GILEAD	AE/SAE REPORT FORM FOR GILEAD NON-INTERVENTIONAL STUDIES (INCLUDING COMPASSIONATE USE, EXPANDED ACCESS PROGRAMS AND OBSERVATIONAL STUDIES) *Please read instructions carefully, then print or type.* *Attach additional information, if available*	FRM-04849 (6.0)

Report in accordance with timelines specified in the applicable agreement/study protocol:
Email: drugsafety.switzerland@gilead.com or Fax: +41 41 580 02 81

Swiss TE			
STUDY NUMBER (if applicable)	COUNTRY	REPORTER NO. (if applicable)	PATIENT NO. (if applicable)

☐ INITIAL REPORT DATE: ☐ FOLLOW-UP #1 DATE: # 2 DATE: # 3 DATE:

1. PATIENT INFORMATION

Birth Year: ____ (YYYY) Sex: ☐ Male ☐ Female Race: ☐ Caucasian ☐ Of African descent ☐ Asian ☐ Hispanic ☐ Other – Specify: ____

Weight: ____ ☐ lb ☐ kg Height: ____ ☐ in ☐ cm

2. ADVERSE EVENT

Event Term	Start Date (DD/MMM/YYYY) Stop Date (DD/MMM/YYYY)	Outcome	Seriousness Criteria Check all of the following that apply for this event	Event Related to check all that apply	Alternative Causality check all that apply
		☐ Continuing ☐ Resolved ☐ Resolved w/sequelae ☐ Fatal ☐ Unknown	☐ Death ☐ Life-Threatening *(Immediate Risk Of Death)* ☐ Required Hospitalization/ Prolonged Hospitalization ☐ Significant Disability/Incapacity ☐ Congenital Anomaly/Birth Defect ☐ Medically Significant ☐ None of the Above	**Suspect Drug(s)** ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	☐ Study Disease-related ☐ Pre-existing Condition ☐ Concomitant Medication: ____ ☐ Intercurrent Illness: ____ ☐ Other: ____ ☐ Study Procedure
Event Term	**Start Date** (DD/MMM/YYYY) **Stop Date** (DD/MMM/YYYY)	**Outcome**	**Seriousness Criteria** Check all of the following that apply for this event	**Event Related to** check all that apply	**Alternative Causality** check all that apply
		☐ Continuing ☐ Resolved ☐ Resolved w/sequelae ☐ Fatal ☐ Unknown	☐ Death ☐ Life-Threatening *(Immediate Risk Of Death)* ☐ Required Hospitalization/ Prolonged Hospitalization ☐ Significant Disability/Incapacity ☐ Congenital Anomaly/Birth Defect ☐ Medically Significant ☐ None of the Above	**Suspect Drug(s)** ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	☐ Study Disease-related ☐ Pre-existing Condition ☐ Concomitant Medication: ____ ☐ Intercurrent Illness: ____ ☐ Other: ____ ☐ Study Procedure
Event Term	**Start Date** (DD/MMM/YYYY) **Stop Date** (DD/MMM/YYYY)	**Outcome**	**Seriousness Criteria** Check all of the following that apply for this event	**Event Related to** check all that apply	**Alternative Causality** check all that apply
		☐ Continuing ☐ Resolved ☐ Resolved w/sequelae ☐ Fatal ☐ Unknown	☐ Death ☐ Life-Threatening *(Immediate Risk Of Death)* ☐ Required Hospitalization/ Prolonged Hospitalization ☐ Significant Disability/Incapacity ☐ Congenital Anomaly/Birth Defect ☐ Medically Significant ☐ None of the Above	**Suspect Drug(s)** ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No ☐ Yes ☐ No	☐ Study Disease-related ☐ Pre-existing Condition ☐ Concomitant Medication: ____ ☐ Intercurrent Illness: ____ ☐ Other: ____ ☐ Study Procedure

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If Patient died, please provide:

Date of Death: _____ / _____ / _____ (DD/MMM/YYYY)

Cause of Death: _____

Autopsy performed? ☐ Yes *(Attach copy)* ☐ No

If Patient required hospital admission or prolongation of an existing hospitalization, please provide:

Admission Date: _____ / _____ / _____ (DD/MMM/YYYY)

Discharge Date: _____ / _____ / _____ (DD/MMM/YYYY)

3. MEDICAL HISTORY

Relevant Medical History: ☐ None ☐ Yes, provide details:

____

____

____

Drug Allergies: ☐ None ☐ Yes, provide details:

_____

Has the patient participated in any previous Gilead Study?

