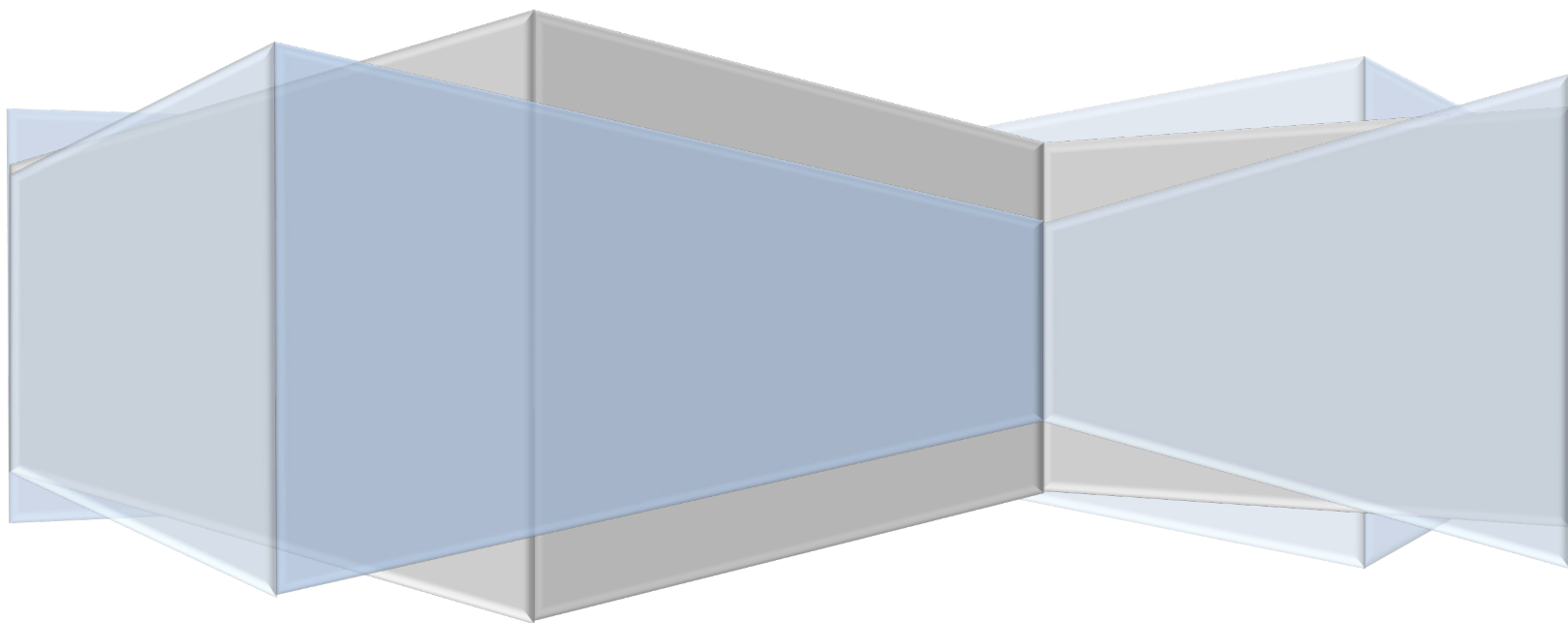


DAIDS Adverse Experience Reporting System (DAERS)

Site User Instructional Guide for EAE Reporting



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Acronyms and Definitions

Adverse Event (AE)

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation participant administered a study agent and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) agent, whether or not related to the medicinal (investigational) agent. (ICH E2A) (Synonym: Adverse Experience)

Clinical Research Site (CRS)

Discrete location (e.g., hospital, outpatient clinic, health maintenance organization, community health center, private practice, clinic, etc.) where qualified professionals conduct clinical trial research in accordance with Good Clinical Practices. (DAIDS)

Clinical Study Information Office (CSIO)

Receives and abstracts protocol and/or contact information into the DAIDS-Enterprise System for use by DAIDS and their collaborators in support of DAIDS-supported and/or sponsored clinical trials.

DAIDS

Division of Acquired Immune Deficiency Syndrome.

DAIDS Adverse Experience Reporting System (DAERS)

DAIDS Adverse Experience Reporting System is an internet-based application to facilitate the reporting and processing of AEs to and by the Division of AIDS.

DAIDS Enterprise System (DAIDS-ES)

A suite of tools, containing multiple integrated modules for key business areas, including DAERS. It was built on a common framework that enhances clinical research by supporting scientific, administrative and regulatory processes. The various modules help the various business areas work together.

Data Management Center (DMC)

Organization contracted by DAIDS to manage safety data for a specific clinical trial.

Expedited Adverse Event (EAE)

An AE that meets the criteria of expedited reporting to DAIDS. The EAE reporting requirements that apply to an individual study/trial are specified by DAIDS and the protocol.

EAE Form

The Expedited Adverse Event (EAE) paper form to be completed if DAERS system is not available.

Food and Drug Administration (FDA)

The federal agency that is responsible for the regulatory oversight of food, drugs, and cosmetics in the United States.

HIV/AIDS

Human immunodeficiency virus is a lentivirus that causes acquired immunodeficiency syndrome.

International Conference on Harmonization (ICH)

A project that brings together the regulatory authorities of Europe, Japan and the United States, as well as experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of product registration with the intent of making recommendations to achieve greater harmonization in guidelines and methods for research and development of new medicines.

Participant Identification (PID)

The participant identification number assigned to the participant at the time of study entry.



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Regulatory Support Center (RSC)

A contract based organization within Technical Resources International, Inc. charged with providing regulatory support to DAIDS.

RSC Safety Office

The RSC team responsible for the processing of AE/SAE(s).

Serious Adverse Event (SAE)

Any untoward medical occurrence that at any dose results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. This includes important medical events that may not be immediately life-threatening or result in death or hospitalization but may jeopardize the patient or may require intervention to prevent one of the outcomes listed in the definition above. (ICH E6 and E2A)

SPT

The Safety and Pharmacovigilance Team at DAIDS.



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Introduction

The Division of AIDS (DAIDS) Adverse Experience Reporting System (DAERS) enables DAIDS Clinical Research Sites to report Expedited Adverse Events (EAEs) effectively, and in accordance with the safety reporting guidelines set forth by DAIDS, the Food and Drug Administration (FDA), and the International Conference on Harmonization (ICH) for the conduct of human participant clinical trials. The DAERS is a Web-based system that enables immediate reporting of and access to EAEs. Built-in data validation checks and value lists ensure accuracy of data capture. Moreover, data entry is minimized because certain information, such as Protocol, Participant, and Site Information, is already captured by other DAIDS Enterprise System (DAIDS-ES) components.

Clinical Research Sites should use DAERS to create and submit EAEs. In addition, DAERS can be used to update EAE reports upon receipt of additional information, search for EAEs, and view EAE information for the applicable Clinical Research Site. The system provides an optional tool that helps determine whether an Adverse Event (AE) should be reported as an EAE.

Users with a DAERS account can access the system through the following link:

<https://daidses.niaid.nih.gov/Phoenix/Login.aspx>.

This instructional guide shows the user how to enter values in each field in DAERS. Examples are provided for each field to help the user select the correct value. It also points the user, where applicable, to special instructions to keep in mind while entering values.

Throughout this guide, the headings for fields required to save the current page and submit the EAE are colored in **red**, while fields required to submit the EAE but not to save the page are colored in **orange**. All fields that are not required are displayed in **blue**. This information is also conveyed in the text describing each field.



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DAERS Site Users Instructional
Guide for EAE Reporting
Version 2.0 – December 2022

A. Create New EAE

Introduction

The Create New EAE screen is the first screen to be displayed when reporting a New EAE Report via DAERS. This screen contains fields that are mandatory to create a New EAE Report. These fields cannot be edited once the user has clicked “Next” and moved to the next screen, so it is important to pay careful attention while entering values in these fields.

Click on a data field in the screen below to jump to a detailed description.

The screenshot shows the 'Create New EAE' web form. At the top, there is a header with the 'Adverse Experience Reporting DIVISION OF AIDS' logo on the left, the title 'Create New EAE' in the center, and a user welcome message on the right: 'Welcome', 'Last successful login: Nov 01, 2013 03:05 PM', and 'No. of unsuccessful login attempts: 0'. Below the header is a navigation bar with 'EAE', 'Search', and 'RSC' links. The main form area contains several fields: '*Site ID:' with a dropdown menu showing 'Select Site'; '*Protocol Number:' with a dropdown menu showing 'Select Protocol'; '*Protocol Version:' with a dropdown menu showing 'Select Protocol Version'; 'Protocol Full Title:' with a text input field; and '*Participant ID:' with a text input field and a person icon. Below these fields is a 'Participant Information:' section with a text box containing the message: 'Participant Information for the selected participant is displayed below. If the data does not match please update on the Participant Information screen.' This section also lists 'Date of Birth:', 'Sex at Birth:', and 'Race:'. At the bottom of the form are 'Next' and 'Clear' buttons. The footer of the page includes links for 'Privacy Notice' and 'Legal Disclaimer', and logos for the NIH, DAIDS, and RSC.



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A1: Site ID

*Site ID:

Instructions:

- The Site ID will automatically populate based on the user login information.
- If user is registered to more than one Site: SELECT Site ID that corresponds to the EAE.
- If Site is not registered to any Protocols, the following error message will appear: *An EAE Report cannot be created for the Site (X) at this time. The Site is not currently registered to any Protocols. If you believe that this is an error, please contact DAIDS-ES Support.*

Example:

- SELECT Site ID:
 - 1008 - Georgetown University CRS (GU CRS)
 - 107 - Brigham and Women's Hosp. ACTG CRS
 - 201 - Johns Hopkins Adult AIDS CRS

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

A2: Protocol Number

*Protocol Number:

Instructions:

- SELECT the specific Protocol Number, under which the EAE occurred, that your Site is reporting through DAERS.
- If user is registered to only one Protocol: Auto-populated after completion of A1 [Site ID].
- If user is registered to more than one Protocol: Multiple Protocols are available in the drop down menu; SELECT the Protocol Number that corresponds to the EAE.
- If Protocol is not listed in the drop down menu: Contact DAIDS-ES Support and report EAE to the DAIDS RSC Safety Office using the paper EAE form.
- EAEs (initial or updates) for Protocols which have reached the status "Closed to Follow Up" **must** be entered in DAERS by the DAIDS RSC Safety Office. Submitting a paper EAE form is required in such cases.

Example:

- SELECT Protocol Number:
 - A5240
 - A5241
 - A5257

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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A3: Protocol Version

*Protocol Version:

Instructions:

- SELECT the version of the protocol the Participant was consented for at the time of the onset of the Primary AE.
- If only one Protocol Version: Auto-populated after completion of A2 [Protocol Number].

Example:

- SELECT Protocol Version:
 - 1.0 - A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers
 - 2.0 - A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

A4: Protocol Full Title

Protocol Full Title:

Instructions:

- Auto-populated after completion of A3 [Protocol Version].

Example:

- Protocol Title: A Phase III Comparative Study of Three Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI)-Sparing Antiretroviral Regimens for Treatment-Naïve HIV-1-Infected Volunteers

Required Field to Save EAE: No

Required Field to Submit EAE: No

A5: Participant ID

*Participant ID: 

Instructions:

- SMART TEXT: TYPE first few digits of Participant ID. For network Protocols, Participant ID number is already in DAERS and will auto-populate in a drop down list. If you type in "333" the drop down list will auto-populate with all Participant IDs in the DMC database which include "333" somewhere in that field (i.e., the "333" may be in the beginning, middle, or end of the Participant ID. SELECT the correct Participant ID on whom the EAE is being reported from the drop down list).
- If Participant ID is not auto-populated:
 - Field will accept FREE TEXT (max 15 characters)
 - Displayed Participant ID text will be red if it is typed by the user and does not match from the DMC-provided list.
 - A dialog box will appear, after you save the information, alerting the user that Participant IDs from FSTRF and SCHARP do not include dashes or letters. The user needs to either SELECT from the DMC-provided list, or enter FREE TEXT without dashes or letters.



