Individual Case Safety Report Form

General Information								
EudraVigilance Local Report Number			EU-EC-10009860999					
Sender Type			Health professional					
Sender's Organisation			PFIZER S.R.L.					
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		
12-17 Years							Male	
Reaction / Event								
MedDRA LLT		Duration		Outcome		e	Seriousness ¹	
Leukemia				Fatal			death., other	
Drug Information								
Role ²	Drug		Duration	Dose		Units in Interval	Action taken	
S	COMIRNATY - TOZINAMERAN					Total	Not applicable	
Drug Information (cont.)								
Info³ Drug			Indication		Pharm. Form		Route of Admin.	
	COMIRNATY - TOZINAMERAN		COVID-19 immunisation					

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

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

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