Individual Case Safety Report Form

LVI W IOSK(S)	individual Case Salety Report Form					Ludravigilarice	
General Information							
EudraVigilance Local Report Number	EU-E	EU-EC-10012163297					
Sender Type	Healt	h professional					
Sender's Organisation	PFIZE	PFIZER S.R.L.					
Type of Report	Spon	Spontaneous					
Primary source country	Europ	European Economic Area					
Reporter's qualification	Non-l	Non-Healthcare Professional					
Case serious?	Yes	Yes					
Patient							
Age Group	Age Group (as pe		er reporter)	reporter)		Sex	
18-64 Years						Female	
Reaction / Event							
MedDRA LLT		Duration		Outcome		Seriousness ¹	
Drug exposure during pregnancy, third trimester				Unknown		other	
Premature uterine contractions				Unknown		other	
Drug Information							
Role ² Drug		Duration	Dose	U	nits in Interval	Action taken	
S COMIRNATY - TOZINAMERAN		1.0 Days			Total	Not applicable	
Drug Information (cont.)							
Info³ Drug		Indication		Pharm. Form		Route of Admin.	
COMIRNATY - TOZINAMERAN		COVID-19 immunis		ation		Intramuscular use	

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

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

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