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## **Unsolicited (Spontaneous) Individual Safety Information (ISI) Collection & Documentation Form**



Global Instructions for completion of the Unsolicited ISI form – V 2.1 – 03 Oct 2025. This instructions document is NOT TO BE SENT with PV data to Sanofi PV

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	n									
Initial Report 1 Choo	rt 1 Choose an item.			of occurr	ence 2					
Sanofi Case ID			Service Provider or Collecting Org 4 /First and Last Name / Phone or Email							
(if applicable) 3			/First and La	st Name / P	hone or E	mail				
Registry/Digital Medi				ISI ider	eceipt	t date 6				
					Local P	V Receipt Date	(if app	licable) 7		
Are you responding to Sand Follow-up Request? 8	Choose an ite	tem. Are you responding Follow-up Question					fi PV	Choose an ite	∍m.	
Reporter Information	on** (the pe	erson who repo	rted the ISI to	you)						
Name or Initials 10				Postal	Addres	s 11				
Healthcare Professional	se an item.									
Telephone/Fax 13										
Email Address 14				Countr	y 15					
Reporter Type 16	Choo	se an item.		If 'Other	' please	specify 17				
Consent for Follow	/-Up Infor	mation for	ISI report	ed by C	onsum	ers**				
Has the patient provided inform additional medical information			his/her treating	health care p	orofessiona	l (HCP) about th	e repor	ted ISI in orde	er to obtain	
HCP First and Last N		HCP Po	ostal Ac	Idress 20						
HCP Email Address	21									
HCP Telephone/Fax 2	22			HCP C	ountry 2	23				
Patient Information	**(provide Age	/Age Group at time	of adverse ever	nt)						
Name (First and Last Name	e) <b>24</b>					Initials 25	,	Gender 2	6 Choose an	iten
Patient ID (include Cente	er ID if applica	able) <b>27</b>				Age 28		С	hoose an item	
Date of Birth 29				Age Group 30		Choose an item.				
Pregnant 31 Choose a	n item Brea	nstfeeding: 32	Choose an ite	em Wa	s there p	parental drug		sure? 33	Choose an ite	m.
Relevant Medical His	tory/Risk	actors (please	add any addit					I		
No History/Risk factors	34		Start Date	35 Stop	Date 36	Ongoing?37	7	Notes 38		
1						Yes				
2						Yes				
3						Yes				
Relevant Lab Test (pl	ease add any	additional inforr	nation on Page	e 5)						
No Test Name 39			Test Date 4	0 Test 41	Result	Test Unit 42	2	Notes 43		
1										
2										
3										
Relevant Investigation	ns (please a	add any addition	al information	on Page 5)						
No Investigations 44			Date 45	Re	sult 46			Notes 47		
1										
2										

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Suspect Product 1					
Trade Name 1 48			Active Ingredient 1 49		
Formulation 1 50	Choose an it	tem.	Indication 1 51		
Location of Administration 1 52	Choose an item	٦.	Route of administration 1 53	Choose an item.	
Dosage Details 1 (dose, unit) 5	4		Action taken 1 55	Choose an item.	
Dosage Frequency 1 56	Choose an item	1	Did reaction reappear after reintroduction? 1 57	Choose an item.	
Start Date 1 58			Stop Date 1 59	Ongoing 60	
Batch/Lot number 1 61			Expiry Date 1 62		
To be completed only if used of the approved product label			?63 Choose an item. at the iiic purpose? 65 Choose an item	nitiative of <b>64</b> 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	1			Ongoing	
Batch/Lot number 4			Expiry Date 4		