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Example:

- Participant ID: 333333

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

A6: Participant Information

Participant Information:

Participant Information for the selected participant is displayed below. If the data does not match please update on the Participant Information screen.

Date of Birth:

Sex at Birth:

Race:

Instructions:

- Auto-populated after completion of A5 [Participant ID] if the Site has registered the Participant ID with the DMC.
- If information not available via DMC:
 - Auto-populated as "Not Available".
 - Dialog box will appear requesting user to enter Participant's age, sex, height/weight, ethnicity, and race. This Information will be entered by the user in the Participant Information section (Section C) later.

Example:

- Participant Information auto-populated after completion of A5 [Participant ID] if information is available:
 - A6.a Date of birth
 - A6.b Sex at birth
 - A6.c Race

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then go to the next section.*

This automatically saves the Create New EAE section.



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B. Reporter and Site Information

Introduction

The Reporter and Site Information screen is the second screen displayed when reporting an EAE via DAERS. This screen contains fields which are applicable to the Reporter and the Site, the most important of which is Site Awareness Date. Once this screen is saved with the required information either verified or entered, as applicable, the EAE Report is assigned an EAE Number. The Reporter and Site Information screen is available for editing at any point prior to the submission of the EAE Report by clicking on the Reporter and Site Information link from the EAE Sections menu located on the left side of the screen.

Click on a data field in the screen below to jump to a detailed description.

Adverse Experience Reporting
DIVISION OF AIDS

Reporter and Site Information

Welcome
Login Time: 17-OCT-2022 3:22 PM
No. of unsuccessful login attempts: 0

EAE Sections

- Reporter and Site Information
- Participant Information
- Primary Adverse Event
- Study Vaccines
- Co-enrollment Information
- Concomitant Medications
- Other Events
- Laboratory Tests
- Diagnostic Tests
- Additional Information

EAE Submission

- View EAE Report (PDF)
- Completion Check
- Submit EAE Report

Reporter and Site Information

EAE Number: Participant ID:
Report Type: Site ID:
Reporting Category: Submission Due Date:
Reporting Manual:

Reporter Name:
Phone Number:
Fax Number:
E-Mail Address:
Pager Number:

*Preferred Mode of Communication: ☒ Office Phone ☐ Email ☐ Fax ☐ Pager

*Site Awareness Date:

*Time Zone:

Alternate Temporary Contact Information:

Remaining Characters: 250

[Privacy Policy](#) [Legal Disclaimer](#) [Viewer Software](#)



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B1: Reporter Name

Reporter Name:

Instructions:

- Auto-populated based on the user's DAERS login information.

Example:

- Reporter Name: John Kim

Required Field to Save EAE: No

Required Field to Submit EAE: No

B2: Phone Number

Phone Number:

Instructions:

- Auto-populated from Master Contact.
- If more than one Phone Number is on file for user: SELECT preferred Number from the drop down menu. Additional Phone Numbers can be added in B10 [Alternative Temporary Contact Information].
- If Phone Number is not correct: TYPE correct Phone Number in B10 [Alternative Temporary Contact Information].
- Remember to provide correct contact information to Clinical Study Information Office (CSIO) via email at CSIO@niaid.nih.gov. *Entry in DAERS will not automatically update the contact list.*
- If no Phone Number is stored for user: Auto-populated as "Phone Number Not Available".

Example:

- Phone Number: +33-3333-3330

Required Field to Save EAE: No

Required Field to Submit EAE: No

B3: Fax Number

Fax Number:

Instructions:

- Auto-populated from Master Contact.
- If more than one Fax Number is on file for user: SELECT preferred Number from the drop down menu.
- If Fax Number is not correct: TYPE correct Fax Number in B10 [Alternative Temporary Contact Information].
- Remember to provide correct contact information to Clinical Study Information Office (CSIO) via email at CSIO@niaid.nih.gov. *Entry in DAERS will not automatically update the contact list.*
- If no Fax Number is stored for user: Auto-populated as "Fax Number Not Available".

Example:

- Fax Number: +33-3333-3331

Required Field to Save EAE: No

Required Field to Submit EAE: No



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B4: E-Mail Address

E-Mail Address:

Instructions:

- Auto-populated from Master Contact.
- If more than one E-mail Address is on file for user: SELECT preferred E-mail Address from the drop down menu.
- If E-mail Address is not correct: TYPE correct E-mail Address in B10 [Alternative Temporary Contact Information].
- Remember to provide correct contact information to Clinical Study Information Office (CSIO) via email at CSIO@niaid.nih.gov. *Entry in DAERS will not automatically update the contact list.*
- If no E-mail Address is stored for user: Auto-populated as "E-mail Address Not Available".

Example:

- E-mail Address: abcdefgh@gmail.com

Required Field to Save EAE: No

Required Field to Submit EAE: No

B5: Pager Number

Pager Number:

Instructions:

- Auto-populated from Master Contact.
- If more than one Pager Number on is file for user: SELECT preferred Number.
- If Pager Number is not correct: TYPE correct Pager Number in B10 [Alternative Temporary Contact Information].
- Remember to provide correct contact information to Clinical Study Information Office (CSIO) via email at CSIO@niaid.nih.gov. *Entry in DAERS will not automatically update the contact list.*
- If no Pager Number is stored for user: Auto-populated as "Pager Number Not Available".

Example:

- Pager Number: +33-3333-3332

Required Field to Save EAE: No

Required Field to Submit EAE: No

B6: Preferred Mode of Communication

*Preferred Mode of Communication: ☐ Phone ☐ Email ☐ Fax ☐ Pager

Instructions:

- SELECT Phone, Fax, E-mail, or Pager to reach contact in B1 [Reporter Name].

Example:

- SELECT Preferred Mode of Communication:
 - B6.a Phone
 - B6.b Fax
 - B6.c E-mail
 - B6.d Pager

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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B7: Site Awareness Date

*Site Awareness Date: 

Instructions:

- TYPE the date the Site first became aware of the Primary AE occurring at a level requiring EAE reporting to DAIDS or SELECT the Date by using the calendar icon.
- This **may or may not** be the date the Primary AE first occurred.
- Refer to the DAIDS EAE Manual v2.0 (dated January 2010) and the EAE section of the Protocol for further guidance on EAE reporting requirements.

Example:

- Site Awareness Date: DD-MM-YYYY

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

B8: Time Zone

*Time Zone:

Instructions:

- Auto-populated after completion of A1 [Site ID] with the Time Zone where the reporting Site ID is located.
- If Time Zone does not auto-populate: SELECT the appropriate Time Zone from the drop down menu.

Example:

- SELECT Time Zone
 - (GMT-5:00) Eastern Time (US and Canada)

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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B9: Alternative Temporary Contact Information

Alternate Temporary Contact Information:

Remaining Characters: 250

Instructions:

- TYPE Alternative Temporary Contact Information corresponding to fields B2 [Phone Number], B3 [Fax Number], B4 [E-mail Address], and/or B5 [Pager Number].

Example:

- FREE TEXT (max 250 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then go to the next section after entering all of the reporter and site information.*



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C. Participant Information

Introduction

The Participant Information screen is the third screen displayed when reporting an EAE via DAERS. In this screen, the user will enter information specific to the study participant who experienced the EAE.

Click on a data field in the screen below to jump to a detailed description.

Participant Information

Welcome
Last successful login: Nov 01, 2013 03:05 PM
No. of unsuccessful login attempts: 0

EAE Search Validation Mode RSC

EAE Sections

- Reporter and Site Information
- Participant Information**
- Primary Adverse Event
- Study Agents
- Co-enrollment Information
- Concomitant Medications
- Other Events
- Laboratory Tests
- Diagnostic Tests
- Additional Information

EAE Submission

- View EAE Report (PDF)
- Completion Check
- Submit EAE Report

EAE Number: **Participant ID:** **Protocol Number:**
Report Type: **Site ID:**
Reporting Category: **Submission Due Date:**
Reporting Manual:

Participant information that has been provided by the DMC has been pre-populated.
This information should be updated if the data does not match the participant's records.
This information must be verified and saved in order to complete the report.

Participant ID: [Change PID](#)

Date of Birth: Day Month Year ***Age:** [Select Age UoM](#)

***Sex at Birth:** [Select Sex at Birth](#)

***Pregnant:** ☐ Yes ☒ No ☐ Unknown **If Yes, Duration:** Weeks

Height: [Select UoM](#)

Weight: [Select UoM](#) **BSA:** NA m²

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Other
☒ Unknown ☐ Not Reported

***Race:** ☐ American Indian or Alaska Native ☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ Not Reported
☐ Unknown ☐ Other

HIV Status: [Select HIV Status](#)

Last HIV Status Test Date: ☐ Estimated? ☐ Unknown

Most recent CD4 Count: [Select UoM](#)

Most recent CD4 Count Date: ☐ Estimated? ☐ Unknown

Most recent HIV Viral Load: copies/mL

Most recent HIV Viral Load Date: ☐ Estimated? ☐ Unknown

Method: [Select Method](#)

Gestational Age at Birth: [Select Gestational Age at Birth](#)

APGAR (1 min): [Select APGAR Score at 1 Minute](#)

APGAR (5 min): [Select APGAR Score at 5 Minutes](#)

APGAR (10 min): [Select APGAR Score at 10 Minutes](#)

Weight at Birth: gms **Head Circumference:** cms

Breastfed: ☐ Yes ☐ No

Comments:

Remaining Characters: 2000

[Save](#) [Restore](#)

[Privacy Notice](#) [Legal Disclaimer](#)



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C1: Participant ID

Participant ID: 

Instructions:

- Auto-populated after completion of A5 [Participant ID].
- If Participant ID needs to be changed: Edit here before the Initial EAE is submitted. Once the Initial EAE has been submitted, the Participant ID cannot be edited via an update.

Example:

- Participant ID: 333333

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

C2: Date of Birth

Date of Birth:

Instructions:

- Auto-populated after completion of A5 [Participant ID] if the Site has registered the Participant ID with the DMC.
- If information is not available via DMC: "Day," "Month," and "Year" are selected by default for each of the drop down fields.

Example:

- SELECT Participant's Date of Birth:
 - C2.a Day
 - C2.b Month
 - C2.c Year

Required Field to Save EAE: No

Required Field to Submit EAE: No

C3: Age/Age UoM

*Age:

Instructions:

- Auto-populated after completion of C2 [Date of Birth].
- If not auto-populated, or if the auto-populated Age is incorrect per the onset of the event: TYPE Age of Participant then SELECT the applicable Unit of Measurement (UoM) at the time of onset of AE.

Example:

- Age: 30 (max 3 characters);
- SELECT Participant's Age Unit of Measurement:
 - C3.a Days
 - C3.b Weeks
 - C3.c Months
 - C3.d Years

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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C4: Sex at Birth

*Sex at Birth:

Instructions:

- Auto-populated after completion of A5 [Participant ID] if the Site has registered the Participant ID with the DMC.
- If not auto-populated: SELECT Participant's Sex at Birth.

Example:

- SELECT Participant's Sex at Birth:
 - C4.a Male
 - C4.b Female
 - C4.c Unknown

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

C5: Pregnant

*Pregnant: ☐ Yes ☒ No ☐ Unknown

Instructions:

This field is active and required only when the value in C4 is "Female".

- SELECT whether Participant is Pregnant.

