## **Individual Case Safety Report Form**

individual case Salety Report Form							
l Information							
gilance Local Report Number EU-EC-10011323051							
Sender Type		Pharmaceutical company					
Organisation	JANS	JANSSEN CILAG INTERNATIONAL					
eport	Spont	Spontaneous					
ource country	Non-E	Non-European Economic Area					
s qualification	Non-H	Non-Healthcare Professional					
Case serious? Yes							
Age Group		Age Group (as per reporter)			Sex		
12-17 Years		Adolesc	nt			Male	
n / Event							
MedDRA LLT		Duration		Outcome		Seriousness <sup>1</sup>	
Clot blood			Unknown		vn	death., other	
				Fatal		death., other	
ministered to patient of inappropriate				Unknown		death., other	
ise			Unknown		vn	death., other	
Heart disorder			Unknown		vn	death., other	
formation							
Drug		Duration	Dose	Dose U		Action taken	
S COVID-19 VACCINE JANSSEN (AD26.COV2.S) - COVID-19 VACCINE JANSSEN (AD26.COV2.S)					Total	Not applicable	
formation (cont.)							
Drug		Indication		Pharm. Form		Route of Admin.	
COVID-19 VACCINE JANSSEN (AD26.COV2.S) - COVID-19 VACCINE JANSSEN (AD26.COV2.S)		Prophylactic vaccination		Suspension for injection		Unknown	
	ance Local Report Number  Ippe Drganisation Eport Druce country Equalification Druce Dryanisation Drug COVID-19 VACCINE JANSSEN (AD26.C) COVID-19 VACCINE JANSSEN (AD26.C) Drug COVID-19 VACCINE JANSSEN (AD26.C) COVID-19 VACCINE JANSSEN (AD26.C) Drug COVID-19 VACCINE JANSSEN (AD26.C)	ance Local Report Number  Ppe Phare Ppe Phare Organisation Spont Pource country Age Group 12-17 Years Physical Phare Proport P	ance Local Report Number  Type  Pharmaceutical company  JANSSEN CILAG INTERNATI  Spontaneous  Non-European Economic Area  Non-Healthcare Professional  Yes  Age Group  Age Group  12-17 Years  Adolesce  The LLT  Duration  Drug  COVID-19 VACCINE JANSSEN (AD26.COV2.S) -  COVID-19 VACCINE JANSSEN (AD26.COV2.S) -	ance Local Report Number  Pe Pharmaceutical company JANSSEN CILAG INTERNATIONAL Spontaneous Non-European Economic Area Non-Healthcare Professional Peror  Age Group 12-17 Years Adolescent  Non-Event  LLT Duration  Drug Drug Drug Drug Drug Drug Drug Dru	ance Local Report Number  Pe Pharmaceutical company JANSSEN CILAG INTERNATIONAL Spontaneous Non-European Economic Area Non-Healthcare Professional Personal	ance Local Report Number  pe Pharmaceutical company Dranisation JANSSEN CILAG INTERNATIONAL Spontaneous Non-European Economic Area Non-Healthcare Professional Yes  Age Group Age Group 12-17 Years Adolescent  Age Group Testal  Unknown Fatal  dministered to patient of inappropriate se Unknown Tormation  Drug COVID-19 VACCINE JANSSEN (AD26.COV2.S) - COVID-19 VACCINE JANSSEN (AD26.COV2.S) - Drug  Indication  Pharmaceutical company  JANSSEN (AD26.COV2.S) - Supposition for injection  Pharmaceutical company  JANSSEN (AD26.COV2.S) - Supposition for injection  Pharmaceutical company  JANSSEN (AD26.COV2.S) - Supposition  Pharmaceutical company  JANSSEN (AD26.COV2.S) - Supposition  Supposition  Supposition  Supposition  Supposition  Pharm. Form  COVID-19 VACCINE JANSSEN (AD26.COV2.S) - Pages Marie Vargering tipes  Supposition  Supposition  Supposition  Supposition  Pharm. Form  COVID-19 VACCINE JANSSEN (AD26.COV2.S) - Pages Marie Vargering tipes  Supposition  Supp	

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

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

<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