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Adverse Event 1										
Event Verbatim 1 66						Event Outcome 1 67	Choose an item.			
Event resulted in Death? 1	<b>58</b>	Co	ongenital Anomaly?1 69			Onset Date 1 70				
Life threatening? 171		Resulted in Hospitalization 172				End Date 173	Ongoing 74			
Disability? 175		Rec	quired Medical Intervention?	176		Transmission of an Infect	ious agent via product 1 77			
Causality 1 to Suspect Prod	luct '	1 78	Choose an item.	Cau	usality	y 1 to Suspect Product 2	79 Choose an item.			
Causality 1 to Suspect Prod	luct	3 80	Choose an item.	Cau	usality	y 1 to Suspect Product 4	Choose an item.			
Adverse Event 2										
Event Verbatim 2						Event Outcome 2	Choose an item.			
Event resulted in Death? 2		Co	ongenital Anomaly? 2			Onset Date 2				
Life threatening? 2		R	esulted in Hospitalization 2			End Date 2	Ongoing			
Disability? 2		R	equired Medical Intervention	? 2		Transmission of an Infect	ious agent via product 2			
Causality 2 to Suspect Product 1 Choose an item.					usality	y 2 to Suspect Product 2	Choose an item.			
Causality 2 to Suspect Product 3 Choose an item.				Cau	ısality	y 2 to Suspect Product 4	Choose an item.			
Adverse Event 3										
Event Verbatim 3						Event Outcome 3	Choose an item.			
Event resulted in Death? 3		Co	ongenital Anomaly? 3			Onset Date 3				
Life threatening? 3		R	esulted in Hospitalization 3			End Date 3	Ongoing			
Disability? 3		R	equired Medical Intervention	? 3		Transmission of an Infect	tious agent via product 3			
Causality 3 to Suspect Prod	luct '	ct 1 Choose an item.			usality	y 3 to Suspect Product 2	Choose an item.			
Causality 3 to Suspect Product 3 Choose an item.					usality	y 3 to Suspect Product 4	Choose an item.			
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		R	esulted in Hospitalization 4			End Date 4	Ongoing			
Disability? 4		Required Medical Intervention? 4				Transmission of an Infect	ious agent via product 4			
Causality 4 to Suspect Proc	luct '	1 C	Choose an item.	Cau	ısality	y 4 to Suspect Product 2	Choose an item.			
Causality 4 to Suspect Product 3 Choose an item.				Cau	usality	y 4 to Suspect Product 4	Choose an item.			

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If the Outcome is Fatal, please provide Death Details:								
Date of Death 82								
Autopsy performed? 84	Choose an item.		Cause(s					
Autopsy Report available? 85 if yes please attach	Choose an item.							
Concomitant Product 1								
Trade name C1 86								
Active Ingredient C1 87				Indication C188				
Formulation C1 89		Choose an ite	m.	Route of admini	istration C1 9	0	Choose an item.	
Dosage Details C1 (dose, unit)	91			Dosage Frequency C1 92			Choose an item	
Start Date C1 93			Stop date C1 94			Ongoing 95		
Concomitant Product 2								
Trade name C2								
Active Ingredient C2				Indication C2	Indication C2			
Formulation C2	Ch	oose an item.		Route of administration C2 Choose a			ose an item.	
Dosage Details C2 (dose, unit)				Dosage Frequency C2		Cho	ose an item	
Start Date C2				Stop date C2			Ongoing _	
Concomitant Product 3								
Trade name C3								
Active Ingredient C3				Indication C3				
Formulation C3	Ch	oose an item.		Route of administration C3 Choose an item.		ose an item.		
Dosage Details C3 (dose, unit)				Dosage Frequency C3		Cho	ose an item	
Start Date C3				Stop date C3			Ongoing	
Concomitant Product 4								
Trade name C4								
Active Ingredient C4				Indication C4				
Formulation C4	Ch	oose an item.		Route of administration C4		Choose an item.		
Dosage Details C4 (dose, unit)						ose an item		
Start Date C4				Stop date C4			Ongoing	
Concomitant Product 5								
Trade name C5								
Active Ingredient C5				Indication C5				
Formulation C5	Ch	oose an item.		Route of admini	stration C5	Cho	ose an item.	
Dosage Details C5 (dose, unit)				Dosage Frequ	uency C5	Cho	ose an item	
Start Date C5				Stop date C5			Ongoing	

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## Unsolicited (Spontaneous) Individual Safety Information (ISI) Collection & Documentation Form



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#### Additional Information: 96