Example:

- SELECT whether Participant is Pregnant:
 - C5.a Yes
 - C5.b No
 - C5.c Unknown

Required Field to Save EAE: Yes (If C4 is "Female")

Required Field to Submit EAE: Yes (If C4 is "Female")

C6: Duration

If Yes, Duration: Weeks

Instructions:

This field is active and required only when the value in C5 is "Yes".

- TYPE the Participant's pregnancy Duration in weeks.

Example:

- Duration: 28 weeks (max 2 characters).

Required Field to Save EAE: Yes (If C5 is "Yes")

Required Field to Submit EAE: Yes (If C5 is "Yes")



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C7: Height/UoM

Height:

Instructions:

- TYPE the Participant's Height and SELECT the UoM.
- If available, provide the Participant's Height at the time of AE onset; otherwise, provide the most recent information available.

Example:

- Height: 63 (max 10 characters)
- SELECT Participant's Height Unit of Measurement:
 - C7.a Inches (in)
 - C7.b Centimeters (cm)

Required Field to Save EAE: No

Required Field to Submit EAE: No

C8: Weight/UoM

Weight:

Instructions:

- TYPE the Participant's Weight and SELECT the UoM.
- If available, provide the Participant's Weight at the time of AE onset; otherwise, provide the most recent information available.

Example:

- Weight: 150
- SELECT Participant's Weight Unit of Measurement:
 - C8.a Grams (gm)
 - C8.b Pounds (lbs)
 - C8.c Kilograms (kg)

Required Field to Save EAE: No

Required Field to Submit EAE: No

C9: BSA

BSA: NA m²

Instructions:

- Auto-populated after completion of C7 [Height] and C8 [Weight].
- This value cannot be edited by the user.

Example:

- BSA: 2.03 m²

Required Field to Save EAE: No

Required Field to Submit EAE: No



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C10: Ethnicity

Ethnicity: ☐ Hispanic or Latino ☐ Not Hispanic or Latino ☐ Other
☒ Unknown ☐ Not Reported

Instructions:

- SELECT the Ethnicity of the Participant.
- TYPE Ethnicity of the Participant in the adjacent field if the selection is "Other".

Example:

- SELECT Participant's Ethnicity:
 - C10.a Hispanic or Latino
 - C10.b Not Hispanic or Latino
 - C10.c Unknown
 - C10.d Not Reported
 - C10.e Other (max 30 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

C11: Race

***Race:** ☐ American Indian or Alaska Native ☐ Black or African American ☐ White
☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☐ Not Reported
☐ Unknown
☐ Other

Instructions:

- SELECT the Race of the Participant.
- TYPE Race of the Participant in the adjacent field if the selection is "Other".

Example:

- SELECT Participant's Race:
 - C11.a American Indian or Alaska Native
 - C11.b Black or African American
 - C11.c White
 - C11.d Native Hawaiian or Other Pacific Islander
 - C11.e Asian
 - C11.f Not Reported
 - C11.g Unknown
 - C11.h Other (max 100 characters)

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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C12: HIV Status

HIV Status:

Instructions:

- SELECT Participant's HIV Status at the time of onset of AE.

Example:

- SELECT Participant's HIV Status:
 - C12.a HIV Infected
 - C12.b HIV Uninfected
 - C12.c Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: No

C13: Last HIV Status Test Date

Last HIV Status Test Date: ☐ Estimated? ☐ Unknown

Instructions:

This field is required only when the value in C12 is "HIV Infected" or "HIV Uninfected".

- TYPE or SELECT using the calendar icon the Participant's most recent HIV Status Test Date.
- CHECK the "Estimated" or "Unknown" box if not sure of the test date.

Example:

- Last HIV Status Test Date: DD-MM-YYYY

Required Field to Save EAE: Yes (If C12 is "HIV Infected" or "HIV Uninfected")

Required Field to Submit EAE: Yes (If C12 is "HIV Infected" or "HIV Uninfected")

C14: Most recent CD4 Count/UoM

Most recent CD4 Count:

Instructions:

This field is required only when the value in C12 is "HIV Infected."

- TYPE the Participant's Most recent CD4 Count and SELECT the UoM.

Example:

- Most recent CD4 Count: 488 (max 10 characters)
- SELECT the CD4 Count Unit of Measurement:
 - C14.a cells/mm³
 - C14.b %

Required Field to Save EAE: Yes (If C12 is "HIV Infected")

Required Field to Submit EAE: Yes (If C12 is "HIV Infected")




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C15: Most recent CD4 Count Date

Most recent
CD4 Count
Date:  ☐ Estimated?
☐ Unknown

Instructions:

This field is required only when the value in C12 is “HIV Infected”.

- TYPE or SELECT using the calendar icon the date of sample drawn from the Participant to test for the Most recent CD4 Count.
- CHECK the “Estimated” or “Unknown” box if not sure of the test date.

Example:

- Most recent CD4 Count Date: DD-MM-YYYY

Required Field to Save EAE: Yes (If C12 is “HIV Infected”)

Required Field to Submit EAE: Yes (If C12 is “HIV Infected”)

C16: Most recent HIV Viral Load

Most recent
HIV Viral Load:  copies/mL

Instructions:

This field is required only when the value in C12 is “HIV Infected”.

- TYPE the Participant’s number of copies/mL of the Most recent HIV Viral Load.


Example:

- Most recent HIV Viral Load: 41,303 copies/mL (max 10 characters)

Required Field to Save EAE: Yes (If C12 is “HIV Infected”)

Required Field to Submit EAE: Yes (If C12 is “HIV Infected”)

C17: Most recent HIV Viral Load Date

Most recent
HIV Viral Load
Date:  ☐ Estimated?
☐ Unknown

Instructions:

This field is required only when the value in C12 is “HIV Infected”.

- TYPE or SELECT using the calendar icon the date of sample drawn from the Participant to test for the Most recent HIV Viral Load.
- CHECK the “Estimated” or “Unknown” box if not sure of the test date.

Example:

- Most recent HIV Viral Load Date: DD-MM-YYYY

Required Field to Save EAE: Yes (If C12 is “HIV Infected”)

Required Field to Submit EAE: Yes (If C12 is “HIV Infected”)



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C18: Method

Method:

Instructions:

This field is required only when the value in C12 is "HIV Infected".

- SELECT Method used to measure Participant's most recent HIV Viral Load.
- SELECT "Unknown" if not sure of the Method.

Example:

- SELECT Method used to measure Most recent HIV Viral Load:
 - C18.a bDNA
 - C18.b NASBA
 - C18.c PCR

Required Field to Save EAE: Yes (If C12 is "HIV Infected")

Required Field to Submit EAE: Yes (If C12 is "HIV Infected")

C19: Gestational Age at Birth

Gestational Age at Birth:

Instructions:

- SELECT the Participant's Gestational Age at Birth from the drop down menu.
- SELECT "Unknown" if not sure of Gestational Age at Birth.
- This field is displayed **only** if value in C3 is 12 months or less.

Example:

- SELECT Gestational Age at Birth:
 - C19.a 20 weeks
 - C19.b >45 weeks
 - C19.c Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: No

C20: APGAR (1 Minute)

APGAR (1 min):

Instructions:

- SELECT the Participant's APGAR score recorded at 1 minute after birth from the drop down menu.
- SELECT "Unknown" if not sure of APGAR score.
- This field is displayed **only** if value in C3 [Age/Age UoM] is 12 months or less.

Example:

- SELECT APGAR (1 min):
 - C20.a 1
 - C20.b 5
 - C20.c 10
 - C20.d Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: No



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C21: APGAR (5 Minutes)

APGAR (5 min):

Instructions:

- TYPE the Participant's APGAR score recorded at 5 minutes after birth from the drop down menu.
- SELECT "Unknown" if not sure of APGAR score.
- This field is displayed **only** if value in C3 [Age/Age UoM] is 12 months or less.

Example:

- SELECT APGAR (5 min):
 - C21.a 1
 - C21.b 5
 - C21.c 10
 - C21.d Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: No

C22: APGAR (10 Minutes)

APGAR (10 min):

Instructions:

- TYPE the Participant's APGAR score recorded at 10 minutes after birth from the drop down menu.
- SELECT "Unknown" if not sure of APGAR score.
- This field is displayed **only** if value in C3 [Age/Age UoM] is 12 months or less.

Example:

- SELECT APGAR (10 min):
 - C22.a 1
 - C22.b 5
 - C22.c 10
 - C22.d Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: No

C23: Weight at Birth

Weight at Birth: gms

Instructions:

- TYPE the Participant's Weight at Birth (grams).
- This field is displayed **only** if value in C3 [Age/Age UoM] is 12 months or less.

Example:

- Weight at Birth: 2400 gms (max 10 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No



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C24: Head Circumference

Head Circumference: cms

Instructions:

- TYPE the Participant's Head Circumference (centimeters) measured at birth.
- This field is displayed **only** if value in C3 [Age/Age UoM] is 12 months or less.

Example:

- Head Circumference: 24 cms (max 10 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

C25: Breastfed

Breastfed: ☐ Yes ☐ No

Instructions:

- SELECT whether the Participant was breastfed after birth.
- This field is displayed **only** if value in C3 [Age/Age UoM] is 12 months or less.

Example:

- SELECT whether the Participant is Breastfed:
 - C25.a Yes
 - C25.b No

Required Field to Save EAE: No

Required Field to Submit EAE: No

C26: Comments

Comments:

Remaining Characters: 2000

Instructions:

- TYPE additional information about the Participant.

Example:

- FREE TEXT (max 2000 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then go to the next section after entering in all of the participant information.*



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D. Primary Adverse Event

Introduction

The Primary Adverse Event screen is the fourth screen displayed when reporting an EAE via DAERS. In this screen, the user is required to provide significant information on the Primary AE, including the narrative case summary in which the user provides a comprehensive “medical story” on the Primary AE.

Click on a data field in the screen below to jump to a detailed description.

Primary Adverse Event

Welcome
Last successful login: Nov 21, 2013 03:34 AM
No. of unsuccessful login attempts: 0

EAE Search Validation Mode RSC

EAE Sections

- Reporter and Site Information
- Participant Information
- Primary Adverse Event**
- Study Agents
- Co-enrollment Information
- Concomitant Medications
- Other Events
- Laboratory Tests
- Diagnostic Tests
- Additional Information

EAE Submission

- View EAE Report (PDF)
- Completion Check
- Submit EAE Report

EAE Number: **Participant ID:**
Report Type: **Site ID:**
Reporting Category: **Submission Due Date:**
Reporting Manual: **Protocol Number:**
Protocol Version:

***Is this a Serious Adverse Event (SAE) as defined by ICH?** ☐ Yes ☐ No !

***Please select all of the categories that apply for the adverse event or select one of the options for "None of the Above": !**

- ☐ Results in Death
- ☐ Is life-threatening
- ☐ Requires inpatient hospitalization or prolongation of existing hospitalization
- ☐ Results in persistent or significant disability/incapacity
- ☐ Is a congenital anomaly/birth defect
- ☐ Other important medical event that may jeopardize the subject or that may require intervention to prevent outcomes listed above
- ☐ None of the above, this is not an SAE, but is a protocol-specific reporting requirement
- ☐ None of the above, this is not an SAE, but is of sufficient concern to report to DAIDS Specify Reason

***Primary AE:** !

***Severity Grade:** !

Date of Death: ☐ Estimated?

***Onset Date:** ☐ Estimated?

Did this AE result in a Fetal Loss?

***Date of Fetal Loss:** ☐ Estimated?

Country of AE Origin:

Status Code at Most Recent Observation:

Chronic Condition? ☐ This is a chronic condition that is not likely to resolve

Status Date:

Include clinical course, therapeutic measures, outcome, relevant past medical history, any other contributing factors, alternative etiologies, and other relevant information.

