

CXCA Notifiable Adverse Event Reporting Data Entry Guide

Introduction

In FY24 Q2, Cervical Cancer Notifiable Adverse Event Reports (CXCA_NAE) data entry was made available in DATIM. All CXCA Notifiable Adverse Events are entered, tracked, and submitted in DATIM’s Tracker Capture App.

Access for DATIM Users

DATIM users will need access to the CXAE Data Stream to View and/or Enter CXCA_NAE data. As a note, CXCA_NAE Data is labeled “CXAE” in the DATIM User Administration App because of character length limitations – CXAE stands for Cervical Cancer Adverse Events.

DATIM User Type	Default CXCA_NAE Access	Possible CXCA_NAE Data Stream Access
Global User Administrator	CXAE Enter	CXAE Enter
Global	None	CXAE Enter, CXAE View, None
Global Agency User Administrator	CXAE View	CXAE View
Global Agency	None	CXAE View, None
Global Partner User Administrator	CXAE View	CXAE View
Global Partner	None	CXAE View, None
OU Interagency User Administrator	CXAE View	CXAE View
OU Interagency	None	CXAE View, None
OU Agency User Administrator	CXAE Enter	CXAE Enter
OU Agency	None	CXAE Enter, CXAE View, None
OU Partner User Administrator	CXAE Enter	CXAE Enter
OU Partner	None	CXAE Enter, CXAE View, None
MOH User Administrator, MOH	None	None

If a DATIM user does NOT see the CXCA_NAE reporting option in the Tracker Capture App dropdown menu, they will need to contact their DATIM User Administrator via <https://register.datim.org/> and request “CXAE Enter Data Access”.

Justification for request *

Requesting CXCA data entry access.

Data Entry

Cervical Cancer Notifiable Adverse Event (CXCA_NAE) reporting data entry can be found in the DATIM **Tracker Capture App**.



Access an existing CXCA_NAE Report

To look up an existing CXCA_NAE Report:

1. Navigate to the DATIM Tracker Capture App.
2. Select an Operating Unit (OU) on the left side.
3. Select CXCA Notifiable Adverse Events Tracker from the dropdown.
4. Then use the “Search” button to search the CXCA_NAE Unique ID.

A screenshot of the application interface. At the top, there is a breadcrumb trail: 'CXCA Notifiable Adverse Events Tracker' with a close button (x) and a dropdown arrow. To the right are 'Lists', 'Search', and 'Register' buttons. Below this is a search bar with the placeholder text 'Search for cxca adverse event'. Underneath the search bar is a text input field labeled 'CXCA_NAE Unique ID' with a search icon (magnifying glass) to its right.

Creating a new CXCA_NAE Report

1. Navigate to the Tracker Capture App in DATIM.
2. Once the Tracker Capture App loads, select the appropriate OU name from the organizational hierarchy “tree” on the left side.
 - Global Accounts may need to expand the OU tree using the small + buttons to the left (example in below screenshot).
3. Then select “CXCA Notifiable Adverse Events Tracker” from the drop down in the middle of the page.
 - Note: It is “selected” when it is highlighted orange.
4. Click “Register” to start a new adverse event report.

A screenshot of the application interface. On the left is a navigation menu with 'Registration and Data Entry' and 'Reports'. Under 'Reports', there is a tree view with 'Global' expanded, showing sub-items: 'Africa', 'Americas', 'Asia', and 'Europe'. A red box highlights this tree, with a '2.' next to it. In the center, a dropdown menu is open, showing 'CXCA Notifiable Adverse Events Tracker' selected and highlighted in orange. Other items include 'Evaluation SOP', 'Surveys, Surveillance, and Research Tracking', and 'VMC Notifiable Adverse Events Tracker'. A red box highlights this dropdown, with a '3.' next to it. On the right, there are 'Lists', 'Search', and 'Register' buttons. A red box highlights the 'Register' button, with a '4.' next to it.

5. Next, you’ll be taken to the “Enrollment and Profile” screen. Once the “Enrollment” page loads, enter the date of the CXCA procedure.
 - The **Date of CXCA Procedure** defaults to the date it is first "registered" (the calendar date when first entering the report).

