## **Individual Case Safety Report Form**

LVI W IOOK(3)		individual Case Salety Report Form				Ludravigilarice
General Information						
EudraVigilance Local Report Number		EU-EC-10010832620				
Sender Type		Regulatory authority				
Sender's Organisation		EEA Regulator				
Type of Report		Spontaneous				
Primary source country		European Economic Area				
Reporter's qualification		Healthcare Professional				
Case serious?		Yes				
Patient						
Age Group		Age Group (as per reporter)			Sex	
		Adolescent			Male	
Reaction / Event						
MedDRA LLT		Duration		Outcome		Seriousness <sup>1</sup>
Acute myocardial infarction			Fatal			death.
Drug Information						
Role <sup>2</sup> Drug	e <sup>2</sup> Drug		Dose	U	nits in Interval	Action taken
S COMIRNATY - TOZINA	MERAN		2.0 (DF)	2.0 {DF}		
Drug Information (cont.)						
Info³ Drug		Indication		Ph	arm. Form	Route of Admin.
COMIRNATY - TOZINAMERAN		Prophylactic vaccination				

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

 $<sup>2 \</sup>quad \text{Drug role: } \textbf{S} \text{=-suspect; } \textbf{C} \text{=-concomitant; } \textbf{I} \text{=-interacting; } \textbf{N} \text{=-not administered}$ 

<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