Narrative Case Summary:

Remaining Characters: 6000

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D1: Is this a Serious Adverse Event (SAE) as defined by ICH?

*Is this a Serious Adverse Event (SAE) as defined by ICH? ☐ Yes ☐ No !

Instructions:

- SELECT whether the Primary AE is a Serious Adverse Event (SAE) as defined by ICH.

Example:

- Is this a Serious Adverse Event (SAE) as defined by ICH:
 - D1.a Yes
 - D1.b No

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

D2: Please select all of the categories that apply for the adverse event or select one of the options for "None of the Above".

*Please select all of the categories that apply for the adverse event or select one of the options for "None of the Above": !

- ☐ Results in Death
- ☐ Is life-threatening
- ☐ Requires inpatient hospitalization or prolongation of existing hospitalization
- ☐ Results in persistent or significant disability/incapacity
- ☐ Is a congenital anomaly/birth defect
- ☐ Other important medical event that may jeopardize the subject or that may require intervention to prevent outcomes listed above
- ☐ None of the above, this is not an SAE, but is a protocol-specific reporting requirement
- ☐ None of the above, this is not an SAE, but is of sufficient concern to report to DAIDS Specify Reason

Instructions:

- SELECT all categories that apply for the Primary AE.
- If D1 is "Yes": SELECT all categories that apply from the choices D2.a to D2.f provided in the example below.
- If D1 is "No": SELECT between choices D2.g and D2.h provided in the example below.
- Refer to the Manual for Expedited Reporting of Adverse Events to DAIDS for further guidance and clarification on Seriousness Criteria as defined by ICH E6 and E2A.
- Seriousness Criteria should be updated when additional significant information becomes available on the previously reported AE.

Example:

- SELECT all categories that apply for the Adverse Event (AE):
 - D2.a Results in Death
 - D2.b Is life threatening
 - D2.c Requires inpatient hospitalization or prolongation of existing hospitalization
 - D2.d Results in persistent or significant disability/incapacity
 - D2.e Is a congenital anomaly/birth defect
 - D2.f Other important medical event that may jeopardize the Participant or that may require intervention to prevent outcomes listed above
 - D2.g None of the above, this is not an SAE, but is a protocol-specific reporting requirement
 - D2.h None of the above, this is not an SAE, but is of sufficient concern to report to DAIDS

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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D3: Primary AE

*Primary AE: !

Instructions:

- TYPE only one Primary AE term. Choose the term that best describes the nature of the AE being reported.
- Report the resulting overall diagnosis, if available, as the Primary AE term instead of reporting signs or symptoms (i.e., Myocardial Infarction should be the Primary AE term, rather than Chest Pain).
- The Primary AE term should be updated when additional significant information becomes available on a previously reported AE.
- “Death” and “Hospitalization” **are outcomes** and **not AEs**. These terms can be used at the time of submission of the initial report if no other information or diagnosis is available, but should be updated as soon as additional information becomes available.

Example:

- Primary AE: Myocardial Infarction (max 200 characters)

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

D4: Severity Grade

*Severity Grade: !

Instructions:

- SELECT Severity Grade of the reported AE.
- Unless otherwise stated in the Protocol, use the DAIDS AE Grading Table to determine the Severity Grade of the AE.
- Severity describes the intensity of a specific event. The Severity of an AE does not determine whether an event meets the definition of seriousness.
- Grade 4 events are referred to as potentially life-threatening events as defined in the DAIDS AE Grading Table. An event is potentially life-threatening if there is a risk of death, should the event occur in a more severe form. This is not the same as immediately life-threatening which refers to an event in which the participant was at immediate risk of death at the time the event occurred.
- Use the “Estimating Severity Grade” table in the DAIDS AE Grading Table if you are unable to find the exact AE term in the Grading Table.
- When laboratory values fall between two grades, SELECT the higher Severity Grade.

Example:

- SELECT Severity Grade:
 - D4.a 1-Mild
 - D4.b 2-Moderate
 - D4.c 3-Severe
 - D4.d 4-Life Threatening
 - D4.e 5-Death

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes




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D5: Date of Death

Date of Death:  ☐ Estimated?

Instructions:

This field is active and required only when the value in D2 is “Results in Death”.

- TYPE or SELECT using the calendar icon, the date the Participant died.
- CHECK the “Estimated” box if not sure of the exact date the Participant died.



Example:

- Date of Death: DD-MM-YYYY

Required Field to Save EAE: Yes (If D2 is “Results in Death”)

Required Field to Submit EAE: Yes (If D2 is “Results in Death”)

D6: Onset Date

*Onset Date:   ☐ Estimated?

Instructions:

- TYPE or SELECT using the calendar icon, the date the Primary AE first occurred at the level requiring expedited reporting to DAIDS (i.e., if the Participant experienced an AE of chest pain which worsened to the extent that the Participant had to be hospitalized two days later, then the Onset Date of the Primary AE is the date the Participant was hospitalized and not the date the Participant first complained of chest pain).
- CHECK the “Estimated” box if not sure of the exact date the Primary AE first occurred at a level requiring expedited reporting to DAIDS.

Example:

- Onset Date: DD-MM-YYYY

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

D7: Did this AE result in a Fetal Loss?

Did this AE result in a Fetal Loss?

Instructions:

This field is available only when the value in C4 is “Female”.

- Select whether the Primary AE resulted in a fetal loss.

Example:

- Did this AE result in a Fetal Loss?:
 - D7.a Yes
 - D7.b No

Required Field to Save EAE: No

Required Field to Submit EAE: No




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D8: Date of Fetal Loss

*Date of Fetal Loss:  ☐ Estimated?

Instructions:

This field is active and required only when the value in D7 is "Yes".

- TYPE or SELECT using the calendar icon, the date when the fetal loss occurred.
- CHECK the "Estimated" box if not sure of the exact date when the fetal loss occurred.

Example:

- Date of Fetal Loss: DD-MM-YYYY

Required Field to Save EAE: Yes (If D7 is "Yes")

Required Field to Submit EAE: Yes (If D7 is "Yes")

D9: Country of AE Origin

Country of AE Origin:

Instructions:

- SELECT the Country in which the Primary AE occurred.
- The Country of AE Origin **may or may not** be the same as where the Site is located.

Example:

- SELECT the Country of AE Origin:
 - D9.a Afghanistan
 - D9.b Aland Islands
 - D9.c Albania

Required Field to Save EAE: No

Required Field to Submit EAE: Yes

D10: Status Code at Most Recent Observation

Status Code at Most Recent Observation:

Instructions:

- SELECT the Status Code of the Primary AE at the Most Recent Observation of the Participant by the study physician.
- If the Status Code is selected as "Not Recovered/Not Resolved," the system will prompt you to clarify if the Primary AE is a chronic condition. If the Primary AE is a chronic condition, (i.e., diabetes mellitus): CHECK the box that states "This is a chronic condition that is not likely to resolve". The Status Code can remain as "Not Recovered/Not Resolved" **only** if this box is checked; otherwise, the Site will be queried regarding an unresolved Status.
- The Status Code "Recovered/Resolved with Sequelae" should be selected **only** when the outcome is such that the Participant retained a condition resulting from the Primary AE (e.g., a Primary AE which results in permanent disability or incapacity, such as blindness).
- If the Status Code is selected as "Unknown," specify the reason for this selection (i.e., the Participant was discontinued OR lost to follow-up). If no reason is specified for this selection, the system will query the Site regarding an unresolved Status.



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Example:

- SELECT Status Code at Most Recent Observation:
 - D10.a Recovered/Resolved
 - D10.b Recovering/Resolving
 - D10.c Not Recovered/Not Resolved
 - D10.d Recovered/Resolved with Sequelae
 - D10.e Death
 - D10.f. Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: Yes

D11: This is a chronic condition that is not likely to resolve

Chronic Condition? ☐ This is a chronic condition that is not likely to resolve

Instructions:

- This field is available only when the value in D10 [Status Code at Most Recent Observation] is "Not Recovered/Not Resolved".
- CHECK the box if the primary AE term entered in D3 [Primary AE Term] is a chronic condition that is not likely to resolve.


Example:

- CHECK the box if the participant has chronic hepatitis which did not resolve at the time of the last study visit.

Required Field to Save EAE: No

Required Field to Submit EAE: No

D12: Status Date

Status Date: 

Instructions:

- TYPE or SELECT using the calendar icon, the date the study physician most recently observed the Participant.
- The Status Date should be on or after the date entered in B7 [Site Awareness Date]. The study physician can observe the Participant for the Primary AE only after being aware of the onset of the Primary AE.
- Status Date should be changed whenever the D10 [Status Code at Most Recent Observation] is updated.

Example:

- Status Date: DD-MM-YYYY

Required Field to Save EAE: No

Required Field to Submit EAE: Yes



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D13: Narrative Case Summary

Narrative Case Summary:

Remaining Characters: 6000

Instructions:

- TYPE a summary of the reported Primary AE. This Narrative Case Summary should include all relevant information on the clinical course, therapeutic measures, diagnostic/laboratory work-up, outcome, relevant past medical history, other contributing factors, and alternate etiologies. Please be advised that this field **does not** check for spelling errors.
- Refer to **Quick Reference Card IIA** for the Narrative Case Summary template. The template guides you on how to write a comprehensive “medical story”. Quick Reference Cards are posted on the Safety Training webpage in the Safety and Pharmacovigilance section on the DAIDS Regulatory Support Center website (<http://rsc.tech-res.com/safetyandpharmacovigilance/>).
- It may be beneficial to type out the Narrative in another electronic format (i.e., MS Word) and copy it into the Narrative Case Summary field to avoid any internet connectivity problems or typographical errors.
- There is a 6000 max character limit for this field. If you have a lengthy Narrative Case Summary that exceeds the character limit, make a note in the field that the complete Narrative Case Summary will be uploaded in DAERS in Section K. Then, upload the Narrative as a document in the “**Additional Information**” screen.

Example:

- FREE TEXT (max 6000 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: Yes

*CLICK **SAVE** and then go to the next section after entering in all the information pertaining to the Primary AE.*



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Introduction

OPTION 1: STUDY AGENTS



Adverse Experience Reporting
DIVISION OF AIDS

Study Agents

Welcome

Login Time: _____

No. of unsuccessful login attempts: _____

EAE Search Person EAE Notification Recipients Validation Mode RSC

EAE Sections

- Reporter and Site Information
- Participant Information
- Primary Adverse Event
- Study Agents
- Study Vaccines
- Co-enrollment Information
- Concomitant Medications
- Other Events
- Laboratory Tests
- Diagnostic Tests
- Additional Information

EAE Submission

- View EAE Report (PDF)
- Completion Check
- Submit EAE Report

EAE Number:
Report Type:
Reporting Category:
Reporting Manual:

Participant ID:
Site ID:
Submission Due Date:


Protocol Number:
Protocol Version:


***Study Agent/Product:**

***Relationship to Primary AE:** Select Relationship to AE ▾

Study Arm/Group:

Dose: Select UoM ▾

Date of First Dose: Select Date  ☐ Estimated?


Date of Last Dose: Select Date  ☐ Estimated?

