EVPM ICSR(s)	Individual Case Safety Report Form						
General Information							
EudraVigilance Local Report Number	EU-E	EU-EC-10012410493					
Sender Type	Regu	Regulatory authority					
Sender's Organisation	EEAI	EEA Regulator					
Type of Report	Spon	Spontaneous					
Primary source country	Europ	European Economic Area					
Reporter's qualification	Non-H	Non-Healthcare Professional					
Case serious?	Yes	Yes					
Patient							
Age Group		Age Group (as per reporter)				Sex	
65-85 Years						Male	
Reaction / Event							
MedDRA LLT		Duration		Outcome		Seriousness ¹	
Lung cancer				Fatal		death., hospital., other	
Death		0.0 Days		Fatal		death.	
Encephalitis				Fatal		death., hospital., other	
Myelitis				Fatal		death., hospital., other	
Drug Information							
Role ² Drug		Duration	Dose	l	Jnits in Interval	Action taken	
S COMIRNATY - TOZINAMERAN							
Drug Information (cont.)							
Info ³ Drug		Indication	Indication		harm. Form	Route of Admin.	
COMIRNATY - TOZINAMERAN		N/A					

¹ 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