## **Individual Case Safety Report Form**

EVPM ICSR(s)	Individual Case Safety Report Form					EudraVigilance	
General Information							
EudraVigilance Local Report Number	EU-E	EU-EC-10008817561					
Sender Type	Healt	Health professional					
Sender's Organisation	PFIZE	ER S.R.L.					
Type of Report	Spon	taneous					
Primary source country	Europ	European Economic Area					
Reporter's qualification	Healthcare Professional						
Case serious?	Yes	Yes					
Patient							
Age Group		Age Group (as per reporter)			Sex		
65-85 Years					Female		
Reaction / Event							
MedDRA LLT	RA LLT		Duration Outcome			Seriousness <sup>1</sup>	
Femur fracture			Recovered/Resolved		olved	other	
Fall			Reco	Recovered/Resolved		other	
Accident			Unknown			other	
Drug Information							
Role <sup>2</sup> Drug		Duration	Dose	U	nits in Interval	Action taken	
S COMIRNATY - TOZINAMERAN						Not applicable	
Drug Information (cont.)							
Info³ Drug		Indication			arm. Form	Route of Admin.	
COMIRNATY - TOZINAMERAN	MIRNATY - 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

<sup>2</sup> Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=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