A screenshot of the application interface. At the top, there is a breadcrumb trail: 'CXCA Notifiable Adverse Events Tracker' with a close button (x) and a dropdown arrow. To the right are 'Lists', 'Search', and 'Register' buttons. Below this is the title 'Enrollment'. Underneath is a form with two fields: 'Enrolling organisation unit' with the value 'Botswana' and 'Date of CXCA Procedure' with the value '2024-01-16'. A red box highlights the 'Date of CXCA Procedure' field, with a '5.' next to it.

6. Under "Profile" please enter basic information to initiate the report:

- PEPFAR Funding Agency
- Implementing Partner (IP) Name
- IP Point of contact
- Facility where the Procedure was performed
- Facility Type
- Client age (at time/date of procedure)
- Precancerous Lesion Treatment Method

7. Click "Save and Continue" to begin data entry.

*The "Unique ID" is automatically generated by the system and should be used to later reference the report you are creating. You will want to note this ID for future reference, as other identifying characteristics will not be visible for searching later.

6. Profile

Completed by Implementing Partner
INSTRUCTIONS: The Implementing Partner (IP) must complete Enrollment the same day they become aware of an NAE by responding to all the questions below. Once complete, the IP should notify their In-Country Agency CXCA Lead via email.

* Unique ID 2024-01-16_BWA_daqim

Basic information	
PEPFAR Funding Agency: *	Select or search from the list
Implementing Partner: *	
Additional Implementing Partner:	
IP Point of Contact Email Address(es): *	
Facility where the Procedure was performed *	
Facility Type: *	Select or search from the list

Client Data	
Client Age *	
Precancerous Lesion Treatment Method: *	Select or search from the list

Complete Enrollment	
To complete Enrollment, please click the "Complete" button below. PLEASE NOTE: Clicking "Complete" will automatically notify S/GAC at CXCA_AE@state.gov; if you need to make changes to the data in this section after submission, click the "Edit" button in the Profile widget, make your edits, then please click "Save".	

7. Save and continue Save and add new Print form Cancel

Section A – Case Details

After creating/enrolling a new CXCA_NAE report, the Tracker Capture data entry dashboard will load.

1. **START:** To add a section, Implementing Partners should navigate to the “Timeline Data Entry” section and click the “+” button on the right side of the widget box



2. After clicking the “+” button, a pop-up should appear to “Add a new event stage for Section A – Case Details.”
 - a. The “Program Stage” field should auto-populate with Section A
 - b. Select your current PEPFAR Funding Mechanism from the options.
**Please note, users should select their current funding mechanism, even if the CXCA procedure or device placement date previously occurred under an expired funding mechanism.*
 - c. Today’s date should auto-populate.

A screenshot of a pop-up form titled "1. Add new event for stage Section A – Case Details". The form has three input fields:

- a. Program stage: A dropdown menu with "Section A – Case Details" selected.
- b. Funding Mechanism: A dropdown menu with "Select or search from the list" selected.
- c. Date Section A Initiated: A text input field with "2024-02-17" entered.

At the bottom right of the form, there are two buttons: "Save" (in blue) and "Cancel".

3. Click “Save”, and the Section A data entry fields will load.
4. Enter all required and relevant data.
 - a. Do not include any PII!
 - b. DATIM will automatically save the data you enter as it is being entered. This means you can navigate away from data entry and return to this section later.
5. Once finished with data entry, clicking “Complete” will close the section and automatically submit a notification to GHSD PEPFAR HQ that Section A has been completed.

Section A Quick Tips

- Section A is completed by Implementing Partners (IP)
- Any guidance questions or concerns about the information being requested can be emailed to CXCA-AE@state.gov. Technical issues should be sent to [DATIM Support](#)
- Do not include Personally Identifiable Information (PII), such as client name or initials

Section A – Notifiable Adverse Event Selection

While entering data for Section A, at least one Notifiable Adverse Event (NAE) will have to be selected. It is important to note the timing of the NAE as having occurred DURING or AFTER the client was discharged.

1. **Intraoperative adverse events** (during procedure through to discharge from facility)
2. **Postoperative adverse events** (0-4 weeks post procedure)

What type of NAE is this?

Select whether this was an intraoperative adverse event, postoperative adverse event, or post-operative death with no alternate explanation, and then select the type of NAE from that category. If there was more than one NAE for this client, select "Yes" below and repeat the steps above.