☐ No

☐ Yes, Study No. if applicable:

4. EVENT DESCRIPTION

Describe signs and symptoms, possible causes, progression, treatments, etc. Did the event abate after suspect drug was stopped; did the event recur after suspect drug was restarted?

____

____

____

____

____

____

____

5. SUSPECT DRUG(S)

Drug	Dose	Route	Frequency	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Action Taken due to Event	Blinded? (If applicable)
						☐ None ☐ Dose Reduced ☐ Dose Interrupted ☐ Permanently Discontinued	☐ No ☐ Yes
Drug	Dose	Route	Frequency	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Action Taken due to Event	Blinded? (If applicable)
						☐ None ☐ Dose Reduced ☐ Dose Interrupted ☐ Permanently Discontinued	☐ No ☐ Yes
Drug	Dose	Route	Frequency	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Action Taken due to Event	Blinded? (If applicable)
						☐ None ☐ Dose Reduced ☐ Dose Interrupted ☐ Permanently Discontinued	☐ No ☐ Yes
Drug	Dose	Route	Frequency	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Action Taken due to Event	Blinded? (If applicable)
						☐ None ☐ Dose Reduced ☐ Dose Interrupted ☐ Permanently Discontinued	☐ No ☐ Yes
Drug	Dose	Route	Frequency	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Action Taken due to Event	Blinded? (If applicable)
						☐ None ☐ Dose Reduced ☐ Dose Interrupted ☐ Permanently Discontinued	☐ No ☐ Yes

6. CONCOMITANT MEDICATIONS

☐ Check if no concomitant medications were being taken ☐ Attached

Drug (Exclude those used to treat the event)	Start Date (DD/MMM/YYYY)	Stop Date (DD/MMM/YYYY)	Continuing	Indication
			☐	
			☐	
			☐	
			☐	
			☐	
			☐	
			☐	

7. RELEVANT LABORATORY DATA:

☐ Check if none ☐ Attached

Test	Normal range (Units)	Date (DD/MMM/YYYY)	Result	Date (DD/MMM/YYYY)	Result	Date (DD/MMM/YYYY)	Result

8. RELEVANT DIAGNOSTIC PROCEDURES:

☐ Check if none ☐ Attached

Procedure	Date (DD/MMM/YYYY)	Result

9. REPORTER INFORMATION AND SIGNATURE

Reporter Name: _____	Title: _____	
Address: _____	Telephone No. _____	_____ **Signature** of Reporter
	Facsimile No.: _____	_____ **Date** (DD/MMM/YYYY)
	E-Mail: _____	

Please be aware that information provided to Gilead relating to you, may be used to comply with applicable laws and regulations. Gilead processes your personal or sensitive data in accordance with applicable data protection laws and the Gilead Privacy Statement, available to you either on www.gilead.com/privacy or upon request.

Completion Guidelines

GENERAL INSTRUCTIONS

- Record the AE/SAE term(s) on the first page of the form. Up to three AE/SAE terms for the same patient can be reported on the same form. If reporting more than three AE/SAE terms, use additional form(s).
- Type or print using black ball point pen only. Answer questions as concisely as possible.
- To complete an item or section when information is not available, use: **NA** (not applicable), **NI** (no information at this time), or **UNK** (unknown).
- Enter dates in **dd/mmm/yyyy** format, (e.g., 18/Mar/2003)
- Make changes or corrections by drawing a single line through the ~~ERROR~~. **Initial and date all corrections.** DO NOT use correction fluid.
- The form should be signed on page 3 by the Reporter or designee.
- Remember to block patient information on any attached records.
- In the Medical History, Laboratory Data and Diagnostic Procedures sections include data that is relevant, pertinent and crucial to the review and evaluation of the AE/SAE.

STUDY INFORMATION

- Enter (as applicable) the Gilead study number, the country in which the reporter site is located, the reporter number and the patient's study ID on each page of the AE/SAE form.

INITIAL/ FOLLOW-UP REPORT

- Check the type and date of report being submitted.

ADDITIONAL INSTRUCTIONS: FOLLOW-UP REPORTS

Corrected, updated, or new information should be captured on the originally completed report form changing "Initial Report" to "Follow-up Report". Incorrect or old information should be crossed out using a single line, dated, and initialed. New information must be clearly stated, dated and initialed.

