Individual Case Safety Report Form

General Information	
EudraVigilance Local Report Number EU-EC-10010607769	
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 Non-Healthcare Professional	
Case serious? Yes	
Patient	
Age Group Age Group (as per reporter)	Sex
12-17 Years	Male
Reaction / Event	
MedDRA LLT Duration Outcome	Seriousness ¹
Unknown cause of death Fatal	death., other
Drug Information	
Role² Drug Duration Dose Units in Interval	Action taken
S TOZINAMERAN - TOZINAMERAN Total	Not applicable
Drug Information (cont.)	
Info ³ Drug Indication Pharm. Form	Route of Admin.
TOZINAMERAN - TOZINAMERAN COVID-19 immunization	

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

 $^{2 \}quad \text{Drug role: } \textbf{S} \text{=} \text{suspect; } \textbf{C} \text{=} \text{concomitant; } \textbf{I} \text{=} \text{interacting; } \textbf{N} \text{=} \text{not administered}$

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