Route of Administration: Select Route of Administration ▾ ☐ Show more routes

Schedule of Administration: Select Schedule ▾

Site of Administration: Select Site ▾

Action taken with Study Agent/Product: Select Action Taken ▾

Action Date: Select Date 

Distributed by DAIDS: ☐ Yes ☒ No

***Manufacturer:** Unknown ▾

Distributor:

Administered on a cyclic schedule: ☒ Yes ☐ No

***AE occurred during a dosing cycle:** ☐ Yes ☐ No

Comments:

Remaining Characters: 2000

Save
New
Delete
Restore

Study Agent/Product

Relationship to Primary AE

Dose

Action Taken

Action Date

E1: Study Agent/Product

*Study Agent/Product:

Instructions:

- SMART text: TYPE the first few letters of the generic name of the Study Agent/Product or hit the space bar for the system to display the list of Protocol-specific EAE reportable Study Agents/Products in the drop down menu. SELECT the correct option for the Study Agent/Product administered to the Participant prior to or at the time of onset of the Primary AE.
- If the Participant was administered a combination Study Agent/Product: SELECT the combination Study Agent/Product instead of the single Study Agent/Product components from the drop down menu.
- FREE TEXT is NOT accepted for this field.

Example:

- Study Agent/Product: Emtricitabine/Tenofovir Disoproxil Fumarate

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

E2: Relationship to Primary AE

*Relationship to Primary AE:

Instructions:

- SELECT the Relationship between the Primary AE and study agent(s).
- The individual attribution table will display when a combination study agent is selected.
- When the EAE is assessed as not related to the study agent(s), an alternate etiology, diagnosis, or explanation for the EAE should be provided either in D13 [Narrative Case Summary] or E17 [Comments].

Example:

- SELECT Relationship to Primary AE:
 - E2.a Related
 - E2.b Not Related

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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E3: Study Arm/Group

Study Arm/Group:

Instructions:

- TYPE Study Arm/Group to which the Participant is randomized in the study.

Example:

- FREE TEXT (max 30 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

E4: Dose/Dose UoM

Dose:

Instructions:

- TYPE Dose of study agent using the selected UoM administered to the Participant prior to onset of the AE.
- If a combination drug: use forward slashes (/) to separate the Dose of each component.

Example:

- Dose: 200 (max 20 characters)
- SELECT Participant's dosage Unit of Measurement:
 - E4.a Percent(%)
 - E4.b Microgram(mg)
 - E4.c Microliter(mL)

Required Field to Save EAE: No

Required Field to Submit EAE: No

E5: Date of First Dose

Date of First Dose: ☐ Estimated?

Instructions:

- TYPE or SELECT using the calendar icon, the date that the Participant took the first dose of study agent (DD-MM-YYYY).
- The Date of First Dose must be on or before the date entered in D6 [Onset Date].
- CHECK the "Estimated" box if not sure of the exact date the participant took the first dose of the study agent.

Example:

- Date of First Dose: DD-MM-YYYY

Required Field to Save EAE: No

Required Field to Submit EAE: No




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E6: Date of Last Dose

Date of Last Dose:  ☐ Estimated?

Instructions:

- TYPE or SELECT using the calendar icon, the date that the Participant took the last dose of study agent prior to onset of the Primary AE.
- Date of Last Dose must be on or before the date entered in D6 [Onset Date].
- SELECT that value is "Estimated" if not sure of the date the Participant took the last dose of study agent prior to onset of the Primary AE.


Example:

- Date of Last Dose: DD-MM-YYYY

Required Field to Save EAE: No

Required Field to Submit EAE: No

E7: Route of Administration

Route of Administration:  ☐ Show more routes

Instructions:

- SELECT how study agent was administered to the Participant.
- If the list of routes displayed is limited to only one or two options: CHECK the "Show more routes" box to see the complete list.


Example:

- SELECT Participant's Route of Administration:
 - E7.a Auricular (Otic)
 - E7.b Buccal
 - E7.c Conjunctival

Required Field to Save EAE: No

Required Field to Submit EAE: No

E8: Schedule of Administration

Schedule of Administration: 

Instructions:

- SELECT the Schedule of Administration, including frequency and UoM.

Example:

- SELECT Participant's Schedule of Administration:
 - E8.a Twice a day (BID)
 - E8.b Continuous
 - E8.c Five times a day

Required Field to Save EAE: No

Required Field to Submit EAE: No



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E9: Site of Administration

Site of Administration:

Instructions:

- SELECT the Site of Administration.

Example:

- SELECT Participant's Site of Administration:
 - E9.a Deltoid
 - E9.b Inguinal
 - E9.c Nasal

Required Field to Save EAE: No

Required Field to Submit EAE: No

E10: Action Taken with Study Agent/Product

Action taken with Study Agent/Product:

Instructions:

- SELECT Action Taken with Study Agent/Product after the study physician was aware of the EAE.

Example:

- SELECT Action taken with Study Agent/Product:
 - E10.a Continued without change
 - E10.b Course completed or Participant Off Study Agent at AE Onset
 - E10.c Permanently Discontinued
 - E10.d Dose or Schedule Reduced
 - E10.e Temporarily Held
 - E10.f Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: No

E11: Action Date

Action Date:

Instructions:

- TYPE or SELECT using the calendar icon, the date the study physician took action with the study agent/product.
- Action Date must be on or after date entered in B7 [Site Awareness Date]. The study physician can take action with the study agent only once aware of the occurrence of the AE.
- Leave field blank if action taken is "Course completed/Off Study Agent at AE Onset".

Example:

- Action Date: DD-MM-YYYY

Required Field to Save EAE: No

Required Field to Submit EAE: No



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E12: Distributed by DAIDS

Distributed by DAIDS: ☐ Yes ☐ No

Instructions:

- SELECT whether study agent/product was distributed by DAIDS.

Example:

- SELECT whether study agent/product Distributed by DAIDS
 - E12.a Yes
 - E12.b No

Required Field to Save EAE: No

Required Field to Submit EAE: No

E13: Manufacturer

*Manufacturer:

Instructions:

This field is active and required only when the value in E12 is "No".

- SELECT study agent/product Manufacturer.
- The Manufacturers listed in the drop down menu are abstracted from another DAIDS-ES application. If the correct option is not available: SELECT "Other" and TYPE the full name of the Manufacturer as FREE TEXT

Example:

- SELECT study agent/product Manufacturer:
 - E13.a Bristol Myers Squibb
 - E13.b Merck
 - E13.c Other (max 100 characters).
 - E13.d Unknown

Required Field to Save EAE: Yes (If E12 is "No")

Required Field to Submit EAE: Yes (If E12 is "No")

E14: Distributor

Distributor:

Instructions:

This field is active only when the value in E13 is "Unknown".

- TYPE name of Distributor of study agent/product when the study agent is not distributed by DAIDS.

Example:

- FREE TEXT (max 100 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No



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E15: Administered on a cyclic schedule

Administered on a cyclic schedule: ☐ Yes ☐ No

Instructions:

- SELECT whether study agent/product was administered on a recurring cycle.

Example:

- SELECT whether the study agent/product was Administered on a cyclic schedule:
 - E15.a Yes
 - E15.b No

Required Field to Save EAE: No

Required Field to Submit EAE: No

E16: AE occurred during a dosing cycle

*AE occurred during a dosing cycle: ☐ Yes ☐ No

Instructions:

This field is active only when the value in **E15** is "Yes".

- SELECT whether the AE occurred during a dosing cycle of the study agent/product.

Example:

- SELECT whether the AE occurred during a dosing cycle of the study agent/product.
 - E16.a Yes
 - E16.b No

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

E17: Comments

Comments:

Remaining Characters: 2000

Instructions:

- TYPE any additional information about study agent/product.

Example:

- FREE TEXT (max 2000 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then CLICK the **NEW** button to enter information on the next study agent/product by repeating steps E1 to E15.*

*CLICK **SAVE** and go to the next section after entering information on all study agents.*



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OPTION 2: STUDY VACCINES

Click on a data field in the screen below to jump to a detailed description.

Adverse Experience Reporting
DIVISION OF AIDS

[EAE](#)
[Search](#)
[Person](#)
[EAE Notification Recipients](#)
[Validation Mode](#)
[RSC](#)

Study Vaccines

Welcome

Login Time: 17-OCT-2022 3:22 PM

No. of unsuccessful login attempts: 0

EAE Sections

[Reporter and Site Information](#)
[Participant Information](#)
[Primary Adverse Event](#)
[Study Vaccines](#)
[Co-enrollment Information](#)
[Concomitant Medications](#)
[Other Events](#)
[Laboratory Tests](#)
[Diagnostic Tests](#)
[Additional Information](#)

EAE Submission

[View EAE Report \(PDF\)](#)
[Completion Check](#)
[Submit EAE Report](#)

EAE Number:

Report Type:

Reporting Category:

Reporting Manual:

Participant ID:

Site ID:

Submission Due Date:

Protocol Number:

Protocol Version:

Vaccine Regimen

*Study Arm/Group:

Action Taken with Study Vaccine Regimen:

Action Date:

Comments:

Remaining Characters: 2000

Vaccine Details

Select one of the study interventions from the list and enter corresponding details and 'Save'. Repeat this for each study intervention that was administered prior to the onset.

*Study Vaccine:

*Relationship to Primary AE:

Administration Details:

Date	Dose	Route	Site	BodySide	Delete
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		

Add More

Distributed by DAIDS:

*Manufacturer:

Distributor:

Save

New

Delete

Restore

Study Vaccine	Relationship to Primary AE	Dose	Route(s) Of Administration	Site(s) Of Administration
---------------	----------------------------	------	----------------------------	---------------------------

[Privacy Policy](#)
[Legal Disclaimer](#)
[Viewer Software](#)



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E1: Study Arm/Group

*Study Arm/Group:

Instructions:

- TYPE Study Arm/Group to which the Participant is randomized in the study.

Example:

- FREE TEXT (max 30 characters)

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

E2: Action Taken with Study Vaccine Regimen

Action Taken with Study Vaccine Regimen:

Instructions:

- SELECT Action Taken with Study Vaccine Regimen after the study physician was aware of the EAE.


Example:

- SELECT Action Taken with Study Vaccine Regimen:
 - E2.a Continued without change
 - E2.b Course completed or Participant Off Study Agent at AE Onset
 - E2.c Permanently Discontinued
 - E2.d Dose or Schedule Reduced
 - E2.e Temporarily Held
 - E2.f Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: No

E3: Action Date

Action Date: 

Instructions:

- TYPE or SELECT using the calendar icon, the date the study physician took action with the study vaccine.
- Action Date must be on or after date entered in B7 [Site Awareness Date]. The study physician can take action with the study vaccine only once aware of the occurrence of the AE.
- Leave field blank if action taken is "Course completed/Off Study Agent at AE Onset".

Example:

- Action Date: DD-MM-YYYY

Required Field to Save EAE: No

Required Field to Submit EAE: No



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E4: Comments

Comments:

Remaining Characters: 2000

Instructions:

- TYPE any additional information about study vaccine(s).

Example:

- FREE TEXT (max 2000 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

E5: Study Vaccine

*Study Vaccine: ☐ vaccine...

Instructions:

- SELECT Study Vaccine administered to the Participant.

Example:

- SELECT Study Vaccine:
 - E5a. VRC-HIVADV014-00-VP OR VRC-DILUENT013-DIL-VP
 - E5b. VRC-HIVDNA016-00-VP OR Placebo-PBS

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

E6: Relationship to Primary AE

*Relationship to Primary AE:

Instructions:

- SELECT the Relationship between the Primary AE and study vaccine.
- When the EAE is assessed as not related to the vaccine(s), an alternate etiology, diagnosis, or explanation for the EAE should be provided in D13 [Narrative Case Summary].

