Adverse Event Checklist

Have you provided the following information on the case?

Protocol Information:

- ❑ Protocol name/number
- ❑ Protocol version
- ❑ Enrollment date

Participant Identifiers/Descriptors:

Demographics

- ❑ Age
- ❑ Sex at Birth
- ❑ Race/Ethnicity

If Pregnant, please provide information below:

- ❑ Mother's LMP (if known)
- ❑ Gestational age at enrollment and at time of event
- ❑ Timing/Intensity of exposure to Study Agent(s)

If subject is infant/fetus, provide information below:

- ❑ Gestational age at time of event and 1st drug exposure
- ❑ Outcome of pregnancy and date
- ❑ Status at birth (e.g., premature or full-term birth, APGAR score, complications[need for resuscitation/admission to NICU])
- ❑ HIV status: include most recent CD4 count and HIV viral load
- ❑ Congenital anomalies/defects diagnosed at birth
- ❑ Infant illnesses, hospitalizations, drug therapies, breastfeeding
- ❑ Developmental assessment and immunization history

Disease Characteristics

- ❑ HIV Status: include most recent CD4 count and HIV viral load
- ❑ ART experience
- ❑ Other concurrent or recent treatment received for indication other than HIV/AIDS

Study Agent Information:

(If no study agent exposure, please refer to the protocol for reporting criteria.)

- ❑ Relationship to Primary AE
- ❑ Study Arm/Group (if applicable)
- ❑ Start/Stop Dates
- ❑ Dose, Route and Schedule of Administration
- ❑ Action Taken with Study Agent(s)/Date

Adverse Event Checklist (continued)

Have you provided the following information on the case?

Adverse Event Information:

- ❑ Primary AE Term
- ❑ Severity Grade
- ❑ Onset Date
- ❑ Status Code/Date
- ❑ SAE? (Y/N)
- ❑ Seriousness Criteria (select all that apply)
- ❑ Date of Death (if applicable)
- ❑ Country of Origin
- ❑ Expected? [SUSAR Reporting Category only] (Y/N)

Narrative (Refer to Quick Reference Card IIA for details):

- ❑ Relevant signs/symptoms
- ❑ Predisposing factors leading up to AE
- ❑ Diagnostic workup: physical exam, supporting labs, tests, and procedures
- ❑ Treatment provided for the AE (include treatment response)
- ❑ De-challenge/rechallenge of Study Agent(s)
- ❑ If hospitalization: include hospital records, discharge diagnosis, medications and medical follow-up
- ❑ Concomitant meds
- ❑ Past medical history, family history (include alcohol/tobacco/substance use)
  - ❑ Obstetric and gynecologic history (include previous maternal pregnancy complications/fetal-neonatal abnormalities and type, if applicable)
  - ❑ Infant developmental assessment and immunization history (if applicable)
- ❑ Adherence to Study Agent(s)
- ❑ Other supporting information

Before you send in the SAE/EAE, ask yourself the following:

- ❑ Is the information adequate?
  (i.e., is Primary AE term justified by supporting evidence?)
- ❑ What information is still pending?
- ❑ What additional information do I need to include?

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.)

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