

Solicited Individual Safety Information (ISI) Collection & Documentation Form



All ISI (Adverse Events and Special Situations) must be reported to Sanofi within agreed timelines. Please complete all fields where information is available. **Fields to be completed in compliance with local data privacy regulation.

General Information			
Initial Report		Country of occurrence	
Sanofi Case ID (if applicable)		Service Provider First and Last Name / Phone or Email	
Program/Study Name		ISI receipt date	
Program/Study ID		Local PV Receipt Date (if applicable)	
Are you responding to Sanofi PV Follow-up Request?		Are you responding to Sanofi PV Follow-up Questionnaire?	

Reporter Information** (the person who reported the ISI to you)			
Name or Initials		Postal Address	
Healthcare Professional?			
Telephone/Fax			
Email Address		Country	
Reporter Type		If 'Other' please specify	

Consent for Follow-Up Information for ISI reported by Consumers**			
Has the patient provided informed consent for Sanofi to contact his/her treating health care professional (HCP) about the reported ISI in order to obtain additional medical information?			
HCP First and Last Name		HCP Postal Address	
HCP Email Address			
HCP Telephone/Fax		HCP Country	

Patient Information** (provide Age/Age Group at time of adverse event)					
Name (First and Last Name)		Initials		Gender	
Patient ID (include Center ID if applicable)		Age			
Date of Birth		Age Group			
Pregnant		Breastfeeding:		Was there parental drug exposure?	

Relevant Medical History/Risk factors (please add any additional information on Page 5)					
No	History/Risk factors	Start Date	Stop Date	Ongoing?	Notes
1					
2					
3					

Relevant Lab Test (please add any additional information on Page 5)					
No	Test Name	Test Date	Test Result	Test Unit	Notes
1					
2					
3					

Relevant Investigations (please add any additional information on Page 5)				
No	Investigations	Date	Result	Notes
1				
2				

Printed or downloaded documents must be verified against the effective version.

CONFIDENTIAL INFORMATION

Form ISI-001
Version 1.0
Date 2024-05-20

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Suspect Product 1			
Trade Name 1		Active Ingredient 1	
Formulation 1		Indication 1	
Location of Administration 1		Route of administration 1	
Dosage Details 1 (dose, unit)		Action taken 1	
Dosage Frequency 1		Did reaction reappear after reintroduction? 1	
Start Date 1		Stop Date 1	Ongoing
Batch/Lot number 1		Expiry Date 1	
To be completed only if used outside the terms of the approved product labelling	Is it intentional? at the initiative of for a therapeutic purpose?		

Suspect Product 2			
Trade Name 2		Active Ingredient 2	
Formulation 2		Indication 2	
Location of Administration 2		Route of administration 2	
Dosage Details 2 (dose, unit)		Action taken 2	
Dosage Frequency 2		Did reaction reappear after reintroduction? 2	
Start Date 2		Stop Date 2	Ongoing
Batch/Lot number 2		Expiry Date 2	

Suspect Product 3			
Trade Name 3		Active Ingredient 3	
Formulation 3		Indication 3	
Location of Administration 3		Route of administration 3	
Dosage Details 3 (dose, unit)		Action taken 3	
Dosage Frequency 3		Did reaction reappear after reintroduction? 3	
Start Date 3		Stop Date 3	Ongoing
Batch/Lot number 3		Expiry Date 3	

Suspect Product 4			
Trade Name 4		Active Ingredient 4	
Formulation 4		Indication 4	
Location of Administration 4		Route of administration 4	
Dosage Details 4 (dose, unit)		Action taken 4	
Dosage Frequency 4		Did reaction reappear after reintroduction? 4	
Start Date 4		Stop Date 4	Ongoing
Batch/Lot number 4		Expiry Date 4	