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

#### **General Information**

- Initial Report YES/NO: Select YES, if this is the first time you report this safety information. Select 'NO' if
  you are reporting additional information to a previously submitted report (e.g., in response to Sanofi
  PV request for case documentation-refer to fields #8 & #9)
- 2. Country of Occurrence: The country where the AE/other safety-related situation occurred, it may not be the country where you are located
- 3. Sanofi Case ID (if applicable): This field is dedicated to Sanofi PV Case IDs only, which is not applicable to initial reports. If a PTC inquiry number is available, this number should be entered in the Additional Information field (#96)
- **4. Service Provider:** Record your company name, your fist and last name, your phone number and email address
- 5. Registry / Digital Media ID: This field should be populated if you are reporting an AE/other PV data from a registry or from a Digital property requiring PV monitoring. If this is the case, the registry number or the Digital Property (DP) number needs to be entered in this field
- 6. ISI receipt date: The date the AE/other PV data (also referred to as safety information) was received from the reporter. This field must be updated with the actual date of receipt of the safety information for each form with the exception of corrections to previously submitted reports, for which the receipt date of the initial report must remain. Dates must be entered in a DD-MMM-YYYY format a warning message will appear if the format is entered incorrectly
- 7. Local PV Receipt Date (if applicable): This field should be left blank, as it is not applicable
- **8.** Are you responding to Sanofi PV Follow-up Request YES/NO: Select YES if you are reporting additional information in response to a Sanofi Follow-up request. Otherwise, select NO.
- **9.** Are you responding to Sanofi PV Follow-up Questionnaire YES/NO: Select YES if you are reporting additional information in response to a Sanofi Follow-up Questionnaire/Form, including a response to Drug Exposure via Parent Data Collection Form. Otherwise, select NO.

**Reporter Information** (Reporter is the person who reported the AE/other PV data to you)

(Fields to be completed in compliance with local data privacy regulations)

- **10. Name or Initials:** First and last name (or his/her initials) of the person who reported the AE/other PV data to the person completing the form
  - <u>Note</u>: If neither reporter's name nor initials can be shared due to data privacy regulations, then please enter "privacy"
- 11. Postal Address: Address of the person who reported the event to the person completing the form
- 12. Health Care Professional YES/NO: Select YES if the reporter is a health care professional and select the appropriate entries in fields #16 & #17. Please note that reporter could be the patient who could also be a Health Care Professional

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- **13. Telephone/Fax:** Telephone/Fax number of the person who reported the event to the person completing the form
- 14. Email Address: Email address of the person who reported the event to the person completing the form
- 15. Country: Country of the person who reported the event to the person completing the form
- 16. Reporter Type (Physician, Pharmacist, Nurse, Lawyer, Consumer/Non-HCP, Other Health Care Professional, Other): Enter the appropriate selection.
- **17. If "Other", please specify:** If the specific type is not included in the list, please select Other and enter the correct reporter type

## Consent for Follow-Up Information for ISI reported by Consumers

(Fields to be completed in compliance with local data privacy regulations)

- 18. Has the patient provided informed consent for Sanofi to contact his/her treating health care professional (HCP) about the reported ISI to obtain additional medical information YES/NO/Unknown: Select the correct option. If YES is selected, HCP details should be provided in fields 19-23
- 19. HCP First and Last Name: First and last name of treating/prescribing physician
- 20. HCP Postal Address: Address of treating/prescribing physician
- 21. HCP Email Address: Email address of treating/prescribing physician
- 22. HCP Telephone/Fax Number: Telephone/fax number of treating/prescribing physician
- 23. HCP Country: Country where treating/prescribing physician is located

### **Patient Information**

(Fields to be completed in compliance with local data privacy regulations)

- 24. Name (first and last name): First and last name of patient/consumer
- 25. Initials: Initials of patient
  - <u>Note</u>: If none of the patient identifiers (name; initials, date of birth, etc.) can be provided due to data privacy regulations, then please enter "privacy" in the patient's initials field.
- 26. Gender Female/Male/Unknown: Select the appropriate entry from the dropdown list
- **27. Patient ID:** The Patient ID is a unique identifier assigned to each patient where applicable. The unique identifier must not include any special characters and must not contain more than 20 characters For Digital Properties and other activities conducted by Services Providers, this field will not be applicable.
- 28. Age: Include the numerical number of the age and select the appropriate unit from the dropdown list
- 29. Date of Birth: Patient's date of birth
- 30. Age Group: Select the correct group from the dropdown list
  - Fetus (0 month)
  - Neonate (birth <28 days)</li>
  - Infant (28 days < 2 years)</li>
  - Child (2 <12 years)</li>
  - Adolescent (12 <18 years)</li>
  - Adult (18 <65 years)</li>
  - Elderly (>/= 65 years)

