Individual Case Safety Report Form

EVPM ICSR(s)			Individual Case Safety Report Form				Eudravigliance
General Information							
EudraVigilance Local Report Number		EU-E	C-10011096615				
Sender Type		Healtl	h professional				
Sender's Organisation		PFIZE	ER S.R.L.				
Type of Report		Spont	Spontaneous				
Primary source country			Non-European Economic Area				
Reporter's qualification		Healtl	hcare Professional				
Case serious?			Yes				
Patient							
Age Group			Age Group (as per reporter)			Sex	
12-17 Years						Female	
Reaction	on / Event						
MedDRA LLT			Duration		Outcome		Seriousness ¹
Vaccination site pain				Fatal			death.
Stiffness					Unknow		
Coldness					Unknow	'n	
Unresponsive to stimuli				Fatal			death., other
Drug In	formation						
Role ²	Drug		Duration	Dose		Units in Interval	Action taken
S	COMIRNATY - TOZINAMERAN					Total	Not applicable
S	S COMIRNATY - TOZINAMERAN		1.0 Days			Total	Not applicable
Drug In	formation (cont.)						
Info ³	Drug		Indication		Pharm. Form		Route of Admin.
COMIRNATY - TOZINAMERAN COMIRNATY - TOZINAMERAN			COVID-19 immunisation				Intramuscular use
			COVID-19 immunisation				

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