Intraoperative adverse events (during procedure through to discharge from facility)

Postoperative adverse events (0-4 weeks post procedure)

Selected Primary Notifiable Adverse Event that occurred: *

Intraoperative NAEs

Intraoperative NAEs are defined as only occurring during the procedure until the client has been discharged from the facility. After specifying the NAE as "Intraoperative" in DATIM, please then indicate what type of event occurred:

1. Intraoperative or immediate - post procedure bleeding (Class I hemorrhage or greater requiring blood transfusion)
2. Procedure-linked injury to the cervix or uterine body (e.g. cervical amputation/trachelectomy, uterine perforation, thermal injury, or iatrogenic injury beyond expected)
3. Procedure-linked injury to the vaginal wall or bladder (e.g. thermal injury, laceration, or perforation)
4. Procedure-linked injury to the vulva or perineum (e.g. thermal injury or laceration)
5. Intraoperative death

Postoperative NAEs

Postoperative NAEs are defined as occurring after the procedure and the client has been discharged for up to 4 weeks (i.e. 0-4 weeks after procedure occurred).

1. Delayed postoperative/treatment hemorrhage of the cervix, uterus or surrounding pelvic structures (Class I hemorrhage, 1-2 weeks post excisional procedure)
2. Post-operative death with no alternate explanation
3. Posttreatment infection: Fever within two weeks post-procedure, with site-staff measured temperature of > 38 Celsius (> 100.4 Fahrenheit) on non-axillary/oral temperature or non-touch thermal imaging sensors measurement with no alternate explanation (e.g., malaria, other known infective cause) AND evidence of infection (i.e. abscess, purulent drainage, erythema, etc.) of the cervix, vagina, vulva or surrounding tissue on speculum exam:
 1. Signs on per-speculum/pelvic exam (if performed): (key signs from DAIDS FGGT: <https://rsc.niaid.nih.gov/sites/default/files/addendum-1-female-genital-grading-table-v1-nov-2007.pdf> summarized below)
 2. Significant cervical or vaginal edema, abscess, or friability
 3. Significant cervical or vaginal blisters, ulcerations/lesions, or pustules
 4. Evidence of pelvic infection as evidenced by severe abdominal tenderness or pelvic pain

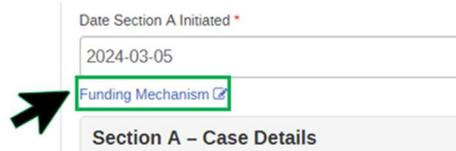
Section B – Notifications

Within 24 hours of receipt of Section A, the In-Country Agency CXCA Lead must notify the PEPFAR Coordinator, and all necessary parties in country as appropriate, and record those notifications in Section B. Reporting in the DATIM Tracker Capture App does not replace Agency or in-country internal reporting requirements and those procedures should be followed in addition to the DATIM report.

To add Section B, Agency users will have to navigate to the “Timeline Data Entry” widget after searching for the CXCA_NAE Unique ID in the Tracker Capture App.



1. Click the “+” button, and a pop-up should appear to “Add a new event stage for Section B – Notifications.”
 - a. The “Program Stage” field should auto-populate with Section B
 - b. Ensure the same PEPFAR “Funding Mechanism” is selected from the dropdown.
 - i. Hint: clicking the “Funding Mechanism” field in the previous section will auto-populate it when generating the next section.



- c. Today’s date should auto-populate.

A screenshot of a pop-up form titled '1. Add new event for stage Section B – Notifications'. It contains three fields:

- a. Program stage: Section B – Notifications
- b. Funding Mechanism: Select or search from the list
- c. Date Section B Initiated: 2024-03-17

At the bottom right, there are 'Save' and 'Cancel' buttons.

2. Click “Save”, and the Section B data entry fields will load.
3. Enter all required and relevant data.
 - a. Do not include any PII!
 - b. DATIM will automatically save the data you enter *as it is being entered*. This means you can navigate away from data entry and return to this section later.
4. Once finished with data entry, clicking “Complete” will close the section and automatically submit a notification to GHSD PEPFAR HQ that Section B has been completed.

Section B Quick Tips

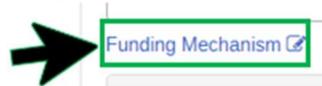
- Section B is completed by the In-Country Agency CXCA Lead
- Any guidance questions or concerns about the information being requested can be emailed to CXCA-AE@state.gov. Technical issues should be sent to [DATIM Support](#).