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- 31. Pregnant: Select the appropriate response from the dropdown list
- 32. Breastfeeding: Select the appropriate response from the dropdown list
- **33. Was there parental drug exposure:** Select the appropriate response from the dropdown list. Record as YES if pregnancy is reported while the patient (mother or father) is on a Sanofi product

### **Relevant Medical History/Risk factors**

- **34. History/Risk Factors:** List all conditions reported by the reporter that occurred to the patient prior to starting treatment with the Sanofi suspect product
- 35. Start Date: Record the start date for each reported condition, if known
- 36. Stop Date: Record the stop date for each reported condition, if known
- 37. Ongoing?: Please check the box if the medical history condition has not been resolved and is still ongoing
- **38. Notes:** Include any additional known information for the listed conditions. Additional information can also be provided in the Additional Information section (#96)

#### **Relevant Lab Test**

- **39. Test Name:** Record the name of any lab tests reported by the reporter, not only lab tests that may be specifically conducted in response to the reported AE/other PV data
- 40. Test Date: Record the date of the lab test if reported by the reporter
- **41. Test Result:** Record the result of the lab test if reported by the reporter
- 42. Test Unit: Record the unit of the lab test result if reported by the reporter
- **43. Notes:** Include any additional known information related to the lab tests. Additional information can also be provided in the Additional Information section (#96)

## **Relevant Investigations**

- **44. Investigations:** Record the name of any relevant investigations reported by the reporter, not only investigations related to the reported AE/other PV data, e.g., imaging studies
- **45.** Date: Record the date the investigation was conducted if reported by the reporter
- 46. Result: Record the result from the investigation if reported by the reporter
- **47. Notes:** Include any additional known information related to the investigations. Additional information can also be provided in the Additional Information section (#96)

### **Suspect Product**

The product that is associated with the reported adverse event/other PV data is to be included in this section. Please note that more than one suspect product can be recorded in this section.

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- **48. Trade Name:** Record the trade/marketed name of the suspect product
- 49. Active Ingredient: Record the active ingredient, i.e., generic name of the suspect product
- 50. Formulation: Select the correct formulation per the product Prescribing Information from dropdown list
- **51. Indication:** Record the indication for which the patient is taking the Sanofi suspect product please do not use codes or abbreviations
- **52.** Location of administration: Select the correct entry from the dropdown list. This question is applicable only to infused products. In case of Enzyme Replacement Therapy (ERT), ensure that the infusion setting (Hospital/Clinic or Home) is always requested during data collection/follow up process for ERT products. For all other products, the field must be left blank
- 53. Route of administration: Select the correct entry from the dropdown list
- **54. Dosage details (dose, unit):** Record the dose of the suspect product when the AE/other PV data occurred
- **55. Action Taken:** Select the correct entry from the dropdown list
- **56. Dosage Frequency:** Select the dosage frequency of the suspect product when the AE/other PV data occurred from the dropdown list
- **57. Did reaction reappear after reintroduction?** Select the correct entry from the dropdown list. YES should be selected if the product was temporarily stopped/withdrawn and the adverse event occurred after re-initiating the treatment.
- **58. Start Date:** Record the date the patient started to take the suspect product. As a general rule, the date when the treatment was first initiated should be reported in this field. If the product is a cycle treatment, the start date of the product should be the first day of the cycle. If known, the last dose before adverse event start can be recorded in the Additional Information section (#96)
- **59. Stop Date:** Record the date the patient stopped taking the suspect product
- 60. Ongoing: Check the box YES if the patient has not stopped taking the suspect product
- 61. Batch/Lot Number: Record the Batch Number for the suspect product following the instructions below:
  - Enter batch/lot number when available
  - Enter "Not Available" when the batch number cannot be obtained (product no longer available)
  - Enter "Unknown at this time" when the product is not available at time of report and can be requested upon follow-up
- 62. Expiry Date: Record the expiration date of the batch/lot number if provided by the reporter

