## **Individual Case Safety Report Form**

EVPIVITCSK(S)	individual Case Safety Report Form				Eudravigilarice	
General Information						
EudraVigilance Local Report Number	EU-EC-10011420973					
Sender Type	Health professional					
Sender's Organisation	PFIZER S.R.L.					
Type of Report	Spontaneous					
Primary source country	Non-European Economic Area					
Reporter's qualification	Healthcare Professional					
Case serious?	Yes					
Patient						
Age Group		Age Group (as pe	er reporter)			Sex
12-17 Years						Male
Reaction / Event						
MedDRA LLT		Duration		Outcome		Seriousness <sup>1</sup>
Head banging			Fatal			death.
Adverse event following immunisation			Fatal			death.
Drug Information						
Role <sup>2</sup> Drug		Duration	Dose	U	Inits in Interval	Action taken
S COMIRNATY - TOZINAMERAN					Total	Not applicable
Drug Information (cont.)						
Info <sup>3</sup> Drug		Indication		Pharm. Form		Route of Admin.
COMIRNATY - TOZINAMERAN	COVID-19 immunis		isation			

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