BLOCK 1: PATIENT INFORMATION

- Year of birth (except for pediatric studies where collection of birth month/date may be decided on study-by-study basis) , sex, race, weight and height (use either metric or imperial; however, please check (√) the applicable box)

BLOCK 2: ADVERSE EVENT

(a) **AE/SAE**

- Enter the clinical event or the FINAL DIAGNOSIS. Provide final diagnosis rather than signs and symptoms whenever possible.
- Event Relationship to Suspect Drug: enter the Reporter's assessment regarding the association of each event to the suspect drug. This area of the form must not be left blank.
  "Yes" – there is a reasonable possibility that there is a causal relationship between the adverse event and the suspect drug.
  "No" – there is no reasonable possibility that there is a causal relationship between the adverse event and the suspect drug. Another cause for the adverse event is most plausible.

(b) **Duration of Event**: enter the Start date and Stop date if the event has resolved at the time of report completion.

(c) **Outcome**: Check (√) the Outcome of the event if known at the time of the report.

(d) **Seriousness Criteria**

- Please check (√) all criteria of seriousness that apply to the AE/SAE:
  - Death should be indicated if the patient died at the time of, or at some time after the onset of this AE.
    - *Please note that death is an outcome and not an event; record the clinical event or diagnosis that resulted in death.*
  - The term "life-threatening" refers to an event in which the patient was at immediate risk of death at the time of the event as it occurred; it does not refer to an event that hypothetically might have caused death if it were more severe.
  - The term "hospitalization" should be indicated if the adverse event resulted in the patient formally being admitted to hospital as a patient or prolonged the stay of an existing hospitalization. An emergency room visit does not qualify.
  - Significant disability/incapacity should be indicated if the AE resulted in a substantial disruption of a person's ability to conduct normal life and functions.
  - Congenital anomaly/birth defect should be indicated if a pregnancy in a patient resulted in an abnormal fetal development (growth retardation, functional deficit, structural malformation, or fetal death).
  - Other – any other Important Medical Event should be indicated if, in the clinician's judgment, the AE jeopardizes the patient, and may require medical or surgical intervention to prevent one of the other serious criteria. Examples of such medical events may include intensive treatment in an emergency room or at home for allergic bronchospasm, blood dyscrasias, or convulsions that do not result in hospitalization; development of drug dependency; or drug abuse
  - None of the Above – events that do not meet any seriousness criteria; non-serious events i.e. observational studies, non-interventional studies

(e) **Event(s) Related to:**

Suspect Drug: Please enter suspect drug name and please check "yes" or "no"

(f) **Alternative Causality**: Check (√) the reporter's assessment of an Alternative Causality where applicable (check all that apply) including study procedure: Adverse events that occur as a result of study-mandated procedures (e.g., invasive procedures such as venipuncture, biopsy, etc.)

BLOCK 3: RELEVANT MEDICAL HISTORY

- Enter date and name(s) of disease(s)/condition(s) considered relevant to the AE/SAE.
- Enter all drug allergies and manifestation (i.e., rash).
- If applicable, enter the Study number of any previous Gilead Study in which the patient had participated.

BLOCK 4: EVENT DESCRIPTION

- Provide a detailed chronological description of the event, including possible cause, confounding factors, treatment(s) including medication(s), outcome, probable/possible etiology, and if the event abated as a result of suspect drug being stopped or reduced or if the event recurred when suspect drug was restarted, if this information is available.
- Attach discharge summaries, autopsy reports, etc., where applicable and if available.

BLOCK 5: SUSPECT DRUG(S)

- List the name of the Suspect Drug or Suspect Drugs when multiple are used.
- Indicate whether or not the suspect drug was blinded.
- Complete the suspect drug history indicating dose, route, frequency, start and stop dates (if suspect drug dose or dosing regimen was altered).
- Enter the action taken with the suspect drug as a result of the adverse event. Where a dose modification has been made, please specify the dose and the date upon which the modification was made.

BLOCK 6: CONCOMITANT MEDICATIONS

- Enter all concomitant medications (including over-the-counter medications and herbal preparations) taken in the 30 days preceding the event.
- If the treatment with a medication is ongoing as of the day of the event, check √ "continuing".
- Enter the indication for use.
- Do not enter medications used to treat this event, those need to be entered in the event description.

BLOCK 7: RELEVANT LABORATORY DATA

- Enter the dates of all laboratory tests that are relevant to the AE/SAE.
- Specify test type and results, providing units and reference ranges for all laboratory values.
- May substitute hospital lab records, if available.

BLOCK 8: RELEVANT DIAGNOSTIC PROCEDURES

- Enter date of diagnostic procedures that are relevant to the AE/SAE.
- Specify name and results of diagnostic procedure
- May substitute hospital lab records, if available.

BLOCK 9: REPORTER INFORMATION

- Enter the Reporter's name and title, address, telephone number/fax/email address (when applicable).
- The form must be signed and dated by the Reporter.