no - n/a		
Fever			/AXZEVRIA - COVID-19 VACCINE ASTRAZENECA CHADOX1 NCOV-19)				no - n/a	
Weakness		VAXZEVRIA - COVID-19 VACCINE ASTRAZENECA (CHADOX1 NCOV-19)				no - n/a		

¹ 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