Section C – Clinical Investigation

To add Section C, the PEPFAR In-Country Incident Lead will have to navigate to the “Timeline Data Entry” widget after searching for the CXCA_NAE Unique ID in the Tracker Capture App.



1. Click the “+” button, and a pop-up should appear to “Add a new event stage for Section C – Clinical Investigation.”
 - a. The “Program Stage” field should auto-populate with Section C.
 - b. Ensure the same PEPFAR “Funding Mechanism” is selected from the dropdown.
 - i. Hint: clicking the “Funding Mechanism” field in the previous section window will auto-populate it when generating the next section.



- c. Today’s date should auto-populate.

A screenshot of a form titled '1. Add new event for stage Section C - Clinical Investigation'. The form has three main sections labeled a, b, and c. Section a: 'Program stage' is a dropdown menu with 'Section C - Clinical Investigation' selected. Section b: 'Funding Mechanism' is a dropdown menu with 'Select or search from the list' displayed. Section c: 'Date Section C Completed' is a text field with '2024-01-17' entered. At the bottom right, there are 'Save' and 'Cancel' buttons.

2. Click “Save”, and the Section C data entry fields will load.
3. Begin entering all required and relevant data.
 - a. Do not include any PII!
 - b. DATIM will automatically save the data you enter *as it is being entered*. This means you can navigate away from data entry and return to this section later.
 - c. Be sure to add investigation updates every two weeks, until the investigation is complete – with all entries dated and entered in chronological order.
4. Once finished with data entry, clicking “Complete” will close the section and automatically submit a notification to GHSD PEPFAR HQ that Section C has been completed.

Section C – Clinical Investigation Quick Tips

- Section C is completed by the PEPFAR In-Country Incident Lead.
- Please add investigation updates every two weeks, until the investigation is complete. Ensure all entries are dated and entered in chronological order wherever possible.
- *Do not include Personally Identifiable Information (PII), such as client name or initials.*
- Attachments can be sent to CXCA-AE@state.gov
- Any guidance questions or concerns about the information being requested can be emailed to CXCA-AE@state.gov.
- Technical issues should be sent to [DATIM Support](#).

Section C - Optional Q & A

This section should be initiated as necessary by the GHSD PEPFAR CXCA Consulting Physician/Clinician, with responses entered by the CXCA In-Country Incident Lead.

If a user loads this section in error, they should utilize the "Delete" button next to the "Print form" button at the bottom of the Data Entry widget.



1. Click the "+" button, and a pop-up should appear to "Add a new event stage for Section C– Optional Q & A."
 - a. The "Program Stage" field should auto-populate with Section C
 - b. Ensure the same PEPFAR "Funding Mechanism" is selected from the dropdown.
 - i. Hint: clicking the "Funding Mechanism" field in the previous section will auto-populate it when generating the next section.



- c. Today's date should auto-populate.

1. Add new event for stage Section C - Optional Q&A

a. Program stage: Section C - Optional Q&A

b. Funding Mechanism: Select or search from the list

c. Date Section C Q&A Completed: 2024-01-17

Save Cancel

2. Click "Save", and the Section C Optional Q & A data entry fields will load.
3. Begin entering all required and relevant data.
 - a. Do not include any PII!
 - b. DATIM will automatically save the data you enter *as it is being entered*. This means you can navigate away from data entry and return to this section later.
 - c. Be sure to add investigation updates every two weeks, until the investigation is complete – with all entries dated and entered in chronological order.
4. Once finished with data entry, clicking "Complete" will close the section and automatically submit a notification to GHSD PEPFAR HQ that Section C Q & A has been completed.

Section C – Optional Q & A Quick Tips

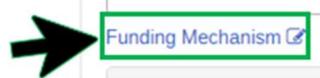
- ❑ Section C is completed by the GHSD CXCA Consulting Physician/Clinician, with responses entered by the CXCA In-Country Incident Lead
- ❑ *Do not include Personally Identifiable Information (PII), such as client name, or initials*
- ❑ Clicking "Complete" will automatically submit Section C Optional Q&A to GHSD HQ. However, any questions or concerns can be emailed to CXCA-AE@state.gov. Technical issues should be sent to [DATIM Support](#).

