| EVPM ICSR(s) | CSR(s) Individual Case Safety Report Form | | | | | | |
|------------------------------------|---|-----------------------------|-----------------------|-------|-------------------|--------------------------|--|
| General Information | | | | | | | |
| EudraVigilance Local Report Number | EU-E | EU-EC-10010868932 | | | | | |
| Sender Type | Health | Health professional | | | | | |
| Sender's Organisation | PFIZE | PFIZER S.R.L. | | | | | |
| Type of Report | Spont | Spontaneous | | | | | |
| Primary source country | Non-E | Non-European Economic Area | | | | | |
| Reporter's qualification | Non-H | Non-Healthcare Professional | | | | | |
| Case serious? | Yes | Yes | | | | | |
| Patient | | | | | | | |
| Age Group | | Age Group (as per reporter) | | | Sex | | |
| 12-17 Years | | | | | | Male | |
| Reaction / Event | | | | | | | |
| MedDRA LLT | | Duration | Outcome | | e | Seriousness ¹ | |
| Diabetes | | | | Fatal | | death. | |
| Difficulty breathing | | | | Fatal | | death. | |
| Chest pain | t pain | | | Fatal | | death. | |
| Fever | | | | Fatal | | death. | |
| Drug Information | | | | | | | |
| Role ² Drug | | Duration | Dose | - L | Jnits in Interval | Action taken | |
| S COMIRNATY - TOZINAMERAN | COMIRNATY - TOZINAMERAN | | | | Total | Not applicable | |
| Drug Information (cont.) | | | | | | | |
| Info ³ Drug | Drug | | Indication | | harm. Form | Route of Admin. | |
| COMIRNATY - TOZINAMERAN | NATY - TOZINAMERAN | | COVID-19 immunisation | | | | |

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