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Adverse Event 1				
Event Verbatim 1				Event Outcome 1
Event resulted in Death? 1	Congenital Anomaly?1		Onset Date 1	
Life threatening? 1	Resulted in Hospitalization 1		End Date 1	Ongoing
Disability? 1	Required Medical Intervention? 1		Transmission of an Infectious agent via product 1	
Causality 1 to Suspect Product 1		Causality 1 to Suspect Product 2		
Causality 1 to Suspect Product 3		Causality 1 to Suspect Product 4		
For Post-Trial Access Programs: Is this information related to an adverse event already reported in the context of the Parent Study If Yes, provide the Parent Study ID and AE Number				

Adverse Event 2				
Event Verbatim 2				Event Outcome 2
Event resulted in Death? 2	Congenital Anomaly? 2		Onset Date 2	
Life threatening? 2	Resulted in Hospitalization 2		End Date 2	Ongoing
Disability? 2	Required Medical Intervention? 2		Transmission of an Infectious agent via product 2	
Causality 2 to Suspect Product 1		Causality 2 to Suspect Product 2		
Causality 2 to Suspect Product 3		Causality 2 to Suspect Product 4		
For Post-Trial Access Programs: Is this information related to an adverse event already reported in the context of the Parent Study If Yes, provide the Parent Study ID and AE Number				

Adverse Event 3				
Event Verbatim 3				Event Outcome 3
Event resulted in Death? 3	Congenital Anomaly? 3		Onset Date 3	
Life threatening? 3	Resulted in Hospitalization 3		End Date 3	Ongoing
Disability? 3	Required Medical Intervention? 3		Transmission of an Infectious agent via product 3	
Causality 3 to Suspect Product 1		Causality 3 to Suspect Product 2		
Causality 3 to Suspect Product 3		Causality 3 to Suspect Product 4		
For Post-Trial Access Programs: Is this information related to an adverse event already reported in the context of the Parent Study If Yes, provide the Parent Study ID and AE Number				

Adverse Event 4				
Event Verbatim 4				Event Outcome 4
Event resulted in Death? 4	Congenital Anomaly? 4		Onset Date 4	
Life threatening? 4	Resulted in Hospitalization 4		End Date 4	Ongoing
Disability? 4	Required Medical Intervention? 4		Transmission of an Infectious agent via product 4	
Causality 4 to Suspect Product 1		Causality 4 to Suspect Product 2		
Causality 4 to Suspect Product 3		Causality 4 to Suspect Product 4		
For Post-Trial Access Programs: Is this information related to an adverse event already reported in the context of the Parent Study If Yes, provide the Parent Study ID and AE Number				

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If the Outcome is Fatal, please provide Death Details:			
Date of Death		Cause(s) of Death	
Autopsy performed?			
Autopsy Report available? if yes please attach			

Concomitant Product 1			
Trade name C1			
Active Ingredient C1		Indication C1	
Formulation C1		Route of administration C1	
Dosage Details C1 (dose, unit)		Dosage Frequency C1	
Start Date C1		Stop date C1	Ongoing

Concomitant Product 2			
Trade name C2			
Active Ingredient C2		Indication C2	
Formulation C2		Route of administration C2	
Dosage Details C2 (dose, unit)		Dosage Frequency C2	
Start Date C2		Stop date C2	Ongoing

Concomitant Product 3			
Trade name C3			
Active Ingredient C3		Indication C3	
Formulation C3		Route of administration C3	
Dosage Details C3 (dose, unit)		Dosage Frequency C3	
Start Date C3		Stop date C3	Ongoing

Concomitant Product 4			
Trade name C4			
Active Ingredient C4		Indication C4	
Formulation C4		Route of administration C4	
Dosage Details C4 (dose, unit)		Dosage Frequency C4	
Start Date C4		Stop date C4	Ongoing

Concomitant Product 5			
Trade name C5			
Active Ingredient C5		Indication C5	
Formulation C5		Route of administration C5	
Dosage Details C5 (dose, unit)		Dosage Frequency C5	
Start Date C5		Stop date C5	Ongoing

Additional Information:

Please provide additional details such as signs & symptoms, progression, possible causes that may explain the occurrence of the Adverse Event, vaccination details, family history, past drug history, corrective treatments, severity