Section D – HQ Assessment

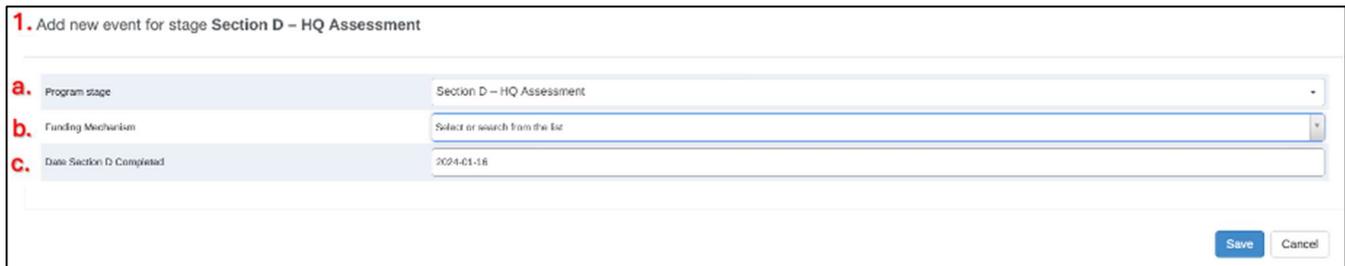
Section D is completed by the GHSD PEPFAR CXCA Consulting Physician/Clinician.



1. Click the "+" button, and a pop-up should appear to "Add a new event stage for Section D".
 - a. The "Program Stage" field should auto-populate with Section D
 - b. Ensure the same PEPFAR "Funding Mechanism" is selected from the dropdown.
 - i. Hint: clicking the "Funding Mechanism" field in the previous section will auto-populate it when generating the next section.



- c. Today's date should auto-populate

A screenshot of a form titled "1. Add new event for stage Section D – HQ Assessment". The form has three rows of input fields:

- Row a: "Program stage" with a dropdown menu showing "Section D – HQ Assessment".
- Row b: "Funding Mechanism" with a dropdown menu showing "Select or search from the list".
- Row c: "Date Section D Completed" with a text input field showing "2024-01-18".

At the bottom right of the form are "Save" and "Cancel" buttons.

2. Click "Save", and the Section D data entry fields will load.
3. Enter all required and relevant data.
 - a. Do not include any PII!
 - b. DATIM will automatically save the data you enter *as it is being entered*. This means you can navigate away from data entry and return to this section later.
4. Once finished with data entry, clicking "Complete" will close the section and automatically submit a notification to GHSD PEPFAR HQ that Section D has been completed.

Section D Quick Tips

- Section D is completed by the GHSD PEPFAR CXCA Consulting Physician/Clinician
- Do not include Personally Identifiable Information (PII), such as client name, or initials
- Clicking "Complete" will automatically submit Section C Optional Q&A to GHSD PEPFAR HQ. However, any questions or concerns can be emailed to CXCA-AE@state.gov. Technical issues should be sent to [DATIM Support](#).

Section E – Report Finalization

ONLY the GHSD PEPFAR CXCA NAERS Manager (or their designee) should access and complete Section E.



1. Click the “+” button, and a pop-up should appear to “Add a new event stage for Section E.”
 - a. The “Program Stage” field should auto-populate with “Section E-Forms Finalization”.
 - b. Ensure the same PEPFAR “Funding Mechanism” is selected from the dropdown.
 - i. Hint: clicking the “Funding Mechanism” field in the previous section will auto-populate it when generating the next section.



- c. Today’s date should auto-populate.

A screenshot of a form titled "1. Add new event for stage Section E - Form Finalization". The form has three rows of input fields:

- Row a: "Program stage" with a dropdown menu showing "Section E - Form Finalization".
- Row b: "Funding Mechanism" with a dropdown menu showing "Select or search from the list".
- Row c: "Section E Completion Date" with a text input field containing "2024-01-17".

At the bottom right of the form are two buttons: "Save" (blue) and "Cancel" (gray).

2. Click “Save” to load Section E.
3. The NAERS Manager should enter the date the form is finalized, and all investigations are concluded.
4. After the date has been entered, click “Complete” to close the section and finalize the entire CXCA_NAE report.

CXCA_NAE General “Quick Tips” for DATIM Tracker

Create a PDF

To create a PDF of your CXCA_NAE report (either what’s been entered so far or the finished report up to Section E, then go to the "Report" widget at the bottom of the page, click where it says "CXCA Notifiable Adverse Events Tracker, then scroll all the way to the bottom and "print form". You can then PDF your document using your computers' print to pdf software (if you have it installed).

