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	Choose an item.	**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?	Choose an item.	**Are you responding to Sanofi PV Follow-up Questionnaire?**	Choose an item.

Reporter Information** (the person who reported the ISI to you)

Name or Initials		**Postal Address**	
Healthcare Professional?	Choose an item.		
Telephone/Fax			
Email Address		**Country**	
Reporter Type	Choose an item.	**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? Choose an item.

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**	Choose an ite
Patient ID (include Center ID if applicable)				**Age**	Choose an item.
Date of Birth				**Age Group**	Choose an item.
Pregnant	Choose an iter	**Breastfeeding:**	Choose an item	**Was there parental drug exposure?**	Choose an item.

Relevant Medical History/Risk factors (please add any additional information on Page 5)

No	History/Risk factors	Start Date	Stop Date	Ongoing?	Notes
1				☐ Yes	
2				☐ Yes	
3				☐ Yes	

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				

Suspect Product 1			
Trade Name 1		Active Ingredient 1	
Formulation 1	Choose an item.	Indication 1	
Location of Administration 1	Choose an item.	Route of administration 1	Choose an item.
Dosage Details 1 (dose, unit)		Action taken 1	Choose an item.
Dosage Frequency 1	Choose an item	Did reaction reappear after reintroduction? 1	Choose an item.
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? Choose an item. at the initiative of Choose an item. for a therapeutic purpose? Choose an item.		

Suspect Product 2			
Trade Name 2		Active Ingredient 2	
Formulation 2	Choose an item.	Indication 2	
Location of Administration 2	Choose at item.	Route of administration 2	Choose an item.
Dosage Details 2 (dose, unit)		Action taken 2	Choose at item.
Dosage Frequency 2	Choose an item	Did reaction reappear after reintroduction? 2	Choose an item.
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	Choose an item.	Indication 3	
Location of Administration 3	Choose an item.	Route of administration 3	Choose an item.
Dosage Details 3 (dose, unit)		Action taken 3	Choose an item.
Dosage Frequency 3	Choose an item	Did reaction reappear after reintroduction? 3	Choose an item.
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	Choose an item.	Indication 4	
Location of Administration 4	Choose an item.	Route of administration 4	Choose an item.
Dosage Details 4 (dose, unit)		Action taken 4	Choose an item.
Dosage Frequency 4	Choose an item	Did reaction reappear after reintroduction? 4	Choose an item.
Start Date 4		Stop Date 4	Ongoing ☐
Batch/Lot number 4		Expiry Date 4	

Adverse Event 1

Event Verbatim 1				**Event Outcome 1**	Choose an item.
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	Choose an item.			**Causality 1 to Suspect Product 2**	Choose an item.
Causality 1 to Suspect Product 3	Choose an item.			**Causality 1 to Suspect Product 4**	Choose an item.

For Post-Trial Access Programs: Is this information related to an adverse event already reported in the context of the Parent Study Choose an item. If Yes, provide the Parent Study ID ☐ and AE Number ☐

Adverse Event 2

Event Verbatim 2				**Event Outcome 2**	Choose an item.
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	Choose an item.			**Causality 2 to Suspect Product 2**	Choose an item.
Causality 2 to Suspect Product 3	Choose an item.			**Causality 2 to Suspect Product 4**	Choose an item.

For Post-Trial Access Programs: Is this information related to an adverse event already reported in the context of the Parent Study Choose an item. If Yes, provide the Parent Study ID ☐ and AE Number ☐

Adverse Event 3

Event Verbatim 3				**Event Outcome 3**	Choose an item.
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	Choose an item.			**Causality 3 to Suspect Product 2**	Choose an item.
Causality 3 to Suspect Product 3	Choose an item.			**Causality 3 to Suspect Product 4**	Choose an item.

For Post-Trial Access Programs: Is this information related to an adverse event already reported in the context of the Parent Study Choose an item. If Yes, provide the Parent Study ID ☐ and AE Number ☐

Adverse Event 4

Event Verbatim 4				**Event Outcome 4**	Choose an item.
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	Choose an item.			**Causality 4 to Suspect Product 2**	Choose an item.
Causality 4 to Suspect Product 3	Choose an item.			**Causality 4 to Suspect Product 4**	Choose an item.

For Post-Trial Access Programs: Is this information related to an adverse event already reported in the context of the Parent Study Choose an item. If Yes, provide the Parent Study ID ☐ and AE Number ☐

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

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

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

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

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

Concomitant Product 5			
Trade name C5			
Active Ingredient C5		Indication C5	
Formulation C5	Choose an item.	Route of administration C5	Choose an item.
Dosage Details C5 (dose, unit)		Dosage Frequency C5	Choose an item
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...