Narrative Case Summary

Identifiers:

- Provide **Age**, **HIV Status**, **Race**, **Sex at Birth**
- Provide **Protocol ID**, **Date of Enrollment** in the study
- Provide study medication details: **Date(s) of Administration**, **Duration**, **Phase of the Study AE occurred [Treatment/Follow-up Phase]**.

For the AE:

- Provide details in chronological order, along with other **Signs/Symptoms**.
- Provide information relevant to **Predisposing Factors** that may have led to the AE.
- Provide details of **Physical Exam**, along with all relevant **Procedures/Tests**, and **Lab Results**.

For the Treatment of the AE:

- Provide details of **Treatment** and **Treatment Rationale** on basis of **Findings/Test Result(s)**.
- Describe **Treatment Response**.

If Hospitalization:

- Provide **Dates of Hospitalization**.
- Describe relevant **Hospital Course**, **Diagnostic Work-up**, **Procedures/Tests** and **Lab Results**, **Treatment**, and **Treatment Response**.
- Provide **Discharge Diagnosis**, **Discharge Medications** and any **Post Discharge Medical Follow-up**.

If Subject Pregnant:

- Provide **Gestational Age at Enrollment** and **At Onset of AE**, **Estimated Date of Delivery**, **Timing of Exposure**, **LMP** (if known)
- Provide **Antenatal Check-up Dates and Results**
- Provide **Exposure to Prescription Drugs/OTC Products**, **Prenatal Supplements** (e.g., folic acid, multivitamins, etc.), **Tobacco**, **Alcohol**, and/or **Illicit Drugs**
- Provide **Gravida/Para status**, **Previous Maternal Pregnancy Complications**, **Previous Fetal-Neonatal Abnormalities and Type**, **Contraception History**, **Family History of Congenital Abnormality/Psychomotor Retardation**

If Reporting Death:

- Provide **Date of Death**, **Primary Cause of Death**, **Copy of Death Certificate/Notice** (if available), **Autopsy Report** (if applicable)

Other Supporting Information:

- Provide pertinent **Past Medical History**, **Family History**, **Concomitant Meds**, **Alcohol/Tobacco/Illicit Substance Use**.
- Provide **Other Clinically Significant Events Associated with the Primary AE**.
- Other **Relevant Documents** (e.g., hospital records, autopsy report).

Clinical Case Evaluation:

The purpose of careful medical review is to ensure correct interpretation of medical information. Preferably, information about the case should be collected from the healthcare professionals who are directly involved in the subject's care. Sites should carefully review the report for the quality and completeness of the medical information before reporting to DAIDS.

The review should include, but not limited to, the following considerations:

- Is a diagnosis possible?
- Have the relevant diagnostic procedures been performed?
- Were alternative causes of the AE(s) considered?
- What additional information is needed?

Identifying the AE:

- Use verbatim terms as often as possible
- May need medical judgment to process multiple subjective symptoms into one diagnostic term
- Determine if only one primary AE or multiple primary AEs
- Comply with protocol specifications for expedited reporting to sponsor/other

Narrative Presentation about the EAE/SAE:

The narrative should serve as a comprehensive, stand-alone "medical story."

- Summarize all relevant clinical and related information,
- Organize "medical story" (e.g. logical time sequence, by body system)
- Provide evidence to substantiate information (e.g., the reported primary AE term, site's relationship assessment)

AE Follow Up:

Sites must follow each AE until the AE has resolved or is stable. For each AE reported to DAIDS, an updated report must be submitted:

- To document the stable or resolved outcome of the AE, unless the initial report included a final outcome
- Any change in the assessment of the severity grade of the AE or the relationship between AE and the study agent, or
- Additional significant information on a previously reported AE (e.g., cause of death, results of re-challenge with study agents(s))

DAIDS RSC Safety Office Contact Information

Email: DAIDSRSCSafetyOffice@tech-res.com

Safety Hotline: 1-301-897-1709 (International) or 1-800-537-9979 (U.S.)

NIH National Institute of Allergy and Infectious Diseases

DAIDS RSC Regulatory Support Center

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