Individual Case Safety Report Form

	IIIUIVI	duai Case Safety	Ludravigilarice				
General Information							
EudraVigilance Local Report Number	EU-E	EU-EC-10011005220					
Sender Type	Healtl	Health professional					
Sender's Organisation	PFIZE	PFIZER S.R.L.					
Type of Report	Spont	Spontaneous					
Primary source country	Non-E	Non-European Economic Area					
Reporter's qualification	Non-H	Non-Healthcare Professional					
Case serious?	Yes	Yes					
Patient							
Age Group		Age Group (as per reporter)			Sex		
12-17 Years							
Reaction / Event							
MedDRA LLT		Duration		Outcome		Seriousness ¹	
Myocarditis			Fatal			death.	
Drug Information							
Role ² Drug		Duration	Dose	U	Jnits 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 immu	nization				

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