



Reporting of adverse events or presumed adverse events
 Report any suspicion of adverse reaction or adverse event and/or any adverse event. You have to fill this form clearly, without overwritten text, erasures or alterations and send it **immediately** to:
pharmacovigilance@inosanbiopharma.com

1. PATIENT DATA

NAME (3 first letters)	First Name (1st letter)	DATE OF BIRTH	AGE	WEIGHT Kg	HEIGHT m	GENRE:
						<input type="checkbox"/> MALE <input type="checkbox"/> FEMALE
ADDRESS :		IMPORTANT MEDICAL HISTORY INFORMATION:				

2. SUSPECTED MEDICINE

ACTIVE SUBSTANCE NAME	COMMERCIAL NAME	NAME OF THE MANUFACTURER		
BATCH NUMBER / EXPIRATION DATES	DOSE / POSOLOGY	ROUTE OF ADMINISTRATION		
REASON FOR PRESCRIPTION	DATES & HOURS OF ADMINISTRATION			
	Administration	Number of vials	Date	Hour
	Administration 1			
	Administration 2			
	Administration 3			
	Administration 4			
	Administration 5			
NB: If more than 5 administrations, use a second form				

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3. DESCRIPTION OF THE ADVERSE EVENT

Must be described: Adverse events (AE) / Lack of efficacy (LoE) / Exposure during pregnancy / Misuse / Accidental exposure to humans. Describe the event thoroughly, setting of occurrences, evolution, with precise description of the progress of the event. Join a copy of the available medical documents (biological exams results, hospitalization reports, etc...)

<p>EXTENSION OF THE HOSPITALIZATION DUE TO THE EVENT?</p> <p><input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>ÉVOLUTION :</p> <p><input type="checkbox"/> RECOVERY WITHOUT SEQUELAE <input type="checkbox"/> RECOVERY WITH SEQUELAE Which ones</p> <p><input type="checkbox"/> ONGOING RECOVERY <input type="checkbox"/> NOT YET RECOVERED <input type="checkbox"/> DECEASED <input type="checkbox"/> OTHER</p>	<p>DATE & HOUR OF OCCURRENCE OF THE EVENT:</p> <p>Date :</p> <p>Hour :</p>
	<p>LENGHT OF THE EVENT :</p>
	<p>PLACE OF THE EVENT :</p>

4. REPORTING PERSON

NAME & SURNAME	ADDRESS	TELEPHONE	E-MAIL
HOSPITAL / INSTITUTION / HEALTH CENTER	COUNTRY	DATE	SIGNATURE OF THE REPORTING PERSON