#### To be completed only if used outside the terms of the approved product labelling

- **63.** Is it intentional: Select the correct response from the dropdown list
- 64. At the initiative of: Select the correct response from the dropdown list
- **65. For a therapeutic purpose:** Select the correct response from the dropdown list. This information is needed for the assessment of off-label, misuse, drug abuse, medication error, etc.

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### **Adverse Event**

- 66. Event Verbatim: The main event description should be entered in this field, e.g. flu. Additional signs and symptoms for the event (e.g., fever, sore throat, body aches) should be entered in the Additional Information section (#96). If together with the flu, other AEs/other PV data are reported, e.g., foot fracture, urinary tract infections, etc., these must be reported as separate events.
- 67. Event Outcome: Select the correct response from the dropdown list. The Not Applicable option is relevant for special situations such as medication error, misuse, etc.
- 68. Event Resulted in Death: Check the box if the event resulted in death
- 69. Congenital anomaly: Check the box if the use of the product, or the adverse event, resulted in congenital anomaly
- 70. Onset Date: Record the date the event first manifested. This field should be left blank if the start date of the event is unknown
- 71. Life threatening: Check the box if the event was described by the reporter as life threatening
- 72. Resulted in Hospitalization: Check the box if the patient was hospitalized due to the event, even if no additional information is reported
- 73. End Date: Record the date the event ended. If the end date of the event is unknown, the field should be left blank and the Ongoing box should be left unchecked
- 74. Ongoing: Check the box YES if the event was continuing
- 75. Disability: Check the box if the event resulted in disability

product and the reporter did not know

- 76. Required Medical Intervention: This check box is applicable only for device. Check the box if the adverse event/other PV data required medical treatment or other intervention, and record any medical treatment in the Concomitant Product section
- 77. Transmission of an Infectious Agent via Product: Check the box if the reporter indicated that the adverse event/other PV data was caused by transmission of an infectious agent via the product
- 78. Causality to Suspect product: The product of the project should be entered as suspect product and the correct value from the dropdown list should be selected regarding the relationship of the adverse event/other PV data to that product as reported by the reporter.

Related: At least reasonable possibility that the suspect product caused the adverse event/other PV data Not Related: No obvious reasonable possibility that the suspect product caused the adverse event/other PV data

Not Reported: The question on whether or not the adverse event/other PV data was caused by the suspect product was not asked to the reporter or causality was not provided by the reporter **Unknown:** The reporter was asked whether the adverse event/other PV data was caused by the suspect

 If the event is related to a concomitant product the concomitant product should be entered as suspect product and the Related value from the dropdown list should be selected regarding the relationship of the adverse event/other PV data to that product as reported by the reporter. In this scenario, the

product of the project, which is also entered as suspect product, should be marked as Not Related

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 If multiple suspect products are associated with the reported adverse event/other PV data, these should be reported in fields 79, 80 and 81

## If the Outcome is Fatal, please provide Death Details

- 82. Date of Death: Record the date the patient passed away as reported by the reporter
- 83. Cause of Death: Try to determine and record the cause of death
- 84. Autopsy performed: Select the correct response from the dropdown list
- 85. Autopsy report available: Select the correct response from the dropdown list

#### **Concomitant Product**

Concomitant products are products taken by the patient at the time the adverse event/other PV data occurred. This includes over the counter (OTC) products. If the patient is taking more than five (5) concomitant medications, these should be included in the Additional Information field (#96).

If the event is related to a concomitant product, the concomitant product should be entered as a suspect product.