Example:

- SELECT the Relationship to the Primary AE:
 - E6.a Related
 - E6.b Not Related

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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E7: Administration Details - Date

*Date	*Dose	Route	Site	BodySide	Delete
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		

Instructions:

- TYPE or SELECT using the calendar icon, the date of vaccine administration of the study vaccine to the Participant prior to onset of the AE.
- If the Date is not available, check the box "Not Available"

Example:

- Date: DD-MM-YYYY

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

E8: Administration Details - Dose/UoM

*Date	*Dose	Route	Site	BodySide	Delete
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		

Instructions:

- TYPE Dose of study vaccine using the selected UoM administered to the Participant prior to onset of the AE.
- If the Dose is not available, check the box "Not Available"

Example:

- Dose: 1.5 (max 10 characters)
- SELECT Participant's Dose Unit of Measurement:
 - E8.a Percent (%)
 - E8.b Microgram(mg)
 - E8.c Microliter(mL)

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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E9: Administration Details - Route

*Date	*Dose	Route	Site	BodySide	Delete
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		

Instructions:

- SELECT how study vaccine was administered to the Participant.
- If additional Routes of Administration are needed: CHECK "Show More Routes".

Example:

- SELECT Participant's Route of administration:
 - E9.a Auricular (Otic)
 - E9.b Buccal
 - E9.c Conjunctival
 - E9.d Other (max 100 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

E10: Administration Details - Site

*Date	*Dose	Route	Site	BodySide	Delete
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		

Instructions:

- SELECT specific area or site on the body where study vaccine was administered to the Participant.
- If additional Sites of Administration are needed: CHECK "Show More".

Example:

- SELECT Site where study vaccine was administered:
 - E10.a Deltoid
 - E10.b Inguinal
 - E10.c Nasal
 - E10.d Oral
 - E10.e Thigh
 - E10.f Rectal
 - E10.g Vaginal
 - E10.d Other (max 100 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No



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E11: Administration Details - Body Side

*Date	*Dose	Route	Site	BodySide	Delete
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		

Instructions:

- SELECT the Body Side (or side of the Body) where the study vaccine was administered.

Example:

- Body Side:
 - E11.a Left
 - E11.b Right

Required Field to Save EAE: No

Required Field to Submit EAE: No

E12: Delete

*Date	*Dose	Route	Site	BodySide	Delete
Select Date	Select UoM	Select Route	Select Site	Select Body Side	
<input type="checkbox"/> Not Available	<input type="checkbox"/> Not Available	<input type="checkbox"/> Show More Routes	<input type="checkbox"/> Show More Sites		

Instructions:

- SELECT when rows need to be deleted.

E13: “Add More” button

--

Instructions:

- By default three rows are provided to enter each individual vaccine administration. If additional rows are needed to enter additional vaccine administrations, click the “Add More” button to add a new row.

Required Field to Save EAE: No

Required Field to Submit EAE: No

E14: Distributed by DAIDS

Distributed by DAIDS: Yes No

Instructions:

- SELECT whether the study vaccine was distributed by DAIDS.

Example:

- SELECT Distributed by DAIDS:
 - E14.a Yes
 - E14.b No

Required Field to Save EAE: No

Required Field to Submit EAE: No



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E15: Manufacturer

*Manufacturer:

Instructions:

This field is active and required only when the value in E14 is "No".

- SELECT the study vaccine Manufacturer.
- The Manufacturers listed in the drop-down menu are abstracted from another DAIDS-ES application. If the correct option is not available: SELECT "Other" and TYPE the full name of the Manufacturer as FREE TEXT.

Example:

- SELECT Manufacturer:
 - E15.a BioWhittaker, Inc.
 - E15.b Cambrex Corp
 - E15.c Other (max 100 characters).
 - E15.d Unknown

Required Field to Save EAE: Yes (If E14 is "No")

Required Field to Submit EAE: Yes (If E14 is "No")

E16: Distributor

Distributor:

Instructions:

This field is active only when the value in E15 is "Unknown".

- TYPE name of Distributer of study vaccine when the study vaccine is not distributed by DAIDS.

Example:

- FREE TEXT (max 100 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then CLICK the **NEW** button to enter information on the next study vaccine by repeating steps E1 to E14.*

*CLICK **SAVE** and go to the next section after entering information on all study vaccines.*



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OPTION 3: STUDY PROCEDURES

Click on a data field in the screen below to jump to a detailed description.



Adverse Experience Reporting
DIVISION OF AIDS

Study Procedures

NIAID CRMS | Help | Logout
Welcome
Login Time:
No. of unsuccessful login attempts: 0

EAE Search Person EAE Notification Recipients Validation Mode RSC

EAE Sections

Reporter and Site Information
Participant Information
Primary Adverse Event
Study Procedures
Co-enrollment Information
Concomitant Medications
Other Events
Laboratory Tests
Diagnostic Tests
Additional Information

EAE Submission

View EAE Report (PDF)
Completion Check
Submit EAE Report

EAE Number:
Report Type:
Reporting Category:
Reporting Manual:

Participant ID:
Site ID:
Submission Due Date:

Protocol Number:
Protocol Version:

*Study Procedure:

Relationship to Primary AE: Select Relationship to Primary AE

Study Arm/Group:

Date of Procedure: Select Date

Comments:

Remaining Characters: 300

Save New Delete Restore

Study Procedure	Relationship to Primary AE	Study Arm/Group	Date of Procedure
-----------------	----------------------------	-----------------	-------------------

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 DAERS Site Users Instructional
 Guide for EAE Reporting
 Version 2.0 – December 2022

E1: Study Procedure

*Study Procedure:



Instructions:

- SMART text: TYPE the Study Procedure or hit the space bar for the system to display the list of Protocol-specific EAE reportable Study Procedures in the drop down menu. SELECT the correct option for the Study Procedure.
- FREE TEXT is NOT accepted for this field.

Example:

- SELECT the Study Procedure:
 - E1.TDS EP Device
 - E2. IV Ring

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

E2: Relationship to Primary AE

Relationship to Primary AE: Select Relationship to Primary AE ▼

Instructions:

- SELECT the Relationship between the Primary AE and study procedure.

Example:

- SELECT Relationship to Primary AE:
 - E2.a Related
 - E2.b Not Related

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes



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E3: Study Arm/Group

Study Arm/Group:

Instructions:

- TYPE Study Arm/Group to which the Participant is randomized in the study.


Example:

- FREE TEXT (max 30 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

E4: Date of Procedure

Date of Procedure: 

Instructions:

- TYPE or SELECT using the calendar icon, the date of the procedure.

Example:

- Date: DD-MM-YYYY

Required Field to Save EAE: No

Required Field to Submit EAE: No

E5: Comments

Comments:

Remaining Characters: 300

Instructions:

- TYPE any additional information about study agent/product.

Example:

- FREE TEXT (max 300 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then CLICK the **NEW** button to enter information on the next study procedure by repeating steps E1 to E5.*

*CLICK **SAVE** and go to the next section after entering information on all study procedures.*



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F. Co-Enrollment Information

Introduction

The Co-Enrollment Information screen is the sixth screen displayed when reporting an EAE via DAERS. In this screen, the user will enter co-enrollment information specific to the Participant who experienced the EAE. This screen is used to indicate whether the Participant was enrolled in more than one study, even if the other study does not require expedited reporting.

Click on a data field in the screen below to jump to a detailed description.

The screenshot displays the DAERS Co-enrollment Information screen. The top navigation bar includes 'DAIDS-ES | Help | Logoff' and a 'Welcome' message with login details. The main header shows 'Co-enrollment Information'. The left sidebar contains 'EAE Sections' (Reporter and Site Information, Participant Information, Primary Adverse Event, Study Agents, Co-enrollment Information, Concomitant Medications, Other Events, Laboratory Tests, Diagnostic Tests, Additional Information) and 'EAE Submission' (View EAE Report (PDF), Completion Check, Submit EAE Report). The main content area has a header with 'EAE Number: Report Type: Reporting Category: Reporting Manual:', 'Participant ID: Site ID: Submission Due Date:', and 'Protocol Number: Protocol Version:'. Below this is an 'Important:' section with bullet points: 'Check the co-enrolled protocol(s) for EAE reporting requirements.', 'You MUST submit a separate EAE report for each co-enrolled protocol in which the event is reportable.', and 'For questions regarding EAE reporting requirements, contact the RSC (RSCSafetyOffice@tech-res.com).'. A question follows: '*Was the participant enrolled in another DAIDS protocol at the time of Primary AE?' with 'Yes' and 'No' radio buttons. Below this is a 'Co-enrolled Protocol Number' field with a search icon, a 'Network/Non-Network' dropdown set to 'Network/Non-Network', and a 'Comments' text area. At the bottom of the form are 'Save', 'New', 'Delete', and 'Restore' buttons. A table at the bottom has columns 'Co-enrolled Protocol Number', 'Network/Non-Network', and 'Comments'. The footer includes 'Privacy Notice' and 'Legal Disclaimer' links.



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F1: Was the participant enrolled in another DAIDS protocol at the time of Primary AE?

*Was the participant enrolled in another DAIDS protocol at the time of Primary AE? ☒ Yes ☐ No

Instructions:

- SELECT whether the Participant was enrolled in another DAIDS Protocol at the time of onset of the Primary AE.
- Check the co-enrolled protocol(s) for EAE reporting requirements.
- Separate EAE report(s) must be submitted for each co-enrolled protocol if the event meets the reporting requirements.

Example:

- SELECT Was the participant enrolled in another DAIDS protocol at time of Primary AE:
 - F1.a Yes
 - F1.b No

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

F2: Co-enrolled Protocol Number

Co-enrolled Protocol Number:

Instructions:

This field is required only when the value in F1 is "Yes".

- SMART TEXT: TYPE first digits of the Protocol Number in which the Participant was Co-enrolled at time of onset of Primary AE. DAIDS Protocols will auto-populate.

Example:

- Co-enrolled Protocol Number: A1000 (max 30 characters)

Required Field to Save EAE: Yes (If F1 is "Yes")

Required Field to Submit EAE: Yes (If F1 is "Yes")

F3: Network/Non-Network

Network/Non-Network: Network/Non-Network

Instructions:

- Auto-populated after completion of F2 [Co-enrolled Protocol Number].

Example:

- Network: ACTG

Required Field to Save EAE: No

Required Field to Submit EAE: No



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F4: Comments

Comments:

Remaining Characters: 500

Instructions:

- TYPE any additional information related to co-enrollment for this Participant.

Example:

- FREE TEXT (max 500 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and go to the next section after entering all co-enrollment information.*



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G. Concomitant Medication

Introduction

The Concomitant Medication screen is the seventh screen displayed when reporting an EAE via DAERS. In this screen, the user will enter information on the concomitant medication taken by the Participant at the time of onset of the EAE.

Click on a data field in the screen below to jump to a detailed description.

DAIDS-ES | Help | Logoff

Welcome
Last successful login: Nov 01, 2013 03:05 PM
No. of unsuccessful login attempts: 0

Concomitant Medications

EAE Sections

- Reporter and Site Information
- Participant Information
- Primary Adverse Event
- Study Agents
- Co-enrollment Information
- Concomitant Medications**
- Other Events
- Laboratory Tests
- Diagnostic Tests
- Additional Information

EAE Submission

- View EAE Report (PDF)
- Completion Check
- Submit EAE Report

EAE Number: Report Type: Participant ID: Site ID: Protocol Number: Protocol Version:
Reporting Category: Reporting Manual: Submission Due Date:

If there were any concomitant medications that may have contributed to the primary adverse event, the details should be entered below. Any additional concomitant medications being taken at the onset of the primary adverse event should be faxed, e-mailed, or attached to this report using the Additional Information screen.

