LVI W 1001X(3)	individual Case Salety Report Form			Eddravigilarice	
General Information					
EudraVigilance Local Report Number	EU-EC-10009528413	EU-EC-10009528413			
Sender Type	Health professional	Health professional			
Sender's Organisation	PFIZER S.R.L.	PFIZER S.R.L.			
Type of Report	Spontaneous	Spontaneous			
Primary source country	Non-European Economic Area	Non-European Economic Area			
Reporter's qualification	Non-Healthcare Professional	Non-Healthcare Professional			
Case serious?	Yes				
Patient					
Age Group		Sex			
		Male			
Reaction / Event					
MedDRA LLT	Duration		Outcome	Seriousness <sup>1</sup>	
Sudden death			Fatal	death., other	
Drug Information					
Role <sup>2</sup> Drug	Duration	Dose	Units in Interval	Action taken	
S TOZINAMERAN - TOZINAMERAN			Total	Not applicable	
Drug Information (cont.)					
Info <sup>3</sup> Drug	Indication		Pharm. Form	Route of Admin.	
TOZINAMERAN - TOZINAMERAN	COVID-19 immu	ınisation			

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