- 86. Trade Name: Record the trade/marketed name of the concomitant product
- 87. Active Ingredient: Record the active ingredient/generic name of the concomitant product, if known
- 88. Indication: Record the indication for which the patient is taking the concomitant product, if known
- 89. Formulation: Select the correct formulation for the concomitant product from dropdown list, if known
- **90. Route of administration:** Select the correct route of administration for the concomitant product from dropdown list, if known
- 91. Dosage Details: Record the dose of the concomitant product, if known
- **92. Dosage Frequency:** Select the dosage frequency of the concomitant product when the AE/other PV data occurred from the dropdown list, if known
- 93. Start Date: Record the date the patient started taking the concomitant product, if known
- 94. Stop Date: Record the date the patient stopped taking the concomitant product, if known
- 95. Ongoing: Check the box YES if the patient has not stopped taking the concomitant product

#### **Additional Information**

**96.** This field should include any additional information related to the adverse event/other PV data, related symptoms and signs, medical and family history, prior medical treatment, etc. Information that is available in addition to the required information to be entered in the dedicated fields should be entered in this section.

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### **How to Report**

### For New Reports:

### When the form is completed in English:

- When the form is complete with all available information, the completed form must be sent to Sanofi PV
  in Microsoft Print to pdf format from the Adobe application, not from the browser following the steps
  below:
- 2. Go to "File" then "Print" and select the printer "Microsoft Print to PDF" then click the "Print" button.



- 3. If your signature contains a logo, the logo needs to be removed prior to sending the form to Sanofi PV
- 4. Each Individual ISI form must be sent in a separate email
- 5. Multiple attachments (e.g., medical history, clinical notes, etc.) can be submitted with the complete ISI form if they pertain to the same patient/report; however, the email cannot exceed 15MB
- 6. The email with the attached completed form (one completed form per email) should be sent to PV-ARTEMIS-SANOFI@IQVIA.COM .
- 7. You will receive an acknowledgement of receipt containing a unique INBOX ID, and the subject line of your initial submission. If you do not receive an acknowledgement of receipt, the junk/spam folder must be checked and if the acknowledgement is still not located, the report should be resent as soon as possible, but no later than one (1) business day. If after resending the report, you still don't receive an acknowledgment of receipt, please contact your local PV.

## When the form is completed in a language other than English:

- When the form is completed in a language other than English, the email with the attached completed ISI form must be sent to your local PV department per the PV contact list provided in the PV Packet. You will receive an email confirming receipt of the report. (The step of Microsoft Print to pdf is not required if the form is sent to the local PV department).
- 2. Each Individual ISI form must be sent in a separate email
- 3. Multiple attachments (e.g., medical history, clinical notes, etc.) can be submitted with the complete ISI form if they pertain to the same patient/report; however, the email cannot exceed 15MB

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4. You will receive an acknowledgement of receipt. If you do not receive an acknowledgement of receipt, the junk/spam folder must be checked and if the acknowledgement is still not located, the report should be resent as soon as possible, but no later than one (1) business day. If after resending the report, you still don't receive an acknowledgment of receipt, please contact your local PV.

### For Corrections to Previously Submitted Reports

When the form is completed in English and the initial report was sent to PV-ARTEMIS-SANOFI@IQVIA.COM

- A corrected version of the Unsolicited ISI form must be sent in a separate email to <u>PV-ARTEMIS-SANOFI@IQVIA.COM</u>
- 2. Specify the following in the email subject line: Correction to Previously Submitted Report Report Inbox ID IN-XXXXXX-XXXX
- 3. The Additional Information field of the form must state "Correction to Previously Submitted report" and must include details of the changes
- 4. You will receive an acknowledgement of receipt containing a unique INBOX ID for correction report, and the subject line of your correction submission. If you do not receive an acknowledgement of receipt, the junk/spam folder must be checked and if the acknowledgement is still not located, the report should be resent as soon as possible, but no later than one (1) business day.

### When the form is completed in a language other than English

- 1. A corrected version of the Unsolicited ISI form must be sent in a separate email your local PV.
- 2. The Additional Information field of the form must state "Correction to Previously Submitted report" and must include details of the changes
- 3. You will receive an acknowledgement of receipt for the correction report. If you do not receive an acknowledgement of receipt, the junk/spam folder must be checked and if the acknowledgement is still not located, the report should be resent as soon as possible, but no later than one (1) business day. If after resending the report, you still don't receive an acknowledgment of receipt, please contact your local PV.