*Check All that apply: ☐ None ☐ Entered below ☐ Uploaded in DAERS ☐ Faxed to RSC ☐ E-mailed to RSC

Medication:

Approximate Duration of Use: Select Duration UoM

Date of Last Dose: Select Date

Indication:

Contributory to AE: ☒ Yes ☐ No ☐ Unknown

Route of Administration: Select Route of Administration

Schedule of Administration: Select Schedule of Administration

Comments:

Remaining Characters: 500

Save New Delete Restore

Medication	Duration	Date of Last Dose	Indication	Comments
------------	----------	-------------------	------------	----------



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G1: How Concomitant Medication Information is Being Recorded (Check all that apply)

*Check All that apply: ☐ None ☐ Entered below ☐ Uploaded in DAERS ☐ Faxed to RSC ☐ E-mailed to RSC

Instructions:

- SELECT how concomitant medication is being recorded in DAERS.
- Multiple options can be selected in this section (i.e., some Concomitant Medications can be entered in the section, while the remaining list can be uploaded in DAERS in Section K).

Example:

- SELECT How Concomitant Medication Information is Being Recorded in DAERS
(Check all that apply):
 - G1.a. None
 - G1.b Entered Below
 - G1.c Uploaded in DAERS
 - G1.d Faxed to RSC
 - G1.e E-mailed to RSC

Required Field to Save EAE: Yes (If "Uploaded in DAERS", "Faxed to RSC", or "E-mailed to RSC" in G1: "Yes" is selected in K)

Required Field to Submit EAE: Yes (If "Uploaded in DAERS", "Faxed to RSC", or "E-mailed to RSC" in G1: "Yes" is selected in K)

G2: Medication

Medication:

Instructions:

This field is active and required only when the value in G1 is "Entered Below".

- TYPE the name of concomitant medication(s) the Participant was using at the time of onset of Primary AE.

Example:

- Medication: Cotrimoxazole (max 50 characters)

Required Field to Save EAE: Yes (If G1 is "Entered Below")

Required Field to Submit EAE: Yes (If G1 is "Entered Below")



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G3: Approximate Duration of Use

Approximate Duration of Use:

Instructions:

- TYPE Approximate Duration of Use of concomitant medication, using selected UoM, before onset of Primary AE.
- Only becomes an active field if “Entered Below” is selected in G1.

Example:

- Approximate Duration of Use: Two (max 5 characters)
- SELECT Duration UoM:
 - G3.a Time(s)
 - G3.b Hour(s)
 - G3.c Day(s)

Required Field to Save EAE: No

Required Field to Submit EAE: No

G4: Date of Last Dose

Date of Last Dose:

Instructions:

- TYPE or SELECT using the calendar icon, the date the last dose was taken by the Participant before the onset of the Primary AE.
- Only becomes an active field if “Entered Below” is selected in G1 [How Concomitant Medication Information is Being Recorded].

Example:

- Date of Last Dose: DD-MM-YYYY

Required Field to Save EAE: No

Required Field to Submit EAE: No

G5: Indication

Indication:

Instructions:

- TYPE reason for taking the concomitant medication.
- Only becomes an active field if “Entered Below” is selected in G1 [How Concomitant Medication Information is Being Recorded].

Example:

- FREE TEXT (max 250 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No



G6: Contributory to AE

Contributory to AE: ☐ Yes ☐ No ☐ Unknown

Instructions:

- SELECT whether the concomitant medication may have contributed to the Primary AE.
- Only becomes an active field if “Entered Below” is selected in G1 [How Concomitant Medication Information is Being Recorded].

Example:

- SELECT Contributory to AE:
 - G6.a Yes
 - G6.b No
 - G6.c Unknown

Required Field to Save EAE: No

Required Field to Submit EAE: No

G7: Route of Administration

Route of Administration:

Instructions:

- SELECT how the concomitant medication was administered to the Participant.
- Only becomes an active field if “Entered Below” is selected in G1 [How Concomitant Medication Information is Being Recorded].

Example:

- SELECT Route of Administration:
 - G7.a Auricular (Otic)
 - G7.b Buccal
 - G7.c Conjunctival

Required Field to Save EAE: No

Required Field to Submit EAE: No

G8: Schedule of Administration

Schedule of Administration:

Instructions:

- SELECT Schedule of Administration of concomitant medication, including frequency and UoM.
- Only becomes an active field if “Entered Below” is selected in G1 [How Concomitant Medication Information is Being Recorded].

Example:

- SELECT Schedule of Administration:
 - G8.a Twice a day (BID)
 - G8.b Continuous
 - G8.c Five times a day

Required Field to Save EAE: No

Required Field to Submit EAE: No




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G9: Comments

Comments: 

Remaining Characters: 500

Instructions:

- TYPE any notes/comments related to the concomitant medication.
- Only becomes an active field if “Entered Below” is selected in G1 [How Concomitant Medication Information is Being Recorded].

Example:

- FREE TEXT (max 500 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then CLICK the **NEW** button to enter information on additional concomitant medications by repeating steps G1 to G9.*

*CLICK **SAVE** and go to the next section after entering information on all concomitant medications.*



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H. Other Events

Introduction

The Other Events screen is the eighth screen displayed when reporting an EAE via DAERS. In this screen, the user will enter information on the clinically significant AEs (signs/symptoms) experienced by the Participant that are associated with the Primary AE.

Click on a data field in the screen below to jump to a detailed description.

Adverse Experience Reporting
DIVISION OF AIDS

DAIDS-ES | Help | Logoff

Welcome
Last successful login: Nov 01, 2013 03:05 PM
No. of unsuccessful login attempts: 0

Other Events

EAE Sections

- Reporter and Site Information
- Participant Information
- Primary Adverse Event
- Study Agents
- Co-enrollment Information
- Concomitant Medications
- Other Events**
- Laboratory Tests
- Diagnostic Tests
- Additional Information

EAE Submission

- View EAE Report (PDF)
- Completion Check
- Submit EAE Report

EAE Number: Participant ID: Protocol Number:
Report Type: Site ID: Protocol Version:
Reporting Category: Submission Due Date:
Reporting Manual:

*Are there any other clinically significant events associated with the Primary AE? ☒ Yes ☐ No

*Event Description:

Severity Grade:

Onset Date: ☐ Estimated?

Comments:

Remaining Characters: 500

Save New Delete Restore

Event Description	Severity Grade	Onset Date	Comments
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H1: Are there any other clinically significant events associated with the Primary AE?

*Are there any other clinically significant events associated with the Primary AE? ☒ Yes ☐ No

Instructions:

- SELECT whether there are other clinically significant events associated with Primary AE.

Example:

- SELECT Are there any other clinically significant events associated with Primary AE:
 - H1.a Yes
 - H1.b No

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

H2: Event Description

*Event Description:

Instructions:

This field is active and required only when the value in H1 is "Yes".

- TYPE description of any clinical event(s) associated with Primary AE.

Example:

- FREE TEXT (max 100 characters)

Required Field to Save EAE: Yes (If H1 is "Yes")

Required Field to Submit EAE: Yes (If H1 is "Yes")

H3: Severity Grade

Severity Grade:

Instructions:

- SELECT Participant's Severity Grade based on the DAIDS AE Grading Table or the grading table specified in the Protocol.
- Severity Grade must be lower than or equal to the Severity Grade entered in D4 [Severity Grade].
- Only becomes an active field if H2 [Event Description] is populated.

Example:

- SELECT Severity Grade:
 - H3.a 1-Mild
 - H3.b 2-Moderate
 - H3.c 3-Severe
 - H3.d 4-Life-Threatening
 - H3.e 5-Death

Required Field to Save EAE: No

Required Field to Submit EAE: No




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H4: Onset Date

Onset Date:  ☐ Estimated?

Instructions:

- TYPE or SELECT using the calendar icon, the date of onset of the clinically significant event associated with Primary AE.
- CHECK the “Estimated” box if not sure of the exact onset date of the clinically significant event associated with Primary AE.
- Only becomes an active field if H2 [Event Description] is populated.

Example:

- Onset Date: DD-MM-YYYY

Required Field to Save EAE: No

Required Field to Submit EAE: No

H5: Comments

Comments:

Remaining Characters: 500

Instructions:

- TYPE additional information on the clinically significant associated event.
- Only becomes an active field if H2 [Event Description] is populated.

Example:

- FREE TEXT (max 500 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then CLICK the **NEW** button to enter information on additional Other Events by repeating steps H1 to H5.*

*CLICK **SAVE** and go to the next section after entering information on all Other Events.*



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I1: How Laboratory Test Information is Being Recorded (Check all that apply)

*Check All that apply: ☐ None ☐ Entered below ☐ Uploaded in DAERS ☐ Faxed to RSC ☐ E-mailed to RSC

Instructions:

- SELECT How the Laboratory Test Information is Being Recorded in DAERS.
- Multiple options can be selected in this section (i.e., some laboratory tests can be entered in the section while the remaining tests can be uploaded in DAERS in Section K).


Example:

- SELECT How Laboratory Test Information is Being Recorded (Check all that apply):
 - I1.a None
 - I1.b Entered Below
 - I1.c Uploaded in DAERS
 - I1.d Faxed to RSC
 - I1.e E-mailed to RSC

Required Field to Save EAE: Yes (If "Uploaded in DAERS", "Faxed to RSC", or "E-mailed to RSC" in I1: "Yes" is selected in K)

Required Field to Submit EAE: Yes (If "Uploaded in DAERS", "Faxed to RSC", or "E-mailed to RSC" in I1: "Yes" is selected in K)

I2: Test Name

Test Name 	Collection Date	Test Value and Reference Range	Infectious Agent	Body Site	Delete 
<input type="text"/>					

Instructions:

This field is active and required only when the value in I1 is "Entered Below".

- SMART TEXT: TYPE the first few letters of the name of the relevant laboratory test performed on the Participant and SELECT an option from the drop down menu. If the laboratory test performed is not displayed as an available option, TYPE the laboratory test, and FREE TEXT (max 300 characters) will be accepted for this field.

Example:

- SELECT Test Name:
 - I2.a Absolute lymphocyte count
 - I2.b Albumin, Fluid
 - I2.c Albumin, Serum

Required Field to Save EAE: Yes (If I1 is "Entered Below")

Required Field to Submit EAE: Yes (If I1 is "Entered Below")





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I3: Collection Date

Test Name 	Collection Date	Test Value and Reference Range	Infectious Agent	Body Site	Delete 
<input type="text"/>					

Instructions:

This field is active and required only when I2 is populated.

- TYPE or SELECT using the calendar icon, the date the specimen was collected.
- If not sure: SELECT the value "Estimated"; if pending: SELECT the value "Pending".



Example:

- Collection Date: MM-DD-YYYY

Required Field to Save EAE: Yes (If I2 is completed)

Required Field to Submit EAE: Yes (If I2 is completed)

I4: Test Value and Reference Range

Test Name 	Collection Date	Test Value and Reference Range	Infectious Agent	Body Site	Delete 
<input type="text"/>					

Instructions:

This field is active and required only when I3 does not contain "Pending".

- TYPE Test Value and Reference Range, for each laboratory test performed on the Participant.
- SELECT Unit of Measurement.

Example:

- FREE TEXT (max 15 characters each for Test Value, Reference Range 1 and Reference Range 2)
- SELECT Test Value Unit of Measurement:
 - I4.a 1000/mm3
 - I4.b 1000/uL
 - I4.c #/hpf

Required Field to Save EAE: Yes (If I3 does not contain "Pending")

Required Field to Submit EAE: Yes (If I3 does not contain "Pending")



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I5: Infectious Agent

Test Name 	Collection Date	Test Value and Reference Range	Infectious Agent	Body Site	Delete
<input type="text"/>					

Instructions:

- SMART TEXT: TYPE the first letters of the name of the organism that caused the infectious disease; certain values will auto-populate.
- If the required Infectious Agent is not auto-populated: This field will accept FREE TEXT (max 100 characters).
- Only becomes an active field if the test entered or selected in I2 [Test Name] was performed to confirm an infection. This will enable the user to enter the organism that caused the infection.

