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 1	Choose an item.	Country of occurrence 2	
Sanofi Case ID (if applicable) 3		Service Provider or Collecting Org 4 /First and Last Name / Phone or Email	
Registry/Digital Media ID 5		ISI identification / receipt date 6	
		Local PV Receipt Date (if applicable) 7	
Are you responding to Sanofi PV Follow-up Request? 8	Choose an item.	Are you responding to Sanofi PV Follow-up Questionnaire? 9	Choose an item.

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

Name or Initials 10		Postal Address 11	
Healthcare Professional? 12	Choose an item.		
Telephone/Fax 13			
Email Address 14		Country 15	
Reporter Type 16	Choose an item.	If 'Other' please specify 17	

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? 18 Choose an item.

HCP First and Last Name 19		HCP Postal Address 20	
HCP Email Address 21			
HCP Telephone/Fax 22		HCP Country 23	

Patient Information**(provide Age/Age Group at time of adverse event)

Name (First and Last Name) 24			Initials 25	Gender 26	Choose an item
Patient ID (include Center ID if applicable) 27			Age 28	Choose an item.	
Date of Birth 29			Age Group 30	Choose an item.	
Pregnant 31	Choose an item	Breastfeeding: 32 Choose an item	Was there parental drug exposure? 33	Choose an item.	

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

No	History/Risk factors 34	Start Date 35	Stop Date 36	Ongoing?37	Notes 38
1				☐ Yes	
2				☐ Yes	
3				☐ Yes	

Relevant Lab Test (please add any additional information on Page 5)

No	Test Name 39	Test Date 40	Test Result 41	Test Unit 42	Notes 43
1					
2					
3					

Relevant Investigations (please add any additional information on Page 5)

No	Investigations 44	Date 45	Result 46	Notes 47
1				
2				

Suspect Product 1			
Trade Name 1 48		Active Ingredient 1 49	
Formulation 1 50	Choose an item.	Indication 1 51	
Location of Administration 1 52	Choose an item.	Route of administration 1 53	Choose an item.
Dosage Details 1 (dose, unit) 54		Action taken 1 55	Choose an item.
Dosage Frequency 1 56	Choose an item	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 outside the terms of the approved product labelling	Is it intentional? 63 Choose an item. at the initiative of 64 Choose an item. for a therapeutic purpose? 65 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 66				Event Outcome 1 67	Choose an item.
Event resulted in Death? 1 68	☐	Congenital Anomaly?1 69	☐	Onset Date 1 70	
Life threatening? 1 71	☐	Resulted in Hospitalization 1 72	☐	End Date 1 73	Ongoing 74 ☐
Disability? 1 75	☐	Required Medical Intervention? 176	☐	Transmission of an Infectious agent via product 1 77	☐
Causality 1 to Suspect Product 1 78	Choose an item.			Causality 1 to Suspect Product 2 79	Choose an item.
Causality 1 to Suspect Product 3 80	Choose an item.			Causality 1 to Suspect Product 4 81	Choose an item.

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.

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.

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.

If the Outcome is Fatal, please provide Death Details:			
Date of Death 82		Cause(s) of Death 83	
Autopsy performed? 84	Choose an item.		
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 item.	Route of administration C1 90	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	
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: 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

1. **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
    Note: 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

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
    Note: 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)
    - Infant (28 days - < 2 years)
    - Child (2 - <12 years)
    - Adolescent (12 - <18 years)
    - Adult (18 - <65 years)
    - Elderly (>/= 65 years)

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.

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.

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
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 product and the reporter did not know

    - 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

- 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

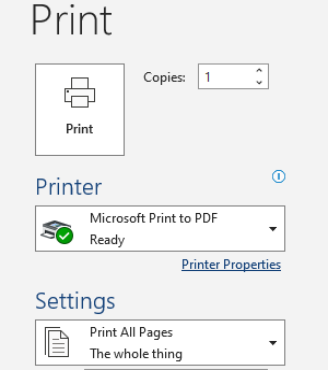
96. This field should include any additional information related to the adverse event/other PV data, related symptoms and signs, medical and family history, prior medical treatment, etc. Information that is available in addition to the required information to be entered in the dedicated fields should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

How to Report

For New Reports:

When the form is completed in English:

1. 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:

1. 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

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

1. A corrected version of the Unsolicited ISI form must be sent in a separate email to PV-ARTEMIS-SANOFI@IQVIA.COM
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.