Example:

- SELECT Infectious Agent:
 - I5.a Actinomycosis
 - I5.b Adenovirus
 - I5.c Amebiasis

Required Field to Save EAE: No

Required Field to Submit EAE: No

I6: Body Site

Test Name 	Collection Date	Test Value and Reference Range	Infectious Agent	Body Site	Delete
<input type="text"/>					

Instructions:

- SMART TEXT: TYPE the first letters of area of the body from which laboratory specimen was obtained; certain values will auto-populate.
- If the required Body Site is not auto-populated: This field will accept FREE TEXT (max 50 characters).
- Only becomes an active field if the test entered or selected in I2 [Test Name] was performed to confirm an infection. This will enable the user to enter the area of the body from where the laboratory specimen was obtained.

Example:

- SELECT Body Site:
 - I6.a Blood
 - I6.b Brain
 - I6.c Bronchi

Required Field to Save EAE: No

Required Field to Submit EAE: No



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I7: Delete

Test Name 	Collection Date	Test Value and Reference Range	Infectious Agent	Body Site	Delete
<input type="text" value=""/>					

Instructions:

- SELECT when rows need to be deleted.

I8: Add more Tests

 Add More Tests:

Instructions:

- SELECT when additional rows need to be added.

Required Field to Save EAE: No

Required Field to Submit EAE: No

I9: Comments

Comments:

Remaining Characters: 500

Instructions:

- TYPE additional information on all relevant laboratory tests performed on the Participant.

Example:

- FREE TEXT (max 500 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

CLICK *SAVE* and go to the next section after entering information on all Laboratory Tests.



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J. Diagnostic Tests

Introduction

The Diagnostic Tests screen is the tenth screen displayed when reporting an EAE via DAERS. In this screen, the user will enter information on all the significant diagnostic tests performed on the Participant related to the Primary AE.

Click on a data field in the screen below to jump to a detailed description.

Adverse Experience Reporting
DIVISION OF AIDS

DAIDS-ES | Help | Logoff

Welcome
Last successful login: Nov 01, 2013 03:05 PM
No. of unsuccessful login attempts: 0

Diagnostic Tests

EAE Sections

Reporter and Site Information

Participant Information

Primary Adverse Event

Study Agents

Co-enrollment Information

Concomitant Medications

Other Events

Laboratory Tests

Diagnostic Tests

Additional Information

EAE Submission

View EAE Report (PDF)

Completion Check

Submit EAE Report

EAE Number: Report Type: Participant ID: Site ID: Protocol Number: Protocol Version:

Reporting Category: Submission Due Date: Reporting Manual:

If there were any diagnostic tests relevant to the primary adverse event, the details of the diagnostic tests should be entered below. Any additional diagnostic test details should be faxed, e-mailed or attached to this report on the Additional Information screen.

*Check All that Apply: ☐ None ☐ Entered below ☐ Uploaded in DAERS ☐ Faxed to RSC ☐ E-mailed to RSC

Test Name:

Body Area:

Test Date: ☐ Estimated ☐ Results Pending

Result/Comments:

Remaining Characters: 500

Test Name	Body Area	Test Date	Estimated?	Test Result
-----------	-----------	-----------	------------	-------------

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J1: How Diagnostic Test Information is Being Recorded (Check all that apply)

***Check All that Apply:** ☐ None ☐ Entered below ☐ Uploaded in DAERS ☐ Faxed to RSC ☐ E-mailed to RSC

Instructions:

- SELECT How Diagnostic Test Information is Being Recorded in DAERS.
- Multiple options can be selected in this section (i.e., some diagnostic tests can be entered in the section while the remaining tests can be uploaded in DAERS in Section K).

Example:

- SELECT How Diagnostic Test Information is Being Recorded in DAERS (Check all that apply):
 - J1.a None
 - J1.b Entered Below
 - J1.c Uploaded in DAERS
 - J1.d Faxed to RSC
 - J1.e E-mailed to RSC

Required Field to Save EAE: Yes (If "Uploaded in DAERS", "Faxed to RSC", or "E-mailed to RSC" in J1: "Yes" is selected in K)

Required Field to Submit EAE: Yes (If "Uploaded in DAERS", "Faxed to RSC", or "E-mailed to RSC" in J1: "Yes" is selected in K)

J2: Test Name

Test Name:

Instructions:

This field is active and required only when the value in J1 is "Entered Below".

- SMART TEXT: TYPE the first few letters of the name of the relevant diagnostic test performed on the Participant; certain values will auto-populate.
- If the required diagnostic Test Name is not auto-populated: This field will accept FREE TEXT (max 250 characters).

Example:

- SELECT Test Name:
 - J2.a Amniocentesis
 - J2.b Anoscopy
 - J2.c Arteriography/Angiography

Required Field to Save EAE: Yes (If J1 is "Entered Below")

Required Field to Submit EAE: Yes (If J1 is "Entered Below")

J3: Body Area

Body Area:

Instructions:

- SMART TEXT: TYPE the first letters of area of the body where diagnostic test was conducted; certain values will auto-populate.
- If the required Body Area is not auto-populated: This field will accept FREE TEXT (max 30 characters).
- Only becomes an active field if a test name is entered or selected in J2.



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Example:

- SELECT Body Area:
 - J3.a Abdomen
 - J3.b Adrenal
 - J3.c Aorta

Required Field to Save EAE: No

Required Field to Submit EAE: No

J4: Test Date

Test Date:  ☐ Estimated ☐ Results Pending

Instructions:

This field is active and required only when J2 is populated.

- TYPE or SELECT using the calendar icon, the date the diagnostic test was performed.
- If not sure: SELECT "Estimated"; if pending: SELECT "Results Pending".

Example:

- Test Date: MM-DD-YYYY

Required Field to Save EAE: Yes (If J2 is completed)

Required Field to Submit EAE: Yes (If J2 is completed)

J5: Result/Comments

Result/Comments:

Remaining Characters: 500

Instructions:

This field is active and required only when J4 does not contain "Results Pending".

- TYPE additional information, such as the result of the relevant diagnostic test performed on the Participant.

Example:

- FREE TEXT (max 500 characters)

Required Field to Save EAE: Yes (If J4 does not contain "Results Pending")

Required Field to Submit EAE: Yes (If J4 does not contain "Results Pending")

*CLICK **SAVE** and then CLICK the **NEW** button to enter information on additional diagnostic tests by repeating steps J1 to J5.*

*CLICK **SAVE** and go to the next section after entering information on all diagnostic tests.*



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K. Additional Information

Introduction

The Additional Information screen is the eleventh screen displayed when reporting an EAE via DAERS. In this screen, the user will either upload additional documents (i.e., hospital progress notes, laboratory/diagnostic test results, discharge summary etc.) relevant to the Primary AE or notify the DAIDS RSC Safety Office if the information will be faxed or emailed.

DAIDS-ES | Help | Logoff

Adverse Experience Reporting
DIVISION OF AIDS

Additional Information

Welcome
Last successful login: Nov 01, 2013 03:05 PM
No. of unsuccessful login attempts: 0

EAE Sections

- Reporter and Site Information
- Participant Information
- Primary Adverse Event
- Study Agents
- Co-enrollment Information
- Concomitant Medications
- Other Events
- Laboratory Tests
- Diagnostic Tests
- Additional Information**

EAE Submission

- View EAE Report (PDF)
- Completion Check
- Submit EAE Report

EAE Number: **Participant ID:** **Protocol Number:**
Report Type: **Site ID:** **Protocol Version:**
Reporting Category: **Submission Due Date:** **Reporting Manual:**

*Is there any additional information or supporting documentation for this Adverse Event? ☒ Yes ☐ No

*Associated EAE Section:

Do you want to upload, fax, and/or e-mail this document? ☐ Upload ☐ Fax ☐ E-mail

Attach Document:

Document Type:

Date Sent to RSC: ☐ Estimated?

Document Details:

Remaining Characters: 500

Associated EAE Section **Upload** **Fax** **E-mail** **Document Type** **Document Details** **Date Sent to RSC**

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K1: Is there any additional information or supporting documentation for this Adverse Event?

*Is there any additional information or supporting documentation for this Adverse Event? ☒ Yes ☐ No

Instructions:

- SELECT whether there is any additional information or supporting documentation to support the Primary AE.

Example:

- SELECT Is there any additional information or supporting documentation for this Adverse Event:
 - K1.a Yes
 - K1.b No

Required Field to Save EAE: Yes

Required Field to Submit EAE: Yes

K2: Associated EAE Section

*Associated EAE Section:

Instructions:

This field is active and required only when the value in K1 is "Yes".

- SELECT the section of the EAE Report for which the additional information or supporting documentation is being provided.

Example:

- SELECT Associated EAE section:
 - K2.a Primary Adverse Event
 - K2.b Concomitant Medications
 - K2.c Laboratory Tests
 - K2.d Diagnostic Tests

Required Field to Save EAE: Yes (If K1 is "Yes")

Required Field to Submit EAE: Yes (If K1 is "Yes")

K3: Do you want to upload, fax, and/or email this document?

Do you want to upload, fax, and/or e-mail this document? ☐ Upload ☐ Fax ☐ E-mail

Instructions:

This field is required only when K2 is populated.

- SELECT how additional information or supporting documentation is being provided to the DAIDS RSC Safety Office.

Example:

- SELECT how additional information or supporting documentation is being provided:
 - K3.a Upload
 - K3.b Fax
 - K3.c Email

Required Field to Save EAE: Yes (If K2 is completed)

Required Field to Submit EAE: Yes (If K2 is completed)



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K4: Attach Document

Attach Document:

Instructions:

This field is active and required only when the value in K3 is "Upload".

- BROWSE to choose document to be uploaded as additional information or supporting documentation.
- If any personal identifiable information is included in additional information or supporting documentation: Remove and confirm by selecting the required box below the field.

Example:

- BROWSE to choose document to be uploaded for EAE Report.

Required Field to Save EAE: Yes (If K3 is "Upload")

Required Field to Submit EAE: Yes (If K3 is "Upload")

K5: Document Type

Document Type:

Instructions:

This field is required only when K2 is populated.

- SELECT type of additional information or supporting documentation being provided.

Example:

- SELECT type of additional information or supporting documentation being provided:
 - K5.a AE Report
 - K5.b Autopsy Report
 - K5.c Concomitant Medications
 - K5.d Diagnostic Imaging
 - K5.e Discharge Summary
 - K5.f Laboratory Reports
 - K5.g Pathology Reports
 - K5.h Progress Notes
 - K5.i Radiology Reports
 - K5.j Others (max 50 characters)

Required Field to Save EAE: Yes (If K2 is completed)

Required Field to Submit EAE: Yes (If K2 is completed)




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K6: Date Sent to RSC

Date Sent to RSC:  ☐ Estimated?

Instructions:

This field is active and required only when the value in K3 is "Fax" or "E-mail".

- TYPE or SELECT using the calendar icon, the date that additional information or supporting documentation was sent to the DAIDS RSC Safety Office.
- SELECT "Estimated" if not sure of the Date Sent to RSC.


Example:

- Date Sent to RSC: DD-MM-YYYY

Required Field to Save EAE: Yes (If K3 is "Fax" or "E-mail")

Required Field to Submit EAE: Yes (If K3 is "Fax" or "E-mail")

K7: Document Details

Document Details: 

Remaining Characters: 500

Instructions:

- TYPE any notes or comments regarding the additional information or supporting documentation.

Example:

- FREE TEXT (max 500 characters)

Required Field to Save EAE: No

Required Field to Submit EAE: No

*CLICK **SAVE** and then CLICK the **NEW** button to enter information on additional documents by repeating steps K1 to K7.*

*CLICK **SAVE** and go to Completion Check after entering information on all additional documents. You can also navigate to any other previously completed section to edit/add information by clicking on the desired section from the top left screen menu.*



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